Improving maximum walking distance in early peripheral arterial disease: Randomised controlled trial

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The purpose of this study was to determine the impact of increased physical activity and cessation of smoking on the natural history of early peripheral arterial disease. We conducted a randomised controlled trial in Perth, Western Australia, involving 882 men with early peripheral arterial disease identified via population-based screening using the Edinburgh Claudication Questionnaire and the ankle:brachial index. Members of the control group (n = 441) received "usual care" from their general practitioner while members of the intervention group (n = 441) were allocated to a "stop smoking and keep walking" regime - a combined community-based intervention of cessation of smoking (where applicable) and increased physical activity. Postal follow-up occurred at two and 12 months post-entry into the trial. The main outcome of interest was maximum walking distance. There were no statistically significant differences in the characteristics of the "intervention" and "usual care" groups at recruitment. Follow-up information at two and 12 months was available for 85% and 84% of participants, respectively. At 12 months, more men allocated to the intervention group had improved their maximum walking distance (23% vs 15%; $\chi^2 = 9.74$, df = 2, $p = 0.008$). In addition, more men in the intervention group reported walking more than three times per week for recreation (34% vs 25%, $p = 0.01$). Although not statistically significant, more men in the intervention group who were smokers when enrolled in the trial had stopped smoking (12% vs 8%, $p = 0.43$). It is concluded that referral of older patients with intermittent claudication to established physiotherapy programs in the community can increase levels of physical activity and reduce disability related to peripheral arterial disease. A combination of simple and safe interventions that are readily available in the community through physiotherapists and general practitioners has the potential to improve early peripheral arterial disease. **[Fowler B, Jamrozik K, Norman P, Allen Y and Wilkinson E (2002): Improving maximum walking distance in early peripheral arterial disease: Randomised controlled trial. *Australian Journal of Physiotherapy* 48: 269-275]**

Key words: Exercise; Peripheral Vascular Diseases; Randomized Controlled Trials; Smoking Cessation

Introduction

One in nine elderly Australian men have symptoms or signs of early peripheral arterial disease (Fowler et al 2002). Once established, the natural history of this condition is uncertain. Most of what is known about the management and outcome of peripheral arterial disease is based on small studies of patients with moderate to severe disease referred for vascular surgical assessment. Housley et al (1988) indicate that "stop smoking and keep walking" has long been the standard first line of management, despite a paucity of adequate studies showing benefits (Robeer et al 1998). Among less advanced cases, however, the risk of the disease progressing to the point where operative intervention is required is very small. Over the five years of follow-up in the Edinburgh Artery Study, fewer than 9% of affected individuals required surgical intervention (Leng et al 1996). Indeed, the relative rarity of major endpoints in peripheral arterial disease means that studies of early disease would have to be very large, or employ extraordinarily efficacious interventions, or both, to have any chance of detecting and declaring significant an effect of treatment on risk of amputation or other surgical intervention.

Conversely, early peripheral arterial disease is associated with several clinical indicators for which the frequency is sufficiently high to allow an intervention study to be of manageable size if these symptoms and signs are also sensitive to intervention. Candidate endpoints for such a study include the presence of intermittent claudication, the maximum walking distance before onset of intermittent claudication, and the ankle:brachial index of systolic blood pressure.

Having ascertained the prevalence of peripheral arterial disease in elderly men in Perth (Fowler et al 2002), we conducted a randomised controlled trial of an intervention regimen based on Housley's dictum of "stop smoking and keep walking". To maximise the broader applicability of our results, we undertook an effectiveness study and were careful to employ interventions that could be delivered via health services that already existed in the local community, including physiotherapy and general medical services.

Methods

Background - cross sectional survey The initial cross-sectional survey of 7,987 men that determined the prevalence of early peripheral arterial disease was part of a population-based trial of ultrasound screening for abdominal aortic aneurysm in Western Australia. Full

details of that study have been published elsewhere (Jamrozik et al 2000). Briefly, it set out to screen for abdominal aortic aneurysms and peripheral arterial disease in a random half of male residents of Perth who were aged from 65 to 79 years in April 1997. Eligible men were identified from electoral rolls, enrolment to vote being compulsory for Australian citizens, and invited to the one of five screening centres that was nearest to their home. Screening for peripheral arterial disease was undertaken at three of these locations.

