Nottingham Health Profile and Short-Form 36 Health Survey questionnaires in patients with chronic lower limb ischemia: Before and after revascularization

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Objective: **The purpose of this study was to compare the usefulness of the Nottingham Health Profile (NHP) and the Short-Form 36 Health Survey (SF-36) as general outcome measures after vascular intervention for lower limb ischemia with respect to patients' quality of life, on the basis of validity, reliability, and responsiveness analyses.**
Patients and Methods: **Eighty patients, 40 with claudication and 40 with critical ischemia, were assessed before and one month after revascularization by using comparable domains of the NHP and the SF-36 questionnaires.**
Results: **The SF-36 scores were less skewed and were distributed more homogeneously than the NHP scores. Discriminate validity results showed that NHP was better than SF-36 in discriminating among levels of ischemia with respect to pain and physical mobility. For both questionnaires, the reliability standards were satisfactory in most respects. The NHP was more responsive than the SF-36 in detecting within-patient changes. All of the NHP domains not zero at baseline were improved significantly one month after hemodynamically successful revascularization for patients with claudication, whereas patients with critical ischemia showed significant abatement of pain and improvements in physical mobility and social isolation. The SF-36 scores indicated a significant decrease in bodily pain and improvements in physical functioning and vitality for patients with claudication, and decrease in bodily pain and improvement in physical functioning for patients with critical ischemia.**
Conclusions: **The findings indicated that both NHP and SF-36 were reliable. The SF-36 scores were less skewed than the NHP scores, whereas NHP discriminated better among levels of ischemia and was more responsive in detecting quality-of-life changes over time than SF-36 in these particular patients. (J Vasc Surg 2002;36:310-7.)**

The fact that one of the primary goals of vascular surgical intervention is to improve patients' quality of life calls for a sensitive measurement of the outcome.

Intermittent claudication is a common problem, with a prevalence of 14% in men older than 68 years from a general Swedish population, and it is estimated that approximately 15% to 20% will progress to critical ischemia.[1] It is known that there is a spectrum of symptoms that affects the lives of these patients—such as claudication or ischemia rest pain, reduced mobility, sleep disorders, and ulceration or gangrene[2,3]—related to the severity of the disease.[4,5] To investigate the need for and efficacy of vascular intervention, a measure is required that is applicable at different levels of the disease and capable of detecting changes in quality of life over time.

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Traditionally, the success of a particular intervention has been described in terms of graft patency and limb salvage.[6] However, these data do not provide information on the ultimate effect of intervention on patients' quality of life. Moreover, the relatively weak correlations among ankle pressure, walking distance, and quality of life found in earlier studies[7,8] indicate that quality-of-life outcome focuses on aspects of the disease other than lower limb perfusion. Two types of instruments measure quality of life: disease-specific and generic.[9] Generic instruments such as the Nottingham Health Profile (NHP) and the Short-Form 36 Health Survey (SF-36) are applicable to a wide variety of populations because they address multidimensional aspects such as physical functioning, emotion or mood, social functioning, role performance, pain, and commonly performed daily activities.[10] Disease-specific instruments such as the Walking Impairment Questionnaire[11] have been developed for patients with claudication, and they address specific aspects including the degree of pain, aching, or cramps; reason for the difficulty in walking; walking distance; walking speed; and stair climbing. At present, no accurate disease-specific instrument exists to evaluate patients with critical ischemia. In previous research, different generic instruments have been used to analyze changes in quality of life following vascular intervention, including the NHP[12] and the SF-36.[13] The main limitation of the NHP scale with regard to sensitivity is the "floor effect," whereby

patients with milder symptoms tend to score zero or near zero and are, therefore, unsuitable for use in examining improvements.[14] On the other hand, bodily pain evaluated in the SF-36 scale has been noted to correlate weakly with a clinically reported knee pain scale.[15] To date, no study has from the same sample analyzed these two instruments to determine which is most appropriate with regard to its responsiveness in detecting clinical changes following vascular intervention.

