Assessment of Generic Health-related Quality of Life in Patients with Intermittent Claudication

G. J. Hicken*, A. G. Lossing and F. M. Ameli

St. Michael’s Hospital, University of Toronto, Ontario, Canada

Objectives: to measure quality of life in patients with intermittent claudication and evaluate the ability of patients and vascular surgeons to make a similar assessment.

Design, materials and methods: in this prospective study patients with intermittent claudication attending two vascular clinics were asked to complete a generic health-related quality of life instrument (MOS SF-36). Patient quality of life and vascular surgeons’ assessment of patient quality of life were further evaluated using a single question/adjectival scale response combination.

Results: patients’ self-assessment of their quality of life correlated better with the SF-36 score than did the surgeons’ assessment. There was little correlation between the surgeons’ and patients’ own assessment of quality of life. The surgeons differed significantly from each other in their assessments. Claudicants had lower SF-36 scores than population norms in pain and physical aspects of quality of life.

Conclusions: claudicants have worse quality of life than the general population, with pain and physical limitations being the most important domains. Surgeons predict the quality of life of claudicating patients less accurately than patients do themselves, and may differ from their colleagues in such assessments. Objective quality of life assessment in claudicants should be undertaken before treatment is decided.

Key Words: Quality of life; Intermittent claudication; Questionnaire; Health status.

Introduction

During the last 20 years the growth in volume of published research on the subject of quality of life in clinical practice has been exponential (Fig. 1). It is only in the last 5 or 6 years, however, that quality of life in patients with intermittent claudication has been formally addressed, and there remains relatively little published on this subject. The scarcity of such publications in the vascular literature suggests that there is limited expertise in this area, a matter of some concern when one considers that it is the maintenance or improvement of quality of life that is the sole aim of intervention for intermittent claudication.1–4

While the majority of claudicants are managed conservatively the ones who are offered bypass surgery or angioplasty are those who are considered, in the subjective opinion of their surgeon, to have symptoms severe enough both to require treatment and to justify the significant risks to life and limb that are associated with such intervention. Identification of such patients requires careful assessment of symptoms and their impact on quality of life, awareness of other general health problems and an understanding of the patients’ expectations, realistic or otherwise, of the proposed intervention. An important part of this process is the

* Please address all correspondence to: G. J. Hicken, 25 Miller Close, Bromsgrove, Worcester B60 3PG, U.K.
assessment of the patients’ overall or generic quality of life, the understanding of which enables the surgeon to more accurately predict, and to keep in context, the likely benefit to that quality of life of increasing their pain-free walking distance.

There is presently little data available on the accuracy and consistency of quality of life assessment in patients with intermittent claudication. In this study we have assessed the ability of vascular surgeons to measure their patients’ generic quality of life and the ability of these patients to measure their own quality of life, and assess the value and consistency of these measurements using a previously validated quality of life instrument.

**Patients and Methods**

**Patients**

Patients were recruited from the vascular outpatient clinics (clinics “A” and “B”) of two experienced senior vascular surgeons (surgeons “A” and “B”) practising in separate university hospitals in Toronto, Canada. All patients were diagnosed as having intermittent claudication using clinical criteria with vascular laboratory measurements being used to support the diagnosis. Clinical criteria for intermittent claudication were based upon a typical history of calf pain, with or without thigh and/or buttock pain, developed while walking, not developed while standing still or sitting, which forced the subject to slow down or stop and which usually disappeared within 10 min or less. The vascular laboratory criteria required that the treadmill exercise should provoke the pain described above and be associated with a pre-exercise ankle–brachial pressure index of <0.9 with a drop in the post-exercise ankle–brachial pressure index.

Patients newly referred to the clinic and those under review were included in the study. Any patient who had undergone lower limb revascularisation (including percutaneous angioplasty) within the preceding 3 months was excluded. Patients were also excluded if they had any coexistent causes of local or referred leg pain (including hip and knee pain, and pain from spinal pathology), and if it was felt they would not, through lack of comprehension and understanding or because of poor English, be able to accurately complete the questionnaires.

