The health-related quality of life of people with peripheral arterial disease in the community: the Edinburgh Artery Study

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SUMMARY

Background: Previous studies investigating the health-related quality of life of those with peripheral arterial disease have focused on patients recruited from hospital clinics. The health-related quality of life of people with peripheral arterial disease in the general population is unknown.

Aims: We aimed to determine the health-related quality of life of people with intermittent claudication and asymptomatic peripheral arterial disease in the general population and to compare it with those with angina and those with no peripheral arterial disease or angina.

Design of study: Analysis of cross-sectional data from the 12-year follow-up of a population-based cohort.

Setting: Edinburgh, Scotland.

Method: Data from the Edinburgh Artery Study cohort’s 12-year follow-up was analysed. Participants’ peripheral arterial disease status was measured using the World Health Organisation intermittent claudication questionnaire and the ankle brachial pressure index. Self-assessed health-related quality of life data was collected using the SF-36 generic questionnaire. Health-related quality of life scores were calculated and their associations with peripheral arterial disease status groups were tested.

Results: Subjects with intermittent claudication had significantly worse median health-related quality of life scores than patients without claudication in all domains except social functioning and mental health. Patients with claudication had a significantly lower physical component summary score than those without claudication (P<0.001). This association remained after adjustment for age, sex, social class, body mass index, smoking, and angina. Those with angina and claudication had significantly worse physical component summary scores than those with no peripheral arterial disease or angina (P<0.001). No significant difference was found in health-related quality of life scores between those with asymptomatic peripheral arterial disease and those with no peripheral arterial disease even after multiple adjustment for confounding factors.

Conclusion: People with intermittent claudication in the community had impaired health-related quality of life related to reduced physical health, but asymptomatic peripheral arterial disease did not significantly affect health-related quality of life.

Keywords: angina pectoris; intermittent claudication; peripheral vascular disease; quality of life.

Introduction

Quality of life in the context of health and disease (health-related quality of life) refers to a number of multidimensional concepts related to wellbeing and satisfaction that can be affected by ill health, including emotional status, physical function, and social wellbeing.1,2 It is widely acknowledged that patients’ judgements of how disease affects their lives can provide health professionals with a greater understanding of the impact of disease than can be gauged from objective clinical investigation alone.3 Thus, studies of health-related quality of life are essential in identifying patient need, aiding clinical decision making, and optimising care.4

Peripheral arterial disease is a condition that generally affects older people — by late middle age about 5% of men and women demonstrate symptoms of intermittent claudication. In previous studies investigating health-related quality of life in patients with intermittent claudication, participants have been recruited from hospitals, usually through outpatient or surgical clinics.5-7 Patients with claudication attending hospital clinics are likely to have more serious symptomatic disease than those who have not sought medical advice or been referred into secondary care. To date, there has been no investigation of the health-related quality of life of those with intermittent claudication in the general population.

Additionally, over 80% of people with peripheral arterial disease are asymptomatic.8 This group has been underinvestigated in relation to health-related quality of life — presumably because the lack of symptoms means they do not seek medical care and there is no obvious impact on their health-related quality of life. However, recent assessment of females with asymptomatic peripheral arterial disease has shown that this condition was associated with impaired lower limb functioning, even when the results were adjusted for other comorbidities.9,10 The presence of previously unrecognised consequences of asymptomatic peripheral arterial disease means that this stage of the disease could potentially affect health-related quality of life.10

The SF-36 has been recommended as a standard health-related quality-of-life questionnaire for use in vascular disease patients.11 Part of its suitability stems from the large number of items on physical functioning, which is especially pertinent when assessing people with peripheral arterial disease. This study aimed to determine the health-related quality of life of participants with either intermittent claudication or asymptomatic peripheral arterial disease in the general population using the SF-36 questionnaire. In addition, comparisons were made with those with angina and with those with no peripheral arterial disease or angina.
Method

Study population

The data was collected as part of the Edinburgh Artery Study, which began in 1987 as a cross-sectional survey of 1592 men and women aged 55–74 years. The participants were randomly selected from 5-year age bands from 11 general practices whose catchment areas were spread geographically and socioeconomically throughout the city of Edinburgh. The response rate was 65% and assessment of 20% of non-responders showed no substantial bias. Details of study procedures have been published previously.8 The study was approved by the Lothian Health Board Ethics Committee, and informed consent was obtained from each participant. The cohort was followed up and clinical examinations held at 5 years and 12 years from baseline. The current analysis used data collected only at the 12-year follow-up when 925 participants took part (a response rate from surviving participants of 84%).