To be useful in clinical practice, a generic outcome measure for patients with vascular disease needs to satisfy different criteria. One consideration regarding validity is an instrument's ability to measure differences between patients with various degrees of lower limb ischemia. Another important characteristic is reliability. One aspect of reliability refers to the extent to which all of the items on the instrument measure the same underlying attribute.[16] Finally, perhaps the most important property of a generic outcome measure is its responsiveness in detecting clinical within-patient changes following vascular intervention. For the purpose of providing recommendations about the usefulness of these instruments as generic outcome measures for these particular patients, empiric comparison of psychometrics, features, and performance are needed. The aim of this study was to compare the usefulness of the NHP and the SF-36 as general outcome measures after vascular intervention for lower limb ischemia with respect to patients' quality of life, on the basis of validity, reliability, and responsiveness analyses.

PATIENTS AND METHODS

Patients. One hundred consecutive patients from one Swedish academic vascular surgery unit in southern Sweden were invited to participate in the study. Inclusion criteria were admission for active treatment of documented lower limb ischemia, no communication difficulties, and no other treated disease in the system of the lower limbs restricting walking capacity. Of 100 patients, twenty (20%) dropped out for various reasons, 16 (16%) did not wish to participate, 3 (3%) had other complications, and one (1%) patient died during follow-up. Thus, the quality-of-life analyses were performed on 80 (80%) patients at baseline and one month after percutaneous transluminal angioplasty (PTA) or surgical revascularization. The selection criterion for "hemodynamically successful" was that the ankle-brachial pressure index (ABPI) increased by 0.15 or more at one month.[17] The severity of patients' lower limb ischemia was graded according to suggested standards for reporting grade of lower limb ischemia.[17] Forty (50%) patients with claudication and 40 patients with critical ischemia were treated by using a surgical bypass graft (73.8%) or by PTA (26.2%).

Clinical parameters. At baseline, routine medical history and risk factors were obtained in accordance with the Swedish Vascular Registry (Swedvasc),[18] and clinical examinations were performed. At the one-month follow-up these measurements were repeated. Palpable pulse, ankle-brachial pressure (ABP), and ABPI were reported. The ABPI was calculated by taking the ABP on the treatment side and dividing it by the highest arm pressure. For patients with claudication, a standard treadmill test (3 km/hour with a 14% incline) was performed at baseline and at the one-month follow-up.

Nottingham Health Profile. The NHP was developed as a measure of perceived distress relating to potentially disabling health conditions.[19] The NHP is a two-part instrument; part I was used in this study. The 38 yes-no items of part I reflect the patient's degree of distress within the domains of pain, physical mobility, emotional reactions, energy, social isolation, and sleep. The answers to the Swedish items are weighted,[20,21] giving a range of possible scores from zero (indicating no problems at all) to 100 (indicating the presence of all problems within a domain). The Swedish version of the NHP is the most frequently used and best evaluated and has been shown to be reliable and valid in different patient groups.[22,23] The NHP scale has also shown responsiveness to changes associated with a variety of treatments such as recovering from limb fracture,[24] heart/lung transplantation,[25] and after successful revascularization in patients with lower limb ischemia.[12]

Short-Form 36 Health Survey. The SF-36 was developed from a previous questionnaire known as the Medical Outcome Study General Health Survey Instrument.[26] It contains 36 items covering eight health domains: bodily pain, physical function, role limitations due to physical problems, mental health, vitality, social function, role limitations due to emotional problems, and general health. Items in two scales are answered in a yes-no format. For the other scales, patients are asked to answer on a three-to-six response scale. For each scale, item scores are summed and transformed into a scale from zero (indicating worse health state) to 100 (indicating best health state). For this study the standard Swedish version of the SF-36 was used.[27] In population studies as well as in other patient groups, the SF-36 has been found to be acceptable with regard to validity and reliability.[15,28,29] The responsiveness of the SF-36 to changes in health status over time has been shown in patients with critical ischemia following infrainguinal reconstruction.[13,30]

Procedure. All patients had given prior consent to participate in the study. During their initial admission, patients were asked by the head nurse to fill out the NHP and the SF-36 questionnaires by themselves, before and one month after intervention. This study followed the routine of follow-up periods in accordance with the Swedvasc guidelines.[18] Demographic characteristics and history of clinical data were obtained from the patients' medical record. Approval for the study was obtained in advance from the ethics committee of the University of Lund.