**Questionnaires**

After their identification in the vascular clinic the patients were requested to complete both the SF-36 questionnaire and an adjectival scale to rate their own quality of life. The SF-36 is a well known generic health-related quality of life questionnaire. We considered it to be an appropriate instrument for our purposes as it has been widely validated in different groups of patients, it is simple and easy to understand and is relatively short allowing for good patient compliance. The SF-36 has also been previously used by other authors studying groups of claudicants and has been recommended by Beattie et al. for use in vascular disease-related health-related quality of life assessments and outcome analyses.

The patients’ “questionnaire” consisted of the single simple question phrased as follows: “Which of the following phrases best describes your overall quality of life?” to which an adjectival scale of six alternative responses were offered. The responses comprised “excellent”, “very good”, “good”, “fair”, “poor” and “very poor”. The patient was asked to indicate the response they felt was most appropriate to them.

The consulting surgeons also completed a “questionnaire” containing an essentially identical question: “Which of the following phrases best describes the patients’ overall quality of life?”. Again an adjectival scale containing six alternative responses ranging from “excellent” to “very poor” was offered and the surgeon was asked to indicate the response they felt was most appropriate to the individual patient in question.

The SF-36 questionnaires were scored and the scores transformed as recommended in the SF-36 scoring booklet with higher scores indicating a better quality of life. The adjectival scales were scored in a linear fashion again with higher scores indicating a better quality of life.

The scores have been abbreviated as follows:

- SF-36 transformed score = SF-36 score.
- Patients rating of their own quality of life = “Patients’ scores”.
- Surgeons rating of their patients quality of life = “Surgeons’ scores”.

The data was analysed using a statistical software package (SPSS for windows v.7.0). Pearson correlations between the SF-36 scores, patients’ scores and surgeons’ scores were generated both within each clinic and between clinics. Finally the SF-36 scores were compared to previously published population norms.

**Results**

During the period of the study 102 patients (57 from clinic A and 45 from clinic B) were identified as having
Table 1. Correlation between questionnaires.

<table>
<thead>
<tr>
<th></th>
<th>Clinic A</th>
<th>Clinic B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon/Patient</td>
<td>$r = 0.33 \ (p = 0.57)$</td>
<td>$r = 0.37 \ (p &lt; 0.05)$</td>
</tr>
<tr>
<td>Surgeon/SF-36</td>
<td>$r = 0.42 \ (p &lt; 0.05)$</td>
<td>$r = 0.42 \ (p &lt; 0.01)$</td>
</tr>
<tr>
<td>Patient/SF-36</td>
<td>$r = 0.75 \ (p &lt; 0.001)$</td>
<td>$r = 0.60 \ (p &lt; 0.001)$</td>
</tr>
</tbody>
</table>

Fig. 2. Patients’ scores and surgeons’ scores for each clinic ‘A’ and ‘B’.

Fig. 3. SF-36 scores for each clinic ‘A’ and ‘B’.

Intermittent claudication in accordance with the criteria set out above. Of these patients, 96 (54 from clinic A and 42 from clinic B) fully completed the SF-36 questionnaire and adjectival scale. The sex distribution was similar (clinic A: 70% male, clinic B: 64% male), as was the age distribution (clinic A: mean age 69, clinic B: mean age 67). The surgeons’ adjectival scales were fully completed for all patients.

Data analysis

The degree of correlation (Pearson two-tailed) between each of the scores is shown in Table 1. In both clinics the surgeons’ scores/patients’ scores correlation was poor, the surgeons’ scores/SF-36 scores correlation moderate and the patients’ scores/SF-36 scores correlation was very good. The degree of correlation for each of these pairings was similar for both clinics.