Identification of subjects with peripheral arterial disease The identification of men with early peripheral arterial disease was based on:

- A classification of either definite intermittent claudication or atypical intermittent claudication on the Edinburgh Claudication Questionnaire (Leng et al 1992); or
- An ankle:brachial index of systolic blood pressure of 0.9 or less in either leg, indicating a reduced blood flow to the lower limbs; or
- Clinical examination and diagnosis of peripheral arterial disease for those men with diabetes who did not meet either criterion (i) or (ii), or who had an ankle:brachial index of systolic blood pressure of 1.2 or more, or leg pain.

At the screening clinic, each man was asked for written consent to his participation in the research. Via a questionnaire, he then provided details of his personal and medical background and lifestyle. As part of the questionnaire he completed the Edinburgh Claudication Questionnaire (Leng and Fowkes 1992), an instrument that has greater sensitivity and specificity for intermittent claudication than the original Rose questionnaire (Rose et al 1962) on which it is based. At two of the three clinics each man was also examined for peripheral arterial disease using the ankle:brachial index of systolic blood pressure (Yao et al 1969), a widely used test that is sensitive and specific for the identification of early peripheral arterial disease (Bernstein and Fronek 1982).

Enrolment for the trial of intervention in early peripheral arterial disease began at one centre in November 1996 and continued simultaneously in two clinics until March 1998.

Randomisation into study groups Using a computer-generated sequence to which the staff enrolling participants were blinded, eligible men were randomised in strata defined by aortic size (< 30mm, 30-39mm) and smoking habits (current smoker or not), into usual care and intervention groups.

Usual care group Men allocated to the usual care group were told by a nurse at the screening clinic that, "the blood flow to your feet and legs is lower than normal. This is not uncommon for men of your age but there is presently no evidence to suggest you should do anything about it at this time". Neither the ankle:brachial index of systolic blood pressure, if measured, nor findings on the Edinburgh Claudication Questionnaire were mentioned in letters to the man or his general practitioner that set out the results of screening for an abdominal aortic aneurysm.

Intervention group Allocation to the intervention group led to the men being told that "your ankle:brachial index of systolic blood pressure or Edinburgh Claudication Questionnaire test showed a reduced blood flow to the muscles in your leg or legs caused by partial blockage of the arteries and this often results in pain on walking". They were provided with an educational package including information on peripheral arterial disease, a brochure on the community physiotherapy service, information on cessation of smoking (where applicable), and a copy of the letter from the clinic to their general practitioner, and were advised to consult the general practitioner about management of the problem. In a separate communication, the general practitioner was sent a package of written materials about cessation of smoking, notes on obtaining optimal results from nicotine replacement products, and a fact-sheet on peripheral arterial disease. In addition, the general practitioner was asked to discuss cessation of smoking with relevant patients and to refer each man with early peripheral arterial disease to the community physiotherapy service, having first checked him for suitability to undertake additional physical activity.

The clinic staff also advised the community physiotherapy service directly about each likely referral. The senior physiotherapist then contacted each man in the intervention group within approximately three weeks of his screening examination.

The objective of the exercise intervention was to increase the level of physical activity undertaken by each man in the intervention group. This exercise could be completed either independently or through an organised program. To facilitate compliance with the intervention, each man was invited to attend the community physiotherapy service's mobility program for seniors - a community based exercise program that has been offered by physiotherapists in the Perth metropolitan area since 1979. Participants in the intervention group of the randomised controlled trial had the choice of attending a weekly mixed-gender group session as part of the established program or a men-only session introduced to support the present trial. As an alternative to attending the mobility program for seniors, the participant could follow a home-based program of physical activity devised specifically for him by the senior physiotherapist from the community physiotherapy service. In addition, all men in the intervention group were advised by the physiotherapist to walk for at least 30 minutes a day. In certain cases, men were referred to hydrotherapy classes or special exercise sessions for the disabled.