Statistical analyses. Analysis of differences in baseline characteristics between patients with claudication and those with critical ischemia were based on chi-square and Mann-Whitney U tests. The prevalence of patients achieving the lowest (floor effect) and highest (ceiling effect) possible quality-of-life score in NHP and SF-36 was also calculated.

Table I. Domains measured by the Nottingham Health Profile and the Short Form 36

Domain	*Nottingham Health Profile*	*SF-36*
Pain	*Pain (8 items)*	*Bodily pain (2 items)*
Physical activity	*Physical mobility (8 items)*	*Physical functioning (10 items)*
Psychological status	*Emotional reactions (9 items)*	*Mental health (5 items)*
	Energy (3 items)	*Vitality (4 items)*
Social activity	*Social isolation (5 items)*	*Social functioning (2 items)*
Other	Sleep	General health
		Physical role
		Emotional role

Comparable domains shown in italics.

Table II. Patients' demographic characteristics and clinical indicators at baseline

	Claudication (n = 40)	*Critical ischemia (n = 40)*	*Total (n = 80)*	P *value*
Mean age (±SD)*	67 (±11)	71 (±10)	69 (±10)	.04
Sex (%)†				NS
Male	21 (52.5)	20 (50)	41 (51.3)	
Female	19 (47.5)	20 (50)	39 (48.8)	
Severity of disease (%)				
Moderate claudication	2 (5)		2 (2.5)	
Severe claudication	38 (95)		38 (47.5)	
Ischemia rest pain		20 (50)	20 (25)	
Ischemia ulcers		17 (42.5)	17 (21.2)	
Gangrene		3 (7.5)	3 (3.8)	
Level of disease (%)				
Iliac	17 (42.5)	12 (30)	29 (36.2)	
Femoral (above knee)	18 (45)	10 (25)	28 (35)	
Below knee (distal)	5 (12.5)	18 (45)	23 (28.8)	
Leg side of disease (%)				NS
Unilateral	37 (92.5)	32 (82.1)	69 (86.2)	
Bilateral	3 (7.5)	8 (17.9)	11 (13.8)	
Type of intervention (%)†				.04
Angioplasty (PTA)	15 (37.5)	6 (15)	21 (26.2)	
Surgical revascularization	25 (62.5)	34 (85)	59 (73.8)	
Risk factors (%)†				
Smoking	7 (17.5)	9 (22.5)	16 (20)	NS
Stroke/TIA	4 (10)	1 (2.5)	5 (6.3)	NS
Diabetes	4 (10)	11 (27.5)	15 (18.8)	NS
Hyperlipidemia	1 (2.5)	1 (2.5)	2 (2.5)	NS
Hypertension	12 (30)	14 (35)	26 (32.5)	NS
Heart disease	7 (17.5)	16 (40)	23 (28.8)	.04
Chronic lung disease	1 (2.5)	3 (7.5)	4 (5)	NS
Kidney disease	1 (2.5)	2 (5)	3 (3.8)	NS

NS, Not significant; *SD*, standard deviation; *TIA*, transient ischemic attack.
*Tested by Mann-Whitney *U* test.
†χ^2 test.

The validity was examined by the Mann-Whitney U test regarding the relative ability of the two instruments to discriminate among levels of lower limb ischemia. The analysis focused on those domains that are comparable between the two instruments, including physical mobility, pain, energy, social isolation, and emotional reactions for the NHP, and physical functioning, bodily pain, vitality, social functioning, and mental health for the SF-36 (Table I). Furthermore, a logistic regression analysis (forward stepwise method) was used to determine which of the five comparable domains in the NHP and SF-36 differentiated between patients with claudication and those with critical ischemia. For this purpose, clinical data, the level of patients' ABPI at baseline, and walking distance for patients with claudication were used as the criteria for disease severity. Each domain for the NHP and SF-36 was divided according to the median value.

