Interventional Cardiology: A portfolio of research pertaining to femoral sheath removal practices and patient education

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Certificate

Kristina Jones Doctor of Nursing

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Portfolio Structure and Overview

This doctoral portfolio contains three separate research projects, that although presented as separate reports, are all related to one area of interest—interventional cardiology. The research sought to identify effective femoral sheath removal practices after interventional cardiac procedures and determine patient's perceptions of the education they receive prior to and after interventional procedures.

The portfolio is divided into 6 main sections:
Section 1—the introduction to this portfolio begins with an overview of the content and structure of the portfolio. The background section situates the area of research interest—interventional cardiology. This begins with a review of the historical development of cardiology, with a particular focus on the development and refinement of the invasive diagnostic and therapeutic modalities of angiography, cardiac catheterisation and angioplasty. This is followed by a general description of the complications associated with cardiac catheterisation. This section of the portfolio concludes with a discussion pertaining to the role of the nurse in interventional cardiology.

Section two—This section of the portfolio is a report on the first study: a systematic review entitled 'The effectiveness of mechanical compression devices in attaining haemostasis after removal of a femoral sheath following femoral artery cannulation for cardiac interventional procedures: A systematic review'. The aim of this systematic review was to summarise the best available evidence on the effectiveness of mechanical compression devices used to obtain haemostasis after femoral sheath removal following cardiac interventional procedures. The systematic review has highlighted the lack of quality research in this area. However, the systematic review does highlight particular compression techniques used to attain haemostasis after femoral sheath removal. This information may assist cardiac nurses to make informed decisions about particular devices and techniques used in clinical practice.

Section three—reports on the second study in the portfolio: 'A randomised controlled

trial comparing the use of manual versus mechanical compression to obtain haemostasis following coronary angiography'. This study was designed to compare two techniques, manual compression and a mechanical compression device—QuicKlamp™, used to achieve haemostasis at the groin puncture site following femoral arterial sheath removal in patients who had undergone coronary angiography. The purpose of this study was to determine which, if any, compression technique was effective and safe for femoral sheath removal. The findings demonstrate that QuicKlamp™ mechanical compression is a safe alternative to manual compression for attaining haemostasis after femoral sheath removal.

Section four—provides a report on the third research study that investigates patients' perceptions of cardiac education prior to and following percutaneous transluminal coronary angioplasty (PTCA) and/or intracoronary stent. This interpretive study was designed to identify the current educational strategies used to inform and prepare cardiac patients for PTCA and/or intracoronary stent procedures; identify whether patients scheduled for PTCA and/or intracoronary stent procedures were educated about the events that would occur in the postoperative recovery period; and, ascertain whether PTCA and/or intracoronary stent patients received information about cardiac rehabilitation programs prior to discharge from hospital. The findings demonstrate that not all patients are adequately educated before cardiac interventional procedures, and therefore deficiencies exist in their understanding about the procedure. In addition, gaps were identified in the type of information patients receive prior to discharge from hospital pertaining to follow-up care and lifestyle changes.

Section five—This section of the portfolio summarises the three pieces of research and provides recommendations for future nursing research in this area.

Section six—The final section of the portfolio contains copies of peer reviewed publications which have to date been generated from this portfolio.

Historical Development

Cardiac catheterisation is a procedure that involves the introduction of diagnostic catheters into the vascular system and heart in order to obtain measurements and radiological details about the structures of the heart and vessels. The clinical development of cardiac catheterisation techniques has rapidly progressed over the last 50 years and these procedures have now become routine and definitive procedures for the diagnosis and evaluation of coronary heart disease.[1] Shepherd and Vlietstra (p.3) state 'For a historical overview, one must realise that technological progression is so rapid that even today's innovations will soon be part of history'.[2]

Although these technologies are recent advances, they developed as part of a continuum of creative discoveries such as x-rays, imaging techniques, contrast media and cardiac catheters. As is usually the case the advances in technology were associated with the high prevalence of cardiovascular disease and the need to improve the diagnosis and treatment using the knowledge gained from research and controlled observation.[3]

The first recorded catheterisation procedure was in 3000 B.C. when the Egyptians performed a bladder catheterisation using metal pipes. In 400 B.C. it was reported that it was possible to investigate the function of cardiac valves in cadavers using catheters fashioned from hollow reeds and pipes. Hales performed the first recorded cardiac catheterisation procedure in 1711 on a horse using brass pipes, a glass tube and the trachea of a goose as catheters during the procedure.[4]

In 1844 a French physiologist, Bernard, used cardiac catheters to measure and record intracardiac pressures in animals. He first coined the term 'cardiac catheterisation' to describe the procedure.[4] Over the next forty years this technique would be refined by Cournand, who in 1863 devised a double lumen catheter to simultaneously measure right atrial and ventricular pressures, and Fick, who in 1870 published a formula for calculating cardiac output measurements during catheterisation.[5]

In 1896 Wilhelm Contrad Röntgen discovered x-rays. The potential for their diagnostic use was quickly appreciated when he observed how the fluorescence of barium platinocyanide crystals on a photographic plate recording of his wife's hand created a clear image of the anatomic structure.[2] A few months later in that same year the first angiogram was obtained. Haschek and Lindenthal injected chalk into the brachial artery of a cadaver and after almost one hour of exposure, the first x-ray photograph of the vessels of the hand was recorded.[2] Others performed arteriograms in cadavers and animals using a variety of contrast agents including air, oxygen, buckshot and other foreign metallic objects.[5] Further developments were soon to follow with the discovery of radiopaque contrast media, allowing detailed pictures of the vascular system to be obtained.[2]

The early 1900's saw the development of the most powerful research and clinical tool in cardiology—the electrocardiograph (ECG). Fye (p.1) said that the ECG invented by Willem Einthoven in 1902 has 'played a major role in defining cardiology as a specialty'.[3] The ECG allowed the electrical activity of the heart to be recorded and cardiac arrhythmias to be studied. In 1909 Thomas Lewis, a British physician and researcher was the first English speaking person in the world to acquire an ECG machine for clinical investigation.[3] The photograph below is a model of the Einthoven electrocardiograph made by the Cambridge Scientific Instrumentation Company in London in 1911 (see figure 1).

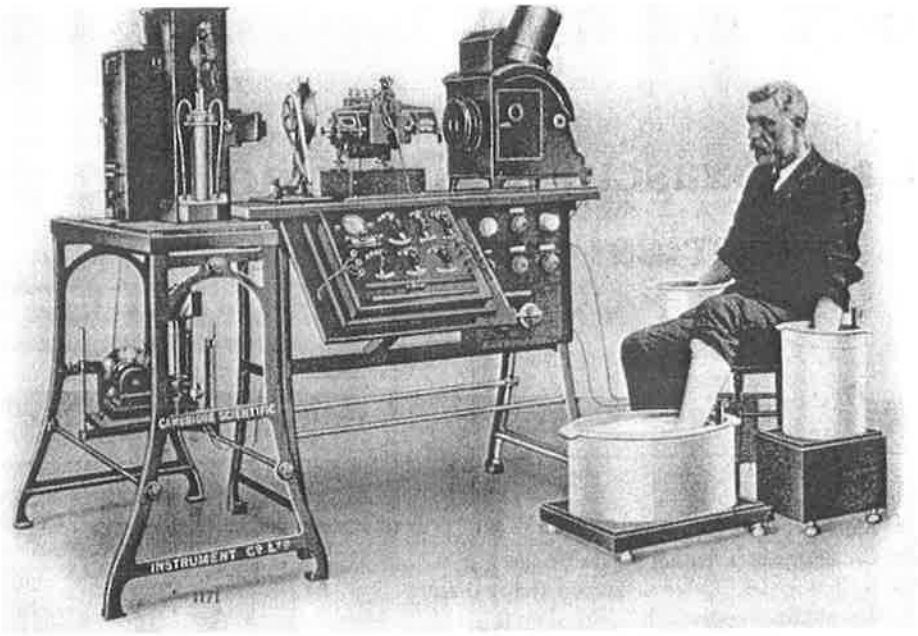

Figure 1: Einthoven electrocardiograph.
(From an advertising leaflet in *Heart* 1912; 4(2) (30 November 1912). Photograph used with permission from Dr W. Bruce Fye's collection.)

Heart specialists began to appear during the 1920's in several of America's largest cities. Although this first generation of heart doctors had little if any formal cardiology training, some had undertaken brief postgraduate courses on heart disease or ECG interpretation.[3] These cardiac specialists developed informal networks and in 1924 formulated the American Heart Association (AHA). The AHA was one of the first organisations to warn the public about the potential risks of heart attack and sudden death and encourage apparently healthy people to periodically have health examinations to identify unrecognised heart disease.[3]

During the 1920's, radiological and peripheral angiography techniques were evolving, with a focus on developing a practical, nontoxic radiopaque substance that could be safely injected into the vascular system. Osborne and colleagues at the Mayo Clinic performed the first excretory urogram by injecting a contrast agent, sodium iodide into the bladder. In 1923 Berberich and Hirsch undertook the first arteriograms and venograms.[2] In 1924 Brooks, an American surgeon, refined this technique and obtained the first femoral arteriogram. He went on to report on a series of early studies that enabled the diagnosis of atherosclerosis to be made.[6]

In 1928 the technique of carotid arteriography was first described, followed in 1929 by the introduction of translumbar arteriography, allowing images of the aorta to be obtained. This approach was favoured until 1941 when a Cuban radiologist used a catheter inserted into the femoral artery to deliver contrast medium allowing good quality images to be obtained of the aorta, brachial, carotid and femoral arteries.[2]

In 1929 in a small hospital in Eberswald Germany, a 25-year-old surgical resident, Werner Forssmann, performed the first documented cardiac catheterisation procedure. With the assistance of a nursing sister, Gerda Ditzen, he performed a cutdown into the cubital fossa vein and anaesthetised his own elbow.[7] Guided by fluoroscopy, he inserted a urethral catheter to its full length into the right side of his own heart through the antecubital vein then walked downstairs to the radiology department to confirm the catheter position by x-ray radiography.[1,5]

Just as Einthoven's ECG machine had made it possible to study cardiac electrophysiology, cardiac catheterisation made it possible to evaluate the heart's structure and function.[3] However, when Forssmann embarked on this self-experimentation his intention was not to advance cardiac diagnosis but rather to determine whether there was a safer means by which drugs could be injected directly into the central circulation during cardiac arrest for an instantaneous effect rather than direct cardiac puncture.[3,5,7] Despite the significance of his discovery, Forssmann was immediately fired for his self-experimentation and the medical establishment of the time branded him as crazy and ignored his work for over a decade. Discouraged by lack of consideration his findings received from his cardiology colleagues, he refocussed his medical career on urology and eventually became a country doctor. In 1956 his was awarded a Nobel Prize for his pioneering efforts.[3,4,7]

Twelve years later, André Cournard, Dickinson Richards and Hilmert Ranges began using cardiac catheterisation on a regular basis as a diagnostic tool to investigate cardiac function in both normal and diseased patients.[3] Cournard and Richards went on to share the Nobel Prize with Forssmann in physiology and medicine for their contributions to the advancement of cardiac catheterisation.[4,7]

During the 1940s and 1950s the techniques of right and left heart catheterisation were developed. In addition, a major advance in x-ray technology occurred during this period, when in 1949 single-plate angiograms were replaced with automatic film cassettes. Within a year image intensifiers and cineangiograms on roll films were developed, allowing better images to be produced with less contrast dye and x-ray exposure.[8]

During the early developments of cardiac catheterisation techniques, access to the vascular system was only via direct exposure or vessel cutdown. The disadvantages of this technique was that it could only be repeated once or twice, arterial thrombosis was common and patients were required to return for removal of sutures.[1] In 1953 the percutaneous technique, now routinely used in order to gain access for cardiac interventions, was introduced by Seldinger.[1] This technique can be used to gain access to either arterial or venous entry and involves the insertion of a percutaneous needle containing a sharp inner obturator into the vessel. The obturator is then withdrawn and a guide wire is passed into the appropriate heart chamber. The needle is then removed leaving behind the guide wire over which diagnostic and therapeutic catheters can be repeatedly exchanged.[1]

A breakthrough occurred in 1959 when Sones, a paediatric cardiologist (pictured below in figure 2), introduced selective arteriography, permitting the diagnostic catheter to be rotated into the right and then left coronary arteries allowing a comprehensive radiological picture to be obtained. Sones discovery inadvertently occurred during an imaging procedure in a patient with valvular disease. He neglected to verify the position of the catheter by fluoroscopy prior to injecting the contrast dye and discovered that the catheter had accidentally entered the patient's right coronary artery (RCA). Before he could pull the catheter out a significant amount of contrast dye had been injected directly into the RCA. He expected the heart to fibrillate as a result of the dye entering the artery.[3,4,5,7] Although asystole occurred for a few seconds, the patients reverted to sinus bradycardia after repeated coughing.[8] Despite this, Sones acquired clear detailed pictures of the entire coronary circulation.[3]

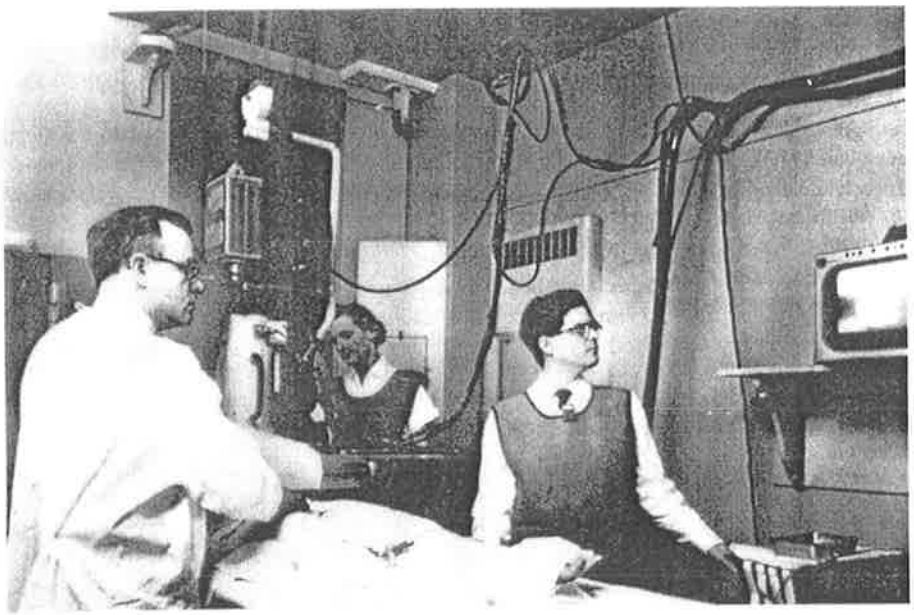

Figure 2: Mason Sones
(Photograph from the archives, Cleveland Clinic Foundation in *Textbook of Cardiovascular Medicine* 1998 Lippincott-Raven, Philadelphia p.7)

The mid 1960s saw the introduction of transluminal angioplasty, the concept of remodelling the artery, introduced by Charles Dotter.[4] In 1967 Melvin Judkins, a radiologist and colleague of Dotter, introduced a new system of diagnostic imaging that involved specialised catheters and the introduction of the catheter via a groin puncture rather than the surgical opening of the brachial artery in the arm that had been used by Sones.[4] These J-shaped catheters, with their right and left shaped 'pigtails', would make it easier to access specific coronary vessels during the procedure.[5] This approach would become known as the Judkins Technique of coronary angiography and the Judkins catheters would become the primary diagnostic tool used during cardiac catheterisation.[4]

With the introduction of cardiovascular surgery in the late 1960's the first truly therapeutic technique for treatment of cardiovascular disease was established.[3] Rene Favaloro conducted the first saphenous vein graft (bypass) surgery in 1967.[4]

In the 1970's a German physician, Andreas Grüentzig, began experimenting with the technique of transluminal angioplasty and toyed with the idea of adding a balloon to Dotter's catheters. His results were met with some scepticism at the American Heart Association meeting in 1976. However, Richard Myler saw the potential of his work

and suggested they work collaboratively and the two performed the first coronary angioplasty during cardiac bypass surgery in May 1977.[4,8]

In 1977 Grüentzig performed the first percutaneous transluminal coronary angioplasty (PTCA) on a conscious patient in Switzerland.[3] This time when he presented the results to the AHA meeting in 1977 he was greeted with applause and finally received appropriate acknowledgment for the breakthrough.[4]

In the 1980's Grüentzig went on to inform other physicians through live demonstrations of the procedure. He also began collecting data from PTCA cases in a registry at the National Heart, Lung and Blood Institute to gather and share his experiences.[4] Much like open-heart surgery and the ECG had done a few generations earlier, PTCA revolutionised cardiology extending cardiac catheterisation as a diagnostic tool to become a therapeutic procedure to treat patients with angina using specialised balloon catheters.[3]

Since that time important advances related to cardiac catheterisation have included therapeutic interventions such as coronary atherectomy and rotablator athrectomy (where specially designed catheter devices allow the cutting of plaque from a blocked artery to restore blood flow), intracoronary stents and intracoronary Streptokinase.[1,4] The figure below shows one type of intracoronary stents that was first introduced in the 1980's (see figure 3). Muller and Sanborn (p.156) state the advent of intracoronary stent, atherotomies and laser therapy '... has extended the original balloon technology to devices capable of ablating or removing atherosclerotic obstructions and of preventing acute vessel closure and ischaemia during interventions'.[5]

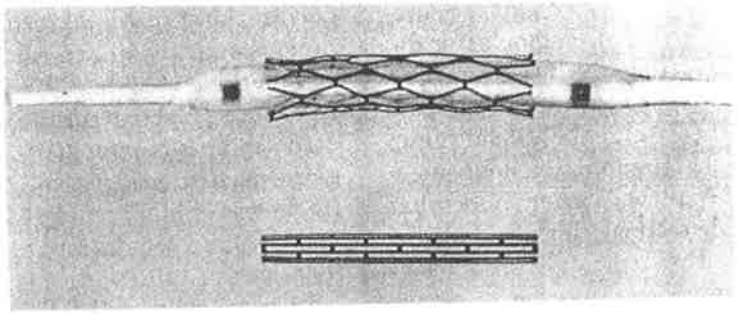

Figure 3: Balloon-expandable stent (Palmaz-Schatz stent, Johnson & Johnson).
(From Schatz R. A view of vascular stents. *Circulation* 1988;79:445-57.)

Complications of Cardiac Catheterisation

Cardiac catheterisation involves the insertion of foreign objects such as catheters and guide wires into the cardiovascular circulation and adverse events or complications can occur. These adverse events can range from minor problems that have no long-term effects, such as transient bradycardia during contrast dye insertion, to major problems that may require surgical intervention, such as pseudoaneurysm, or may even cause irreversible damage, such as stroke, myocardial infarction or death.[9]

The incidence of death as a complication of cardiac catheterisation has progressively declined from 1% mortality in the 1960's[10] to less than 0.1% today.[9] Multivessel disease, high-risk lesions and interventional procedures tend to carry a higher risk of death than purely diagnostic procedures.[11]

Although myocardial ischaemia can commonly occur during diagnostic and interventional procedures, especially during balloon inflation when the coronary blood flow may be impeded, myocardial infarction (MI) is uncommon (less than 0.05%).[11] MI may result from abrupt vessel closure, vessel dissection, coronary artery spasm, thrombosis or distal embolisation.[8] However, the introduction of heparinisation and greater attention to intra-procedural flushing of the catheter has reduced the risk of MI.[11]

Cerebrovascular accidents or stoke although uncommon (<0.1%), are potentially devastating complications of diagnostic and intervention catheterisation. Stroke may

result from emboli, calcified material or thrombus formation occluding cerebral vessels.[11] Measures that may reduce the incidence of stroke are catheter flushing, wiping and immersion of guide wires in heparinised saline, avoidance of air bubbles during contrast injection and keeping wires and catheters out of the aortic arch vessels during the procedure.[11]

The most common problems seen after cardiac catheterisations are local vascular complications.[11] Vascular complications can be grouped into three categories: perforation, occlusion or embolisation. Perforation may result from laceration of the arteries or veins from a scalpel, needle, guide wire or the introducer sheath.[12] This may result in a loss of blood into the surrounding tissues causing ecchymosis, bruising or haematoma (a palpable collection of blood within the soft tissues of the upper thigh).[11] Less common after perforation are complications such as arteriovenous fistula and pseudoaneurysm formation. Arteriovenous (AV) fistulas can form when the perforation creates a channel between an artery and vein.[13] Pseudoaneurysm formation is similar to haematoma formation where blood is lost after perforation and becomes trapped in the perivascular tissue.[12] Often a pulsatile mass develops as a result of blood engorging the haematoma cavity during systole and decompressing back into the arterial lumen during diastole.[11] Both AV fistula and pseudoaneurysm may takes days to weeks to develop and may require surgical repair.[11,12,13]

Uncontrollable bleeding may occur after cardiac catheterisation externally around the puncture sit or into the retroperitoneal cavity.[13] External bleeding may be controlled by application of pressure to the puncture site[9], whereas retroperitoneal bleeding often requires blood transfusion and surgical repair of the artery.[13]

Vascular occlusion at or near the entry site can be caused by thrombosis or plaque, haemorrhage after atherosclerotic plaque puncture, clot formation around a catheter or other device, vessel spasm or vessel dissection.[12] If severe, distal limb ischaemia may result.[13]

Complications can arise from trauma secondary to advancement of the catheter or device used during cardiac catheterisation. Although rare, the incidence of perforation of cardiac chambers, coronary arteries and intrathoracic great vessels has risen in

recent years with the advent of more aggressive technologies, such as directional arthrectomy, rotational arthrectomy and laser angioplasty.[11]

Less serious intimal tears, or dissection of the intima or media from the surrounding vessel, can also occur as an intravascular device is advanced. Dissections may partially or totally occlude the lumen of the vessel.[12] Intimal dissection can occur in up to 25% of cases[14], while approximately 4% of patients may have extensive dissection that may result in abrupt vessel closure.[15] Reinflation of the balloon catheter or intracoronary stent deployment over the perforated segment of the artery can effectively seal the laceration.[11]

Restenosis, with clinical symptoms of angina, may occur within 6 months of PTCA in approximately 20% of patients. Another 5-10% have evidence of partial renarrowing of the dilated segment but remain symptom free.[15] Platelet adhesion to the area of endothelial damage at the dilatation site, together with release of potent smooth muscle vasoconstrictors and mitogens (such as platelet-derived growth factor) are believed to cause restenosis.[15] To minimise this complication post-procedural heparinisation is given and antiplatelet therapy, commonly Ticopidine or Clopidogrel, are continued for 4 weeks after intracoronary stent deployment.[13]

Cardiac arrhythmias (both tachycardias and bradycardias) or conduction disturbances may occur during diagnostic or therapeutic cardiac catheterisation due to irritation caused by the catheters, excess catheter manipulation during the procedure and after intracoronary contrast injection.[9] Vasovagal reactions, where bradycardia is associated with hypotension, nausea, sweating and yawning may result from pain, anxiety or occur during insertion or removal of the femoral sheath.[9]

Other complications associated with cardiac catheterisation include anaphylactic reactions resulting from the local anaesthetic or ionic contrast agents[9], contrast-induced renal dysfunction[19] or technically related problems that may occur as a result of knotted, entrapped or fragmented catheter.[9] Devices such as vascular snares, bioptomes and baskets can assist in the recovery of arrant fragments.[16]

Despite the potential for complications to occur after cardiac catheterisation, the risk of major complications is less than 1%. Baim and Grossman (p.17) state

> ... the risk-benefit ratio still favours performing cardiac catheterisation as part of the investigation or treatment of cardiac disorders that are themselves life-threatening or symptom-limiting.[9]

The potential for complications to occur may be dependent on individual patient factors such as gender, age, cardiac anatomy, the type of procedure (diagnostic catheterisation or angioplasty) and clinical situation at the time (unstable angina or cardiogenic shock).[11] Careful consideration of these factors prior to the procedure may alert medical and nursing staff to the potential for adverse events to occur. Appropriately trained personnel and adequate catheterisation equipment and facilities will assist in minimising potential problems.

The Nurse and Interventional Cardiology

Nurses play a significant role in caring for patients before, during and after cardiac interventional procedures. The acuteness of the patient's condition, the uncertainty of the procedure and the associated potential complications can lead to patient anxiety and emotional stress.[17] Preparatory and supportive nursing interventions for cardiac interventional patients and their families can reduce stress and anxiety before, during and after the procedure.[17]

Patient education is an important aspect of nursing care and can influence patient outcomes. Gardner et al (p.66) state 'providing information in an accurate and timely fashion contributes to improved patient compliance and greater procedural success'.[18] It has been suggested that nurses who provide education and instructions to patients and their families about cardiac interventional procedures, themselves require an in-depth knowledge about the procedures.[19]

The nursing aim of pre-procedural preparation is to determine the patient's present understanding and knowledge about the cardiac interventional procedure and establish rapport with the patient and their family.[20] Nursing staff may also be required to

undertake physiological preparation, including electrocardiogram, chest x-ray, cardiac enzymes, serum electrolytes and prothrombin time to assure patient stability and establish baseline clinical data.[19]

The nurse has an integral role in pre-procedural teaching. Information should be given to patients prior to interventional procedures including: instructions that a local anaesthetic will be injected into their groin (or vascular access area); a warm flushing sensation may be felt when the contrast dye is injected; and chest pain or anginal symptoms may be experienced during balloon inflations for PTCA.[18] Nurses need to describe the procedure, the laboratory equipment and ensure patients know what to expect during the procedure.[18] Patients should also be instructed that they may be asked to change position, take a deep breath or cough vigorously to aid catheter placement and distribution of the contrast dye.[17] Teaching should be aimed at preparing patients for the procedural experience.[1] Details should also be given about the immediate post-procedural care and the expected length of bed rest after cardiac catheterisation to prepare them for the recovery events. Adequate explanations will help to minimise patient anxiety and reduce physiological responses associated with stress that may cause intra-procedural difficulties.[17]

During the cardiac interventional procedure nurses are directly responsible for some technical aspects of the procedure and for the care of the patient during the procedure.[19] Although the specific role(s) of the nurse during cardiac catheterisation will depend on the specific protocols of the cardiac catheterisation laboratory, at least three nurses are required during interventional procedures. One nurse may be required to prepare equipment and assist the doctor during the procedure. Another nurse will be assigned to constantly monitor the patient's haemodynamic status, heart rhythm, psychological state and comfort[20] to assure patient safety and detect procedural problems during the procedure.[19] A third circulating nurse may be require to assist with administration of medications, provide additional equipment and initiate emergency procedures if required and constantly observe and communicate with the patient.[19]

The aim of nursing care during the immediate recovery period after the procedure should be directed at prevention of acute closure of the dilated artery and early

detection of adverse events and complications of the procedure.[1] Although complications are infrequent, early detection and intervention may prevent permanent disability or death.[1]

The nurse frequently undertakes a thorough clinical assessment of the patient during the recovery period. The important elements of nursing assessment include observation of:

- Heart rate and rhythm for cardiac arrhythmias, vasovagal response, myocardial infarction or ischaemia;
- Elevated temperature indicating infection or pyrogenic reaction;
- Hypotension indicating possible hypovolaemia, or in response to intra-procedural drugs such as vasodilators;
- Increased urinary output as a result of the osmotic diuretic effect of the contrast medium;
- Circulatory integrity of vascular access site for visible bleeding, swelling or tenderness. Capillary filling, presence of distal pulses in cannulated limb and warmth of the limb should also be evaluated for adequate tissue perfusion[1]; and
- Coagulation profiles. Prolonged intensive anticoagulation (prothrombin times >100) has been associated with increased vascular complications. Spokojny and Sanborn recommend prothrombin levels should be kept at 1.5 to 2.0 times normal.[21]

Femoral sheath removal can be a part of nursing care after the procedure. This practice may vary amongst cardiac catheterisation laboratories but is increasingly becoming a part of nursing responsibility.[22,23] The aim of nursing care during femoral sheath removal is to control bleeding and reduce the potential for complications.[23] Attaining haemostasis and controlling bleeding may be achieved by nurse-initiated digital pressure (manual compression) or the application of mechanical compression using a C-clamp or pneumatic device. During the process of attaining haemostasis the nurse must apply adequate constant pressure to stop bleeding while ensuring limb perfusion is maintained. The patient's vital signs must be frequently monitored for signs and symptoms of vasovagal syncope and shock during this period.[23]

Once bleeding has stopped compression can be slowly released. To assist in reducing haematoma formation and associated groin complications a pressure dressing is applied over the arterial puncture site. Distal pulses are regularly checked and the pressure dressing adjusted until adequate flow is established to the distal limb.[24] Patients are instructed to lie flat without moving the affected leg for at least 4 hours after femoral sheath removal. Nurses should regularly assess the degree of discomfort and pain patient's experience during this period.

Psychological assessment and patient teaching is also important during the recovery. The patients may need further explanation about the results of the procedure. They may also need to express feelings of concern and anxiety. It may be necessary to re-emphasise the need for bedrest and the need to keep the catheterised limb immobile.[1] Comfort measures such as repositioning, backrubs, analgesics and sedation may be required during this bedrest period.[18]

As in-hospital stay after cardiac interventional procedures is short (usually no longer than 3 days), discharge planning is initiated on admission.[20] Patient education should focus on groin care, psychological reactions, resumption of functional activities and limitations, recognition of complications and adverse reactions and instructions about medications.[25] Goals for modification of health and lifestyle patterns should be formulated in conjunction with patients and families in an effort to improve compliance.[20] Patients need to understand that although there are certain risk factors which contribute to coronary heart disease over which they have no control, such as family history, gender and age, they have the power to control other personal factors such as stress, body weight, smoking, hypertension and sedentary lifestyle.[19] These factors need to be individually assessed and discussed by nurses with patients and families prior to discharge from hospital and patients need to be advised of resources and support cardiac rehabilitation programs that they can access after discharge.

Conclusion

The aim of the first section of this portfolio was to establish the context and area of research focus—interventional cardiology. An overview of the structure and content of the portfolio has been outlined. A review of the historical development of

cardiology was provided in order to highlight the rapid developments that have occurred in relation to interventional cardiology in recent years.

All three pieces of research presented in this portfolio have a link to potential problems and complications that can occur during and after cardiac interventional procedures. In order to provide a complete picture of the potential adverse events that can occur, a summary of the possible complications related to cardiac catheterisation are discussed.

Finally, a discussion pertaining to the role of the nurse in interventional cardiology was provided. Nurses play an integral role in the success and outcome of patients undergoing cardiac interventional procedures. Clinical assessment, education and early intervention during adverse events are crucial aspects of nursing practice. Significant nursing intervention is therefore required before, during and after cardiac interventional procedures.

References

1. Newton K. Cardiac Catheterisation. In: Woods SL, Froelicher S, Halpenny CJ, Underhill MS, (Editors). *Cardiac Nursing*. 3rd Edition ed. Philadelphia: J.B. Lippincott, 1995.
2. Shepherd R, Vlietstra R. The History of Interventional Cardiology. In: Holmes D, Vlietstra R, (Editors). *Interventional Cardiology*. Philadelphia: F.A. Davis Company, 1989.
3. Fye WB. Cardiovascular medicine: A historical perspective. In: Topol EJ, (Editor). *Textbook of Cardiovascular Medicine*. Philadelphia: Lippincott-Raven Publishers, 1998:1-10.
4. History of angioplasty: The PTCA Anniversary Project, 1996.
5. Muller D, Shamir K, Ellis S, Topol E. Peripheral vascular complications after conventional and complex percutaneous coronary interventional procedures. *American Journal of Cardiology* 1992;69(1):63-68.
6. Brooks B. New methods for study of diseases of the circulation of the extremities. *Journal of Bone and Joint Surgery* 1925;7:316.
7. Bauer G. Historical sketches. *On the pulse*, 2001:8-10.
8. Mueller R, Sanborn T. The history of interventional cardiology: Cardiac catheterization, angioplasty, and related interventions. *American Heart Journal* 1995;129(1):146-172.
9. Baim D, Grossman W. *Cardiac catheterization, angiography, and intervention*. 5th edition Baltimore: Williams & Wilkins, 1996.
10. Braunwald E, Gorlin R, McIntosh H, Ross R, Rudolph A, Swan H. Cooperative study on cardiac catheterisation. *Circulation* 1968;37(5 supplementary):1193-2101.
11. Baim D, Grossman W. Complications of cardiac catheterisation. In: Baim D, Grossman W, editors. *Cardiac catheterisation, angiography, and intervention*. 5th edition. Baltimore: Williams & Wilkins, 1996:17-38.
12. Rooke T. Vascular complications of interventional procedures. In: Holmes D, Vlietstra R, (Editors). *Interventional Cardiology*. Philadelphia: F.A. Davis Company, 1989:340-358.

13. Deelstra H. Interventional cardiology techniques. In: Woods S, Froelicher E, Motzer S, (Editors). *Cardiac Nursing*. 4th Edition. Philadelphia: Lippincott, 2000:541-559.
14. Vliestra R, Bresnahan J, Holmes D. Coronary balloon angioplasty. In: Holmes D, Vlietstra R, (Editors). *Interventional Cardiology*. Philadelphia: F.A. Davis Company, 1989:55-72.
15. Baim D. Interventional catheterization techniques: percutaneous transluminal balloon angioplasty, valvuloplasty, and related procedures. In: Braunwald E, (Editor). *Heart Disease: A textbook of cardiovascular medicine*. Philadelphia: W.B. Saunders Company, 1992:1365-1381.
16. Grabenwoeger F, Bardach G, Dock W, Pinteritis F. Percutaneous extraction of centrally embolized foreign bodies-a report of 16 cases. *The British Journal of Radiology* 1988;61(73):1014-1018.
17. Shillinger F. Percutaneous transluminal coronary angioplasty. *Heart & Lung* 1983;12(1):45-50.
18. Gardner E, Joyce S, Iyer M, Mowery M, Olson K, Piontek S. Intracoronary stent update: Focus on patient education. *Critical Care Nurse* 1996;16(4):65-75.
19. Partridge S. The nurse's role in percutaneous transluminal coronary angioplasty. *Heart & Lung* 1982;11(6):505-511.
20. Loan T. Nursing interaction with patients undergoing coronary angioplasty. *Heart & Lung* 1986;15:368-375.
21. Spokojny A, Sanborn T. Management of the arterial puncture site. *Journal of Interventional Cardiology* 1994;7(2):187-193.
22. Peet GI, McGrath MA, Brunt JH, Hilton JD. Clinical rounds. Femoral arterial sheath removal after PTCA: a cross-Canada survey. *Canadian Journal of Cardiovascular Nursing* 1995;6(3-4):13-9.
23. Walker S, Cleary S, Higgins M. Comparison of the FemoStop device and manual pressure in reducing groin puncture site complications following coronary angioplasty and coronary stent placement. *International Journal of Nursing Practice* 2001;7(6):366-375.
24. Schickel S, Cronin SN, Mize A, Voelker C. Removal of femoral sheaths by registered nurses: issues and outcomes. *Critical Care Nurse* 1996;16(2):32-6.

25. Tooth L, McKenna K. Cardiac patient teaching: application to patients undergoing coronary angioplasty and their partners. *Patient Education and Counselling* 1995;25:1-8.

Study One: The effectiveness of mechanical compression devices in attaining haemostasis after removal of a femoral sheath following femoral artery cannulation for cardiac interventional procedures: A systematic review.

NB. This systematic review was conducted from February 1999-November 1999. Therefore only research reports that were identified prior to November 1999 have been included in this systematic review. In addition, the scale used to categorise the quality of the research reports[27] was changed in 1999 by the National Health and Medical Research Council (NHMRC) with level IV evidence, opinion of respected authorities, based on clinical experience, being deleted from the scale. This was also deleted from scales used to rank evidence by the Joanna Briggs Institute (JBI) in 2001.

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Abstract

BACKGROUND: Cardiac interventions have gained widespread acceptance as a viable treatment option for coronary artery disease. Despite this, few changes have taken place in regard to percutaneous arterial cannulation techniques and attaining haemostasis after cardiac interventions. Research to date has investigated techniques that achieve optimal haemostasis at the time of arterial catheter removal and minimise the impact and complications of arterial puncture.

OBJECTIVE: The aim of this systematic review was to summarise the best available evidence on the effectiveness of mechanical compression devices used to obtain haemostasis after femoral sheath removal following cardiac interventional procedures.

METHOD: The search strategy sought to identify both published and unpublished research reports that evaluated mechanical compression techniques used to attain haemostasis after femoral sheath removal. Methodological quality was assessed using pre-designed criteria. Data were extracted from randomised controlled trials (RCTs) and statistically combined in meta-analysis where possible. Evidence was also synthesised using narrative summaries.

RESULTS: Twelve studies met the inclusion criteria with only three studies included in statistical meta-analysis. The meta-analysis for haematoma formation favoured the mechanical compression technique. There was no significant difference in the incidence of bleeding, bruising, pulsatile mass or arteriovenous (AV) fistula formation. The time taken to attain haemostasis varied between studies generally favouring manual compression. Patient discomfort after 30 minutes of compression was significantly greater after manual compression.

CONCLUSION: In this systematic review a rigorous pre-planned process was used to identify primary research pertaining to mechanical compression devices used to attain haemostasis after femoral sheath removal from cardiac interventional patients. This systematic review has highlighted the lack of quality research in this area. However, this systematic review does highlight particular compression techniques used to attain

haemostasis after femoral sheath removal. This information may assist cardiac nurses to make informed decisions about particular devices and techniques used in clinical practice.

Introduction

Cardiac interventions have gained widespread acceptance as a viable treatment option for coronary artery disease. Femoral artery puncture and cardiac catheterisation are widely used in diagnostic and interventional cardiology[1] and increasingly, cardiac catheterisation and related procedures are performed safely in an outpatient setting.[2] In addition, revascularisation techniques such as percutaneous transluminal coronary angioplasty (PTCA), first introduced into clinical practice in 1977[3], provide a viable alternative for individuals affected by atherosclerotic heart disease.[4]

It has been common place for doctors to remove femoral sheaths following cardiac interventional procedures, however more recently removal of the femoral sheath has become a component of the expanding role of the cardiac nurse.[4] Nurses need information on the effectiveness and reliability of various techniques to achieve haemostasis after femoral sheath removal. This information will enable cardiac nurses to choose the appropriate technique to facilitate a reduction in groin complications following femoral sheath removal after cardiac interventional procedures.

Background

Despite major advances in coronary revascularisation techniques in recent years, few changes have taken place in regards to establishing percutaneous arterial cannulation techniques and attaining haemostasis after cardiac interventions.[5,6] The use of larger cannulation devices and the need for more aggressive anticoagulation has increased the incidence of peripheral vascular complications.[5] Complications that may occur after cardiac interventions are costly, increase patient hospitalisation time and affect patient morbidity.[7] Inadequate haemostasis is one problem that can lead to one or all of the following: significant blood loss, patient discomfort, vessel occlusion, thrombosis, arteriovenous fistula formation and pseudoaneurysm requiring surgical intervention.[5,8,9] It is estimated that access site complications involving arterial puncture prior to cardiac catheterisation occur in 1% to 5% of cases, but may rise as high as 14% with some cardiac interventional procedures.[10] The potential high incidence of complications has stimulated investigation of techniques that achieve

optimal haemostasis at the time of arterial catheter removal and minimise the impact and complications of arterial puncture.

Most diagnostic and interventional cardiac procedures require the insertion of a femoral artery sheath or introducer to gain access for various diagnostic and therapeutic catheters. The femoral sheath provides support at the puncture site and reduces potential arterial trauma if multiple catheter exchanges are required.[1] On completion of the procedure the femoral sheath is removed and the femoral artery compressed to control bleeding until haemostasis is attained. Femoral sheaths may be left in place for longer periods (at least four and up to twenty-four hours) with some procedures, such as PTCA.[11] A survey conducted by Peet and colleagues found that 29 of the 30 cardiac units surveyed left femoral sheaths in overnight.[4] The reasons given for this practice were convenience for staff, continuation of heparin administration and emergency access for possible urgent reinvestigation.[4] In addition they found that occasionally decisions were made by the cardiologist to leave the femoral sheath in overnight due to morphological issues such as coronary artery dissection during the procedure, prior artery occlusion, less than optimal dilatation results following PTCA, complex or multiple lesions, difficult cases, threatened occlusion or thrombus prior to PTCA, unstable angina and acute myocardial infarction.[4]

Although manual compression is commonly employed to attain haemostasis, this technique has limitations. Application of manual compression may be required for up to twenty minutes or longer in order to control bleeding and allow coagulation to occur[12] and inconsistent pressure as a result of imprecise hand and arm fatigue, may potentially lead to haematoma and/or thrombus.[12,13]

The increase in outpatient catheterisation, the desire for earlier patient mobilisation and an effort to decrease vascular injury and complications has led to the development and use of alternate haemostatic devices such as mechanical clamps, pneumatic or inflatable pressure devices, implantable collagen plugs and manual pressure aids.[10] These devices can be used as an adjunct to, or provide an alternative to manual compression to attain haemostasis. Some devices have transparent domes that provide direct visualisation of the puncture site during compression, while others, which use

pneumatic or clamp pressure to compress the femoral artery, may be considered less labour-intensive than manual compression.[14] As with manual compression, these devices may have limitations, including patient discomfort and prolonged immobilisation.

Several studies have attempted to examine the efficacy of mechanical devices such as the FemoStop™ pneumatic belt system[14,15] the Compressar clamp[12], the HOLD compression device[2], a Stasis Button system[16] and the Clamp Ease device[5] in attaining and maintaining haemostasis after femoral sheath removal. Although these studies concluded that the mechanical device appeared to be a safe alternative to manual compression, conflicting recommendations exist within these studies as to the preferred use and efficacy of mechanical compression devices in attaining haemostasis after femoral sheath removal.

More recently, collagen vascular haemostatic sealing devices were developed to attain haemostasis after femoral sheath removal. With these devices, an absorbable bovine collagen plug is instilled into the tract from the femoral artery to the skin surface. Haemostasis occurs after formation of a fibrin clot within this tract, sealing the puncture site.[6] Preliminary clinical trials have reported these devices to be effective in achieving haemostasis with significantly reduced groin compression time.[17,18,19] Although these preliminary findings show promise for the future management of artery puncture sites, their use for routine procedures such as coronary angiography may be limited because of associated costs.

The use of various haemostatic devices appears to have gained widespread acceptance in the use of diagnostic and interventional cardiology but the effectiveness of these techniques remains largely undefined. Although the literature is replete with a variety of options for establishing haemostasis, no uniform method is evident. Owing to the variation in mechanical techniques used to attain haemostasis after femoral sheath removal following femoral artery cannulation for cardiac interventional procedures, it is essential that a systematic review of the literature be performed to critically examine and assess the effectiveness of such techniques.

Objectives

The objective of this review was to examine the effectiveness of mechanical compression devices in achieving haemostasis following femoral artery sheath removal from patients after cardiac interventions.

The specific null hypothesis (H_0) tested was:
There is no difference in the effectiveness of mechanical compression devices in attaining haemostasis after femoral sheath removal as compared with manual compression or other compression techniques.

In addition to examining the efficacy of these mechanical devices, a sub-category for review was patient tolerability of mechanical compression devices after femoral sheath removal.

Review Method

The process of systematic review involves a concise methodical investigation of a subject using a predetermined plan that involves the summary, appraisal and synthesis of multiple primary studies.[20,21] The findings of well-conducted systematic reviews can help define the evidence on a topic through the assessment and integration of large volumes of relevant information. In addition, the findings may explain variations in practice and resolve conflicting evidence about a topic, thereby assisting health professionals in making rational decisions about health care practices.[22] The aim of this systematic review was to determine the best available evidence on the effectiveness of mechanical compression devices in achieving haemostasis and reducing the potential for adverse effects after removal of femoral artery sheaths.

Selection Criteria

Types of Participants

All adult men and women who underwent cardiac diagnostic or investigational procedures using a femoral sheath approach were included in the review.

If the review identified more than one study that addressed the efficacy of mechanical compression devices in attaining haemostasis after specific cardiac interventions, these were analysed as separate participant sub-groups. Examples of patients that were considered in these sub-groups were those who had undergone coronary angiogram, PTCA, cardiac catheterisation or intracoronary stent deployment.

Exclusion Criteria

Studies were excluded that had participants who had radial or brachial approach procedures, as this review was only interested in the femoral artery approach because it is the most common artery cannulated for cardiac interventional procedures.[23] Studies that included patients who had either a collagen sealing or suture-mediated closure devices to attain haemostasis were excluded from the review. This decision was made as these devices either used an absorbable bovine collagen plug to seal the femoral artery[6], or tied off the femoral artery with a percutaneous suture on top of the arterial wall through the subcutaneous tract[24], rather than using a mechanical compression technique.

Those studies that included patients who had a haematoma prior to femoral sheath removal were also excluded from the review as it would be difficult to determine if any post procedural haematomas were caused by the compression technique or remained from pre-procedure. Patients who did not have oral anticoagulation medications ceased at least two days prior to the procedure were also excluded, as these therapies may increase bleeding tendencies and result in post procedural bleeding rather than the compression technique being ineffective in attaining haemostasis.

Types of Interventions

Primary research studies in which the investigators compared any mechanical compression device with (1) manual compression, (2) another mechanical compression device, or (3) any other form of compressive technique that was used to attain haemostasis in adult patients after cardiac interventional procedures in which a femoral sheath approach was used were included in this review. In practice, the femoral sheath may be removed immediately on completion of the interventional procedure (as with coronary angiography) or may be left in place for up to 24 hours

(after PTCA). The decision of when to remove the femoral sheath is made by the cardiologist and is dependent upon the type of interventional procedure performed, anticoagulant and/or antiplatelet regimes and the patient's haemodynamic state.[25] Studies involving mechanical compression devices used to obtain haemostasis either *immediately* upon sheath removal in the catheter laboratory, or at a *later* period (up to 24 hours) in the cardiac unit after procedures such as PTCA, were included in this review.

Types of Outcome Measures

All quantifiable outcome measures related to the effectiveness of the compression technique used to attain haemostasis after femoral sheath removal were of interest. Outcomes included the time to achieve haemostasis and the incidence of bleeding, bruising, haematoma formation, inadequate distal blood flow, arteriovenous (AV) fistula and pseudoaneurysm formation. Any outcome measure that described the level of patient satisfaction or discomfort with the compression technique were also included.

The following outcome definitions were used during this systematic review:

- *Bleeding* was defined as any ooze, leaking or frank blood drainage from the puncture site.
- A *bruise* or *ecchymosis* was identified by any discolouration of the subcutaneous tissue around the puncture site.
- A *haematoma* was defined as any swelling, palpable mass or newly formed bruit —a sound heard during auscultation suggesting non-laminar flow through the femoral artery.[5]
- *Inadequate distal blood flow* was identified by the absence of distal foot pulses.
- *Arteriovenous (AV) fistula* was defined as an abnormal connection between the femoral arterial and the femoral vein.[5]
- *Pseudoaneurysm* was defined as an extraluminal pouch encapsulated by solidified blood in the interstitial tissue outside the arterial vessel.[9]

Types of Studies

Randomised controlled trials (RCTs) that addressed the effectiveness of mechanical compression techniques used to attain haemostasis after removal of femoral sheaths were of primary interest because these studies provide the highest level of recognised evidence.[26,27] For other studies, such as uncontrolled clinical trials and descriptive studies, that met the inclusion criteria, the results of these studies were incorporated in a narrative review. Although the level of evidence in these studies is considered less rigorous than that of randomised controlled trials, the inclusion of the narrative summary will help identify current approaches used to attain haemostasis after femoral sheath removal.

A checklist that outlined the inclusion criteria for this review was attached to each retrieved research article (see Appendix 1).

Search Strategy for Identification of Studies

Rosenfeld states that the basic steps in performing a systematic literature search are: define the search terms and their interrelationships; refine the search based on a review of identified articles; supplement the computer search with manual cross-checks; attempt to locate unpublished material; and document the search strategy in a reproducible manner.[28]

The literature search in this review sought to identify both published (in peer-reviewed journals or reference books) and unpublished studies. Whilst the inclusion of unpublished studies opens the systematic review up to criticism that these studies may not have been peer reviewed,[29] the rigorous requirements for data inclusion should have reduced the possible negative effects of the inclusion of unpublished work. Databases searched for published studies included MEDLINE (1966 through June 1999), CINAHL (1982 through January 1999), HEALTHSTAR ((1975—1999), EBM Reviews-Evidence Based Database (1991 through June 1999), Current Contents (1998—1999), Embase, DARE and the Cochrane Library (1999 Issue 1). Dissertation Abstracts International database (1992—1999), Proceedings First database (1992—1999) and hand searching of cardiac conference proceedings was undertaken

to detect unpublished research. The search was restricted to research reported in the English language only. It is acknowledged that this strategy would limit the results of the review as pertinent research may be excluded on this basis, but appropriate translation of non-English reported studies was beyond the scope of this review due to time and resource limitations.

A search of MEDLINE, CINAHL, Current Contents, and the Cochrane Library for the period October 1999, when this systematic review was done, through December 2001 did not reveal any other published studies comparing manual and mechanical compression techniques.

It was the intention of the reviewer to extensively hand search articles in cardiology journals and reference lists and/or bibliographies at the end of chapters within cardiology books to check if any articles that met the review inclusion criteria could be found. However, time restraints meant that hand searching was limited to those journals and books accessible to the reviewer from their hospital and university libraries. Where possible hand searching of cardiology journals was extended to a fourteen-year period from 1985 to 1999. Although a few papers were published in the 1970's that addressed various compression techniques[30,31], research involving mechanical compression devices did not begin to appear within the published literature until the late 1980's and 1990's, and therefore hand searching of journals was restricted to this period. No new articles in addition to those identified through electronic database and reference list searching were found during this process. The reference books that were hand searched are listed in Table 1.

Table 1: Hand searched reference books

Author	Year	Title	Publisher
Braunwald	1992	Heart Disease. A textbook of Cardiovascular Medicine (Vol 1 and 2)	WB Saunders Company
Brown	1998	Cardiac Intensive Care	WB Saunders Company
Woods et al	1995	Cardiac Nursing	JB Lippincott Company
Holmes and Vlietstra	1989	Interventional Cardiology	FA Davis Company

The journals that were hand searched are listed in Table 2.

Table 2: Hand searched journals

Journal	Year
American College of Cardiology Journal	1985–1998
American Heart Journal	1991–1997
American Journal of Critical Care	1991–1997
Australian Critical Care (Confederation of Australian Critical Care Nurses)	1986–1999
British Heart Journal	1985–1995
Circulation	1990–1997
Critical Care Nurse	1991–1999
Heart and Lung	1991–1998

In addition, hand searching of specific cardiac conference proceedings was undertaken. This was also limited to those proceeding books available to the reviewer, therefore limiting the scope of hand searching this source. The conference proceedings that were searched are listed in Table 3.

Table 3: Hand searched conference proceedings

Conference	Year
TransAustralian Interventional Coronary Symposium '96—Brisbane, Australia	1996
45th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand—Hobart, Australia	1997
46th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand—Perth, Australia	1998
47th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand—Wellington, New Zealand	1999

A two-step search process based on the searching strategy outlined by Dickersin, Scherer and Leferbvre was used.[26] This involved an initial search to identify key words that appeared in the title, abstract and medical subject heading MeSH sections of the electronic databases. Key terms used to frame the search process were subject terms such as: cardiac catheterisation, femoral sheath removal, mechanical compression; manual compression; device; pneumatic clamp; haemostatic techniques; haemostasis and bleeding. Once these key subject terms had been identified from the initial search, the second step was to conduct a more comprehensive search of the identified databases. The initial search had identified only a few RCTs undertaken

within the area of interest. Therefore the aim of the second step was to cast a wide net in order to identify all articles concerning mechanical compression devices, irrespective of study methodology. This meant that search strategies that incorporated search filters aimed at confining or limiting the scope of the search process were not necessary. Search filters are predetermined database searches, which when combined with the subject terms, identify high quality articles and filter out all papers except RCTs.[32] As few RCTs were identified, it was necessary for the 'explosion' of some terms to be undertaken in order to increase the retrieval of relevant citations.[33] Every electronic database had its own indexing terms, and although many of the terms used were the same, individual search strategies were developed for each database.

Whenever a search resulted in the identification of less than 500 citations, all titles and abstracts were individually scanned to determine if they satisfied the inclusion criteria for the review. The reviewer felt that to individually check more than 500 citations was beyond the scope of this review and further refinement was undertaken to reduce the yield to a more manageable number. The search process continued until the reviewer was satisfied that no new citations were emerging from individual electronic databases that had not been previously identified.

During the conduct of the search consideration was given to the possibility of different terminology and spelling of key terms that may occur between different countries, as it was thought that this may influence the identification of relevant studies. Examples of this were the terms hemostasis and hematoma, although most commonly spelt in this fashion, were also found during the searching process to be spelt as haemostasis and haematoma.

Rosenfeld advocates that the literature search for a systematic review must be documented in sufficient detail so that replication can be undertaken.[28] The sources and findings of the search process are reported below.

Cochrane Library (1999, Issue 1)

The Cochrane Library was the first electronic database searched as it was important to ascertain if a systematic review had previously been conducted in relation to

mechanical compression devices used to attain haemostasis after femoral sheath removal.

The search terms used were:

— haemostasis, femoral and (sheath and removal), mechanical and compression, femostop, hemo* and clamp, arterial and seal.

The Cochrane Database of Systematic Reviews did not reveal any completed systematic reviews pertaining to the use of mechanical compression devices for attaining haemostasis after femoral sheath removal. The Database of Abstracts of Review of Effectiveness (DARE) did however identify five prospective randomised controlled trials that appeared to meet the review inclusion criteria. These citations were retrieved.

MEDLINE EXPRESS (R) 1966—1999/06

The following search history was used to search the Medline database.

No.	Record	Request
1	13983	haemostasis
2	37128	device
3	223	#1 and #2
4	76220	mechanical
5	2591	mechanical and #2
6	33322	compression
7	2328	#4 and compression
8	134	#7 and #2
9	56169	femoral*
10	13194	femoral* in TI
11	55974	femoral
12	16936	sheath
13	25	femoral sheath
14	14391	manual
15	33322	compression
16	150	#14 and #15
17	92334	removal
18	467	#12 and #17
19	2833	pneumatic
20	33323	clamp*
21	46862	bleeding
22	331	#20 and #21
23	158665	arterial
24	4025	seal
25	63	#23 and #24
26	440905	hemo*
27	25328	clamp
28	1048	#26 and #27
29	8	femostop

30	217260	cardiac
31	235	#26 and #27 and #30
32	5845	hemostatic
33	324444	techniques
34	217260	cardiac
35	68775	catheterization
36	8	hemostatic techniques and cardiac catheterization
37	272	mechanical pressure
38	21	#30 and #37

CINAHL (R) 1982—1999/01

A similar search history was used to search the CINAHL electronic database.

No.	Record	Request
1	360	haemostasis
2	2994	device
3	21	#1 and #2
4	4574	mechanical
5	450	#4 and #2
6	1653	compression
7	1653	#4 and #6
8	48	#7 and #2
9	893	femoral*
10	182	femoral* in TI
11	893	femoral
12	122	sheath
13	9	#11 and #12
14	9102	manual
15	1653	compression
16	8	#14 and #15
17	1546	removal
18	35	#12 and #17
19	234	pneumatic
20	270	clamp*
21	1171	bleeding
22	16	#20 and #21
23	2461	arterial
24	359	seal
25	13	#23 and #24
26	7217	hemo*
27	161	clamp
28	30	#26 and #27
29	3	femostop
30	8494	cardiac*
31	15	#28 and #30
32	7217	hemo*
33	161	clamp
34	8492	cardiac
35	15	hemo and clamp and cardiac
36	175	hemostatic
37	11621	techniques
38	8492	cardiac
39	1994	catheterization
40	7	hemostatic techniques and cardiac catheterization
41	360	haemostasis
42	4574	mechanical
43	1653	compression
44	893	femoral
45	122	sheath
46	0	haemostasis and mechanical compression and femoral sheath

47	175	hemostatic
48	11621	techniques
49	893	femoral
50	122	sheath
51	0	hemostatic techniques and femoral sheath
52	175	hemostatic
53	11621	techniques
54	64	#52 and #53
55	4574	mechanical
56	11113	pressure
57	25	#55 and #56
58	8494	cardiac*
59	9	#57 and cardiac*

EMBASE (The EXCERPTA MEDICA Database)

The following search terms were entered into the Embase electronic database.

Search 1—femoral sheath

—and (haemostasis)

—and (removal)

Search 2—mechanical

—and (compression)

Search 3—pneumatic

—and (compression)

—and (clamp)

Current Contents (1998—1999)

The following search history was used for the Current Contents electronic database.

No.	Search History	Result
1	haemostasis.mp [mp=abstract, title, author keywords, keywords plus]	686
2	femoral.mp [mp=abstract, title, author keywords, keywords plus]	3631
3	sheath.mp [mp=abstract, title, author keywords, keywords plus]	1657
4	1 and 2 and 3	11
5	mechanical.mp [mp=abstract, title, author keywords, keywords plus]	20656
6	compression.mp [mp=abstract, title, author keywords, keywords plus]	7185
7	1 and 5 and 6	4
8	pneumatic.mp [mp=abstract, title, author keywords, keywords plus]	538
9	clamp.mp [mp=abstract, title, author keywords, keywords plus]	3447
10	1 and 8 and 9	1
11	bleeding.mp [mp=abstract, title, author keywords, keywords plus]	4338
12	arterial.mp [mp=abstract, title, author keywords, keywords plus]	11378
13	seal.mp [mp=abstract, title, author keywords, keywords plus]	818
14	11 and 12 and 13	1
15	hemostatic.mp [mp=abstract, title, author keywords, keywords plus]	541

16	techniques.mp [mp=abstract, title, author keywords, keywords plus]	39987
17	15 and 16	20

HealthSTAR (1975—1999)

The following search terms were used to search the HealthSTAR electronic database. The search strategy excluded any Medline references and included all study groups and English language reports.

No.	Search History	Result
1	haemostasis	104
2	femoral and sheath	4
3	femoral and sheath	11
4	mechanical and compression and device	13
5	hemostatic device	11
6	femostop	8
7	compression device	15
8	arterial and seal	2

EBM Reviews—Evidence Based Database

The following search terms were used in the Evidence Based database.

No.	Search History	Result
1	femoral.mp [mp=abstract, title, author keywords, keywords plus]	28
2	sheath.mp [mp=abstract, title, author keywords, keywords plus]	4
3	1 and 2	0
4	haemostasis. mp [mp=abstract, title, author keywords, keywords plus]	5
5	mechanical.mp [mp=abstract, title, author keywords, keywords plus]	56
6	compression.mp [mp=abstract, title, author keywords, keywords plus]	47
7	5 and 6	4
8	clamp.mp [mp=abstract, title, author keywords, keywords plus]	1
9	6 and 8	0
10	hemostatic device.mp [mp=abstract, title, author keywords, keywords plus]	0
11	hemostatic.mp [mp=abstract, title, author keywords, keywords plus]	0
12	technique.mp [mp=abstract, title, author keywords, keywords plus]	81
13	11 and 12	0

The search for unpublished studies included:

Proceedings (1992—1999)—an electronic database that includes citations of every congress, symposium, conference, exposition, workshop and meeting received at The British Library.

Dissertations Abstracts International (1992—1999)—an electronic database that includes a complete range of academic subjects appearing in dissertations accepted at accredited institutions.

The searches conducted in these databases were restricted to English language only and included the following terms:

> —haemostasis, hemostasis, mechanical compression, femoral sheath, hemostatic techniques, compression and clamp.

No citations were identified from the Proceedings database but two Master of Nursing Theses were identified from the Dissertation Abstracts International database that appeared to meet the review inclusion criteria. Both citations originated from the United States of America and were ordered and purchased.

The reference lists and/or bibliographies of all retrieved articles were checked for additional studies. The studies identified from these sources were assessed for initial inclusion on the citation title alone.

Management of the Review References

EndNote version 4.0 software was used to manage the articles that were retrieved from the search process, as it was able to store and organise bibliography references by numbering each citation. This process assisted the search strategy as the EndNote database identified articles previously cited and reports could be generated that outlined all identified citations. In addition, the EndNote database enabled all citations to be allocated a reference number that allowed the retrieval of specific citations to be made more easily.