The mobility program for seniors program for peripheral arterial disease consisted of a structured physical activity intervention involving a weekly exercise group of 45 minutes supervised by an experienced community physiotherapist. The session included a warm-up phase of stretching the calf, hamstring and upper limb muscles,

Table 1. Comparison of characteristics of study groups at enrolment. Except where otherwise specified, data are percentages. *P*-values are from *t*-test (age), Mann-Whitney U test (body mass index, systolic blood pressure, ABI) or chi-square test (all other variables).

	Usual care n = 441 %	Intervention n = 441 %	*p*
Age (mean years)	73.1	73.1	0.96
Intermittent claudication *			0.68
No pain on walking	27.9	26.8	
Definite IC (Grade 2)	21.1	20.0	
Definite IC (Grade 1)	22.4	25.6	
Atypical IC (Grade 2)	3.4	2.9	
Atypical IC (Grade 1)	7.1	5.1	
Pain on walking (not vascular)	18.1	19.8	
Maximum walking distance			0.51
Less than 100 yards	11.0	10.3	
100 to 440 yards	24.8	21.7	
Greater than 440 yards	36.2	41.0	
Pain-free walking	28.0	27.0	
Smoking status			
Current smoker	18.1	19.3	0.67
Body mass index (mean kg/m^2)	26.5	26.4	0.44
Systolic blood pressure (mean mm Hg)	159.8	161.4	0.57
Diastolic blood pressure (mean mm Hg)	86.6	87.2	0.57
ABI (mean, ratio)	0.79	0.79	0.89
Physical activity for recreation, sport or fitness less than weekly	31.6	28.6	0.34
Medical history			
Diabetes mellitus	19.7	14.6	0.06
Angina	34.6	30.2	0.20
Myocardial infarction	25.3	22.6	0.40
Stroke	12.5	13.2	0.76

* Categories taken from the Edinburgh Claudication Questionnaire.

ABI, ankle:brachial index. IC, intermittent claudication.

followed by 20 minutes of fast walking, usually to music, and ending with a cool-down period. The participant was encouraged to continue walking until intermittent claudication forced him to stop.

Follow-up Men in both study groups were followed up by reply-paid postal questionnaire at two and 12 months after enrolment with, in each case, up to two reminders to non-respondents at intervals of three weeks. At each follow-up,

Table 2. Details of response to follow-up. Data are counts except where specified.

	Two months		12 months *	
	Usual care	Inter-vention	Usual care	Inter-vention
Eligible	441	441	437	432
Return to sender	1	1	5	5
Dead	3	4	21	14
Too ill to respond	1	0	4	0
Inadvertently not sent a questionnaire	10	7	0	0
Adjusted denominator	*426*	*429*	*407*	*413*
Completed and returned questionnaire	348	378	336	361
Returned questionnaire blank	31	26	27	19
Withdrew from study	1	5	9	7
No response	46	20	35	26
Crude response**	78.9%	85.7%	76.7%	83.4%
Adjusted response***	81.7%	88.1%	82.6%	87.4%

* Men who withdrew or had died at two months follow-up have been omitted from eligibility at 12 months.
** Completed questionnaires as a proportion of those eligible. *** Calculated using adjusted denominators.

men were asked to complete the Edinburgh Claudication Questionnaire and to estimate their maximum walking distance before the onset of pain in the legs (less than 100 yards, 100-440 yards, more than 440 yards, or no pain on walking). Other sections of the questionnaire concerned current smoking habits, patterns of physical activity (weekly frequency and duration of vigorous and non-vigorous activity and of walking for fitness or recreation. "Vigorous" exercise was defined as non-work activity that made the man breathe harder or puff and pant, while "non-vigorous" activity covered all other forms of exercise including walking (National Heart Foundation 1991)). A man was classified as "physically active" if he engaged in either vigorous or non-vigorous exercise at least weekly. Health-related quality of life was measured on a scale of -1.2 (worst) through 0 (dead) to 1.0 (best) using an instrument devised by Rosser et al (1991).