Internal consistency based on correlations between items for each scale was measured by using Cronbach's α.[31] There are two ways to report internal consistency: one is to show the α value and the other is to show the reliability coefficient. A reliability coefficient in the vicinity of 0.70 is reported to be a recommended reliability standard for group-level comparisons, whereas ideally, decisions about

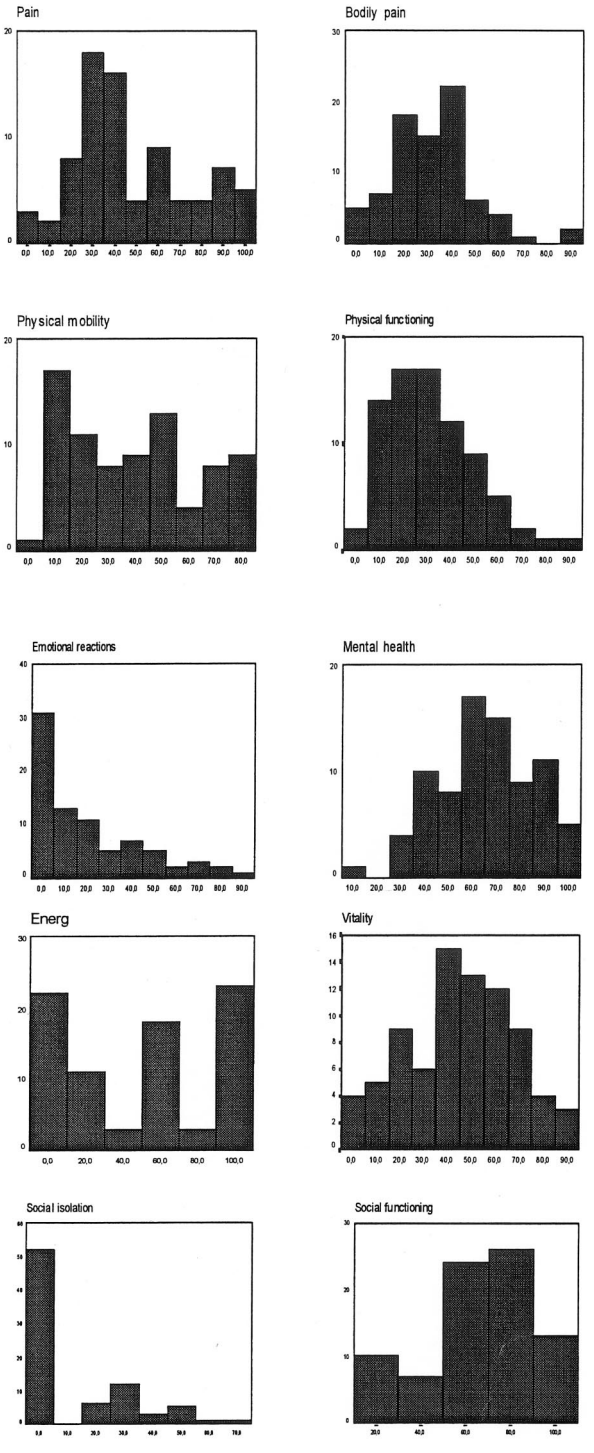

Fig 1. Frequency distribution of scores on the NHP (**left panel**) and comparable dimensions on the SF-36 (**right panel**).

individuals should be based on a reliability coefficient of 0.90 or better.[16]

The responsiveness of the two instruments in detecting within-subject changes over time in the group as a whole as well as in patients with claudication and those with critical ischemia was analyzed with use of the Wilcoxon signed rank test. The correlation between quality of life scores, ABPI, type of intervention, age, and gender was analyzed by using the Spearman rank correlation. Data analysis was performed by using the statistical package SPSS 8.0 (Lund, Sweden) for overall comparison, and a two-tailed P value of $<.05$ was considered statistically significant.[32]

RESULTS

Of 80 patients, 64 patients had a hemodynamically successful revascularization, whereas 16 had an unsuccessful revascularization. Statistically significant differences in age were found, showing that patients with critical ischemia were older than patients with claudication ($P < .04$) (Table II). Angioplasty was significantly more common in patients with claudication, whereas patients with critical ischemia more often had surgical revascularization ($P < .04$). In addition, a history of heart disease ($P < .04$) was significantly higher among patients with critical ischemia than among patients with claudication (Table II). After successful revascularization there was a significant improvement in walking distance ($P < .0001$) for patients with claudication. There were no significant differences in quality of life (NHP and SF-36) between patients who had undergone PTA (n = 11) and those who had undergone surgery (n = 53). No significant correlation was found between the measured quality-of-life domains and ABPI, walking distance for patients with claudication, age, or sex.