Assessment of Methodological Quality

The methodological quality of those studies that satisfied the inclusion criteria were critically appraised. A checklist based on the work of the Cochrane Collaboration[34] and the Centre for Reviews and Dissemination at the University of York[21] was developed to critically appraise the research (see Appendix 2). The checklist was used

to determine if the RCTs identified through the search process met the systematic review inclusion criteria. The checklist was pilot tested on five research articles by the primary reviewer, who had no experience in critical appraisal used in systematic reviews, and by another person who did have such experience. Not only did this pilot test assess the validity of the critical appraisal tool but also it allowed the reviewer to check their assessment of methodological quality against a more experienced reviewer. The findings of the two reviewers were identical for all five articles.

Once studies had been identified for inclusion in the review, each reference was coded with a specific number. To facilitate the identification of selected articles this number correlated with the reference number in the stored EndNote citation. On completion of the critical appraisal process, the checklist was completed and left attached to the article. Randomised controlled studies were assessed for inclusion in a meta-analysis. Studies scoring "yes" to questions 1 to 5 on the checklist were considered for inclusion in a meta-analysis.

In the absence of sufficient randomised controlled trials the review was extended to include research utilising other methodologies, such as uncontrolled clinical trials or descriptive studies. Another checklist was developed to critically appraise these studies. This checklist was also based on the work of the Cochrane Collaboration[34] and the Centre for Reviews and Dissemination at the University of York[21] (see Appendix 3). These studies were then included in a narrative summary that describes the efficacy of the mechanical device. Non-RCT's were assessed for inclusion using a checklist (see Appendix 3); its design being informed by those developed by the Joanna Briggs Institute (JBI) and based on the work of the Cochrane Collaboration[34] and the Centre for Reviews and Dissemination at the University of York.[21]

The quality of each study varied with respect to bias and error. Studies were excluded from the data synthesis phase of systematic review (meta-analysis) if they had: an inadequately defined randomisation technique (selection bias); apart from the study intervention, displayed a difference in care within the study groups (performance bias); different treatment groups due to study participant withdrawal or drop out (attrition bias); and different outcome assessment measures (detection bias).

Studies were categorised according to the strength of their evidence using the following scale published by the Australian Quality of Care and Health Outcomes Committee.[27]

Level I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
Level II	Evidence obtained from a least one properly designed randomised controlled trial.
Level III.1	Evidence obtained from well designed controlled trials without randomisation.
Level III.2	Evidence obtained from well-designed cohort or case control analytic studies preferably from more than one centre or research group.
Level III.3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments.
Level IV	Opinion of respected authorities, based on clinical experience, Descriptive studies, or reports of expert committees.

Ideally two reviewers should independently appraise *all* studies included in the review. As this systematic review is a section of the author's research portfolio for a higher degree award, this step was not possible and only a small sample of five studies were assessed in this manner. It is acknowledged that the exclusion of a second independent reviewer to critically appraise all papers may limit the strength of this systematic review.

Data Extraction

Data that met the outcome inclusion criteria for the review were extracted from the results of each study using a data extraction tool. The tool was developed and tested for reliability by the JBI, Adelaide, Australia (see Appendix 4).

The tool consists of three sections each pertaining to a specific area of research methodology, methods and analysis. In addition, demographic details and data related to the study institution(s), the diagnostic or interventional procedure, the compression technique(s) and its application method(s), and outcome measures used to determine the effectiveness of the compression technique were recorded. Study design details including randomisation, allocation and blinding of participants were also collected. All results pertaining to the review subject were recorded on the data collection tool.

Data from non-randomised controlled studies pertaining to mechanical compression devices deemed to be important were also recorded to ensure the review captured the available current evidence on this topic. The data and major findings extracted from these studies were briefly summarised and included in a narrative report. However, it is acknowledged that the strength of this evidence is lower than that generated by quality RCTs.

Data were extracted only from those studies that met the quality standards specified for critical appraisal. Financial and time constraints meant that if data were missing or inadequately reported it was not possible to contact the primary researchers, limiting the use of these papers in meta-analysis.

To add rigour to the data extraction process, data were extracted independently by another reviewer in a small sample of studies. When the data were compared between the two reviewers for five articles that met the inclusion criteria, the findings were identical. On completion of the data extraction process the data collection tool was attached to each reviewed paper.

Data Analysis

An RCT design was either rarely used or insufficient information was available from the identified studies that would allow statistical techniques that combined results in a meta-analysis to occur.

Where sufficient data were available, the Peto odds ratio (for categorical outcome data) or standardised mean differences (for continuous outcome data) and their respective 95% confidence intervals (CIs) were calculated for each study. Where statistical pooling of results was not appropriate or possible, the findings were summarised in narrative form. While the value of this information is limited because of threats of bias, this information was considered important in order to present a complete summary of evidence in relation to mechanical devices used to attain haemostasis after femoral sheath removal.

The Review Manager software program (RevMan 4.0), developed by the Cochrane Collaboration was used to graphically present these results and pool statistical data when appropriate in a meta-analysis. The statistical analyses presented in the tables should be interpreted as follows. Clinical outcomes are conventionally expressed as unwanted (or adverse) events. For odds ratios (categorical data) CIs that did not cross 1.0 were considered statistically significant, while for the mean differences (continuous data), CIs that did not cross zero were statistically significant. Statistical significance refers to the situation where the results are due to the treatment effect and not to chance or random variation.

Results

Included Studies

A total of 53 articles met the initial systematic review inclusion criteria. Of these there were:

- randomised controlled trials 17
- non-randomised controlled studies 3
- uncontrolled clinical trials 5
- descriptive studies 7
- descriptive survey 2
- chart review 1
- case study/case series 4
- reports or general subject overviews 14

Studies were included in this systematic review if they satisfied the inclusion criteria for the review (see Appendix 1) and the inclusion criteria after critical appraisal for meta-analysis or inclusion as a narrative summary (see Appendices 2 & 3).

Of the 53 retrieved articles only 12 papers were of an acceptable methodological quality for inclusion in the systematic review, being randomised controlled trials or descriptive cohort studies. These 12 studies are listed chronologically in appendix 5, which outlines the study design, sample, study intervention(s), study outcomes and strength of the evidence reported using a scale published by the Australian Quality of Care and Health Outcomes Committee.[27]

Only randomised controlled trials were considered for inclusion in the meta-analysis. These studies required sufficient information to be detailed within the study report to be able to determine if the study groups were comparable on entry; the method of randomly allocating participants to the study groups was adequate; other than the research intervention, the participants in each group were treated the same; the study outcomes were measured in the same manner for all participants; and the attrition rate was explained within the study report.

In the identified RCTs a wide variety of outcome measures were used, including: time to effect haemostasis, haematoma formation, bleeding, arteriovenous (AV) fistula formation, pseudoaneurysm, bruising or ecchymosis, and patient comfort and/or discomfort with the study intervention. In some of the reported RCTs the author(s) failed to provide sufficient data to allow their inclusion in a meta-analysis. Only three studies used the same outcome measures (bleeding and haematoma formation) and provided sufficient detail to allow data to be synthesised in a meta-analysis.[5,14,35]. Had sufficient data been available from studies of different types of mechanical devices, this data would have been synthesised in a meta-analysis. Consequently meta-analysis was limited due to inadequate reporting of results or missing data. For this reason the result are predominantly reported in narrative form. It is acknowledged that for the purpose of meta-analysis the reviewer would typically contact the investigator of the original study if data were insufficiently reported or missing. Financial and time constraints meant that this was not possible.

It was possible to extract sufficient data from some individual studies to include the findings in a narrative summary. Where possible the reporting of these results will be presented in figure format.

Excluded Papers

Papers were excluded from the review if they did not satisfy the inclusion criteria for the review (see Appendix 1) and/or the inclusion criteria after critical appraisal for meta-analysis or inclusion as a narrative summary (see Appendices 2 & 3).

After critical appraisal, a total of 41 articles were excluded from the review. Fourteen were literature reviews or overviews (not systematic reviews) outlining the application and/or management of various haemostasis techniques. Fifteen studies did not evaluate mechanical compression techniques specifically, being studies that compared collagen sealing devices or involved the use of mechanical devices to treat various vascular complications such as iatrogenic femoral artery pseudoaneurysm rather than to attain haemostasis after femoral sheath removal. Four papers were single or case series reports and three studies used brachial or radial artery sheaths rather than femoral sheaths. Four papers did not contain sufficient information for data to be extracted from the primary research studies to allow critical appraisal to be undertaken. One study was undertaken in swine subjects, not human participants. The citation and specific rationale for exclusion is detailed in appendix 6.

This section of the report will present the findings of studies included in the review under the following categories:

I Manual compression versus mechanical compression techniques
II Mechanical technique versus another mechanical compression technique
III Mechanical compression technique versus other compression techniques
IV Mechanical compression techniques versus no compression.

I Manual Compression versus Mechanical Compression

Meta-analysis

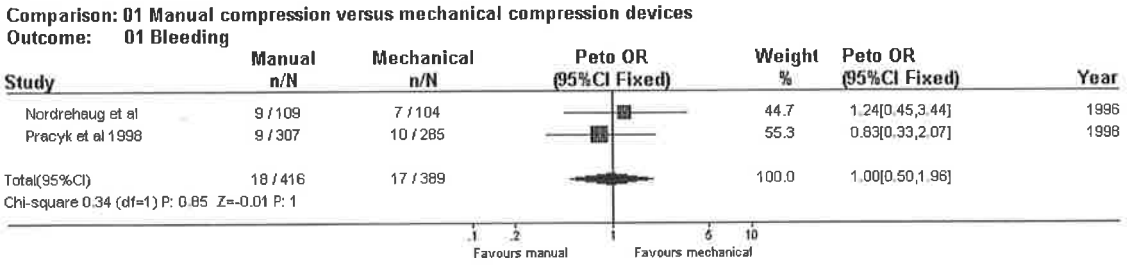
Only three studies comparing manual compression with mechanical compression were identified during critical appraisal that fulfilled the inclusion criteria for this systematic review, and the inclusion criteria for meta-analysis.[5,14,35] Data on bleeding could be synthesised from the studies by Nordrehaug et al[14] and Pracyk et al[5] because the outcome measures in these studies were homogeneous. The details are presented in table and figure format.

(i) bleeding

Table 4
Manual versus Mechanical Compression

Study	Intervention	Outcome	Results			
			Manual		Mechanical	
			No. Bleeding	Total No. in Group	No. Bleeding	Total No. in Group
Nordrehaug 1996	Manual versus Mechanical Compression	Bleeding	9	109	7	104
Pracyk 1998			9	307	10	285

Figure 1
Manual versus Mechanical Compression



The meta-analysis of data collected from these studies (Figure 1) indicated that bleeding from the femoral puncture site after femoral sheath removal did not differ significantly when either a mechanical compression device or manual compression was used to attain haemostasis.

Although this data can statistically be combined in a meta-analysis it must be noted that volume of blood loss from the femoral puncture site in either study was not reported. However, the definition of 'bleeding' was similar in both studies. Nordrehaug et al (p.383) defined it as 'any ooze or frank bleeding occurring after the puncture site'[14], while Pracyk et al (p.972) considered it to be 'a leakage of blood from the puncture site'.[5]

(ii) haematoma formation

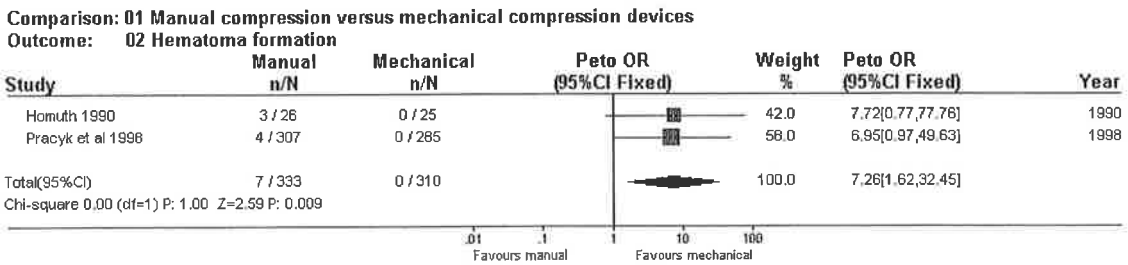
Outcome data relating to haematoma formation after femoral sheath removal were extracted from the randomised controlled trials by Homuth[35] and Pracyk et al.[5]

The table and figure below detail this data.

Table 5
Manual versus Mechanical Compression

Study	Intervention	Outcome	Results			
			Manual		Mechanical	
			Haematoma Numbers	Total No. in Group	Haematoma Numbers	Total No. in Group
Homuth 1990	Manual versus Mechanical Compression	Haematoma formation	3	26	0	25
Pracyk 1998			4	307	0	285

Figure 2
Manual versus Mechanical Compression



When the data were pooled from these studies the meta-analysis for haematoma formation indicated that the mechanical compression technique was most effective, with no incidents of haematoma formation in either study. This result was statistically significant with a P value of 0.009.

Although Pracyk et al (p.972) defined a haematoma as a 'non-pulsatile mass > 4 cm in diameter'[5] neither study recorded the specific size, or significance of the haematomas that were present after manual compression.

Manual Compression versus ClampEase Mechanical Compression

The RCT undertaken by Pracyk et al compared manual compression, using a two hand method of compression for at least 15 minutes with the ClampEase mechanical compression device (Pressure Products Inc., Rancho Palos Verdes, California) after femoral sheath removal from all coronary interventional patients in their institution.[5] A physician blinded to randomisation, demographic and clinical data independently assessed clinical outcome measures, such as bleeding, ecchymosis and a pulsatile mass. Clinical assessment was therefore subject to staff availability (n=592). The presence of more serious vascular pathology, such as haematoma formation,

pseudoaneurysm and AV fistula formation was detected though ultrasonographic examination (n=390). Table 6 provides a summary of this study. This is followed by graphical representation of the study outcomes.

Table 6

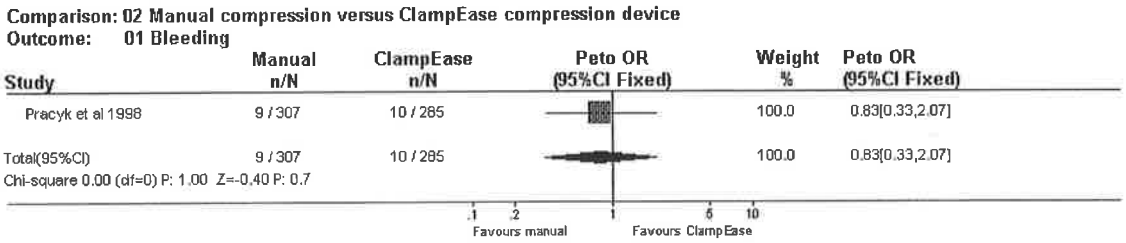
Manual versus ClampEase

Study	Intervention	Outcome	Results			
			Manual		ClampEase	
			Outcome numbers	Total No. in Group	Outcome numbers	Total No. in Group
Pracyk 1998	Manual compression versus ClampEase Compression	Bleeding	9	307	10	285
		Ecchymosis	103	307	112	285
		Pulsatile mass	4	307	0	285
		Haematoma formation	8	208	4	182
		Pseudoaneurysm	6	208	2	182
		AV fistula formation	3	208	0	182

(i) bleeding

Figure 3 (i)

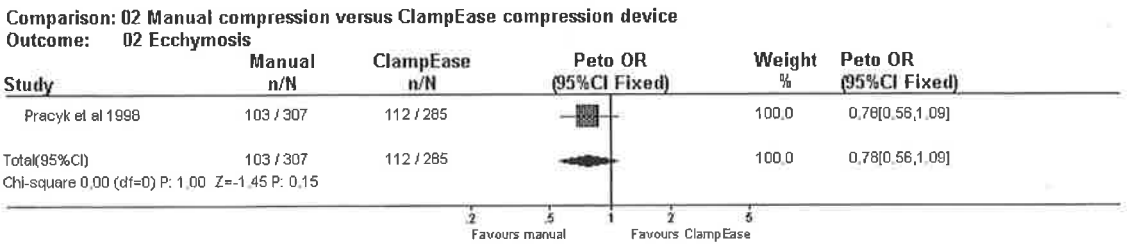
Manual Compression versus ClampEase Compression



This figure demonstrates that in the RCT reported by Pracyk et al there was no difference in the incidence of bleeding after femoral sheath removal using either manual or mechanical compression with the ClampEase compression device.[5]

(ii) ecchymosis

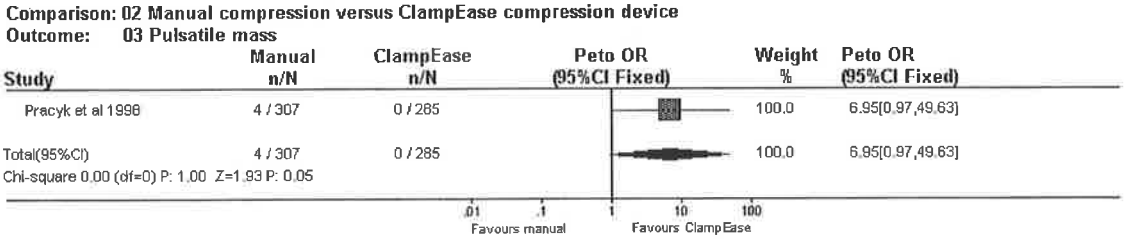
Figure 3 (ii)
Manual Compression versus ClampEase Compression



Pracyk et al (p.972) defined ecchymosis as a bruise that 'reflected the effects of bleeding into subcutaneous tissue planes (without a mass effect), causing bluish-purple skin discolouration'.[5] This study demonstrated that although there was a trend towards ecchymosis favouring the manual compression intervention group, the incidence was not statistically significantly.

(iii) pulsatile mass

Figure 3 (iii)
Manual Compression versus ClampEase Compression



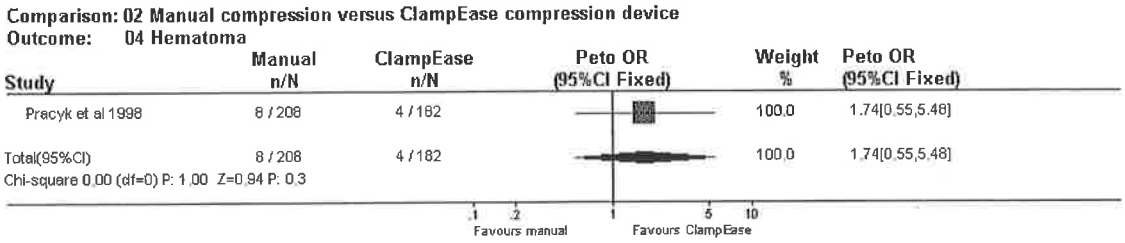
Pracyk et al (p.972) considered a pulsatile mass to be 'an object with a palpable movement corresponding to systole and diastole'.[5] If found on clinical assessment, any new palpable mass was considered evidence suggestive of more serious vascular complications such as limb ischaemia, pseudoaneurysm and/or AV fistula. Although the figure above demonstrates a trend towards pulsatile mass favouring the ClampEase technique, the result is not statistically significant.

The study outcomes bleeding, ecchymosis and pulsatile mass were all considered femoral vascular complications that were diagnosed on physical examination. In regards to these clinical outcomes, no significant difference was demonstrated

between the two study interventions, that is, manual compression and mechanical compression using the ClampEase device in this study.[5]

(iv) haematoma formation

Figure 3 (iv)
Manual Compression versus ClampEase Compression

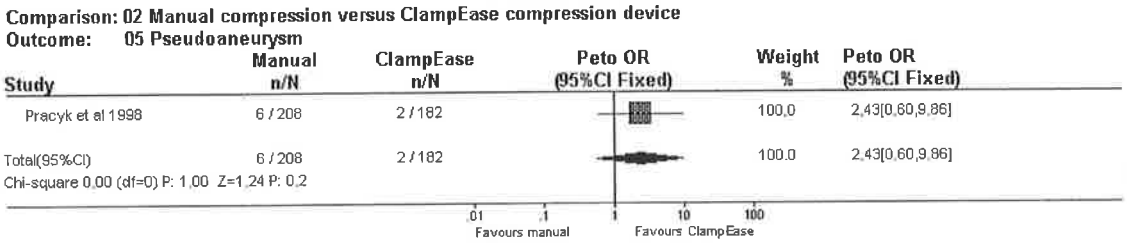


There was no significant difference in the incidence of haematoma formation that occurred after either manual or mechanical compression using the ClampEase mechanical compression device in this study. Although it was reported by Pracyk et al (p.972) that a haematoma was considered to be a 'non-pulsatile mass > 4 cms in diameter, the size of individual haematomas that occurred in either study group was not reported.[5]

A descriptive study undertaken by Simon compared the ClampEase mechanical compression device with manual compression to attain haemostasis after femoral sheath removal from cardiac catheterisation patients.[7] This was a historical controlled trial where data were collected from 100 consecutive cardiac catheterisation patients that had the ClampEase mechanical compression device to attain haemostasis after femoral sheath removal. This data were compared to data retrospectively collected from 100 patients who had received manual compression after femoral sheath removal (the control group). No statistical data were available from this study to include in a meta-analysis, but their findings support those of Pracyk et al in that no significant difference was demonstrated between the two study groups (manual compression and ClampEase mechanical compression) in respect to haematoma formation after femoral sheath removal.[5]

(v) pseudoaneurysm

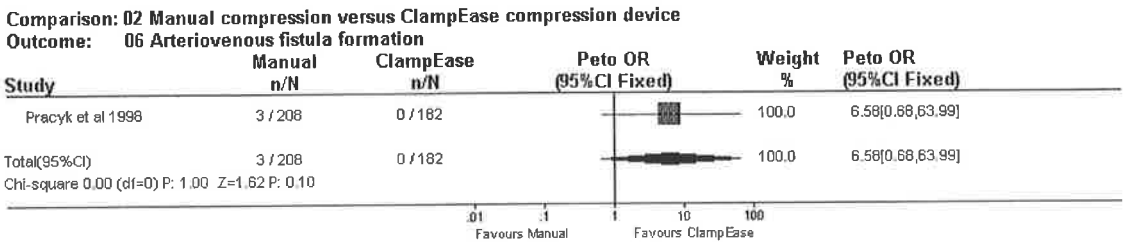
Figure 3 (v)
Manual Compression versus ClampEase Compression



A pseudoaneurysm, or false aneurysm, occurs when there is an interruption of the artery wall causing an extraluminal pouch encapsulated by solidified blood in the interstitial tissue outside the vessel. Often caused by traumatic or iatrogenic puncture to the artery, this interruption allows blood to jet back and forth from the pouch to the bloodstream with the potential to rupture.[9] Although the incidence of pseudoaneurysm formation after femoral sheath removal was not significantly different between either study group (Figure 3v), Pracyk et al demonstrated a trend towards pseudoaneurysm in the manual compression study group (3%) as compared to the ClampEase mechanical compression group (1%).[5]

(vi) AV fistula formation

Figure 3 (vi)
Manual Compression versus ClampEase Compression



Arteriovenous (AV) fistula was defined by Pracyk et al (p.972) as 'an abnormal communication between the femoral artery and vein'.[5] Of the 182 patients examined for serious vascular access site pathology using ultrasonography, no patients developed an AV fistula after the application of the ClampEase mechanical compression device. The incidence of AV fistula formation was not statistically significant in either study intervention group (Figure 3 vi).

An unexpected finding of this study was the discrepancy between complications detected by ultrasonic examination compared to clinical examination alone. Ultrasound-defined pathology was missed in 89% of clinically examined cases and different conclusions were reached after the clinical and ultrasound examinations. No apparent difference was demonstrated between the ClampEase mechanical compression device and manual compression after clinical examination alone, yet ultrasound revealed a reduction in serious vascular complications as a direct result of using the clamp technique to attain haemostasis after femoral sheath removal.[5] Therefore the authors of the study concluded (p.975) that 'mechanical compression reduces the incidence of serious vascular complications but has no effect on the cosmetic consequences of femoral access for coronary intervention'.[5]

Manual Compression versus FemoStop™ Mechanical Compression

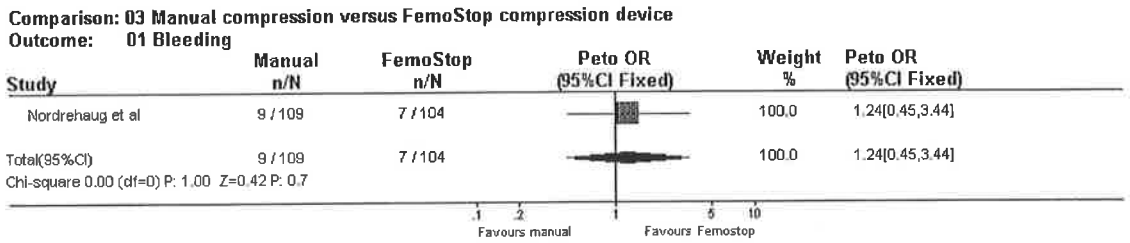
Two studies were identified from the search process that satisfied the systematic review inclusion criteria (see Appendix 1) comparing manual and FemoStop™.[14,15] Nordrehaug conducted a RCT that compared manual compression with mechanical compression using the FemoStop™ device (RADI Medical Systems AB, Uppsala, Sweden).[14] This study met the critical appraisal criteria for inclusion in a meta-analysis (see Appendix 2) but apart from the clinical outcome bleeding, contained insufficient statistical data for the other study outcomes to be included in a meta-analysis. Sridhar et al also compared manual compression with the FemoStop™ compression device[15] but insufficient statistical data and inadequate randomisation of patients to the respective study groups (retrospective controlled trial), meant that this study did not meet the criteria for inclusion in a meta-analysis. However it was possible to included these studies in a narrative summary. The study details are listed in Table 7 and some outcomes are presented in the figures below.

Table 7
Manual versus FemoStop™

Study	Intervention	Outcomes				
		Bleeding	Haematoma	Pseudoaneurysm	AV fistula	Days hospital stay
Nordrehaug 1996	Manual versus Mechanical Compression	✓	✓	✓	✓	
Sridhar 1996			✓	✓	✓	✓

(i) bleeding

Figure 4 (i)
Manual versus FemoStop™



Although Nordrehaug et al did not state the amount of bleeding that occurred in either study group, bleeding was defined (p.382) as 'any ooze or frank bleeding occurring at the puncture site'.[14] There was no significance difference in the incidence of bleeding that occurred after femoral sheath removal in either the manual compression or FemoStop™ compression groups. Except for one patient who bleed 12 hours later in the FemoStop™ group, bleeding was reported to have occurred during the first three hours after the procedure. Episodes of bleeding were successfully managed by further compression using the allocated compression technique. This study demonstrated that a high systolic blood pressure (>160 mmHg) and dose of aspirin (150-330mg) were major predictors of bleeding after femoral sheath removal. The study by Sridhar et al did not report bleeding as a study outcome.[15]

(ii) haematoma formation

Both studies inspected the femoral puncture site for evidence of haematoma formation after femoral sheath removal.[14,15] Nordrehaug et al (p.382) defined a haematoma as

any new 'swelling >10 cms in diameter'.[14] There was no significant difference in the incidence of haematoma formation between the groups in this study as two patients in each treatment group developed a new haematoma after femoral sheath removal.

Although the criterion used to define a haematoma was not reported in the study by Sridhar et al, a significant difference in the incidence of haematoma formation was reported.[15] Haematoma requiring transfusion or surgery occurred in 12% of patients after manual compression as compared to no reported episodes in the FemoStop™ compression group ($P = 0.02$).[15]

(iii) pseudoaneurysm

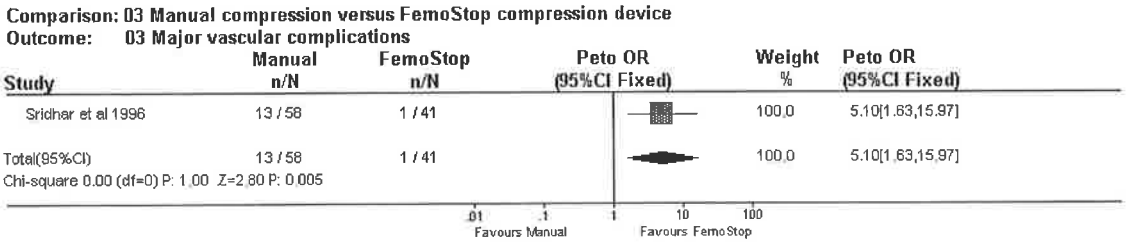
A statistically significant difference in the incidence of pseudoaneurysm formation was reported in the study by Sridhar et al, with 19% in manual compression group versus 2% in the FemoStop™ group ($P = 0.01$).[15] However, it must be noted that the data were collected from the manual compression intervention group retrospectively in this study and data were accumulated over an unknown time period and therefore poorly controlled. It is likely that the observed differences in the study may have been at least partly due to improvements in techniques generally and/or due to random variation in the small sample. No episodes of pseudoaneurysm formation occurred in the study by Nordrehaug et al.[14]

(iv) AV fistula formation

There was no significant difference in the incidence of AV fistula formation in the study by Sridhar with a reported occurrence of 2% in the manual compression group as compared to no AV fistulas occurring after the application of FemoStop™ mechanical compression.[15] No episodes of AV fistula formation occurred in the study by Nordrehaug et al.[14]

(v) Major vascular complications

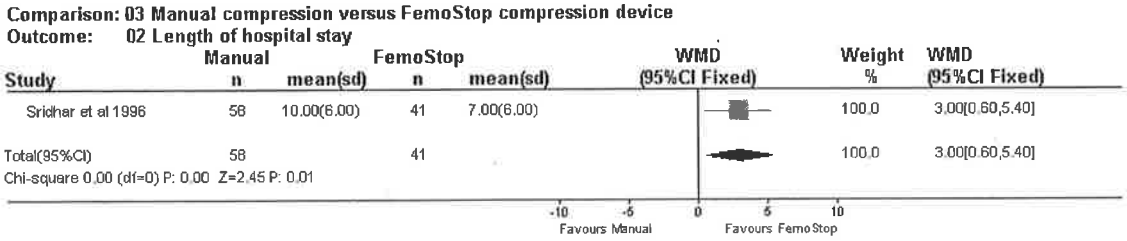
Figure 4 (ii)
Manual versus FemoStop



A major vascular complication, including pseudoaneurysm, AV fistula formation and haematoma formation requiring transfusion or surgery, occurred significantly more often after manual compression (22.4%) as compared to mechanical compression using the FemoStop™ device in this study (2.4%)[15] (Figure 4 ii). As a result there was a significant reduction in the length of hospital stay (reported in days) in patients allocated to the FemoStop™ compression group as can be seen in the figure below.

(vi) Length of hospital stay

Figure 4 (iii)
Manual versus FemoStop™



Manual Compression versus Compressar Mechanical Compression

Four studies were identified which compared manual compression with the Compressar mechanical compression clamp (Instromedix Inc. Hillisboro, Ore) used to attain haemostasis after femoral sheath removal.[12,35,36,37] Only one study met both the review inclusion criteria (see Appendix 1) and the RCT appraisal criteria for inclusion in meta-analysis (see Appendix 2).[35] The table below lists the citation and study outcomes.

Table 8
Manual versus Compressar

Study	Intervention	Outcomes				
		Bleeding	Haematoma	Comfort level	Lower limb ischemia	Time to haemostasis
Bogart 1995	Manual versus Mechanical Compression	✓	✓			✓
Homuth 1990		✓	✓	✓		✓
Semler 1985			✓		✓	✓
Simon 1998			✓	✓		✓

(i) bleeding

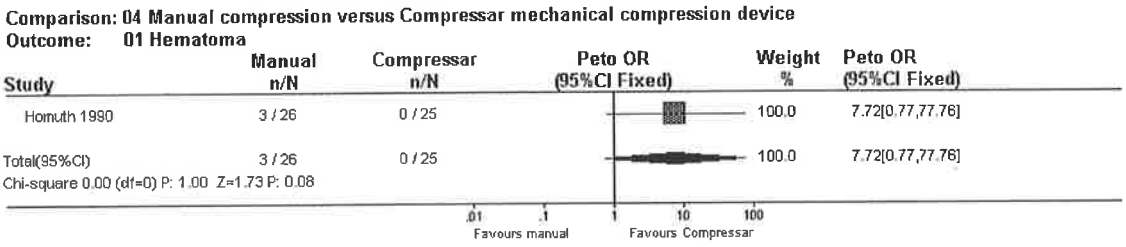
The study by Bogart reported 12 of 168 cases (13%) where recurrent bleeding continued after release of the Compressar mechanical compression device.[36] These patients were crossed over to the manual compression group to achieve haemostasis. Crossover also occurred in three of 355 patients (1%) from manual to mechanical compression to achieve haemostasis after persistent bleeding.

Bleeding was a study outcome included by Homuth as past experience in their practice had shown this to be a potential complication after femoral sheath removal.[35] However, no incidence of bleeding occurred in this study.

(ii) haematoma

All four studies assessed the femoral puncture site for evidence of haematoma formation but only Homuth included sufficient statistical information to allow this outcome to be represented in the figure below.[35]

Figure 5 (i)
Manual versus Compressar



Although no statistically significant difference in the incidence of haematoma formation was demonstrated in this study, there is a trend favouring the Compressar device. This finding was supported by the work undertaken by Semler[12] and Simon et al.[37] Although neither study demonstrated a statistical significant difference, Semler reported a 6% incidence of haematoma formation in the manual compression group as compared with 2% in the mechanical compression group.[12] Simon et al reported the incidence of haematoma formation to be 3% in the manual compression group as compared with 2% in the Compressar mechanical compression group.[37] Bogart however, reported three episodes out of 168 cases where haematoma formation developed while the mechanical compression device was in place, suggesting a different trend.[36] Of these four studies, no statistically significant differences occurred between these intervention groups for haematoma formation.

It should also be noted that the definitions used by these researchers varied between studies. Homuth (p.14) defined a haematoma as 'collection of extravasated blood ... that is manually palpable as a soft mass'[35], but made no reference to the size of the mass. Simon et al (p.311) only reported 'significant haematoma' formation, defined as a 'palpable mass greater than 7.6cm in diameter'.[37] The criterion used to determine the detection of haematoma formation was not reported in the studies conducted by either Bogart[36] or Semler.[12]

(iii) comfort level

Two investigators were interested in assessing the comfort level patients had in relation to manual or Compressar compression techniques.[12,35] Semler used a questionnaire to determine if patients had any pain or discomfort at the puncture site 72 hours after cardiac catheterisation.[12] The response was not significantly different between compression groups, with 4.9% in the mechanical compression group responding they had pain or discomfort as compared with 5.7% in the manual compression group.[12] Homuth used a 9-point verbal descriptor scale (VDS) to assess the patient's level of comfort during compression to attain haemostasis.[35] A scale of 0 to 8 was used, with 0 being no pain and 8 being the most severe pain. Measurements were recorded at 15 and 30 minutes intervals. No significant difference in the level of

comfort was found at the 15-minute interval, with mean values of 2.03 for manual compression and 2.10 for mechanical compression. At 30 minutes a statistically significant difference (P=0.5) was seen between the level of comfort with mean values of 2.42 reported for manual compression as compared with 1.56 for mechanical compression. This finding demonstrated that after 30 minutes a greater level of comfort was experienced with the Compressar compression device as compared to manual compression.[35]

(iv) lower limb ischemia

The degree of pressure applied with any techniques must be consistent to effect haemostasis and prevent haematoma formation but must not be of such intensity that circulation to the lower limb is compromised. Although not measuring this outcome specifically, Semler reported that no ischaemic events, thrombosis, or traumatic neuropathies occurred in either group (manual versus Compressar mechanical compression).[12]

(v) time to effect haemostasis

All studies that compared manual compression with the Compressar mechanical compression device reported on the time taken to effect haemostasis after femoral sheath removal, however incomplete reporting of design methods and missing data meant this information could not be synthesised in a meta-analysis. However, three of the four studies that were identified presented findings that supported mechanical compression using the Compressar devices as taking longer to effect haemostasis as compared with manual compression. Bogart reported the average length of time to effect haemostasis was 22 minutes for manual compression as compared with 31 minutes for mechanical compression.[36] Homuth stated the mean compression time for manual compression was 31.6 minutes as compared with 38.3 minutes using the Compressar device.[35] The two study groups differed significantly (P = 0.001) for mean compression time in the study by Simon et al, where the mean manual compression time was 14.93 minutes as compared with 17.13 minutes in the mechanical compression group.[37]

The study by Semler et al was the only study that reported the time to effect haemostasis using Compressar mechanical compression (mean = 19.9 minutes) as shorter than the manual compression time (mean = 33.5 minutes).[12]

Manual/Mechanical Compression versus Mechanical (ClampEase or Compressar) Compression

A two-phase study was undertaken by Rudisill et al that compared various forms of manual and mechanical compression techniques.[38] Although this paper met the inclusion criteria for review (see Appendix 1) it did not satisfy the criteria for inclusion in meta-analysis as patients were not randomly allocated to treatment groups and it was unclear from the study report how the outcomes were measured. It was possible however to include this paper in the review as a narrative summary.

The study methodology undertaken by Rudisill et al was complex and not well described in the study report.[38] The compression technique within each study group varied according to the cardiac interventional procedure performed, that was either PTCA and PTCRA or DCA. The study interventions and outcomes reported are listed in Table 9.

Table 9

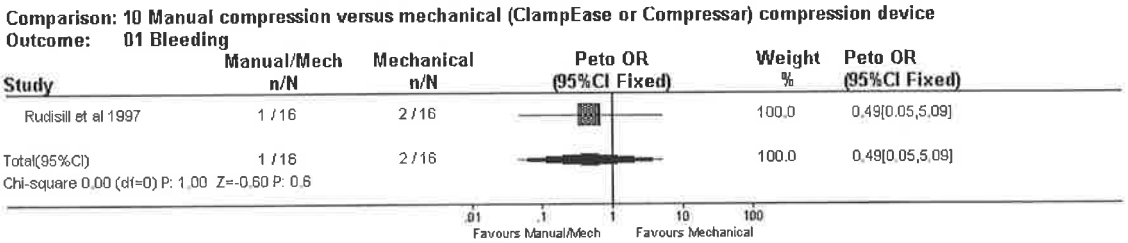
Manual/Mechanical versus Mechanical Compression

Study	Group 1 Intervention	Group 2 Intervention	Outcome
Rudisill 1997 Study 1	PTCA-manual compression only for 20 mins PTCRA/DCA - manual compression for 20 mins then 1 hr mechanical compression	PTCA-mechanical compression 40 mins PTCRA/DCA - mechanical compression 1 hr 20 mins	Bleeding Haematoma
Rudisill 1997 Study 2	ClampEase mechanical compression PTCA patients for 40 mins PTCRA/DCA for 80 mins	Compressar mechanical compression PTCA patients for 40 mins PTCRA/DCA for 80 mins	Haematoma

(i) bleeding

Figure 6 (i) Study 1

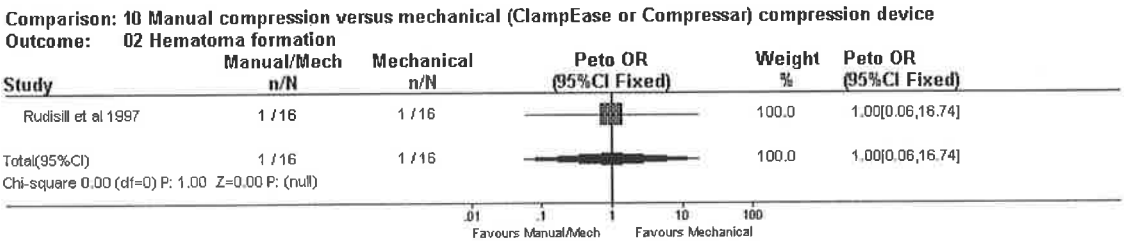
Manual/Mechanical versus Mechanical



This figure demonstrates there was no significance difference in the incidence of bleeding in the first study undertaken by Rudisill et al.[38] It should be noted that the sample size was small in this study (16 patients in each study group) and no information was included in regards to the volume of bleeding that occurred.

(ii) haematoma formation

Figure 6 (ii) Study 1
Manual/Mechanical versus Mechanical



There was also no significant difference in the incidence of haematoma formation in the first study as seen in the figure above. Information was not included that detailed the size of the haematoma's that occurred. In addition, it is unclear from the study report whether those incidents of bleeding or haematoma formation reported in the manual/mechanical intervention group occurred in the PTCA patients who received manual compression alone, or the PTCRA/DCA patients who received a combination of manual and mechanical compression. As there was no significant difference found between the two intervention groups in this study the researchers in this study concluded that it was safe to implement the use of mechanical devices (ClampEase or Compressar) for compression after femoral sheath removal into practice.

The second study was designed to evaluate groin complications after the change in practice had been implemented. Of the twenty patients enrolled in this study twelve patients (60%) received the Compressar compression device and eight patients (40%) received the ClampEase compression device after femoral sheath removal. Only one patient in this study developed a groin complication of a haematoma.[38] It is unclear from the study report from which interventional group this complication occurred.

II Mechanical Compression versus Another Mechanical Compression Technique

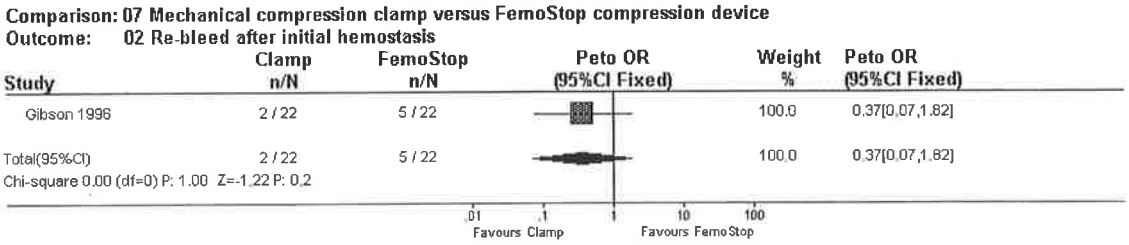
Two studies were identified from the search process that met the inclusion criteria for the systematic review (see Appendix 1) and the criteria for inclusion in a meta-analysis (see Appendix 2).[39,40] Both studies compared the use of mechanical compression devices in attaining haemostasis after femoral sheath removal using the FemoStop™ and ClampEase devices, but the study report presented by Janerot Sjoberg et al contained insufficient data to allow meta-analysis to be undertaken.[40] A narrative summary, with representation in figure format of data from the study by Gibson is reported below.[39] Table 10 lists the study outcomes for each citation.

Table 10
ClampEase versus FemoStop™

Study	Intervention	Outcomes				
		Bleeding	Haematoma	Comfort level	Pseudoaneurysm	Time to haemostasis
Gibson 1996	Mechanical versus Mechanical Compression	✓	✓	✓		✓
Janerot-Sjoberg 1998			✓		✓	

(i) bleeding

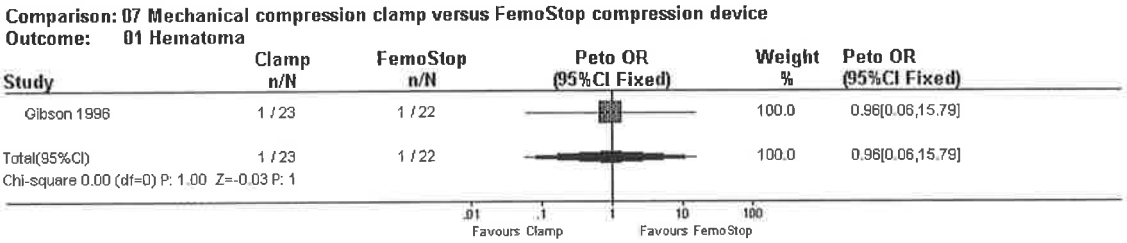
Figure 7 (i)
ClampEase versus FemoStop™



In the study by Gibson seven patients re-bleed after initial haemostasis, requiring further mechanical compression.[39] Although there was no significant difference in the incidence of bleeding between the two groups, there was a trend towards bleeding in the FemoStop™ group. Further analysis revealed that characteristics of those patients who re-bled after initial haemostasis differed only in terms of systolic blood pressure prior to sheath removal (re-bleed group = 106 ± 7.29 mmHg; no re-bleed group = 123 ± 14.8 mmHg) and the amount of meperidine (analgesic agent) given immediately prior to sheath removal (re-bleed group = 25 ± 0.0 mg; no re-bleed group = 19.5 ± 9.5 mg).[39]

(ii) haematoma formation

Figure 7 (ii)
ClampEase versus FemoStop™

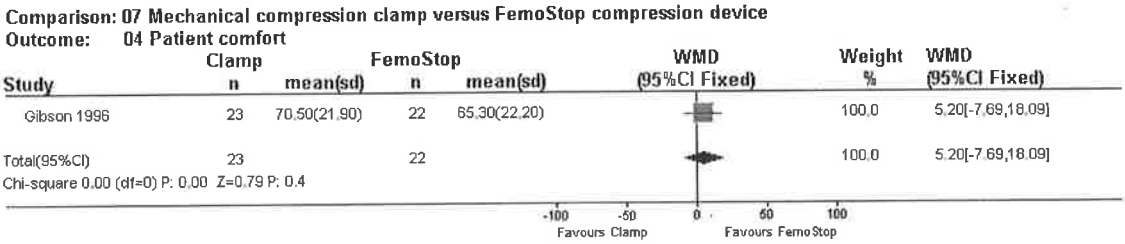


Gibson reported only two episodes (not statistically significant) of haematoma formation, one in either intervention study group as can be seen in the figure above. Janerot Sjoberg et al supported this finding.[40] Of the 1017 patients analysed in this study (FemoStop™ = 546 patients; ClampEase = 433 patients) only one patient in each group developed a haematoma after femoral sheath removal.[40] Neither study

gave details about the size of the haematoma's that occurred nor the method of detection.

(iii) comfort level

Figure 7 (iii)
ClampEase versus FemoStop™



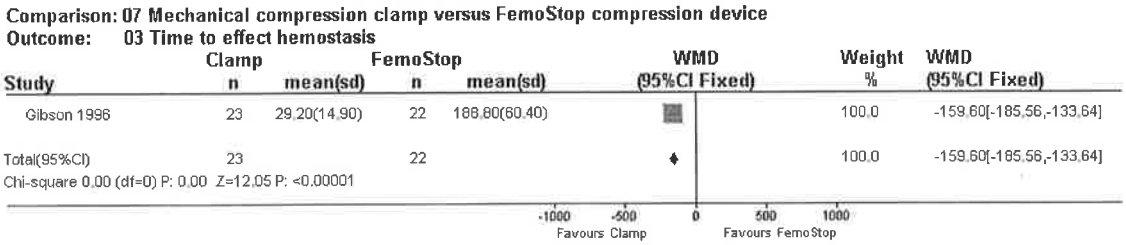
The study by Gibson explored how patient comfort differed with use of the FemoStop™ compression device as compared with the ClampEase compression device.[39] A visual analogue scale (VAS) was used to quantify comfort during the haemostasis compression period. Patients were asked to draw a line through the VAS, a 100mm scale with "not at all comfortable" at the left endpoint and "completely comfortable" at the right endpoint. As demonstrated in the figure above, there was no statistical significance in the degree of comfort that was experienced by patients in either mechanical compression group.[39] Although the study by Janerot Sjoberg et al did not measure patient comfort specifically they state (p.283) both devices were "well tolerated" by the patients in the study.[40]

(iv) pseudoaneurysm

The study by Janerot Sjoberg et al only reported on the outcome, pseudoaneurysm.[40] Two episodes of pseudoaneurysm occurred in the ClampEase mechanical compression group (0.5% of that group) as compared with none in the FemoStop™ compression group (not statistically significant). Pseudoaneurysm was diagnosed by ultrasonic Doppler examination performed within 24 hours of angiography because of clinical suspicion of a local vascular complication. Of these two cases, one required surgical repair while the other was successfully repaired with ultra-sound-guided compression.[40]

(v) time to effect haemostasis

Figure 7 (iv)
ClampEase versus FemoStop™



As can be seen in the figure above, the study by Gibson demonstrated a statistically significant difference in the time to effect haemostasis (measured in minutes) between the two treatment groups.[39] The study reported the FemoStop™ mechanical compression device taking significantly longer to attain haemostasis as compared with the Compressar mechanical compression device. However it is possible that a Type 1 error may have influenced the time to effect haemostasis. The reported mean and standard deviation for the FemoStop™ group suggests that there were a small number of outliners within the small group of 22 that have biased the parametric statistics. Unfortunately it is not possible to determine the extent of the outliers due to an inability to access the raw study data. Never the less, this result should be interpreted with caution.

Janerot Sjoberg et al did not report the time taken to attain haemostasis with either mechanical device in their study.[40]

III Mechanical Compression versus Other Compression Techniques

A study undertaken by Lehmann et al was identified during the search process to have met the inclusion criteria for the systematic review (see Appendix 1) and the criteria for inclusion in a meta-analysis (see Appendix 2).[2] This was a prospective RCT that investigated the efficacy of four different methods of femoral artery puncture site management after sheath removal from patients that had undergone invasive cardiac

procedures. This study was divided into two phases. During the first phase of the study patients were randomly assigned to one of three techniques used to attain initial haemostasis (manual compression, clamp compression device or FemoStop™ compression device). The second phase of the study compared four different methods of maintaining haemostasis, after initial haemostasis had been obtained.[2] The focus of the research report related primarily to the second phase of the study. Although this paper met the systematic review inclusion criteria, no other study was identified that contained sufficient data for comparisons within a meta-analysis to be made, therefore the information will be presented as a narrative summary with representation in figure format for some outcome measures. The study interventions and outcomes are listed in Table 11.

Table 11
Mechanical Compression versus other Compression Techniques

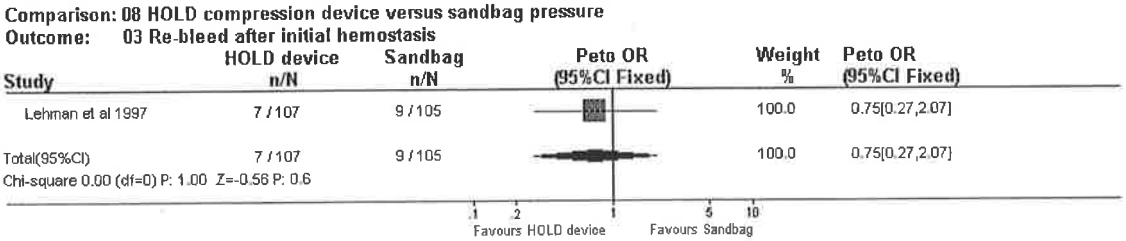
Study	Interventions				Outcomes
	Sandbag	Pressure Dressing	Compression Device	No Compression	
Lehmann 1997	4.5kg sandbag 32cm X 12cm X 8cm placed directly over site	10 X 10cm, 12 ply sterile gauze sponges folded. Final dimension —5 X 5cm Held by elastic adhesive bandage	HOLD device —8cm diameter hemispheric disk held under tension by a belt system around waist and upper thigh	The puncture site was not treated with any compression technique after initial haemostasis	Bleeding Haematoma Ecchymosis Time to haemostasis Discomfort —during compression —after compression, before ambulation —after compression, during ambulation

HOLD Compression Device versus Sandbag Compression

In this study all compression devices were scheduled to be removed 5 hours after femoral sheath removal and ambulation was commenced shortly after.

(i) re-bleeding

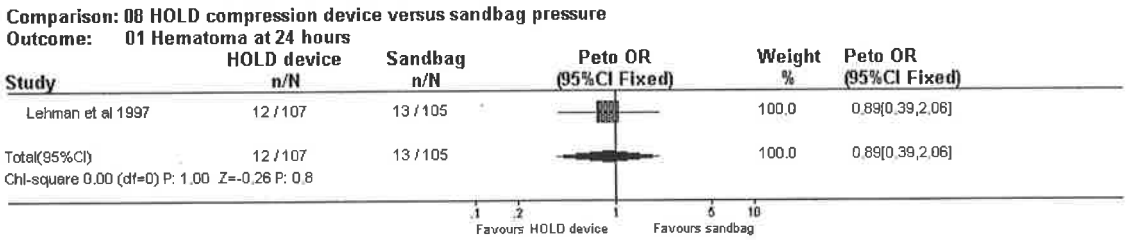
Figure 8(i)
HOLD device versus Sandbag Pressure



Minor re-bleeding (6.3% of the total patient population) was noted at the femoral puncture site after the initial compression technique used to attain haemostasis.[2] It was unclear from the report by Lehmann et al what compression technique(s) were used to attain initial haemostasis in these patients that demonstrated minor re-bleeding.[2] There was no significant difference in the incidence of re-bleeding that occurred in the second phase of the study between the HOLD compression device and sandbag pressure in maintaining haemostasis as demonstrated in the figure above.

(ii) haematoma formation

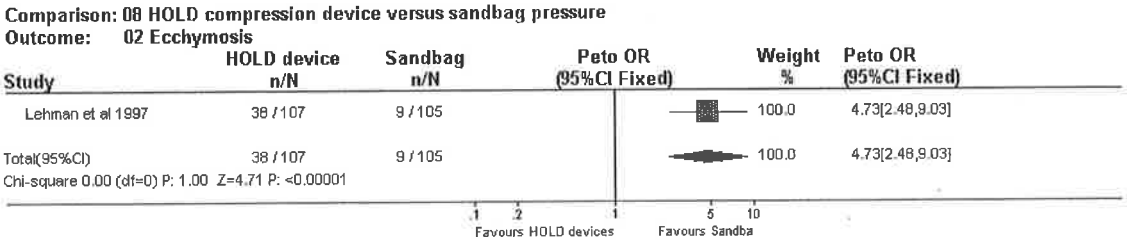
Figure 8(ii)
HOLD device versus Sandbag Pressure



Small haematomas (not present before sheath removal) were also noted in 11.1% of the total study population after initial haemostasis. A physical examination at 24 hours by a single observer showed there was no significant difference in the incidence of new haematoma formation between the HOLD compression device and sandbag pressure in maintaining haemostasis. The mean surface area of the haematoma was 6.9cm ± 18.4 cm^2, occurring in an average of 12% of patients in each study group.[2]

(iii) ecchymosis

Figure 8 (iii)
HOLD device versus Sandbag Pressure

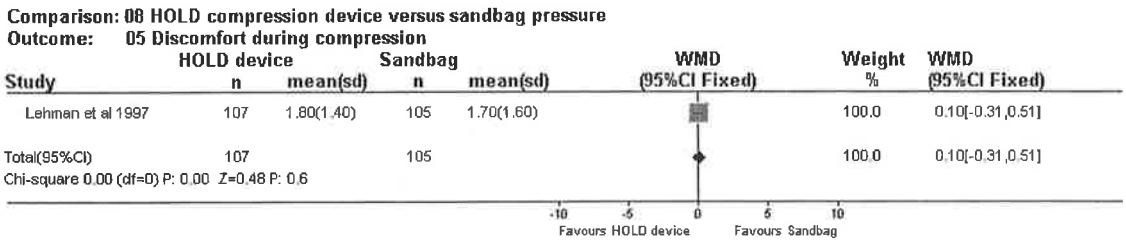


This study demonstrated a statistically significant difference in the incidence of ecchymosis between the HOLD compression device and sandbag pressure as seen in the figure above. Ecchymosis, or bruising, was more likely to occur after the HOLD compression device as compared to sandbag pressure [2]

(iv) patient discomfort

Patient discomfort was measured using a verbal descriptor scale (VDS) of 1 to 10, with 10 being the most discomfort. Discomfort was measured at three phases: during compression; after compression and before ambulation; and after compression and after ambulation.

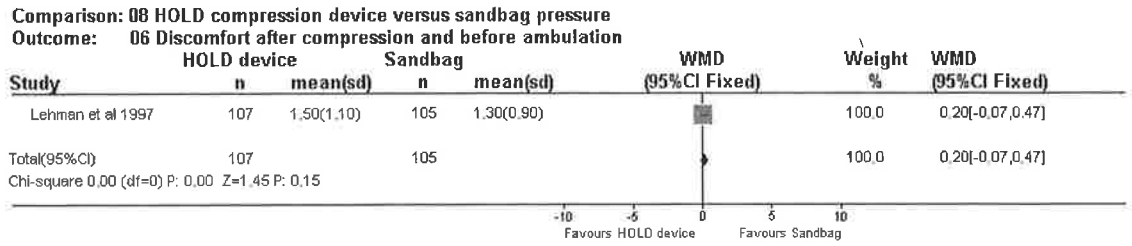
Figure 8 (iv)
HOLD device versus Sandbag Pressure
Discomfort During Compression



There was no significant difference in the degree of discomfort that patients felt during compression to maintain haemostasis with either the HOLD compression device or sandbag pressure.[2]

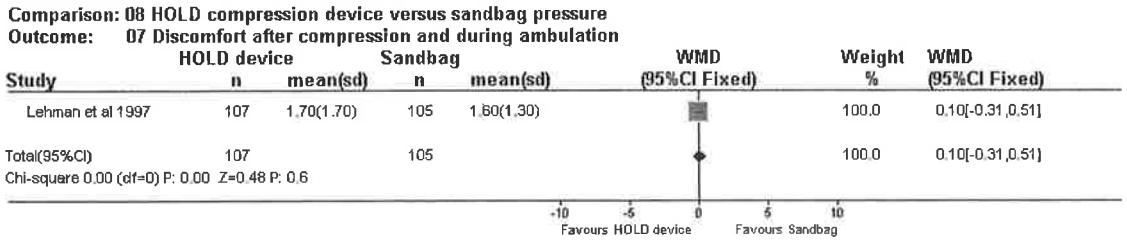
All patients, unless medically unable, were encouraged to ambulate as they would at home starting 5 hours after femoral sheath removal and when the compression technique employed to maintain haemostasis was ceased. Of the total number of patients in the study, 80% (n=287) were able to ambulate after sheath removal. Patients were asked to describe their level of activity at 24 hours after the cardiac procedure. Patients described their level of activity as mild in 72%, average (normal daily activity) in 25% and strenuous in 3% of cases.[2]

Figure 8(v)
HOLD device versus Sandbag Pressure
Discomfort after Compression and Before Ambulation



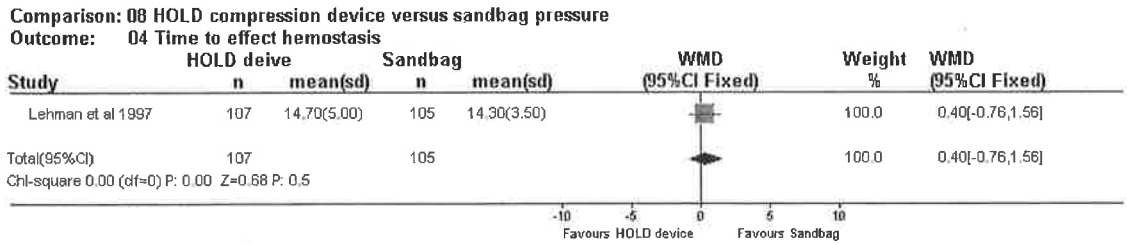
This figure demonstrates that the mean level of discomfort was not significantly different after compression, using either the HOLD device or sandbag, and before ambulation had commenced. In addition, there was no significant difference in the mean discomfort level after compression to maintain haemostasis had been ceased and during ambulation, as seen in the figure below.[2]

Figure 8 (vi)
HOLD device versus Sandbag Pressure
Discomfort After Compression and During Ambulation



(vii) time to effect haemostasis

Figure 8 (vii)
HOLD device versus Sandbag Pressure



There was no significant difference in the time taken to effect haemostasis in these intervention groups. The figure above demonstrates that the mean time to haemostasis

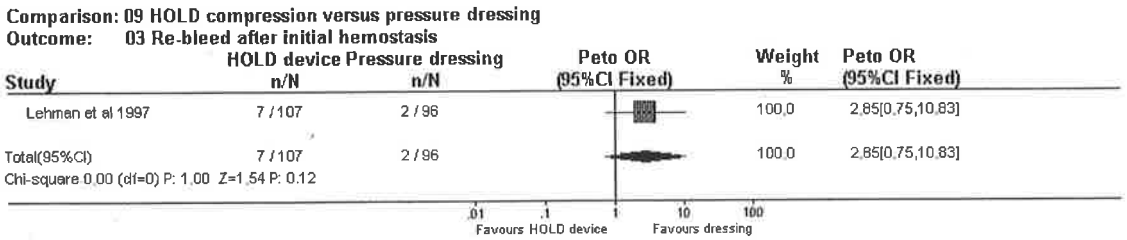
in the HOLD compression device study group was 14.7 minutes (± 5.0 minutes) as compared to 14.3 minutes (± 3.5 minutes), the mean time to haemostasis with sandbag pressure.[2]

HOLD Compression Device versus Pressure Dressing

The study by Lehmann et al also compared a sterile pressure dressing, as described in Table 8, with the HOLD compression device.[2] The same clinical outcomes were assessed.