Clinical examination

Those taking part at the 12-year follow-up examination were invited to a university clinic. Each participant completed a self-administered questionnaire; this contained validated questions regarding personal characteristics, social class, smoking, and intermittent claudication and angina status using the World Health Organisation (WHO) questionnaires.12 Health-related quality of life was measured using version 1 of the SF-36 questionnaire.13 The SF-36 is a generic health-related quality-of-life questionnaire that contains 36 questions covering eight domains related to wellbeing (namely, physical functioning, role limitation [physical], role limitation [emotional], social functioning, mental health, energy/vitality, pain, general health perception). The SF-36 domain scores for every individual were calculated using weighted algorithms as directed by the questionnaire developers.13 Missing domain data was calculated for scales with more than two items where ≥50% of the individuals’ answers were completed. In such cases, the individual-specific mean of the completed items in a domain was calculated and this figure was imputed. Participants’ scores from the eight domains can also be used to calculate two summary scores — the physical component score and mental component score — by using factor scores calculated previously from large population studies using the SF-36.13,14

In this analysis the two summary scores were calculated using the recommended United States (US) factor scores.14 US factor scores were considered more applicable for this analysis because they were based on data from an older population than United Kingdom (UK) factor scores. In fact, a comparison of the US and UK methods of weighting the SF-36 summary measures concluded that the measures were similar and it was suggested that the US factor scores be used universally.14 To calculate the two summary scores, a standardised score was calculated for each domain and multiplied by the relevant factor scores. These new scores were then standardised against a mean of 50 and a standard deviation of 10. The summary scores were checked as recommended by the developers of the questionnaire.13 Since both final scores were negatively skewed, they were transformed to normality for analysis by squaring.

Data analysis

Information from the questionnaires was checked by staff and then entered into a database using double entry. The WHO intermittent claudication questionnaire was used to assess participants’ claudication status. The ankle brachial pressure index was calculated by dividing the ankle systolic pressure by the brachial systolic pressure: the lower of the two leg measurements was used in the analysis. All participants who scored positively on the WHO questionnaire were classed as having intermittent claudication. Of the participants who scored negatively on the WHO questionnaire, those with an ankle brachial pressure index ≤0.9 were considered as having asymptomatic peripheral arterial disease; those with an ankle brachial pressure index >0.9 were considered to have no peripheral arterial disease.

The association between peripheral arterial disease status and health-related quality of life was investigated; all statistical analysis was carried out on SPSS (version 11) and Microsoft Excel. Associations between two categorical variables were assessed using the χ^2 test. Differences in health-related quality-of-life domain data were assessed using the Mann–Whitney test for the comparison of two groups, or the Kruskal–Wallis test where there were more than two groups. Statistical testing on the square of the two summary scores was carried out using analysis of variance or Student’s t-test.
with Bonferroni’s correction where appropriate. All significance tests were two-sided and the 5% significance level was used to denote statistical significance.

Two multiple linear regression models were constructed to examine the independent relationship of claudication and either the physical component score or the mental component score. An a priori model was specified detailing the variables that could potentially confound the relationship between intermittent claudication and health-related quality of life. These variables were: age (years), sex, social class, body mass index, smoking (assessed using pack years, which was squared root transformed to normality), ankle brachial pressure index, and angina, the significant association between intermittent claudication and health-related quality of life when defined as no evidence of claudication from the WHO questionnaire alone (of these, a quarter had an ankle brachial pressure index <0.9). 43.0% had asymptomatic peripheral arterial disease when defined as no evidence of claudication from the WHO questionnaire and an ankle brachial pressure index ≥0.9, and 35.4% of the population had no peripheral arterial disease when defined as no evidence of claudication from the WHO questionnaire and an ankle brachial pressure index >0.9. The remaining 15.9% of participants could not have their peripheral arterial disease status classified because of missing examination data.