Comparison of the frequency distribution of NHP and SF-36 scores on the comparable domains showed that the NHP scores were more skewed than the SF-36 scores (Fig 1). The prevalence of patients with best possible scores, referred to as "ceiling effect" (SF-36 = 100; NHP = 0), was higher for the NHP scale (range, 1.3%-65%) than for the SF-36 scale (range, 0%-16.3%). The prevalence of worst possible scores, "floor effect" (SF-36 = 0; NHP = 100), was also higher for the NHP scale (range, 0%-28.8%) than for the domains of SF-36 (range, 0%-6.3%) (Table III).

Validity. Increasing lower limb ischemia resulted in a significant deterioration in NHP-measured quality-of-life domains with regard to pain ($P < .01$) and physical mobility ($P < .03$), indicating lower quality of life at baseline in patients with critical ischemia (Table IV). Emotional reactions, energy, and social isolation were domains assessed by the NHP not influenced significantly by increasing lower limb ischemia. None of the domains assessed by the SF-36 was influenced significantly by increasing lower limb ischemia. Further analysis showed that belonging to the critical ischemia group was significantly associated with high pain scores of the NHP (odds ratio, 9.7; 95% confidence interval, 2-47.1; $P < .004$). Physical mobility, emotional reactions, energy, and social isolation for the NHP and all of the SF-36 domains failed to reach statistical significance as independent factors.

Reliability. All domains measured by the two instruments were statistically reliable, with α values of >0.70, except for the NHP-measured social isolation ($\alpha = .60$)

Table III. Comparison of "floor" and "ceiling" effects and reliability in comparable NHP and SF-36 scales

*NHP**	*Floor*	*Ceiling*	α *values*†	*SF-36*	*Floor*	*Ceiling*	α *values*
Pain	6.3	3.8	.77	Bodily pain	6.3	0	.69
Physical mobility	0	1.3	.73	Physical functioning	2.5	0	.90
Emotional reactions	0	38.8	.78	Mental health	0	3.8	.83
Energy	28.8	27.5	.71	Vitality	5	0	.71
Social isolation	0	65	.60	Social functioning	0	16.3	.68

Data are percentages unless otherwise indicated.
*The NHP scores are reversed for consistency with the SF-36.
†Cronbach's α.

Table IV. Differences in NHP- and SF-36-measured quality of life domains between patients with claudication and those with critical ischemia at baseline

	Claudication (n = 40)	*Critical ischemia (n = 40)*	
Domain	*Md (q¹,q3)*	*Md (q¹,q3)*	P *value**
NHP†			
Pain	37.6 (27.3-56.6)	53.7 (27.8-87.4)	.01
Physical mobility	32.8 (10.2-52.4)	48.7 (21.7-67.3)	.03
Emotional reactions	11.1 (0-42.2)	8.8 (0-25.6)	.39
Energy	60.6 (5.9-100)	60.6 (0-100)	.59
Social isolation	0 (0-25.1)	0 (0-25.1)	.99
SF-36‡			
Bodily pain	36.5 (22-42)	31 (22-41)	.4
Physical functioning	25 (15-40)	25 (15-43.8)	.84
Mental health	66 (52-83)	66 (49-76)	.73
Vitality	42.5 (31.3-60)	45 (21.3-58.8)	.49
Social functioning	68.8 (50-87.5)	62.5 (50-75)	.43

*Mann-Whitney *U* test.
†Score 100, a high score indicates a greater perceived health problem.
‡Score 100, a high score indicates a smaller perceived health problem.

and for the SF-36-measured bodily pain (α = .69) and social functioning (α = .68) (Table III). The SF-36 showed the highest reliability of the two instruments tested, attaining α values of >0.90 in physical functioning and of >0.83 in mental health.