To reduce any trend for men to give responses perceived as being socially desirable, the letter accompanying each questionnaire used the logo of another local university and the funding body and the text made no reference to peripheral arterial disease or to the "stop smoking and keep walking" program.

Statistical considerations In a pilot study undertaken to assess sample size requirements, we recalled 181 men approximately one year after enrolment for a re-assessment that included the Edinburgh Claudication Questionnaire,

Table 3. Comparison of study groups at follow-up at two months. Data are percentages except where indicated otherwise.

	Usual care	Intervention	*p*
Status of men who smoked at enrolment *	n = 79	n = 85	
Stopped smoking	1.3	3.5	0.62
Current smoker	98.7	95.3	
Physical activity	n = 325	n = 353	
Walking for recreation (≥ 3/week)	31.4	36.8	0.14
Vigorous activity (≥ 1/week)	31.1	29.9	0.73
More activity than usual	9.0	10.2	0.62
Membership of an exercise group	10.1	14.0	0.08
Maximum walking distance #	n = 432	n = 433	0.81
Better	21.8	20.3	
Same	52.5	52.4	
Worse	25.7	27.3	
Maximum walking distance ##	n = 323	n = 339	0.63
Better	29.1	26.0	
Same	36.5	39.2	
Worse	34.4	34.8	
Health-related quality of life [mean (SD)]	0.85 (0.14)	0.83 (0.16)	0.33

* Men who were alive but lost to follow-up were assumed to have continued smoking.

\# Includes all those alive at 2 months, with men who did not respond to follow-up included as having the same maximum walking distance as at baseline

\## Limited to those alive at 2 months who responded

maximum walking distance and the ankle:brachial index of systolic blood pressure. Of the 123 (74%) of available men who attended, 62 also undertook a 6min timed walking test (Montgomery and Gardner 1998) to validate the self-reported maximum walking distance. Examination of the between-group differences indicated that to have an 80% chance of declaring the impact of the intervention significant, using a two-sided $\alpha = 0.05$, the study would have to enrol 2,400 men if the endpoint chosen was the ankle:brachial index of systolic blood pressure ($\delta = 0.027$) and 20,400 men if the primary endpoint was the prevalence of intermittent claudication ($\delta = 1.6\%$). However, 882 men randomised into two groups of equal size would yield 90% power for declaring significant ($\alpha = 0.05$) a between-group difference of 7.9% in the proportion of men able to walk

Table 4. Comparison of study groups at follow-up at twelve months. Data are percentages except where indicated otherwise. *P*-values are from *t*-test (health-related quality of life) or chi-square tests (all other variables).

	Usual care %	Intervention %	*p*
Status of men who smoked at enrolment *	n = 77	n = 82	
Stopped smoking	7.8	12.2	0.43
Current smoker	92.2	87.8	
Physical activity	n = 328	n = 340	
Walking for recreation (≥ 3 /week)	25.0	33.8	0.01
Vigorous activity (≥ 1/week)	35.3	38.5	0.39
More activity than usual	5.9	11.1	0.03
Membership of an exercise group	1.8	16.5	< 0.001
Maximum walking distance #	n = 413	n = 419	
Better	14.8	22.9	0.003
Same	68.5	59.9	0.01
Worse	16.7	17.2	0.84
Maximum walking distance ##	n = 317	n = 347	0.04
Better	19.2	27.7	
Same	59.0	51.6	
Worse	21.8	20.7	
Health-related quality of life [mean (SD)]	0.84 (0.14)	0.83 (0.13)	0.13
Intermittent claudication**	n = 327	n = 347	0.26
No pain on walking	37.0	40.9	
Definite IC (Grade 2)	16.8	19.0	
Definite IC (Grade 1)	14.1	9.5	
Atypical IC (Grade 2)	2.8	1.2	
Atypical IC (Grade 1)	1.2	0.9	
Pain on walking (not vascular)	28.1	28.5	

IC, intermittent claudication.

* Men who were alive but lost to follow-up were assumed to have continued smoking.