(i) re-bleeding

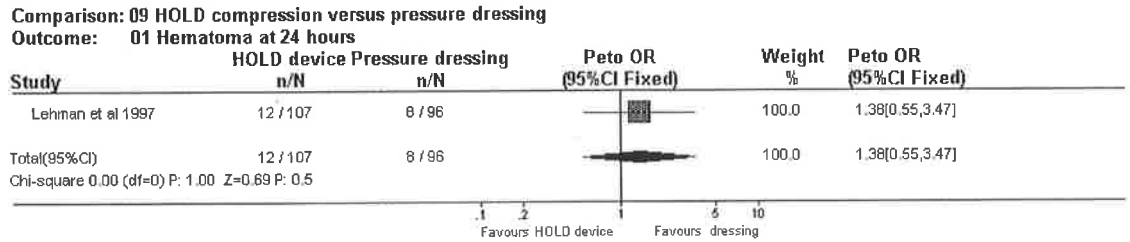
Figure 9(i)
HOLD device versus Pressure Dressing



Although no statistical difference was demonstrated in the incidence of re-bleeding after initial haemostasis was attained, the figure above shows a trend favouring the pressure dressing compression technique.[2]

(ii) haematoma formation

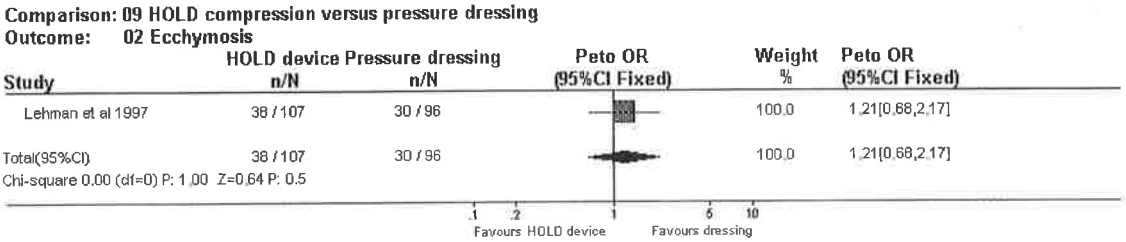
Figure 9(ii)
HOLD device versus Pressure Dressing



The physical examination of the femoral puncture site at 24 hours post cardiac intervention showed no statistical difference in the incidence of haematoma formation (figure 9, ii) or the incidence of bruising or ecchymosis (figure 9,iii).[2]

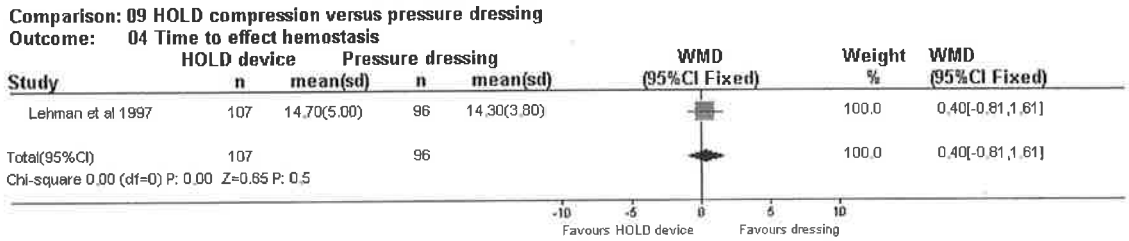
(iii) ecchymosis

Figure 9(iii)
HOLD device versus Pressure Dressing



(iv) time to effect haemostasis

Figure 9(iv)
HOLD device versus Pressure Dressing



As was demonstrated with sandbag pressure, there was no statistical difference in the mean time to haemostasis between the HOLD compression device (14.7 ± 5.0 minutes) when compared to the pressure dressing technique (14.3 ± 3.8 minutes).[2]

(v) patient discomfort

Patient discomfort, assessed using the verbal descriptor scale, showed no significant difference in the mean level of discomfort between the two intervention groups (HOLD compression device and the pressure dressing technique) during compression, after compression and before or during ambulation.[2] The figures below demonstrate these findings.

Figure 9(v)

HOLD device versus Pressure Dressing
Patient Discomfort during Compression

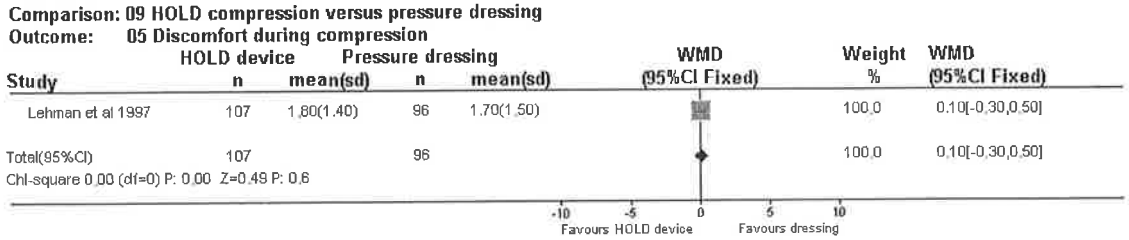


Figure 9(vi)
HOLD device versus Pressure Dressing
Patient Discomfort after Compression and Before Ambulation

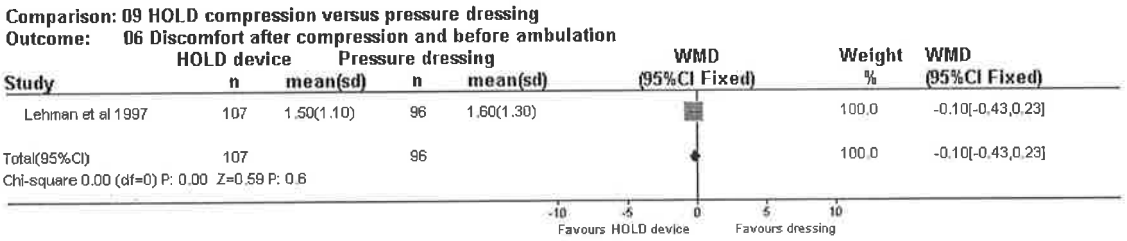
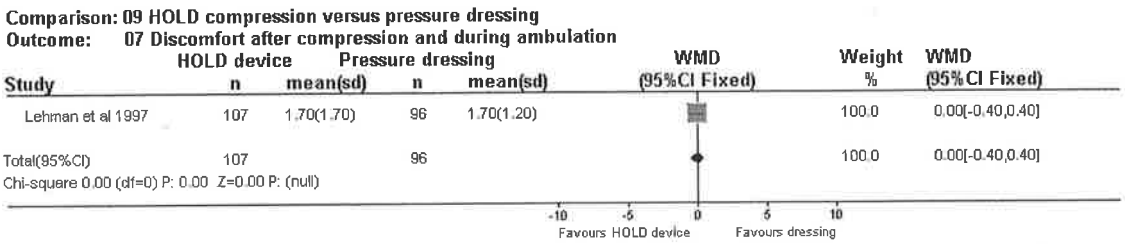


Figure 9(vii)
HOLD device versus Pressure Dressing
Patient Discomfort after Compression and During Ambulation



Each of the three compression techniques investigated by Lehmann et al were considered by the researchers to have unique advantages.[2] Although the sandbag was easy to apply and discouraged leg mobility due to its bulk, this compression technique only exerted diffuse (and therefore minimal) pressure directly over the femoral puncture site, and tended to slip easily off the groin site. The pressure dressing

technique was more effective in exerting direct pressure over the puncture site and was therefore more stable in position, but took time to construct, hindered direct visual inspection of the puncture site and could potentially result in skin damage or irritation from the attachment of the elastic adhesive bandage used to hold the dressing in place. The commercially available HOLD compression device appeared to address some of the shortfalls of the pressure dressings but was more expensive to use, and the support belt used to hold the device in position was easily soiled.[2]

IV Mechanical Compression versus No Compression

The study by Lehmann et al compared the techniques outlined in the previous section (HOLD compression device, the pressure dressing technique and sandbag pressure) with no compression at all over the femoral puncture site after initial haemostasis.[2] The table below provides the findings of data when the HOLD compression device is compared with no compression.

Table 12
HOLD device versus No Compressive Technique

Study	Outcome	Intervention			
		HOLD Device		No Compression	
		Outcome No.	Total No.	Outcome No.	Total No.
Lehmann 1997	Re-bleeding	7	107	8	89
	Haematoma	12	107	11	89
	Ecchymosis	38	107	29	89
		Mean & SD	Total No.	Mean & SD	Total No.
	Time to haemostasis	14.7 ± 5.0	107	14.9 ± 4.6	89
	Discomfort —during compression	1.8 ± 1.4	107	1.8 ± 1.8	89
	—after compression, before ambulation	1.5 ± 1.1	107	1.8 ± 1.8	89
	—after compression, during ambulation	1.7 ± 1.7	107	1.8 ± 1.8	89

This table demonstrates that there was no statistical difference in the incidence of re-bleeding, haematoma formation and ecchymosis (after initial haemostasis) between the HOLD compression device as compared with no compression. No significant difference was demonstrated in regards to the time taken to effect haemostasis or the level of patient discomfort during compression, after compression and before ambulation, and after compression and during ambulation.[2] When these results are

compared with the findings of the two other compression groups in this study (sandbag pressure and the pressure dressing technique) the findings demonstrate that none of the compression techniques investigated by Lehmann et al proved statistically superior in terms of clinical outcome or patient discomfort when compared with no compression at all.[2]

Discussion

This systematic review of the effectiveness of mechanical compression devices used to attain haemostasis after cardiac interventional procedures has summarised the best available evidence. Although 53 articles were identified, that on preliminary review appeared to meet the inclusion criteria, after critical appraisal only 12 articles were considered to be of an acceptable methodological quality. A total of 41 articles were excluded from the review as they proved to be overviews or reports of various haemostatic techniques, did not evaluate mechanical compression devices, or were single or case series reports. Although there were experimental studies that did meet the inclusion criteria for this review, some were rejected due to deficiencies in study design, or from insufficient reporting of study design details.

Although statistical meta-analysis was initially confined to studies of the same intervention measuring conceptually similar outcomes, had sufficient data been available from studies of different types of mechanical devices this data would have been synthesised in a meta-analysis. Consequently meta-analysis was limited due to inadequate reporting of results or missing data. For this reason the majority of this report is in narrative form. Where possible, table and figure formats were utilised in the report to emphasise particular findings.

Results were considered statistically significant when they occurred as a result of the treatment effect and were not due to chance or random variation. Confidence intervals that for odd ratios did not include 1.0 were considered statistically, where as confidence intervals for mean differences that did not include zero were statistically significant. However, several studies did show a trend favouring certain interventions. Although the confidence intervals for several clinical outcomes did not prove to be statistically significant these trends may have some clinical significance for those

health carers required to make decisions about the use of particular compression techniques. Considering this issue, this report has highlighted those clinical outcomes that tend to favour certain compressive techniques.

The following discussion will summarise the findings of the review.

Bleeding

Almost all of the identified studies in the review included bleeding as a study outcome. The incidence of bleeding after femoral sheath removal did not differ significantly between any interventions in these studies. The studies that compared manual compression with a mechanical compression device (ClampEase[5], FemoStop™[14,15] or Compressar[35]) did not show any significant difference in the incidence of bleeding. Bogart, in a study comparing manual compression with Compressar mechanical compression, reported the incidence of bleeding in the mechanical intervention group to be 13%, but no statistical information in regards to the incidence of bleeding in the manual compression group was reported.[36]

A small study by Rudisill et al that compared a combination of manual and mechanical compression with mechanical compression alone, did not demonstrate a significant difference in the incidence of bleeding after femoral sheath removal.[38]

Gibson compared two mechanical compression devices, the FemoStop™ with the Compressar mechanical compression device.[39] Although there was no significant difference in the incidence of bleeding in this study, there was a trend favouring the Compressar. This finding should be considered cautiously as the sample size was small (n=45).

Lehmann et al assessed re-bleeding after initial haemostasis.[2] They found no statistical significant difference between the study groups (sandbag pressure, pressure dressing, HOLD compression device and no compression).[2]

Haematoma Formation

As with bleeding, haematoma formation was a widely reported clinical outcome measure in the studies included in this review. Some variation in the incidence of haematoma formation was found between the studies in this review. Statistical synthesis of data from the studies by Homuth[35] and Pracyk et al[5] in a meta-analysis, demonstrated that haematoma formation was more likely to occur after manual compression as compared with mechanical compression devices, this result being statistically significant. In fact, it was reported that no haematomas occurred in the mechanical intervention groups in either of these studies.

When manual compression was compared with the FemoStop™[14], the ClampEase[5,7] or the Compressar[12,35,37] mechanical compression devices, no significant difference in the incidence of haematoma formation was demonstrated. The study by Sridhar et al (manual compression versus FemoStop™ mechanical compression) opposed this finding.[15] This study demonstrated a statistically significant difference ($P = 0.02$) in the incidence of haematoma formation, with 12% occurring in the manual compression group as compared with 0% in the FemoStop™ group.[15] As this study was poorly controlled with some data collected retrospectively over an unknown time period, these results should be cautiously interpreted.

When a combination of manual and mechanical compression was compared with mechanical compression alone, no significant difference was seen in the incidence of haematoma formation.[38] Two studies that compared two mechanical compression devices, the ClampEase and FemoStop™ devices[39,40], found no statistical difference for this clinical outcome.

Lehmann et al when comparing the HOLD compression device with sandbag pressure, the pressure dressing technique and no compression found no significant difference in the frequency of haematoma formation.[2]

Overall, the incidence of haematoma formation was low and occurred significantly more often in the manual compression groups than the mechanical compression groups.

Ecchymosis

Bruising, or ecchymosis, was reported as a clinical outcome in two studies. Lehmann et al found no significant difference in the incidence of ecchymosis when the HOLD compression device was compared with sandbag pressure, the pressure dressing technique or no compression.[2] Pracyk et al did not find a statistically significant difference in the incidence of ecchymosis between mechanical compression using the ClampEase compression device and manual compression.[5]

Pulsatile Mass

The study by Pracyk et al was the only one that assessed the femoral puncture site for clinical evidence of a pulsatile mass.[5] Independent physicians blinded to randomisation and demographic and clinical data examined the puncture site between 12 and 24 hours after sheath removal. A pulsatile mass was considered to be a mass located in the groin with a palpable movement corresponding to systole and diastole. This clinical outcome only occurred in the manual compression group (4 episodes) and did not occur with mechanical compression using the ClampEase device.[5] This result was not statistically significant.

Pseudoaneurysm

Pseudoaneurysm is a more serious vascular complication that can occur after femoral sheath removal and may require surgical intervention to prevent rupture. Careful examination of the puncture site is required as pseudoaneurysm is often difficult to recognise and may be masked by the presence of a haematoma.[9] Only four studies identified in this review reported pseudoaneurysm as a clinical outcome.[5,14,15,40] Although pseudoaneurysm was identified by ultrasonic examination to have occurred in both intervention groups (3% in the manual compression group and 1% in the ClampEase mechanical compression group) in the study by Pracyk et al, the incidence was not statistically different between the two groups.[5]

No episodes of pseudoaneurysm formation occurred in the study by Nordrehaug et al comparing manual compression with FemoStop™ mechanical compression.[14] The study by Sridhar et al opposed this finding.[15] When manual compression was compared to the FemoStop™ mechanical device the incidence was significantly higher with manual compression.[15] However, data were collected from the manual compression group retrospectively in this study and were accumulated over an unknown time period, and therefore poorly controlled.

No statistically significant difference in the incidence of pseudoaneurysm, detected by ultrasonic Doppler examination, was seen when two mechanical compression devices (the ClampEase and FemoStop™ devices) were compared by Janerot Sjoberg et al.[40]

Arteriovenous (AV) Fistula Formation

Only two studies reported on the incidence of AV fistula formation after femoral sheath removal.[5,15] Although the incidence was not significantly different in either study, AV fistula formation only occurred in the manual compression intervention group in both studies. No episodes of AV fistula formation occurred after mechanical compression with the ClampEase device [5] or the FemoStop™ device.[15]

Time to Effect Haemostasis

Factors differed between studies in respect to the time taken to attain haemostasis after application of the haemostatic technique. In three studies the Compressar device took significantly longer to effect haemostasis than manual compression.[35,36,37] Only Semler et al found that manual compression required more time than did the Compressar device.[12] Meta-analysis was not possible due to insufficient data. Gibson reported that significantly more time was required to attain haemostasis with the FemoStop™ than with the ClampEase device.[39] However, in this small sample, a few patients might have skewed the data in favour of the ClampEase device, and so this finding should be interpreted with caution. No significant difference was found in the time required to effect haemostasis after sandbag pressure, pressure dressing or no compression when these three methods, were compared with the HOLD compression device.[2]

Patient Comfort/Discomfort

The degree of comfort or discomfort with various interventions was assessed using either a visual analogue scale (VAS)[39], or a verbal descriptor scale (VDS).[2,35] Both Gibson (ClampEase versus FemoStop™ devices) and Lehmann et al (HOLD device versus sandbag pressure, pressure dressing or no compression) did not show a significant difference in the degree of patient discomfort during or after compression between the various interventions.[2,35]

When the patients enrolled in the study by Homuth described the level of comfort associated with either manual or mechanical compression (using the Compressar device), no significant difference was demonstrated in regards to the level of comfort after 15 minutes of compression.[35] When assessed after 30 minutes of compression time the findings indicated a significant difference (P=0.05) in the level of comfort between manual and mechanical compression. Patient discomfort was greater after 30 minutes of manual compression as compared to 30 minutes of mechanical compression using the Compressar device.[35]

The Implications for Practice

Removal of the femoral sheath after cardiac interventional procedures can be a time-consuming procedure within cardiac nursing practice. Although manual compression has been the favoured method of attaining haemostasis after removal of the sheath, alternative techniques, such as mechanical compression devices, are being used more often in clinical practice.

The objective of this systematic review was to identify effective interventions used to attain haemostasis after femoral sheath removal. This systematic review has highlighted the lack of quality research in this area. Researchers often failed to provide a reasonable description of the research design, making critical appraisal of quality research difficult. Some studies failed to use rigorous research methods or provide a complete description of the study intervention or process used to assess

clinical outcomes, making replication of the research impossible and implementation of the findings into clinical practice difficult.

From a clinical viewpoint, the development of protocols and procedures for femoral sheath removal must be based on evidence that indicates which practices are most effective. Although this review found articles on primary research related to attaining haemostasis after femoral sheath removal, several of the articles did not address mechanical compression techniques specifically or contained insufficient primary research data for inclusion. The limited depth and breath of this review are due to the quality of the research findings available.

It is not possible to assert the null hypothesis, that is, there is no difference in the effectiveness of mechanical compression devices in attaining haemostasis after femoral sheath removal as compared with manual compression, or any other compression techniques, as differences were identified in this systematic review. Although Sridhar et al reported a significant difference in between manual compression and a mechanical compression device in the incidence of haematoma formation, their findings should be cautiously interpreted because of the poorly controlled retrospective study design.[15] In those studies in which the time required to effect haemostasis was measured, some significant differences between study interventions occurred, but the conflicting findings make it difficult to draw clear conclusions about this clinical outcome. Although differences were identified, when these findings are considered, it is not possible to make clear recommendations that a particular mechanical device is more effective than another mechanical device. However, the meta-analysis that indicated no difference between techniques in regards to bleeding and a statistically reduced incidence of haematoma formation after mechanical compression makes it possible to make a clinical recommendation for the use of mechanical devices.

The paucity of nursing studies identified in this review related to femoral sheath removal highlight the need for further studies on this topic to be undertaken by nursing researchers. A recommendation that can be made is that there is a need for more benchmark randomised controlled trials to be undertaken. The protocols for these trials should include a rigorous randomisation process, inclusion criteria and

establishment of the power of sample. These requirements may be challenging because the low frequency of complications may necessitate trials requiring large participant numbers and careful control of these strategies to accommodate the variability between manual compression skills and application techniques for various compression devices.

Conclusion

In this systematic review a rigorous pre-planned process was used to detect primary research pertaining to mechanical compression devices used to attain hemostasis after femoral sheath removal from cardiac interventional patients. The results highlight the lack of quality research on this topic. Nevertheless, results do highlight particular compression techniques used to attain hemostasis after femoral sheath removal. This information may help cardiac nurses make informed decisions about particular devices and techniques used in clinical practice.

References

1. Schickel S, Cronin SN, Mize A, Voelker C. Removal of femoral sheaths by registered nurses: issues and outcomes. *Critical Care Nurse* 1996;16(2):32-6.
2. Lehmann K, Ferris S, Heath Lange S. Maintenance of hemostasis after invasive cardiac procedures: implications for outpatient catheterization. *Journal of the American College of Cardiologists* 1997;30(2):444-51.
3. King S. Percutaneous transluminal coronary angioplasty: the second decade. *American Journal of Cardiology* 1988;62:2-6.
4. Peet GI, McGrath MA, Brunt JH, Hilton JD. Clinical rounds. Femoral arterial sheath removal after PTCA: a cross-Canada survey. *Canadian Journal of Cardiovascular Nursing* 1995;6(3-4):13-9.
5. Pracyk JB, Wall TC, Longabaugh JP, Tice FD, Hochrein J, Green C, et al. A randomized trial of vascular hemostasis techniques to reduce femoral vascular complications after coronary intervention. *American Journal of Cardiology* 1998;81(8):970-6.
6. Gibbs H, Sanborn T. Percutaneous vascular hemostasis devices for arterial sealing after interventional procedures. In: Topol E, editor. *Textbook of Interventional Cardiology*. Philadelphia: W.B. Saunders Company, 1994:629-637.
7. Simon AW. Use of a mechanical pressure device for hemostasis following cardiac catheterization. *American Journal of Critical Care* 1994;3(1):62-4.
8. Spies J, Berlin L. Malpractice Issues in Radiology Complications of Femoral Artery Puncture. *American Journal of Roentgenology* 1998;170(1):9-11.
9. Jones C, Holcomb E, Rohrer T. Femoral Artery Pseudoaneurysm After Invasive Procedure. *Critical Care Nurse* 1995;15(4):47-51.
10. Kussmaul W, Buchbinder M, Whitlow P, Aker U, Heuser R, King S, et al. Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: results of a randomized trial of a novel hemostatic device. *Journal of the American College of Cardiologists* 1995;25(7):1685-92.
11. Lanoue A, Snyder B, Galan K. Percutaneous transluminal coronary angioplasty: non-operative treatment of coronary artery disease. *Journal of Cardiovascular Nursing* 1986;1:30-44.

12. Semler HJ. Transfemoral catheterization: mechanical versus manual control of bleeding. *Radiology* 1985;154(1):234-5.
13. Beyer Enke S, Soldner J, Zeitler E. Immediate sealing of arterial puncture site following femoropopliteal angioplasty: a prospective randomized trial. *Cardiovascular and Interventional Radiology* 1996;19(6):406-10.
14. Nordrehaug JE, Chronos NAF, Priestley KA, Buller NP, Foran J. Randomized evaluation of an inflatable femoral artery compression device. *Journal of Interventional Cardiology* 1996;9(5):381-387.
15. Sridhar K, Fischman D, Goldberg S, Zalewski A, Walinsky P, Porter D, et al. Peripheral vascular complications after intracoronary stent placement: prevention by use of a pneumatic vascular compression device. *Catheterization and Cardiovascular Diagnosis* 1996;39(3):224-9.
16. Roth R, Modrosic K, Brown M, Kern MJ. Initial experience with a new compression device for hemostasis after femoral arterial puncture. *Catheterization and Cardiovascular Diagnosis* 1992;26(3):241-4.
17. Ernst J, Kloos R, Schrader R. Immediate sealing of arterial puncture sites after catherterization and PTCA using a vascular haemostasis device with collagen: An international registry. *Circulation* 1991;84 (suppl II):68.
18. Gibbs J, Slade A, Nordrenhaug J, Rickards A, Buller N, Sigwart U. Femoral arterial hemostasis using a collagen plug after coronary stent implantation. *Journal of Interventional Cardiology* 1992;5(2):85-8.
19. Ernst S, Gin M, Mast G. Percutaneous application of collagen seal femoral arterial puncture sites in fully anticoagulated patients. *Journal of the American College of Cardiologists* 1992;19 (suppl A):217A.
20. Cook D, Mulrow C, Hayes B. Systematic Reviews: Synthesis of Best Evidence for Clinical Decisions. *Annals of Internal Medicine* 1997;126(5):376-380.
21. National Centre for Reviews and Dissemination. Undertaking systematic reviews of research on effectiveness: CRD guidelines for carrying out or commissioning reviews. 1996.
22. Jones T, Evans D. Conducting a systematic review. *Australian Critical Care* 2000;13(2):66-71.
23. Spokojny A, Sanborn T. Management of the arterial puncture site. *Journal of Interventional Cardiology* 1994;7(2):187-193.

24. Gerckens U, Cattelaens N, Lampe E, Grube E. Management of arterial puncture site after catheterisation procedures: evaluating a suture-mediated closure device. *The American Journal of Cardiology* 1999;83(15):1658-1663.

25. O'Brien C, Recker D. How to remove a femoral sheath. *American Journal of Nursing* 1992;92(10):34-7.

26. Dickersin K, Scherer R, Lefebvre C. Identifying relevant studies for systematic reviews. *British Medical Journal* 1994;309:1286-1291.

27. Quality of Care and Health Outcomes Committee. *Guidelines for the development and implementation of clinical guidelines*. Canberra: Australian Government Publishing Service, 1995.

28. Rosenfeld R. How to systematically review the medical literature. *Otalaryngology-Head and Neck Surgery* 1996;115(1):53-63.

29. Chalmers T, Levin H, Sacks H, Reitman D, Berrier J, Nagalingam R. Meta-analysis of clinical trials as a scientific discipline. Control of bias in comparison with large co-operative trials. *Statistics in Medicine* 1987;6:315-325.

30. Segal A. A simple haemostatic device. *Lancet* 1973;1(7799):378.

31. Semler HJ. Experience with an external clamp to control bleeding following transfemoral catheterization. *Radiology* 1974;110(1):225-6.

32. Jadad A, McQuay H. Searching the literature: be systematic in your searches. *British Medical Journal* 1993;307:66.

33. Lowe H, Barnett G. Understanding and Using the Medical Subject Headings (MeSH) Vocabulary to Perform Literature Searches. *JAMA* 1994;271(14):1103-1108.

34. Oxman A. *The Cochrane Collaboration Handbook*. Oxford, UK.: The Cochrane Collaboration, 1994.

35. Homuth G. Relationship of methods for removal of femoral sheaths to the incidence of hematomas and patient comfort [Master of Science]. Northern Illinois, 1990.

36. Bogart MA. Time to hemostasis: a comparison of manual versus mechanical compression of the femoral artery. *American Journal of Critical Care* 1995;4(2):149-56.

37. Simon A, Bumgarner B, Clark K, Israel S. Manual versus mechanical compression for femoral artery hemostasis after cardiac catheterization. *American Journal of Critical Care* 1998;7(4):308-13.

38. Rudisill PT, Williams LB, Craig S, Schopp P. Study of mechanical versus manual/mechanical compression following various interventional cardiology procedures. *Journal of Cardiovascular Nursing* 1997;11(2):15-21.

39. Gibson C. A comparison of compression devices for femoral artery hemostatsis [Master of Science in Nursing]. Gonzaga University, 1996.

40. Janerot Sjoberg B, Broqvist M, Fransson SG. Femoral artery haemostasis with a pneumatic compression device versus a clamp after coronary angiography. *Scandinavian Cardiovascular Journal* 1998;32(5):281-284.

41. Aker UT, Kensey KR, Heuser RR, Sandza JG, Kussmaul WG, 3rd. Immediate arterial hemostasis after cardiac catheterization: initial experience with a new puncture closure device. *Catheterization and Cardiovascular Diagnosis* 1994;31(3):228-32.

42. Babu SC, Piccorelli GO, Shah PM, Stein JH, Clauss RH. Incidence and results of arterial complications among 16,350 patients undergoing cardiac catheterization. *Journal of Vascular Surgery* 1989;10(2):113-6.

43. Barbiere CC. A new device for control of bleeding after transfemoral catheterization... the FEMOSTOP system. *Critical Care Nurse* 1995;15(1):51-3.

44. Botti M, Williamson B, Steen K, McTaggart J, Reid E. The effect of pressure bandaging on complications and comfort in patients undergoing coronary angiography: a multicenter randomized trial. *Heart Lung* 1998;27(6):360-73.

45. Bowden S, Worrey J. Assessing patient comfort: Local infiltration of Lidocaine during femoral sheath removal. *American Journal of Critical Care* 1995;4(5):368-369.

46. Cardenas J, Yellayi S, Schatz R, Franklin M. A new method for brachial artery hemostasis following percutaneous coronary angiography. *Journal of Invasive Cardiology.* 1994;6(9):285-8.

47. Chatelain P, Arceo A, Rombaut E, Verin V, Urban P. New device for compression of the radial artery after diagnostic and interventional cardiac procedures. *Catheterization and Cardiovascular Diagnosis* 1997;40(3):297-300.

48. Chatterjee T, Do DD, Mahler F, Meier B. Pseudoaneurysm of femoral artery after catheterisation: Treatment by a mechanical compression device guided by colour Doppler ultrasound. *Heart.* 1998;79(5):502-504.

49. Cheng TO. Mechanical versus manual compression of radial artery following percutaneous transradial approach for coronary arteriography and angioplasty [editorial]. *Catheter and Cardiovascular Diagnosis* 1997;40(3):301.

50. Christenson R, Staab EV, Burko H, Foster J. Pressure dressings and postarteriographic care of the femoral puncture site. *Radiology* 1976;119(1):97-9.

51. Davis C, VanRiper S, Longstreet J, Moscucci M. Vascular complications of coronary interventions. *Heart and Lung* 1997;26(2):118-27.

52. Dangas G, Mehran R, Duvvuri S, Ambrose J, Sharma S. Use of a pneumatic compression system (FemoStop) as a treatment option for femoral artery pseudoaneurysms after percutaneous cardiac procedures. *Catheter and Cardiovascular Diagnosis.* 1996;39(2):138-42.

53. De Jong MJ, Morton PG. Research Analysis. Control of vascular complications after cardiac catheterization: a research-based protocol. *Dimensions of Critical Care Nursing* 1997;16(4):170-81.

54. Eisenberg RL, Mani RL. Pressure dressings and postangiographic care of the femoral puncture site. *Radiology* 1977;122(3):677-8.

55. Gawlinski A, Ecklund MM, Ackerman MH. Ask the experts... What is the standard of practice for using the FemoStop pump after sheath removal for PTCA and/or stent patients?... The use of heat moisture exchange (HME) filters. *Critical Care Nurse* 1995;15(4):82-4.

56. Gershony G, Brock JM, Powell JS. Novel vascular sealing device for closure of percutaneous vascular access sites. *Catheterization and Cardiovascular Diagnosis* 1998;45(1):82-88.

58. Hogan-Miller E, Rustard D, Sendelbach S, Goldenberg I. Effects of three methods of femoral site immobilization on bleeding and comfort after coronary angiogram. *American Journal of Critical Care* 1995;4(2):143-148.

59. Juran N, Smith D, Lang Rouse C, DeLuca S, Rund M. Survey of current practice patterns for percutaneous transluminal coronary angioplasty. *American Journal of Critical Care* 1996;5(6):442-448.

61. Lazzara D, Pfersdorf P, Sedlacek M. Femoral compression device. *Nursing* 1997;27(12):54-7

62. Massey EW, Tim RW. Femoral compression neuropathy from a mechanical pressure clamp. *Neurology* 1989;39(9):1263.

63. Merino A, Faulkner C, Corvalan A, Sanborn TA. Percutaneous vascular hemostasis device for interventional procedures. *Catheter and Cardiovascular Diagnosis* 1992;26(4):319-22.

64. Muller D, Shamir K, Ellis S, Topol E. Peripheral vascular complications after conventional and complex percutaneous coronary interventional procedures. *American Journal of Cardiology* 1992;69(1):63-68.

65. Nordrehaug J, Chronos N, Foran J. Randomised evaluation of a new inflatable femoral artery compression device after coronary angiography (Abstract). *Circulation* 1992;86(Suppl I):382.

67. Petula SM, Hudacek S. The FemoStop compression device: utilization guidelines for the critical care nurse. . *Dimensions of Critical Care Nursing* 1995;14(5):259-64.

68. Rowe PW, Jones TK. The hemo-clamp. *Radiology* 1972;102(1):208.

69. Sanborn T, Brinker J, Kosinski E, Knopf W. Reduced compression time using a vascular haemostasis device after diagnostic angiography and angioplasty: A multi-centered randomized trial. *Circulation* 1992;86(I):372.

70. Sanborn T, Gibbs H, Brinker J, Knopf W, Kosinski E, Roubin G. A multicenter randomized trial comparing a percutaneous collagen hemostasis device with conventional manual compression after diagnostic angiography and angioplasty. *American College of Cardiology* 1993;22(5):1273-1279.

71. An alternative to digital pressure after cardiac catheterization. *RN* 1994;57(12):20.

72. Slaughter PM, Chetty R, Flintoft VF, Lewis S, Sykora K, Beattie DM, et al. A single centre randomized trial assessing use of a vascular hemostasis device vs. conventional manual compression following PTCA: what are the potential resource savings? *Catheterization and Cardiovascular Diagnosis* 1995;34(3):210-4.

73. Stables R, Sigwart U. Post-stent management with a pneumatic groin compression device and self injected low molecular weight heparin. *Heart* 1996;75(6):588-590.

74. Ward SR, Casale P, Raymond R, Kussmaul WG, Simpfendorfer C. Efficacy and safety of a hemostatic puncture closure device with early ambulation after coronary angiography. *American Journal of Cardiology* 1998;81(5):569-72.

Appendix 1

Inclusion Criteria : Mechanical Compression Devices

Author _____ Year _____ Record Number _____

Types of Participants

Adults who have undergone cardiac diagnostic or interventional procedures using a femoral sheath approach. ☐

Types of Intervention

Mechanical compression device ☐

Types of Outcome Measures

Bleeding, bruising, haematoma formation ☐

Other _____ ☐

Types of Studies

Randomised control trial ☐

Other _____ ☐

Appendix 2

RCT Critical Appraisal Form

Mechanical Compression Device Systematic Review

Author _____ Year _____ Record Number _____

Questions 1 to 5 must be answered "yes" for the study to be included in the meta analysis. If any questions are answered "no" the study may then be considered in the systematic review as a narrative summary.

1) Were the participants randomly allocated to the study groups?

yes ☐ no ☐ not clear ☐

2) Other than the research intervention, were participants in each group treated the same?

yes ☐ no ☐ not clear ☐

3) Were the study outcomes measured in the same manner for all participants, regardless of the treatment groups?

yes ☐ no ☐ not clear ☐

4) Were the study groups comparable at entry?

yes ☐ no ☐ not clear ☐

5) Was there adequate follow-up of participants? (ie was the attrition rate explained?)

yes ☐ no ☐ not clear ☐

(> 20% not followed up)

6) Was allocation of participants to the treatment groups concealed from the allocator?

yes ☐ no ☐ not clear ☐

7) Were those assessing the objective study outcomes blinded to treatment allocation?

yes ☐ no ☐ not clear ☐

SUMMARY

Decision

Use in the meta analysis

Include as a narrative summary

Reject from the systematic review

Comments

Appendix 3

Checklist for Assessing Validity of Non-RCT Studies

Mechanical Compression Device Systematic Review

Author _____ Year _____ Record Number _____

Is the method of allocating patients to the treatment groups clearly defined?

Yes **No** **Unsure** **N/A**

Are the criteria for inclusion of participants in the treatment groups clearly defined?

Yes **No** **Unsure** **N/A**

Were outcome measures assessed using objective criteria?

Yes **No** **Unsure** **N/A**

If comparisons were made, was there a sufficient description of the treatment groups?

Yes **No** **Unsure** **N/A**

Was an appropriate method used to analyse the data collected?

Yes **No** **Unsure** **N/A**

SUMMARY

Total

Yes _____ No _____ Unsure _____ N/A _____

Decision

Include in a narrative summary

Reject from the systematic review

Further information needed

Comments

Appendix 4

Data Extraction Form

Mechanical Compression Device Systematic Review

Record Number _____

Author(s)_____

Journal _____

Year _____

Issue _____

Method _____

_____

_____

Institutional Setting

_____

Participants (male or female and cardiac intervention)

_____

_____

Number of Participants

Group A ☐ Group B ☐ Group C ☐

Interventions

Intervention A _____

_____

_____

_____

Intervention B _____

_____

_____

_____

Intervention C _____

_____

_____

_____

Outcome Measures

Definition of bleeding, haematoma or bruise

_____

_____

_____

_____

Other Outcome Measures

Outcome Description	Scale / Measure

Results

Dichotomous Data

Outcome	Treatment group number / total number	Control Group number / total number

Continuous Data

Outcome	Treatment group mean & SD (number)	Control Group mean & SD (number)

Other Study Findings

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Authors Conclusions

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Comments

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Level of Evidence

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Appendix 5

Included Studies

Citation	Study Design	Sample	Interventions		Outcome	Level Evidence
			Group A	Group B		
Bogart 1995[36]	RCT	503 patients 332 males 171 females Group A: N=173 Group B: N=168 Group C: N=162	Group A: Manual compression with a pressure dressing applied after haemostasis consisting of a roll of 4X4 sponges covered by 2 or 3 strips of 3 inch elastic tape	Group B: Mechanical compression using the Compressar clamp Group C: Manual compression with stasis button and 2lb weight after haemostasis	Time to effect haemostasis and bleeding were the main study outcomes	II
Gibson 1996[39]	RCT	45 patients 31 males 14 females Group A: N= 23 Group B: N= 22	Mechanical compression clamp applied to femoral puncture site during and after sheath removal for at least 20 minutes	FemoStop compression device applied to femoral puncture site during and after sheath removal for at least 20 minutes	The study outcomes were: AV fistula Haematoma pseudoaneurysm Patient comfort Thromboemboli Time to effect haemostasis Vasovagal reaction	II
Homuth 1990[35]	RCT	51 patients 40 males 11 females Group A: N= 26 Group B: N= 25	Manual compression	Mechanical compression using the Compressor clamp	Data was collected at the time of sheath removal, 15 & 30 mins & 24 hrs after sheath removal for: Haematoma Re-bleeding Patient comfort	II
Janerot Sjoberg et al 1998[40]	RCT	979 patients Group A: N=433, 75% males Group B: N=546, 71% males	Mechanical compression using the ClampEase device for at least 15 minutes and replaced by pressure dressing for total compression time of 2 hrs	Mechanical compression using the FemoStop device at various pressure levels for at least 2 hrs compression time	If there was clinical suspicion of a vascular site complication after compression ceased vascular ultrasound examination was performed to detect pseudoaneurysm, haematoma or any other complications	II

Citation	Study Design	Sample	Interventions		Outcome	Level Evidence
			Group A	Group B		
Lehman et al 1997[2]	RCT	397 patients 389 males 8 females Group A: N= 107 Group B: N=105 Group C: N=96 Group D: N=107	Group A Mechanical compression (HOLD device). 8cm diameter disk held under tension by a belt system Group B 4.5 kg sandbag, 32 cm X 12 cm X 8 cm placed directly over site	Group C Pressure dressing made of six 10 X 10 cm sterile gauze folded vertically and horizontally and taped with 30 cm strips of elastic adhesive bandage 8 cm wide over femoral puncture site Group D No compression technique	Femoral puncture site observed after sheath removal and prior to study intervention. 24 hrs later the femoral puncture site was re-assessed by a single observer for: Haematoma Ecchymosis Re-bleeding Discomfort	II
Nordrehaug et al 1996[14]	Multicentre RCT	213 patients 167 males 46 females Group A: N=109 Group B: N=104	Manual compression for at least 8 minutes and until haemostasis was obtained.	Mechanical compression applied using the FemoStop device for at least 60 minutes after sheath removal.	Assessed by cardiologist at 6 and 24 hours post procedure: bleeding haematoma AV fistula pseudoaneurysm	II
Pracyk et al 1998[5]	RCT	778 patients 516 males 262 females. Group A: n=396 Group B: N=382	Manual compression for at least 15 minutes and until haemostasis obtained.	Mechanical compression applied using the ClampEase device for at least 15 minutes and maintained until haemostasis obtained.	Assessed by an independent physician blinded to randomisation, demographic and clinical data at 12 & 24 hours after femoral sheath removal. Only 592 pts (Group A 307 pts, Group B 285 pts) examined due to unavailable-trained personnel.	II
Rudisill et al 1997[38]	RCT	32 patients Group A: N=16 Group B: N=16 (no other demographic data was available)	PTCA patients: manual compression for 20 minutes Direct coronary athrectomy (DRA) and rotoblator PTCA patients (PTCRA) had 1 hr of mechanical compression after manual compression	Mechanical compression in PTCA patients for 40 mins. DCA and PTCRA patients had mechanical compression for 1 hr and 20 mins	The study outcome consisted of any groin complication. No specific outcomes were stated.	II

Citation	Study Design	Sample	Interventions		Outcome	Level Evidence
			Group A	Group B		
Semler 1985[12]	Multicentre Non-RCT (author states the method as RCT but patients allocated alternatively to treatment groups not randomised)	3255 patients Group A: N=2250 Group B: N=1005 (no other demographic data available	Manual compression	Mechanical compression using the Compressar clamp	The study outcomes were mean compression time, presence of haematoma and lower extremity ischaemic symptoms or complications (not defined)	III-1
Simon 1994[7]	Descriptive study (Group A retrospective review, Group B consecutive sample)	200 patients Group A: n=100 Group B: N=100 (no other demographic data available)	Manual compression	Mechanical compression using the ClampEase device for at least 15 minutes	Assessment by the investigator 2 to 6 hrs after the procedure. The study outcome was any hemostatic complication including haematoma, arterial occlusion, ischaemia and traumatic neuropathy	IV
Simon et al 1998[37]	Non-RCT	720 patients 478 males 242 females Group A: N=377 Group B: N=377	Manual compression for at least 10 minutes	Mechanical compression using the Compressar clamp for at least 10 minutes	Site specific and functional status questions asked 1 to 2 days and again 3 days after procedure. Included appearance of the insertion site, bleeding, bruising discomfort, pain and current activity level	III-1
Sridhar et al 1996[15]	Descriptive, retrospective study	99 patients 84 males 15 females Group A: N=58 Group B: N=41	Manual compression	Mechanical compression using the FemoStop device for at least 30 minutes	Primary outcome measure was the development of a peripheral vascular complication such as haematoma requiring surgery or transfusion, AV fistula or pseudoaneurysm	IV

Appendix 6

Excluded Papers

Citation	Method	Reason for Exclusion	Level of Evidence
Aker 1994[41]	Uncontrolled clinical trial	This study reviewed the efficacy of a bioabsorbable collagen device. No mechanical devices were evaluated.	II
Babu 1989[42]	Descriptive study	This study reported the incidence of arterial complications after cardiac catheterisation. It was not possible to extract data that primarily related to mechanical compression techniques after femoral sheath removal alone.	III-3
Barbiere 1995[43]	Report	This article is a report that instructs nurses in the use of a new mechanical compression device, the FemoStop system. No primary research data is included.	IV
Beyer Enke 1996[13]	RCT	This prospective study evaluated the efficacy of a new puncture closure system that contained a collagen plug. No mechanical techniques were used.	II
Botti 1998[44]	Prospective, multicentre RCT	This study evaluated the effectiveness of pressure bandaging in reducing bleeding and bruising in cardiac interventional patients. It did not examine the effectiveness of any mechanical compression device.	II
Bowden 1995[45]	Descriptive study	This paper detailed the results of a patient survey that assessed patient comfort during femoral sheath removal. Mechanical devices were not specifically addressed.	IV
Cardenas 1994[46]	Uncontrolled clinical trial	This study described an alternative method to digital pressure for achieving haemostasis after PTCA via the percutaneous brachial approach, as opposed to the femoral approach.	IV
Chatelain 1997[47]	Descriptive study	This study reported the experience of a radial artery mechanical compression technique (RadiStop) to attain haemostasis as opposed to the femoral approach.	IV
Chatterjee 1998[48]	Uncontrolled clinical trial	This study explored the effectiveness of the FemoStop mechanical compression device as an alternative treatment for iatrogenic femoral artery pseudoaneurysm rather than to attain haemostasis after femoral sheath removal.	IV
Cheng 1997[49]	Report	A report describing the use of a the RadiStop mechanical compression device to attain haemostasis after radial artery sheath removal, as opposed to the femoral artery approach.	IV
Christenson 1976[50]	Uncontrolled clinical trial	This prospective study assessed the use of a pressure dressing technique on femoral puncture sites after sheath removal and not the use of a mechanical device.	IV

Citation	Method	Reason for Exclusion	Level of Evidence
Davis 1999[51]	Report	This paper is a review of vascular complications post-coronary interventions. It does not provided sufficient primary research information to include in this review.	IV
Dangas 1996[52]	Uncontrolled clinical trial	This study evaluated the use of a FemoStop system as a treatment option for femoral artery pseudoaneurysm after percutaneous cardiac procedures rather than for attaining haemostasis after femoral sheath removal.	IV
De Jong 1997[53]	Report	This review paper reports the findings of primary research relating to management of cardiac catheterisation, including techniques to achieve haemostasis and femoral site care but insufficient information from the primary research is reported.	IV
Eisenberg 1977[54]	Retrospective chart review	This is a report of the incidence of complications in patients who did not receive pressure dressings following PTCA. This report did not relate to mechanical compression devices.	IV
Gawlinski 1995[55]	Report	This is a paper that outlines the application and management of the FemoStop compression device. No primary research data is reported.	IV
Gershony 1998[56]	Descriptive study	This study reviewed the efficacy of a collagen hemostatic device in dogs, not humans. No mechanical devices were evaluated.	II
Gibbs 1994[6]	Report	This paper is a report that reviews haemostasis devices for arterial sealing after interventional procedures. Mechanical techniques are reviewed but insufficient information is available from the primary research to include in this review.	II
Hogan-Miller 1995[57]	Non-RCT	This study compared three methods of femoral puncture site immobilisation techniques: sandbag; sheet tuck; and verbal instruction to keep the leg straight and still. No mechanical compression techniques were assessed.	IV
Juran 1996[58]	Descriptive survey	This paper reported the results of a questionnaire designed to determine current practice patterns for PTCA. Although the uses of various mechanical compression techniques are discussed, insufficient information is reported to include this paper in the review.	IV
Kussmaul 1995 [10]	Prospective multicentre RCT	This study evaluated the efficacy of a bioabsorbable hemostatic device with manual compression. No mechanical devices were included in the study.	II
Lazzara 1997 [59]	Report	A descriptive report that outlines the application technique for attaining haemostasis using the FemoStop compression device. No primary research data is included.	IV

Citation	Method	Reason for Exclusion	Level of Evidence
Massey 1989 [60]	Case report	This paper is a single case report of a patient who developed femoral compression neuropathy from a mechanical pressure clamp.	IV
Merino 1992 [61]	RCT	This study examined the use of a vascular haemostasis device as compared to manual compression in swine subjects, not humans.	II
Muller 1992 [62]	Descriptive study	This paper reported the incidence of adverse complications after cardiac interventions but results are not attributed to specific mechanical compression techniques.	IV
Nordrehaug 1992 [63]	RCT	This paper is an abstract only and insufficient information was available to include it in the review. The information is repeated in the full research report [14].	II
O'Brien 1992 [25]	Report	A review article that outlines the technique of femoral sheath removal. No primary research data is included.	IV
Peet 1995 [4]	Descriptive survey	A cross-sectional survey of the management of patients after femoral sheath removal post PTCA. Insufficient information is available for inclusion in this review.	IV
Petula 1995 [64]	Report	This paper reports on the technique of mechanical compression using the FemoStop device. No primary research data is included.	IV
Roth 1992 [16]	Case series	This paper describes a series of 330 patients in whom a stasis system was used. This consisted of a disposable plastic stasis button, stasis weight and elastic bandage. No primary research data is included.	IV
Rowe 1972 [65]	Report	This paper reports on the application technique for the Hemo-Clamp compression device. No primary research data is included.	IV
Sanborn 1992 [66]	RCT	Abstract report only. Insufficient primary research data is included.	IV
Sanborn 1993 [67]	Prospective multicentre RCT	This study compared a collagen compression device with manual compression. Mechanical compression techniques were not evaluated.	II
Schickel 1996 [1]	Report	This paper describes how to remove femoral sheaths after interventional procedures but no primary research data is included.	IV
Segal 1973 [30]	Report	Describes a simple dressing technique of prolonged local pressure to control haemorrhage. Mechanical compression techniques are not included.	IV
Semler 1974 [31]	Case report	This paper reports a case series where an external "C" clamp is used as an alternative to digital pressure to attain haemostasis after femoral sheath removal. No primary research data is included.	IV

Citation	Method	Reason for Exclusion	Level of Evidence
(No author stated) 1994 [68]	Report	This is a review only. No primary research data is included.	IV
Slaughter 1995 [69]	RCT	The haemostasis device that was compared to manual compression in this study was a collagen vascular haemostasis device, not a mechanical compression device.	II
Spokojny 1994 [23]	Report	This paper outlines the various issues related to management of the arterial puncture site after femoral sheath removal. No primary research data is included.	IV
Stables 1996 [70]	Case series	This paper presents 100 patients who had a protocol of FemoStop mechanical compression and low molecular weight heparin post-coronary stent deployment. Excluded, as it is a report of a case series of patients.	IV
Ward 1998 [71]	RCT	A collagen hemostatic device was compared to manual compression in this study. No mechanical devices were evaluated.	II

Study Two: A randomised controlled trial comparing the use of manual versus mechanical compression to obtain haemostasis following coronary angiography.

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Abstract

BACKGROUND: Cardiac interventions have become a commonly accepted treatment option for patients with coronary heart disease. Managing the arterial puncture site and femoral arterial sheath removal is an important and challenging aspect of cardiac nursing practice for patients who have had cardiac diagnostic and interventional procedures. To ensure these patients receive efficient and safe care, nursing practice should be based on the best available evidence. This evidence should highlight the effectiveness and reliability of various techniques to achieve haemostasis after femoral sheath removal. This knowledge is essential for nurses to ensure quality patient care and for patients to receive safe and efficient management.

OBJECTIVE: This study was designed to compare two techniques, manual compression and a mechanical compression device—QuicKlamp™, used to achieve haemostasis at the groin puncture site following femoral arterial sheath removal in patients who had undergone coronary angiography. The purpose of this study was to determine which, if any compression device, was effective and safe for femoral sheath removal.

METHOD: A convenience sample of 100 patients scheduled to have elective coronary angiography were randomly allocated to one of the two compression protocols: manual or QuicKlamp™. Data collected over a 12-month period included the time taken to attain haemostasis, the incidence of haematoma formation, bruising and/or bleeding at the puncture site and the patient's pain perception. Follow-up telephone calls on the fifth day after patient discharge were undertaken to ascertain if any late complications had occurred. Inter-group comparisons were analysed using either Chi-squared analysis for nominal data, or the Mann Whitney-*U* test for continuous variables. A *P* value of 0.05 or less was considered statistically significant.

RESULTS: Of the 100 subjects recruited to participate in the study 70 were males and 30 were females with a median age of 62 years. The numbers of subjects on aspirin

prior to the procedure were similar in each group, as was the number of cardiac risk factors with family history, hypercholesterolaemia and hypertension most common. The majority of subjects had a left groin approach (98%), using only one arterial stab (98%) for femoral sheath insertion. The largest proportion of subjects (63%) had a 6 French (F) gauge sheath inserted. Most subjects (91%) had an ionic contrast agent (Urografin), with 9% having a non-ionic contrast agent (Ultravist 2%, Optiray 7%) during the procedure. Although bruising and haematoma formation was evident in both groups, there was no statistically significant difference in the incidence of bruising at any assessment stage. A statistically significant difference in haematoma formation was identified, with more haematomas following manual compression after pressure dressing removal (P=0.027). Minimal bleeding occurred in either intervention group. QuicKlamp™ mechanical compression took significantly longer to effect haemostasis after femoral sheath removal (P=0.000). Similar pain scores were reported during either manual or QuicKlamp™ compression. The time to mobilisation was significantly longer for subjects in the QuicKlamp™ compression group. At 5-day follow-up a statistically significant difference in bruising was identified, with more bruising identified in those subjects in the QuicKlamp™ compression group (P=0.046), as was swelling in female subjects (P=0.044). Those subjects in the manual compression group reported statistically more episodes of chest pain at 5 days following hospital discharge (P=0.014).

CONCLUSION: The findings demonstrate that QuicKlamp™ mechanical compression is a safe alternative to manual compression for attaining haemostasis after femoral sheath removal.

Introduction

Cardiac interventions have become a commonly accepted treatment option for patients with coronary heart disease. Femoral artery puncture, cardiac catheterisation and revascularisation techniques such as percutaneous transluminal coronary angioplasty (PTCA) are now widely used in diagnostic and interventional cardiology.[1]

With the advances of more complex interventional procedures in the last few years there has been an increased focus on the management of the arterial puncture site.[2] Access for catheterisation is most commonly via the femoral artery using a percutaneous transfemoral technique.[3,4] This approach to cardiac catheterisation has proven to be safe and effective with few serious peripheral vascular complications, such as arteriovenous fistula and pseudoaneurysm formation.[5]

In recent years the techniques and types of sheaths used for femoral artery cannulation have been refined, making it easier to exchange different size and shape diagnostic and interventional catheters during the procedures.[2] To reduce the potential for acute occlusion, more aggressive anticoagulation regimes have been instigated. As a consequence, the incidence of peripheral vascular events associated with femoral artery catheterisation has risen, despite the improved success rates associated with the procedure.[2] Therefore, research investigating techniques that may assist with attaining haemostasis at the time of arterial catheter removal and minimising the impact and complications of arterial puncture, is warranted.

The study reported here compares two techniques used to attain haemostasis after femoral sheath removal: manual compression, a commonly used technique involving digital or hand pressure over the femoral puncture site, and a mechanical compression device, the QuicKlamp™.

Background

Cardiac Catheterisation

According to Gensini (p.63) cardiac catheterisation is a

> ...combined haemodynamic and angiographic procedure undertaken for diagnostic purposes and consisting of the introduction of a catheter or probe into the vascular system and heart in order to perform certain measurements ... draw blood samples, inject indicators or any combination thereof.[6]

Although cardiac catheterisation is indicated for a variety of circumstances, it is most frequently used to confirm or define the extent of suspected coronary heart disease (CHD). In addition, the procedure allows the anatomic and physiologic severity of the disease to be determined and the presence or absence of related conditions to be explored.[7]

There are few contraindications to cardiac catheterisation. However, the safety of the procedure is improved if correctable conditions such as drug toxicities, congestive heart failure (CHF) and arrhythmias are well managed prior to the procedure.[6] Controversy surrounds the debate about whether anticoagulation is a contraindication to cardiac catheterisation. It has been reported that patients receiving anticoagulants have had an increase in haemorrhage and other complications[8,9], whereas others have reported anticoagulants to be safe, and at times, beneficial.[10,11] Warfarin therapy is generally stopped two to three days prior to the procedure, while patients who require intravenous heparin for acute myocardial infarction have therapy discontinued for elective cardiac catheterisation at least four hours before arterial needle puncture.[4] Heparin binds to circulating antithrombin III, inhibiting the formation of thrombin and other coagulation factors. In addition, the inhibition of thrombin prevents platelet aggregation.[12] Therefore, heparin therapy is routinely administered during some interventional procedures, such as percutaneous transluminal coronary angioplasty (PTCA), to prevent thrombus formation.[13]

Patients undergoing elective cardiac catheterisation are usually admitted the day of the procedure. Routine patient preparation is undertaken including informed consent, chest x-ray, blood workup, 12 lead electrocardiogram (ECG) and nil by mouth for at least six hours prior to the procedure.[7]

The demands to contain health care costs has meant that many invasive procedures, once done on an inpatient basis are now conducted as outpatient procedures.[14] Cardiac catheterisation is no exception with many institutions primarily undertaking outpatient procedures.[7] Outpatient cardiac catheterisation has been shown to be a safe and cost effective procedure, avoiding overnight hospital stay for patients.[14]

Vascular Access

Arterial cannulation for cardiac catheterisation can be accomplished by direct exposure of the artery or by percutaneous methods using the Seldinger technique.[15] Direct exposure is using the brachial artery, whereas the percutaneous approach is used for femoral artery cannulation. Both approaches have been evaluated to have a high degree of safety.[7]

It is often the cardiologists personal preference that dictates the cannulation approach used. However, there are specific factors that may favour one approach over another. The direct brachial approach is indicated in cases where vascular disease of the abdominal aorta, iliac or femoral arteries are known to exist and with severe obesity, as direct visualisation of the vessel and better control of bleeding is possible.[7] Disadvantages of this approach include that it can only be used once or twice, arterial thrombus occurs more frequently and patients must return for removal of sutures.[7]

The percutaneous femoral approach is often preferred as it can be used repeatedly, is easily and quickly achieved and arterial repair is not required.[5] In addition, larger calibre devices can be introduced into the femoral artery but not usually into the

smaller brachial artery.[16] It is specifically indicated in cases of decreased or absent radial or brachial pulses.[7]

On completion of the procedure the catheters and introducer sheath are removed and pressure is applied to the site of entry.[5] Compression of the arterial puncture site must be maintained until haemostasis occurs. Usually this is followed by the application of a pressure dressing. Patients are required to remain in bed, head up with an elevation of no more than 15°, keeping their affected leg straight and immobile until the sheath is removed.[1] It has been asserted that immobilisation decreases the incidence of haematoma formation and bleeding at the arterial puncture site.[17]

Haemostasis is achieved by the application of pressure to the femoral artery puncture site using either manual pressure and/or a mechanical compression device. Manual compression involves the application of firm finger or hand pressure directly over the femoral artery puncture site for at least ten minutes to control bleeding.[1] Several mechanical devices have been developed using the same principle to assist with the procedure or to provide an alternative to manual compression.

The Clinical Setting

Cardiac catheterisation and coronary angiography is primarily performed on day patients in the cardiac catheterisation laboratory of the study institution. The usual clinical practice at the time of this study was that femoral sheaths were removed in the cardiac recovery unit immediately following the procedure unless the patient was experiencing chest pain or hypertension (systolic blood pressure >150 mmHg). For those patients who had episodes of chest pain or hypertension during the immediate recovery period, femoral sheath removal was delayed until either, or both conditions resolved.

In some cardiac units medical personnel (interns, residents, cardiologists) are primarily responsible for removing femoral sheaths.[18] Due to the busy working schedule of

medical personnel it is not uncommon for patients to wait one to five hours to have their femoral sheath removed after some interventional procedures such as PTCA. This wait is in addition to the minimum 4-hour period after anticoagulation has been ceased, often resulting in patients having femoral sheaths insitu for extended periods. This unnecessary waiting proves inconvenient for patients as they are confined to bed rest for an extended period, increases patient discomfort, and potentially increases the risk of complications and subsequent length of inpatient stay.[17]

Although it has been common for doctors to remove femoral sheaths following cardiac interventional procedures, more recently removal of the femoral sheath has become a component of the expanding role of the cardiac nurse.[18] Nurses removing femoral sheaths must be educated about femoral sheath removal practices and have information that will assist them to plan patient care to achieve optimal patient outcomes. Part of the femoral sheath removal procedure includes attaining haemostasis at the femoral puncture site after removal of the catheter. Nurses must ensure that they are aware of appropriate and effective techniques to attain haemostasis and thereby prevent adverse outcomes.

Nurses are primarily responsible for removal of femoral sheaths after coronary angiography in the catheterisation laboratory where this study was undertaken. A national survey in the United States of America (USA), undertaken by the American Association of Critical Care Nurses (AACN), identified that critical care nurses removed femoral sheaths after most cardiac interventional procedures, removing 91% of cardiac catheterisation sheaths and 83% of percutaneous PTCA sheaths.[19] No reported statistics are available that reflect the practice of sheath removal by nurses in Australia.

