

## Quality of Life in Patients with Intermittent Claudication

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**Objective:** As intermittent claudication (IC) infrequently progresses to limb loss many clinicians adopt a conservative approach to treatment. Recently percutaneous transluminal angioplasty (PTA) has been applied to patients with IC. If this were to become the first line treatment for IC it would have major implications in terms of hospital facilities as well as cost. A measure is required, therefore, to decide on rationing of limited financial resources. "Quality of life" may be more influential in determining demand on services since objective medical criteria cannot give an insight into the patients feelings of well being.

**Design:** We applied the Nottingham Health Profile, by post, to a group of claudicants and age/sex matched controls. 70% responded from both groups. Claudicants who had recently received intervention were excluded, as were controls complaining of any leg pains on walking.

**Results:** The results showed that claudicants have greater perceived problems in the areas of energy, pain, emotional reactions, sleep, and physical mobility compared to controls ( $p < 0.05$ ; Mann-Whitney Test). This was reflected by a significantly greater positive response rate to problems with activities of daily living ( $0.05 > p > 0.02$ ; Chi-square Test) in the claudicant group.

**Conclusion:** Because of the cost and resource implications of introducing measures such as PTA to the treatment of vast numbers of patients with IC, we suggest that trials are needed to compare various treatments using quality of life measurements in addition to traditional efficacy/safety parameters.

### Introduction

Intermittent claudication (IC) is the commonest manifestation of peripheral vascular disease, affecting more than 5% of men over the age of 50 years.<sup>1</sup> Reconstructive surgery has not been widely applied to patients with intermittent claudication because the discomfort and restriction in lifestyle are not considered, by clinicians, severe enough to justify the surgical risks.<sup>2</sup> Treatment for IC has, therefore, been largely conservative. Recently there has been controversy about the role percutaneous transluminal angioplasty (PTA) has to play in the treatment of patients with mild IC<sup>3–7</sup> as up to 40% of patients with IC have arterial lesions amenable to angioplasty. These reports have concentrated on technical success, improvements in ankle-brachial pressure index, and patency rates for evaluating outcome. It has been suggested that the beneficial effect on increased quality of life should be considered in deciding which

treatment modality is best.<sup>8</sup> Claudication is a subjective phenomenon and therefore the impact it has on life can only be perceived by the patient. Also improvement, if any, after therapy can only be assessed by the patient — hence the need for objective evaluation of the patient's quality of life before and after intervention.

Quality of life encompasses many aspects of an individual's life incorporating socioeconomic factors, housing, interpersonal relationships, and job satisfaction.<sup>9</sup> Studies have shown disparity in clinicians' and patients' judgements of quality of life.<sup>10,11</sup> A review of the literature revealed only two studies looking at quality of life in patients with peripheral vascular disease.<sup>12,13</sup> Hunt *et al.*<sup>12</sup> did not look specifically at patients with IC. Arfvidsson *et al.*<sup>13</sup> studied claudicants and linked quality of life with mobility, however the controls used in this study comprised an historical group of women only.

We, therefore, looked at the quality of life using the Nottingham Health Profile (NHP)<sup>14</sup> in a group of patients with intermittent claudication to assess the actual degree of the problem compared to age and sex matched controls.

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## Methods

Ethics Committee approval was obtained for this study. One hundred questionnaires were sent with a covering letter to patients with IC on a register kept by the department. All of these patients had been fully investigated and diagnosed as having IC based on ankle-brachial pressure indices less than 0.8 and a decrease in ankle pressures of >30mmHg after exercise. A covering letter explained the purpose of the questionnaire and requested the patients to complete and return it in the enclosed reply-paid envelope. In addition to the NHP, the patients were asked about other illnesses and about any treatment they may have had. One hundred age and sex matched controls, with minor non-debilitating surgical problems such as herniae and varicose veins, were chosen from a waiting list and sent the questionnaire with similar instructions. No attempt was made to contact non-responders.