The geometric mean ages of the participants (range 66–87 years) were significantly different between subgroups but the mean body mass index (range 14–59) did not differ significantly. More males than females had either claudication or asymptomatic peripheral arterial disease. In the asymptomatic peripheral arterial disease group, 58.5% of people were from social class I and II; only 5.5% were from the lowest social class groups. In contrast, almost a fifth of the claudication group were from social class IV and V. The intermittent claudication group had the highest proportion of current smokers (20.8%) and the highest prevalence of angina (32.7%). This prevalence was more than twice that of the asymptomatic peripheral disease group or the no peripheral arterial disease group.

### Intermittent claudication and health-related quality of life

A total of 53 participants were identified as having intermittent claudication. Of these, 49 (92.5%) had a valid SF-36 score. Table 2 shows that those with claudication had a significantly lower median score ($P<0.01$) in each SF-36 domain except mental health and social functioning. For the role limitation (emotional) domain a significant difference was found ($P = 0.007$) although the medians and 5–95 percentiles were the same; this occurred due to the Kruskal–Wallis test examining the different distribution of the groups’ scores rather than the summary measures.

The differences between the groups’ summary scores reflect the differences observed in the eight domains (Table 3). The mean physical component score for participants with claudication (39.4, 95% confidence interval [CI] = 36.0 to 42.6) was significantly lower than the scores for participants without claudication (46.3, 95% CI = 45.6 to 47.0; $P≤0.001$). No significant difference was found between the two groups for the mental component score. After adjusting for age, sex, social class, body mass index, smoking, ankle brachial pressure index, and angina, the significant association between intermittent claudication and reduced physical component score ($P = 0.008$) and the non-significant association for the mental component score ($P = 0.415$) remained.

### Angina, intermittent claudication, and health-related quality of life

In the study population, 32.7% of people with claudication had angina.
had angina compared to 13.0% of people without claudication ($P \leq 0.001$). Those with both angina and intermittent claudication had the lowest health-related quality-of-life score in every domain and those free from both diseases had the highest score, or equal-highest score, in every domain (Table 4). The differences for mental health were not significant across the groups ($P = 0.115$). Those with claudication alone had slightly higher domain scores than those with angina alone in all domains except mental health and both physical and emotional role limitation. The four disease groups had highly significant overall differences in physical component scores ($P \leq 0.001$) but not in mental component scores ($P = 0.442$).

We then examined two-group comparisons and, using Bonferroni’s correction, there were significant differences between the no angina or claudication group physical component score (47.1, 95% CI = 46.4 to 47.8) and the scores for the combined claudication and angina group (35.5, 95% CI = 29.1 to 41.0, $P \leq 0.001$) and the angina only group (41.0, 95% CI = 38.8 to 43.0, $P \leq 0.001$).

### Asymptomatic peripheral arterial disease and health-related quality of life

A total of 36.9% of the study population had asymptomatic peripheral arterial disease (having an ankle brachial pressure index of $\leq 0.9$ and no claudication) and also had no angina (Table 1). This was compared to 30.1% of the study population who had no peripheral arterial disease (having an ankle brachial pressure index $>0.9$ and no claudication) and also had no angina. The domain score medians for the asymptomatic peripheral arterial disease and no peripheral arterial disease groups were significantly different only for the physical functioning domain ($P = 0.001$) and the mental health domain ($P = 0.003$), where the group with asymptomatic peripheral arterial disease had higher median scores than those with no peripheral arterial disease.

