Equipment

A Prospective Clinical Comparison of Two Intravenous Polyurethane Cannulae[#]

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SUMMARY

Tissue irritation, as evidenced by phlebitis, associated with Optiva™ (Johnson & Johnson Medical) and Insyte™ (Becton Dickinson) polyurethane cannulae was studied. The integrity of the cannulae on removal, the incidence of infection at the cannula site and the factors which influence phlebitis were also examined.

One thousand and eight patients had a polyurethane cannula placed for induction of anaesthesia for cardiac surgery. After surgery, the cannula was examined every 24 hours. If evidence of phlebitis occurred, the cannula was removed and sent for culture. All remaining cannulae were removed at 72 hours and the site examined daily for a further three days.

There were 503 Optiva™ and 505 Insyte™ cannulae studied. The distributions between the two cannulae with respect to patient characteristics, gauge of cannula, number of attempts and difficulty of insertion, cannula site and anaesthetist inserting were similar. The early removal rate for both groups was 47%.

Overall phlebitis rate with Optiva™ was 31% and Insyte™ 33%. This difference is not statistically significant. The cumulative phlebitis rate increased with time but did not differ between the two types of cannulae.

Minor tip distortion or shaft kinking of the cannulae occurred in 16.2% of Optiva™ and 23.5% of Insyte™. This difference is statistically significant and may relate to the slightly more acute taper at the Optiva™ cannula tip. Both cannulae were similar in clinical performance.

Key Words: EQUIPMENT: polyurethane cannulae; ANAESTHETIC TECHNIQUES: intravenous cannulation; COMPLICATIONS: phlebitis

Phlebitis is a well-recognized complication of intravenous therapy. Several factors have been shown to contribute to phlebitis. Maki and Ringer reported a risk of phlebitis over 50% after four days insertion[1] and identified patient and other factors which contributed to the phlebitis rate. Female patients were found to be 1.9 times more likely to get phlebitis and insertion on the forearm was more likely to result in phlebitis than insertion into the hand or wrist. They also reported that the catheter material affected the incidence of phlebitis. A cannula made from Teflon™ was 1.37 times more likely after a few days to cause phlebitis than one made with polyurethane (Vialon™). Larsson and colleagues suggested that this might be explained by chemical leeching from the different cannula materials[2]. A difference in phlebitis rates for the two materials was supported by a study by McKee et al in 191 patients. They found a phlebitis rate at 72 hours of 31% for Vialon™ and a 51% rate for Teflon™[3]. A larger study of 645 cannulae used for induction of anaesthesia by Gaukroger et al but which remained in for up to four days also found that Vialon™ had only 54% of the phlebitis risk of Teflon™[4]. However, a double-blind randomized controlled comparison of both types of cannulae at the Central Middlesex Hospital in London failed to find any difference in phlebitis rate over five days[5].

The difference in findings is difficult to explain. One possible explanation is the difference in treatment of the Teflon™ surface. All the positive studies were comparing the Insyte™ made of Vialon™ by Becton Dickinson with the Jelco™ made of Teflon™ by Johnson & Johnson Medical. The negative study used a Teflon™ Vasculon™ cannula made by Viggo-Spectramed. The microscopic surface properties of similar material can be different. A study by Tebbs et al of polyurethane catheters showed that the smoothness of the surface differed substantially[6] and the smoother surfaces were associated with a lower bacterial colonization after one hour of incubation. Thus even if cannulae are made of the same material, other factors may still create a significant difference in the clinical phlebitis rate. Although the new Optiva™ cannula is made of polyurethane, the cannula is transparent and claimed by the company to be an improvement on the Vialon™ polyurethane. In addition, the inserting needle is of a different profile, being back-sharpened and it is claimed that about a 20-30% smaller force is required for needle and cannula insertion. This could alter the tissue damage on insertion.

As the major concern for most clinicians is how long they can use an intravenous cannula, a trial was designed to prospectively compare the two clinically available polyurethane cannulae, Optiva™ from Johnson & Johnson Medical and Insyte™ from Becton Dickinson with particular reference to phlebitis, which is the most common limiting factor for long term use.

METHODS

Patients undergoing cardiac surgery were randomly allocated to have their induction through either an Optiva™ or Insyte™ polyurethane cannula. Randomization was determined by a table of random numbers. All patients were greater than 18 years old and gave informed consent as approved by the Royal Adelaide Hospital Ethics Committee.