Schickel et al examined issues associated with registered nurses (RNs) removing femoral sheaths.[1] They concluded that with appropriate training RNs could remove femoral sheaths with an acceptable margin of safety. However, they concluded that

appropriate protocols, removal techniques and specific actions to take if complications occur, need to be formalised and in place prior to this procedure being included as part of the RNs responsibility in caring for the cardiac interventional patients.

Compression Techniques

A systematic review of the published and unpublished literature did not find any definitive evidence to support any one technique of compression as opposed to another.[20] Although 53 papers were identified on the review topic, after critical appraisal only 12 papers were considered to be of an acceptable methodological quality for inclusion in the systematic review.[20]

The findings of this review found no significant difference in the incidence of bruising, bleeding or pulsatile mass. Some variation in the incidence of haematoma formation did exist between the studies in this review. Although the incidence of haematoma was found to occur significantly more often after manual compression as compared with various mechanical compression devices[21,22,23], the results from the study by Sridhar et al [23] should be interpreted cautiously due to a poor study design.[20] Similar findings were found in respect to pseudoaneurysm formation, occurring significantly more often after manual compression.[23] However, data were collected from the manual compression group retrospectively in this study and were accumulated over an unknown time period, and therefore poorly controlled.[20]

The time taken to effect haemostasis after femoral sheath removal also varied between studies within the review, generally favouring manual compression[21,24,25], with only one study reporting a significantly longer manual compression time.[26] However, insufficient reporting of information from some studies meant it was not possible to make statistical comparisons in a meta-analysis.[20]

Some studies within the review had assessed the degree of comfort or discomfort with

various haemostasis interventions using either a visual analogue scale (VAS)[27], or a verbal descriptor scale (VDS).[14,21] A significant difference between the patient's perceptions of pain or discomfort associated with a particular compression technique was only found in one study, where discomfort was greater after 30 minutes of manual compression as compared to mechanical compression.[21]

Although this systematic review identified primary research related to attaining haemostasis after femoral sheath removal, several studies did not address mechanical compression techniques specifically or contained insufficient primary research data for inclusion. The limited depth and breath of this review was due to the quality of the research findings available. However, from the findings of the review it was possible to assert that there was no difference in the effectiveness of mechanical compression devices in attaining haemostasis after femoral sheath removal as compared with manual compression, or any other compression techniques. Further research is required before recommendations can be made about specific mechanical devices being more effective in attaining haemostasis than others.

Although nurses need information on the effectiveness and reliability of various techniques to achieve haemostasis after femoral sheath removal, this systematic review has demonstrated that there is still insufficient evidence to support a particular compression technique as being most effective in attaining haemostasis. This knowledge is essential for nurses to ensure quality patient care.

Manual compression after femoral sheath removal is often time consuming (taking at least 10 minutes and up to an hour to attain haemostasis), labour intensive for the nurse or doctor removing the sheath and uncomfortable for the patient. If performed incorrectly a number of serious complications may result. These complications include haemorrhage, haematoma formation, vessel occlusion, thrombosis, arteriovenous fistula formation and pseudoaneurysm, which may require surgical repair.[28,29] Many factors have been associated with access site complications

including: obesity, advanced age, female sex, diabetes, hypertension, peripheral vascular disease, multiple arterial punctures to gain vascular access, larger sheath size, delayed removal of sheaths, thrombolytic therapy, higher levels of anticoagulation and infection.[28,30] It is estimated that access site complications occur in 1% to 5% of procedures, but may rise as high as 14% with some cardiac interventional procedures.[31] If complications arise they may result in the need for surgical repair, resuscitation requiring blood transfusion and increasing periods of bed rest for the patient, ultimately prolonging hospital stay, with associated escalating inpatient costs.[2]

It appears that conflicting recommendations still exist in the literature as to the preferred use and efficiency of manual and mechanical compression techniques. An extensive search of the literature using MEDLINE and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases was undertaken but failed to find a study that directly compared the use of the QuicKlamp™ and manual compression to achieve haemostasis post femoral sheath removal after cardiac investigation procedures. This study was designed to compare these two techniques.

Study Method

The Purpose of the Study

The purpose of this study was to compare the use of manual compression with a mechanical compression device, the QuicKlamp™ in achieving haemostasis after femoral sheath removal in coronary angiography patients and to determine the ability of these two techniques to reduce groin complications. This information will assist nursing staff to formulate evidence-based protocol(s) that will direct and educate nursing staff in regards to effective and safe femoral sheath removal practices.

Research Question

The research questions addressed in this study were:

Does the percentage and type of groin complications differ between the use of the QuicKlamp™ compression device and manual compression?

Does the time to affect haemostasis differ between the use of the QuicKlamp™ compression device and manual compression?

Do the patients' perceptions of pain and discomfort during compression differ between the use of the QuicKlamp™ compression device and manual compression?

The null hypothesis (H_0) was:

There is no difference in the effectiveness of the QuicKlamp™ compression device in attaining haemostasis after femoral sheath removal compared with manual compression.

The alternate hypothesis (H_A) was:

There is a difference in the effectiveness of the QuicKlamp™ compression device in attaining haemostasis after femoral sheath removal compared with manual compression.

Method

A randomised controlled trial (RCT) was designed to compare two techniques used to obtain haemostasis after femoral sheath removal.

Subjects and Setting

A power analysis was used to determine the sample size necessary to achieve sufficient *power* (an 80 percent chance of detecting a relationship between variables).[32] Using haematoma formation as a specified outcome variable to determine the necessary effect size, a sample of at least 50 subjects per intervention group was required with an alpha level of 0.5. Between June 1999 and March 2001 a convenience sample of 100 patients scheduled to have elective coronary angiography from a large metropolitan tertiary referral hospital were recruited to participate in the study. The cardiac catheterisation procedure list was assessed at the beginning of each day to

determine those patients scheduled for coronary angiography. Those patients identified as potential inclusions for the study were approached and asked prior to their procedure if they would be involved in the study. Written consent was obtained before subjects were entered into the study. If they agreed to consent then they were randomly allocated to one of the two compression protocols.

Inclusion Criteria

Those patients with the following criteria were eligible for inclusion in the study:

- Elective coronary angiography patients.
- Patients with an introducer sheath inserted into the femoral artery.
- Patients with a Body Mass Index (BMI) of <30 kg/m^2.

Exclusion Criteria

Patients with the following criteria were excluded from the study:

- Patients with known bleeding abnormalities.
- Those on anticoagulation medications including: warfarin therapy, thrombolytic therapy during, or within, 24 hours of the procedure, and ReoPro™ as these therapies may have increased bleeding tendencies.
- BMI>30 kg/m^2. The body mass index (defined as weight [in kilograms—kg] divided by height [in metres—m]squared) above 30 kg/m^2 is a measure of obesity.[33] It was considered that it would be difficult to apply adequate compression using the mechanical device or visualise the puncture site in obese patients.
- Any patient who had coronary angiography via a brachial or radial vascular approach as this study was only interested in the femoral sheath approach, which is predominantly used to gain access for cardiac interventional procedures.[5]

Ethical Considerations

Clearance from the Chair of the Human Ethics Committee of the study institution was obtained prior to commencing this research. Approval was also sought from the

Medical Director of the Cardiovascular Investigation Unit and the Nursing Director of the Cardiovascular Service area at the study institution prior to commencement.

Participation in this study was voluntary and confidential was maintained throughout. The Patient Information Sheet (see Appendix 1) assured participants that they would not be identifiable from the research, informed them of the nature and purpose of the study, and provided the name and telephone number of the chief researcher in case further information or feedback was required. The researchers also assured those patients willing to participate that defining information relating to any person or institution uncovered during the course of this study would be deleted or changed to protect their identify. Participants were informed of their right to withdraw from the study at any time and that if they chose to do so, that other medical care and treatment would not be affected now or in the future. The participants were asked to sign a consent form (see Appendix 2) indicating that they were willing to participate in this study and that the nature and purpose of the study had been explained to them.

During the study period all data collection and consent forms were stored in a locked cabinet in the primary researcher's office. This data will be kept secure in a locked cabinet for 5 years.

Randomisation

The research design of randomised controlled trials (RCTs) enables the outcome and effect of particular clinical interventions to be reliably measured. The potential for bias is reduced by the random assignment of subjects and careful control of the study variables in each study group and ensures the observed effects are attributed to the intervention and are not a result of other factors.[34,35] The scientific evidence produced by RCTs is often considered the 'gold standard'[36] as RCTs designed to evaluate the effectiveness of health interventions provide the most reliable and valid information to guide clinical practice decisions.[37] As the purpose of this study was to compare two techniques of compression after femoral sheath removal, manual and QuicKlamp™

mechanical compression, to determine which technique was most effective in attaining haemostasis and minimising groin complications, a RCT was considered the most appropriate research design for this study.

During the study patients were randomly assigned to receive either manual compression or mechanical compression using the QuicKlamp™ device to attain haemostasis after femoral sheath removal. One hundred study packages were collated prior to the research. Each study package contained a patient information sheet (see Appendix 1), patient consent form (see Appendix 2) and data collection forms (see Appendices 5 & 6). The data collection form indicated the allocated intervention group to be used, either manual or QuicKlamp™ compression. All items included in the study package were placed into a large individual opaque envelope. These envelopes were sealed, shuffled and placed into a box. After the patient agreed to sign the written consent form to be involved in the study the researchers randomly selected an envelope from the box allocating the patient to either study group. It was not known until the envelope was opened what compression protocol the patient had been assigned.

Compression Techniques

Two separate standardised intervention protocols were designed for both compression techniques: Manual compression (see Appendix 3) and QuicKlamp™ mechanical compression (see Appendix 4). This ensured the technique followed during femoral sheath removal and compression was uniform amongst the researchers. The protocols were freely accessible in the study area and individually distributed during education sessions conducted with the staff by the researchers.

Manual compression was achieved by placing firm digital or hand pressure just above the puncture site for at least 10 minutes after which time pressure was slowly released and haemostasis determined. If haemostasis was not achieved pressure would be reapplied and maintained and until bleeding stopped.

The QuicKlamp™ is a mechanical "C" clamp compression device that consists of a hand adjustable clamp, or C-arm, attached to a broad, flat base. The flat base is positioned under the patients' hips and the C-arm lowered so that it applies pressure through a transparent sterile disc positioned over the femoral puncture site. Continued pressure can be applied without completely occluding the femoral artery and thus allowing perfusion to the lower limb. Regular checking of the subjects pedal pulse was undertaken during compression to ensure distal limb perfusion was maintained. The transparent disk overlying the femoral puncture site allowed assessment of bleeding to be undertaken. To ensure uniformity, pressure using the QuicKlamp™ device was also applied for a minimum of 10 minutes and was maintained until bleeding stopped.

After haemostasis was attained a pressure dressing, or 'groin roll', was applied over the femoral puncture site and remained in place until mobilisation occurred. This pressure dressing consisted of a roll of gauze swabs place over the puncture site and tightly strapped from across the inner thigh and groin, to the outer hip with an Elastoplast tape bandage. This pressure dressing was applied to all subjects in both intervention groups.

Femoral Sheath Removal Team

In order to reduce bias, a group of Registered Nurses (RNs) permanently assigned to work in the study catheterisation unit became part of the team responsible for removal of femoral sheaths during this study. In addition to the primary investigator, two other RNs participated in the study. These nurses were clinical leaders in the study unit and had extensive experience with femoral sheath removal techniques and had undergone specific training in the use of the QuicKlamp™ device. Although it is acknowledged that some variation may have existed between the RNs application of manual or mechanical compression, the 'femoral sheath removal team' was introduced in an effort to reduce the threat to internal validity and minimise technique variability. An

extensive education program was conducted prior to commencement of the study to ensure all nurses on the team were familiar with the designed study protocols, data collection sheet, assessment of groin complications and pain perception score. However, interrater reliability was not measured between the nurses on the femoral sheath removal team.

Instrumentation

A clear, disposable, round disc with millimetre markings was intended to be used to measure the size of any haematoma formation or bruising at the puncture site after removal of the sheath and haemostasis had occurred. An outline of the bruise/haematoma was to be drawn onto the disc. A grid using graph paper would then be used to calculate the exact size of the bruise or haematoma formation. The intention of designing this instrument was to ensure a consistent and accurate measure of any bruise or haematoma formation was taken on patients who developed these outcomes after sheath removal. Unfortunately this instrument was not consistently used with all patients who developed a bruise or haematoma post sheath removal and several assessment measures were made subjectively by the researchers.

Bruising was defined as any bluish/purple discolouration of the skin. A *haematoma* was defined as a palpable mass beneath the skin surface around the femoral puncture site. *Bleeding* was defined as any ooze, leaking or frank blood drainage from the puncture site. Bleeding was assessed as *mild* (0—50 ml), *moderate* (50—300 ml) or *severe* (> 300 ml). As it would be difficult to precisely measure the amount of bleeding, the researcher was required to make a subjective assessment of bleeding from the puncture site. The subjective assessment of bleeding is a routine assessment made by nurses in nursing practice.

Subjects were asked to rank their perception of pain during the haemostasis compression phase after sheath removal using a 11-point ordinal verbal descriptor scale (VDS) with 0 indicting no pain and 10 indicating the worse possible perception

of pain. This scale was commonly used as a measurement of patient's pain perception in many areas of the study institution and therefore those nurses involved in the study were familiar with this tool.

Data Collection

An independent variable is that variable which can be manipulated and cause an effect on the dependent variable.[35] The independent variable in this study was the compression technique used to obtain haemostasis after femoral sheath removal, either manual or QuicKlamp™ compression. Dependent variables are those variables that are affected by the independent variable.[35] The dependent variables in this study were the time taken to attain haemostasis, haematoma formation, bruising and/or bleeding at the puncture site and the subject's pain perception.

A data collection form (see Appendix 5) was designed to allow the following information to be collected:

- Demographic details including age, gender and cardiac risk factors
- Weight and height (in order to calculate BMI)
- Procedure details including: femoral sheath size, groin approach, number of arterial stabs, contrast dye and procedure duration
- Sheath removal time and compression technique used
- Post procedure assessment details included: assessment for groin complications, including the presence of bruising, haematoma formation and/or bleeding at the femoral puncture site, subjects pain perception during compression, time to haemostasis and time to mobilisation
- An assessment for the presence of groin complications was undertaken after the procedure and prior to femoral sheath removal, immediately following haemostasis after sheath removal and application of the compression technique, and after removal of the pressure dressing prior to mobilisation.

In addition, the primary investigator made follow-up telephone calls on the fifth day after the procedure to all subjects enrolled in the study to ascertain if any late

complications had occurred after hospital discharge. The questions that were asked (see Appendix 6) were adapted from the usual Post Angiogram Discharge Questionnaire routinely used in the catheterisation unit at the study institution.

Data Analysis

Data from the collection tool were coded and entered onto a spreadsheet for analysis using Statistical Package for Social Sciences (SPSS) software version 10.0 for Macintosh. The classification of the data determined the type of data analysis to be completed. According to the appropriate scale of measurement, descriptive statistics such as frequency distributions (percentages), measures of central tendency (mean, median, mode) and measures of dispersion (range, variance, standard deviation) were used to analyse and describe the data.

The statistical tests applied to the data are determined by the attributes of the data collected. Parametric tests rely on certain characteristics to be fulfilled in order to use them:

- the data must be interval or ratio in nature (measured on a scale where the distance between each point is identical) such as time and age, not nominal or ordinal (data which does not have any absolute measures and is grouped into named categories) such as gender;
- the data must be approximately normally distributed in the population with the range of data being fairly similar between each of the groups of subjects; and
- the subjects should be selected at random so that a true representation of the given population is achieved.[35]

By contrast non-parametric tests do not rely on set parameters. These types of tests are not as sensitive as parametric tests as they involve less restrictive assumptions concerning the distribution of critical variables.[35,36]

Chi-square test and Mann-Whitney *U* test were the non-parametric tests used in this study. Chi-square test was used to see whether there was a relationship between two different variables, not to predict whether one variable was better off than another. In order to analyse data using this test the data was required to satisfy the following criteria:

- data were nominal (named categories with no absolute measure);
- data were collected from two or more separate groups of subjects with two or more nominal categories; and
- the sample size were at least 20 to allow for a minimum of five in each category of analysis.[35]

Clifford and Harkin (p.77) state 'The Mann-Whitney *U* test is a non-parametric test that is used to see whether there are significant differences between two sets of data which have come from *different* sets of subjects'.[35] In order to utilise the Mann-Whitney *U* test two sets of data derived from subjects must be used. The data must be ordinal or interval/ratio in nature.[35]

Due to the measurement scale of the data collected in this study, inter-group comparisons were undertaken to determine whether there were associations between some variables using either Chi-squared analysis for categorical data such as gender, or the Mann-Whitney *U* test for continuous variables such as time and age.

Parametric tests, such as independent-samples *t*-test were undertaken on continuous data (such as age and time) that were normally distributed. The independent-samples *t*-test is used to compare the mean scores of two different groups of subjects or conditions.[32] A 2-way Analysis of Variance (ANOVA) was used to test significant differences between the mean values of three or more independent groups[36], such as the subjects pain score during compression.

The independent variables were the compression techniques (manual or

QuicKlamp™). All other variables were dependent.

Statistical significance in experimental research means that the obtained results are unlikely to have occurred by chance, at some specified level of probability.[36] A *P* value of 0.05 or less was considered statistically significant and was used as the criterion for rejecting the null hypothesis in this study. In health and social sciences a level of significance or *P* value of 5% (*P*=0.05) is acceptable.[33]

Results

Following categorisation of the data into the units of measurements (such as nominal and ordinals data), statistical analysis was undertaken. The results of the statistical analysis are presented in five sections. The first section describes the characteristics of the subjects' demographic data, followed by a description of the characteristics related to the angiography procedure, such as the femoral sheath size, contrast dye and procedure time. The third section relates to the compression technique details, including the type of compression technique and the time taken to effect haemostasis after femoral sheath removal. The fourth section describes the post-procedural events, such as the incidence of bruising, bleeding and haematoma formation, the subjects' perceptions of pain during compression and the time from sheath removal until mobilisation and any relationships that were identified between these events and the compression technique used to attain haemostasis. The final section describes the results of the subject telephone questionnaire undertaken five days following the interventional procedure.

A total of one hundred subjects were recruited into the study and their data analysed. Subjects were randomised into either study group (n=50 manual compression, n=50 QuicKlamp™ compression) using the randomisation technique outlined in the methods section. This sample size provided sufficient numbers for a power of 0.8 in this study.

Subject Demographics

Subjects randomised to either the group who received manual compression or the QuicKlamp^{TM} group were similar for general demographic characteristics, such as gender, age, Body Mass Index (BMI) and cardiac risk factors (see Table 1). There were more male subjects enrolled in this study compared to females (n=70 and 30 respectively), the median age was 62 years for all subjects in both intervention groups. The mean BMI was 26 kg/m^2 for subjects in each group. These groups were similar in terms of cardiac risk factors, with family history as a risk factor for n=28/50 for the manual group and n=25/50 for the QuicKlamp^{TM} compression, for hypercholesterolaemia n=22/50 for the manual group and n=23/50 for QuicKlamp^{TM} compression group and hypertension n=19/50 for the manual group and n=22/50 for QuicKlamp^{TM} compression group being most commonly identified. The number of subjects within each group who were taking Aspirin prior to the procedure was 50% (n=25/50) in the manual compression group and 60% (n=30/50) in the QuicKlamp^{TM} mechanical compression group. However, this was not statistically significant (P=0.3) (see Table 1).

Table 1: Subject's characteristics [1]

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Gender			
male/female	34/16	36/14	0.66
Age (years)*			
male	63.5 (37-75) 60.6±10.07	62 (37-77) 60.4±9.4	0.8†
female	58 (42-80) 61.3±10.3	62.5 (36-76) 60.7±10	0.82†
total	62 (37-80) 60.8±10.05	62 (36-77) 60.5±9.5	0.88† 0.89**
BMI kg/m^2 *			
male	28.4 (21-36) 28.4±3.5	28.5 (22-36) 28.6±3.7	0.56†
female	26.1 (17-35) 25.9±4.1	27.7 (22-38) 28.9±4.9	0.13†
Total	28 (17-36) 27.6±3.8	28.3 (22-38) 28.7±3.7	0.16†
Aspirin			
male	18	21	0.65
female	7	9	0.26
	25	30	0.3
# Cardiac risk factors*			
male	2 (0-4) 1.7±1.1	2 (0-6) 1.83±1.3	0.97 †
female	2 (0-4) 2±1.2	3 (0-5) 2.36±1.4	0.49 †
Total	2 (0-4) 1.8±1.15	2 (0-6) 2±1.33	0.83†
Cardiac risk factors			
Hypertension			
male/female	12/7	15/7	0.59/0.73
Total	19	22	0.54
Family history			
male/female	17/11	18/7	1.0/0.23
Total	28	25	0.55
Hypercholesterolaemia			
male/female	12/10	14/9	0.76/0.91
Total	22	23	0.84
Diabetes			
male/female	7/2	2/3	0.06/0.51
Total	9	5	0.25
Smoker			
male/female	6/1	7/2	0.85/0.46
Total	7	9	0.59
Obesity (BMI > 30 kg/m^2)			
male/female	6/1	5/11	0.108/0.77
Total	7	19	0.14

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
† Mann-Whitney *U* test ** Independent sample *t*-test

[1] Unless indicated, any differences between groups are not statistically significant (chi-square).

Age

Subjects were similar within both intervention groups for age. Although the overall range of age for subjects enrolled within the study was 36 to 80 years, the largest proportion of subjects, 74% (n=37/50) for manual and 76% (n=38/50) for QuicKlamp™ compression, were aged between 55 to 70 years. There was no statistically significant difference between the mean age of male and female subjects within each group (60.6/61.3 manual and 60.4/60.7 QuicKlamp™ groups respectively see Table 1 and Figures 1a and 1b).

Figure 1a: Frequency of patient's age for the manual compression group

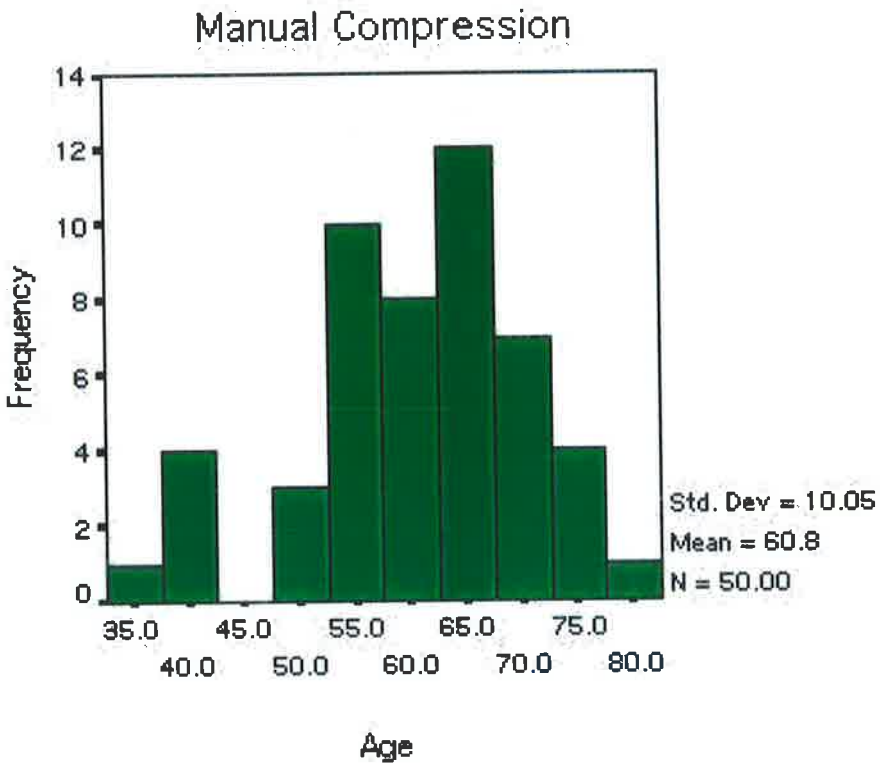
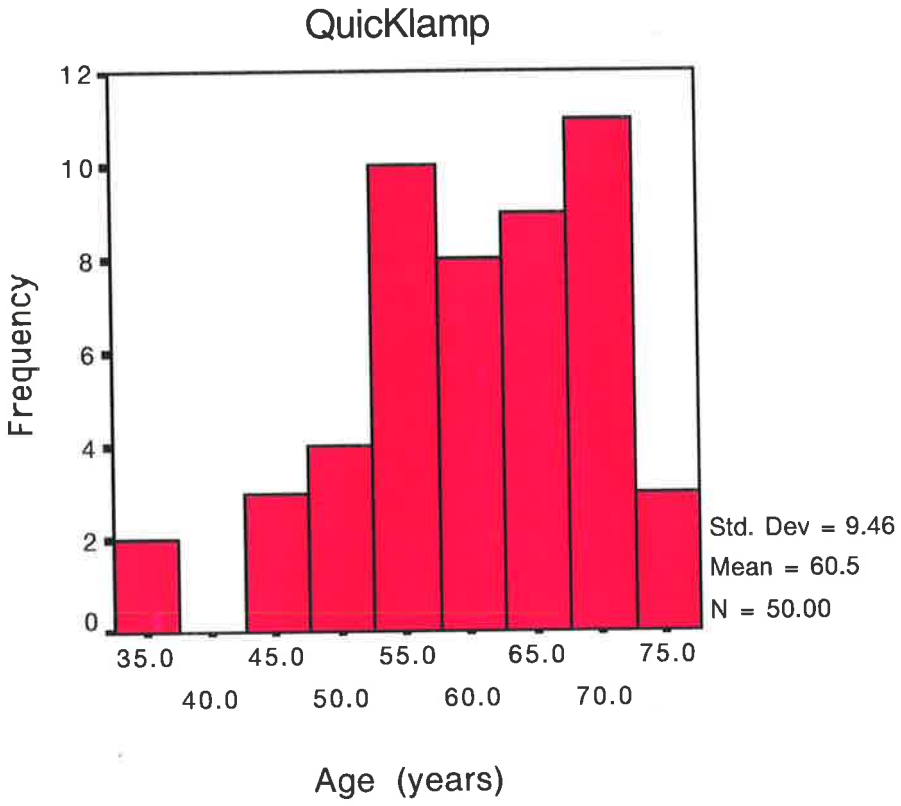


Figure 1b: Frequency of patient's age for QuicKlamp™ compression group



Body Mass Index (BMI)

The body mass index (defined as weight [in kilograms—kg] divided by height [in metres—m] squared) above 30 kg/m^2 is a measure of obesity.[32] It was considered that it may have been difficult to apply adequate compression using the QuicKlamp™ mechanical device, as it may not have been possible to apply even pressure with the hand adjustable clamp through the transparent sterile disc positioned over the femoral puncture site, in the groin of 'obese' subjects. Although this notion is discussed in the literature and previous studies comparing manual and mechanical compression techniques have excluded patients based on BMI or weight[22,39], there is no research that conclusively states that mechanical compression devices are more difficult to apply, or that they distribute uneven or inadequate pressure over the femoral puncture site in obese patients as compared to those within a normal weight range. As the design of this study was based on previous research within this field[22], BMI> 30 kg/m^2 was listed as an exclusion criterion. However, when subjects were consented to

be involved in the study, the researchers made a subjective assessment of obesity, based on their experience of femoral sheath removal in cardiac interventional subjects believing that their subjective assessment would be congruent with the objective measure. As subjective assessment was part of the standard clinical practice used by the clinicians in this cardiac catheterisation unit when determining the type of compression technique to use, they did not calculate the objective measure of obesity at the time of enrolment of subjects. As a result, 23 subjects (n=7 manual group, n=16 QuicKlamp compression group) who were subjectively assessed to be of normal weight and not obese, had an objective BMI measurement greater than 30 kg/m^2 when calculated using the height and weight data. When the data were stratified into BMI greater or less than 30 kg/m^2, chi-square analysis identified a statistically significant difference between the two intervention groups, with more subjects having a BMI>30 kg/m^2 in the QuicKlamp™ mechanical compression group (see Table 1).

Although BMI was calculated for each patient, it was by subjective assessment that subjects were excluded from the study on the basis of being obese. As a result, 23 subjects were included in the study whose BMI when calculated would have excluded them. Because these subjects were included in the study the results of adverse effects such as bruising, haematoma formation and bleeding will be analysed with all subjects included and then with those with a BMI> $30kg/m^2$ excluded to see if any statistically significant difference is evident.

Cardiac Risk Factors

Data were collected on the following cardiac risk factors: tobacco smoking, hypertension, known family history of coronary heart disease, high blood cholesterol levels, diabetes and obesity (using the BMI measurement >30 kg/m^2). There was no statistically significant difference in the number of cardiac risk factors identified for subjects within either intervention group (see Table 1). The largest proportion of patient's, 82% (n=41/50) for the manual compression group and 80% (n=40/50) for QuicKlamp™ compression group, had between 1 to 3 cardiac risk factors (see Figures

2a and 2b). When the data were stratified for gender the largest proportion of both male (83%, n=58/70) and female (77%, n=23/30) subjects still had between 1 and 3 cardiac risk factors.

Figure 2a: Number of cardiac risk factors for all subjects in the manual compression group

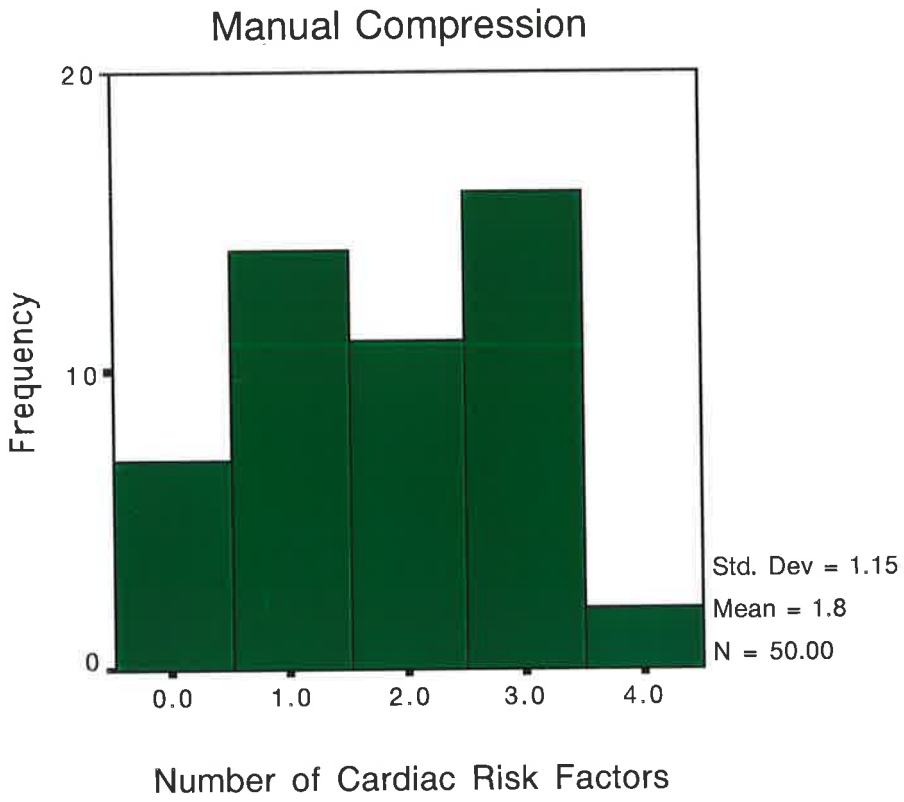
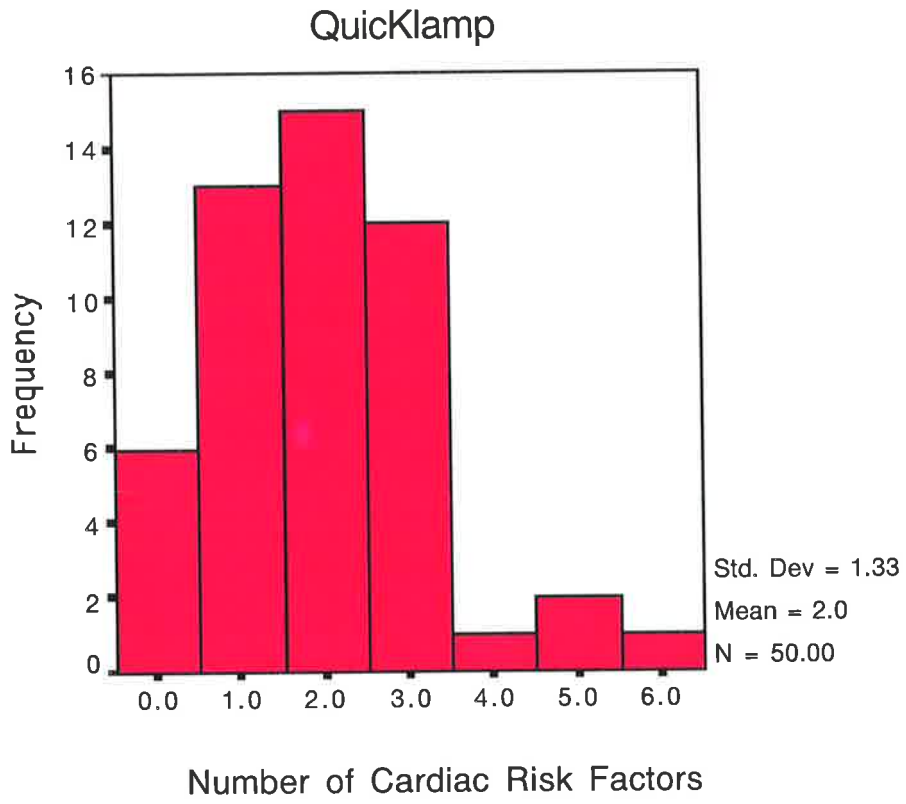


Figure 2b: Number of cardiac risk factors for all subjects in the QuicKlamp™ compression group



Procedural Details

The data related to procedural details, such as the groin approach used for insertion of the femoral sheath and the number of arterial stabs required to correctly position the sheath within the femoral artery, were similar between the intervention groups. The groin approach used during coronary angiography for all females from either intervention group was via the right groin and only one arterial stab was required to correctly position the femoral sheath within the femoral artery for female subjects in both intervention groups. Ninety seven percent of male subjects within either compression groups (n=33/34 in the manual compression group and 35/36 in the QuicKlamp™ compression group) required only one arterial stab to correctly position the femoral sheath within the right femoral artery via a right groin approach. Unless difficulty in identifying the position of the femoral artery was experienced by the Interventional Cardiologist, only one arterial stab was required to cannulate the

femoral artery.

Only one male patient in both intervention groups had a left groin approach during the procedure. From clinical experience, a patient would only have a left groin approach if the right femoral artery were not accessible due to abnormal vascular anatomy or a previous procedure where a bruise or haematoma was evident. However, it was not clear from the data why this subject had a left groin approach for femoral sheath cannulation. In addition, one male patient in both the manual and QuicKlamp™ compression groups required two arterial stabs to correctly position the femoral sheath. The male subjects identified as having a left groin approach and two arterial stabs were not the same subjects within either intervention group (see Table 2).

Table 2: Procedure details

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Groin approach			
Male*			
right/left	33/1	35/1	0.96†
Female**			
right/left	16/0	14/0	1.0†
Arterial stabs			
Male*			
1 stab/2 stabs	33/1	35/1	0.97††
Female**			
1 stab/2 stabs	16/0	14/0	1.0††

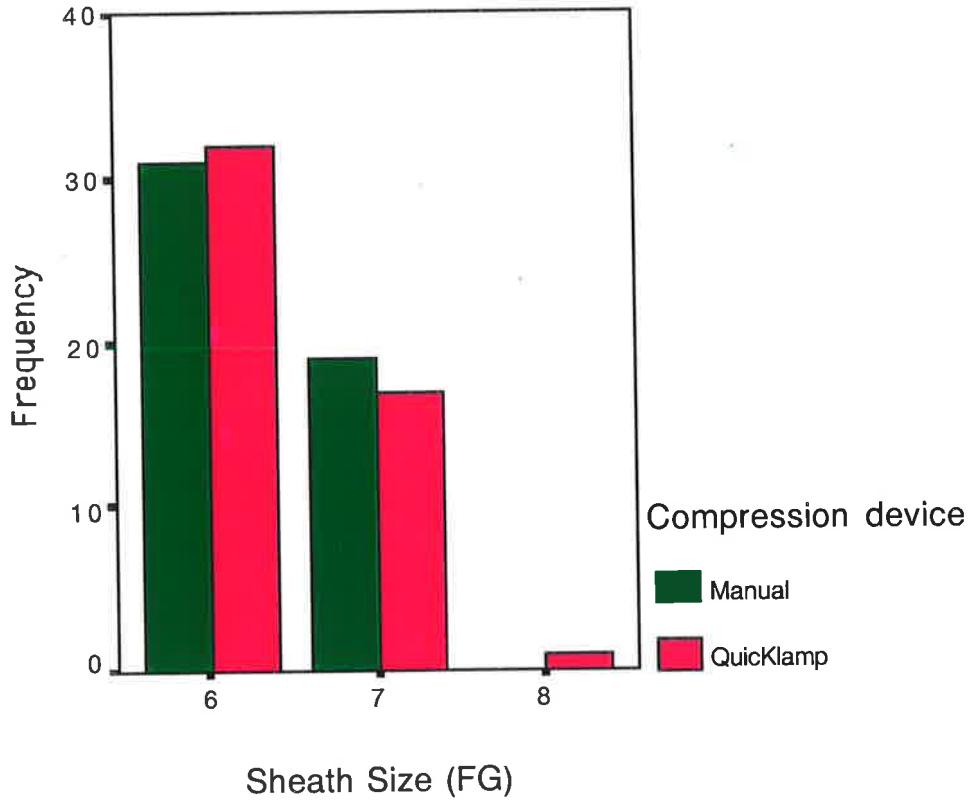
† Chi-square analysis †
† Mann-Whitney *U* test
* Male n=34 manual compression, n=36 QuicKlamp™compression
** Female n=16 manual compression, n=14 QuicKlamp™compression

Sheath Size

The size of the femoral sheath used during the coronary angiography procedure were similar in both compression groups, with the largest proportion of subjects (63%) having had a 6 French Gauge (FG) sheath inserted (n=31 manual and n=32 QuicKlamp™). Thirty-six percent of subjects received a size 7 FG sheath (n=19 manual and n=17 QuicKlamp™). Only one female patient from the QuicKlamp™

compression group had an 8 FG sheath inserted during coronary angiography. The figure below demonstrates the frequency of sheath sizes used during the procedure for both compression techniques (see Figure 3).

Figure 3: Frequency of sheath sizes for both intervention groups



Contrast Dye

There was no statistically significant difference in the number of subjects who had a particular type of contrast dye during the procedure between either intervention groups (P=0.5, chi-square analysis). Three different contrast agents were used for cardiac interventional procedures in the cardiac catheterisation unit of the study institution. In clinical practice, the contrast agent most commonly used during cardiac interventional procedures in this catheterisation unit was Urografin, unless subjects had a known sensitivity to this dye. This is reflected in the data from this study, with the largest proportion of subjects having received Urografin contrast dye (91% in

total, with 47/50 in the manual compression group and 44/50 in the QuicKlamp™ compression group) (see Table 3).

Two non-ionic agents were used as contrast dye for subjects in this study who had a known sensitivity to ionic agents: Ultravist and Optiray. Only one patient in either compression group received Ultravist contrast dye (see Table 3). This was because Ultravist was only available for use in the study unit for a short time as the Supply Department of the study institution changed their purchase preference to Optiray. It is not known exactly why this decision was made, but it may have been related to cost and product availability.

Seven subjects in total (2/50 in the manual compression group and 5/50 in the QuicKlamp™ compression group) received Optiray contrast dye (see Table 3). Optiray was the preferred non-ionic contrast agent used in the cardiac catheterisation unit of the study institution.

Table 3: Type and frequency of contrast dyes used during coronary angiography

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	Total (N=100)
Contrast Dye			
Urografin	47	44	91
Ultravist	1	1	2
Optiray	2	5	7

Procedure Duration

There was no statistically significant difference in the coronary angiography procedure duration between the manual and QuicKlamp™ compression groups, with a median time of 20 minutes for both groups, indicating that the mid-point for this data set between the shortest and longest procedure duration was 20 minutes (see Table 4).

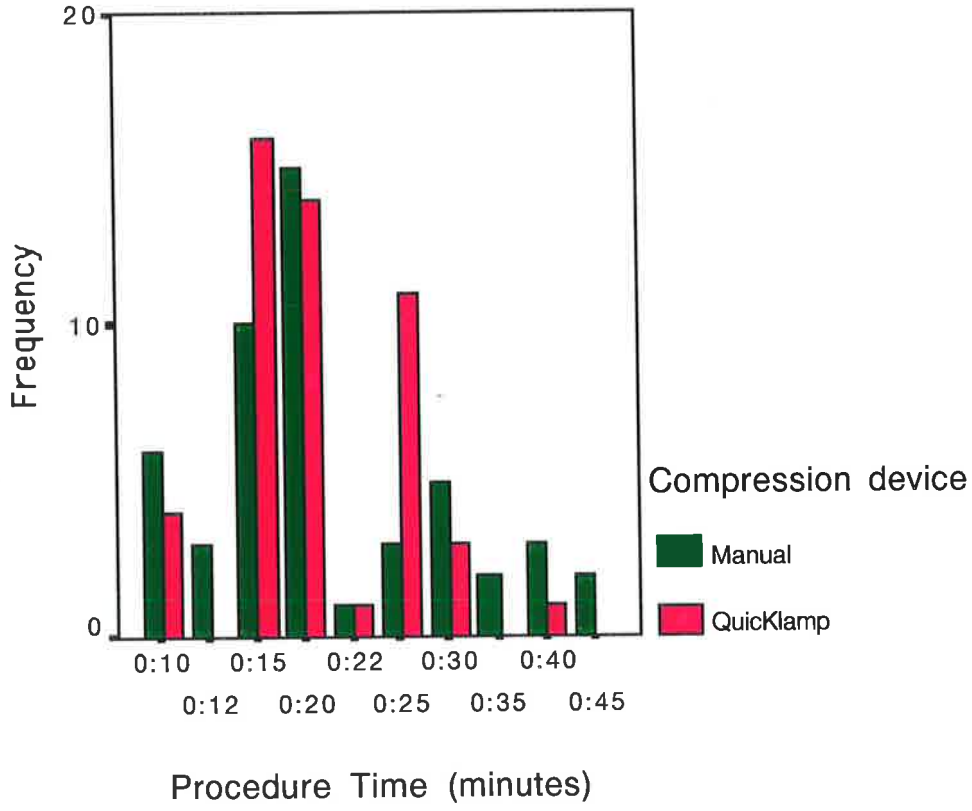
Table 4: Coronary angiography procedure duration

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Procedure Time (minutes)*			
male**	20 (10-45) 22±9	20 (10-40) 20±6	0.66†
female***	20 (10-45) 20±9	20 (10-30) 18±5	0.92†
total	20 (10-45) 21±9	20 (10-40) 19±6	0.78†

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
† Mann-Whitney *U* test
** Male n=34 manual compression, n=36 QuicKlamp™compression
*** Female n=16 manual compression, n=14 QuicKlamp™compression

The figure below demonstrates the frequency of procedure duration for both compression techniques. Although the overall procedure duration for all subjects in the study ranged from 10 to 45 minutes, the largest proportion of subjects within the manual compression group (70%, n=35/50) had procedure duration of 10 to 20 minutes. However, the largest proportion of subjects within the QuicKlamp™ mechanical compression group (80%, n=40/50) had procedure duration of 15 to 25 minutes (see Figure 4). It was not possible to ascertain why the procedure duration was different between subjects within the study.

Figure 4: The frequency of procedure duration (in minutes)



Bruising, Haematoma and Bleeding Prior to Femoral Sheath Removal

Bruise

After the procedure and prior to removal of the femoral sheath there was no statistically significant difference in bruise formation at the femoral puncture site for either intervention group (see Table 5). Two subjects in the manual compression group (n=1 male, n=1 female) had a bruise 2 centimetres in size present prior to sheath removal and one patient from the QuicKlamp™ compression group had a bruise of 1 centimetre present prior to sheath removal. None of the subjects who had a bruise prior to femoral sheath removal had a BMI> 30kg/m^2, indicating their weight was not a contributing factor in bruise formation.

Haematoma

There was no statistically significant difference in the formation of haematoma present at the femoral puncture site after the procedure and prior to femoral sheath removal for the study groups (see Table 5).

Table 5: Presence of bruise/haematoma prior to femoral sheath removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value†
Bruise prior to removal			
*male	1	0	0.3
**female	1	1	0.9
Total	2	1	0.56
Haematoma prior to removal			
*male	1	0	0.3
**female	1	2	0.5
Total	2	2	1.0

† Chi-square analysis
* Male n=34 manual compression, n=36 QuicKlamp™compression
** Female n=16 manual compression, n=14 QuicKlamp™compression

Two subjects in the manual compression group (n=1 male, n=1 female) had a haematoma 2 centimetres in size present prior to sheath removal. Two female subjects in the QuicKlamp™ compression group had a haematoma: one was 2 and the other 3 centimetres in size. Only one of these subjects who had haematomas present after the procedure (a female in the QuicKlamp™ compression group) was obese with a BMI of 33.33 kg/m^2. Three subjects (1 male and 2 females) had a bruise and haematoma after the procedure and prior to femoral sheath removal (see Table 6).

Table 6: Subjects' characteristics and the frequency and size of bruise/haematoma after the procedure and prior to femoral sheath removal

Characteristic	Patient ID number	Gender	Manual (N=50)	QuicKlamp™ (N=50)	Size (cms)
Bruise prior to removal					
	2	F	√		2.0
	29	M		√	1.0
	64	M	√		2.0
Haematoma prior to removal					
	2	F	√		2.0
	19	F		√	2.0
	29	F		√	3.0
	64	M	√		2.0

When subjects with a BMI>30 kg/m^2 were excluded from analysis for both intervention groups (as discussed previously), there was still no statistically significant difference between those subjects with a BMI<30 kg/m^2 who had a bruise or haematoma present after the procedure and prior to femoral sheath removal in either intervention group (see Table 7). There was only one patient (a female) in the QuicKlamp™ mechanical compression group who had a haematoma after the procedure and prior to femoral sheath removal with a BMI>30 kg/m^2.

Table 7: Frequency of Body Mass Index < 30 kg/m^2 and bruise and haematoma after the procedure and prior to femoral sheath removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
BMI < 30 kg/m^2			
Bruise	2	1	0.7
Haematoma	2	1	0.7

* Chi-square analysis

Bleeding

There was no evidence of bleeding in either intervention group after the procedure and prior to femoral sheath removal.

Compression Technique

After randomisation, 50 subjects were allocated to receive manual compression and 50 subjects were allocated to receive QuicKlamp™ compression to attain haemostasis after femoral sheath removal. Manual compression involved the application of firm finger or hand pressure directly over the femoral artery puncture site after femoral sheath removal. To apply the QuicKlamp™ mechanical compression device a transparent sterile disc was positioned over the femoral puncture site. Pressure was then applied over the disc to the femoral puncture site using a hand adjustable clamp. Continuous pressure was applied using the allocated compression technique for a minimum of 10 minutes and maintained until bleeding stopped and haemostasis was attained.

Time to Effect Haemostasis

A statistically significant longer time to effect haemostasis after femoral sheath removal (measured in minutes), was identified with the QuicKlamp™ compression device, as compared to manual compression (P=0.000). The mean time taken to attain haemostasis after manual compression was 15 minutes as compared to 29 minutes in the QuicKlamp™ compression group (see Table 8).

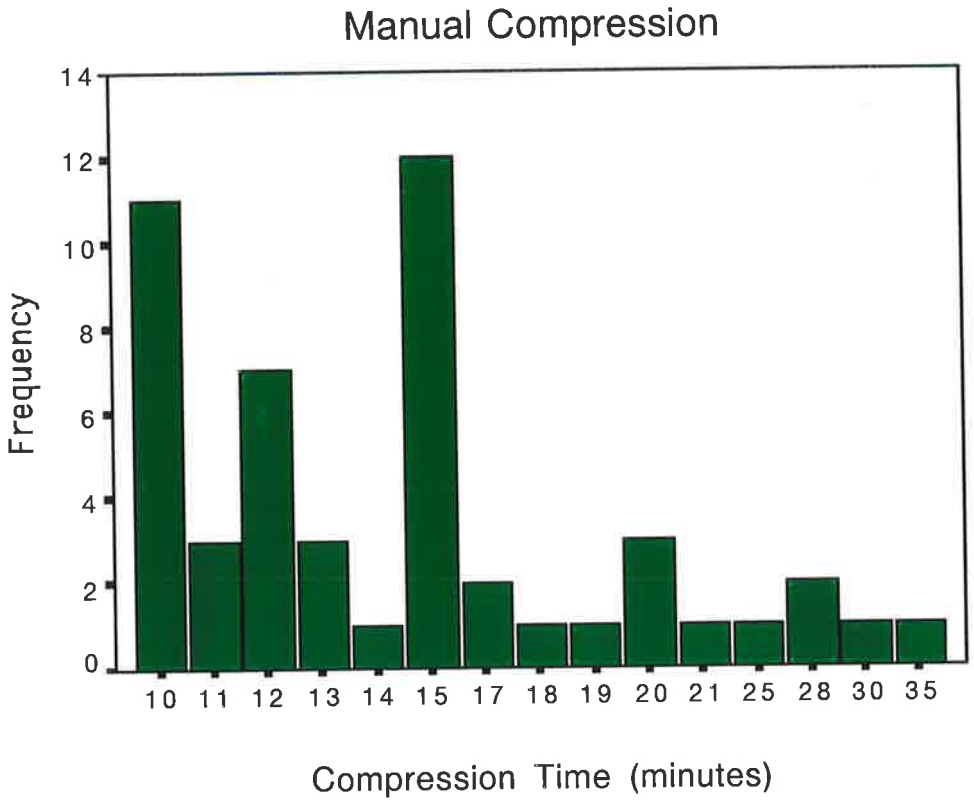
Table 8: Compression times (in minutes)

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Compression Time (minutes)*			
male**	15 (10-35) 15±6	28 (10-60) 29±12	**0.000†**
female***	14 (10-28) 16±6	30 (10-70) 30±14	**0.001†**
total	15 (10-35) 15±5	30 (10-70) 29±12	**0.000†**

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
† Mann-Whitney *U* test and Independent Sample *t*-test
** Male n=34 manual compression, n=36 QuicKlamp™compression
*** Female n=16 manual compression, n=14 QuicKlamp™compression

Although the compression time ranged from 10 to 35 minutes in the manual compression group, the compression time required to attain haemostasis ranged from 10 to 15 minutes in the largest proportion of patient's (72%, n=36/50) in this group, with only two subjects requiring 30 minutes or greater to attain haemostasis (see Figure 5a).

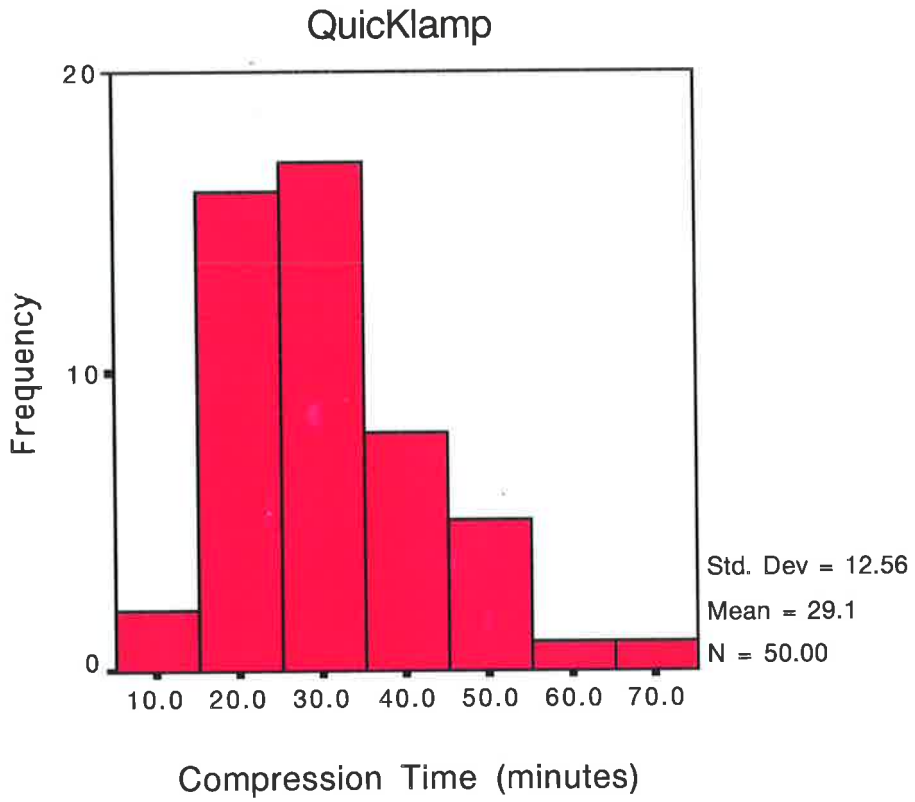
Figure 5a: The frequency of compression times (measured in minutes) in the manual compression group



However, the range of compression times in the QuicKlamp™ mechanical compression group was significantly longer than the manual compression group (P=0.000). For the largest proportion of subjects in the QuicKlamp™ compression group (68%, n=34/50), the compression time required to attain haemostasis ranged from 15 to 30 minutes. Only two subjects took between 10 and 15 minutes (which was the range for the largest proportion of subjects in the manual compression group) to attain haemostasis after QuicKlamp™ mechanical compression. Thirty percent of

the QuicKlamp subjects (n=15/50) took greater than 30 minutes to attain haemostasis, the longest being 70 minutes in a female subject (see Figure 5b). This female subject did not have a BMI >30 kg/m^2, indicting that her weight was not a factor influencing the compression time.

Figure 5b: The frequency of compression times (measured in minutes) in the QuicKlamp™ mechanical compression group



When the data for compression time by gender was calculated within each intervention group, it can be seen that the largest proportion of males (82%, n=28/34) required at least 10 to 15 minutes of manual compression and 20 to 40 minutes of QuicKlamp™ mechanical compression (83%, n=30/36) to attain haemostasis, with one male subject taking 60 minutes (see Figures 5c and 5d). Overall, there was a statistically significant difference in the time taken to effect haemostasis for males, with those in the QuicKlamp compression group taking longer (P=0.000, see Table 8).

For female subjects, the largest proportion (88%, n=14/16) required at least 10 to 20

minutes of manual compression and 20 to 40 minutes of QuicKlamp™ mechanical compression (79%, n=11/14) to attain haemostasis, with one female subject taking 70 minutes (see Figures 5e and 5f). There was a statistically significant difference in the time taken to effect haemostasis, with those in the QuicKlamp compression group taking longer (*P*=0.001, see Table 8).

Figure 5c: The frequency of compression times (measured in minutes) for males in the manual compression group

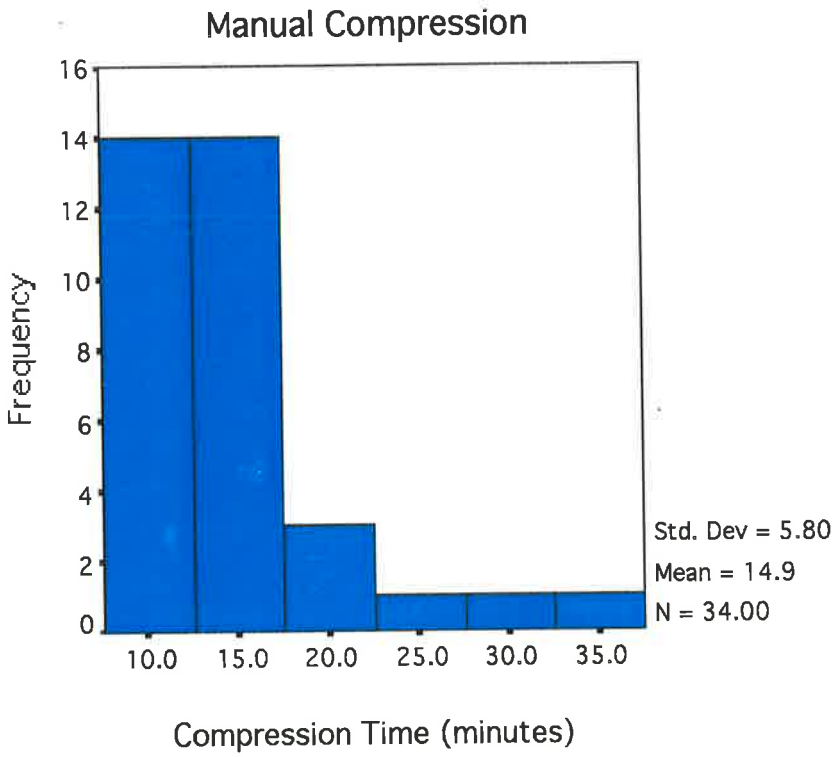


Figure 5d: The frequency of compression times (measured in minutes) for males in the QuicKlamp™ compression group

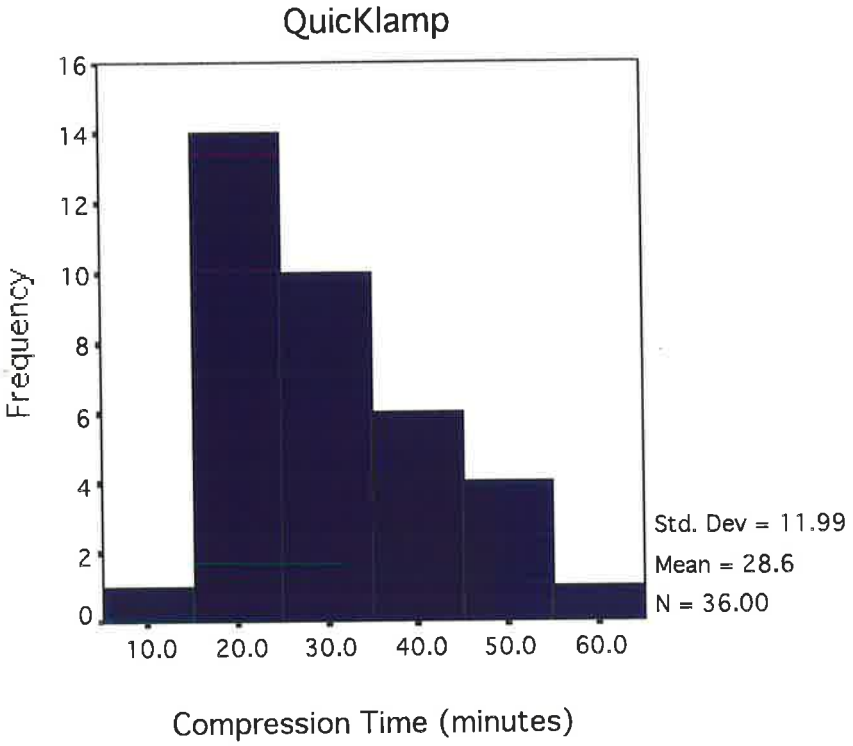


Figure 5e: The frequency of compression times (measured in minutes) for females in the manual compression group

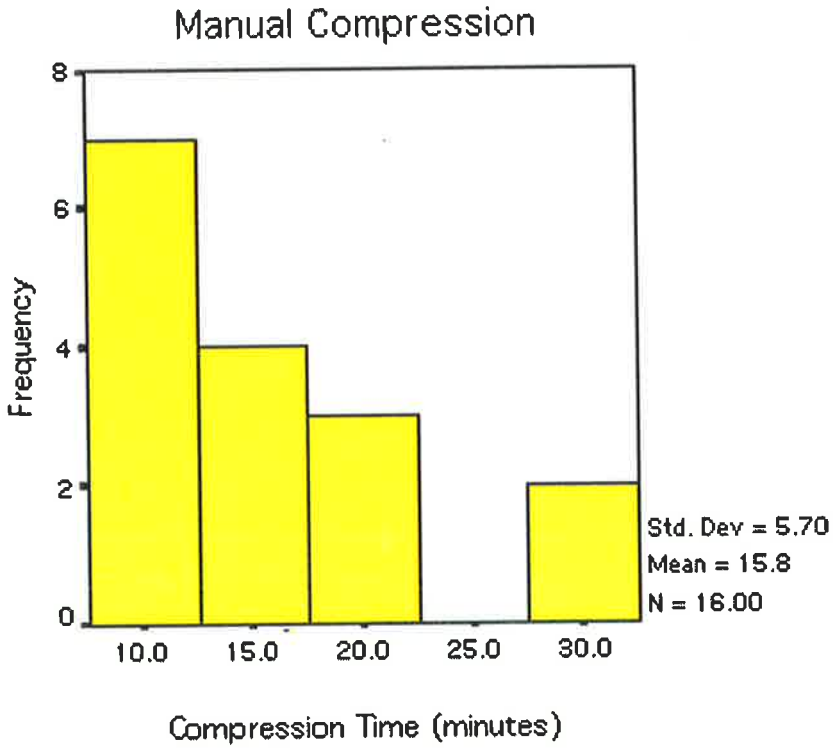
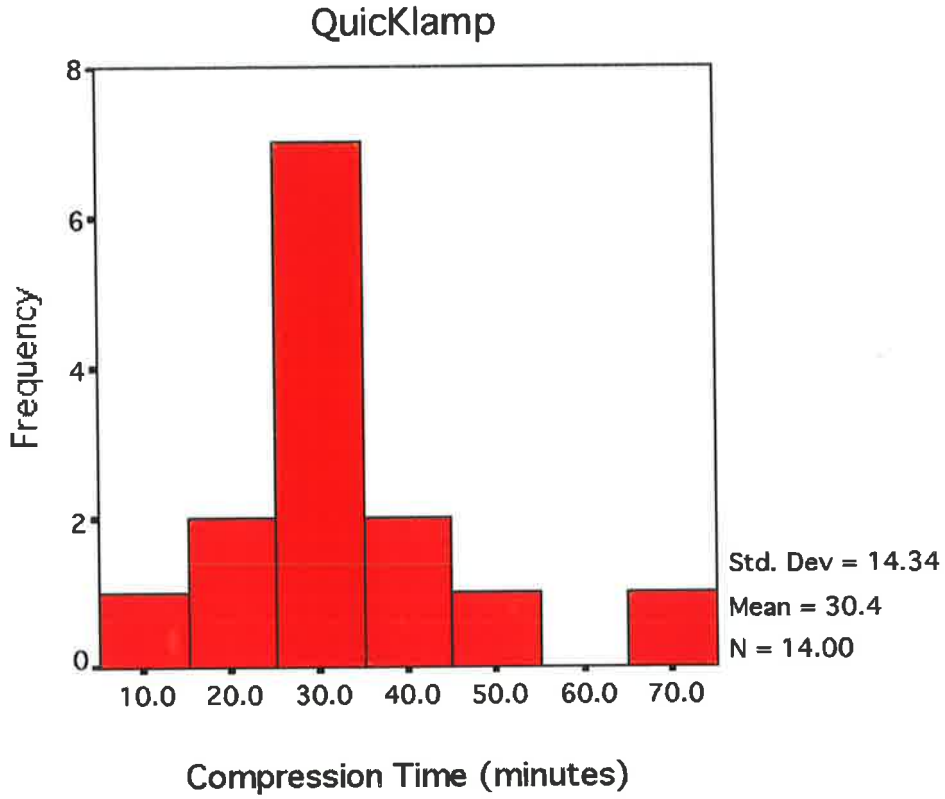


Figure 5f: The frequency of compression times (measured in minutes) for males in the QuicKlamp™ mechanical compression group



Post Procedural Events

After coronary angiography it is standard practice for the femoral sheath to be removed as soon as the patient is transferred to the cardiac catheterisation recovery unit, unless the patient experiences chest pain or hypertension (systolic blood pressure > 150 mmHg), when the removal would wait until either the chest pain and/or hypertension, had resolved. No subjects in this study had any adverse effects that meant the femoral sheath could not be removed according to standard clinical practice.