The mean physical component score of the group with asymptomatic peripheral arterial disease (48.3, 95% CI = 47.3 to 49.2) was higher than that of the group of those with no peripheral arterial disease (46.8, 95% CI = 45.6 to 48.0) although the mean difference was non-significant ($P = 0.058$). No significant difference was found in mental component score between the groups. When adjustments were made for age, sex, social class, body mass index, and smoking there was no significant difference between those with asymptomatic peripheral arterial disease and those with no peripheral arterial disease for either the physical or mental component scores ($P$-values of 0.948 and 0.644 respectively).

### Discussion

#### Summary of main findings

**Intermittent claudication and health-related quality of life.** The findings from this study suggest that those with intermittent claudication in the general population have lower health-related quality of life related to physical functioning when compared with those with no claudication. The physical component score highlights that this reduction was mainly due to

### Table 3. Linear regression models for the relationship between intermittent claudication and the physical and mental summary scores

<table>
<thead>
<tr>
<th></th>
<th>Physical component score</th>
<th>Mental component score</th>
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<tbody>
<tr>
<td></td>
<td>B</td>
<td>Standard error</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Standard error</td>
</tr>
<tr>
<td>Intermittent claudication</td>
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<td>141.96</td>
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<tr>
<td>(Yes; reference group no)</td>
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<tr>
<td>Age</td>
<td>-3193.44</td>
<td>455.74</td>
</tr>
<tr>
<td>Sex (Male; reference group female)</td>
<td>187.46</td>
<td>65.99</td>
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<tr>
<td>Social class</td>
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<td></td>
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<tr>
<td>(I and II; reference group IV and V)</td>
<td>284.19</td>
<td>125.94</td>
</tr>
<tr>
<td>(III; reference group IV and V)</td>
<td></td>
<td></td>
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<tr>
<td>Body mass index</td>
<td>-5.06</td>
<td>203.89</td>
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<tr>
<td>Smoking</td>
<td>5.36</td>
<td>1.73</td>
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<td>ABPI ($\leq 0.9$; reference group $&gt;0.9$)</td>
<td>26.07</td>
<td>66.92</td>
</tr>
<tr>
<td>Angina (Yes; reference group no)</td>
<td>500.55</td>
<td>91.31</td>
</tr>
</tbody>
</table>

*adjusted for age, sex, social class, body mass index, smoking, ankle brachial pressure index, and angina. ABPI = ankle brachial pressure index.
the disease’s detrimental effect on physical health. Additionally, the non-significant difference between the mental component scores of those with claudication and those without supports previous findings, indicating that claudication is not associated with reduced psychological health, or depression. In general, doctors should be more alerted to the physical rather than the psychological consequences of claudication in patients.

The mean physical component score in men and women aged >65 years in the US is 42 and the mean mental component score is 51. The physical component score of people with claudication in this study was 39, lower than the US >65 years population mean, whereas the people without claudication had a physical component score of 46, slightly higher than the US >65 physical component summary mean. The mental component scores of people with and without claudication were above the population mean; this occurred in all groups investigated in this study. The use of US factor scores also allowed summary scores from this study to be compared with population summary scores for different conditions calculated by Ware et al. The claudication group’s physical component score was lower than the US’ population physical component scores for arthritis (US score = 43), cancer (US score = 45), chronic lung disease (US score = 42), but higher than the US population scores for angina (US score = 36) and congestive heart failure (US score = 31). The results suggest that the physical consequences of claudication are comparable to those of other major diseases.

**Angina, intermittent claudication, and health-related quality of life.** Although it is common for people with intermittent claudication to suffer from angina, no study has investigated the combined effect of intermittent claudication and angina on health-related quality of life. Angina has been reported to reduce SF-36 population physical component scores to well below population means. In this study, participants with both claudication and angina had worse physical component scores than the claudication only and the angina only group. These differences, however, were not statistically significant, probably because of the small numbers in the claudication and angina group. There was also no significant difference between the physical component score of the claudication only group and the angina only group. However, the combined claudication and angina group, the claudication only group, and the angina only group all had significantly worse physical component scores when compared with the combined no peripheral arterial disease or angina group.