Patients were excluded if informed consent was not possible or the patient refused. They were also excluded if there was evidence of infection, or the cannulae were not suitable for the patient.

The chosen cannula was inserted by an experienced anaesthetist and then connected to an infusion set running a balanced electrolyte solution. This set was used for the induction of anaesthesia and the administration of drugs and fluids during the operation. After the patient was in the cardiac intensive care and

stable so that this IV line was no longer required, the cannula was capped and flushed with heparin saline. This cannula then remained in for a total of three days, after which it was removed and the site observed daily for a further three days for evidence of phlebitis or infection. After capping, an injection through the cannula of heparin saline flushing solution (50 units in 5 ml) was ordered eight hourly prn.

Daily monitoring of the cannula site was performed by one of the three study nurses. The cannula site was assessed for any signs of phlebitis such as erythema, oedema, pain or tenderness, streak formation, a palpable venous cord or any exudate. If this occurred within the three days, the cannula was removed. If evidence of phlebitis occurred at any time during the six days observation, the site was swabbed and the swab sent for culture. In addition, the degree of phlebitis was graded as mild (pain and/or erythema), moderate (oedema and/or streaking along vein) or severe (a palpable venous cord and/or exudate at cannula site). If a patient had more than one symptom or sign, then the highest appropriate category was used. This scoring was done at the time the cannula was removed or during the subsequent post-decannulation observation and the maximum reaction scored.

Immediately after removal, the cannula was examined macroscopically and any damage or deformation recorded.

Demographic data was collected on the patients and a record was kept of all drugs administered during the three days the cannula was in. In addition, data about the insertion was also recorded. This included the anaesthetists, the size of the cannula, the site of insertion, and the ease of insertion.

Statistical analysis of the cannula duration was by survival analysis using a Kaplan-Meier estimation and multivariate modelling was done using a Cox proportional hazards model with co-variates. The initial variables for the stepwise regression were chosen by a t-test, Chi square, or Wilcoxon as appropriate with a threshold P value of 0.2.

RESULTS

One thousand and eight patients had cannulae inserted for more than 12 hours. Five hundred and three received Optiva™ cannulae and 505 received Insyte™ cannulae. These two groups are well matched with respect to age, sex, weight, diabetes, preoperative white cell count and preoperative blood sugar (Table 1). Similarly the two groups were well matched for factors relating to the insertion of the

TABLE 1

Patient Characteristic		All Patients (n= 1008)	
		Optiva™ (n= 503)	Insyte™ (n= 505)
Age (years)	Mean	61.5	61.2
	SD	10.7	10.9
	Min-Max	18-85	26-85
Sex	Male	387 (77%)	384 (76%)
	Female	116 (23%)	121 (24%)
Weight (kg)	Mean	77.0	76.9
	SD	13.8	12.8
	Min-Max	40-121	40-121
History of diabetes	Yes	58 (12%)	80 (16%)
	No	445 (88%)	425 (84%)
White cell count ($\times 10^3$)	Mean	7.4	7.5
	SD	2.0	2.2
	Min-Max	1.1-22	1.1-20.5
Blood sugar level (mmol/l)	Mean	6.3	6.5
	SD	2.7	3.0
	Min-Max	1.5-19.7	1.6-23.0

TABLE 2

Cannula Characteristics		All Patients (n= 1008)	
		Optiva™ (n= 503)	Insyte™ (n= 505)
Cannula gauge	14 ga	95 (19%)	100 (20%)
	16 ga	379 (75%)	370 (73%)
	18 ga	29 (6%)	35 (7%)
Cannula site (arm)	Left	464 (92%)	464 (92%)
	Right	39 (8%)	41 (8%)
Cannula site (position)	Upper Arm	1 (0.2%)	1 (0.2%)
	Antecubital Fossa	80 (16%)	74 (15%)
	Forearm	143 (28%)	161 (32%)
	Wrist	134 (27%)	137 (27%)
	Hand	145 (29%)	132 (26%)
Degree of difficulty	Easy	440 (88%)	434 (86%)
	Some difficulty	5 (1%)	3 (1%)
	Extreme difficulty	58 (11%)	68 (13%)
Number of attempts	1	445 (88%)	445 (88%)
	2	47 (9%)	51 (10%)
	3	8 (2%)	9 (2%)
	≥4	3 (0.6%)	0 (0%)
Anaesthetist	1	92 (18%)	113 (22%)
	2	15 (3%)	12 (2%)
	3	123 (24%)	101 (20%)
	4	28 (6%)	38 (8%)
	5	37 (7%)	35 (7%)
	6	3 (0.6%)	3 (0.6%)
	7	78 (15%)	67 (13%)
	8	38 (8%)	37 (7%)
	9	64 (13%)	74 (15%)
	10	27 (5%)	23 (5%)