Bruising, Haematoma and Bleeding after Femoral Sheath Removal and Compression

Bruise

Immediately after haemostasis was attained (using the randomly allocated compression technique), and following femoral sheath removal the femoral puncture site was assessed for bruising, haematoma formation and bleeding. No statistically significant difference was found in the number of subjects who had a bruise present immediately after femoral sheath removal, between the two compression technique groups (see Table 9).

Table 9: Frequency and size (in centimetres) of bruise immediately after femoral sheath removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Bruise post sheath removal			
male	3	3	0.95**
female	3	4	0.53**
Total	6	7	0.8**
Bruise Size (cm)*			
male	.000 (0.0-2) 0.2±0.58	.000 (0.0-5) 0.2±0.9	0.91††
female	.000 (0.0-1) 0.9±2.5	.000 (0.0-8) 1.2±2.4	0.54† 0.71††
Total	.000 (0.0-10) 0.4±1.51	.000 (0.0-8) 0.48±1.5	0.77† 0.792††

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation

** Chi-square analysis

† Mann-Whitney *U* test

†† Independent Sample *t*-test

Male n=34 manual compression, n=36 QuicKlamp™compression

Female n=16 manual compression, n=14 QuicKlamp™compression

Six subjects in the manual compression group had a bruise post sheath removal (n=3 males, n=3 females). Four subjects (2 male and 2 females) developed a new bruise after femoral sheath removal and manual compression, 3 of these had bruises 2 centimetres (cm) in size and one subject had a bruise 10-centimetre in size. Of these 4 subjects, none had a BMI >30 kg/m^2, indicating they were not obese. The size of the

bruise in both the female subjects in this group who had a bruise after the procedure and prior to femoral sheath removal remained unchanged at 2 cm after femoral sheath removal and manual compression (see Table 10).

Six subjects in the QuicKlamp™ mechanical compression group (n=2 males, n=6 females) had a bruise present after femoral sheath removal. Five of these subjects had developed a new bruise. Two subjects who had developed a new bruise had a BMI > 30 kg/m^2, indicating that it may have been difficult to apply firm pressure due to patient obesity. One patient (a female) with a BMI of 35.8 kg/m^2 had developed a new bruise 2 cm in size. The other patient (a male) who had developed a new one cm bruise had a BMI of 32.18 kg/m^2. Of the remaining subjects who had a BMI <30 kg/m^2, the size of the bruise varied in size, being 1 cm (a male patient), 5 cm bruise (a female) and 8 cm bruise (another female patient). Only 1 patient in this group (a female) had a bruise present after the procedure and prior to femoral sheath removal. The bruise in this patient increased in size from 1 cm after the procedure and prior to sheath removal to 2 cm after femoral sheath removal (see Table 11).

To ensure that the presence of a bruise after femoral sheath removal was not as a result of bruising after the procedure these subjects were excluded from analysis. When those subjects who had a bruise present after the procedure and prior to femoral sheath removal (n=2 manual group, n=1 QuicKlamp™ compression group) were excluded from analysis of bruise presence after femoral sheath removal, there remains no statistically significant difference between the two compression techniques (P=0.53, chi-square analysis) for numbers of subjects who developed a bruise.

Table 10: Progression of bruise

Characteristic	Patient ID number	Gender	Manual (N=50)	QuicKlamp™ (N=50)	Size (cms)
Bruise prior to removal					
	2	F	√		2.0
	29	M		√	1.0
	64	M	√		2.0
Bruise after sheath removal					
	2	F	√		2.0
	3	F	√		10.0
	12	F	√		2.0
	18	F		√	5.0
	22	F		√	8.0
	29	F		√	2.0
	30	F		√	2.0
	43	M	√		2.0
	62	M	√		2.0
	64	M	√		2.0
	71	M		√	1.0
	93	M		√	1.0

Haematoma

There was no statistically significant difference in the numbers of subjects who had a haematoma present at the femoral puncture site immediately after femoral sheath removal, between the two compression techniques (see Table 11).

Table 11: Frequency and size (in centimetres) of haematoma immediately after femoral sheath removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Haematoma post sheath removal			
male	3	6	0.32**
female	3	6	0.15**
Total	6	12	0.118**
Haematoma Size (cm)*			
male	.000 (0.0-4) 0.24±0.82	.000 (0.0-10) 0.74±1.99	0.178††
female	.000 (0-10) 0.87±2.5	.00 (0-8) 1.2±2.4	0.54† 0.71††
Total	.000 (0.0-5) 0.38±1.12	.000 (0.0-10) 0.91±1.98	0.189† 0.31††

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
** Chi-square analysis
† Mann-Whitney *U* test
†† Independent Sample *t*-test
Male n=34 manual compression, n=36 QuicKlamp™compression
Female n=16 manual compression, n=14 QuicKlamp™compression

Six subjects in the manual compression group (n=3 males, n=3 females) had haematomas present at their femoral puncture site immediately after manual compression. Four subjects (2 males and 2 females) had developed a new haematoma after femoral sheath removal and manual compression. None of the subjects in this group had a BMI> 30 kg/m^2, indicating they were not obese. Three subjects (n=2 males, n=1 female) had 2 cm haematomas, 2 subjects (n=1 male, n=1 females) had 4 cm haematomas and one patient (a female) had a 5cm haematoma (see Table 12). The size of the haematomas in both subjects (n=1 male, n=1 female) who had haematomas present after the procedure and before femoral sheath removal and still had haematomas present after femoral sheath removal and manual compression, remained unchanged at 2 cm (see Table 12).

Table 12: Progression of haematoma formation

Characteristic	Patient ID number	Gender	Manual (N=50)	QuicKlamp™ (N=50)	Size (cms)
Haematoma prior to removal					
	2	F	√		2.0
	19	F		√	2.0
	29	F		√	3.0
	64	M	√		2.0
Haematoma after sheath removal					
	2	F	√		2.0
	3	F	√		5.0
	12	F	√		4.0
	18	F		√	5.0
	19	F		√	6.0
	22	F		√	2.0
	25	F		√	2.0
	29	F		√	2.0
	30	F		√	2.0
	43	M	√		2.0
	62	M	√		4.0
	64	M	√		2.0
	68	M		√	5.0
	70	M		√	3.0
	72	M		√	10.0
	81	M		√	2.5
	84	M		√	3.0
	93	M		√	3.0

Twelve subjects in the QuicKlamp™ mechanical compression group (n=6 males, n=6 females) had haematomas present at the femoral puncture site immediately after QuicKlamp™ mechanical compression (see Table 11). Ten subjects in this group had developed a new haematoma. Two females and one male patient who had a new haematoma had a BMI>30 kg/m^2, indicating that obesity may have resulted in inadequate pressure being applied through the QuicKlamp™ device. Both females, one

having a BMI of 31.95 kg/m^2 and the other having a BMI of 35.8 kg/m^2, had new haematomas 2 cm in size. The male patient with a BMI 31.21 kg/m^2 had a new haematoma 3 cm in size. Of the remaining female subjects with a BMI< 30 kg/m^2 two had developed new haematomas 2 cm in size and one 5 cm in size. Of the remaining five male subjects whose BMI was < 30 kg/m^2, one had a 2.5cm haematoma, 2 had 3cm haematomas, one had a 5cm haematoma and one a 10cm haematoma. Two female subjects in the QuicKlamp™ intervention group had 2cm haematomas present after the procedure and before femoral sheath removal. These haematomas were still present after sheath removal and QuicKlamp™ mechanical compression, however one subject's haematoma increased in size from 2 to 6 cm, while the other decreased in size from 3 to 2cm (see Table 12).

Subjects who had a haematoma present after the procedure and prior to femoral sheath removal (n=2 manual group, n=2 QuicKlamp™ compression group) were excluded from the analysis of haematoma formation after femoral sheath removal to ensure that the haematoma was not a result of the procedure as opposed to the compression technique used. When these subjects were excluded, there was still no statistically significant difference between the two compression techniques (P=0.08, chi-square analysis) for haematoma development.

Bleeding

A subjective assessment of bleeding at the femoral puncture site was made after femoral sheath removal and application of either manual or QuicKlamp mechanical compression. Zero to 50 millilitres (ml) of blood ooze from the femoral puncture site was considered 'mild' bleeding, while 'moderate' bleeding was blood ooze of 50 to 300 ml. Bleeding assessed to be greater than 300 ml was considered 'severe' bleeding. There was no statistically significant difference in bleeding after femoral sheath removal between either intervention group (see Table 13).

Table 13: The frequency of bleeding immediately after femoral sheath removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value*
Mild / Moderate Bleeding			
**male	2/1	3/1	0.92
***female	1	2	0.46
Total	4	6	0.76

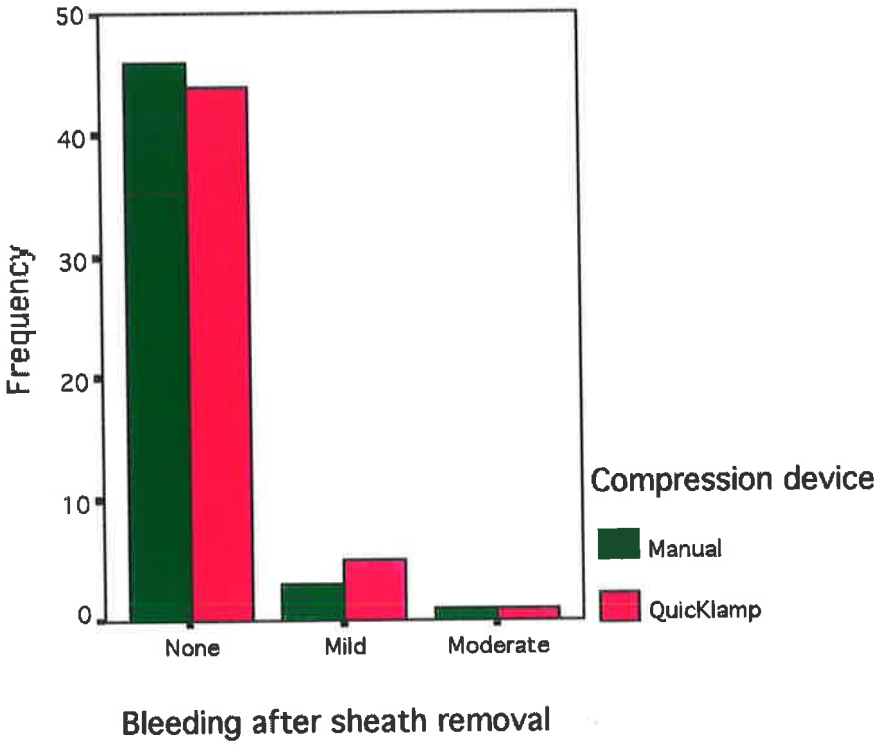
* Chi-square analysis

** Male n=34 manual compression, n=36 QuicKlamp™compression

*** Female n=16 manual compression, n=14 QuicKlamp™compression

No subjects had evidence of severe bleeding immediately after femoral sheath removal. Eight subjects, 3 in the manual compression group and 5 in the QuicKlamp mechanical compression group, had mild bleeding. Of these, one subject (a female) in the QuicKlamp™ compression group had a BMI> 30 kg/m^2 (35.8 kg/m^2), indicating that obesity may have made it difficult to apply adequate pressure over the femoral puncture site to stop bleeding. One male subject in each of the intervention groups had evidence of moderate bleeding at the femoral puncture site immediately after femoral sheath removal (see Figure 6). This subject did not have a BMI> 30 kg/m^2 and was therefore not obese.

Figure 6: Bleeding after femoral sheath removal



When the data were stratified by factors that may cause bleeding, such as aspirin, hypertension and contrast dye, there was no statistically significant difference between these factors and bleeding immediately after femoral sheath removal and the compression technique used to attain haemostasis (see Table 14). Neither of the subjects in intervention groups who had Ultravist contrast dye during the procedure bled after femoral sheath removal. There were no incidents of 'severe' bleeding in either intervention group.

Table 14: Frequency and relationship of bleeding after femoral sheath removal and aspirin, hypertension and contrast dye

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value*
Aspirin			
Mild / Moderate bleeding	1/1	3/1	0.69
Hypertension			
Mild / Moderate bleeding	1/1	2/0	0.51
Dye			
Urografin			
Mild / Moderate bleeding	3/1	4/1	0.89
Optiray			
Mild / Moderate bleeding	0/2	1/5	0.5

* Chi-square analysis

When subjects with a BMI> 30 kg/m^2 were excluded from analysis (therefore excluding those subjects considered obese), there was still no statistically significant difference in the numbers of subjects with a BMI< 30 kg/m^2 who had a bruise or haematoma present, or bled after femoral sheath removal in either intervention group (see Table 15).

Table 15: Frequency of Body Mass Index <30 kg/m^2 and bruise, haematoma and bleeding after femoral sheath removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
BMI <30 kg/m^2			
Bruise	6	5	0.93*
Haematoma	6	8	0.28*
Mild/moderate bleeding	3/1	3/1	0.73†

* Chi-square analysis
† Mann-Whitney *U* test

Subjects Perception of Pain during Compression

Subjects were asked to rate their pain while the compression technique was being applied on a verbal descriptor scale (VSD) with 0 representing no pain and 10 being the worse pain. There was no statistically significant difference (*P*=0.53) in the subjective pain score of subjects after removal of the femoral sheath and during application of either manual compression or the QuicKlamp™ compression device.

The median pain score for all subjects in both intervention groups was one, indicating the mid-point of this data set between the highest and the lowest pain scores was one (see Table 16).

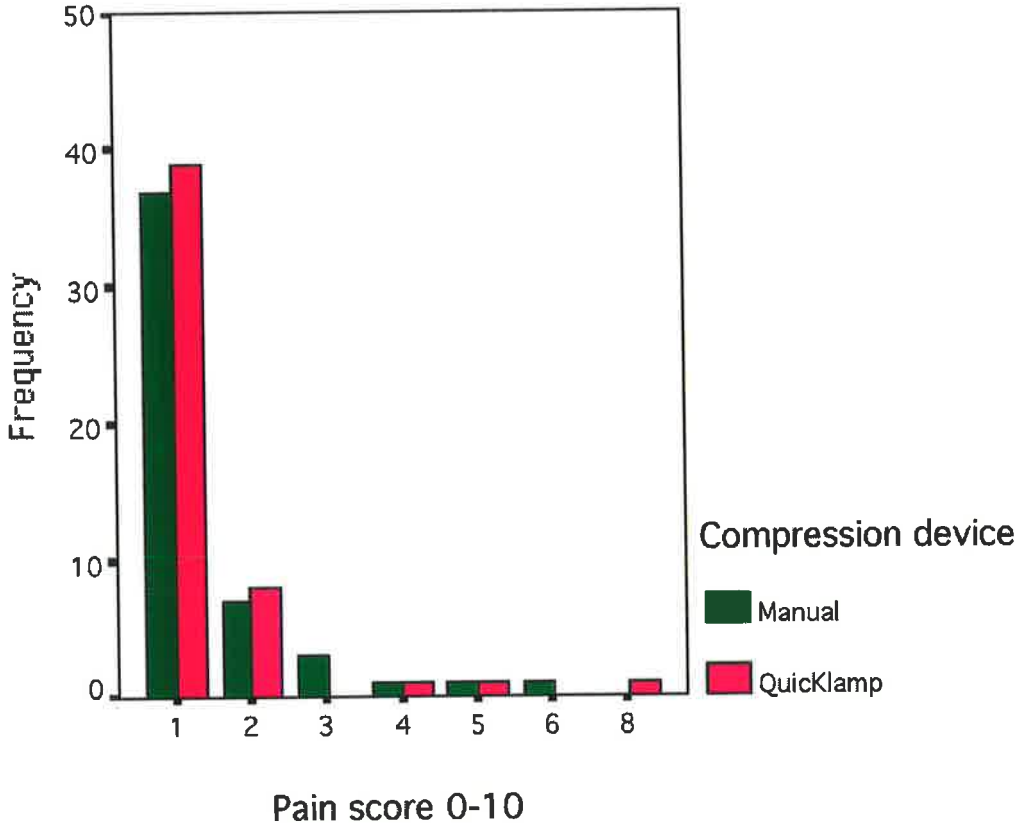
Table 16: Subjects' perceptions of pain during the application of the compression technique

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value†
Pain score*			
**male	1 (1-5) 1.3±0.8	1 (1-5) 1.36±0.87	0.65
***female	1 (1-6) 1.94±1.44	1 (1-8) 1.64±1.86	0.2
Total	1 (1-6) 1.5±1.07	1 (1-8) 1.44±1.21	0.59

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
† Mann-Whitney *U* test
** Male n=34 manual compression, n=36 QuicKlamp™compression
*** Female n=16 manual compression, n=14 QuicKlamp™compression

A parametric test, the 2-way Analysis of Variance (ANOVA) can be used to test whether there are statistical differences between the mean values of 3 or more independent sample groups.[37] A 2-way Analysis of Variance (ANOVA) was conducted with the following mean data: compression technique, gender and pain scores. No statistically significant difference was found between these groups (*P*=0.47). The largest proportion of subjects, 76% (n=37/50 in manual group and n=39/50 in the QuicKlamp mechanical compression group), had a pain score of one (see Figure 7).

Figure 7: The frequency distribution of subjects' perceptions of pain



Time to Mobilisation after Femoral Sheath Removal

In the catheterisation recovery unit, subjects who have had coronary angiography rest in bed for a minimum period of 3 hours after haemostasis is attained following femoral sheath removal, until mobilisation is allowed (personal communication with the Clinical Nurse Manager, Cardiac Catheterisation Unit, 2001). When the data were analysed for all subjects in the study there was a statistically significant difference for the time to mobilisation between the two intervention groups, with the time to mobilisation being longer after QuicKlamp™ mechanical compression (P=0.001, Mann-Whitney U test). When mobilisation time data was analysed between intervention groups for gender, a statistically significant difference was also found between the intervention groups for male subjects, with the time to mobilisation being longer after QuicKlamp™ mechanical compression (P=0.001, Mann-Whitney U test). However, there was no statistically significant difference in the time to mobilization

with females in both compression groups (see Table 17).

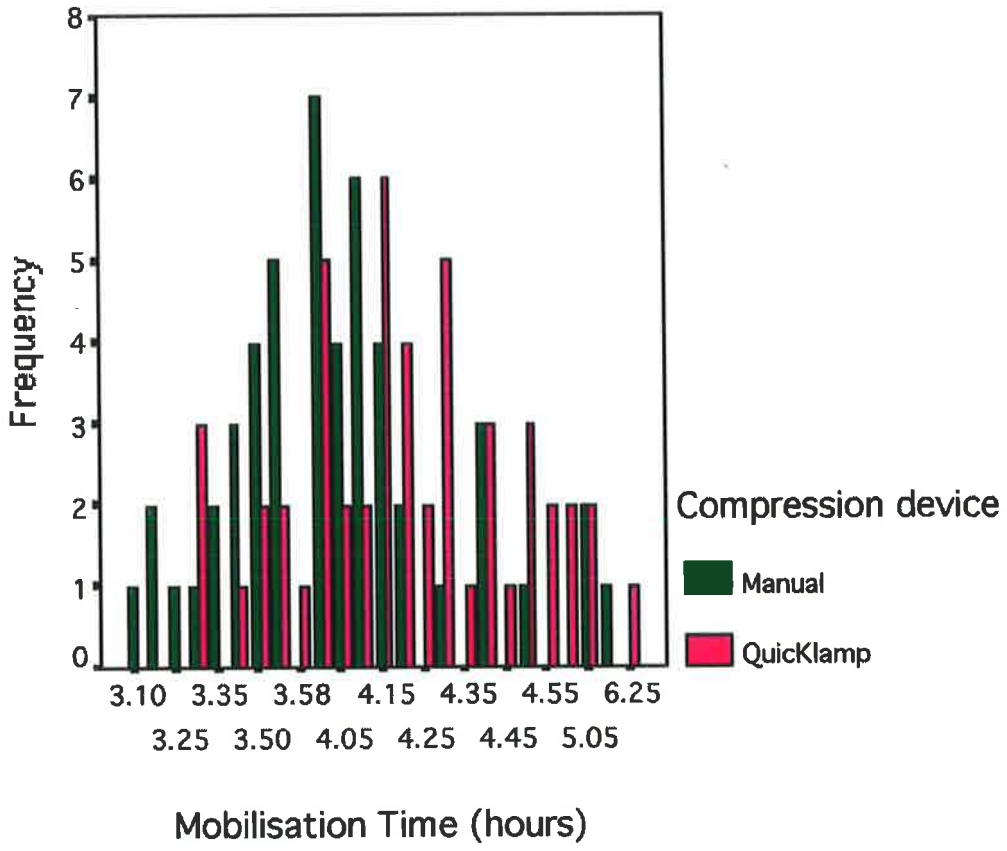
Table 17: Time to mobilisation after femoral sheath removal (in hours)

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Mobilisation Time (hrs)*			
male**	4 (3.1-5.25) 3.87±0.5	4.2 (3.3-5.05) 4.21±0.42	**0.001**† **0.002**††
female***	4.1 (3.25-5.05) 4.01±0.45	4.15 (3.3-6.25) 4.15±0.73	0.504† 0.543††
total	4 (3.1-5.25) 3.9±0.49	4.2 (3.3-6.25) 4.2±0.51	**0.001**† **0.006**††

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
† Mann-Whitney *U* test
†† Independent Sample *t*-test
** Male n=34 manual compression, n=36 QuicKlamp™compression
*** Female n=16 manual compression, n=14 QuicKlamp™compression

The mobilisation times ranged from 3 hours 10 minutes to 6 hours 25 minutes for all the subjects in the study. In the manual compression group after haemostasis was attained, the time to mobilisation ranged from 4 hours to 4 hours 15 minutes in the largest proportion of patient's (52%, n=26/50). In the QuicKlamp™ mechanical compression group, the time to mobilisation following haemostasis ranged from 4 hours to 4 hours 30 minutes in the largest proportion of patients (also 52%, n=26/50) (see Figure 8).

Figure 8a: The frequency of time to mobilisation (measured in hours) between the compression groups



Bruising, Haematoma and Bleeding after Pressure Dressing Removal prior to Mobilisation

After haemostasis was attained a pressure dressing, or 'groin roll', was applied over the femoral puncture site and remained in place until mobilisation occurred. This pressure dressing consisted of a roll of gauze swabs placed over the puncture site and tightly strapped from across the inner thigh and groin, to the outer hip with an Elastoplast tape bandage. Prior to mobilisation, subjects had the pressure dressing removed and the femoral puncture site was re-assessed for signs of bruising, haematoma formation and bleeding.

Bruise

No statistically significant difference was found in the number of subjects who had a bruise after the pressure dressing was removed and prior to mobilisation, between the two compression technique groups (see Table 18).

Table 18: Frequency and size (in centimetres) of bruise after pressure dressing removal and prior to mobilisation

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Bruise post dressing removal			
male	5	4	0.65**
female	2	4	0.27**
Total	7	8	0.78**
Bruise Size (cm)*			
male	.00 (0-5) 0.4±1.24	.00 (0-15) 0.64±2.62	0.68† 0.62††
female	.00 (0-10) 1.25±3.42	.00 (0-10) 1.64±1.27	0.37† 0.75††
Total	.00 (0-10) 0.67±2.14	.00 (0-15) 0.92±2.86	0.77† 0.622††

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
** Chi-square analysis
† Mann-Whitney *U* test
†† Independent Sample *t*-test
Male n=34 manual compression, n=36 QuicKlamp™compression
Female n=16 manual compression, n=14 QuicKlamp™compression

Of the 7 subjects in the manual compression group (n=5 males, n=2 females) who had a bruise present after the pressure dressing was removed, 2 (males) had developed new bruises. Only one of these males had a BMI>30 kg/m^2 (36.6 kg/m^2). Of the two female subjects, the size of the bruise remained the same (10cm) for one, whereas for the other female patient the 2cm bruise present after sheath removal had increased in size to 10 cm after the pressure dressing was removed. Of the male subjects (n=3) one had a bruise that remained the same size (2cm), another had increased in size from 2 to 3cm, and the remainder had decreased in size from 2 to one centimetre after the pressure dressing was removed. The bruise had resolved in one female subject after pressure dressing removal (see Table 19).

Eight subjects in the QuicKlamp™ mechanical compression group (n=3 males, n=4 females) had a bruise present after pressure dressing removal. Four subjects (n=3 males, n=1 female) had developed a new bruise, one 9cm in size (a female), another (in a male subject) was 2 cm, while 2 other male subjects in this group had new 5 cm bruises. Two of the subjects in the QuicKlamp™ mechanical compression group who developed a new bruise (1 male and 1 female), and according to the BMI criteria were obese (BMI being 31.24 and 33.33 kg/m^2 respectively), indicating that the bruising may have been a result of in adequate pressure through the QuicKlamp™ device.

Of those subjects in the QuicKlamp™ who had a bruise present after femoral sheath removal and also had a bruise present after pressure dressing removal, two female subjects who had a 2cm bruises remained the same, while the other subjects bruise increased from 8 to 10cm. Only the female whose bruise remained the same size (2 cm) was obese with a BMI of 35.8 kg/m^2, indicating that the bruising may have been a result of in adequate pressure through the QuicKlamp™ device. The size of the bruise still present after pressure dressing removal in the male patient in this group, increased in size from 1 to 15cm (see Table 19). This subject was not obese with a BMI of 25.8 kg/m^2.

Table 19: Progression of bruise

Characteristic	Patient ID number	Gender	Manual (N=50)	QuicKlamp (N=50)	Size (cms)
Bruise prior to sheath removal					
	2	F	√		2.0
	29	M		√	1.0
	64	M	√		2.0
Bruise after sheath removal					
	2	F	√		2.0
	3	F	√		10.0
	12	F	√		2.0
	18	F		√	5.0
	22	F		√	8.0
	29	F		√	2.0
	30	F		√	2.0
	43	M	√		2.0
	62	M	√		2.0
	64	M	√		2.0
	71	M		√	1.0
	93	M		√	1.0
Bruise after pressure dressing removal					
	3	F	√		10.0
	12	F	√		10.0
	19	F		√	9.0
	22	F		√	10.0
	29	F		√	2.0
	30	F		√	2.0
	36	M	√		5.0
	40	M	√		3.0
	43	M	√		3.0
	62	M	√		2.0
	64	M	√		1.0
	70	M		√	5.0
	72	M		√	5.0
	92	M		√	2.0
	93	M		√	15.0

When those subjects who had a bruise present after the procedure and prior to femoral sheath removal (n=2 manual group, n=1 QuicKlamp™ compression group) were excluded from the analysis of bruise after pressure dressing removal, there is still no statistically significant difference between the two compression technique groups (*P*=0.78), chi-square analysis). These subjects were excluded to ensure that the bruise present after removal of the femoral sheath was not a result of the procedure.

Haematoma

There was a statistically significant difference in haematoma formation between the two intervention groups after pressure dressing removal, with more haematomas detected after manual compression (*P*=0.027) (see Table 20).

Table 20: Frequency and size (in centimetres) of haematoma after pressure dressing removal and prior to mobilisation

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
Haematoma post dressing removal			
male	5	1	0.075**
female	2	0	0.7**
Total	7	1	**0.027****
Haematoma Size (cm)*			
male	.000 (0.0-6) 0.47±1.29	.000 (0.0-1) NA	0.068† **0.045**††
female	.000 (0-10) 0.93±0.48	NA	0.178† 0.2††
Total	.000 (0.0-10) 0.62±1.85	.000 (0.0-1) NA	0.24† 0.25††

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation
** Chi-square analysis
† Mann-Whitney *U* test
†† Independent Sample *t*-test
Male n=34 manual compression, n=36 QuicKlamp™ compression
Female n=16 manual compression, n=14 QuicKlamp™ compression

Seven subjects in the manual compression group (n=5 males, n=2 females) had haematomas present after pressure dressing removal. Three of the seven subjects, all males, had developed a new haematoma, one being 2cm in size and the others being

2.5cm and 6cm in size, respectively. None of these subjects with new haematomas detected after pressure dressing removal in the manual compression group were obese, all having a BMI< 30 kg/m^2. Of the remaining 4 subjects who had a haematoma present after femoral sheath removal and also had a haematoma present after pressure dressing removal, two haematomas (in a male and a female patient) remained unchanged in size, being 2 cm and 5 cm respectively. A female subject's haematoma had increased in size from 4 to 10cm, whereas the male subject, who had a haematoma present after femoral sheath removal and was still present after pressure dressing removal, had decreased in size from 4 to 3.5cm (see Table 21). Two subjects in the manual compression group who had a haematoma after femoral sheath removal did not have a haematoma after pressure dressing removal.

Haematoma formation was only detected in one male subject after pressure dressing removal in the QuicKlamp™ mechanical compression group. This subject's haematoma had also been present after femoral sheath removal, however it had decreased in size from 10 to 1 cm. Eleven subjects who had a haematoma after femoral sheath removal did not have evidence of haematoma formation at their femoral puncture site after pressure dressing removal (see Table 21).

Table 21: Progression of haematoma formation

Characteristic	Patient ID number	Gender	Manual (N=50)	QuicKlamp (N=50)	Size (cms)
Haematoma prior to removal					
	2	F	√		2.0
	19	F		√	2.0
	29	F		√	3.0
	64	M	√		2.0
Haematoma after sheath removal					
	2	F	√		2.0
	3	F	√		5.0
	12	F	√		4.0
	18	F		√	5.0
	19	F		√	6.0
	22	F		√	2.0
	25	F		√	2.0
	29	F		√	2.0
	30	F		√	2.0
	43	M	√		2.0
	62	M	√		4.0
	64	M	√		2.0
	68	M		√	5.0
	70	M		√	3.0
	72	M		√	10.0
	81	M		√	2.5
	84	M		√	3.0
	93	M		√	3.0
Haematoma after pressure dressing removal					
	3	F	√		5.0
	12	F	√		10.0
	34	M	√		2.5
	36	M	√		5.0
	44	M	√		6.0
	62	M	√		3.5
	64	M	√		2.0
	72	M		√	1.0

When those subjects who had a haematoma present after the procedure and prior to

femoral sheath removal (n=2 manual group, n=2 QuicKlamp™ compression group) are excluded from the analysis of haematoma formation after pressure dressing removal, there is still a statistically significant difference between the two compression technique groups (P=0.05, chi-square analysis), indicating that haematoma formation was more likely to occur after manual compression as compared to QuicKlamp™ mechanical compression.

Bleeding

A subjective assessment of bleeding at the femoral puncture site was made after removal of the pressure dressing. The same scale of subjective assessment was used as after femoral sheath removal being: zero to 50 millilitres (ml) of blood ooze was considered 'mild' bleeding, while 'moderate' bleeding was blood ooze of 50 to 300 ml. Bleeding assessed to be greater than 300 ml was considered 'severe' bleeding. There was no statistically significant difference in amount of bleeding after pressure dressing removal between intervention groups (see Table 22).

Table 22: The frequency of bleeding immediately after pressure dressing removal

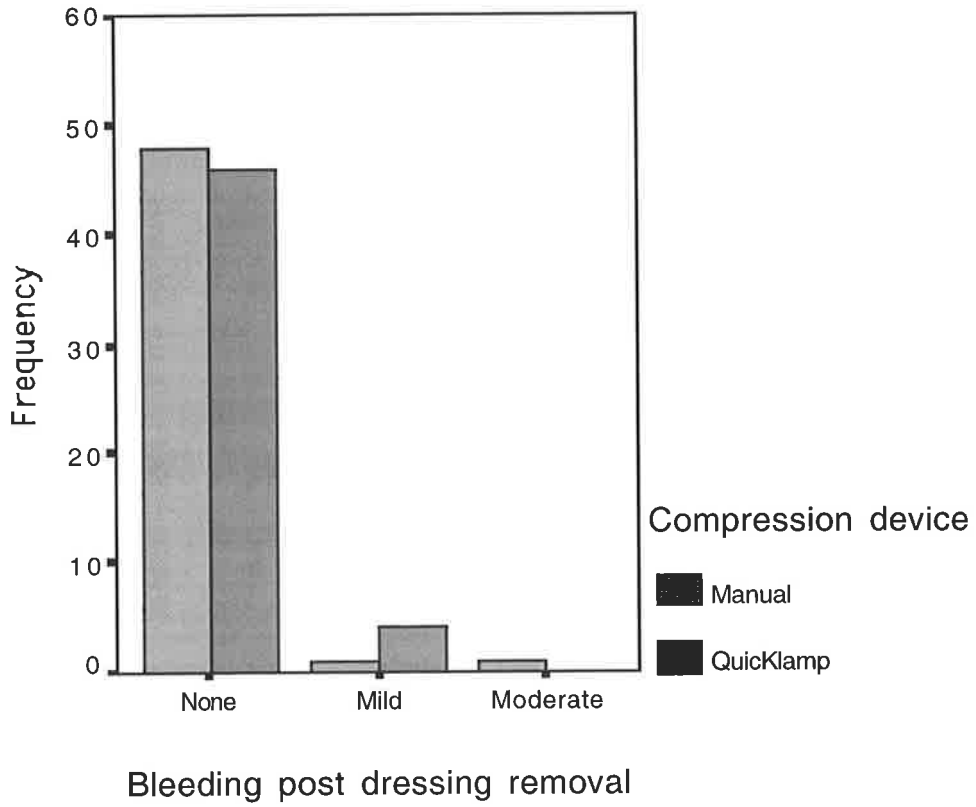
Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value*
Mild / Moderate Bleeding			
**male	1/1	3/0	0.75
***female	0/0	1/0	0.28
Total	2	4	0.24

* Chi-square analysis
** Male n=34 manual compression, n=36 QuicKlamp™compression
*** Female n=16 manual compression, n=14 QuicKlamp™compression

No subjects had evidence of severe bleeding after pressure dressing removal. Mild bleeding was detected in 5 subjects after pressure dressing removal, one male in the manual compression group and 3 males and one female in the QuicKlamp™ mechanical compression group. Two of these subjects, a male in the manual compression group and a male in the QuicKlamp™ compression group, had a BMI> 30kg/m^2 (BMI 31.02 kg/m^2 and 33.56 kg/m^2 respectively), indicating that bleeding may

have been a result of obesity causing inadequate application of pressure through the QuicKlamp™ device. Only one subject (a male) in the manual compression group had evidence of moderate bleeding at the femoral puncture site immediately after pressure dressing removal (see Table 22 and Figure 9). This subject had a BMI of 36 kg/m^2 indicating that obesity may have made it difficult to apply pressure over the femoral puncture site resulting in bleeding.

Figure 9: Bleeding after pressure dressing removal



Two of the subjects who bled after removal of the pressure dressing had also bled after femoral sheath removal (both males in the QuicKlamp™ intervention group). When these subjects are removed from analysis of bleeding after pressure dressing removal, there is still no statistically significant difference between the two compression technique groups (P=0.51, chi-square analysis) for the occurrence of bleeding, indicating that bleeding is not more likely to occur in any one intervention group.

When the data were stratified by factors that may cause bleeding, such as aspirin, hypertension and contrast dye, there was no statistically significant difference between these factors and bleeding after pressure dressing removal (see Table 23). Neither of the subjects in intervention groups who had Ultravist contrast dye during the procedure bled after pressure dressing removal. There were no incidents of 'severe' bleeding in either intervention group.

Table 23: Frequency and relationship of bleeding after pressure dressing removal and aspirin, hypertension and contrast dye

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value*
Aspirin			
Mild bleeding	2	3	0.67
Hypertension			
Mild / Moderate bleeding	0/1	1/0	0.85
Dye			
Urografin			
Mild / Moderate bleeding	1/1	3/0	0.35
Optiray			
Mild / Moderate bleeding	0/2	1/5	0.5

* Chi-square analysis

When subjects with a BMI> 30 kg/m^2 were excluded from analysis, there was still no statistically significant relationship between those subjects with a BMI<30 kg/m^2 who had a bruise or haematoma present after pressure dressing removal in either intervention group (see table 24).

When the data for bleeding after pressure dressing removal were stratified by BMI status (excluding those with a BMI>30 kg/m^2), a statistically significant difference was identified with more subjects bleeding after pressure dressing removal in the QuicKlamp™ mechanical compression group (see Table 24). When the data were analysed for both male subjects who bled after pressure dressing removal in the manual compression group, both had BMI's >30 kg/m^2 and were therefore excluded from analysis. Only one male subject in the QuicKlamp™ mechanical compression group had a BMI>30 kg/m^2, therefore being excluded from analysis. After all subjects

with a BMI>30 kg/m^2 were excluded there were no subjects who bled after pressure dressing removal in the manual compression group and 3 subjects who bled after pressure dressing removal in the QuicKlamp™ mechanical compression group. Mann Whitney *U* test indicated there was a statistically significant difference between the two intervention groups when all subjects with a BMI >30 kg/m^2 were excluded, indicating that more patients bled after QuicKlamp™ mechanical compression than manual compression in this study (*P*=0.05) (see Table 24).

Table 24: Frequency of Body Mass Index <30 kg/m^2 and bruise, haematoma and bleeding after pressure dressing removal

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value
BMI <30 kg/m^2			
Bruise	6	5	0.93*
Haematoma	6	1	0.083*
Mild bleeding	0	3	**0.05**†

* Chi-square analysis
† Mann-Whitney *U* test

Post Procedural Follow-up

Follow-up telephone calls were made to all subjects on the fifth day after the procedure to ascertain if any late adverse events related to the procedure had occurred since hospital discharge. Yes/no response questions were asked in relation to bruising, swelling and bleeding at the femoral puncture site, numbness or changes in sensation to the leg where the catheter was inserted and episodes of chest pain since discharge from hospital (see Appendix 6).

At 5-day follow up, there was no statistically significant difference between the incidence of bleeding from the puncture site or leg numbness for the intervention groups. A statistically significant difference was identified between the intervention groups in relation to bruising at the femoral puncture site at 5 days after the procedure (*P*=0.046, chi-square analysis), indicating a bruise was more likely to occur after

QuicKlamp™ mechanical compression. Although there was no statistically significant difference in the incidence of bruise for female subjects in either compression group, there was a statistically significantly difference in males with more bruises after QuicKlamp™ mechanical compression (P=0.032, chi-square analysis)(see Table 25).

A statistically significant difference was identified between the intervention groups in relation chest pain at 5 days after the procedure (P=0.014, chi-square analysis), indicating that chest pain was more likely to occur at 5 day follow-up after manual compression. Although there was no statistically significant difference in the incidence of chest pain for female subjects in either compression group, there was a statistically significant difference for males, with more males in the manual compression group having chest pain at home (P=0.019, chi-square analysis).

Although no statistically significant difference was identified between the intervention groups in relation to swelling at the femoral puncture site at 5 days post discharge from hospital, there was a statistically significant difference between the intervention groups for females, with more swelling identified in the QuicKlamp™ mechanical compression group (P=0.044, chi-square analysis) (see Table 25). This indicated that females in the QuicKlamp™ mechanical compression group were more likely to have swelling at the femoral puncture site at 5 days after the procedure.

Table 25: Follow-up telephone questionnaire

Characteristic	Manual (N=50)	QuicKlamp™ (N=50)	*P* value*
5 Day Follow-up			
Bruise			
**male	13	23	**0.032**
***female	7	7	0.73
Total	20	30	**0.046**
Swelling			
**male	5	3	0.4
***female	1	5	**0.044**
Total	6	8	0.56
Bleeding			
**male	1	0	0.3
***female	0	2	0.12
Total	1	2	0.56
Leg Numbness			
**male	0	0	
***female	1	1	0.92
Total	1	1	1.0
Chest Pain			
**male	7	1	**0.019**
***female	3	1	0.35
Total	10	2	**0.014**

* Chi-square analysis

** Male n=34 manual compression, n=36 QuicKlamp™compression

** Female n=16 manual compression, n=14 QuicKlamp™compression

Discussion

Despite a significant improvement in death rates since the late 1960s, coronary heart disease remains the largest single cause of death in Australia, claiming approximately 28,000 lives in 1998.[40] Acute coronary ischaemic syndrome, or angina, results from a reduced blood supply to the heart muscle caused by atherosclerotic plaque.[16] Plaque rupture and platelet deposition within a coronary artery will cause coronary thrombus and result in acute myocardial infarction, or heart attack.[16]

Coronary angiography allows the coronary arteries to be visualised, thereby providing diagnostic information that allows therapeutic options to be determined for patients with coronary heart disease, such as coronary angioplasty or coronary artery bypass graft surgery. In 1997-98 there were 76,362 coronary angiograms conducted in

Australia.[41] Considering the incidence of coronary heart disease and the large number of patients who undergo coronary angiography in Australia each year, studies that are aimed at improving patient outcomes during this procedure are warranted. The purpose of this study was to compare the effectiveness of two techniques for achieving haemostasis after femoral sheath removal in coronary angiography patients. By identifying effective techniques of attaining haemostasis, safe femoral sheath removal practices can be developed.

Subject Demographics

The demographic data collected from the 100 participants in this study is similar to the data collected and reported by the Australian Institute of Health and Welfare on patients with coronary heart disease. The demographic characteristics of subjects recruited to this study were evenly distributed between each compression group in relation to gender and age. However, the number of male patients enrolled in the study was greater than females (70% and 30% respectively). These proportions are consistent with the Australian Institute of Health and Welfare (AIHW) 2000 morbidity data that revealed coronary heart disease was three times more common among men than women in the 35-69 age group.[40]

Although there were more males enrolled in this study than females (70/30 respectively), the numbers of females and males randomised to each intervention group were similar with 34 males and 16 females in the manual compression group and 36 males and 14 females in the QuicKlamp™ compression group.

The major preventable risk factors for coronary heart disease are smoking, hypertension, high blood cholesterol, obesity and insufficient exercise.[40] Data in this study relating to risk factors were collected on: hypertension, family history, high blood cholesterol, diabetes, smoking and obesity (using the BMI>30 kg/m^2 formulae). Family history, hypertension and hypercholesterolaemia were the most common cardiac risk factors identified in these subjects. Specific national data from AIHW is

only available in relation to the incidence of hypertension and hypercholesterolaemia in the Australian population in 1999. In 1999/2000, 31% of Australian men and 26% of Australian females aged 25 years and over had hypertension.[40]

The proportion of subjects in this study who had hypertension was males 38% and females 46%. The average age of male subjects was 60.5 years (SD ± 9.67 years) and for females was 61 years (SD ± 10 years). When compared with the national data for patients in the age group 55 to 64 years, the incidence of hypertension in the study population was similar to that of the Australian population, being about 45% of males and 40% of females.

In 1999/2000, approximately 50% of Australian men and women aged 25 years and over had blood cholesterol levels above 5.5 mmol/L.[40] The incidence of hypercholesterolaemia in male subjects in this study was 37%, and 46% for females. When this data are compared with the national Australian data for 1999 for the age group 55 to 64 years, the incidence for subjects in this study is lower with 60% of Australian males and 70% of Australian females having high blood cholesterol levels in 1999.[40] However the trend is similar with more females having hypercholesterolaemia than male subjects.

Thrombus formation in coronary arteries is primarily the result of platelet aggregation and activated coagulation at the sites of atherosclerotic plaque.[42] Over the last 25 years several large randomised controlled clinical trials have shown that antiplatelet therapy (mainly aspirin) have reduced the risk of vascular death by about one sixth and the risk of non-fatal myocardial infarction by about one third in 'high risk' subjects with clinical vascular disease.[43] The beneficial use of aspirin therapy in 'healthy' subjects, including those with known vascular risk factors, remains uncertain.[43] Despite this, aspirin is commonly prescribed to subjects with coronary heart disease. In addition, the Heart Foundation of Australia recommend that aspirin be used in stable and unstable angina in association with an overall coronary heart disease prevention

program, including smoking cessation, healthy eating and regular exercise.[44] In this study 56% of male subjects and 53% of female subjects were regularly taking aspirin.

Procedural Details

Coronary angiography is a cardiac catheterisation procedure that allows selective examination of the coronary circulation using contrast radiographic imaging techniques.[45] It is performed in conjunction with a number of ancillary diagnostic and therapeutic procedures. Coronary angiography is considered the reference standard for clinical evaluation of patients with known or suspected coronary heart disease.[45]

Increasingly cardiac catheterisation is performed on an outpatient basis as it has been identified to be a safe, practical and highly cost-efficient procedure.[45] A multicentre randomised controlled trial of 381 subjects comparing outpatients (n=192) and inpatient (n=189) cardiac catheterisation procedures did not demonstrate a statistically significant difference in the incidence of adverse effects, such as haematoma formation, limb ischaemia or myocardial infarction, between the two study groups.[46]

At the study institution elective cardiac catheterisation for coronary angiography is predominantly performed as an outpatient procedure. All patients who entered this study were admitted to the cardiac catheterisation unit as outpatients. Although the American College of Cardiology and the American Heart Foundation suggest guidelines for cardiac catheterisation[45], a typical cardiac catheterisation procedure will utilise a percutaneous femoral artery approach, using 7FG catheters, manual compression for a minimum of 10 minutes over the femoral artery to obtain haemostasis after the procedure, followed by placement of a pressure dressing and sandbag for at least four hours with 15 minute interval groin checks while lying supine for four to five hours, prior to discharge after at least a one hour observed ambulatory period.[16] Baim and Grossman suggest that outpatients be interviewed by phone the next day to ascertain if any late adverse effects were evident.[16] The findings of this study demonstrate that the outpatient coronary angiography procedures that the subjects had during this study were consistent with the procedural recommendations of Baim and Grossman[16]

and Block et al.[46]

In general, the percutaneous right femoral artery cannulation approach is preferred, except when specific anatomic or pathological problems limit access.[45] In this study all female subjects (n=30) and the majority of male subjects (97%, n=68/70) had a right femoral approach for the procedure, with only two male subjects (one in each compression group) having a left femoral approach.

The choice of femoral sheath and guiding catheter size is an important factor in the success of cardiac interventional procedures.[47] In recent years, there has been a tendency for Cardiologists to use smaller catheters and femoral sheaths during cardiac catheterisation to reduce peripheral vascular complications and permit earlier ambulation after the procedure.[47] The factors that influence the choice of femoral sheath size in coronary angiography are the cardiologist preference and type of interventional procedure. A large, multicentre randomised controlled trial (n=460) by Metz et al[47] compared 6 French (F), 7F and 8F catheters during coronary angioplasty. The findings suggested that 6F catheters were more effective than larger diameter catheters as they decreased vascular complications, reduced procedural time and the amount of contrast dye used.[47] Sixty three percent (63%) of the femoral artery sheaths utilised during coronary angiography in this study were 6F gauge sheaths.

Considerable experimentation and research has been undertaken since the early 1980s for an effective and non-toxic contrast agent to define vascular anatomy.[16] Early experimentation involved the use a heavy metals such as Barium and Thorium. Modern contrast agents are based exclusively on iodine, which has proven to be an excellent agent for intravascular opacification due to its high atomic number and chemical versatility.[16] However, inorganic iodine agents caused marked toxic reactions. Experimentation during the 1930s to 1950s focussed on the development of organic iodine agents. In order to have the iodine concentration required for left ventricular and coronary contrast injection, solutions were highly hypertonic (with an osmolality

exceeding 1500 mOsm/kg, approximately six times that of blood).[16]

Urografin is an ionic contrast agent. The high osmolality of this agent can predispose patients to a number of adverse electrophysiologic and haemodynamic effects during coronary angiography.[48] Unless patients have had a previous sensitivity to Urografin, adverse effects cannot be predicted.

In the mid-1980s, lower osmolality contrast materials were developed. Although still ionic (approximately three times the osmolarity of blood), undesirable side effects related to hypertonicity were significantly reduced.[16] Further developments in the late 1980s introduced a true non-ionic contrast agent that has a substantially reduced osmolality level as compared with ionic agents.[48] Clinical trials have shown a lower incidence of adverse electrophysiologic and haemodynamic effects associated with non-ionic contrast agents when compared with ionic agents.[49,50] They produce fewer episodes of bradycardia and hypotension, cause less nausea and heat responses and precipitate less angina than traditional high osmolar contrast agents.[51,52]

However, low-osmolality agents, such as Optiray, cost 10 to 15 times that of high-osmolality agents, such as Urografin.[48] In addition, ionic contrast agents have been found to have an inhibitory effect on clot formation when mixed with blood and hence may predispose subjects to more thrombotic events than non-ionic agents.[53,54,55] This may be of benefit during coronary angiography procedures as thrombus formation within the femoral sheath and diagnostic catheters is likely to occur.

The largest proportion of subjects in this study (91%) had ionic contrast agent (Urografin). Non-ionic compounds were used in 9% of cases (Ultravist 2% and Optiray 7%). The cost of these contrast agents was a factor that influenced the choice of contrast agents used in the cardiac catheterisation unit of the study institution. (Personal communication with the Clinical Nurse Manager, cardiac catheterisation unit, 2001).

The coronary angiography procedural duration was similar for subjects in both intervention groups ranging from 10 to 45 minutes in the manual compression group and 10 to 40 minutes in the QuicKlamp™ mechanical compression group. The median duration for both groups of subjects was 20 minutes.

Post Procedural Events

Cardiac catheterisation is not without the risk of potential adverse events (complications). These complications can range from minor problems that have no long-term sequelae, such as transient bradycardia associated with injection of contrast agents, to major problems and irreversible damage such as stroke, myocardial infarction, renal failure or even death.[16] In general, the risk of major complications in current practice is less than 1%[16], so that the benefits of performing cardiac catheterisation as part of the investigation or treatment of cardiac disorders far outweighs its risks and costs.[45]

Local complications at the catheter introduction site are the most commonly identified problems seen after cardiac catheterisation.[16] These are related to vascular injury at the arterial access site and include, vessel thrombosis, haematoma, arteriovenous fistula and pseudoaneurysm formation, distal limb embolisation and poorly controlled bleeding at the puncture site.[16,45] The frequency of serious complications, such as death, myocardial infarction or stoke, are approximately 1/1000 patients, while peripheral vascular complications occur in approximately 5/1000 patients. Contrast agent reactions occur in approximately two to three cases/1000 patients.[45] The table below presents aggregated data by Pepine et al from multiple reports investigating more than 400,000 patients for the expected frequencies of coronary angiography complications.[45]

Table 26: Expected frequencies of coronary angiography complications[45]

Complication	Expected frequency (%)
Death	0.10
Myocardial infarction	0.08
Cerebrovascular accident	0.08
Arrhythmia	0.50
Vascular	0.50
Any other	0.50

In order to answer the research question of whether the percentage and type of groin complications differed between the use of the QuicKlamp^{TM} compression device and manual compression, data were collected on post procedural events including clinical signs of bruising, bleeding and haematoma formation at the femoral puncture site. For the purpose of this study *bruising* was defined as any bluish/purple discolouration of the skin. *Haematoma* was defined as a palpable mass beneath the skin surface, while *bleeding* was any ooze, leakage or frank blood drainage from the femoral puncture site. The femoral puncture site was assessed for bruising and haematoma formation immediately after the procedure and prior to sheath removal. Signs of bruising, haematoma formation and bleeding at the puncture site were re-assessed immediately after femoral sheath removal and again after pressure dressing removal prior to mobilisation.

The findings revealed evidence of bruising and haematoma formation in both compression groups. Bruising, although variable in size from one to 15 centimetres, could be considered to be a minor clinical complication and often expected after cardiac interventional procedures. But for the patient, bruising may be painful and minimise the degree of mobility if extensive. There was no statistically significant difference in the incidence of bruising seen at any assessment stage between the two compression groups. As it was postulated that adequate and even compression might have been difficult to apply in those subjects considered to be obese (as defined by a BMI > 30 kg/m^2), they were later excluded from analysis. No statistically significant difference in

the incidence of bruising between compression groups was found when subjects considered obese by objective measurement (BMI) were excluded from the analysis. This finding cannot be compared with the results of other research in the professional literature investigating complications after cardiac interventional procedures, as they do not report the incidence of bruising.

Haematoma formation is a more serious complication and is associated with swelling and a palpable mass at the puncture site from a collection of blood within the soft tissues of the upper thigh. Haematomas usually resolve over one to two weeks as the blood gradually spreads and is reabsorbed into the soft tissues.[16]

Statistically, more haematomas occurred following manual compression as opposed to the QuicKlamp^{TM} compression device in this study. When stratified by gender, no statistical significant difference was found for either male or female subjects. There was no statistically significant difference between the two intervention groups for haematoma formation when those subjects with a BMI>30 kg/m^2 were excluded from analysis (P=0.083), indicating that obesity did not effect the likelihood of haematoma formation. In addition, the overall incidence of haematoma formation decreased over time in the QuicKlamp compression group, suggesting that the pressure from the QuicKlamp^{TM} compression device may have been sufficient to resolve haematoma formation in some cases. This finding may have clinical significance for these subjects as haematoma formation may be considered uncomfortable and may require further treatment, such as transfusion or surgical repair.[16] The findings of this study are consistent with those in the professional literature. A recent systematic review found that although the incidence was low, haematoma formation occurred significantly more often after manual compression.[56] Meta-analysis from data pooled from two randomised controlled trials comparing manual and mechanical compression devices[22,21] indicated that mechanical compression devices were more effective in preventing haematoma formation, with no reported incidents in either study.[56]

Other researchers have suggested that inconsistent pressure during manual compression as a result of imprecise hand and arm fatigue may potentially lead to haematoma formation.[26,57] This may have accounted for an increased frequency of haematomas after manual compression in this study. Further investigation to fully understand the factors that lead to haematoma formation is required.

Baim and Grossman suggest that bleeding from the arterial puncture site is a more common problem after cardiac catheterisation and if uncontrollable suggests laceration of the femoral artery.[16] Uncontrolled bleeding from the femoral puncture site has the potential to lead to serious vascular complications, such as retroperitoneal bleed, pseudoaneurysm and arteriovenous fistula formation.[4,16,58]

A subjective assessment of bleeding at the femoral puncture site was made after femoral sheath removal and again after pressure dressing removal in this study. Zero to 50 millilitres (ml) of blood ooze from the femoral puncture site was considered 'mild' bleeding, while 'moderate' bleeding was blood ooze of 50 to 300 ml. Bleeding assessed to be greater than 300 ml was considered 'severe' bleeding. Minimal bleeding from the femoral puncture site occurred in either intervention group in this study. There was no statistically significant difference in the incidence of bleeding at the femoral puncture site at any assessment stage between the two compression groups. There were no incidents of 'severe' bleeding in this study. These findings on the incidence of bleeding are consistent with those reported in the systematic review undertaken by Jones comparing manual and mechanical compression devices.[56]

When the data were stratified by factors that may cause bleeding such as aspirin, hypertension and contrast dye, there was no still no statistically significant difference. When those subjects with a BMI>30 kg/m^2 were excluded from analysis (therefore excluding subjects considered obese), there was no difference in the number of subjects who bled in either intervention group.

Considering the results on groin complications, such as bruising, haematoma formation and bleeding (as discussed above), the findings of this study assert that there is no difference in the percentage and type of groin complications between the QuicKlamp™ compression device and manual compression.

Post procedural data were also collected on the time to effect haemostasis to address the research question of whether the time to affect haemostasis differed between the use of the QuicKlamp™ compression device and manual compression.

The time taken to attain haemostasis was measured in minutes and calculated from the time when the femoral sheath was removed and the compression technique applied until there was no evidence of bleeding from the femoral puncture site. As suggested by the American College of Cardiology and the American Heart Foundation (ACC/AHA) guidelines[45], both compression protocols used throughout the study required a minimum compression time of 10 minutes. After this time, pressure was gradually reduced and the femoral puncture site assessed for haemostasis. If haemostasis had not been attained firm pressure was reapplied. The time to attain haemostasis using the QuicKlamp™ compression did differ as compared to manual compression, with the QuicKlamp™ device taking significantly longer (P=0.000), with a median compression time of 10 minutes for manual compression as compared to 30 minutes for the QuicKlamp™ mechanical compression device.

Previous research in this field has demonstrated similar findings in respect to haemostasis time. Three studies comparing a similar clamp compression device with manual compression[21,24,25] demonstrated that the clamp device took significantly longer to effect haemostasis than did manual compression.[56]

This finding was clinically significant for the nursing staff involved in femoral sheath removal, as their time at the bedside with the subject during application of the compression technique was prolonged. Nordrehaug, et al suggest that mechanical

compression devices are advantageous to clinicians as they allow staff to leave the patient bedside during compression time and attend to other activities.[39] It would appear that the nursing staff caring for subjects in this study were not confident or comfortable to leave the subjects unattended during compression time and therefore this prolonged period may have impacted on their overall workload. This outcome appears to have had the most impact on the nurses in this study and hence the accepted technique for attaining haemostasis after femoral sheath removal may continue to be manual compression in the study institution.