Responsiveness. The ability to detect significant quality-of-life changes between baseline and the one-month follow-up was not equally good in all domains for the NHP and SF-36 (Table V). All of the comparable domains measured by the NHP improved significantly in the 64 patients one month after hemodynamically *successful* revascularization. For the SF-36-measured domains there were significant improvements in bodily pain ($P < .0001$), physical functioning ($P < .0001$), and vitality ($P < .04$), whereas mental health and social functioning showed no significant improvements. One month after hemodynamically *unsuccessful* revascularization, the 16 patients had a significantly lower score in energy ($P < .007$) and emotional reactions ($P < .02$) measured by the NHP, whereas the SF-36 showed significant improvements in physical functioning ($P < .02$). The 31 patients with claudication had one month after hemodynamically *successful* revascularization significant improvements in all NHP-measured quality-of-life domains that were not zero at baseline, whereas the 33 patients with critical ischemia had improvements in pain ($P < .0001$), physical mobility ($P < .0001$), and social isolation ($P < .02$), but not in emotional reactions and energy (Fig 2). The SF-36-measured quality-of-life domains showed significant improvements in bodily pain ($P < .001$), physical functioning ($P < .0001$), and vitality ($P < .03$) for patients with claudication, and in bodily pain ($P < .004$) and physical functioning ($P < .01$) for patients with critical ischemia, whereas mental health and social functioning were not improved in any of the subgroups (Fig 3). After hemodynamically *unsuccessful* revascularization, none of the patients showed significant improvements in quality of life, except for in emotional reactions ($P < .04$) and energy ($P < .04$) for patients with claudication measured by the NHP.

DISCUSSION

Findings indicated that the SF-36 scores were less skewed and more homogeneously distributed than the NHP scores. Discriminate validity results, however, showed that NHP was better than SF-36 in discriminating among levels of ischemia with regard to pain and physical mobility. For both questionnaires, the reliability standards were satisfactory in most respects. The NHP questionnaire was more responsive than the SF-36 in detecting within-patient changes. All of the NHP domains not zero at baseline were significantly improved one-month after hemodynamically successful revascularization for patients with claudication, whereas patients with critical ischemia showed improvements in pain, physical mobility, and social isolation. The SF-36 questionnaire detected improvements in bodily pain, physical functioning, and vitality for patients with claudication and in bodily pain and physical functioning for patients with critical ischemia.

The NHP and the SF-36 are both generic instruments for assessing health-related quality of life.[9] They have been tested extensively and used for different purposes in many populations, including patients with lower limb ischemia.[4,12] For the purpose of assessing the utility of these instruments as general outcome measures in clinical prac-

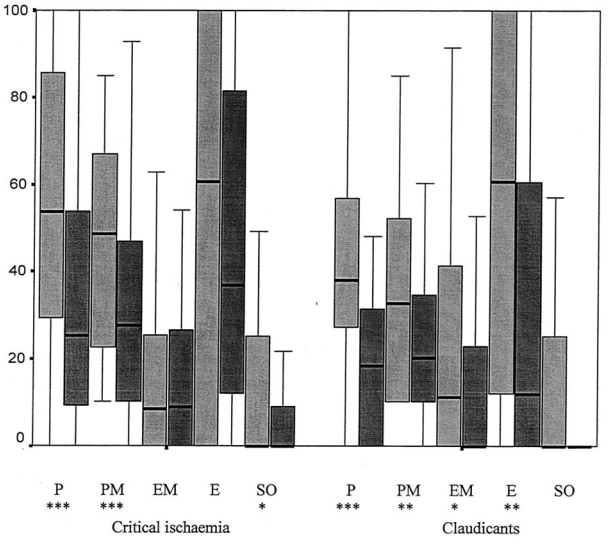

Fig 2. Changes in median score for the NHP in claudicants (n = 31) and patients with critical ischemia (n = 33), before (*gray bars*) and one month after (*black bars*) successful revascularization. Pain (P), physical mobility (PM), emotional reactions (EM), energy (E), and social isolation (SO). Analyzed with use of Wilcoxon signed rank test. A higher score indicates greater perceived health problems. $*P < .05$; $**P < .01$; $***P < .001$.