\# Includes all those alive at 12 months, with men who did not respond to follow-up included as having the same maximum walking distance as at baseline.

\## Limited to those alive at 12 months who responded.

** Categories taken from the Edinburgh Claudication Questionnaire.

Table 5. Categories of maximum walking distance at follow-up.

Factor and category	Usual care %	Intervention %	*p*
2 months	n = 348	n = 378	0.19
Less than 100 yards	11.2	15.7	
100 to 440 yards	29.4	26.6	
Greater than 440 yards	31.2	33.6	
Pain-free walking	28.2	24.1	
12 months	n = 336	n = 361	0.01
Less than 100 yards	15.3	8.2	
100 to 440 yards	21.5	27.6	
Greater than 440 yards	24.5	23.0	
Pain-free walking	38.7	41.2	

100 to 400 yards before onset of intermittent claudication. Moreover, the kappa statistic (Bland and Altman 1988) summarising concordance between categories of self-reported and measured maximum walking distance was 0.61, indicating good agreement. Enrolment was therefore closed with 441 allocated to each study group.

The primary analyses of outcomes were based on intention-to-treat (including those men who were alive but did not respond to follow-up as having the same maximum walking distance as at baseline) using the chi-square test and $\alpha = 0.05$ to compare proportions of men whose category of self-reported maximum walking distance had improved, become worse or stayed the same. These were supported by comparisons of proportions in each category of maximum walking distance at baseline and each follow-up point. Additional analyses concerned differences between the groups in quality of life (*t*-test) and in smoking status and self-reported physical activity at two and 12 months post-enrolment. At each follow-up point, response fractions were adjusted for men who had died or for whom letters were returned and no new address could be found.

Ethical considerations With permission from the Committee for Human Rights at The University of Western Australia, the study was conducted as a double-blind randomised controlled trial with neither group of men made aware that they had been enrolled in an experiment. Staff members who coded follow-up questionnaires were also blind to the group allocation of individual men.

Results

Of the 928 men identified with early peripheral arterial disease at screening, 41 were ineligible for inclusion in the randomised controlled trial on the basis of aortic size and five were not randomised due to late return of the questionnaire, leaving 882 eligible men. Equal numbers of participants were allocated to the usual care (n = 441) and intervention (n = 441) groups. Of the 406 individual general practitioners, 123 (30%) had participants in both the usual care and intervention groups. However, as the diagnosis of early peripheral arterial disease for men in the usual care group was not communicated to the doctor in correspondence from the screening clinic, little contamination between study groups was expected.

Table 1 shows that the two study groups were well balanced at recruitment in terms of factors related to the intervention, pattern of intermittent claudication and significant cardiovascular co-morbidity. The prevalence of diabetes mellitus was somewhat higher in men allocated to usual care ($\chi^2 = 3.90$, df = 1, $p = 0.06$), but the two groups were well matched in terms of age, ankle:brachial index of systolic blood pressure, systolic and diastolic blood pressure, and body mass index (all $p > 0.35$ on *t*-test), place of birth and level of education.

The adjusted response fraction at two months was 84.9% (see Table 2). At this follow-up, there were no statistically significant differences between the study groups in smoking status, any of three different measures of physical activity, membership of an exercise group, self-reported maximum walking distance or health-related quality of life (Table 3). However, among those who smoked at enrolment, more men allocated to the intervention group had given up smoking, and the frequencies of walking for recreation and of membership of an exercise program were somewhat higher in the intervention group. These modest differences probably reflect the long lead time involved in consulting the general practitioner and undergoing an initial assessment by the community physiotherapist.