To address the research question as to whether the patients' perceptions of pain and discomfort during compression differed between the use of the QuicKlamp™ compression device and manual compression, subjects were asked to verbally rank their perception of pain while the compression technique was being applied on a verbal descriptor scale (VDS), with 0 representing no pain and 10 being the worse pain. There was no difference in regards to the subjects' perceptions of pain and discomfort during compression using either the QuicKlamp™ compression device or manual compression. Similar pain scores were reported during application of either compression technique with the median pain score being one for both groups. Pain scores were not frequently reported in previous research in this field. A recent study comparing the FemoStop™ pneumatic compression device with manual compression did not find a difference in pain perception between subjects in either study group.[59]

In the cardiac catheterisation unit of the study institution, subjects rested in bed after coronary angiography for a minimum period of 3 hours after haemostasis was attained following femoral sheath removal (personal communication with the Clinical Nurse Manager, Cardiac Catheterisation Unit, 2001). When the data were analysed for all subjects in this study, there was a statistically significant difference for the time to mobilisation between the two intervention groups, with the time to mobilisation being longer after QuicKlamp™ mechanical compression (P=0.001). The median time to mobilisation was 4 hours in the manual compression group as compared to 4 hours 20

minutes in the QuicKlamp™ mechanical compression group. Considering the significantly longer time to attain haemostasis after femoral sheath removal for subjects in this group, this finding is not surprising.

Post procedural follow-up

Follow-up telephone calls were conducted with all subjects in this study to ascertain if any late adverse events related to the procedure had occurred since hospital discharge. Statistically more bruising at the femoral puncture site (P=0.046) after QuicKlamp™ mechanical compression and statistically more episodes of chest pain were identified in subjects after manual compression at 5-day follow-up (P=0.014). No statistically significant difference was seen between the two compression groups in relation to bleeding at the femoral puncture site or leg numbness. When data were stratified by gender, significantly more females had swelling at the puncture site after QuicKlamp™ mechanical compression.

The overall findings of this study assert the alternative hypothesis that there is a difference between the effectiveness of the QuicKlamp™ compression devices in attaining haemostasis after femoral sheath removal compared with manual compression. Although the QuicKlamp™ device took significantly longer to attain haemostasis and consequently longer for subjects to mobilise after femoral sheath removal, these findings do not have an adverse outcome for the patient. Significantly more haematomas occurred after manual compression as compared to QuicKlamp™ mechanical compression. As haematoma formation may be considered a more serious adverse event, this finding may instead negatively influence patient outcomes.

Study Limitations

Controlling extraneous variables during clinical research is challenging. Polit and Hungler (p.291) state that

> The researcher strives to control extraneous variables to determine the true nature of the relationship between the independent and dependent variables under investigation.[37]

Although the study design and randomisation process used in this research was rigorous, some study limitations exist. A possible limitation was the use of more than one operator to apply compression using either the manual or QuicKlamp™ techniques. A femoral sheath team was introduced to minimise the risk of error associated with application of the compression technique. However, interrater reliability was not assessed in this study, these nurses were experienced clinicians and one might reasonably assert their techniques were comparable.

Polgar and Thomas suggest that in experimental research it is critical that the person recording measurements and administering treatments is blinded.[60] The researchers who collected data in this study and assessed the femoral puncture sites for adverse events were not blinded to the compression technique. This may be considered a study limitation, as the researcher knew to which intervention group the subject had been allocated. There was potential for a Rosenthal effect, where the expectations of the researcher are conveyed to the subjects, as double blinding did not take place in this study.[60] It was not practical to blind the nurses who participated in this study to the interventions as they were required to remove the femoral sheaths. In addition, in order to limit bias by controlling the number of nurses who collected data in this study they were required to remove femoral sheaths from study subjects and assess the puncture site for adverse events.

Another limitation was that the scale designed to measure bleeding and the patient's perceptions of pain during compression were subjective scores. The pain assessment tool is routinely used at the study institution to rank patient's perceptions of pain. Although this assessment is subjective, pain is an individual assessment and may differ between patients. Fuller and Schaller-Ayers (p.373) state that 'pain experience is personal and subjective, and does not need to be validated by obtaining objective

assessment data'.[61]

Although these limitations exist, the findings of this study suggest that the QuicKlamp™ mechanical compression device is as effective as manual compression in attaining haemostasis and reducing groin complications in patients following coronary angiography.

Future Research

There are several areas for further research in this field. This study was concerned with comparing manual compression with a mechanical compression device, the QuicKlamp™ in elective coronary angiography patients. Replication of the study design with other cardiac interventional patients, such as after coronary angioplasty or electrophysiology studies, is required in order to make the results generalisable to other cardiac interventional patients. Several other mechanical compression devices are commercially available, including other compression clamps, pneumatic pressure devices and weight systems[31] therefore replication of this study using other mechanical compression techniques is warranted.

Although the findings of this study indicate that the QuicKlamp™ mechanical compression device is effective in attaining haemostasis after femoral sheath removal and is not associated with an increase in adverse events, the nurses in the cardiac catheterisation unit of the study institution were reluctant to use the QuicKlamp™ device. Further research is required to ascertain why they do not routinely use mechanical compression devices to attain haemostasis after femoral sheath removal. As suggested by Walker et al, exploration of the financial issues associated with compression devices is also warranted.[59] The mechanical device may have associated costs of replacement consumables, such as the disposal disks of the QuicKlamp™ that are placed over the femoral puncture site during compression. A study that examines

the costs of these devices versus the nursing time and patient-nurse dependency associated with manual compression may provide valuable information that could assist nurses to plan nursing budgets and assign nursing workloads more effectively.

Conclusion

The purpose of this study was to compare two compression techniques, manual compression and QuicKlamp™ mechanical compression device, used to attain haemostasis after femoral sheath removal following coronary angiography.

The study findings indicate that minimal bleeding occurred after removal of the femoral sheath in this study. Although there was evidence of bruising and haematoma formation using both compression techniques, the frequency of haematoma formation occurred more often in the manual compression group as compared to QuicKlamp™ mechanical compression. The time taken to effect haemostasis and the time to mobilisation after application of the QuicKlamp™ compression device was significantly longer than manual compression.

This study has provided evidence that supports the current practice protocol for using manual compression to attain haemostasis after femoral sheath removal following coronary angiography. There is sufficient evidence to say that the QuicKlamp™ compression device is a safe alternative to manual compression. In addition a protocol for using the QuicKlamp™ mechanical compression device has been formulated and validated. Despite these findings, the cardiac nurses in the study institution were reluctant to routinely use the QuicKlamp™ mechanical compression device in practice. Further research is required to determine the reason for this.

References

1. Schickel S, Cronin SN, Mize A, Voelker C. Removal of femoral sheaths by registered nurses: issues and outcomes. *Critical Care Nurse* 1996;16(2):32-6.
2. Spokojny A, Sanborn T. Management of the arterial puncture site. *Journal of Interventional Cardiology* 1994;7(2):187-193.
3. Judkins M. Selective coronary arteriography: A percutaneous transfemoral technique. *Radiology* 1967;89:815-824.
4. Muller D, Shamir K, Ellis S, Topol E. Peripheral vascular complications after conventional and complex percutaneous coronary interventional procedures. *American Journal of Cardiology* 1992;69(1):63-68.
5. Kennedy J. Complications associated with cardiac catheterisation and angiography. *Catheter and Cardiovascular Diagnosis* 1982;8:5-11.
6. Gensini G. Indications for cardiac catheterisation, angiography and coronary arteriography. *Geriatrics* 1975;30:63-68.
7. Newton K. Cardiac Catheterisation. In: Woods SL, Froelicher S, Halpenny CJ, Underhill MS, editors. *Cardiac Nursing*. 3rd Edition ed. Philadelphia: J.B. Lippincott, 1995.
8. Braunwald E, Gorlin R, McIntosh H, Ross R, Rudolph A, Swan H. Cooperative study on cardiac catheterisation. *Circulation* 1968;37(5 suppl):1193-2101.
9. Mortensen J. Clinical sequelae from arterial needle puncture, cannulation and incision. *Circulation* 1967;35:1118-1123.
10. Kloster R, Bristow J, Seaman A. Cardiac catheterisation during anticoagulation therapy. *American Journal of Cardiology* 1971;28:675-678.
11. Walker W, Mundell S, Broderick H, Prasad B, Kim J, Ravi J. Systemic heparinisation for femoral percutaneous angiography. *New England Journal of Medicine* 1973;288(16):826-828.
12. Markwardt F, Klocking H. Heparin induced release of plasminogen activator. *Haemostasis* 1977;6:370-374.
13. Rath B, Bennett H. Monitoring the effect of heparin by measurement of activated

clotting time during and after percutaneous transluminal coronary angioplasty. *British Heart Journal* 1990;63:18-21.

14. Lehmann K, Ferris S, Heath Lange S. Maintenance of hemostasis after invasive cardiac procedures: implications for outpatient catheterization. *Journal of the American College of Cardiology* 1997;30(2):444-51.
15. Shepherd R, Vlietstra R. The History of Interventional Cardiology. In: Holmes D, Vlietstra R, editors. *Interventional Cardiology*. Philadelphia: F.A. Davis Company, 1989.
16. Baim D, Grossman W. *Cardiac catheterization, angiography, and intervention.* Fifth edition. Baltimore: Williams & Wilkins, 1996.
17. Fowlow B, Price P, Fung T. Ambulation after sheath removal: A comparison of 6 and 8 hours bed rest after sheath removal in patients following a PTCA procedure. *Heart and Lung* 1995;24(1):28-37.
18. Peet GI, McGrath MA, Brunt JH, Hilton JD. Clinical rounds. Femoral arterial sheath removal after PTCA: a cross-Canada survey. *Canadian Journal of Cardiovascular Nursing* 1995;6(3-4):13-9.
19. American Association of Critical Care Nurses. VIPs Survey Results. *AACN News* 1993(February):4.
20. Jones T. The effectiveness of mechanical compression devices in attaining hemostasis after removal of a femoral sheath following femoral artery cannulation for cardiac interventional procedures. Adelaide: The Joanna Briggs Institute for Evidence Based Nursing and Midwifery, 2000:1-71.
21. Homuth G. Relationship of methods for removal of femoral sheaths to the incidence of hematomas and patient comfort [Master of Science]. Northern Illinois, 1990.
22. Pracyk JB, Wall TC, Longabaugh JP, Tice FD, Hochrein J, Green C, et al. A randomized trial of vascular hemostasis techniques to reduce femoral vascular complications after coronary intervention. *American Journal of Cardiology* 1998;81(8):970-6.
23. Sridhar K, Fischman D, Goldberg S, Zalewski A, Walinsky P, Porter D, et al.

Peripheral vascular complications after intracoronary stent placement: prevention by use of a pneumatic vascular compression device. *Catheter and Cardiovascular Diagnosis* 1996;39(3):224-9.

24. Bogart MA. Time to hemostasis: a comparison of manual versus mechanical compression of the femoral artery. *Am J Crit Care* 1995;4(2):149-56.
25. Simon A, Bumgarner B, Clark K, Israel S. Manual versus mechanical compression for femoral artery hemostasis after cardiac catheterization. *American Journal of Critical Care* 1998;7(4):308-13.
26. Semler HJ. Transfemoral catheterization: mechanical versus manual control of bleeding. *Radiology* 1985;154(1):234-5.
27. Gibson C. A comparison of compression devices for femoral artery hemostatsis [Master of Science in Nursing]. Gonzaga University, 1996.
28. Jones C, Holcomb E, Rohrer T. Femoral artery pseudoaneurysm after invasive procedures. *Critical Care Nurse* 1995;15(4):47-51.
29. Spies J, Berlin L. Malpractice issues in radiology complications of femoral artery puncture. *American Journal of Roentgenology* 1998;170(1):9-11.
30. Chamberlin J, Lardi A, McKeever L, Wang M, Ramadurai G, Grunenwald P, et al. Use of vascular sealing devices (Vasoseal and Perclose) versus assisted manual compression (FemoStop) in transcatheter coronary interventions requiring Abciximab (ReoPro). *Catheterization and Cardiovascular Interventions* 1999;47:143-147.
31. Kussmaul W, Buchbinder M, Whitlow P, Aker U, Heuser R, King S, et al. Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: results of a randomized trial of a novel hemostatic device. *Journal of the American College of Cardiology* 1995;25(7):1685-92.
32. Pallant J. *SPSS survival manual*. Crows Nest: Allen & Unwin, 2001.
33. Jorde L. *Genes, Environment, and Common Diseases*. 3rd edition ed. St Louis: Mosby, 1998.
34. National Centre for Reviews and Dissemination. Undertaking systematic reviews

of research on effectiveness: CRD guidelines for carrying out or commissioning reviews. 1996.

35. Clifford C, Harkin L. *Inferential statistics in nursing and health care*. New York: Churchill Livingston, 1997.

36. Dunn S. Perspectives on evidence-based practice (Editorial). *Australian Critical Care* 1998;11(1):2-4.

37. Ohlsson A. Systematic reviews - theory and practice. *Scandinavian Journal of Clinical Laboratory Investigation* 1994;54(Suppl 219):25-31.

38. Polit D, Hungler B. *Nursing Research: Principles and Methods*. 6th edition ed. Philadelphia: Lippincott, 1995.

39. Nordrehaug JE, Chronos NAF, Priestley KA, Buller NP, Foran J. Randomized evaluation of an inflatable femoral artery compression device. *Journal of Interventional Cardiology*. 1996;9(5):381-387.

40. Australian Institute of Health and Welfare. Australia's health 2000: the seventh biennial health report of the Australian Institute of Health and Welfare. Canberra: AIHW, 2000.

41. Australian Institute of Health and Welfare. Heart, stroke and vascular disease: Australian facts 1999. Canberra: AIHW, 1999.

42. Stein B, Fuster V, Israel D. Platelet inhibitor agents in cardiovascular disease: an update. *Journal of American College of Cardiologists* 1989;14:813-836.

43. Collaborative overview of randomised trials of antiplatelet therapy - 1: Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients. *British Medical Journal* 1994;308:81-106.

44. Australia Heart Foundation. Aspirin in cardiovascular disease. http://www.heartfoundation.com.au/prof/06_aspirin.html, 2002.

45. Pepine C, Allen H, Bashore T, Brinker J, Cohn L, Dillion J, et al. ACC/AHA guidelines for cardiac cathaterization and cardiac catheterization laboratories. American College of cardiology/American Heart Association Ad Hoc Task Force on Cardiac Catheterization. *Circulation* 1991;84(5):2213-2247.

46. Block P, Ockene I, Goldberg R, Beutterly J, Block E, Degon C, et al. A

prospective randomized trial of outpatient versus inpatient cardiac catheterization. *New England Journal of Medicine* 1988;319(19):1251-1255.

47. Metz D, Meyer P, Touati C, Coste P, Petiteau P, Durand P, et al. Comparison of 6F with 7F and 8F guiding catheters for elective coronary angioplasty: results of a prospective, multicenter, randomized trial. *American Heart Journal* 1997;134(1):131-137.
48. Levin D, Gardiner G. Coronary arteriography. In: Braunwald E, editor. *Heart Disease: A textbook of cardiovascular medicine*. 4th edition ed. Philadelphia: W.B. Saunders Company, 1992:235-275.
49. Bettmann M, Bourdillon P, Barry W, Brush K, Levin D. Contrast agents for cardiac angiography: effects of nonionic agents vs. a standard ionic agent. *Radiology* 1984;153(3):583-587.
50. Bettmann M, Higgins C. Comparison of an ionic with a nonionic contrast agent for cardiac angiography. Results of a multicenter trial. *Investigative Radiology* 1985;20((1 Suppl)):S70-S74.
51. Matthai W, Kussmaul W, Krol J, Goin J, Scheartz J, Hirshfeld J. A comparison of low- with high-osmolality contrast agents in cardiac angiography. Identification of criteria for selective use. *Circulation* 1994;89(1):291-301.
52. Steinberg E, Moore R, Powe N, Gopalan R, Davidoff A, Litt M, et al. Safety and cost effectiveness of high-osmolality as compared with low-osmolality contrast material in patients undergoing cardiac angiography. *New England Journal of Medicine* 1992;326(7):425-430.
53. Grollman J, Lui C, Astone R, Lurie M. Thromboembolic complications in coronary angioplasty associated with the use of non-ionic contrast medium. *Catheter and Cardiovascular Diagnosis* 1988;14(3):159-164.
54. Hwang M, Piao Z, Murdock D, Giardina J, Pacold I, Leob H, et al. The potential risk of thrombosis during coronary angiography using nonionic contrast media. *Catheter and Cardiovascular Diagnosis* 1989;16(3):209-213.
55. Piessens J, Stammens I, Vrdix M, Glazier J, Benit E, DeGeest H, et al. Effects of an inonic versus nonionic low osmolar contrast agent on the thrombotic

complications of coronary angioplasty. *Catheter and Cardiovascular Diagnosis* 1993;28(2):99-105.

56. Jones T, McCutcheon H. Effectiveness of mechanical compression devices in attaining hemostasis after femoral sheath removal. *American Journal of Critical Care Nursing* 2002;11(2):155-162.
57. Beyer Enke S, Soldner J, Zeitler E. Immediate sealing of arterial puncture site following femoropopliteal angioplasty: a prospective randomized trial. *Cardiovascular and Interventional Radiology* 1996;19(6):406-10.
58. Davis C, VanRiper S, Longstreet J, Moscucci M. Vascular complications of coronary interventions. *Heart and Lung: The Journal of Acute and Critical Care* 1997;26(2):118-27.
59. Walker S, Cleary S, Higgins M. Comparison of the FemoStop device and manual pressure in reducing groin puncture site complications following coronary angioplasty and coronary stent placement. *International Journal of Nursing Practice* 2001;7(6):366-375.
60. Polgar S, Thomas S. *Introduction to Research in the Health Sciences.* Melbourne: Churchill Livingstone, 1998.
61. Fuller J, Schaller-Ayers J. *Health Assessment: A nursing approach.* 2nd Edition ed. Philadelphia: J.B. Lippincott Company, 1994.

APPENDIX 1

PATIENT INFORMATION SHEET

Study Title: A Comparison of Manual Compression versus Mechanical Compression Used to Obtain Haemostasis Following Coronary Angiography.

Study Investigator: Ms T. Jones

Purpose of the study:
In order for your Cardiologist to perform your coronary angiogram procedure they need to insert a tube into a large blood vessel at the top of your leg. The procedure is performed through this tube. After the procedure is completed this tube will be removed. There is a risk that bleeding can occur from the puncture site from which the tube is removed. To minimise the bruising and tenderness that may result it is important that firm, constant pressure is applied over the area from which the tube was removed. This pressure can be applied by firm hand or finger pressure, or using a mechanical clamp. The purpose of this study is to compare these different techniques of applying firm pressure after removal of the tube in the top of your leg. You will be randomly selected to have firm pressure applied using one of these techniques.

The tube will be removed straight after the procedure. Registered Nurses in the Catheter Laboratory will remove your tube at the appropriate time. They will need to frequently observe the puncture site at the top of your leg for bleeding or bruising, take you pulse and blood pressure and feel the temperature and pulse in your lower leg and foot regularly. They will also ask you to tell them about any pain or discomfort that you experience during when the firm pressure is applied after the tube is removed. Within one week the nurse will call you at home to ask a few simple questions about the puncture site.

Possible benefits from this study:
By comparing these techniques of applying firm pressure in this study it will be possible to identify which technique causes the least amount of bleeding, bruising and discomfort after the tube is removed. It will then be possible to develop a protocol for removal of the tube that is reliable and safe for other patients and nursing staff. Although this study may not benefit you directly, it may help other patients in the future.

Confidentiality:
All information and documentation containing your personal details and identity collected during this study will remain confidential. Even though results of the study may be presented in a public forum or submitted and published in medical or nursing journals no information that could identify a particular individual will be made public.

Your participation in this study is **voluntary** and you have the right to withdraw from the study at any time. Should you wish to withdraw from the study this will not alter the medical treatment or nursing care you receive now or in the future.

Contact Details:
Should you wish to discuss your involvement in this study with any member of the research team you can contact: **Ms Tina Jones**, 8222 4387 (work)

If you wish to discuss the study with someone not directly involved in the research, you can contact: XXXX, the Chairperson of the XXXX Ethics Committee, on **XXXXXXX**.

Thank you for agreeing to participate in this study.

APPENDIX 2

PATIENT CONSENT FORM

Study Title: A Comparison of Manual Compression versus Mechanical Compression Used to Obtain Haemostasis Following Coronary Angiography.

Study Investigators: Ms T. Jones

THIS IS TO CERTIFY THAT I,

_____

(Print name)

agree to participate as a volunteer in the above named project.

The nature and purpose of the study has been explained to me. I understand it and agree to take part.

I understand that while information gained during this study may be presented at a public forum or published in medical or nursing journals, I will not be identified and my personal details will remain confidential.

I understand that I can withdraw from the study at any time and that this will not affect my medical treatment or nursing care now or in the future.

I understand that I will not receive any payment for participating in this study.

Signed: _____

(Participant)

I certify that I have explained the study to the patient and consider that he/she understands what is involved:

Investigators signature: _____ **Date:** _____

APPENDIX 3

XXXXXX HOSPITAL

STUDY PROTOCOL—SHEATH REMOVAL USING MANUAL COMPRESSION

DESCRIPTION

The use of digital pressure used to achieve haemostasis with continuos pressure following coronary angiography.

REQUIREMENTS

Gloves
Gauze swabs
Groin roll
Tape used for strapping
Suture cutter

PROCEDURE

1. Check Blood Pressure, Pulse and Pedal pulse. Check that patient has no chest pain. Ensure it is appropriate to remove sheath.
2. Apply gloves, lay the bed flat, give the patient the buzzer.
3. Apply digital pressure above the sheath insertion site, feeling for the femoral pulse, remove the sheath.
4. Ensure there is no bleeding and check for a haematoma. If there is either of these then it is an indication that your fingers are incorrectly placed or that there is not enough pressure.
5. Continue to apply firm pressure for at least 10 minutes or until bleeding stops.
6. Once haemostasis has been obtained place the groin roll over the insertion site and with the patients knee bent apply the tape commencing application on the inner thigh and stretching over the groin roll to the top of the hip.
7. Straighten the patient's leg. The tape should pull tight.
8. Place a 2kg sandbag over the pressure dressing.
9. Neurovascular observations, blood pressure, and pulse should be observed 15 minutely.
10. The sandbag can be removed after 3 hours then the patient can sit up at approximately 45 degrees. Mobilisation should be approximately 3 to 4 hours after sheath removal.

APPENDIX 4

XXXXXXX HOSPITAL

STUDY PROTOCOL—SHEATH REMOVAL USING THE QUICKLAMP™ DEVICE

DESCRIPTION

The QuicKlamp is a mechanical device used to achieve haemostasis with constant and continuous pressure following coronary angiography.

COMPONETS

Quicklamp base and `C' arm
DisCo discs

REQUIREMENTS

Gloves
Gauze swabs
Groin roll
Tape used for strapping

PROCEDURE

1. Check Blood Pressure, Pulse and Pedal pulse. Ensure patient has no chest pain and that it is appropriate to remove the sheath.
2. Lay the patients bed flat, give the patient the buzzer.
3. Place the QuicKlamp support under the mattress and position over the puncture site.
4. Attach sterile DisCo disc to the distal end of the vertical control knob.
5. Confirm disc is snapped securely into place.
6. Position disc directly over puncture site.
7. Hold the trigger release to lower the disc onto the puncture site.
8. When removing the sheath apply firm pressure on vertical control knob (holding trigger release) to compress skin and control bleeding.
9. Turn the vertical control knob for fine pressure adjustment and observe the puncture site through the disc. Adjust as necessary.
10. Neurovascular observations and puncture site should be observed 15 minutely while the QuicKlamp is in place.
11. Apply firm pressure for at least 10 minutes.
12. Once haemostasis has begun, (usually after 10 minutes) gradually turn the vertical knob to release the pressure on the artery. Final release should occur with haemostasis.
13. Mobilisation should occur approximately 3 to 4 hours after sheath removal.

APPENDIX 5

DATA COLLECTION SHEET

DEMOGRAPHIC DETAILS

Patient sticky label

Subject's Phone number ☐

PRE-PROCEDURAL MEDICATIONS

Anticoagulants - Ticlid ☐
Heparin + APTT ☐ ☐
Enoxaparin ☐
Warfrin + INR ☐ ☐
Aspirin ☐
Thrombolytics + date ☐ ☐

Other Medications - ☐

CARDIAC RISK FACTORS

Hypertension ☐ Cholesterol ☐

Family History ☐ Diabetes ☐

Smoker ex ☐ Smoker current ☐

Weight ☐ Height ☐

PROCEDURE DETAILS

Date ☐

Arterial stabs ☐

Right or Left groin approach ☐

Procedure Time ☐

Sheath size ☐

Intraprocedural Medications ☐

Dye used ☐

SHEATH REMOVAL

Haematoma size prior to removal ☐

Bruise size prior to removal ☐

Sheath removal time ☐

Length of compression ☐

Method of removal QUICKLAMP ☐ MANUAL ☐

Haematoma size post removal ☐

Bruise size post removal ☐

Bleeding post removal none ☐ mild ☐ mod ☐ severe ☐

0 ml 0-50 ml 50-300 ml >300 ml

Pain / Discomfort rating

(Post Sheath Removal)

1 2 3 4 5 6 7 8 9 10

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 = no pain 10 = maximum pain

MOBILIZATION

Time when mobilised ☐

Haematoma size post dressing removal (cm) ☐

Bruising size post dressing removal (cm) ☐

Bleeding post dressing removal ☐

Bleeding post dressing removal none ☐ mild ☐ mod ☐ severe ☐

0 ml 0-50 ml 50-300 ml >300 ml

APPENDIX 6

POST PROCEDURE FOLLOW-UP QUESTIONNAIRE

1. Has there been any bruising in your groin and at the femoral puncture site?
YES / NO

2. Has there been any bleeding from the femoral puncture site? YES / NO
If yes, was it small and easily stopped, or large and medical advice sought?

Comment:

2. Has there been any swelling at the puncture site? YES / NO
If yes, was it small or large and was medical advice sought?

Comment:

3. Has there been any leg numbness or changes inn sensation? YES / NO
If yes, describe:

4. Have you had any chest pain? YES / NO
If yes, what action was taken?

Comment:

Researchers signature: _____ Date: _____

Study Three: Patients' perceptions of cardiac education prior to and following percutaneous transluminal coronary angioplasty (PTCA) and/or intracoronary stent.

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Abstract

BACKGROUND: Percutaneous transluminal coronary angioplasty (PTCA) and intracoronary stent procedures have become a viable alternative to cardiac bypass graft surgery for revascularisation of stenosed coronary arteries. This minimally invasive procedure is generally undertaken in a high turnover, short stay environment. Although the procedure offers the advantages of shorter hospital stay and reduced cost, the time available for nurses to educate patients is also reduced. The challenge for nurses is to establish and meet the needs of these patients within a reduced time frame.

OBJECTIVES: The objective of this study was to determine what education patients receive prior to, or after PTCA/intracoronary stent procedure and to determine whether they received information prior to discharge related to cardiac rehabilitation.

METHOD: Thirteen patients who underwent PTCA/intracoronary stent procedures agreed to participate in an unstructured interview that was conducted within four weeks of the procedure. The interview aimed to: identify the current educational strategies used to inform and prepare cardiac patients for PTCA and/or intracoronary stent procedures; identify whether patients scheduled for PTCA and/or intracoronary stent procedures were educated about the events that would occur in the postoperative recovery period; and, ascertain whether PTCA and/or intracoronary stent patients received information about cardiac rehabilitation programs prior to discharge from hospital. Participant responses were audio taped during the interview and then transcribed verbatim to allow data analysis to be undertaken.

Thematic analysis was used to analyse the text generated from the transcribed interviews. A constant comparative method was adapted for use during the concurrent data collection and analysis to identify and develop recurrent themes and ideas. Recurrent patterns emerged and formed the basis of themes that constitute the educational experience of these participants.

FINDINGS: Three major themes emerged from the participants' interviews—survival, knowledge and communication. The theme 'survival' incorporated the following sub-themes: *no choice* about having the procedure, the need to consider *lifestyle changes*, *concern* about some aspect related to the procedure, *contentment* about the events that occurred, *discomfort*

during or after the procedure and *no discomfort*. In some way these issues have impacted on the participants' ability to lead a complete and satisfying life. In some sub-themes, such as *no choice* and *lifestyle changes* it appeared that the participants perceived their survival to be dependent on these concepts. The theme 'knowledge' incorporated the following sub-themes: *understanding* of the treatment, more questioning and *uncertainty* about various issues, the use of *informal education* techniques for patient learning, *planned education* sessions and *family involvement* in acquiring knowledge and understanding. The third theme entitled 'communication' incorporated the following sub-themes: a *lack of information* about their care; *instructions* after the procedure; *language and informed consent*; *retention and reinforcement* of information; and *time and information* sharing.

Many of the concepts and sub-themes that emerged linked in some way across the three major themes. The different perceptions expressed by participants about their health and survival were linked in some way to their level of expectation, understanding and knowledge about the procedure and follow-up care. In addition, the level of understanding and knowledge gained by participants was also related to the manner in which information was communicated.

CONCLUSION: The findings of this research have identified several areas where education of cardiac interventional patients needs improvement. Educational preparation and follow-up rehabilitation that has traditionally focussed on patients after cardiac surgery or myocardial infarction cannot be routinely applied to cardiac interventional patients. The urgency of the procedure and the short hospital stay means those educational programs, both in-hospital and after discharge, need to be reassessed and re-structured in order to accommodate the needs of these patients. In addition, the degree and depth of information should be based on an individual evaluation of what patients perceive to be important and the risk of future cardiac problems.

Introduction

Heart disease is a major cause of morbidity and mortality in Australia. In 1998, heart disease was responsible for 29% of all deaths in Australia.[1] Coronary heart disease (CHD), resulting from blockage of the coronary arteries from abnormal plaque deposits, is the most common form of heart disease affecting Australians.[1] There are a range of treatment options for CHD, including percutaneous transluminal coronary angioplasty the use of which has grown dramatically over the last twenty years[1] because it is a viable alternative to cardiac bypass graft surgery for revascularisation of stenosed coronary arteries. This minimally invasive procedure is generally undertaken in a high turnover, short stay environment. Although the procedure offers advantages for patients with coronary artery disease over open-heart surgery, including shorter hospital stay and reduced cost,[1] the time available for nurses to spend helping and teaching patients is also reduced. The challenge for nurses is to establish and meet the needs of these patients within a reduced time frame. This study will identify the information patients received prior to the procedure and on discharge from hospital. The knowledge gained from this study will highlight information that patients perceive to be important about the procedure and immediate recovery period.

It has been well established that in-hospital counselling and education in the acute phase of hospital admission significantly reduces anxiety and is therapeutically beneficial after acute myocardial infarction.[2] Evidence exists that demonstrates cardiac rehabilitation programs can reduce cardiovascular mortality[3,4] and improve health-related quality of life[5] in these patients. This study has the potential to identify areas where cardiac rehabilitation may be improved by providing information that can be used by clinicians that may reduce physiological distress, improve lifestyle and reduce the necessity for other cardiac interventions in coronary angioplasty patients.

Background

Cardiovascular Disease

Progress has been made in the fight against cardiovascular disease with a dramatic decrease in morbidity in recent years. Despite this, cardiovascular disease remains one of the most

prevalent diseases in Western society.[6]

Statistics from the National Heart Foundation (NHF) of Australia indicate that death rates from coronary heart disease (CHD) peaked in 1968 and have since fallen by 60%.[7] This reduction has been attributed primarily to an increased awareness of potential risk factors of coronary heart disease and major advancements in the treatment and care of these patients. Nevertheless, cardiovascular disease continues to place a heavy burden on Australians in terms of illness, disability and death and the associated health care costs exceed those of any other disease.[7] These issues are expected to become more acute over the next decade with the growing number of elderly Australians, among who cardiovascular disease is common. The Australian Institute of Health and Welfare (AIHW) have shown that the prevalence of cardiovascular conditions increase with age.[8] In 1995, over 60% of people aged 75 and over had a cardiovascular condition.[8]

In 1998, the AIHW revealed that about 2.9 million Australians (about 16% of the population) had cardiovascular conditions including heart, stroke and vascular disease. Coronary heart disease is the largest single cause of death in Australia, claiming 29,051 lives in 1997. Every day around 80 Australians die from coronary heart disease.[8]

Percutaneous Transluminal Coronary Angioplasty

A variety of medical procedures are used to diagnose and treat coronary heart disease with coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA) being the primary revascularisation treatment options. In 1994, 14,941 Australians had CABG surgery. In 1996/97 there were 68,335 coronary angiograms performed throughout Australia. Percutaneous transluminal coronary angioplasty was performed on 18,094 patients in 46 units throughout Australia in 1998. This was a 37% increase in procedure numbers since 1995.[1] The majority (89.9%, n=16,262) were single-vessel angioplasty procedures with 18.6% (n=2,626) of these procedures being repeat PTCA for restenosis of the coronary vessel. Although the success rate of PTCA is high, restenosis occurs in 25% to 40% of coronary vessels, most frequently within six months of the procedure.[9] Intracoronary stents were deployed in 87.3% (n=9,188) of coronary angioplasty patients in 1998. Since 1993 there has been a dramatic increase in stent deployment as an adjunct to coronary angioplasty from 3% to 87%.[1] Although CABG surgery has traditionally

been the most common revascularisation treatment option available for coronary heart disease, these figures demonstrate the changing trend, with cardiac interventions such as PTCA and intracoronary stenting becoming an alternative and viable option.

Percutaneous transluminal coronary angioplasty (PTCA) was first introduced into clinical practice in 1977.[10] Since that time this procedure has gained widespread popularity as a non-surgical approach to the treatment of coronary artery disease. PTCA involves a balloon catheter being inserted percutaneously into the femoral artery, via an introducer sheath, to dilate a stenosed coronary artery. During PTCA a small, inflatable balloon is positioned within the narrowed or stenosed section of the coronary artery. Inflation of the balloon catheter causes the balloon to push outward against the narrowing and surrounding wall of the coronary artery, splitting and compressing the plaque and slightly stretching the intima wall of the artery until the stenosed vessel is opened sufficiently to improve coronary blood flow.

PTCA avoids the major trauma of cardiac bypass graft surgery as it does not involve the surgical opening of the patient's chest. PTCA is generally only used where coronary artery vessel lesions are suitable or in patients in whom cardiac surgery is contraindicated.[1] Data from the AIHW/NHF national coronary angioplasty register revealed that the indications for PTCA in 1998 were stable angina pectoris (43%), unstable angina pectoris (43.2%), acute myocardial infarction (6.8%) and prognostic reasons (2.9%).[1]

Various types of angioplasty procedures are performed such as 'primary angioplasty', when the procedure is undertaken as soon as possible for acute myocardial infarction (AMI) or 'rescue angioplasty' for those patients having an AMI when thrombolytic therapy has failed.[1] Hospitalisation for PTCA/stent patients can be as short as one to two days.[11,12] Angioplasty is considered successful when there has been more than a 20% diameter increase in the arterial lumen.[13]

Over time restenosis of the vessel can occur.[14] Although the exact reason for restenosis remains uncertain, it is thought to be related to the composition of the stenosis, platelet deposition, and/or thrombus formation.[15] In an attempt to reduce the incidence of restenosis, intracoronary stents have become available. The purpose of the stent is to provide a scaffold to hold the artery open. The intention is to promote intraluminal structure and patency by reducing formation of thrombi.[16] Indications for coronary stent deployment include threatened

or abrupt vessel closure, dissection of the arterial wall, residual vessel narrowing greater than 50% and ongoing clinical symptoms such as chest pain and electrocardiograph (ECG) changes.[16] Despite significant improvements in the design and placement of intracoronary stents, restenosis remains a problem.

Although the incidence of restenosis in PTCA remains up to 40% [17], the safety and efficacy of an angioplasty procedure is well documented[18], with reduced length of hospital stay, decreased costs and comparative success to open heart surgery.[19,20] In addition, the procedure provides several advantages for patients including, a shorter hospital stay, minimal procedural discomfort, immediate potential relief of pain or discomfort from cardiac symptoms, rapid convalescence and decreased cost.[17,21] Despite this, PTCA is not a cure for coronary heart disease and ongoing progression of atherosclerosis can occur.[9] Patients need to undergo coronary risk factor assessment with appropriate lifestyle modifications introduced to reduce the risk of restenosis and return of anginal symptoms. Cardiac nurses can contribute significantly to the education of patients prior to their interventional procedures and particularly during the immediate recovery phase post procedure, by emphasising the health value of life-style changes and the promotion of specific cardiac rehabilitation behaviours.[21]

Cardiac Rehabilitation

The benefit of cardiac rehabilitation programs, particularly in relation to coronary heart disease and after acute myocardial infarction (MI), have been well documented.[3,4,5,22] In a meta-analysis of prospective trials by Oldridge et al, cardiac rehabilitation programs were associated with a decrease in mortality of 8% when patients participated for less than 12 weeks.[3] These rehabilitative programs focussed primarily on exercise, education and psychosocial support. Mortality declined by 24% when patients participated for between 12 and 52 weeks, with a further 38% decline being demonstrated after 36 months of participation.[3] In addition to an overall reduction in mortality, O'Connor et al in another meta-analysis, found a statistically significant association between exercise training and a decrease in the incidence of sudden cardiac death in the first year.[4]

The overall aims of cardiac rehabilitation programs are to improve functional capacity and to help cardiac patients return to an active and satisfying life by relieving symptoms, enhancing quality of life and preventing the recurrence of cardiac events. Comprehensive rehabilitative

services should include physical activity, risk factor modification, health education and counselling programs tailored to meet individual and cultural needs of patients and their families.[23]

Cardiac rehabilitation programs generally target four phases of recovery: in-hospital, early post discharge, later post discharge, and long term follow-up.[24] Three essential elements span these phases. The first element is the process of explanation and understanding, which should start simultaneously with the process of medical diagnosis and management. The second element includes specific rehabilitative interventions such as secondary prevention, exercise training and psychological support. The third element encompasses long-term processes involving re-adaptation and re-education to modify life-style. Although each phase has a discrete area of focus, the essential elements may interlink or overlap.[24]

Although it is accepted that cardiac rehabilitation should be available to those who require it, some services are limited and questions remain about their individual effectiveness, access and delivery. Cardiac education and rehabilitation should be an integral part of comprehensive cardiac care and should begin once the patient has entered the health care setting for a cardiac interventional procedure. Unfortunately with cardiac interventional patients the formal rehabilitative process may not commence until the time of discharge. It is not unusual for a patient to experience acute chest pain or unstable angina, go to the cardiac catheterisation laboratory, be diagnosed with critical disease in one or more coronary vessels, undergo an angioplasty and go home the next day.[25] It is possible that these patients may not recognise the seriousness of their cardiac problem or see the importance of initiating or maintaining suggested lifestyle modification behaviours, as compared to other cardiac patients.[26,27] Langton and Thompson contend that family members may also dismiss the seriousness of coronary angioplasty and not recognise the significance of the event.[28] Consequently, lifestyle changes may not be recognised as important by the family unit as a whole.[29]

Difficulties arise with patients undergoing PTCA as these patients do not stay in hospital long enough to undergo the first phase of cardiac rehabilitation.[25,30] Pashkow (p.116) states that with the decreasing length of stay for these cardiac patients '... it is not reasonable to expect that inpatient rehabilitation will produce tangible improvements in physical capacity or significant retention of information and instructions' in such a short period of time.[25] Thompson suggests that the priority for cardiac rehabilitation should be to provide good early

advice using a wider range of flexible skills and services.[23] Pashkow indicates that health professionals need to rethink the goals and objectives of inpatient cardiac rehabilitation in order to accommodate the needs of these patients.[25]

Most formal cardiac rehabilitation programs have concentrated on patients recovering from myocardial infarction or open-heart surgery, such as coronary artery bypass graft surgery. This perception is based on the premise that these patients have the maximum potential for health gain.[24] Considering the trend of increasing revascularisation techniques such as PTCA and intracoronary stenting in the management of patients with coronary heart disease, it is appropriate that educational strategies be extended to include these patient groups. It is possible that patients may view coronary angioplasty as a less threatening treatment option to cardiac bypass surgery due to the rapid non-invasive nature of the technique and immediate potential success of PTCA[21] and therefore these patients may not appreciate the need to attend cardiac rehabilitation programs.[31] To date there is no evidence within the literature of the differences in compliance with risk factor reduction between patients having undergone PTCA and cardiac bypass surgery. Gardner et al (p.66) state that 'patient non-compliance can influence outcome ... [and] providing information in an accurate and timely fashion contributes to improved compliance and greater procedural success'.[16]

Patient Perceptions, Information and Education

A review of the literature found research has previously has been undertaken to determine patients' views[32], perspectives[33] and coping styles associated with cardiac catheterisation.[34] A questionnaire developed by Foulger was delivered to 103 elective day-case cardiac catheterisation patients to measure patients' opinions and satisfaction with day-case cardiac catheterisation.[32] Patients' views on issues related to early discharge, explanation of test results, changes to medication or treatment, complications and health education were surveyed. Although the findings revealed that patients' needs were being effectively met in most areas, some aspects of care were sub-optimal. These specifically related to lack of understanding about information and test results given to them by the doctor and inadequate education about their health and heart in the future.[32]

A phenomenological study with 10 male patients after cardiac catheterisation highlighted feelings of anxiety and fear of possible procedural outcomes, trust and confidence in medical

personnel and loss of physical and mental control during the procedure.[33] In order to reduce anxiety related to cardiac catheterisation, the effect of various kinds of preparatory information have been investigated.[34] A meta-analysis by Suls and Wan indicated that a combination of procedural information (describing steps involved in the procedure) and sensory information (describing what a patients will see, hear or feel during the procedure) is more effective in reducing anxiety than procedural information alone.[35]

To date nursing research on PTCA has focused primarily on procedural and post procedural care[13,36] and more recently on the experience of the patient during and immediately after the procedure[9,17] and the identification of possible lifestyle changes.[21] In a descriptive study using two questionnaires Gulanick and Naito examined patients concerns and experiences during the immediate recovery period and attempted to identify risk factor modification behaviours during a twelve-week follow-up period.[9] The majority of patients in this study felt the procedure had achieved the benefits they expected as their activity level was improved and they experienced reduced anginal symptoms. Although these patients were initially highly motivated to reduce risk factors, the follow-up questionnaire revealed motivation and performance had decreased over time.[9]

Gulanick et al examined patients' recovery patterns and lifestyle changes after PTCA using focus group interviews.[17] Most participants expressed positive experiences related to educational and emotional support before the procedure and trust in the competence of medical staff. However, several negative themes emerged from the participant interviews including anger over unmet comfort or support needs after the procedure, long-waits for scheduled procedures, depersonalised "assembly-line" environment and frustration over lack of control in decision-making about the procedure.[17] The authors highlighted the need for health carers to be aware of these feelings in order to anticipate patient needs and to intervene where necessary.

Gaw interviewed fourteen patients about their concerns and perceptions of PTCA and their motivation to modify life-style risk factors upon returning home.[21] The findings demonstrated that less than half of the patients interviewed were motivated to make life-style changes or reduce cardiac risk factors related to their cardiac disease, as they believed the procedure had cured their coronary heart disease.[21] Although the majority of patients were satisfied they had been adequately prepared for the procedure, several had difficulty describing what had been

done by the cardiologist during the procedure. The researcher concluded that it should not be taken for granted that all patients are adequately prepared for PTCA or understand the importance of rehabilitative life-style changes.[21]

Eastwood also investigated lifestyle changes in patients 3 months after coronary angioplasty and intracoronary stenting.[29] Of the four male participants, only one had made a noticeable lifestyle change during this period. The remaining participants had not made any discernable lifestyle change or had continued with their previous behaviours.[29]

Cronin et al used a descriptive survey to determine concerns and needs for information after PTCA.[30] Less than half (43%) of the 105 patients surveyed mentioned any concerns related to the recovery period. This study identified that further information was needed in regards to emotional issues such as anxiety and depression, medications, stress management and training in cardiopulmonary resuscitation for family members. When asked to indicate whether life-style modifications had been suggested, less than a quarter of respondents (24%) did not recall that a change had been recommended.[30] Shortened length of stay for PTCA patients has markedly reduced the time available to educate patients and assess the patient's knowledge and teaching needs. Tooth and McKenna suggest that due to the shortened hospital stay, PTCA patients have more anxiety during teaching and may have less time to assimilate the information.[37]

Using a grounded theory design, Higgins et al explored the recovery experiences and perceptions of coronary angioplasty patients.[38] The findings from the semi-structured interviews revealed feelings of anxiety associated with uncertainty of their health in the future, a 'good' recovery associated with absence of chest pain and improvement in well being and energy levels, whilst a 'bad' recovery experience was associated with post-procedural complications and lack of psychological improvement.[38]

These studies have highlighted patient experiences after coronary angioplasty, identifying their concerns and emphasising areas where educational preparation and motivation to change lifestyle patterns has been inadequate. An extensive search of the literature using MEDLINE and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases was undertaken but failed to find any research that described educational or cardiac rehabilitation programs specifically designed to meet the needs of patients undergoing cardiac

interventional procedures such as PTCA and intracoronary stenting that had been evaluated effectively. It is possible that these specific groups of patients with coronary heart disease are not being provided with the appropriate educational preparation or follow-up cardiac rehabilitation required to reduce the risk of ongoing cardiac disease and/or restenosis. This study is designed to determine whether cardiac patients at the study institution receive education prior to, and/or after, interventional procedures such as PTCA and intracoronary stenting and whether they were involved in cardiac rehabilitation programs following hospital discharge.

Study Method

The Purpose of the Study

The purpose of this study was to determine whether cardiac patients undergoing diagnostic or cardiac interventional procedures in the study institution have access to and or receive education prior to, or after the procedure and to determine whether they received information prior to discharge related to cardiac rehabilitation.

The study objectives were: to identify the current educational strategies used to inform and prepare cardiac patients for PTCA and/or intracoronary stent procedures; identify whether patients scheduled for PTCA and/or intracoronary stent procedures were educated about the events that would occur in the postoperative recovery period; and, ascertain whether PTCA and/or intracoronary stent patients received information about cardiac rehabilitation programs prior to discharge from hospital. If educational programs were identified, an additional objective was to determine whether these programs were meeting the needs of these specific cardiac interventional patients.

Research Questions

The research questions in this study were:

What educational preparations do patients scheduled for PTCA and/or intracoronary stent procedures receive to prepare them for the procedure and the immediate recovery period after the procedure?

What information do these patients receive in relation to cardiac rehabilitation and life style changes prior to discharge?

What type of information or learning resources do these patients receive?
How do these patients feel about the educational information provided?
If information was received, were significant family members present or involved during the process and how did they feel about the educational information provided?

Study Setting and Participants

The setting from which the participants were recruited is an acute medical cardiology ward of a designated trauma and tertiary referral centre with approximately 600 to 700 beds. PTCA has been performed at this institution since 1983. This hospital has become a major centre for interventional cardiology with more than 2,000 coronary angiograms performed each year.[39] In 2000, more than 800 patients had PTCA procedures, with coronary stents deployed in 72% of these patients. Several patients received multiple stents for diffuse coronary artery stenosis.[40]

Inclusion Criteria

Patients scheduled to have percutaneous transluminal coronary angioplasty (PTCA) and/or intracoronary stent procedures at the study institution were invited to participate in the study. These patients were identified from the daily procedure lists available from the cardiac catheterisation unit.

Patients who were scheduled for PTCA and/or intracoronary stent procedures were admitted to the acute medical cardiology unit of the study institution prior to the procedure and returned to the ward after the procedure for recovery and observation. Patients were approached and invited to participate in the study after PTCA and/or intracoronary stent, but prior to discharge, usually within two days after the procedure. Patients whom had undergone PTCA and who had intracoronary stent deployment during the procedure were included, as they comprised 80% to 90% of PTCA patients at the study institution.[41] Patients who could understand and speak English were included in the study.

Exclusion Criteria

Patients who had previously undergone a PTCA and/or intracoronary stent procedure were excluded from the study as they may have had an increased awareness of what to expect from the procedure and may not have perceived the need for pre-procedural education. Those patients who were admitted for other interventional procedures such as electrophysiology

studies or permanent cardiac pacemaker implantation were not included in this study as these procedures are commonly indicated in patients who have a primary cardiac arrhythmia, the aetiology of which may not always be related to coronary heart disease. Patients who had 'rescue PTCA' as a result of unsuccessful revascularisation following the administration of thrombolytic agents were also excluded, as these patients may not have had the opportunity to receive preoperative education.

Recruitment of Participants

Permission was sought from the nursing and medical directors of the cardiac service of the study institution to invite patients to be involved in the study. An information sheet (see Appendix 1) was given to participants after coronary angioplasty and/or intracoronary stent procedures. The information sheet provided details about the researcher, a brief outline of the aims and purpose of the research, an invitation to participate in an interview, and a guarantee of participant confidentiality. The participants were the first fourteen patients who volunteered to take part in the study after reading the information sheet. Although one patient signed a consent form and agreed to be involved in the study, the researcher decided not to proceed with the interview. In the two weeks after the procedure this patient had several recurrent episodes of chest pain, indicating that restenosis had occurred. He was scheduled for repeat angioplasty. The decision not to proceed with the interview was based on the researchers observation that the patient was extremely anxious and distressed by the recurrent chest pain. The researcher did not want to add to this anxiety. Data were therefore collected from thirteen participants.

The number of participants in interpretive research is typically small as large volumes of data may be generated.[42] Thirteen participants was considered to be appropriate when no new ideas appeared to be emerging from the interviews. This technique is known as 'saturation' of the data. Morse (p.142) defines saturation as 'data adequacy' and is reached when 'no new information is obtained'.[42] She explains that no published guidelines exist for estimating the sample size required to reach saturation and that although data may initially appear diverse and disconnected, through a process of data saturation, patterns and themes begin to emerge and make sense.[42] It is not possible to estimate prior to data collection the amount of data required to create these patterns and themes.

Ethical Considerations

Clearance from the Chair of the Human Ethics Committee of the study institution was obtained prior to commencing this research. Approval was also sought from the nursing and medical directors of the cardiac service of the study institution prior to commencement.

Participation in this study was voluntary and confidentiality was maintained. The information sheet (see Appendix 1) informed participants that they would not be identifiable from the research, informed them of the nature and purpose of the study, and provided the names and telephone numbers of the chief researcher, Chairperson of the Ethics Committee and the student's supervisor in case further information or feedback was required. The researcher assured those patients willing to participate that defining information relating to any person or institution uncovered during the course of this study would be deleted from the transcripts or changed to ensure anonymity. Participants were informed of their right to withdraw from the study at any time without prejudice to their medical and/or nursing care at that time or in the future. The participants were asked to sign a consent form (see Appendix 2) indicating that they were willing to participate in this study and that the nature and purpose of the study has been explained to them.

During the study period the taped interviews, transcribed texts of the participants and consent forms were stored in a locked cabinet in the researcher's office. On completion of the study all identifying details, tapes and transcripts and consent forms will be kept secure in a locked cabinet for at least 5 years.

Data Collection

This study used an interpretive inquiry approach collecting qualitative data during semi-structured interviews.[43] The design of the semi-structured interview enabled the researcher to explore the educational experience of PTCA and/or intracoronary stent patients. Of particular interest was the information the patients received prior to the procedure, during the immediate recovery period after the interventional procedure and whether cardiac rehabilitation issues were discussed prior to hospital discharge.

A single semi-structured interview lasting no longer than one hour in duration was scheduled within the first month of discharge from hospital after their cardiac interventional procedure.

A period of up to one month between the procedure and interview was allowed so that participants could either incorporate rehabilitative changes into their lifestyle or return to pre-procedure behaviour.

Those participants who lived in the local metropolitan area were interviewed in their own home. A telephone interview was conducted with those participants who resided in the country. The researcher arranged for the interviews to be undertaken at a time convenient to the participant. The use of open-ended questions in a semi-structured interview gave the participants the opportunity to talk freely about their educational experience without the bias of suggested responses from the researcher (see Appendix 3 for examples of the open-ended questions that were asked during the interview). In addition, this interview technique allowed the researcher to prevent the interview from stagnating, maintain the focus of the interview on the topic area, clarify issues and gain further explanations and information during the interview if required.[29,38]

Participant responses were audio taped during the interview to ensure an accurate and comprehensive record of the discussions. The audio taped interviews were then transcribed verbatim to allow data analysis to be undertaken. To ensure an accurate record of the interview was achieved the researcher verified each tape recording against the transcribed text. Each participant's text was assigned a code number and pseudonym in order to preserve confidentiality of the participants.

In addition to the taped interview, field notes were recorded in a journal. These field notes summarised the researchers subjective impressions of the participants during the interview, the interview setting and the participant's mood during the interview. Notations of impressive words or phrases were also recorded.

Additional data were collected from the patients' medical record including demographic characteristics of each participant such as gender, age, cardiac risk factor history, date of the procedure, type of procedure undertaken, number and identity of the coronary vessel(s) involved and whether an intracoronary stent was deployed. The intention of collecting this demographic information was not to draw comparisons between participants, but rather to add context to each individual's story.

Data Analysis

The theoretical framework that informs this study is situated within the interpretive paradigm. However, it is not within the scope of the research portfolio or this study to discuss in any detail the ontology, epistemology or specific methodological considerations of this paradigm. Rather the researcher has concentrated on describing the technique of thematic analysis, a method of analysis frequently used within the interpretive paradigm and useful in clinical research.

Prior to thematic analysis each transcript was read and re-read and the corresponding audio tape was listened to repeatedly. This enabled the researcher to become familiar with the transcribed texts. After checking the transcripts for accuracy an original copy of the interview transcription was retained unchanged. Another copy was then 'cleaned' of any identifying information pertaining to the participant, any hospital or personnel, and the study institution. Participants were then assigned a pseudonym and the text units were numbered. A further copy of the transcription was then generated for initial coding and analysis.

Thematic analysis was used to analyse the text generated from the transcribed interviews and recognise emergent ideas and concepts. A constant comparative method was adapted for use during the concurrent data collection and analysis to identify and develop recurrent themes and ideas. The constant comparison of patients' perceptions can either strengthen or challenge the emerging themes.[38]

The process of data analysis was based on the work of Leininger[44] and Ekman and Segesten.[45] This involved the following four steps: examination of the entire material gathered from the participants in order to gain a sense of the whole picture; the identification of indicators and categories within the data; the identification of recurrent patterns; and the development of themes that summarised the research findings.[45] During thematic analysis it was necessary to listen to the tapes many times, and re-read the transcripts to develop insight and confirm developing ideas and impressions. Recurrent patterns emerged and formed the basis of themes that constitute the educational experience of these participants. Narratives from the participant's text illustrate the themes. These extracts will be quoted in italics and be followed by an identifying code when used throughout this research. The code will be the initial of the pseudonym name followed by the numbered line/s in the texts. For example a three line

extract from Henry's transcript will be referenced: (H:45-48).

Results -The Participants

As can be seen in the table below, there were 9 male and 4 female participants, 7 who lived in the metropolitan city area and 6 from the country. The median age of participants was 65 years and ranged from 43 years to 74 years (see Table 1).

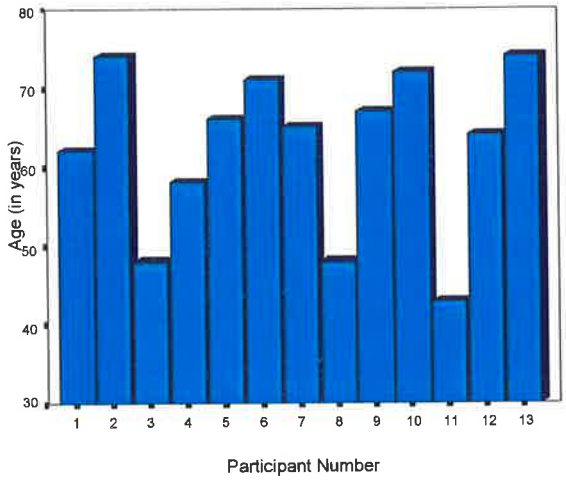
Table 1: Participants' characteristics

Characteristic	Frequency
Gender	
male	9
female	4
Age (years)*	
male	65 (43-74 61.56±10.28
female	68 (48-74) 64.5±11.82
total	65(43-74) 62.46±10.37
Place of Residence	
city	7
country	6

* Expressed as median (Interquartile Range, IQR) and mean ± standard deviation

The figure below presents the age distribution data for the participants (see Figure 1).

Figure 1: Age distribution



The following narrative provides a summary of the events that lead up to each participant requiring a PTCA and/or intracoronary stent procedure. To maintain confidentiality, all participants have been given pseudonyms and the names of medical personnel and health institutions have been deleted. I began each interview by asking the participants to tell me whether they had a family history of heart disease and then tried to determine what, if any, cardiac risk factors they had.

Participant 1—Henry

Henry is a 62 years old self-employed bricklayer who is married with three daughters and lives about 10 kilometres (kms) from the city. Henry had a family history of heart disease and smoked cigarettes. Prior to this acute event of chest pain, he had considered himself to have been quite fit and healthy with no previous history of chest pain.

Henry had suffered an acute lateral myocardial infarction. Coronary angiography revealed mild coronary heart disease with minor blockages to the left coronary and right coronary arteries. A major blockage was identified in the obtuse marginal coronary artery that branches off from the left circumflex artery and supplies blood to the lateral aspect of the left ventricle.[46] Three days later Henry was scheduled to have an elective coronary angioplasty. This was successfully undertaken and an intracoronary stent was inserted. Up until the time of the interview (three weeks after the procedure), Henry had not experienced any adverse events after the procedure.

Participant 2—Dorothy

Dorothy is a 74-year old lady who lived by herself in a small unit about 10 kms out of the city. Dorothy had never been married and had no children. Dorothy had a family history of heart disease and a medical history of hypertension and hypercholesterolemia, for which she was taking regular medication. She was not overweight, did not have diabetes and had never smoked cigarettes, despite this being common in her family.

Over a period of several weeks Dorothy had been having episodes of recurrent chest pain. Her doctor scheduled her to have an exercise stress test and coronary angiogram. The coronary angiogram revealed two blockages in the left anterior descending (LAD) coronary artery. She went on to have a successful PTCA procedure that opened both occluded areas in the LAD, with an intracoronary stent being inserted into the proximal lesion. Since the procedure (nearly four weeks prior to the interview) her recovery had progressed well. Although she still remained tired and had some oedema evident in her right leg, she had not experienced any adverse events after the procedure.

Participant 3—Betty

Betty is a 48-year-old woman who is married with two grown up children and lives in a country town about 450 kms from the city. Betty did not have a medical history of hypertension, hypercholesterolaemia or diabetes prior to this event. She did not consider herself to be overweight, rather healthy and active. Despite this, Betty was a smoker and had a family history of coronary heart disease.

Betty had never had chest pain prior to this episode and was surprised and anxious about the possibility that she had had a heart attack. She was admitted to the intensive care unit of the country hospital. After six days she was discharged home without complications. She was scheduled to have a coronary angiogram at the study institution three weeks later. The coronary angiogram revealed an acute occlusion of the left anterior descending coronary artery. A few days later she had a successfully PTCA and intracoronary stent insertion to the occluded area of the LAD coronary artery. She did not experience any adverse events after the procedure and was discharged back to her home in the country the next day.

Participant 4—Malcolm

Malcolm, a 58-year-old gentleman who also came from the country, is married with two grown up children who no longer live at home. He considered himself to be active prior to this event, regularly playing golf and working outdoors as a labourer. Although Malcolm had no history of hypertension, hypercholesterolaemia or diabetes, his parents had a medical history of coronary heart disease. Malcolm had been a previous cigarette smoker but had stopped smoking about twelve years ago. This event was the first time Malcolm had experienced acute chest. He did not have a coronary angiogram prior to the procedure as the blood tests and electrocardiogram confirmed he had suffered an acute myocardial infarction. He had a successful PTCA procedure with an intracoronary stent inserted into the distal right coronary artery (RCA) a few days later.

After the procedure Malcolm did have an unexpected event. His platelet count was abnormally low. Although the exact course of this disorder was unclear, it was thought to be due to the contrast dye used during the procedure. Malcolm had an ionic contrast agent during the procedure. Ionic contrast agents have been found to have an inhibitory effect on clot formation when mixed with blood and hence may predispose subjects to thrombotic events.[47,48,49] This may be of benefit during coronary angiography procedures as thrombus formation within the femoral sheath and diagnostic catheters is less likely to occur, but it may predispose to bleeding.[49] For Malcolm, the only inconvenience caused from this event was that he was required to lie in bed with the femoral sheath in his groin for a prolonged period so as to avoid potential bleeding as a result of the low platelet level. He did not experience any other adverse events after the procedure.