The NHP consists of two parts. Section I assesses perceived health problems in the areas of sleep, energy, emotional reactions, social isolation, physical mobility, and pain. Section I comprises 38 questions, each with a yes/no response, which provide weighted scores<sup>15</sup> for the areas mentioned. Section II assesses the extent to which such problems affect daily activities, such as occupation, hobbies, holidays etc. The NHP has been well validated as a self-administered questionnaire.<sup>14</sup>

Differences between the two groups were assessed using the Mann-Whitney test for section I of the NHP and the Chi-square test for section II. Correlations between the various factors in section I were assessed using Spearman's Rank Correlation Test. A value of  $p < 0.05$  was taken as statistically significant.

## Results

The response rate was 68% for claudicants and 72% for controls. Nine controls complained of leg pains and were therefore excluded. Of the claudicant group, five had had recent treatment and three returned incomplete questionnaires — these were also excluded. The demographic data for the remaining patients in both groups is shown in Table 1.

Patients with IC had significantly worse mean scores in the areas of energy, pain, emotional reactions, sleep, and physical mobility than controls (Fig. 1). There was no difference between the two groups for feelings of social isolation (such as "I feel lonely" and "I feel there is nobody I am close to").

Table 1. Demographic data for the claudicant and control groups showing good age and sex matching

	Claudicants	Controls	
<i>n</i>	60	63	
Median age (range) years	66 (43–84)	64 (29–78)	$p=0.1^*$
Male : female	43:17	43:20	$p>0.5^\dagger$

\* Mann-Whitney Test.

† Chi-square Test.

Table 2 shows the correlation coefficients for the components of section I for claudicants, demonstrating statistically significant correlations (Spearman's Rank Correlation Test). Logistic regression analysis was used to determine which of the six areas of section I were significant in predicting cases and controls. A stepwise elimination procedure was used and showed that physical mobility was the only factor with a significant predictive effect (Score statistic for test: chi-square = 8.714, DF = 1,  $p = 0.003$ ).

The percentage positive responses for areas of daily activity (section II of the NHP) are shown in Fig. 2. There were significant differences between the two groups in social life, home life, and holidays. Activities around the home just failed to reach statistical significance. Taking all aspects of daily life together, however, there was a significant difference between the claudicants and controls ( $0.05 > p > 0.02$ , Chi-square test).

## Discussion

Most measures of treatment outcome have until recently been based on technical success, patency rates, and safety parameters,<sup>16</sup> and in patients with IC have considered changes in walking distance or other objective measurements such as ankle-brachial pressure index. The limitation in independence and mobility, however, may have profound effects on life style.<sup>7</sup> It has been suggested therefore that the traditional efficacy/safety methods of assessing outcome should be extended to include quality of life as a third parameter.<sup>18,19</sup> This will also allow better assessment of the cost-effectiveness of various treatment modalities and help optimise utilisation of health-care resources.

Clinicians are poor at assessing the impact of an illness on the patients' perception of quality of life<sup>10,11</sup> and many instruments have been designed for measuring it.<sup>20</sup> There are two basic types, disease specific and generic. The NHP is an example of a generic instrument designed to be applicable to a wide range of health problems.<sup>21</sup> Such a broad approach may,

however, reduce the sensitivity of this tool to the effects of various treatment modalities.<sup>22</sup> The NHP has been well validated for self-administration.<sup>14</sup>

The conservative approach to the treatment of patients with IC has been based on the perception, by clinicians, that the discomfort and restriction in lifestyle caused by the condition is generally not severe enough to justify the risks of surgical intervention.<sup>2</sup> The introduction of PTA has, however, led to controversy about its exact role in the treatment of patients with IC, up to 40% of whom have an arterial lesion amenable to treatment with this modality.<sup>4</sup> Looking at traditional outcome parameters of ankle-brachial pressure index and walking distance it has been suggested that an organised exercise programme is better than PTA.<sup>5</sup> The introduction of either treatment would have major implications in terms of hospital facilities and costs.