The mean patient’s score for clinic A was significantly lower than the mean patient’s score for clinic B (1.62 vs. 2.05, $p < 0.015$, two-tailed) (Fig. 2), suggesting a significantly poorer quality of life for patients in clinic A as compared to patients in clinic B. In contrast, the mean surgeon’s score for clinic A was significantly higher than the mean surgeon’s score for clinic B (2.19 vs. 1.53, $p < 0.001$, two-tailed) (Fig. 2), indicating that surgeon A assigned his patients in clinic A a significantly better quality of life score than surgeon B assigned to his patients in clinic B. The overall mean SF-36 scores were very similar for each clinic (60.69 vs. 61.98, $p > 0.6$, two-tailed) (Fig. 3).

When the claudicants’ individual domain scores were compared to SF-36 population norms we found the greatest differences in scores were in those domains that featured a physical aspect of quality of life ("physical functioning", "role physical", and "bodily pain") rather than emotional, mental or social aspects (Table 2).

Discussion

Intermittent claudication secondary to peripheral vascular disease is neither limb nor life threatening but may impact severely on a patient’s quality of life. It is known to coexist with significant cardio- and cerebrovascular disease and is associated with a high mortality rate and a significant anaesthetic risk. Because of this, treatment of intermittent claudication by interventional means is restricted to those patients who are felt to have symptoms severe enough to justify the risks associated with percutaneous angioplasty or conventional bypass surgery.

The decision to undertake angioplasty or surgery (assuming such an approach is technically feasible) is based on an assessment of the impact of intermittent claudication on the patients’ quality of life. This assessment, made by the vascular surgeon who is responsible for the patient, ideally demands both accurate evaluation of the specific impact of intermittent claudication on the patients’ quality of life and, to keep in context
Table 2. SF-36 population norms and mean patient scores.

<table>
<thead>
<tr>
<th></th>
<th>Population norm</th>
<th>Mean patient score in this study</th>
<th>Difference</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>73.21</td>
<td>47.29</td>
<td>-25.92</td>
<td>-35.4%</td>
</tr>
<tr>
<td>Role physical</td>
<td>56.69</td>
<td>48.44</td>
<td>-8.25</td>
<td>-14.6%</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>68.67</td>
<td>53.22</td>
<td>-15.45</td>
<td>-22.5%</td>
</tr>
<tr>
<td>General health</td>
<td>60.04</td>
<td>60.97</td>
<td>0.93</td>
<td>+1.5%</td>
</tr>
<tr>
<td>Vitality</td>
<td>53.51</td>
<td>49.79</td>
<td>-3.92</td>
<td>-7.3%</td>
</tr>
<tr>
<td>Social functioning</td>
<td>80.53</td>
<td>75.39</td>
<td>-5.14</td>
<td>-6.4%</td>
</tr>
<tr>
<td>Role emotional</td>
<td>68.83</td>
<td>72.97</td>
<td>4.14</td>
<td>+6.0%</td>
</tr>
<tr>
<td>Mental health</td>
<td>71.44</td>
<td>74</td>
<td>2.56</td>
<td>+3.6%</td>
</tr>
</tbody>
</table>

(Population norms taken from McHorney et al. 15).

the value of predicted improvements following intervention, a good understanding of the patients’ overall quality of life.

In practice, the evaluation of the patients’ quality of life remains subjective and informal and although small numbers of claudicants have been assessed using generic quality of life instruments6,23,25,32–34 the validity of the results has been disputed.35 The relative scarcity of published research on quality of life in claudicants probably reflects infrequent application of formal objective quality of life measurement in most vascular surgeons’ clinical practice. Such lack of formal testing is a matter of some concern. The aim of our study was to evaluate the surgeons’ ability to assess their patients’ quality of life by comparing this assessment with both self-assessment of quality of life made by the patients themselves and objective assessment using a validated generic health-related quality of life instrument, the SF-36.

The assessment of quality of life made by surgeons in their everyday clinical practice is essentially based on their own subjective opinion and by its very nature rather simplistic. To enable us to measure this opinion it was necessary to devise a method to reflect the simple and relatively unsophisticated nature of the surgeons’ assessments. We therefore devised a simple and relatively unsophisticated question to ask of the surgeons about their patients and one which we considered to be a reasonable representation of the sort of question a surgeon might apply in everyday clinical practice.