Participant 5—Albert

Albert is a 66-year-old married man who lives about 100 kms from the city in a large country town. Although Albert had never smoked cigarettes he did have a medical history of diabetes and hypertension. To complicate issues, he also had a history of chronic renal failure. This would make Albert's recovery after the procedure slower than expected as his renal impairment was exacerbated by the contrast dye used during the procedure. With the dye being excreted through the kidneys, Albert's renal function took several weeks to return to a level where the doctors were happy for him to be discharged. As a consequence he was not interviewed until four weeks after the procedure.

Albert had experienced recurrent episodes of mild chest pain over the previous eighteen months. He was admitted to hospital after an acute episode of chest pain and had PTCA with two intracoronary stents inserted into a distal and proximal portion of the LAD coronary artery. There were no adverse events during the procedure and the occluded portions of the LAD were successfully opened.

Since hospital discharge Albert's recovery had been slow as a result of his impaired renal function and he did not feel as well as he expected. The local General Practitioner was checking on Albert's progress each week and he was due to visit the Cardiologist in the next few weeks. Although he was requiring regular vitamin K injections for anaemia related to his chronic renal failure, his condition was slowly improving.

Participant 6—Frank

Frank is a 71-year-old widow who lives by himself in the foothills of the city. He has three grown up children, one who is a nurse working at the study institution. Although there was no family history of coronary heart disease, Frank had a medical history of hypertension, hypercholesterolaemia and has suffered from angina for the last few years. He had never smoked cigarettes, regularly walked for exercise and was conscious of trying to maintain a healthy diet.

After an unexpected episode of acute chest pain Frank had a successful PTCA and intracoronary stent procedure to the left circumflex coronary artery. After the procedure, while still in the recovery unit of the cardiac catheterisation laboratory, Frank had an episode of bleeding around the femoral sheath. Manual pressure was applied to the insertion site and a sandbag applied until the bleeding was controlled. As a result, the femoral sheath was left in place overnight. However, no further complications occurred and Frank's recovery was otherwise uneventful.

Participant 7—Jeffrey

Jeffrey is a 65-year-old man who is married with two grown up children and lives about 200 kms north of the city in a small country town. Jeffrey has had asthma since he was a child, had a family history of heart disease and had a previous myocardial infarction a year earlier.

However, Jeffrey had never smoked cigarettes, was not overweight and did not have a medical history of hypertension, hypercholesterolaemia or diabetes.

Prior to this acute event, Jeffrey had been experiencing exertional angina for about one month. As this acute episode of chest pain occurred at rest, Jeffrey had an exercise stress test and coronary angiogram that confirmed he had two blocked coronary arteries. Jeffrey had PTCA to the LAD and left circumflex coronary arteries with two intracoronary stents inserted. During the procedure Jeffrey suffered another acute myocardial infarction that meant he needed to stay in hospital after the procedure for a few extra days, but his post-procedural recovery was uneventful.

Participant 8—Karl

Karl is a 48-year-old man who lives in a defacto relationship in a large country town 400 kms from the city. He has a family history of coronary heart disease and smoked cigarettes. He did not have any other cardiac risk factors and prior to this event had no history of angina.

After admission to the local hospital with acute chest pain, it was confirmed that Karl had suffered a heart attack. He was admitted to the coronary care unit where he stayed for five days. They arranged for him to be seen by a cardiologist in the city and was scheduled to have a coronary angiogram six weeks later. The day after hospital discharge Karl experienced chest pain again, this time at rest. He was readmitted to the local hospital and Royal Flying Doctor Service flew him to the study institution. Karl was scheduled for PTCA the next day when he had a successful PTCA procedure and intracoronary stent inserted into the LAD coronary artery. His recovery was uneventful and he was discharged home three days after the procedure.

Participant 9—Les

Les is a 67-year-old gentleman who is married with five children and lives in an outer city suburb. Les has a long standing history of coronary heart disease and several cardiac risk factors including diabetes, hypertension, hypercholesterolaemia, all managed with medication and diet control, and he used to smoke cigarettes, although had given this up about thirty years ago. He had a medical history of angina and in 1988 had coronary artery bypass graft (CABG) surgery. This was the first time that Les had had experiences chest pain since CABG

surgery.

Tests at the local hospital after the event confirmed that Les had a myocardial infarction. He was admitted to the Intensive Care Unit where he stayed for a couple of days before being transferred to a medical ward prior to discharge. A week later he had a coronary angiogram that confirmed the distal portion of the saphenous vein graft inserted during the CABG had occluded. He was scheduled to have PTCA at the study institution a few days later. The procedure was successful and an intracoronary stent was inserted across the area that had been blocked. No post-procedural complications occurred and Les at the time of interview was feeling better.

Participant 10—Tanya

Tanya, a 72 year old married woman, lived on a farm in the country about 65 kms from the city. Although Tanya had a medical history of hypertension and hypercholesterolaemia she did not have any other cardiac risk factors. Although Tanya said she did not have a history of angina, she had been experiencing chest pain on various occasions prior to this event. Tanya had a coronary angiogram that confirmed an occlusion of the right coronary artery. She had a successful PTCA procedure at the study institution with an intracoronary stent inserted in the right coronary artery. She was discharged home the following day with no adverse effects. Although still feeling very tired nearly four weeks later, her post-procedural recovery had been uneventful.

Participant 11—William

William, a 43-year old married father of three children, lived in the city, was self-employed and worked from home. Although his mother had a history of hypertension and had suffered a stroke late in her life, he did not know of any specific family history of CHD. He considered that over the last five years his level of activity and exercise had been deteriorating. He first became aware of symptoms of chest pain when he began a program of regular exercise.

William went to see his local doctor who referred him to a cardiologist. He then had an echocardiogram, an ultrasonic procedure used to examine the heart structures, blood flow and function of the myocardium and detect structural abnormalities and myocardial damage.[51] Although this was normal, the cardiologist was still concerned about his history of chest pain

and performed an exercise stress test. He experienced acute chest pain during the exercise test and was scheduled to have a coronary angiogram the next week. As coronary angiography revealed an acute occlusion of the LAD coronary artery, PTCA and an intracoronary stent procedure was undertaken immediately. The procedure was successful in opening the occluded lesion and William was discharged home the following day with no ill effects. His post-procedural recovery has been uneventful.

Participant 12—Carol

Carol is a 72-year-old widower who lives alone in the city. She has a family history of CHD with her grandparents, parents, uncles and aunties all having a medical history of CHD. In addition, Carol has a medical history of diet controlled diabetes and hypertension. Carol had been to see the local doctor after being concerned about her *'cold feet'*. She mentioned that she also had *'...started to get tight up in the chest' (C: 38).* He prescribed anginine spray to help relieve the chest pain and referred her to a cardiologist. She was scheduled to have a coronary angiogram but unfortunately had to wait a month for this appointment. During that time she experienced several episodes of central chest pain. Considering this, the cardiologist suggested that if the coronary angiogram identified a blocked coronary artery that he should go onto perform a PTCA at the same time. An acute occlusion of the right coronary artery was revealed and PTCA and intracoronary stent insertion was successfully undertaken. Carol was discharged home the following day. At the time of the interview (two weeks later) Carol had extensive bruising and swelling of her right leg. This was limiting her mobility and causing some discomfort. She was scheduled to visit the cardiologist two weeks later.

Participant 13—Gerald

Gerald is a 74-year-old married man who lives in the city. He has three daughters; one being a nurse and another had a history of cancer several years ago. His wife, who also had cancer, was currently receiving treatment at the study hospital. In fact, while Gerald was in hospital for the PTCA procedure she was in an adjacent ward receiving chemotherapy. Gerald admitted that his wife's health did cause him substantial stress. Gerald's own medical history had not been uneventful, with a medical history of hypertension, he had suffered two minor strokes and had surgery to repair an aortic aneurysm over the last few years. He did not smoke cigarettes, nor had diabetes or hypercholesterolaemia.

This acute episode of chest pain had unexpectedly occurred late one night after he returned from his regular billiard session at the local club. Initially dismissing the event as nothing to be concerned about, by the morning the intensity of the chest pain had increased. He went to hospital where he was diagnosed as having a subendocardial myocardial infarction. He was admitted to the medical cardiology ward and was scheduled to have PTCA three days later. A successful PTCA and intracoronary stent procedure was undertaken with no complications occurring. Gerald was discharged from hospital the next day.

The participants in this study had a diverse history of cardiac disease and the events that preceded PTCA varied from recurrent to acute episodes of chest pain. Although they had varying degrees of coronary artery stenosis, every participant had PTCA with an intracoronary stent inserted during the procedure. Although the diversity amongst participants made data analysis complex, a range of experiences have been presented.

Results—Themes

During the thematic analysis of the text, three major themes emerged from the participants' interviews—survival, knowledge and communication. Within each of these themes are a number of sub themes, that when considered together, fit within a theme. The table in appendix 4 provides an overview of the key concepts, sub-themes and major themes that developed during the thematic analysis.

Survival

In some way the participants' perceptions about their condition and the need for the cardiac interventional procedure (PTCA and/or intracoronary stent) related to survival. The theme 'survival' incorporated the following sub-themes: *no choice* about having the procedure, the need to consider *lifestyle changes*, *concern* about some aspect related to the procedure, *contentment* about the events that occurred, *discomfort* during or after the procedure and *no discomfort*. In some way these issues have impacted on the participants' ability to lead a complete and satisfying life. In some sub-themes, such as *no choice* and *lifestyle changes* it appeared that the participants perceived their survival to be dependent on these concepts.

The table below demonstrates how key phrases developed into key concepts, sub-themes and

the major theme—survival (see table 2).

Table 2: Theme 1—Survival

Key Phrase	Key Concept	Sub-theme	Theme
I'll die if I don't have it done (H:39) It had to be done (C 159) They had no choice (A:44) I could have kneeled over (D:289) Needed to do that (D: 107) I just about died (A: 44) They told me I need it (D: 110) Feel like trusting these people (W: 139) They know what their doing (W: 140)	No choice Die without it Necessary Nearly died Advice Trust	No choice	**Survival**
Trying to change our diet (M: 191) I don't need this (smoking) (H: 143) Tried to change (W: 456) Changed the diet completely (K:184) It is very difficult (K: 193) We eat healthy (B: 153) Negligent in exercising (W: 455) It's up to you (G: 367)	Need to change Try to change Change Difficulty with change Healthy lifestyle Activity Ownership	Lifestyle changes	
Drives you nuts (B: 123) Hardest part …to slow down (K: 158) The only concern …(J: 68) The thing that worried me … ((M: 92) I got really scared (J: 61) A relative rather frightened me (T: 91)	Frustration Concern Worry Fear	Concern	
I was quite happy (H: 111) I wasn't … wondering (D: 118) He was pleased with himself (D: 314) No complaints with anything (A: 128) Pleased with what was done (F: 294)	Happy Content Satisfied Reassurance	Contentment	
Laying in one position pissed me off (H: 98) I was in agony (D: 210) Uncomfortable to lay on your back (J: 132) Pain afterwards (T: 191)	Annoyance Agony Uncomfortable Pain	Discomfort	
You can't feel anything (B: 69) No pain (W: 108)	No feeling No pain	No discomfort	

No Choice

The sub-theme *no choice* incorporated concepts that described the participants' perceptions that they had no choice but to have the angioplasty procedure and that for them it was a decision between life or death. Carol said '*When they said it had to be done I just realised*

there was no choice' (C: 159).

Although the participants were saying that they did not have a choice, the decision of whether to have the procedure involved making a choice. However, not having the procedure may mean that they would have to live with the discomfort and symptoms of their cardiovascular disease and risk having further complications that may lead to death. Death was not considered an option and therefore having the procedure offered them the best possibility of survival.

After Henry's coronary angiogram the cardiologist informed him of the need to have PTCA to reopen the blocked coronary artery. He recalls

> *I remember she* [the cardiologist] *told me that you can die from it. I said 'what would you have done?' She said 'this'. I said 'well, do it'. I said 'I'll probably die if I don't have it done' (H: 38-39).*

Although Henry was warned he could die during the procedure he considered that he must have the procedure or death from the blockage in his coronary artery was inevitable. William also weighed up the risks associated with the procedure against the risk of death:

> *There is this risk and that risk. I suppose at that point you probably lay there and think there's a risk in every way. There is possibly a greater risk if these people* [who can perform this procedure] *didn't exist and you'd be dead (W: 284-295).*

The participants understood the seriousness of their condition and realised that having the procedure gave them a chance to survive and that without it they may die. Dorothy emphasised this by saying *'I realise in my life—I suppose I could have kneeled over, you know, with the clot ... I realise it's no joke. It's no light matter' (D: 289-292).*

After his MI, and with his pre-existing renal failure, Albert's condition was at times unstable. In his case the decision to have the procedure was one predicated on the notion that there was no choice. It appears that he also felt the doctors considered he had no choice. He explained that at first they (the Doctors) did not want to proceed with the procedure

> *'... because they didn't reckon me heart and kidneys was good enough to have it. That's why the doctor didn't want to do it. Then I got that crook in hospital, I just about died. They had no choice—they had to do it (A: 41-44).*

The advice of the medical staff was considered when participants made the decision to have the procedure. Dorothy explains how '*She* [the doctor] *came and told me they found this* [blockage], *and that I needed it—to have the angioplasty ... When they told me that I needed it I thought well—whatever it takes. I have to have it and I don't think I thought a great deal' (D: 105-114).* Dorothy trusted the doctor's advice enough that she didn't have to think too much about the decision. William also expressed this trust in the advice of the medical staff. He said *'... you feel like trusting these people* [the doctors] *that they know what they're doing, so that's all right ... If I didn't I'd probably be dead' (W: 135-141).*

The notion of trust and confidence in the medical staff expressed by patients having cardiac interventional procedures has been previously identified by other researchers as being reassuring to patients and promotes feelings of security.[33] Another study by Gulanick et al investigating patients' responses to angioplasty, found patients expressed confidence in the medical staff's ability to make decisions that were in their best interest.[17] In order for patients to make choices about their treatment it appears they seek the opinion of those they trust and feel confident to guide them in making decisions about their survival.

Lifestyle Changes

Most participants articulated their need to change their lifestyle in some way in order to improve their long-term survival. When asked if he understood why it was important to assess various aspects of his lifestyle Malcolm replied, *'I understand it might make me live a bit longer' (M: 212).* Les also recognised the need to change his lifestyle: *'It does make you think. How you reacted before and now after. I've got to make a few changes. I know that' (L: 300).*

Some were trying to change the factors they had recognised as important such as diet, stopping smoking and increasing physical activity. The study by Gulanick et al identified that the majority of participants had actively changed at least one factor of their lifestyle, usually related to smoking cessation, diet and exercise.[9] Cronin et al found that most modifications to lifestyle changes after PTCA related to activity and diet.[30] However, for some, such as Karl, any lifestyle change was difficult:

> *I don't smoke, I've changed my diet. Getting my cholesterol down to below 3,*

which I think is going to be fairly hard ... Just changed the diet completely. No salt, no red meats and more vegetables and generally healthy living ... It is hard ... I can understand why, but it is very difficult. I have got to learn to slow down and take things easy and stick to the diet really (K: 183-194).

For those who smoked tobacco prior to the procedure, this risk factor appeared the most difficult to stop. Betty found it hard especially when her friend who had the same procedure was still smoking with no perceived problems. She said *'I have stopped smoking ... I don't know if I can keep it up. Because I have a friend that had the same done ten years ago and she smokes quite a lot and feels fine' (B: 162-163).* Henry wanted to give up smoking and although it was difficult, he was determined. He said *'You would think, when I got a shock like I did, you'd be able to give it* [smoking] *up easily. But I come out of the hospital and thought I'll just have one. Tasted absolutely shocking, but I still smoked part of it and then threw it away. I thought I don't need this' (H: 140-142).*

Although a few participants stated they were satisfied with their lifestyle and changes were not necessary, they had still made subtle modifications. When Albert was asked if he felt he needed to make changes to any aspects of his lifestyle he replied *'No, not really, I'm pretty well right ... The only thing is I have stopped having salt in the meals and that now, which is a bit horrible' (A: 170-172).* William also felt no real modifications were necessary:

'The only thing that, I suppose also from my point of view, I thought in my general lifestyle I don't think I really do anything that's terribly excessive. The only thing that I could identify is that I really have been negligent in exercising for the past few years and that might then have [had] *an effect' (W: 152-155).*

It is possible that these participants felt cured of their coronary heart disease after the procedure and that there was no need to change their lifestyle. However, William had been one of the participants who had not received any information or instructions about how he could modify his lifestyle. Although he found this 'surprising' he appeared to have dismissed it as being of importance saying, *'I get the feeling that they think that all the medication they are throwing at me sort of will cure all the evils that exist in an average person and that possibly telling people not to do this little thing and that little thing may not be really relevant' (W: 445-447).* This is an example of how patients look to health professions for information and direction. If it is not forthcoming it can be perceived as unimportant. As Gaw suggests, health professionals should not assume that patients have adequate information about lifestyle changes.[21]

Gerald, who received discharge information about lifestyle changes, recognised that the responsibility for change rested with the individual. He said

> *There are different things that the person does in his life, how can I put it. Can you tell a person that is always physically active to sit still ... A person knows when he's overweight. He knows. He or she knows. Sometimes they can't do nothing about it. Same as people can't stop smoking. But to tell you* [about lifestyle changes], *then it's up to you (G: 355-367).*

Although it has been suggested that some patients tend to want others to make decisions and assume responsibility for their health and well being, this was not the perception of participants in this study.[21]

Concern

Some of the participants in this study expressed emotion that indicated there were issues that concerned them.

Tanya was frightened of the risks associated with the procedure. She said

> *The doctor I saw beforehand, he explained to me what I was having and what could happen—that you can have a stroke or heart attack. That frightened me, but I'd already been told that when I had the angiogram.* [However] *I was still nervous' (T: 88-90).*

As opposed to Tanya who was frightened by the potential for problems, Jim unexpectedly experienced chest pain during the procedure that frightened him, as he had not been advised of the potential for pain. He described the event:

> *The only time I got really scared, I got the shock when I got really bad chest pains. I knew something wasn't right then and that was the only time that I was really a bit concerned because the pain was unbelievable. (J: 61-63).*

The emotions expressed by Tanya and Jim have been previously highlighted by Higgins et al[38] and Gaw[21] who identified anxiety related to the presence of chest pain and complications from the angioplasty.

Malcolm's concern related to the events that occurred during the procedure when it became apparent that the cardiologist was having difficulty with the balloon catheter placement.

> *The only thing that worried me on the table was I could hear everything that was going on. They were having trouble getting there* [into the correct position with the balloon] *and it didn't sound like they were going to get there ... you could hear everything that was going on and you think what is going to happened to me, am I going to get there or not? ... Several attempts getting down there and then you know they have to pull it out again* [the catheter], *and start again, and you think then, 'what's going to happen to me?' (M: 92-105).*

Previous research has identified similar tensions arising from activities occurring in the catheter laboratory during the procedure.[52] This event highlights the need for health professionals to be aware that cardiac interventional patients are conscious during the procedure and aware not only of the physical environment but also the conversations and activities that take place around them.

Some of the participants were frustrated by events that occurred after the procedure. Carol explains that one issue of concern was:

> *I was flat on my back. They brought tea and then they put it on my chest and said 'eat it!' It was a big dinner plate full and the nurse cut it up and she said here you are. There—have that! It was a bit hard to lie and eat like that (C: 196-197).*

Betty also found that lying flat in bed was frustrating. She said *'You mean like—I'm not allowed to do nothing and I just keep quiet and rest and rest ... It drives you nuts. Especially when I'm normally an active person' (B: 123-125).* Although the participants understood the need to lie flat in bed after femoral sheath removal, none were normally dependent on others for assistance (as in Carol's case with her meal), nor were they used to long periods of inactivity (highlighted by Betty). Peterson, who also identified lying flat for prolonged periods as a source of concern to patients after cardiac catheterisation, stressed the need for staff to provide support and reassurance during recovery from interventional procedures.[53]

Contentment

Although there were some issues that caused concern for the participants, they also expressed contentment when reflecting on the events that occurred. Although Henry was frustrated that he couldn't come home as early as he would have liked, he was content with the care he had received. He said *'The whole process in there I was quite happy with. Nothing upset me, except that I couldn't come home' (H: 111-112).* Dorothy also was happy with the care she received. She felt well informed and reassured by the doctor's contentment with how things had progressed.

'I wasn't at any time wondering where I was going or what they were going to do (D: 118) ... I think I was fairly happy. I knew what was going on. My heart coil—I knew [about] *the balloon and why the coil would hold it. The doctor said the job was finished and he was pleased with himself' (D: 312-314).*

As with Dorothy, Betty also felt reassured by how others perceived her health after the procedure. She said *' Lot's of people—my friends say I look heaps better now' (B: 200).* Betty appeared content that others could see an improvement in her health. Some of the participants felt contentment because they could see the improvement in their condition and felt better after the procedure. Albert said

I was that pleased to have it done, with what I'd gone through before, I didn't care what happened really. I was past the stage of caring ... I had no complaints with anything (A: 125-128) Everything is pretty right now ... Pretty good job I reckon (A: 210-225).

Although Frank's recovery had been slower than expected he was pleased with the outcome after the procedure.

I've been pretty good since I've had it done. It took me a little while to get back on my feet properly again ... Really I am quite pleased with what was done ... Beforehand it was very tight across there [points to chest]. *But since I've been home—no—it's been great (F: 284-297).*

Higgins et al reported that participants felt a positive response when a total relief or reduction of chest pain occurred after angioplasty, as this symptom had generally been the motivation for undergoing the procedure.[38] Previous findings from a study by Eastwood suggested that PTCA/stent procedure renews feelings of well-being, improved quality of life and enhanced physiological outcomes for patients.[29] Participants such as Frank, who had severe chest pain and Albert, who was unstable after his MI attributed their improved state of health and well being to the PTCA/intracoronary stent procedure.

Discomfort

Some concerns the participants expressed were related to pain and physical discomfort either during the procedure or during the recovery period. Jim, who had a MI during the procedure, was concerned about the *'unbelievable'* chest pain when this occurred. He also found it *'uncomfortable to lay on your back for a day and a half* [when] *you can't move' (J: 132-133).* Most of the participants made some reference to the discomfort they felt having to lie flat and

immobile for prolonged periods before and after femoral sheath removal. For Dorothy this immobility became an issue of major discomfort and anxiety. She explains how she felt:

> *I have a dread now—a real dread of that time—keeping that leg straight ... because I needed to go to the toilet ... I was in agony, because they brought me a pan and I couldn't go ... I wanted to move my leg and eventually they lowered my bed down, because I was moaning ... I brought it on myself, with the delay, thinking 'oh well, when the operation is over I'll be able to get up' (D: 198-220).*

Angioplasty patients in the study by Gulanick et al (p.29) also expressed 'a terrible urge to urinate and not knowing what to do'.[17] Prior to the procedure Dorothy had felt the urge to urinate but thought she could wait until after the procedure. It may be that patients, such as Dorothy, do not anticipate how long the procedure will take and are uncertain about how long they will be expected to be immobile in bed afterwards.

No Discomfort

In contrast, some participants were amazed there was no physical discomfort associated with the procedure. Betty said *'It's amazing to me. You can't feel anything* [during the procedure], *but you're still awake' (B: 69-70).* William expected to feel something during the procedure and was surprised when he did not. *'You have an expectation that if someone is sliding something through your artery that you should feel it. It's just your expectation, but of course, you can't. You haven't got a clue' (W: 156-158).*

The expectation expressed by William was common amongst the participants as they all said they had been warned of the discomfort and 'hot flush' associated with the dye and that they could feel some chest pain associated with the pressure exerted during the balloon inflations. However not all participants experienced this. William described his expectation:

> *No, no pain. I didn't feel anything. There was just a hot flush when they first put the dye in, but that was, you know, as if you wet yourself. You would swear you had—it had run down your legs and everywhere. Just a flush went through your chest. I hardly felt anything. You feel it going in. That's all. They warned you about that ... Warned about that and they drummed in to me that you'll think you've wet yourself ... I was preparing myself for a lot more pain and hot flushes, but that just didn't—you could feel it go in and that was about all (W: 108-116).*

The broader theme 'survival' demonstrated the participants desire to overcome their illness and live a healthy life. For some participants 'survival' involved making decisions about their

treatment and lifestyle and overcoming emotional concerns and physical discomforts associated with the procedure. Others appeared content and happy with their condition. The different perceptions expressed by participants appeared to be associated in some way to the level of expectation, understanding and knowledge they had about the procedure and follow-up care.

Knowledge

The theme 'knowledge' incorporated the following sub-themes: *understanding* of the treatment, more questioning and *uncertainty* about various issues, the use of *informal education* techniques for patient learning, *planned education* sessions and *family involvement* in acquiring knowledge and understanding.

The table below demonstrates how key phrases developed into key concepts, sub-themes and the major theme—knowledge (see table 3).

Table 3: Theme 2—Knowledge

Key Phrase	Key Concept	Sub-theme	Theme
The cardiologist explained all this before he did it (J: 60) They explained everything to me (K: 146) I knew exactly what was going to take place (A: 87) I sort of had that in my mind (W: 103) I know what they did now (F: 110)	Explanation Expectation Preconception Understanding	Understanding	**Knowledge**
Happened … without me knowing (W: 209) Will it last forever? (B: 250) There are things you want to know (W: 541) They never explained the reason (M: 138) I don't know one from another (F: 206)	Unprepared More questions Additional information No explanation Unsure	Uncertainty	
Heaps of books (H: 155) Lots of pamphlets and things (B: 121) They showed us what it was (M: 78) Showed a stent (L: 137) Gave us a video (A: 54) They sat down and talked to you (B: 185)	Written materials Visual teaching Auditory media Verbal teaching	Informal education	
Classes— exercise classes (H: 132) I went to the lecture (D: 241) Every Wednesday up here (B: 47)	Rehabilitation Regular sessions	Planned education	
He wants to know (B: 55 My wife was there every day (J: 45) She is supportive (M: 264) She reassured me (G: 204)	Seeking information Family presence Family support Reassurance	Family involvement	

Understanding

The participants who had an understanding about the procedure were those who had their general practitioner, the cardiologist or a nurse at the hospital, explain why they needed to have the procedure and what it would involve. When asked about their understanding of the PTCA procedure the participants had varied perceptions and understandings. Jim described what he understood to have occurred. He said

> *The cardiologist explained all this to me before he did it—what they were going to do, and then they would insert the stent, so I already knew what was going to*

happen (J: 56-61) ... It's [the stent] *a type of stainless steel piece of wire mechanism and they feed it through the artery to where the artery is blocked, which they open up with this balloon. Then when they get it into position, whatever they do, it opens up and stays open and leaves the artery wide open. They gave me photographs of what they did after and it's just absolutely amazing what they do. It was like comparing the gutter that runs down the front of the house here before they started with it and by the time they finished with this stent in it— it looked like the River Murray! It was amazing.*

Karl also felt he understood what the procedure involved after his local doctor's explanation. He described the procedure as *'... put*[ing] *the balloon through the vein to actually clear any build-up or any narrowing's in the main veins and arteries and if there's a weak point they put in a stent, which I had, and other than that, that's about it' (K: 111-113).* Les gave a vivid description of PTCA when he said *'It's a tube put into your artery, isn't it, with a balloon on the end and they blow it up—when they get to the part where it's choked up, they blow it up and they squeeze all the fat out against the walls of the artery' (L: 114-116).*

For those who understood the explanations they were given prior to the procedure they felt prepared about what to expect. Albert *'...knew exactly what was going to take place ... as they* [the doctors] *had prepared him right up to the* [procedure]*' (A: 86-87).*

Some participants had preconceptions about the procedure from information they had received from friends who previously had PTCA or through the media. This preconception was reinforced by the explanations they were given prior to the procedure. William's response was an example of this *'I suppose they were reasonably specific about what it* [the procedure] *would involve. I had remembered seeing a TV program on it a couple of years ago, so I sort of had that in my mind as well, to back up the things I was being told' (W: 102-104).*

Although Frank did not have an understanding of PTCA before the procedure, he developed an understanding afterwards from reading information he was provided with in the ward. Frank said *'To make it clear, before I came out of the ward they came with a little booklet ... I know what they did now' (F: 107-110).*

Uncertainty

As opposed to those participants who had been given explanations prior to PTCA, others felt unprepared for the procedure. Frank, was one of the participants who were initially scheduled

for coronary angiography. Although he had been warned about the possibility of going onto to have PTCA if a stenosed lesion was identified, nobody really discussed with him what PTCA involved. The only thing the cardiologist had said was *'Well, I think we had better do an angiogram and see what is causing this* [the chest pain*]... if we can do anything to fix it when we are doing it—we will' (F: 34-36).*

William had a similar experience as he *'... was admitted on the view that they were going to let* [him] *out* [of hospital] *a few hours later' (W: 98)* after the angiogram. When he was asked whether anyone talked to him about the possibility of PTCA he said:

> *Look, they might have, but I suppose because you don't know and you don't necessarily expect it—I think the specialist might have told me that you go in and you have the angiogram and then, based on that, there was this chance you would have this other intervention, but it didn't really seem to connect to me at the time because I had no idea (W: 118-121).*

As a consequence, William also felt unprepared for the events that would occur when he returned to the ward.

> *All of that happened really without me knowing what was going on, because I got wheeled out, sort of was laying there. The lady came up, showed me the photos, a few people came around with forms, this that and the other—and people might have said you are going to get shifted to a ward or something. But I had no idea that was going to happen. I didn't know that I'd just be laying there for 24 hours (W: 209-216).*

Although some participants developed an understanding from reading written materials after the procedure, they were still uncertain about various issues related to the event. Consequently they asked questions throughout the interview. Dorothy said *'I had some literature later, so I read it when I got home... What I haven't understood was will that* [stent] *last for years? Will it ever have to be taken out and replaced?' (D: 132-134).* Questions related to the intracoronary stent were common: *'This stent—is it going to last forever? Will that last forever?' (B: 250); 'Just a question—can they ever take it out?' (G: 424).* It appears that patients want to be more informed about their condition and that a little bit of knowledge about one particular aspect of their management led to a desire for more information. As William said *'You're told a little bit of information but you really don't know' (W: 197) ...I suppose now that it's happened there are things you want to know' (W: 541).* This desire for

additional information has been identified in previous research[30] and it has been suggested that additional information is sought to demystify the unknown and reduce fear and anxiety about the procedure.[33]

However, not all participants had issues of uncertainty. Malcolm was uncertain about some of the medications he was prescribed after the procedure. *'It wasn't explained to me—just take the tablets I was given—I have got to take them. They never explained the reason for the tablets or anything, they just said these are tablets you've got to take, you know (M: 137-139).* Frank was also unsure about his medications: *'...I've got tablets I'm taking. I don't know one from the other'(F: 206).* It appears that when just given instructions without any explanation, patients are left uncertain but do not always seek further clarification and explanation. Beckerman also found that some individuals deal with stress by not seeking additional information as this could increase their anxiety.[33] William alluded to this by saying *'I suppose, because you probably can't give too much information before it [the procedure] because you don't want to scare some people' (W: 429).*

Uncertainty about PTCA and how it would reduce cardiac symptoms was identified by Gaw[21]. However, she identified that although these patients were uncertain about the events that had occurred, they were certain that PTCA would alleviate their heart problems and hopefully cure them.[21]

Informal Education

A major focus of this study was to identify what type of information or learning resources were used in the education of PTCA/stent patients. Although a variety of tools appeared to have been utilised, every participant in this study received some form of written material that pertained to coronary angioplasty or lifestyle changes. Frank and Malcolm, made comments such as: '[They] *brought little books and brochures' (F: 176)* and *'They gave me several books to read on what to expect' (M: 69).*

Betty felt well informed and pleased with the amount of information she had received, particularly in relation to a friend who had previously been through a similar experience. She said

> *'... we got all these things after heart attack—what you should be doing,*

what you shouldn't be doing' (B: 59-60)... Like I said, a friend of mine had it done ten years ago and she said she got no information at all. So I showed her all the things I got and she thought that was amazing' (B: 229-230).

However, despite being given written materials, some participants such as Henry had not read the materials. He said *'I think they gave us a heap of books—on diet'*, but when asked if he had read them, he replied *'No'. (H: 155-157).* Although Henry had not read the materials it was obvious his wife (who was present during the interview) had. It appeared that Henry was confident his wife was informed and it was not essential that he read the information.

In addition to written materials other resources were used to educate participants about the procedure. Several participants had viewed videos of the procedure: *'I saw the videos in* [country hospital] *before I went over* [to the study institution]. *They were all available' (K: 94).* In this study those participants who were transferred from a country hospital to the study institution for the procedure, such as Karl, Malcolm, Jim and Albert, all made reference to seeing videos. One of the city participants, although expecting to view a video, never did. She explains *'The nurse did tell me that they should have showed me a video before—but they never showed it' (C: 128-129).* Perhaps the high turnover of patients in the acute hospital setting and the short hospital duration of cardiac interventional patients does not always allow the time to utilise all available teaching resources.

Visual teaching aids seemed to reinforce the participants understanding and expectations about the procedure. Malcolm, who had been shown a stent prior to the procedure, said *'It's a type of spring, or a collapsible spring. They showed us what it was' (M: 78).* Les also had been able to visualise a stent beforehand: *'One of the nurses showed a stent acting as a paperweight. It was inside a paperweight' (L: 137-138).* Conversely, William who felt he did not receive enough information about the procedure suggested that being able to see a stent beforehand would have been beneficial. He explains:

I really would have loved someone to come up to me and show me a stent ... I would have loved to have held in my hand either a cheap plastic imitation of it or a real one, just to see what this thing is that's inside of me. Or even a little model in your hand that has a stent inside a pretend artery. It think that would be important to get this idea in your head (W: 174-181).

It appears that although stents are available for patients to visualise before the procedure not all participants were offered the opportunity to do so. Another participant, Gerald also

suggested that showing patients what was happening during the procedure would help them to understand things more. He said *'I think it would be better, if you ask me, then I would say just show the people what's going to happen and then that's it. It's the same as me teaching people to cut a piece of wood—like in my trade. You show them' (G: 243-245).*

During the interview every participant referred to the angiogram photographs they were given that showed the blockage in their artery before and after the PTCA/stent procedure. As Albert said, this visual aid was educational: '*I have the x-ray copies* [angiogram photographs] *here at home ... They showed where the blowouts were and how they fixed them and all. It was really educational that' (A: 76-80).*

In addition, a few participants were also given audiotapes about 'heart attack' and 'lifestyle' to listen to. Betty found these audiotapes, together with the opportunity she had when the nursing staff *'...sat down and talked to you' (B: 185)* gave her an understanding of what was expected after discharge from hospital.

Tooth et al suggest videotapes; audiotapes, pamphlets and other written material are the most effective means of educating patients.[37] They also suggest patients learn best by viewing videos of, or talking to other patients who have had PTCA. Although there may be limited opportunity to educate cardiac interventional patients before and after PTCA and/or intracoronary stent procedures informal educational efforts are effective.[17]

Planned Education

Only three participants had the opportunity to attend the formal cardiac rehabilitation lecture prior to discharge. Although reluctant to attend, Henry found the session worthwhile. '[The nurse] *told me to go to this rehabilitation thing. I thought ... if I don't go they probably won't let me home, so I went and it was interesting ... I was quite surprised how interesting it was' (H: 118-121).* Dorothy also found the rehabilitation lecture useful in preparing her for what to expect after discharge. She explains

> *I went to the lecture. I didn't think I would be able to go because I was having someone pick me up at a certain time and so I said no I couldn't go. I think it was then that she handed me the books and then I got a message it was going to be picked up later than I thought, so I followed the other ladies down to the lecture. I found that very helpful, especially that I wouldn't feel so well, which has helped*

me because I am alright for a little while then I get this terrible tiredness. The lecturer said to expect that for a couple of weeks. It would take about six to eight weeks (D: 241-249).

It was clear when talking with the participants that not all of them had been informed about the rehabilitation lecture. As these formal sessions were not scheduled daily, it is unclear whether they did not attend because they were not informed or whether there was insufficient time prior to discharge to attend.

The study institution also provides a six-week follow-up cardiac rehabilitation program. Not one participant in this study attended these sessions. Henry explains

I got a letter—I was supposed to go to the classes, exercise classes ... But I'm getting more exercise than I would there anyway and besides, they had it about half past ten, eleven o'clock. I'd have to go to work, come home, have a shower, get in there. I mean, I'd only go to work for an hour in the morning, so I haven't worried about going. I guarantee I'll get enough exercise (H: 132-137).

Although Henry was informed about the follow-up program, it was not convenient for him to attend. Tanya, who lived in the country, wanted to attend but the long distance required to travel to the study institution would have been inconvenient. Betty, who had been transferred from a country hospital to the study institution for the procedure, had attended a follow-up cardiac rehabilitation program but this had been organised by the country hospital rather than the study institution. The country hospital had regular follow-up rehabilitation sessions that Betty had been attending.

... every Wednesday up here, people who have heart attacks and have had angioplasty done—in the morning on Wednesday, there is a thing [cardiac rehabilitation]*—you can go there and you can talk to a lot of people who have had it* [angioplasty] *done (B: 44-49).*

Family Involvement

Almost every participant had family members involved in some aspect of their hospital admission for PTCA. Betty explained that it was important for her husband to hear what the doctor was going to say about the procedure *'... because he wants to know things about that* [angioplasty] *too' (B: 55).* For some participants family presence was important, as they were also present during information and education sessions. Jim said *'My wife was there every day while I was in there* [hospital] *... so she got to see the video too' (J: 45-46).*

Previous research found well-educated partners of myocardial infarction patients retained more knowledge from education sessions than patients and consequently passed on and reinforced information to the patient.[54] Family members have been found to promote increased motivation and keep patients within an established lifestyle modification regimen.[21] Eastwood highlighted the need and potential value of family involvement.[29] This author also identified that family involvement in patient education, reduced anxiety and promoted better understanding of the patient's situation.[29]

Gerald said *'My daughter stayed for a while. She reassured me all those things when you're nervous' (G: 204)*. Like Gerald, several participants found family presence to be reassuring. However, the increased knowledge of family members may also lead to further questioning. Malcolm said *'She* [my wife] *is very supportive but she is not coping the best ... she is concerned about the diet part of it ... Can you talk to her for a while?' (M: 264-268)* Tooth et al identified that family members are more likely to seek information about psychological reactions and recovery issues as these areas impact on themselves.[37] It may be necessary to also consider family needs when educating patients and their partners about recovery and rehabilitation issues.

The participants 'knowledge' about their condition and the events that had occurred were often dependent on their understanding and expectation of the situation. Although some seemed satisfied with explanations about the procedure and the type of information they had received, others were uncertain and still required further information. The participants 'knowledge' appeared to be related to the manner in which information was communicated.

Communication

The third theme entitled 'communication' incorporated the following sub-themes: a *lack of information* about their care; *instructions* after the procedure; *language and informed consent*; *retention and reinforcement* of information; and *time and information* sharing.

The table below demonstrates how key phrases developed into key concepts, sub-themes and the major theme—communication (see table 4).

Table 4: Theme 3—Communication

Key Phrase	Key Concept	Sub-theme	Theme
Nobody really said … (W: 451) No one talked to me (F: 259) I didn't know (G: 150) Left up in the air … guess work (W: 241)	No communication Unprepared No information	Lack of information	**Communication**
Got to lay straight (H: 95) Not move at all (J: 115) They tell me I have to lie flat on my back (B: 90) Told me I had to take it very easy (K: 149)	Orders Being told	Instructions	
Described in possibly the most gruesome manner …(W: 287) Die if I don't have it done (H: 39) She told me … that I needed it (D: 105) I had to sign (F: 80) Stroke or heart attack … they've got to tell me (T: 144) They could have said about the reaction to the drugs (M: 134)	Graphic description Threatening Persuasion Consent Potential problems	Language and informed consent	
A bit day-dreamy … worried about other things (W: 199) You hear it but it doesn't register (G: 81) I can't remember (T: 212) I would have liked if he had come the next day (G: 78) Go home with it…read it (W: 528)	Distracted Not retained No memory Reinforcement	Retention and reinforcement	
Was it before or after … (D: 92) Time didn't mean much (F: 70) Overnight, but not 30 hours (M: 129) I didn't know it was going to take that long (B: 95) Wouldn't have been able to take it in (H: 44) But afterwards a little bit more information (W: 432)	No concept of time Longer than expected Not ready More afterwards	Time and information	

Lack of Information

For some participants there appeared to be a lack of communication about information they required in order to understand and be informed about their condition. William would have liked for someone to give him some suggestions about lifestyle modifications. *'I felt that nobody really said to me what I should or shouldn't be doing ... I* [would have been] *quite*

happy if somebody said "do this or don't do that ... the do's and don'ts for the future' (W: 451-466). Frank had a similar experience: *'No one talked to me ... It probably would have been a help just to sit down for half an hour or twenty minutes, or whatever, and just talk about it' (H: 259-160).* As a consequence, neither William nor Frank had acknowledged the need to make lifestyle changes.

When participants, such as Gerald, were not fully informed about the procedure they were left unprepared for some of the events that occurred. *'The balloon*—[I saw] *the picture of it—and they put it in and pumped it up and spread it and when it is out—but I didn't know they were going to put a stent in ... a stent is probably something special' (G: 149-153).* It appears that in some cases participants are not given as much information as they required. It may be that health professionals assume that patients have some prior knowledge of their condition or issues related to their management. William had never been hospitalised prior to having PTCA. Not only was he not fully informed about the procedure, nobody said anything about being a patient in hospital.

> *I'd never been to hospital before. I suppose that made it probably a little different for me compared to a normal person who has been in hospital regularly. So I had no idea what would happen to me. I had no idea even how the ward would operate ... Even something simple like what happens with meals, the TV or whatever. All those things were left up in the air as a sort of guesswork (W: 234-241).*

Instructions

Some participants were instructed to behave in certain ways, particularly during the recovery phase rather than being given informal or planned education sessions. Although explanations for the instructions were sometimes given, they were usually relayed as orders and accompanied by the threat of complications if they did not comply. Henry said *'When they brought me back they said they were leaving the sheath in there for a while—got to lay straight they said, because we have got to thicken your blood up because it has been thinned out. We can't take it out or you will haemorrhage' (H: 94-96).*

Jim had a similar experience related to the femoral sheath. *'They said I had to lay flat on my back for nearly a couple of days and not move at all. They said to me ... Because of the danger ... So I had to lay there about a day and half without moving (J: 115-120).*

Others were told what to do without any explanation. Betty gave an example: *'They tell me I have to lie flat on my back and not move ... then after a certain amount of hours they will take that* [femoral sheath] *out' (B: 90-91).* Prior to discharge from hospital Karl had a similar experience: *'... they told me I had to take it very easy and not do too much and make sure a diet was kept to and any chest pain at all—go straight back (K: 150-151).* It is possible when information is communicated in this manner and without explanation that patients are not fully informed about their care and may become anxious and frightened about what to expect during their recovery.

Language and Informed Consent

The language used by the doctor to inform the participants about the procedure appeared to influence the participants' perceptions of choice. Rather than discussing all of the management options so that participants could make informed decisions about their treatment, the language and manner in which these conversations took place made participants feel they had 'no choice' but to have the procedure. Williams' doctors gave a graphic description of cardiac surgery as an alternative to PTCA.

> *He* [the cardiologist] *has an interesting way of communicating things ... there's no mucking around. He stood there and he said 'bad luck, you've got this' and then he said the alternatives. You could have a bypass* [cardiac surgery], *which he then graphically described in possibly the most gruesome manner you can ... Hacking the chest open! It was very graphic! I thought that—I thought no thanks. He did his job of really graphically saying that and then he said we could try the stent and it may not be 100% successful and we don't know. There is this risk and that risk. I suppose at that point you probably lay there and think there's a risk in every way. There is possibly a greater risk if these people didn't exist and you'd be dead (W: 284-295).*

In effect, this description "persuaded" William to have the interventional procedure, as he perceived he had 'no choice' as the alternative, cardiac surgery, was not appealing. It was not uncommon for participants to have explanations in a coercive manner such as this. Both doctors who discussed the procedure with Henry and Dorothy told them they *'...needed it' (D: 105)* and they would *'... probably die if* [they didn't] *... have it done' (H: 39).* When doctors use such language it may be perceived that participants were coerced, albeit not consciously, into having the procedure.

Although consent for the procedure was not always obtained using highly emotive language often participants, such as William, felt obliged to sign the consent form. *'If someone says you've got to sign this, unless you have any real great objection to signing it, what are you going to do, say no' (W: 130-131).*

On occasion the language used by the doctor to obtain consent was more casual. Jim explains: *'... they said to me, when you are dealing with this sort of situation that there are complications that can arise, but most cases you are only going to be in there for twenty or thirty minutes maximum' (J: 69-73).* Franks example was similar: *'I had to sign ... The surgeon came and said what he was going to do, and I'll be all right and that sort of thing (H: 74-84).* Although the doctors had not dismissed the possibility of complications during the procedure, they had barely alluded to them. Malcolm was concerned that he had not been warned about the possibility of having an allergic reaction to the contrast dye. *'They could have said about the reaction to the drug that brings your platelets down. One in one hundred react to it and there was nothing said about that' (M: 134-137).*

However, for Tanya it was different. Her doctor had been specific about the potential problems that could occur during the procedure. *'... he explained to me ... that you can have a stroke or heart attack. (T: 88) ... That's what I was really afraid of, but I mean I know that they've got to tell me that*—[even though] *it isn't common for it to happen (T: 144).*

Retention and Reinforcement

It is possible that during the interview some of the participants could not remember being told about particular aspects of their care. Williams explained that he recalled being told *'... a bit of information'* but could not recall what he was specifically told about the recovery period. He said *'... after the operation you are still a bit day-dreamy and you are worried about other things' (W: 198-199).* It is possible that William does not recall this information as he was distracted by thoughts related to the procedure and his concern that everything had gone okay. William had a lot to contend with as he had only been expecting to have an angiogram and ended up having PTCA and intracoronary stent deployment.

Gerald admitted that he was anxious before the procedure and consequently he did not retain everything that he was told. *'You rely on the nurse, one nurse says something, another nurse*

mentions another thing. Personally I was rather uptight—pretty uptight. You hear it but it doesn't register—in my case' (G: 79-81).

Tanya could not be sure that she was given any information before she was discharged from hospital, as she could not remember. *'I don't think that was mentioned—unless I forgot. I can't remember anything like that. I just thought, oh well, I felt all right' (T: 210-213).* It is possible that because Tanya felt better after the procedure and she was keen to go home she did not retain information that was given to her prior to discharge.

Gerald was pleased that his daughter, who was a nurse, was able to reinforce the information he had not retained prior to the procedure, as he could not remember everything he was told. In addition, he wanted the doctor to come back after the procedure to reinforce information: *'I would have liked if he had come the next day and said this is what happened' (G: 78).*

William suggested that being given written information and instructions about lifestyle modifications prior to discharge would reinforce patients understanding about what to expect as they could review it as necessary. *'They go home with it. Their children, who can speak English better, read it, and say what granny should do, or, I can go back and think what did they say about doing this and I look back and go oh—yes' (: 528-530).*

Burke previously identified that single education sessions did not always ensure patients understanding due to poor learning and information retention in the acute care setting.[55] They suggest several information sessions, both in hospital and after discharge, may be required for patients to effectively remember information about their condition.[55]

Time and Information

Time emerged as a concept that was linked in some way to the type and amount of education and information the participants received. Dorothy knew she had seen a video about angioplasty but could not remember when it was that she saw it. *'Was it before of after? I think it was before ... that the nurse brought in a video and, I think it was before? So I had an idea, but I didn't have a lot of information* [about the procedure] *(D: 92-97).* She goes onto say *'I think I got most of the information—I think I got it more on the spot, rather than before' (D: 116-117).* Although Tanya thinks she saw a video beforehand the information she retained appeared to have been given to her at the time of the procedure rather than

beforehand.

When Frank talked about the events that had occurred leading up to having the procedure he commented that *'He forgot what time it was* [when he had the procedure]. *Time didn't mean much' (F: 70).* However, for others such as Karl, the time spent waiting to have the procedure was an issue of concern. He said *'we flew from* [country town] *to* [the city] *expecting to get straight to the ward and we were actually stuck there for hours. Got there at 11.30 and we weren't admitted to the room until 4.30 in the morning' (K: 241-243).* Karl knew that the country hospital had arranged for his transfer to the study institution and consequently could not understand why it took so long for them to arrange for him to be admitted. Considering the technology of today, he felt that the *'transfer of information could be a lot better' (K: 243).*

Although some of the participants had been given information about having to wait for certain things to occur, they were still surprised at how long it took. Malcolm did not expect to wait as long as he did to have the femoral sheath removed. *'I had to wait 30 hours because the platelets had gone down that far they couldn't take it* [the femoral sheath] *out. I was expecting to be overnight, but not for 30 hours' (M: 127-129).* Betty didn't expect it to take as long as it did for the bleeding to stop after the sheath was removed. *'He took, about twenty minutes. I didn't know it was going to take that long, you know, to get the blood to stop' (B: 90-95).* Whereas for Albert *'it didn't take that long to stop the bleeding—it was just the time he was pressing down on the wound afterwards which seemed to take hours' (A: 108-109).* Beckerman et al found that unexpected or prolonged waiting without explanation was associated with fear and anxiety of possible complications.[33]

When asked about the kind of information the participants were given prior to the procedure, some commented that they were not ready to take it all in. Although Henry did not recall being told very much before the procedure, he felt he was not ready for a lot of information because *'he was too far out of it ...* [He was] *really very vague on the Sunday and the Monday in the hospital. It wasn't until about Tuesday night that I started to feel myself again (H: 42-45).* Perhaps for those patients who have had episodes of acute chest pain immediately prior to the procedure, it is not possible for them comprehend detailed information and education sessions prior to the procedure. William felt he could take too much information beforehand, but suggested *'afterwards a little bit more information would have been fine'. (W: 432).*

The ideal time for patient education and teaching has not been established as individuals process information and learn in different ways.[37] With less opportunity to educate patients in hospital prior to cardiac interventional procedures, where possible alternative education strategies, such as pre-admission assessment and teaching, may need to be considered to prepare patients for procedures.[37]

The language and manner with which information pertaining to the procedure, follow-up care and lifestyle were communicated to participants, appeared to shape the perceptions they expressed. In addition, the timing of education and information sessions appeared to influence what information was retained by participants and the need for further reinforcement.

Discussion

This study was designed to identify the educational methods used to inform cardiac patients undergoing cardiac interventional procedures prior to, or after PTCA and/or intracoronary stent procedures and to determine whether they received information prior to hospital discharge about cardiac rehabilitation. An unstructured interview was undertaken to elicit this information from the 13 participants who agreed to participate in the study. During the thematic analysis, three major themes emerged from the participants' interviews—survival, knowledge and communication. Within each of these themes are a number of sub themes. Some of the key words and concepts that emerged during analysis were common to more than one sub-theme. However, when considered within a major theme these words and concepts took on related but different meaning for the participants. In addition, although each major theme has been presented separately, many of the concepts linked in some way across the three major themes.

The theme 'survival' demonstrated the participants desire to overcome their illness and live a healthy life. Despite the associated risks, several participants perceived they had no choice but to have the angioplasty procedure as it was perceived that this option would resolve the symptoms of their cardiac disease and improve their overall health. In addition, most of the participants recognised the need to make some modification to their lifestyle, as this was perceived as beneficial for their long-term survival. The participants perception of their

survival and well being was influenced by emotional and physical responses to events that occurred during and after the procedure. Although participants talked about issues that showed they had some emotional concerns and physical discomfort, others were not concerned, did not feel any physical discomfort and appeared satisfied and content with their condition. The different perceptions expressed by participants about their health and well being were linked in some way to their level of expectation, understanding and knowledge about the procedure and follow-up care.

The theme 'knowledge' emerged in relation to the participants level of knowledge about their condition and the events that had occurred. Knowledge appeared to be dependent on their understanding of the situation. Those who had a preconception of what would occur, or had prior explanations, appeared to understand what had occurred, whereas those who were unprepared because they had no explanation remained uncertain about some events. These participants expressed a need for more information. Knowledge was gained using various informal educational techniques, utilising written visual and auditory teaching tools. For some participants knowledge was gained by the attendance of planned rehabilitative education sessions. The presence of family during education sessions appeared important in providing support, reassurance and reinforcement to participants. However, the level of understanding and knowledge gained by participants was also related to the manner in which information was communicated.

The theme 'communication' emerged in relation to what, how and when information and education was given to participants. For some a lack of information left participants feeling unprepared and uncertain about events. In addition, the level of explanation that was given about certain aspects of their care left participants with either an understanding and clear expectation of the events that would occur, or feeling unprepared and seeking additional information and reinforcement. The language and manner with which explanations and information was imparted appeared to influence the participants perception of their ability to make choices about their condition, with those having explanations in a threatening and persuasive manner perceiving there was no choice but to have the procedure.

It became evident that not only did the need for information vary amongst participants but so did the level or degree of description and the need for additional information in a variety of forms such as written, visual and auditory tools to reinforce the verbal education. In addition

the timing of education sessions influenced some participants ability to retain information, particularly if they were distracted or concerned about their acute illness. These participants suggested that more information and education be given after the procedure to reinforce the initial explanations. Family presence during these follow-up education sessions would also seen to be beneficial in providing reinforcement.

In response to the proposed research questions, the overall findings of this study demonstrated that all of the participants received some form of educational preparation prior to their cardiac interventional procedure. The person that prepared them for the procedure varied from the local doctor, cardiology specialist, nursing staff present at their local hospital or the study institution, or a combination of these people. On occasion, family members were present during explanations and educational tools such as audiotapes and videos were utilised during teaching. Most participants were prepared for the immediate recovery periods after the procedure but not all of them felt comfortable about what to expect. Not all participants were given information prior to discharge about their follow-up care at home and as a result several of the participants were concerned that they still had unanswered questions. Although most of the participants were informed about the pre-discharge cardiac rehabilitation lecture, they were not all able to attend as it did not coincide with the timing of their discharge. Few participants were informed about the six-week follow-up cardiac rehabilitation program that was offered by the study institution and as a consequence, no participants had attended. One person had been given information from a country hospital about a similar program and had chosen to attend as it was more convenient. Considering these issues and within the scope of this research report, several issues need to be considered in relation to the educational preparation and follow-up care of cardiac interventional patients.

Preparatory Education

There are two phases of educational preparation for patients scheduled for cardiac interventional procedures. The first phase being prior to the procedure and the second phase being in relation to the immediate recovery period after the procedure. The difficulty that arises for this group of cardiac patients is that the time available to educate patients prior to the procedure may vary depending on the acuteness of their illness and the urgency with which the patient requires the procedure. For those who have planned admission schedules and are informed days or even weeks in advance of the procedure, there is more time for

planned and detailed education to occur. This group of patients can also have education reinforced by a variety of health professionals (including their general practitioner, cardiologist and nursing staff) at different stages leading up to their hospital admission. However, for the participants in this study, this level of education was not always assured. Those participants who were admitted to hospital after suffering an acute myocardial infarction were inundated with information about coronary angioplasty and lifestyle changes. Those admitted initially to country hospitals also appeared to have more formalised education sessions, using a variety of educational tools. However, those admitted directly to the study institution, even at the time of an acute episode, did not always receive appropriate explanations about the procedure. It is possible that extraneous factors such as staff availability and skill, workload of the cardiac unit and admission time may have influenced the structure and detail of pre-procedural education sessions.

To ensure that those patients with planned admission schedules are adequately informed about the procedure the introduction of pre-admission teaching clinics could be considered. Although a pre-admission clinic is available at the study institution, the primary focus is on undertaking physiological examinations (x-rays, blood tests and electrocardiogram) rather than education preparation for the procedure. A more focussed pre-admission teaching role for nurses in pre-admission clinics may better prepare cardiac interventional patients for scheduled procedures. Tooth et al suggest an advantage of pre-admission teaching is reduced anxiety and improved retention of knowledge as patients do not immediately face the threat of the procedure.[37]

However, some patients will not have access to a pre-admission teaching clinic because of the urgency of their procedure. Perhaps in these cases, a dedicated nurse from the pre-admission teaching clinic could be called to visit the patients in the emergency department or the catheter laboratory prior to admission to provide a more detailed and concise educational preparation session that follows and reinforces any explanations provided by the doctor. This would also allow patients to ask questions that may arise after initial discussions. If pre-admission teaching clinics were staffed with nurses who have specialty knowledge and experience with the needs of cardiac interventional patients, education sessions could be tailored to individual patient needs, taking account of their physical and emotion states at the time.

Currently one part-time nurse has a dedicated cardiac teaching role within the study institution. However, due to the limitations of time, large patient numbers and a diversity of cardiac patients, it is not possible for her to see all patients prior to cardiac procedures, whether they are related to surgical or interventional procedures. It was during fieldwork experience that the researcher began to observe that few patient visits were made to cardiac interventional patients but focussed instead on those scheduled for cardiac surgery or after acute MI. As the number of patients scheduled for interventional procedures increases, recognition of this patient case mix by hospital managers is required so that appropriate resources can be allocated to enable specialist nurses to attend to the educational needs of these patients.

Patient education needs to incorporate not only information about the practicalities of PTCA/intracoronary stent procedures but potential complications, possible alternative treatment options and information about the immediate recovery care and explanations of the rationale for post-procedural instructions. Regardless of whether this information is delivered in a pre-admission teaching clinic or during acute admission prior to an interventional procedure, it is important to ensure that in-hospital follow-up education occurs within the first 24 hours of the procedure. The focus of this session would be dependent on the extent of pre-procedural education and may need to be more extensive for those patients who were admitted for urgent procedures. At the very least this in-hospital follow-up will reinforce initial education to ensure patients understand what has occurred, allow them an opportunity to ask questions and discuss any potential problems that may have occurred. Family involvement and the use of a variety of visual and auditory tools should be utilised during education sessions.

Education at Hospital Discharge

Few participants in this study were given any information on discharge from hospital that informed them about their care at home. One of the participants remarked that he would have benefited from information related to how much weight he could lift, how long before he could drive a car again and when he could return to work. Some direction from health professional about potential limitations related to everyday activities such as these prior to hospital discharge is routinely warranted. In addition, several participants had questions about their medications. It appears that with the short hospital stay and high turnover of cardiac

interventional patients there is insufficient time to provide adequate pre-discharge education. Discharge planning must take into account patient information sessions that provide an opportunity to discuss medications, everyday physical activities and restrictions, resumption of work, groin and puncture site care and the potential for late problems to occur at home.

Gaw advocates giving patients the opportunity to express their anxieties and fears and discuss their concerns.[21] During the interview some of the participants in this study expressed fear related to the potential for problems after the procedure, recurrent episodes of chest pain, anxiety related to events that occurred during the procedure and frustration at having to lie flat and still in bed after the procedure. With shortened hospital stay and the potential for fragmented follow-up care where patients return to the country after PTCA, health professionals need to be alerted to the potential for concern about aspects of the patients recovery.[30] Prior to hospital discharge time should be allocated to discuss emotional reactions and concerns and strategies to alleviate concerns should be suggested.

A formal pre-discharge lecture for cardiac patients is scheduled weekly at the study institution. However, for a large proportion of cardiac interventional patients this lecture does not coincide with the timing of their discharge. Of the thirteen participants in this study only three were able to attend as the scheduled lecture time was inconvenient or they were not informed about the lecture. Those that attended gave positive feedback about the session particularly in relation to cardiac risk factors and lifestyle modification behaviours. They also gained an understanding of the causes and symptoms of coronary heart disease. However, as these sessions are attended by a diversity of cardiac patients (those having had an acute MI, cardiac bypass surgery, cardiac valvular surgery and angioplasty and intracoronary stent procedures), the sessions seemed to focus on general issues related to cardiac disease. Although important, some benefit would be obtained from sessions that focussed just on cardiac interventional patients as their needs, recovery and post-procedural care differs from other cardiac patients.

Follow-up Education

In order to maximise the beneficial effects of PTCA and/or intracoronary stenting, maintain a healthy outlook and improve long-term survival, patients must assess their lifestyle and consider modifications to factors that may increase cardiovascular disease in the future.

However, it has been suggested that the short hospital stay, rapid procedural technique and immediate potential success of PTCA may decrease patients motivation to reduce known cardiac risk factors after the procedure.[21] This study attempted to identify whether participants recognised the need to assess and modify potential risk factors. Most of the participants had recognised some aspect of their lifestyle where modification was required. Some had already made changes while others, who had found making change more difficult, were still in the process.