Before one can determine the impact any treatment will have on the quality of life in patients with IC, it is important to assess the actual degree of the problem. To this aim we applied the NHP to a group of claudicants and comparable controls. Previous studies looking at this have not concentrated on claudicants alone<sup>12</sup> or have used inappropriate controls.<sup>13</sup> In their study Hunt *et al.*<sup>12</sup> included patients who had undergone treatment for vascular disease or had been referred for surgical treatment. This would suggest a heterogeneous group with varying degrees of disease

severity. We have shown that a surprisingly high number of problems are experienced by patients with stable IC compared to controls who have undergone a similar sequence of referral by General Practitioners and review in surgical clinics, unlike the controls used by Arfvidsson *et al.*<sup>13</sup>

We excluded nine out of 72 controls complaining of pain in the legs on walking as many patients with symptoms of intermittent claudication do not consult their doctor. In a study from Oxford,<sup>23</sup> only 50% of those with symptoms of intermittent claudication (determined by questionnaire) consulted a doctor, and this figure was only 10% in a study from London.<sup>24</sup> It is unlikely that all of these suffered from IC as this would give a prevalence of 12.5% which is excessive for this age group. It is more likely, therefore, that some of these patients had musculoskeletal conditions causing exercise-induced leg pain.

Section II of the NHP is designed to assess the aspects of daily life which are being affected by perceived health problems. Although there is a significant difference between claudicants and controls for all the aspects of this section taken together, individually there was no difference for job of work, looking after the home, sex life, and interests and hobbies. Considering job of work, most of the subjects are of retirement age (90% had retired), or will have taken early retirement for health reasons, and will therefore answer "no" — this will invalidate the

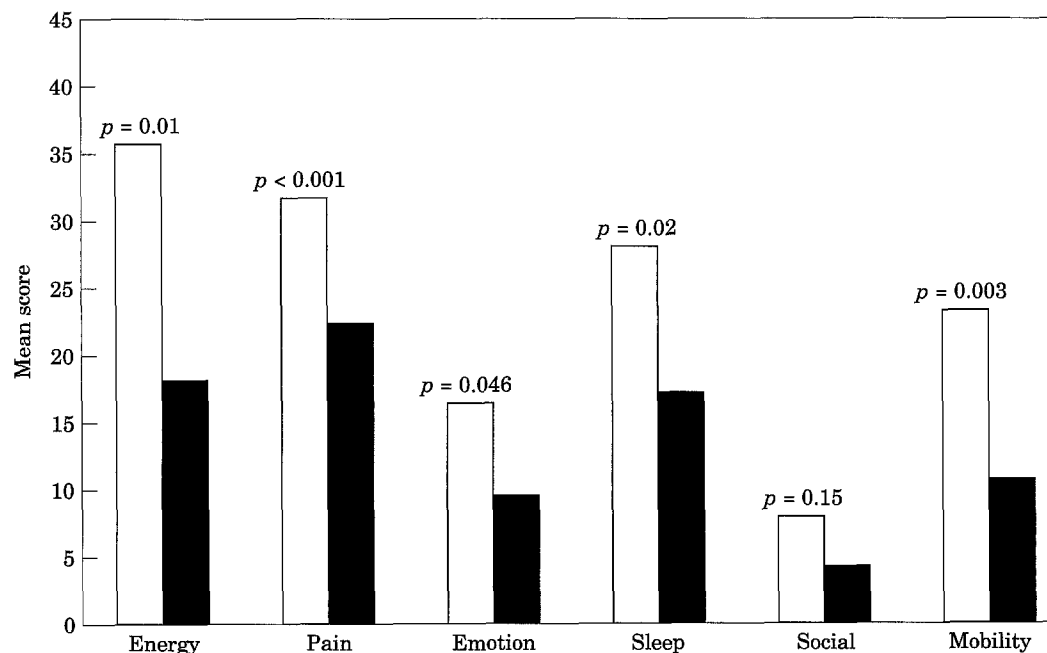


Fig. 1. Graph showing mean scores in Section I of the NHP for claudicants and controls. There are significant differences between the two groups for energy, pain, emotional reaction, sleep, and physical mobility ( $p$  values determined using Mann-Whitney Test). (□) claudicants; (■) controls.

**Table 2. Correlation coefficients for the components of Section I of the NHP for patients with intermittent claudication**

	Energy	Pain	Emotion	Sleep	Social isolation
Pain	0.572**				
Emotion	0.719**	0.445**			
Sleep	0.656**	0.613**	0.461**		
Social isolation	0.379*	0.162	0.440**	0.275*	
Mobility	0.720**	0.637**	0.501**	0.651**	0.406**

\* $p < 0.05$ ; \*\* $p < 0.002$  (Spearman's Rank Correlation Test).