A virtually identical question was used for the patients’ own self-assessment to allow direct comparison with the answers supplied by the surgeon. While we do not suggest that the responses to this question represent an accurate and complete measure of the patients’ overall quality of life, we do feel they reflect the relatively crude assessment which is made in clinical practice. In fact the absolute values of each of the scores have no true meaning as no norms have been established and no control group employed, rather it is the relationship between scores which is important to allow comparison between the patient population and the two clinicians.

We were very reassured to find that the patients’ responses to their question had an extremely good degree of correlation with the results from the SF-36 thus conferring a degree of validity on the patients’ question as a measure of quality of life. While the surgeons’ responses to their question did attain significant correlation with the SF-36 scores the degree of correlation was only moderate. It is important to note that it is the degree of correlation (the $r$ value) rather than the degree of significance (the $p$ value) which is the more robust statistic.36 Poor correlation was seen between the surgeons’ responses and the patients’ responses, suggesting that the surgeons’ subjective evaluation of their patients overall quality of life has questionable accuracy.

Comparison of the SF-36 scores with population norms (Table 2) indicates that overall quality of life in these patients with intermittent claudication is worse than the general population and it appears that, as would be expected, the greatest influence on their quality of life are those aspects which relate to pain and physical limitations.

Our results also, and perhaps most importantly, suggest that individual surgeons can differ significantly from each other in their evaluation of patients’ quality of life. Patients in clinic A assigned themselves a significantly lower score than did patients in clinic B. Despite this, the surgeon in clinic A scored his patients significantly higher than they did themselves, whereas the surgeon in clinic B scored his patients significantly lower than they did themselves. This implies that surgeon A was over-optimistic about his patients’ quality of life whereas surgeon B was pessimistic in his evaluation, in turn suggesting poor comparability between surgeons in the assessment of patients’ quality of life.

Treadmill walking distances were not compared with quality of life scores. It has been previously
demonstrated that walking distances in claudicants have limited correlation with disability and quality of life.19,37,38

The inclusion of only two surgeons in this study imposes a limitation on not only the number of subjects available to be included in quality of life assessment, but also on the breadth of professional opinion canvassed. The authors acknowledge this limitation and accept that increasing the number of participating surgeons would increase the power of the study. However, the fact that the highlighted difference in opinion between two surgeons of similar experience achieved statistical significance supports the validity of these results and suggests that they would be reproduced with other clinicians.

The validity of the study would be further enhanced by test–retest analysis (to evaluate reliability), allowing an appropriate period of time between tests. This was not done because of practical and time restraints, but would be of great interest in further studies. As regards the problem of inter-observer variability in the use of questionnaires, while we have demonstrated indirectly that there can be significant differences between the opinions of experienced clinicians as to the severity of the impact of the symptoms, we have not been able to evaluate the difference there might be between the assessment the two clinicians might make of individual patients. To do this would require both clinicians to have an equally good knowledge of individual cases, a situation which is impractical when assessing clinicians who have entirely separate caseloads and who work in different hospitals.

The apparent inconsistency and inaccuracy in the assessment of claudicants’ quality of life which has been demonstrated in this study has the potential to result in inappropriate treatment being offered to a patient. Some patients might receive invasive treatment inappropriate to their overall level of activity, lifestyle and expectations, while others who actually need such treatment might be inadvertently denied it. Inconsistencies in patient assessment also have the potential to make audit of, and comparisons between, the practice of individual surgeons less accurate and less valuable than they otherwise might be. This has important implications when services are being audited and budgets allocated, and is contrary to the principles of evidence-based medicine.

Conclusion

We have shown in patients with intermittent claudication that surgeons do not necessarily assess quality of life as accurately as the patients do themselves and that individual surgeons may differ significantly in the quality of life score they assign to patients. We feel that only by employing objective methods of assessing quality of life in these patients can comparisons between the practice of individual surgeons be considered valid. To enhance assessment methods further research into generic health-related quality of life issues is necessary and the development of a validated disease-specific instrument for patients with intermittent claudication is essential.

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References

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