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Quality of Life Analysis in Patients with Lower Limb Ischaemia: Suggestions for European Standardisation

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Introduction and Objectives: In this era of evidence-based medicine and limited resources we seem obliged, on clinical and economic grounds, to demonstrate that we improve not only patient survival but also the quality of patients' lives. This study aims to determine the impact of increasing lower limb ischaemia on quality of life (QOL) and which of three commonly used generic QOL instruments is the most valid, reliable, and responsive to change in patients with lower limb ischaemia.

Patients and Methods: Two hundred and thirty-five patients, 144 men and 91 women, median age 68 years (range 41–87 years) were graded according to ISCVS suggested reporting standards, i.e. 16 mild, 116 moderate and 25 severe claudicants; 33 patients had rest pain and 45 tissue loss. Patients completed Short Form 36 (SF36), EuroQol (EQ-5D) and Nottingham Health Profile (NHP) questionnaires at interview. Additional copies of questionnaires were posted to 80 patients prior to attendance. Correlation between the two sets of responses reflects test–retest reliability. Correlation between domains measured by the three instruments reflects convergent and divergent validity. Kruskal Wallis ANOVA detected QOL changes across the whole group. Spearman Rank was used to analyse validity and reliability. Responsiveness was analysed using the Mann–Whitney U-test.

Results: Increasing lower limb ischaemia confers significant ($p < 0.05$) deterioration in:

SF36 measured: physical functioning, physical role, pain, general health, vitality, social functioning and mental health.

EQ-5D measured: mobility, self-care, usual activities, pain and anxiety/depression.

NHP measured: energy, pain, emotional reaction, sleep, social isolation and physical mobility.

All three instruments are significantly reliable ($r_s > 0.7$). The validity of SF36 and NHP ($r_s = 0.68–0.78$) is superior to EQ-5D ($r_s = 0.37–0.7$). SF36 & NHP are equally responsive to changes in physical activity and pain. SF36 and EQ-5D are most responsive to changes in social activity. SF36 is most responsive to changes in psychological status.

Conclusion: QOL deteriorates markedly with increasing lower limb ischaemia. The SF36 would appear to be the most appropriate generic QOL analysis tool for these patients. We recommend its widespread adoption throughout Europe, thus providing a standardised tool for reporting generic QOL.

Key Words: Quality of life, Lower limb ischaemia; Validity, Reliability; Responsiveness.

Introduction

Lower limb ischaemia is a common problem in Western countries. The measured prevalence of intermittent claudication is 5% in the population over 50 years, and the estimated incidence of critical ischaemia is 150–200

people per million of the population per year.^{1,2} The overall prognosis of these patients is poor, with a 5-year mortality in claudicants of 12–52% and a yearly mortality of almost 20% in patients with critical ischaemia.^{3,4} Outcome measures conventionally used in clinical practice would seem to justify the use of surgical and radiological procedures in the management of these patients. However, these procedures are costly and their impact on patients' quality of life (QOL) has not been adequately assessed. All this being taken into account, the balance of benefit, especially in terms of health economics, of treating lower limb ischaemia is

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finely poised. Perhaps, in this climate of evidence-based medicine and limited resources, further justification for intervention is required. The success of a particular intervention should not only be based on an improvement in lower limb perfusion, but also on an improvement in the patient's overall QOL. Thus, QOL analysis is becoming increasingly popular as an outcome measure in vascular surgery, with studies analysing the impact of specific degrees of lower limb ischaemia on quality of life or the impact of specific interventions on QOL.^{5,6} However, no study has previously analysed the impact of increasing lower limb ischaemia on patient-reported QOL across the whole spectrum of the disease. In previous studies generic QOL in patients with lower limb ischaemia has been analysed utilising a vast array of different instruments including the Nottingham Health Profile (NHP),⁵ the EuroQol (EQ-5D),⁶ and Short Form 36 (SF36).^{7,8} This use of different QOL instruments makes comparison between studies and interventions difficult. No paper has analysed which generic QOL instrument is most appropriate for use in these patients. This paper aims, firstly, to assess the impact of increasing lower limb ischaemia on patient-reported QOL across the whole spectrum of the disease. Secondly, we aim to make recommendations for the widespread adoption across Europe of a single generic QOL instrument for use in patients with lower limb ischaemia based upon validity, reliability and responsiveness analysis.