Surprisingly none of the participants talked about stress management as an important aspect of lifestyle modification. Gulanick identified stress management as an area of concern to the participants in her study.[9] She found that few of the participants had attempted to deal with issues of stress due to lack of confidence in managing this issue. She concluded that the participants had focussed primarily on changing lifestyle behaviours that were perceived to be more concrete and more easily measurable such as tobacco smoking cessation and increased activity.[9] These factors, together with dietary changes, were most commonly recognised by these participants as lifestyle factors requiring modification.

Patients need to consistently be given enough information about cardiac risk factors so they can make appropriate assessments and informed decisions about the lifestyle modifications required to maximise their health and well being. Although most of the participants in this study had been informed that the study institution offered a six-week follow up cardiac rehabilitation program, none of the participants had attended. Their reason for not attending was that the timing of the program made it difficult for them to attend, or for those in the country, the distance required to travel to attend the program was not practical. One participant had attended a similar program offered by the local country hospital, as this was more convenient. However, a few participants were not aware that cardiac rehabilitation programs such as these were available. Assurance through discharge planning strategies is required for all patients to be informed about follow-up cardiac rehabilitation sessions. These sessions need to be tailored to maximise attendance. This may involve consideration being given to the timing of rehabilitation sessions so that they are more assessable to a wider range of people. Perhaps having repeated sessions that are outside of normal business hours may decrease attendance difficulties for some patients.

Almost half (46%, n=6/13) of the participants in this study were transferred from a country

hospital or by a country doctor to the study institution for the angioplasty procedure. Follow-up care for country patients is fragmented with few having the opportunity to attend any formal cardiac rehabilitative sessions. Besides a recommended visit with their local general practitioner and a scheduled follow-up visit after a few months with their cardiologist, these patients do not have any structured follow-up care. Prior discharge education is particularly important for this patient group. Some provision for country patients to make inquiries or seek further information if required after discharge is also warranted. In addition, more formal liaison between institutions where cardiac intervention procedures are performed and local country health services are required so that more formalised follow-up care can occur.

An important factor that has emerged from the findings of this study is that educational preparation and follow-up rehabilitation that has traditionally focussed on patients after cardiac surgery or myocardial infarction cannot be routinely applied to cardiac interventional patients. The urgency of the procedure and the short hospital stay means those educational programs, both in-hospital and after discharge, need to be reassessed and re-structured in order to accommodate the needs of these patients. In addition, the degree and depth of information should be based on an individual evaluation of what patients perceive to be important and the risk of future cardiac problems.[37]

Study Limitations and Recommendations

There are some factors related to the conduct of this study that may be perceived as potential limitations. Although the purpose of this study was to identify the perceptions of these participants, the methodology does not make it possible to transfer the findings of this study to the broader PTCA/intracoronary stent population nor to any other cardiac interventional patient group. In addition, time restrictions did not allow for contact with the study participants after the interview was transcribed in order to validate the data. Although this step may have added validity to the overall study, during the interview the researcher endeavoured to clarify unclear statements or the meaning of responses through further questioning. In addition, interviews were conducted within the first month after hospital discharge following the procedure. This meant that participant responses were dependent on their ability to recall the events that occurred. It is possible that several interviews conducted over different time periods may have assisted in more accurate recall by some participants.

It is recommended that future research be conducted with a larger more diverse sample to enable a broad and comprehensive understanding of the educational experiences of cardiac interventional patients. Innovative in-hospital education programs that take into consideration the specific needs of cardiac interventional patients need to be developed and evaluated. Further longitudinal research into factors that influence long-term lifestyle modification for this patient group is warranted.

Conclusion

In conclusion, this study has provided insight into the educational experiences of thirteen patients who had PTCA/intracoronary stent procedures. Although some participants appeared satisfied with the care they received and understood the events that occurred, others did not receive sufficient information and were left uncertain and questioning of some aspects of their care. The degree of information received prior to discharge from hospital related to follow-up care, physical recovery, functional activities and medications was inadequate. In addition, information related to follow-up cardiac rehabilitation and lifestyle modification programs was inconsistent and not always accessible. Nurses are in the best position to provide relevant information that adequately prepares interventional patients for cardiac procedures and to inform them about follow-up care and healthy life-style patterns, as they spend the greatest amount of time with patients during hospitalisation. The challenge for nurses is to tailor education to the individual needs of these patients within a short stay, high turnover environment.

References

1. Davies J, Senes S. Coronary angioplasty in Australia in 1998. Canberra: Australian Institute of Health and Welfare and National Heart Foundation of Australia, 2001:1-44.
2. Thompson D, Meddis R. A prospective evaluation of in-hospital counselling for first time myocardial infarction men. *Journal of Psychosomatic Research* 1990;34(3):237-248.
3. Oldridge N, Guyatt G, Fischer M, Rimm A. Cardiac rehabilitation after myocardial infarction: combined experience of randomized clinical trials. *JAMA* 1988;260:945-950.
4. O'Connor G, Buring J, Yusuf S, Goldhaber S, Olmstead E, Paffenbarger R, et al. An overview of randomized trials of rehabilitation with exercise after myocardial infarction. *Circulation* 1989;80(234-244).
5. Oldridge N, Guyatt G, Jones N, Crowe J, Singer J, Feeny D, et al. Effects of quality of life with comprehensive rehabilitation after acute myocardial infarction. *American Journal of Cardiology* 1991;67:1084-1089.
6. World Health Organization. World Health Report 2000: WHO Statistical Information System, 2000.
7. Australia Institute of Health and Welfare. Heart, stroke and vascular disease: Australian facts 1999. Canberra: AIHW, 1999.
8. Australia Institute of Health and Welfare. Australia's health 1998: the sixth biennial health report of the Australian Institute of Health and Welfare. Canberra: AIHW, 1998.
9. Gulanick M, Naito A. Patients' reaction to angioplasty: realistic or not? *American Journal of Critical Care* 1994;3(5):368-373.
10. King S. Percutaneous transluminal coronary angioplasty: the second decade. *American Journal of Cardiology* 1988;62:2-6.
11. Murphy C, Fishman J, Shaw R. Education of patients undergoing coronary angioplasty: Factors affecting learning during a structured educational program. *Heart Lung* 1989;18:36-45.
12. Tooth L, McKenna K, Maas F, McEniery P. The effects of pre-coronary angioplasty education and counselling on patients and their spouses: A preliminary report. *Patient Education and Counselling* 1997;32:185-196.
13. Loan T. Nursing interaction with patients undergoing coronary angioplasty. *Heart Lung*

1986;15:368-375.

14. Pearson T, Rapaport E, Criqui M, Furberg C, Fuster V, Hiratzka L, et al. Optimal risk factor management in the patient after coronary revascularisation: A statement for healthcare professionals from an American Heart Association Writing Group. *Circulation* 1994;90(6):3125-3133.
15. McCarthy C. Percutaneous transluminal coronary angioplasty: Therapeutic intervention in the cardiac catheterization laboratory. *Heart Lung* 1982;11(6):499-504.
16. Gardner E, Joyce S, Iyer M, Mowery M, Olson K, Piontek S. Intracoronary stent update: Focus on patient education. *Critical Care Nurse* 1996;16(4):65-75.
17. Gulanick M, Bliley A, Perino B, Keough V. Patients' responses to the angioplasty experience: a qualitative study. *American Journal of Critical Care* 1997;6(1):25-32.
18. Mullin S, Passamani E, Mock M. Historical background of the National Heart, Lung and Blood Institute registry for percutaneous transluminal coronary angioplasty. *American Journal of Cardiology* 1984;53:3C-6C.
19. Gray D, Hampton J, Bernstein S, Kosecoff J, Brook R. Audit of coronary angioplasty and bypass surgery. *Lancet* 1990;335:1317-1320.
20. Hlatky M, Lipscob J, Nelson C, Califf R, Wallace A, Mark D. Resource use and cost of initial coronary revascularization. Coronary angioplasty versus coronary bypass surgery. *Circulation* 1990;85(5 suppl):IV 208-213.
21. Gaw B. Motivation to change life-style following PTCA. *Dimensions of Critical Care Nursing* 1992;11(2):68-74.
22. Leon A, Certo C, Comoss P, Franklin B, Froelicher V, Haskell W, et al. Scientific evidence of the value of cardiac rehabilitation services with emphasis on patients following myocardial infarction. *Journal of Cardiopulmonary Rehabilitation* 1990;10:79-87.
23. Thompson D. Cardiac Rehabilitation: How can it be improved? *Journal of Psychosomatic Research* 1995;39(5):519-523.
24. Thompson D, Bowman G, Kitson A, de Bono D, Hopkins A. Cardiac rehabilitation in the United Kingdom: guidelines and audit standards. *Heart* 1996;75:89-93.
25. Pashkow F. Cardiac rehabilitation: not just exercise any more. *Cleveland Clinic Journal of Medicine* 1996;63(2):116-123.
26. Gaw-Ens B, Laing G. Risk factor reduction behaviours in coronary angioplasty and myocardial infarction patients. *Canadian Journal of Cardiovascular Nursing* 1994;5(1):4-12.

27. Maier W, Meier B. Interventional cardiology in perspective: impact on cardiac rehabilitation. *European Heart Journal* 1998;19 (Supplementary O):O24-O28.

28. Langton P, Thompson P. Helping heart attack victims to save their own lives. *Australian Journal of Medicine* 1997;166:228-229.

29. Eastwood G. Lifestyle pattern changes in males following percutaneous transluminal coronary angioplasty/intracoronary stenting. *International Journal of Nursing Practice* 2001;7:131-137.

30. Cronin S, Holbrook L, Ryan G, Drake D. Recovery after percutaneous transluminal coronary angioplasty: Assessment after discharge. *Critical Care Nurse* 2000;20(2):70-76.

31. Shillinger F. Percutaneous transluminal coronary angioplasty. *Heart Lung* 1983;12(1):45-50.

32. Foulger V. Patients' views of day-case cardiac catheterisation. *Professional Nurse* 1997;12(7):478-480.

33. Beckerman A, Grossman D, Marquez L. Cardiac catheterization: The patients' perspective. *Heart Lung* 1995;24(5):213-219.

34. Davis T, Maguire T, Haraphongse M, Schaumberger M. Preparing adult patients for cardiac catheterization: Informational treatment and coping style interactions. *Heart and Lung* 1994;23(2):130-139.

35. Suls J, Wan C. Effects of sensory and procedural information on coping with stressful medical procedures and pain: A meta-analysis. *Journal of Consulting and Clinical Psychology* 1989;57:372-379.

36. Barbiere C. Percutaneous transluminal coronary angioplasty in high risk patients. *Critical Care Nurse* 1990;10:66-69.

37. Tooth L, McKenna K. Cardiac patient teaching: application to patients undergoing coronary angioplasty and their partners. *Patient Education and Counselling* 1995;25:1-8.

38. Higgins M, Dunn S, Theobald K. The patients' perception of recovery after coronary angioplasty. *Australian Critical Care* 2000;13(3):83-88.

39. Cardiovascular Investigation Unit. Annual Statistics. Adelaide: Royal Adelaide Hospital, 1999.

40. Cardiovascular Investigation Unit. Annual Statistics. Adelaide: Royal Adelaide Hospital, 2000.

41. Cardiovascular Investigation Unit. Annual Statistics. Adelaide: Royal Adelaide Hospital,

1997 -1998.

42. Morse J. The significance of saturation (Editorial). *Qualitative Health Research* 1995;5(2):147-149.

43. Streubert H, Carpenter D. *Qualitative Research in Nursing*. Philadelphia: J.B. Lippincott, 1995.

44. Leininger M. *Culture Care Diversity and Universality: A theory of nursing*. New York: National League for Nursing Press, 1991.

45. Ekman I, Segesten K. Deputed power of medical control: the hidden message in the ritual of oral shift reports. *Journal of Advanced Nursing* 1995;22:1006-1011.

46. Levin D, Gardiner G. Coronary arteriography. In: Braunwald E, editor. *Heart Disease: A textbook of cardiovascular medicine*. 4th edition ed. Philadelphia: W.B. Saunders Company, 1992:235-275.

47. Grollman J, Lui C, Astone R, Lurie M. Thromboembolic complications in coronary angioplasty associated with the use of non-ionic contrast medium. *Catheter and Cardiovascular Diagnosis* 1988;14(3):159-164.

48. Hwang M, Piao Z, Murdock D, Giardina J, Pacold I, Leob H, et al. The potential risk of thrombosis during coronary angiography using nonionic contrast media. *Catheter and Cardiovascular Diagnosis* 1989;16(3):209-213.

49. Piessens J, Stammens I, Vrdix M, Glazier J, Benit E, DeGeest H, et al. Effects of an ionic versus nonionic low osmolar contrast agent on the thrombotic complications of coronary angioplasty. *Catheter and Cardiovascular Diagnosis* 1993;28(2):99-105.

50. American Association of Critical Care Nurses. VIPs Survey Results. *AACN News* 1993(February):4.

51. Feigenbaum H. Echocardiography. In: Braunwald E, editor. *Heart Disease: A textbook of cardiovascular medicine*. Philadelphia: W.B. Saunders Company, 1992:64-115.

52. Finesilver C. Preparation of adult patients for cardiac catheterization and coronary cineangiography. *International Journal of Nursing Studies* 1978;15:211-221.

53. Peterson M. Patient anxiety before cardiac catheterization: an intervention study. *Heart and Lung* 1991;20:643-647.

54. Thompson D. Effect of in-hospital counselling on knowledge in myocardial infarction patients and spouses. *Patient Education and Counselling* 1991;18:171-177.

55. Burke L. Learning and retention in the acute care setting. *Critical Care Quarterly* 1981;4(4):67-73.

APPENDIX 1

Patient Information Sheet

Study Title: A study to determine the adequacy of education and cardiac rehabilitation in patients who have undergone PTCA and/or intracoronary stent procedure.

Study Investigator: Ms T. Jones
Lecturer in the Department of Clinical Nursing at The University of Adelaide and doctoral candidate in the Doctor of Nursing degree.

Purpose of the study:
The purpose of this study is to determine the extent to which patients undergoing cardiac interventional procedures such as coronary angioplasty and intracoronary stent, are prepared and educated before and after the procedure and whether information is given prior to hospital discharge in relation to cardiac rehabilitation. Information will be generated in an interview that will focus on identifying how patients are educated before and after the interventional procedure, who delivered this information and whether the information provided adequately prepared patients for the procedure. Questions will also be asked about information provided in the immediate recovery period and prior to hospital discharge related to cardiac rehabilitation. The taped interviews will be transcribed and the text analysed for themes that will describe the educational preparation and experience of these patients.

Possible benefits from this study:
With the knowledge gained from this study nurses can advise patients on what to expect during the procedure and immediate recovery period. This study will assist nurses in determining the information patients require prior to and immediately after the procedure thereby making it possible to develop specific educational programs that will adequately prepare cardiac interventional patients for their procedure and assist them to understand the expected recovery process. Cardiac rehabilitation programs that focus on the needs of cardiac interventional patients may also be formulated.

Your involvement:
If you agree to participate, the researcher will travel to your home, or place of your choice, to conduct the interview. Interviews will not last longer than one hour. Simple unstructured questions will be asked about the education you received before and after your cardiac interventional procedure. The interviews will be tape-recorded and the researcher will take notes.

Confidentiality:
All information and documentation containing your personal details and identity collected during this study will remain confidential. Even though results of the study may be presented in a public forum or submitted and published in medical or nursing journals, no information that could identify a particular individual will be made public.

Volunteering:
Your participation in this study is **voluntary** and you have the right to withdraw from the study at any time. If you do not wish to participate, this will not alter the medical treatment or nursing care you receive now or in the future.

Contact Details:
Should you wish to discuss your involvement in this study with the researcher or her supervisor at any time you can contact:
Researcher: **Ms Tina Jones**,
Supervisor: **Dr Helen McCutcheon**,

If you wish to discuss the study with someone not directly involved in the research, you can contact: **XXXX** from the XXX Hospital Ethics Committee, on **XXXXXXXX**.

Thank you for agreeing to participate in this study.

APPENDIX 2

Patient Consent Form

Study Title: A study to determine the adequacy of education and cardiac rehabilitation for patients who have undergone PTCA and/or intracoronary stent procedure.

Study Investigator: Ms T. Jones

THIS IS TO CERTIFY THAT I,

_____

(Print name)

agree to participate as a volunteer in the above named project.

The nature and purpose of the study has been explained to me. I understand it and agree to take part.

I understand that while information gained during this study may be presented at a public forum or published in medical or nursing journals, I will not be identified and my personal details will remain confidential.

I understand that I can withdraw from the study at any time and that this will not affect my medical treatment or nursing care now or in the future.

I understand that I will not receive any payment for participating in this study.

Signed: _____

(Participant)

I certify that I have explained the study to the patient and consider that he/she understands what is involved:

Investigators signature: _____ **Date:** _____

APPENDIX 3

Example Interview Questions

Can you tell me about the information you were given before your cardiac procedure?
Who in your family was present when this information was provided?
Who provided the information?
How did this information help you to prepare for the procedure?

What, if any, knowledge did you already have about this procedure?
Describe your understanding of the procedure (percutaneous transluminal coronary angioplasty and/or coronary stent)?
What other information do you think may have helped to prepare you for the procedure?

Can you tell me about the information you were given about what to expect immediately after the procedure and on your return to the ward?
How did this information help you to prepare for how you would feel after the procedure?
What other information do you think may have helped to prepare you for the events that occurred in the immediate recovery period (the first 24 hours after the procedure)?

How was the information you received prior to discharge helpful for your recovery at home?
Now that you have been home for a few weeks is there any additional information that you think may have been useful?
Who contacted you at home after your discharge to check on your progress?

How did you find the formal cardiac rehabilitation sessions before and after the procedure (in terms of preparation and recovery)?
What modifications to your life-style have been recommended?
Have you made changes to your lifestyle? If so, in what way?
What is your understanding of why these recommendations have been suggested?

APPENDIX 4

Themes

Key Concepts	Sub-theme	Major Theme
No choice, die without it, necessary, nearly died, advice, trust	No choice	Survival
Need to change, try to change, change, difficulty with change, healthy lifestyle, activity, ownership	Lifestyle changes	
Frustration, concern, worry, fear	Concern	
Happy, content, satisfied, reassurance	Contentment	
Annoyance, agony, uncomfortable, pain	Discomfort	
No feeling, no pain	No discomfort	
Explanation, expectation, preconception, understanding	Understanding	Knowledge
Unprepared, more questions, additional information, no explanation, unsure	Uncertainty	
Written materials, visual teaching, auditory media, verbal teaching	Informal education	
Rehabilitation, regular sessions	Planned education	
Seeking information, family presence, family support, reassurance	Family involvement	
No communication, unprepared, no information	Lack of information	Communication
Orders, being told	Instructions	
Graphic description, threatening, persuasion, consent, potential problems	Language and informed consent	
Distracted, not retained, no memory, reinforcement	Retention and reinforcement	
No concept of time, longer than expected, not ready, more afterwards	Time and information	

Conclusion: Summary of the portfolio and future research

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Summary of the Research Portfolio and Recommendations for Future Research

This portfolio of research is made up of three pieces of work pertaining to interventional cardiology. As was highlighted in section one of this portfolio, the clinical development of diagnostic and interventional cardiac catheterisation techniques has made rapid progress over the last 50 years.[1] Several potential problems and complications can occur during and after cardiac interventional procedures.[2] However, the role of the nurse is integral to the success and outcome of patients undergoing cardiac interventional procedures. Two areas where nurses have established roles with cardiac interventional patients are femoral sheath removal practices and patient education.

Nurses, as with other health care professionals, have a responsibility to ensure that individual patients receive optimal care and treatment.[3] This has become particularly important within the current health care environment where as a result of economic constraints and increased demand for services, the focus of health care has shifted to outcomes rather than input.[4] Those involved in clinical practice need to be accountable for the effectiveness and efficiency of what they do.[5] As a consequence, there has been an important shift from the traditional rituals of delivering health care to one that emphasises the need to base clinical decisions and practices on sound evidence.[3] Clinical evidence can be attained through the conduct of systematic research.[6] The research in this portfolio aimed to identify effective femoral sheath removal practices and determine patients' perceptions of the education they received prior to and after cardiac interventional procedures.

The first piece of research in this portfolio was a systematic review of literature pertaining to studies that investigated the use of mechanical compression devices to attain haemostasis after femoral sheath removal following cardiac interventional procedures. The systematic review process utilises a methodical, predetermined plan to summarise, appraise and synthesis the findings of primary research on a topic of interest.[7] Systematic

reviews provide a reliable method of summarising the best available evidence in order to guide clinical decision-making and practice.[4] The aim of this systematic review was to summarise the best available evidence on the effectiveness of mechanical compression devices used to obtain haemostasis after femoral sheath removal following cardiac interventional procedures. This information would identify the best available evidence to guide nurses in the decision-making and practice of femoral sheath removal.

Overall the findings from this systematic review indicated that mechanical compression devices are effective in attaining haemostasis after femoral sheath removal. Although it is not possible to make clear recommendations that a particular mechanical device is more effective than another mechanical device, it is possible to make a clinical recommendation for the use of mechanical devices to attain haemostasis after femoral sheath removal. Although manual compression has traditionally been favoured as the primary method of attaining haemostasis after sheath removal, alternative techniques, such as mechanical compression devices, are being introduced into clinical practice. This systematic review provides nurses with evidence to support the use of mechanical compression devices as a safe alternative to manual compression.

Despite this, the systematic review did highlight the lack of quality research in this area. In particular, the paucity of nursing studies identified in this review highlighted the need for further studies to be undertaken by nursing researchers into this topic.

The second piece of research in this portfolio resulted from the systematic review and the need for further quality nursing studies to be undertaken in this area of practice. Although supporting the use of mechanical compression devices in attaining haemostasis after femoral sheath removal, the systematic review did not find sufficient evidence to support a particular compression technique as being most effective. At the time of this research, mechanical compression devices were infrequently used during clinical practice in the study institution to attain haemostasis after femoral sheath removal. In addition, nurses in the study institution did not appear confident to make decisions about the use of the

devices, nor were there standardised protocols for mechanical compression devices. Nurses appeared to favour the use of manual compression, as this was a technique they were confident and familiar with.

The purpose of the second study was to compare the use of manual compression with a mechanical compression device (the QuicKlamp™) in achieving haemostasis after femoral sheath removal in coronary angiography patients and to determine the ability of these two techniques to reduce groin complications. By evaluating these techniques through research, it was intended that the findings would assist nurses to formulate evidence-based protocol(s) that will direct and educate nursing staff in regard to effective and safe femoral sheath removal practices.

As the research design of randomised controlled trials (RCTs) enables the outcome and effect of particular clinical interventions to be reliably measured and the evidence provided by RCTs is considered the most reliable and valid in guiding clinical practice decision making[8], this research method was used in the second piece of work in this portfolio. The RCT was designed to compare these compression techniques in a convenience sample of 100 patients scheduled to have elective coronary angiography. A discrete group of Registered Nurses permanently assigned to work in the study catheterisation unit agreed to be responsible for removal of femoral sheaths during the study period from June 1999 to March 2001.

The findings of this study demonstrated that both compression techniques were effective in attaining haemostasis after femoral sheath removal. Although evidence of bruising, haematoma formation and bleeding were identified in both compression groups, significantly more haematomas occurred after manual compression as opposed to the QuicKlamp™ compression device in this study. No patients in the study developed any other major groin complications and subjects did not perceive either compression technique to be painful.

However, the QuicKlamp™ mechanical compression device took significantly longer to effect haemostasis than manual compression. This finding was consistent with previous research comparing a similar clamp device with manual compression.[9,10, 11] A consequence of prolonged compression was that the time from femoral sheath removal until mobilisation was also significantly longer after QuicKlamp™ mechanical compression. These findings appeared to have an impact on clinical practice as coronary angiography patients, who would normally expect to be discharged from hospital about 4 to 6 hours after the procedure, were being delayed by longer compression times. Although this created a degree of inconvenience for patients, no patient required overnight admission to hospital. However, some nurses were required to stay on duty longer than rostered to recover those QuicKlamp™ patients who had prolonged compression times. In addition, for those nurses involved in application of the QuicKlamp™ compression device, the time at the bedside with the subject during application of the compression technique was prolonged. Although previous research has suggested that clinicians can leave the patient bedside during compression with mechanical devices and attend to other activities[12], the nurses in this study did not appear confident or comfortable to leave the subjects unattended during compression time and therefore this prolonged period may have impacted on their overall workload. Anecdotally, it appears that despite the reduced incidence of adverse events, nurses in the study institution will continue to favour the use of manual compression to attain haemostasis after femoral sheath removal above the QuicKlamp™ compression device.

It is unclear why it took longer for haemostasis to be attained after compression with the QuicKlamp™ device. It is possible that technical aspects related to application of the device may not have allowed the same degree of force to be directly applied to the femoral puncture site as manual compression. In addition, manual compression allows the operator to easily assess whether pressure is being applied directly over the femoral artery, as the can feel the arterial pulsation. Direct application over the femoral artery cannot be assured when mechanical compression devices are applied. Anecdotally, nurses say that they prefer to use manual compression after femoral sheath removal as they can

'feel' haemostasis developing. In addition, some nurses have commented that they can feel if blood is accumulating under the skin surface and consequently they can adjust their manual compression technique to minimise this. As direct control of these factors is removed from the nurse when utilising mechanical compression techniques they may not be confident to readily use mechanical devices. Future research needs to explore the reasons why nurses are not confident to use mechanical compression devices in practice or to leave patients unattended during application of mechanical compression. Perhaps if nurses can be encouraged to use the QuicKlamp^{TM} compression device more often they will develop confidence in its use and the ability of the devices to attain haemostasis with few minimal adverse effects for patients.

Although some subjects in the QuicKlamp^{TM} compression group had prolonged compression times, this study did not explore whether this prolonged compression time and subsequent immobilisation affected them. A subjective assessment of pain was only undertaken during application of the compression technique. No assessment was made of pain or discomfort that subjects may have been experienced as a result of prolonged immobilisation. Coronary angiography patients, such as in this study, are requested to lie flat and immobile for at least 3 hours after femoral sheath removal. Further research is required into the affects of prolonged immobilisation, particularly in those patients who have had interventional procedures such as PTCA and intracoronary stenting. It is not uncommon for these patients to wait one to five hours to have their femoral sheath removed. This wait is in addition to the minimum 4-hour period after anticoagulation has been ceased, often resulting in patients having femoral sheaths insitu for extended periods. If this period is further extended as a result of prolonged mechanical compression, patients may have increased discomfort that results in an increase in complications and subsequent length of inpatient stay. However, further research is required to assess whether prolonged immobilisation affects patients outcomes.

Cardiac intervention procedures are undertaken in a high turnover, short stay environment. Although this offers the advantages of shorter hospital stay and reduced

cost, the time available for nurses to educate patients is also reduced. With more patients opting for PTCA and intracoronary stenting as revascularisation treatments for coronary heart disease, the challenge for nurses is to ensure they meet the needs of these patients within a reduced time frame. Preparatory and supportive nursing interventions can reduce stress and anxiety before, during and after the procedure.[13] Patient education is an important aspect of nursing care and if done well, can positively influence patient outcomes.[14]

The third piece of research in this portfolio was directed towards patient education of cardiac interventional patients. The objective of this study was to determine what education PTCA/intracoronary stent patients receive prior to, or after the procedure and to determine whether they received information prior to discharge related to cardiac rehabilitation.

Over a ten-month period from August 2001 until May 2002, thirteen patients who underwent PTCA/intracoronary stent procedures agreed to participate in an unstructured interview that was conducted within four weeks of their PTCA/intracoronary stent procedure. The interview aimed to: identify the current educational strategies used to inform and prepare cardiac patients for PTCA and/or intracoronary stent procedures; identify whether patients scheduled for PTCA and/or intracoronary stent procedures were educated about the events that would occur in the postoperative recovery period; and, ascertain whether PTCA and/or intracoronary stent patients received information about cardiac rehabilitation programs prior to discharge from hospital.

The findings of this study demonstrated that all of the participants received some form of educational preparation prior to their cardiac interventional procedure. Although the participant's doctor was most commonly the person who initially educated the participants about the need for PTCA, nurses frequently reinforced these explanations. Where possible, family members were included in preparatory education and educational

materials were frequently distributed to reinforce information. The focus and depth of this education appeared to vary amongst participants and was often influenced by the preceding events. Those participants who were hospitalised after myocardial infarction had more opportunity to receive education than those who had coronary angiography for acute chest pain and immediately went on to have PTCA and intracoronary stent procedures after acute occlusion was diagnosed. These participants were often admitted to hospital as day patients, and although warned they may have PTCA, often expected to go home after the procedure. It appears that this group of patients are not assured of detailed discussion about the procedure and may not always have the opportunity to access education materials for explanations due to the urgency of their condition.

Nurses need to accommodate the needs of these patients by developing and extending their practice to include specialist roles that allow them to leave the cardiac catheterisation unit to spend time and be involved in preparatory education of patients in the emergency department or wherever they may be situated. If nurses were appropriately educated with specialty knowledge and experience about the needs of cardiac interventional patients, education sessions could be tailored to individual patient need, taking account of their physical and emotion states at the time. This is important, as the findings of this study indicate that traditional, standardised education programs are not always suitable for all cardiac interventional patients. As patient presentation and circumstances that lead up to cardiac interventional procedures may vary, so must patient education. A traditional attitude that one specific education program is suitable for all cardiac patients is no longer appropriate in an environment where patients can be admitted directly into cardiac catheterisation units for procedures at any time during the day or night. Further research is required to develop these nursing roles and explore differing techniques to deliver education to short stay cardiac interventional patients.

Most participants were prepared for the immediate recovery periods after the procedure but not all of them felt comfortable about what to expect. Nurses primarily undertook this education and the degree of detail provided appeared to have been dependent on the time

and opportunity for education to occur. Nurses need to ensure that all cardiac interventional patients have follow-up education during the immediate recovery period to reinforce initial education and explanations and be available to clarify issues of concern that arise after the procedure. Nurses need to ensure that cardiac interventional patients understand their cardiac condition and the procedure they have undergone. Short hospital stay patients, such as those who have cardiac interventional procedures, may not always appreciate the seriousness of their condition. Understanding the events that have occurred through post-procedural education will increase the patients awareness of their condition and lead to improved patient outcomes.

Not all participants were given information prior to discharge about their follow-up care at home and as a result several of the participants were concerned they still had unanswered questions. If the opportunity arose, these participants asked their doctor to clarify issues of concern, but for some this opportunity did not arise for several weeks after the procedure. If they did not get this chance at all then their questions remained unanswered, as they were not given follow-up information about whom they could contact if problems or issues arose after discharge. Nurses must ensure that discharge planning takes into account patient information sessions that provide an opportunity to discuss medications, everyday physical activities and restrictions, resumption of work, groin and puncture site care and the potential for late problems to occur at home.

Patients appear to recognise the need to reassess their lifestyle and behaviour to maximise their long-term outcome and survival after cardiac interventional procedures. Although the study institution offered a pre-discharge cardiac rehabilitation lecture that discussed issues related to behaviour modification, not all participants were able to attend, as the scheduling of the lecture did not coincide with the timing of their discharge. In addition, few participants were informed about the six-week follow-up cardiac rehabilitation program that was offered by the study institution and as a consequence, attendance was poor. Nurses need to ensure that all cardiac interventional patients are informed about follow-up cardiac rehabilitation sessions. These sessions need to be tailored to maximise

attendance and may require more flexible delivery modes to accommodate a wider range of people. Perhaps follow-up cardiac rehabilitation sessions conducted after discharge may need to be repeatedly offered outside of normal business hours to maximise accessibility. In addition, more formal networks need to be established so that cardiac interventional patients can seek help, information or support if required after discharge. This should include formalised liaison between General Practitioners and local country health services where cardiac intervention procedures are performed to accommodate patients who do not live close to large regional centres where cardiac interventional procedures are undertaken.

Finally an important factor that has emerged from the findings of this study is that educational preparation and follow-up rehabilitation that has traditionally focussed on patients after cardiac surgery or myocardial infarction cannot be routinely applied to cardiac interventional patients. The urgency of the procedure and the short hospital stay means those educational programs, both in-hospital and after discharge, need to be reassessed and re-structured in order to accommodate the needs of these patients. Nurses can take the lead in the development of such programs and develop research projects that focus on evaluation of their effectiveness and impact on long-term patient outcomes.

This portfolio of research has investigated nursing practice in two major areas of interventional cardiology—femoral sheath removal and patient education before and after cardiac interventional procedures. Several areas have been highlighted where nursing practice can be improved, particularly in relation to investigating alternative compression techniques for attaining haemostasis after femoral sheath removal; the development of extended speciality nursing roles that incorporate the educational needs of patients and their families at various stages of their short term hospital stay; and, the development of cardiac rehabilitation programs that focus on the specific needs of cardiac interventional patients after hospital discharge that aim to improve the long term survival of these patients.

References

1. Newton K. Cardiac Catheterisation. In: Woods SL, Froelicher S, Halpenny CJ, Underhill MS, (Editors). *Cardiac Nursing*. 3rd Edition ed. Philadelphia: J.B. Lippincott, 1995.

2. Baim D, Grossman W. *Cardiac catheterization, angiography, and intervention.* Fifth edition. Baltimore: Williams & Wilkins, 1996.

3. Burls A, Milne R. Evaluating the evidence: an introduction. *Journal of Clinical Effectiveness* 1996;1(2):59-62.

4. Jones T, Evans D. Conducting a systematic review. *Australian Critical Care* 2000;13(2):66-71.

5. Popay J, Williams G. Qualitative research and evidence-based healthcare. *Journal of The Royal Society of Medicine* 1998;91(Supplement 35):32-37.

6. Sackett D, Rosenberg W, Muir Gray J, Hayes R, Richardson W. Evidence-based medicine: what it is and what it isn't. *British Medical Journal* 1996;312:71-72.

7. Jones T, McCutcheon H. Effectiveness of mechanical compression devices in attaining hemostasis after femoral sheath removal. *American Journal of Critical Care Nursing* 2002;11(2):155-162.

8. Ohlsson A. Systematic reviews - theory and practice. *Scandinavian Journal of Clinical Laboratory Investigation* 1994;54(Supplement 219):25-31.

9. Homuth G. Relationship of methods for removal of femoral sheaths to the incidence of hematomas and patient comfort [Master of Science Thesis]. Northern Illinois, 1990.

10. Bogart MA. Time to hemostasis: a comparison of manual versus mechanical compression of the femoral artery. *American Journal of Critical Care* 1995;4(2):149-56.

11. Simon A, Bumgarner B, Clark K, Israel S. Manual versus mechanical compression for femoral artery hemostasis after cardiac catheterization. *American Journal of Critical Care* 1998;7(4):308-13.

12. Nordrehaug JE, Chronos NAF, Priestley KA, Buller NP, Foran J. Randomized evaluation of an inflatable femoral artery compression device. *Journal of Interventional. Cardiology* 1996;9(5):381-387.

13. Shillinger F. Percutaneous transluminal coronary angioplasty. *Heart & Lung* 1983;12(1):45-50.

14. Gardner E, Joyce S, Iyer M, Mowery M, Olson K, Piontek S. Intracoronary stent update: Focus on patient education. *Critical Care Nurse* 1996;16(4):65-75.

Appendices: Publications arising from the research portfolio

Conducting a systematic review

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ABSTRACT:– In response to the growing volume of health care literature and the variable quality of reported studies, systematic reviews have increasingly been used to guide health care decisions because of their rigorous summary of the research. Systematic reviews utilise planned methods of identifying, appraising, then summarising the results from individual studies.

The steps in performing a systematic review include: preparing a detailed research protocol; selecting criteria for inclusion of articles in the review; systematically searching the published and unpublished literature; determining which articles meet the predefined inclusion criteria; critically appraising the quality of the research; extracting outcome data from the research report and statistically combining data, where appropriate, in order to summarise the best available evidence on the topic of interest. These processes are documented in the systematic review report, and can be subject to peer review and critique like other research.

Jones T & Evans D. Conducting a systematic review. Aust Crit Care 2000; 13(2)66-71.

INTRODUCTION

The current health care environment with economic constraints, increased demand for services and increasing workloads have forced health care workers to reconsider practices and decisions in regard to the delivery of health care services. Policy makers are now focussing on health outcomes rather than input, and practitioners are reassessing practice in light of the best available evidence for effective health care.

In an endeavour to improve the health of patients within the restraints of finite resources, health carers are now assessing the effectiveness of health interventions. There has been an important shift from the traditional delivery of care to one that emphasises the need to base clinical decisions and practices on sound evidence [1]. Although the intention of health care delivery has undoubtably been to provide the best possible care to patients, sometimes ineffective practices are unknowingly instituted. This has been demonstrated within critical care nursing practice where the ritual of normal saline installation in conjunction with endotracheal suctioning continues, despite evidence that reports no decrease in the viscosity of mucus and an increased likelihood of lung infection and hypoxia [2, 3].

Despite a dramatic growth in health related literature, these inconsistencies in practice continue. Booth [4] described this dilemma as "drowning in information, thirsting for evidence". This flood of information is a result of between 20,000 and 30,000 biomedical journal publications and 17,000 biomedical texts per annum, making the finding of best available evidence on a particular topic a daunting prospect [4]. When all the relevant papers have been identified, the variability in the quality of studies and contradictory findings, compounds the difficulty of selecting the most appropriate studies on which to base practice.

In 1976, Glass proposed a new technique, called *meta–analysis*, that allowed the integration and statistical analysis of study data from a number of separate studies to be pooled in order to address these problems [5]. In the late 1980s, medicine and other health care disciplines adopted meta–analysis from the social sciences [6]. The early 1990s saw an extension of meta–analysis to include a systematic and rigorous approach to searching, appraising and summarising the research literature and the term *systematic review* came into use. Nursing has now begun to utilise the systematic review process as a reliable method of summarising the best available evidence in order to guide clinical decision making and practice. This paper will present an overview of the purpose and processes of systematic review.

WHAT IS A SYSTEMATIC REVIEW?

When used in contemporary literature, the term *systematic* refers to 'methodical', or something 'done or conceived according to a plan or system'. The term *review* is defined as 'a general survey or assessment of a subject or thing' [7]. A *systematic review* therefore could be defined as a methodical assessment of a subject using a predetermined plan.

In research literature, a systematic review has been defined as a concise scientific investigation, with pre–planned methods that summarise, appraise, synthesise and communicate the results of multiple primary research[7,8].

As with traditional narrative reviews of the literature, systematic reviews are retrospective and may be subject to bias and random error[8,9]. As with primary research, the methodical process followed during the review should be transparent to the reader[10]. The quality and usefulness of the final systematic review will be determined by the extent and rigour with which it was conducted and the effort of the reviewer to minimise bias and error[8].

There are several critical differences that distinguish traditional narrative literature reviews from systematic reviews. Traditional reviews often address a broad clinical topic; the source of studies, searching strategies and selection of literature for inclusion are not usually specified and therefore their comprehensiveness is not known. Variable appraisal techniques are used in these reviews and synthesis of the results of studies is usually by a narrative summary, making broad recommendations, which are difficult to distinguish from personal opinion. In contrast, systematic reviews have a focused clinical question; the sources and search strategies for locating the studies are explicitly stated; the criteria for selection of studies are uniformly applied; critical appraisal is rigorous; and, synthesis may involve a statistical summary, or meta–analysis[8,11]. Readers of the review can therefore evaluate the strength of the evidence used to generate recommendations as a result of the systematic review.

Occasionally the term meta–analysis has been used interchangeably with the term systematic review[11], implying that all systematic reviews must involve the scientific synthesis of statistical data collected from randomised controlled trials (RCTs). This is not always the case and so when the results of primary studies are summarised but not statistically combined, a narrative, or qualitative, systematic review is produced[8]. However, the lack of meta–analysis within a systematic review does not diminish its potential value, as this type of review brings together all current knowledge of the topic and helps identify future research directions.

THE PURPOSE OF SYSTEMATIC REVIEW

Systematic reviews can be an invaluable resource for health practitioners, consumers, researchers and policy makers. Well conducted reviews can help define the evidence on a topic by stating what is know, and what is not known, about the topic of interest[8]. A landmark review that exemplified the value of this process, was the work undertaken by Lau and colleagues[12] regarding the treatment of acute myocardial infarction (AMI). They compared the evidence from RCTs which were summarised by a systematic review, with the recommendations made by 'experts' writing in textbooks. While the review found that strong evidence to support the use of thrombolytic agents in reducing mortality of AMI patients was available in 1977, the 'experts' did not recommend the use of thrombolytic agents in textbooks until 13 years later[9,13]. This delay in implementing research evidence has important implications for critical care practice, as beneficial interventions may result in significant improvements in patient outcomes, while ineffective interventions may delay recovery.

With the move of nursing education into the tertiary sector, nurses are beginning to develop skills in research. Although Pearson and colleagues believe this has contributed to the development of nursing as an academic discipline, much of nursing research has been grounded in the humanities and social sciences and nurses are still learning to use defendable research and apply best–available evidence in nursing practice[14]. Nurses often find themselves inundated with unmanageable amounts of research literature and little or no time to read research. Many also lack the confidence to critically appraise research[15]. With the increasing number of medical and nursing periodicals available to health practitioners, accessing the appropriate literature can be a difficult and daunting process. A systematic review can provide an efficient means of integrating large volumes of valid information, resolve conflicting evidence and explain variations in practice, thereby providing a basis for rational decision making about health care practices. Although these uses point to the value and purpose of systematic review, Hughes[9] reminds us that the value of the review is limited by the rigour of the review and the extent and validity of the primary research data.

SYSTEMATIC REVIEW PROTOCOL

If a systematic review is to provide a useful summary of primary research, the review must utilise the same standard and rigour as the research it seeks to summarise. To facilitate this, the systematic review follows a pre–planned protocol, not unlike a research proposal, and as such can be peer reviewed before commencement.

Preparation of the systematic review protocol is perhaps the most important step in the process of review. Careful thought and planning at this stage is important to ensure the process is rigorous and well defined, while still maintaining a practical perspective[16]. Developing a protocol for review *a priori* reduces the risk of bias from reviewers choosing only research that supports their own views, as it sets out the specific processes that will occur throughout the review. The components of the protocol are: the review question; inclusion criteria; search strategies; critical appraisal; data extraction and data analysis.

FORMULATING THE PROBLEM

Prior to formulating the question of the systematic review, a brief perusal of the literature should be undertaken in order to assess the volume and study design of the primary research in the review field. It is important to identify the main issues and focus of past research.

A well–formulated question should address several key components including: the study participants; the interventions to be considered; the outcomes that will be used to evaluate the success of the chosen topic and the types of research methods that best answer the question(s) of the review[7,16]. The scope of the review question(s) may be broad or narrow. Broad questions may focus on the general management of a particular disease state, whereas narrow questions may only focus on the effectiveness of a particular intervention.

INCLUSION CRITERIA

The inclusion criteria of a systematic review are intended to clearly define what research will be included for review. Specifying unambiguous inclusion criteria will limit the risk of reviewer bias and ensure that articles are similar enough to be statistically

combined [11]. The population of participants to be included for review should be predetermined and will make explicit the types of people, their disease or health condition and the setting of interest for review. The treatment criteria of interest for inclusion in the review will define the types of health interventions to be assessed.

Explicit criteria for establishing the presence of outcomes of interest are detailed in the inclusion criteria. All outcomes that are likely to be meaningful to those people involved in health care decisions should be included in the review.

The choice of a particular research methodology is usually dependent on the actual research question. Quantitative methodologies can be used to evaluate the cause and effect and relationships amongst particular variables [17], whereas qualitative methodologies focus on describing the experiences, interpretations and impressions of particular individuals [18]. Although either methodology contributes valuable knowledge about clinically effective practice, certain study designs are considered superior to others when answering particular questions [16]. When developing a systematic review protocol, the types of studies for inclusion in the review must be considered. RCTs designed to evaluate the effectiveness of health interventions provide the most reliable and valid information to guide clinical practice decisions [19].

RCTs are more amenable to reviews that include meta–analysis, as study outcomes tend to be more consistent and therefore more suitable for statistical pooling than those recorded from observational studies [11]. There is, however, increasing recognition for using other research designs in systematic reviews so that a complete summary can be made and the best available evidence on a clinical topic presented [16]. Inclusion of non–RCTs in systematic reviews may limit the strength of any recommendations, but their inclusion in a narrative summary may help to identify current approaches and possible future directions for clinical practice.

LOCATING AND SELECTING STUDIES FOR INCLUSION

Searching the literature for relevant studies is an onerous task. The aim is to perform an extensive, comprehensive and unbiased systematic search for all studies that meet the protocol inclusion criteria. The search should attempt to identify all relevant published (in peer–reviewed journals and other texts) and unpublished studies using a wide variety of sources.

There are a number of electronic databases that may be searched including Medline, EMBASE, CINAHL, Current Contents and the Science Citation Index. These databases have the advantage of being very quick to search but cannot be relied on to comprehensively identify all studies [20,21].

The Cochrane Library is a valuable source to utilise for identifying RCTs, as it maintains a register of controlled trials. In addition, the Cochrane Library includes the York Database of Abstracts of Reviews of Effectiveness (DARE) which provides information on previously published reviews of effects of health care interventions [16]. Unpublished research may be found by scanning the international dissertation abstracts, conference proceedings, index to theses and through personal communication with expert clinicians and researchers in the field of review. Other databases are available to track the 'grey literature', a term used to cover material published in reports, booklets, discussion papers and other formats which are not indexed on the main databases. Librarians experienced in database searching may assist the novice reviewer to identify the databases most likely to detect research on the review topic.

To increase the possibility of identifying all relevant literature, the bibliographies and reference lists of all retrieved articles should be scanned for further studies that appear to meet the inclusion criteria. Hand searching key journals may also identify recent publications that have not yet been indexed on the electronic databases.

A two–step search process is recommended that involves an initial preliminary search to identify keywords that may appear in the title, abstract and Medical Sub–Headings (MeSH) sections of the electronic database [20]. The second step involves a more comprehensive search using all keywords that were identified during the preliminary search. The search should continue until the reviewer is confident that no additional citations are emerging.

Due to the lack of standardisation between the various databases, individual search strategies need to be developed for each database [22]. The search strategies should be documented in sufficient detail to allow other investigators to assess the search for rigour and allow replication if required [11].

If the search relies solely on electronic databases and reference lists for identification of research on the review topic, there is a risk of publication bias. Reviewers can minimise this threat by including completed research that may be published as an abstract only or in non–peer reviewed form rather than only including those studies found in peer reviewed journals [23].

On completion of the searching process, care must be taken that the selection of studies to be included in the review minimises reviewer bias. Decisions about the inclusion of studies should be made according to the predetermined criteria stated in the systematic review protocol. Other strategies to consider in order to reduce selection and reviewer bias include having two or more investigators review each study independently, blinding of reviewers to the source and authorship of articles in order to make their judgements as impartial as possible, and selecting a non–expert reviewer unfamiliar with the field of study [9,23].

ASSESSING THE VALIDITY OF STUDIES

The critical appraisal of individual studies selected for inclusion is a crucial step in the review process. Critical appraisal should aim to assess the validity of the selected studies, determine the reasons why, other than chance, there is a difference between study results, and provide sufficient information for the reader to determine if the systematic review is applicable to their clinical practice [23].

As each study may vary in respect to their risk of bias and error, the major focus of critical appraisal is on the interpretation of the study findings and the applicability of these findings to practice [16]. The objective of critical appraisal is to identify high quality studies that are at least risk of error. The appraisal achieves this by evaluating critical components of the study design. In clinical trials, this evaluation focuses on selection, performance, attrition and detection [19].

- *Selection bias* results from the way that comparison groups are assembled in the primary study. A patient entering a trial with a random allocation to the treatment group ensures they have an equal chance of receiving the experimental treatment or being assigned to a comparator or control group.

- *Performance bias* occurs when, apart from the study intervention, differences in care occur within or between the study groups.

- *Attrition bias* results when a difference between treatment groups results from loss or withdrawal of participants from the study.

- *Detection bias* relates to differences in outcome assessment measures between study groups[16].

Appraisal tools should be designed to assess the degree of bias within the individual study. Several tools have been designed to assess RCTs [24, 25], observational and case–control studies [26]. Evaluation criteria are also available for qualitative research [27-29]. A limitation with these tools is that they rely on primary researchers to comprehensively report all details of the study, regardless of the actual findings, in order to determine the risk of bias.

After critical appraisal, studies may be categorised according to the strength of their evidence. While many hierarchies of evidence have been developed, one example used for studies evaluating the effectiveness of an intervention, published by the Australian Quality of Care and Health Outcomes Committee [30], is:

Level I	Evidence obtained from a systematic review of all relevant RCTs.
Level II	Evidence obtained from a least one properly designed RCT.
Level III.1	Evidence obtained from well designed controlled trials without randomisation.
Level III.2	Evidence obtained from well–designed cohort or case control analytic studies preferably from more than one centre or research group.
Level III.3	Evidence obtained from multiple time series studies with or without an intervention. Dramatic results in uncontrolled experiments.
Level IV	Opinion of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Similar hierarchies have been used for studies addressing prognosis and diagnosis [31]. As with the selection process, the critical appraisal of studies for inclusion in the review should be undertaken by two or more reviewers [9].

DATA EXTRACTION

The data collected in a systematic review are the findings of the primary research studies. Data that meets the outcome inclusion criteria for the review should be extracted from the results of each study using a data extraction tool. The study design, including details relating to randomisation, allocation, blinding and participant numbers should also be collected. Any narrative data deemed to be important, such as expert opinion or anecdotal evidence will also be extracted. A brief summary of major findings and any other results pertinent to the review subject will also be noted on the data extraction sheet.

The intent of data extraction is to collect and record all relevant data and minimise the risk of error during transcription. As with any research tool, the development and testing of the data extraction sheet is an important step in the review process [9] as data extraction may occasionally require subjective judgement and is therefore prone to human error [7]. Involving a second independent reviewer to extract data for comparison with the primary reviewer may overcome this problem [9].

Pilot testing the data collection tool using a representative sample of the studies to be reviewed may also assist in identifying data not needed or missing [16]. Unclear or missing data from the study report is problematic and contacting the primary researchers may be the only strategy to overcome this limitation. Some studies will be excluded from the meta–analysis as a result of inadequate or incomplete reporting of results.

DATA SYNTHESIS

National Health Service (NHS) Centre for Reviews & Dissemination [7] state the overall aims of data synthesis is to, where possible, provide an estimate of the average effect of the intervention, "... investigate whether the effect is roughly the same in different studies, settings and participants, and if not ... investigate apparent differences in the effectiveness of the intervention".

Meta–analysis is used to combine the results of data extracted from RCTs with the same type of participants, the same type of intervention(s) and the same outcome measures. The use of meta–analysis allows the results of small comparable studies to be integrated, thereby increasing the sample size and thus the power of the results [32]. During meta–analysis, the results from comparable studies are integrated after individual results are converted to a common scale or measure [9].

Some diversity of results can be expected in each meta–analysis as it is difficult to ensure the population under study, the treatment protocol and the timing of outcome assessment were identical, especially in studies with a small sample size [19]. This heterogeneity, or difference in findings, may indicate that differences exist between studies and so combining results may therefore be inappropriate. Mulrow, Langhorne and Grimshaw [33] suggest that heterogeneity is a 'double–edged sword', as it allows examination of consistency and applicability across studies, thereby allowing a more comprehensive review of feasibility, benefit and harm, but it may introduce ambiguity into the synthesis of evidence.

Quantitative data synthesis may not be possible in all reviews. But a systematic review that does not include statistical analysis can still be valuable to health practitioners [16]. Although the strength of the evidence within a systematic review that results from a narrative synthesis of data is limited in comparison to data pooled into a meta–analysis from quality RCTs, these reviews are useful in providing a broad perspective on a particular topic rather than an in–depth review of one particular component [8].

THE IMPLICATIONS FOR NURSING

Nurses undertaking systematic reviews should generate reports that comprehensively detail the purpose, process (detailed evidence of the review protocol) and findings of the systematic review. These reports, if critical and rigorous in nature, can inform nursing practice by providing clear guidelines on effective or ineffective nursing interventions.

In addition to developing skills in the critique of primary research, nurses must also learn how to appraise systematic reviews. Occasional discordance amongst reviews is not uncommon and poses difficulties for those relying on their evidence to assist them in decision–making [34]. French [35] suggests that nursing education must focus on increasing nurses awareness of the requirements for evidence based practice and begin to equip nurses with appropriate skills to recognise, appreciate and use systematic reviews.

There is still a paucity of reviews conducted by nurses relating to the organisation of nursing care and innovative nursing practice [13]. Some have been indexed in the Cochrane Library. Examples of reviews that impact on critical care nursing include hyperventilation of the acute head injured patient [36], coagulation sampling from arterial lines [37] and positioning infants in the neonatal intensive care unit [38]. More recently, Elliott published a systematic review of studies that measured patient outcomes from adult general intensive care unit patients [39]. However, more work is needed in order to assess the effectiveness of nursing interventions in critical care practice.

To enhance the effectiveness of nursing care delivery we must embrace the concept of evidence based nursing and systematic review, but in doing so must not lose sight of the complexity and diversity of nursing as a discipline. Research grounded in interpretive and critical paradigms is needed to answer questions such as how illness impacts on the lives of individual people. These methodologies can be incorporated into the systematic review process through qualitative synthesis and will provide valuable information to key stakeholders in health care.

CONCLUSION

Systematic literature reviews are an essential element in the development of evidence based policies, procedures and guidelines that can assist health carers in informed decision making. If rigorously planned and conducted, a systematic review can comprehensively synthesise current research through a skillful blend of quantitative and narrative data to provide the best available evidence on a topic of interest [11].

Rigorous planning will ensure that a clear direction is followed and reduce the risk of reviewer bias. A careful systematic process should be followed that includes the location and selection of studies for inclusion, critical appraisal of studies, data extraction and data synthesis. It is not an easy process and requires considerable time and resources to ensure the precision, accuracy and validity of the review process are enhanced, but it is vital to ensure effective health care practices are maintained.

REFERENCES

1. Burls A & Milne R. Evaluating the evidence: an introduction. Journal of Clinical Effectiveness 1996; 1(2):59–62.

2. Gray J, MacIntrye N & Kronenberger W. The effects of bolus normal–saline instillation in conjunction with endotracheal suctioning. Respiratory Care 1990; 35(8):785–90.

3. Ackerman M. The effects of saline lavage prior to suctioning. American Journal of Critical Care Nursing 1993; 2(4):326–30.

4. Booth A. In search of the evidence: informing effective practice. Journal of Clinical Effectiveness 1996; 1(1):25–29.

5. Glass G. Primary, secondary and meta–analysis of research. Educational Researcher 1976; 5(10):3–8.

6. Dickersin K. Meta–analysis: state of the science. Epidemiologic Review 1992; 14:154–76.

7. National Centre for Reviews and Dissemination. Undertaking systematic reviews of research on effectiveness: CRD guidelines for carrying out or commissioning reviews, 1996.

8. Cook D, Mulrow C & Hayes B. Systematic reviews: synthesis of best evidence for clinical decisions. Annals of Internal Medicine 1997; 126(5):376–80.

9. Hughes E. Systematic literature review and meta–analysis. Seminars in Reproductive Endocrinology 1996; 14(2):161–69.

10. Evans D, Kowanko I & Hodgkinson B. Systematic reviews in nursing research. Australian Nursing Journal 1998; 5(10):42.

11. Rosenfeld R. How to systematically review the medical literature. Otolaryngology – Head and Neck Surgery 1996; 115:53–63.

12. Lau J, Antman E, Jimenez–Silva J, Kupelnick B, Mosteller F & Chalmers T. Cumulative meta–analysis of therapeutic trials for myocardial infarction. New England Journal of Medicine 1992; 327:248–52.

13. Droogan J & Cullum N. Systematic reviews in nursing. International Journal of Nursing Studies 1998; 35:13–22.

14. Pearson A, Borbasi S, FitzGerald M, Kowanko I & Walsh K. Evidence Based Nursing: an examination of nursing within the international evidence based health care practice movement. Nursing Review 1997; February:2–16.

15. Pearcey P. Achieving research–based nursing practice. Journal of Advanced Nursing 1995; 22:33–39.

16. Mulrow C & Oxman A. The Cochrane Collaboration Handbook. London: BMJ Publishing Group, 1997.

17. Carter D. Quantitative Research. In: Cormack D (ed). The Research Process in Nursing. Oxford: Blackwell Science, 1996.

18. Porter S. Qualitative Analysis. In: Cormack D (ed). The Research Process in Nursing. Oxford: Blackwell Science, 1996.

19. Ohlsson A. Systematic reviews – theory and practice. Scandinavian Journal of Clinical Laboratory Investigation 1994; 54(Suppl 219):25–31.

20. Dickersin K, Scherer R & Lefebvre C. Identifying relevant studies for systematic reviews. British Medical Journal 1994; 309:1286–91.

21. Cullum N. Identification and analysis of randomised controlled trials in nursing: a preliminary study. Quality in Health Care 1997; 6:2–6.

22. Sindhu F & Dickson R. The complexity of searching the literature. International Journal of Nursing Practice 1997; 3:211–17.

23. Meade M & Richardson S. Selecting and appraising studies for a systematic review. Annals of Internal Medicine 1997; 127(7):531–37.

24. Moher D, Jadad A & Tugwell P. Assessing the quality of randomised controlled trials, current issues and future directions. International Journal of Technology Assessment in Health Care 1990; 12(2):195–208.

25. Chalmers T, Smith H, Blackburn B, Silverman B, Schoreder B, Reitman D *et al*. A method for assessing the quality of a randomised controlled trial. Controlled Clinical Trials 1981; 2:31–49.

26. Sackett D. Bias in analytical research. Journal of Chronic Disease 1979; 32:51–63.

27. Leininger M. Ethnomethods: the philosophic and epistemic bases to explicate transcultural nursing knowledge. Journal of Transcultural Nursing 1990; 1:40–51.

28. Madison G. The Hermeneutics of Postmodernity. Bloomington: Indiana University Press, 1990.

29. Forchuk C & Roberts J. How to critique qualitative research articles. Canadian Journal of Nursing Research 1993; 25(4):47–57.

30. Quality of Care and Health Outcomes Committee. Guidelines for the development and implementation of clinical guidelines. Canberra: Australian Government Publishing Service, 1995.

31. Meltzer S, Leiter L, Daneman D, Gerstein H, Lau D, Ludwig S *et al*. 1998 Clinical practice guidelines for the management of Diabetes in Canada. Canadian Medical Association Journal 1998; 159(Suppl 8):51–529.

32. Lau J, Ioannidis J & Schmid C. Quantitative synthesis in systematic reviews. Annals of Internal Medicine 1997; 127(9):820–26.

33. Mulrow C, Langhorne P & Grimshaw J. Integrating heterogeneous pieces of evidence in systematic reviews. Annals of Internal Medicine 1997; 127(11):989–95.

34. Jadad A, Cook D & Browman G. A guide to interpreting discordant systematic reviews. Canadian Medical Association Journal 1997; 156:1411–16.

35. French B. Developing the skills required for evidence–based practice. Nurse Education Today 1998; 18:46–51.

36. Geraci E & Geraci T. A look at recent hyperventilation studies: outcomes and recommendations for early use in the head–injured patient. Journal of Neuroscience Nursing 1996; 28(4):222–24, 229–33.

37. Laxson C & Titler M. Drawing coagulation studies from arterial lines: an integrative literature review. American Journal of Critical Care 1994; 3(1):16–24.

38. Long T & Soderstrom E. A critical appraisal of positioning infants in the neonatal intensive care unit. Physical and Occupational Therapy in Paediatrics 1995; 15(3):17–31.

39. Elliott D. Measuring the health outcomes of general ICU patients: a systematic review of methods and findings. Australian Critical Care 1999; 12(4):132–40. ▲

Jones, T. (2000). *The effectiveness of mechanical compression devices in attaining hemostasis after removal of a femoral sheath following femoral artery cannulation for cardiac interventional procedures*. Adelaide: Joanna Briggs Institute for Evidence Based Nursing and Midwifery.

Jones, T., & McCutcheon, H. (2002). Effectiveness of mechanical compression devices in attaining hemostasis after femoral sheath removal. *American Journal of Critical Care, 11*(2), 155-162.