The adjusted response fraction at 12 months was 85% (Table 2). By this time, there was a highly significant difference in membership of an exercise class (17% intervention, 2% usual care, $p < 0.001$; Table 4). At 12 months more men in the intervention group had improved their maximum walking distance (23% vs 15%; $\chi^2 = 9.74$, df = 2, $p = 0.008$), and significant differences were also apparent when the analyses were limited to men who completed and returned questionnaires (Table 4), or when overall patterns of maximum walking distance at baseline and follow-up were compared (Table 5). In addition, significantly more men in the intervention group reported walking at least three times weekly for recreation (34% vs 25%, $p = 0.01$) and that their level of physical activity in the preceding two months had been greater than had been usual for them (11% vs 6%, $p = 0.03$; Table 4). More men in the intervention than in the usual care group claimed to have given up smoking although this did not reach statistical significance. The two groups did not differ significantly with regard to intermittent claudication and their scores on the Index of Health Related Quality of Life were also similar.

Discussion

Using a double blind, randomised controlled design, we have demonstrated that a simple intervention for early peripheral arterial disease based on increased physical activity and cessation of smoking results in a greater maximum walking distance 12 months later. Despite some concern that asking elderly men to change their lifestyle and behaviour might have an adverse psychological effect, we were reassured to see no between-group difference in health-related quality of life at follow-up. We deliberately designed our study to test the effectiveness of the intervention in the setting of everyday community practice rather than its efficacy under ideal conditions. Because of its imperfect specificity, use of the Edinburgh Claudication Questionnaire (Leng and Fowkes 1992) as a screening instrument almost certainly means that we included men whose pain on walking was not due to peripheral arterial disease and who were therefore less likely to respond to our intervention. Similarly, enrolling some men on the basis of the ankle:brachial index of systolic blood pressure will have meant that a proportion of participants in the study had no intermittent claudication at baseline and thus less possibility for improvement in maximum walking distance. An intention-to-treat analysis is also inherently conservative.

Even though each of these features of our design made it more difficult to disprove our null hypothesis, a significant effect of the intervention was still apparent. The blinding of participants to the experimental protocol and the care taken in the follow-up phases to avoid responses perceived as desirable add to the confidence in our results. Our validation of self-reported maximum walking distance indicated good agreement with objectively measured distance. In addition, there is internal consistency between several different measures of physical activity at 12 months, and the impact of the intervention on smoking is consistent with that reported from a systematic review of the impact of anti-smoking advice from medical practitioners (Law and Tang 1995). Moreover, our overall findings are consistent with well-established patterns of management of more severe peripheral arterial disease evident in a Cochrane Review (Leng et al 1997).

Peripheral arterial disease affects up to one in every nine elderly men in Perth (Fowler et al 2002), which probably reflects, at least in part, the long legacy of high levels of smoking in generations born before 1935 (Hyndman et al 1991). Despite later cohorts smoking less, the rapid growth of the elderly population and the increasing incidence of diabetes that will follow the steady rise in average BMI currently seen in Australia (National Health and Medical Research Council 1997) mean that absolute numbers of cases of peripheral arterial disease will not fall rapidly. While few of these patients will ever come to surgical intervention, a sizeable proportion will experience worsening claudication (Leng et al 1996).

There have been a large number of studies of the role of exercise in symptomatic claudication. A recent review (Chong et al 2000) identified 27 such studies: only one study had more than 50 cases; only nine studies, involving a total of 294 patients, had follow-up at six months; and only one study of 25 patients extended to 12 months post-intervention. Although the majority of these reports indicate some benefit from exercise in claudication, individual studies were limited by small sample sizes.

Most previous studies of exercise and claudication have focused on patients referred with symptoms severe enough to warrant surgical intervention. The majority of participants in our trial had evidence of early peripheral arterial disease but were not candidates for invasive management. We have shown that this early, and potentially progressive, disability can be limited in older men by a combination of simple and safe interventions that are readily available in the community. While statistically significant, the between-group differences evident after 12 months were modest, but being able to walk up to 440 yards is clinically and functionally important, as it means the individual would be able to leave home, walk to a bus stop and use public transport to undertake such activities as shopping or visiting a general practitioner. Although beyond the scope of the present study, it is possible that in addition to being able to walk further, the intervention we employed may have other cardiovascular benefits (Fowkes at al 1998, Shephard and Balady 1999).

Conclusion

A combination of simple and safe interventions that are readily available in the community through physiotherapists and general practitioners has the potential to improve early peripheral arterial disease.

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