Materials and Methods

This study was approved by the ethical committee of St James's and Seacroft University Hospitals. Over a period of 9 months a consecutive series of patients presenting to the department of Vascular and Endovascular Surgery at St James's University Hospital, Leeds with lower limb ischaemia were invited to participate in the study. Two hundred and thirty-five patients with varying degrees of lower limb ischaemia were enlisted, 144 men and 91 women with a median age of 68 years (range 41–87 years). The severity of patients' lower limb ischaemia was graded according to ISCVS-suggested standards for reports dealing with lower extremity ischaemia.⁹ Sixteen patients had mild, 116 moderate and 25 severe claudication. Thirty-three patients had rest pain and 45 tissue loss. Patients completed the SF36, EQ-5D and NHP at interview.

Patient details for each subgroup of lower limb ischaemia are shown in Table 1.

Short form 36

The SF36 was developed from a previous questionnaire known as the Medical Outcomes Study General Health Survey Instrument.⁹ The objectives of the authors were to develop a general health survey which was comprehensive and psychometrically sound, yet short enough to be of practical use in large scale studies. The result was a standardised generic questionnaire, designed for self or interview completion. It contains 36 questions covering eight dimensions of health and produces a health profile. It is not designed to generate a single index or tariff of health. For each dimension, question scores are coded, summed and transformed on a scale from 0 (worst health) to 100 (best health). For this study the anglicised, or U.K., version of the SF36 was used. In population studies and in other patient groups, the SF 36 has been found to be acceptable, valid, reliable and satisfies conventional psychometric criteria.^{10–12}

EuroQol

The EQ-5D was developed by a multi-disciplinary group of researchers from different European centres whose aims were to develop a standardised generic instrument to describe health-related QOL in a way that reflected the salient features of health as perceived by the general population. The capability of generating a single index value for each health state was also desired. The instrument was also designed to be interview- or self-completed and to be sufficiently brief to be used in conjunction with more specific instruments, not as a stand-alone instrument.¹³ After initial assessment of the original six dimension instrument (EQ-6D), two dimensions were combined, resulting in the present instrument, the EQ-5D, which measures five dimensions, each on three levels. The EQ-5D also incorporates a visual analogue scale on which patients are requested to rate their health on a scale 0 (worst imaginable health) to 100 (best imaginable health). Thus, EQ-5D generates 244 (excluding dead) theoretically possible health states, some of which are unlikely to occur in practice. Single tariffs or indices of health can be derived for each of these health states.¹⁴ The EQ-5D has been found to be acceptable, valid and reliable in population studies and other patient groups.^{15,16}

Table 1. Patient characteristics and clinical indicators of lower limb ischaemia.

	Mild claudication	Moderate claudication	Severe claudication	Rest pain	Tissue loss	Kruskal Wallis ANOVA
<i>n</i>	16	116	25	33	45	
Median age (years)	60	67	72	67	74	<i>p</i> = <0.01
Age range (years)	49, 76	41, 87	44, 86	42, 82	43, 87	
Male:female ratio	13:3	78:38	12:13	19:14	22:23	
Median resting ABPI	0.81	0.65	0.52	0.44	0.3	<i>p</i> = <0.01
IQR resting ABPI	0.6, 0.85	0.57, 0.75	0.44, 0.58	0.19, 0.58	0, 0.4	

Table 2. Domains measured by the three instruments with "like" domains in italics.

Domain	Short Form 36	Nottingham Health Profile	EuroQol
Pain	<i>Pain</i>	<i>Pain</i>	<i>Pain/Discomfort</i>
Physical activity	<i>Physical functioning</i>	<i>Physical mobility</i>	<i>Mobility</i>
			<i>Usual activities</i>
			<i>Self-care</i>
Psychological status	<i>Mental health</i>	<i>Emotional reaction</i>	<i>Anxiety/depression</i>
	<i>Vitality</i>	<i>Energy</i>	
	<i>Emotional role</i>		
Social activity	<i>Social functioning</i>	<i>Social isolation</i>	<i>(Usual activities)</i>
Other	<i>General health</i>	<i>Sleep</i>	
	<i>Physical role</i>		

Nottingham health profile

The NHP was developed as a measure of health that utilised patients' perceptions and language rather than medical judgements and categories.¹⁷ It consists of two parts which may be used independently. Part 1 consists of 38 questions, grouped into six domains. The number of questions in each domain varies from three to nine. Scores for each domain are calculated by applying a weight to each question and summing the question scores for that domain. All scores range from 0 (the best possible score) to 100 (the worst possible score). Part 2, which was not used in this study, analyses the impact of health on the activities of everyday life. Thus, Part 1 produces a profile of health but no single index. It can be self- or interview-completed, and has been shown to be valid and reliable; its responsiveness, however, has been questioned.^{18,19}

Domains measured by the SF36, EQ-5D and NHP questionnaires are listed in Table 2. Several domains are common to all three questionnaires; these (in italics) are known as "like" domains.