TABLE 3

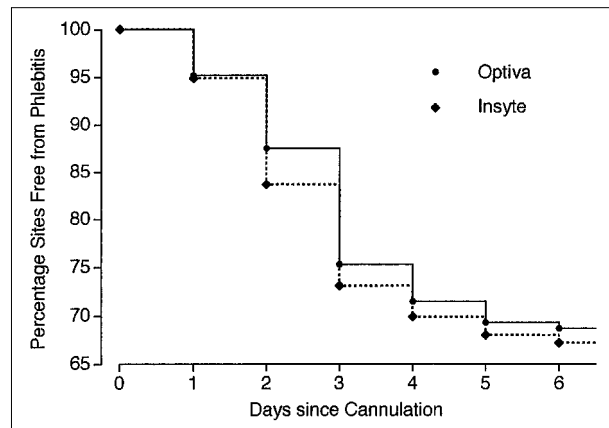| Cannula Removal		All Patients (n= 1008)	
		Optiva™ (n= 503)	Insyte™ (n= 505)
Cannula-related		185 (37%)	186 (37%)
	Phlebitis	111 (22%)	124 (25%)
	Infiltration	30 (6%)	26 (5%)
	Leakage	31 (6%)	26 (5%)
	Other	13 (3%)	10 (2%)
Non cannula-related		318 (63%)	319 (63%)
	End of Trial	264 (53%)	266 (53%)
	Dislodgement	32 (6%)	28 (6%)
	Other	22 (4%)	25 (5%)

FIGURE 1: The survival of the two types of cannulae for the freedom from phlebitis at the cannula or cannula site. The Optiva™ survival line is shown as solid dots joined by a continuous line. The survival curves have been extended beyond day 6 for clarity. The Insyte™ is shown as a solid diamond joined by a dashed line. Although there is a better survival of the Optiva™ cannulae, this is not statistically significant.

TABLE 4

Variable		Coeff	Std Error	Hazards Ratio	95% CI	P value
Esmolol						
	(Yes:No)	0.66	0.23	1.94	1.24-3.05	0.0039
Site of cannula						
	(Antecubital:Wrist)	0.03	0.12	1.03	0.81-1.30	0.8096
	(Forearm:Wrist)	0.18	0.09	1.20	1.00-1.43	0.0414
	(Hand:Wrist)	−0.15	0.10	0.86	0.70-1.05	0.1357
Nurse assessor						
	1:3	0.20	0.08	1.22	1.05-1.42	0.0088
	2:3	0.04	0.08	1.04	0.89-1.21	0.6499

cannula (Table 2).

In both groups 47% of the cannulae were removed before the three days had expired. The commonest reason for removal was phlebitis (Optiva™ 22% and Insyte™ 25%); the difference is not significant (P= 0.37 Fisher). A complete list is given in Table 3.

With both cannulae there was a progressive increase in phlebitis while the cannula remained in and some continued phlebitis in the three days after removal (Figure 1). However, although the Optiva™ cannulae had a slightly lower progressive incidence, this difference was not statistically significant. The adjusted survival for Optiva™ after six days was estimated at 68.7% (95% CI 64.6-72.8) and for Insyte™ was 67.2% (95% CI 63.1-71.3).

Only three factors were identified as influencing the incidence of phlebitis with the Cox proportional hazards model. These were: the use of esmolol, the site of the cannulation and the nurse observer identifying phlebitis (Table 4). The hazard ratio expresses the increased risk of the factor being present, e.g. cannulation on the forearm increased the risk of phlebitis 20% (confidence interval 0-43%, P= 0.04).

The severity of phlebitis with each type of cannula was also assessed. At each grade the level of phlebitis was similar with both cannulae (P= 0.41 Chi square, Figure 2). In addition, the type of reaction was also similar (Figure 3). None of these reaction differences between cannulae was statistically significant (all categories P> 0.02).

When the cannulae were removed, the shaft and tip of every cannula were examined. Evidence of damage was noted in 80 Optiva™ cannulae and 120 Insyte™ cannulae (Figure 4). Shaft kinking occurred to both types in about equal frequency (6.1% and 8.2% respectively). However, the incidence of tip damage or distortion with Insyte™ was significantly greater than with Optiva™ (P= 0.0001 Fisher).