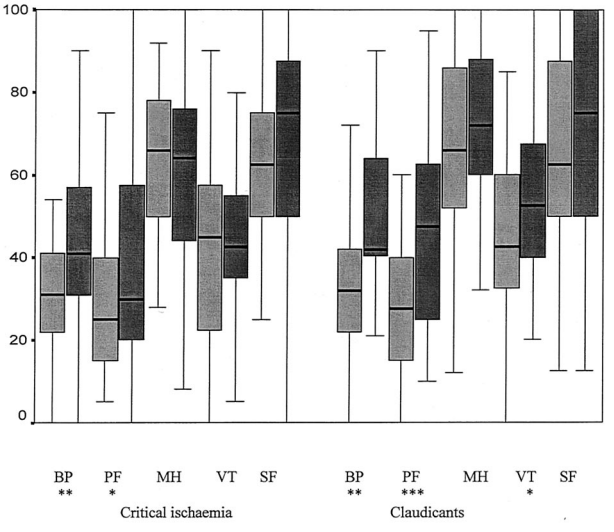

Fig 3. Changes in median score for the SF-36 in claudicants (n = 31) and patients with critical ischemia (n = 33), before (*gray bars*) and one month after (*black bars*) successful revascularization. Bodily pain (BP), physical functioning (PF), mental health (MH), vitality (VT), and social functioning (SF). Analyzed with use of Wilcoxon signed rank test. A higher score indicates less perceived health problems. $*P < .05$; $**P < .01$; $***P < .001$.

Table V. Changes in NHP- and SF-36–measured quality of life domains, before and 1 month after hemodynamically successful revascularization in patients with lower limb ischemia

	*NHP**			*SF-36†*	
Domain	*Md (q1,q3)‡*	P *value§*	*Domain*	*Md (q1,q3)*	P *value*
Pain	20.7 (0-36.2)	.0001	Bodily pain	10 (0-31)	.0001
Physical mobility	13.9 (0-29)	.0001	Physical functioning	10 (0-25)	.0001
Emotional reactions	0 (0-11.8)	.04	Mental health	4 (8-12)	.77
Energy	0 (0-39.4)	.02	Vitality	2.5 (5-18.8)	.04
Social isolation	0 (0)	.002	Social functioning	0 (12.5-9.4)	.26

*Score 100, a high score indicates a greater perceived health problem.
†Score 100, a high score indicates a smaller perceived health problem.
‡Changed median values (25th and 75th percentiles).
§Wilcoxon signed rank test.

tice for vascular surgery there are different criteria that have to be taken into consideration. First, the questionnaire should be brief and easy to use. The NHP and the SF-36 seemed to meet that criterion, requiring just 10 minutes each to complete. Secondly, the questionnaire should be acceptable for use by older patients. This acceptance was indicated by the high response rate of 80%. Brazier et al,[29] however, reported a high level of missing data for the SF-36 in persons over 65 years of age. Lastly, the study design might be limited by the fact that the NHP and the SF-36 questionnaire domains differ in their nature and content. Nevertheless, consistent with the World Health Organization[10] both questionnaires include basic domains of physical, social, and mental health.

It is widely accepted that the more homogeneous the distribution of scores, the lower the floor and ceiling effects, the better the measuring instrument.[16] Although both questionnaires provided nonsymmetric distributions, the analysis showed that the responses to the SF-36 questionnaire were less skewed and more homogeneously distributed than the responses to the NHP. Similarly, Prieto et al[33] showed that SF-36 was less skewed and exhibited a more homogeneous distribution of scores (other than for mental health) than the NHP in patients with chronic obstructive pulmonary disease. Furthermore, the two questionnaires differed somewhat in their measurement of the full range of health. Four of the SF-36–measured but only two of the NHP-measured domains achieved recom-

mended standards of score distributions (≤15%).[34] Both questionnaires exhibited minor floor effects. However, the NHP showed higher ceiling effects than the SF-36 regarding social isolation, emotional reactions, and energy. Previously, Prieto et al[33] reported less ceiling and floor effects in SF-36 than in NHP, whereas McHorney et al[35] reported very small floor effects for SF-36 in diverse patient groups. In addition, substantial ceiling effects have been reported for the NHP, ranging from 48% to 78% in community-based studies.[29,36] The superiority of the SF-36 questionnaire in this respect may be the result of increasing number of possible different scores, whereas NHP items are based on dichotomous responses (yes/no) and the measuring of items tap more extremes end of ill health.