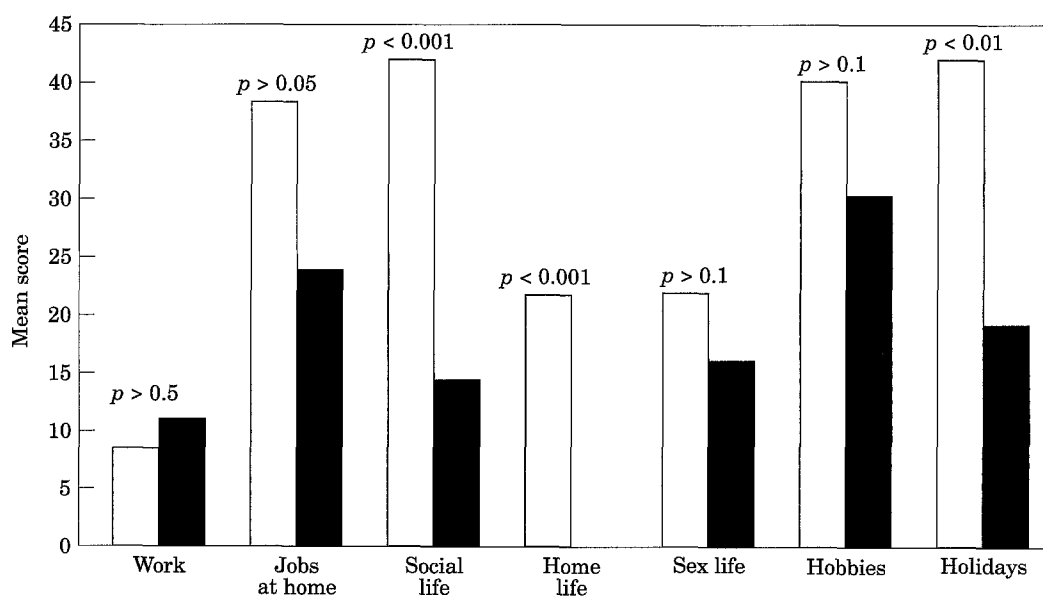
usefulness of the question which refers to paid employment. The lack of a difference in the other areas of daily living may be explained by the presence of other illnesses in the two groups. If patients with these additional ailments are removed from the data analysis we are left with 41 patients in the claudicant group and 39 in the control group. Both groups are still age and sex matched. Now we find significant differences in all areas of section II except work and sex life.

Section I of the profile shows no difference between patients and controls in feelings of social isolation. However, this is not reflected in section II where there is an obvious difference in effect on social life (e.g. going out to see friends). There are a number of possible explanations: (1) all the factors in section I will have an effect on the responses to section II and thus one cannot compare feelings of social isolation from section I to the overall effect on social interactions; (2) this may reflect a limitation of the profile as

a large number of zero scores in section I, as indicated by the very low mean scores for Social Isolation, results in highly skewed and, therefore, unreliable data; and (3) there may be interference from additional illnesses — removing those patients with additional illnesses results in a greater difference between patients and controls in feelings of social isolation but just fails to reach statistical significance ( $p = 0.06$ ).

There are significant correlations between the components of section I of the NHP, suggesting an interrelationship amongst the various factors. This has been shown previously when the NHP was used in a group with limited mobility (amputees).<sup>25</sup> Using a logistic regression analysis model with stepwise elimination, physical mobility was found to be the only factor with a significant predictive effect — again similar to previous reports using the NHP.<sup>25</sup> This suggests, therefore, that restriction in mobility is the underlying cause of the differences between claudicants and controls.

Thus, we have shown with this profile that patients with IC have significantly higher scores in the areas of perceived health problems compared to controls and that these have significant impact on activities of daily living. Because of the cost and resource implications of introducing measures such as surgery, PTA, or structured exercise classes to the treatment of the vast numbers of patients with IC, prospective controlled trials are necessary to compare various treatments using instruments to measure quality of life in addition to traditional efficacy/safety parameters.



**Fig. 2.** Graph showing the percentage positive responses for aspects of daily life in section II of the NHP. There are significant differences for social life, home life, and holidays ( $p$  values determined using Chi-square Test). (□) claudicants; (■) controls.

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