DISCUSSION

The two cannulae groups are very well matched for the characteristics examined and gives grounds for confidence in the randomization. There was no statistically significant difference in phlebitis between the two cannulae three days after insertion and in the subsequent three days of observation. The incidence of phlebitis over the six days was 31% with the Optiva™ cannula and 33% with the Insyte™. With 1008 patients and assuming an α= 0.20, this trial has an estimated power of 87% to detect a real difference of 5%. As the difference in phlebitis seen was 2% it is unlikely that a clinically significant difference in these two cannulae has been missed.

Although 22% of the Optiva™ and 25% of the Insyte™ were removed because phlebitis was identified, a further 15% of Optiva™ and 12% of Insyte™ cannulae were removed early for other reasons. The survival incidence at day 3 adjusted for the non-phlebitis removals is 75.3% (95% confidence intervals 71.5-79.1) for Optiva™ and 73.1% (95% CI 69.2-77.0) for Insyte™ respectively. At day 6 the survival
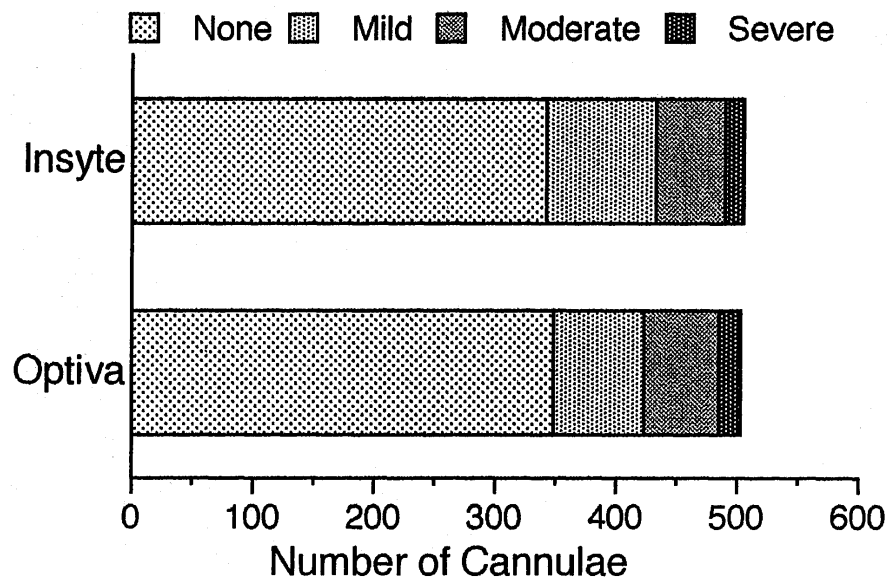

FIGURE 2: Comparison of the incidence and degree of phlebitis found in the Optiva™ and Insyte™ cannulae. Most cannulae showed no phlebitis but in those which did the grades of severity were equally distributed between the two types.
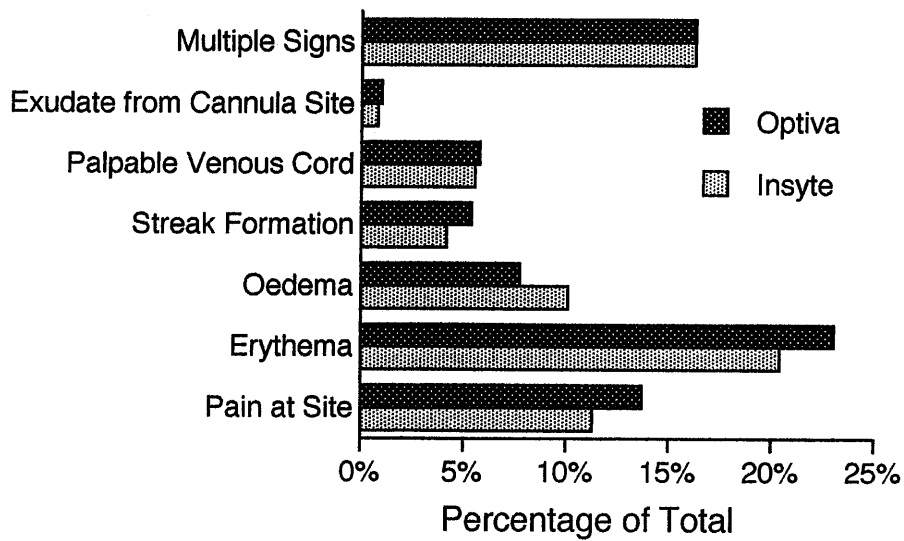
FIGURE 3: Comparison of the type and frequency of phlebitis found in the Optiva™ and Insyte™ cannulae. Most cannulae showed no phlebitis but in those which did the patterns of the phlebitic response were equally distributed between the two types.
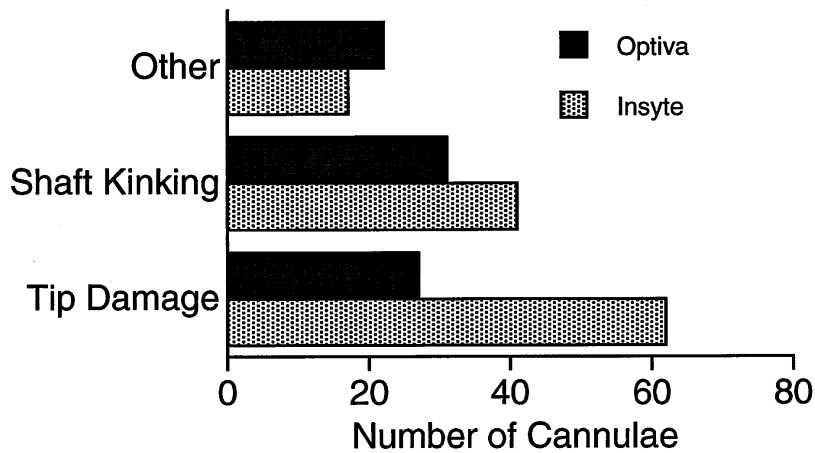