All domains measured by the two instruments exceeded the minimum reliability of ≥0.70 recommended for group comparisons,[16] except bodily pain (α = .69) and social functioning (α = .68) for SF-36, and social isolation (α = .60) for NHP. Physical functioning (α = .90) for the SF-36 was the only domain that met the minimum standard for individual-level application of 0.90 to 0.95.[16] Previously, Wiklund et al[22] reported reliability coefficients of 0.81 to 0.34 for the NHP in patients with arthrosis of the hip joint, and McHorney et al[35] showed reliability coefficients of 0.93 to 0.82 for the SF-36 across diverse patients group. However, in a study if patients with lower limb ischemia, Chetter et al[4] indicated that the NHP might be more reliable than the SF-36, attaining reliability coefficients of >0.80 for all of the NHP domains. These findings suggest that although both questionnaires meet the reliability standards for group-level application in most respects, none of them achieved the degree of reliability that would be desirable in individual-based assessment and decision-making, except for physical functioning.

In terms of validity, the questionnaires should be sufficiently sensitive to discriminate between levels of disease.[16] Surprisingly, the result showed that the NHP questionnaire was better than SF-36 at discriminating between levels of ischemia, indicating significant deterioration in the domains of pain and physical mobility in patients with critical ischemia. Nevertheless, Chetter et al[4] found that SF-36 and NHP were equally responsive to variations in physical activity and pain, whereas SF-36 was more responsive to variations in psychological status. In addition, Prieto et al[33] suggested that both instruments were similar in discriminating among different levels of respiratory impairment. The small sample size in the subgroups in this study may be one explanation of the absence of the ability for the two instruments to discriminate among levels of ischemia. Despite the fact that the NHP score had more skewed distribution, these findings suggest that the NHP is more sensitive in explaining the quality-of-life phenomena in these particular patients with respect to pain and physical mobility.

Perhaps one of the most important characteristics of an effective outcome measure is the instrument's ability to detect changes in general health over time. The analysis showed that NHP was most responsive to within-patient changes, indicating immediate improvements after hemodynamically successful revascularization in all measured domains, whereas SF-36 showed improvements in all domains, except for social functioning and mental health. The responsiveness in detecting changes in the subgroups was also in favor of the NHP. The NHP questionnaire has previously shown improvements for patients with claudication in all health domains that were not zero at baseline after a hemodynamically successful bypass grafting or angioplasty.[12] Whereas Chetter et al reported improvements in all the SF-36 measured domains for patients with claudication[30] and significantly improved physical functioning, pain, vitality, and social functioning for patients with critical ischemia.[13] These results suggest good responsiveness for the NHP in general quality-of-life changes based on short-time evaluation. However, one-month follow-up may be too short a period for recovery from a surgical procedure, and the essentials of measuring within-patient changes should, therefore, also have evidence pertaining to the responsiveness of quality-of-life changes in longitudinal studies. Furthermore, generic quality-of-life questionnaires such as NHP and SF-36 are global in their nature, and improvements in functional status are often difficult to define, especially in patients with critical ischemia, because of the presence of numerous and often severe comorbid conditions. Therefore, disease-specific instruments capable of detecting improvements in functional status and predicting and selecting patients with critical ischemia may be needed.[37]

In conclusion, the findings indicated that both NHP and SF-36 were reliable. The SF-36 scores were less skewed than the NHP scores, whereas NHP discriminated better among levels of ischemia and was more responsive in detecting quality of life changes over time than SF-36 in these particular patients.

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