**Asymptomatic peripheral arterial disease and health-related quality of life.** Although it has been reported that females with asymptomatic peripheral arterial disease have reduced lower leg functioning, it was not known whether asymptomatic disease impacts on health-related quality of life. This study is the first to investigate the health-related quality of life of those with asymptomatic peripheral arterial disease in the general population. Where there were significant differences in domain scores, the asymptomatic group had the higher scores. The asymptomatic group also had higher physical component scores than those with no peripheral arterial disease, although the P-value was of borderline significance at 0.058. However, when markers for comorbidities (such as smoking and body mass index) and other variables (for example, social class) were adjusted for, there was no significant independent association between the asymptomatic peripheral arterial disease group and the physical component score, and the no peripheral arterial disease group and the physical component score.

The increased health-related quality-of-life scores of the group of participants with asymptomatic peripheral arterial disease compared with the group of those without the disease may be related to the social class distribution of the groups. This would explain why adjustment for social class in the regression model removes the significant difference between the two groups. The asymptomatic group had a higher number of people from social class I and II and fewer people from social class IV and V when compared with the groups of participants with claudication and those with no disease. Not only do higher classes report better health-related quality of life, it has been reported that those from higher social classes generally respond better to interventions. Although asymptomatic peripheral arterial disease may affect leg functioning, this study suggests that it does not lead to a reduced health-related quality of life, especially when other comorbidities and confounding factors are adjusted for. However, the health-related quality of life for specific sub-groups of those with peripheral arterial disease may need to be examined further.
Strengths and limitations of the study

Intermittent claudication is a debilitating disease that causes pain and physical disability. Rigorous investigation of health-related quality of life in participants with claudication was essential in order to gain a comprehensive understanding of this disease group’s needs. The advantage of this study over other studies on peripheral arterial disease is that the results can be generalised to the community and not just those with the most serious claudication. It also acknowledges that people with peripheral arterial disease often have other cardiovascular comorbidity, such as angina, which can further limit physical functioning and cause pain.

However, an accurate measurement of health-related quality of life is recognised as being a difficult process that depends on the correct selection of a measurement instrument as well as its correct administration. Although the SF-36 questionnaire has been recommended for use with patients with peripheral arterial disease,11 as a short and generic questionnaire it does not cover all areas related to peripheral arterial disease. For example, erectile dysfunction has been reported in males with peripheral arterial disease,21 but sexual function is not assessed by the SF-36. It has been suggested that disease-specific questionnaires, such as the Claudication Scale,22 remove the risk of attributing low health-related quality-of-life scores caused by non-peripheral arterial disease to peripheral arterial disease.23 However, as our study involved the general population rather than a population with known peripheral arterial disease, a disease-specific measure was not suitable as this would not accurately capture health-related quality-of-life data from people without peripheral arterial disease. If the aim was to measure the health-related quality of life of people with known peripheral arterial disease, a disease-specific measure would most likely be used, as long as it had previously been validated.

Implications for clinical practice

Intermittent claudication is a common illness, yet its impact on patients’ lives is often underestimated. It has been argued that much less awareness and support is given to patients with claudication, compared with that available for other common chronic conditions, such as diabetes.24

This study suggests that the reduction in health-related quality of life of a person with claudication may be lower than population health-related quality-of-life scores for other serious illnesses, such as chronic lung disease and cancer. Additionally, many people with intermittent claudication suffer from other cardiovascular diseases, such as angina, and the effect of having two medical conditions may have a cumulative effect on health-related quality of life. The considerable reduction in health-related quality of life in patients with claudication highlights the need for successful interventions to alleviate this condition.

It is important that health-related quality of life is recognised as an important outcome for those with peripheral arterial disease, rather than relying on clinical measures alone, especially as there is often weak correlation between clinical measures of peripheral arterial disease and health-related quality-of-life scores.25 Therefore, this study also highlights that health professionals, especially those in primary care, must be aware of the potential impact of this disease on their patients’ lives by assessing health-related quality of life as well as using traditional clinical measures. Health-related quality-of-life assessment is most important as part of the initial assessment of a patient, if there has been deterioration in symptoms, or where an invasive treatment, such as surgery, is being considered.

References


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