FIGURE 4: Comparison of the type of cannula damage found with the Optiva™ and Insyte™ cannulae. Tip damage was more frequent with the Insyte™ (*P*= 0.0001). However, this did not appear to affect the incidence of clinical phlebitis.

(i.e. non-phlebitis rate) is 68.7% (95% confidence intervals 64.6-72.8) for Optiva™ and 67.2% (95% CI 63.1-71.3) for Insyte™. This shows that in both groups there was about 10% additional phlebitis over the three days after removal. The first day post-removal however, has about 50% of the additional phlebitis and if the second day is included this will cover over 80% of the delayed phlebitis. Thus this pattern is faster than an exponential decay and it can be reasonably extrapolated that over 90% of the addi-

tional change will be observed within the three days.

The Cox's proportional hazard model to identify the major factors in phlebitis in this study found three parameters of interest. The use of esmolol is identified as the most significant factor. This must remain in doubt as the number of patients receiving esmolol was very small. However esmolol is well known to provoke histamine release so that a phlebitic enhancement may be expected. The site of cannulation is of significance as the use of the mid forearm veins is common. Possibly in the cardiac scenario when patients are cold and vasoconstricted these veins are experiencing an unusually low flow as they tend to be superficial.

It appears that in spite of differences in appearance and needle profile, both the Optiva™ and the Insyte™ cannulae have a similar risk of phlebitis in clinical use and similar survival expectations.

REFERENCES

1. Maki D, Ringer M. Risk factors for infusion-related phlebitis with small peripheral venous catheters. Ann Intern Med 1991; 114:845-854.
2. Larsson N, Stenberg K, Linder L-E, Curelaru L. Cannula thrombophlebitis: a study in volunteers comparing polytetra-fluorethylene, polyurethane, and polyamide-ether-elastomer cannulae. Acta Anaesthesiol Scand 1989; 33:223-231.
3. McKee JM, Shell JA, Warren TA, Campbell VP. Complications of intravenous therapy: a randomized prospective study—Vialon vs. Teflon. J Intravenous Nursing 1989; 12:288-295.
4. Gaukroger PB, Roberts JG, Manners TA. Infusion Thrombophlebitis: a prospective comparison of 645 Vialon™ and Teflon™ cannulae in anaesthetic and postoperative use. Anaesth Intensive Care 1988; 16:265-271.
5. Payne-James JJ., Rana SK, Rogers J, McSwiggan D, Bray MJ, Silk DBA. Development of thrombophlebitis in peripheral veins with Vialon and PTFE-Teflon cannulas: a double-blind randomised controlled trial. Ann R Coll Surg Engl 1991; 73:322-325.
6. Tebbs SE, Sawyer A, Elliott TSJ. Influence of surface morphology on *in vitro* bacterial adherence to central venous-catheters. Br J Anaesth 1994; 72:587-591.