Validity is defined as "the extent to which an instrument measures what it purports to measure."²⁰ In this study, we utilised convergent/divergent validity, a form of factor analysis (a statistical method of analysing construct validity); i.e., the correlation between "like" domains should be greater than that between "non-like" domains.

Reliability is defined as "the extent to which an instrument yields the same results on the same population under different conditions."²¹ Eighty patients, 40 men and 40 women, were requested to complete two sets of questionnaires. The first set of questionnaires was sent with the patient's hospital appointment with a request to complete them that day at home. The second set of questionnaires were completed 1 week later at interview in the vascular laboratory when the patients attended hospital. The correlation between the two sets of completed questionnaires reflects test-retest reliability.

Responsiveness, or the instrument's ability to detect "small but clinically significant changes", was also analysed.¹⁹

Statistical analysis

This was performed using Microsoft Office Professional (Microsoft Ltd., Wharfedale Road, Winnersh Triangle, Wokingham, Berks, U.K.) with the Astute statistics add-in for Microsoft Excel (DDU Software, The University of Leeds, Old Medical School, Leeds, U.K.). Kruskal Wallis analysis of variance was used to analyse changes in QOL domains across the groups of increasing severity of lower limb ischaemia. Spearman rank correlation was used to assess convergent validity, divergent validity and test-retest reliability. Responsiveness analysis was performed using

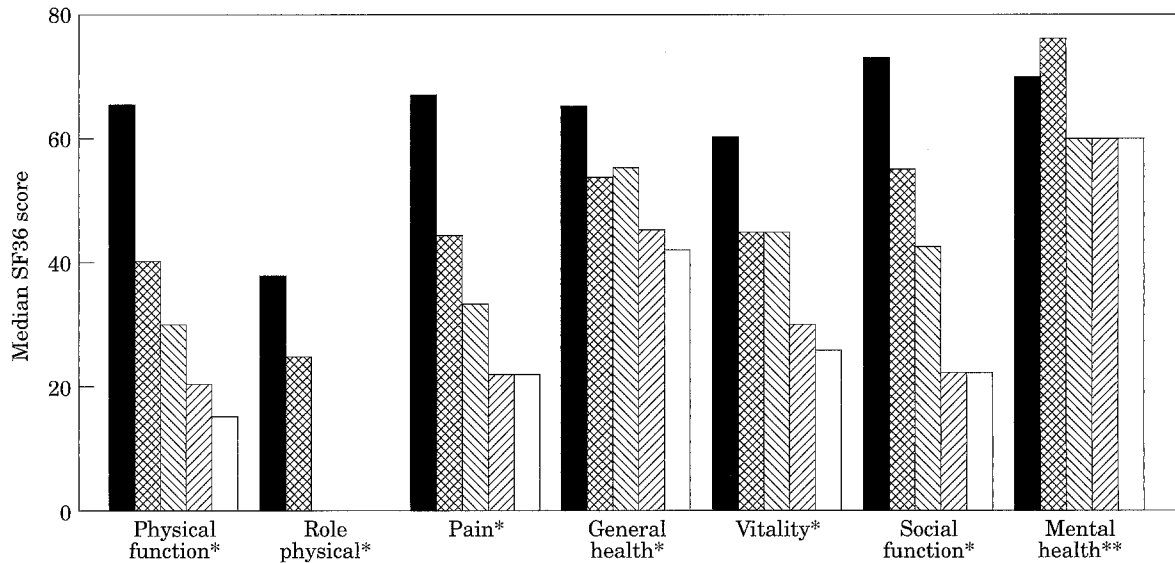


Fig. 1. Variation in Short Form 36 (SF36) quality of life domains with increasing lower limb ischaemia. Kruskal Wallis ANOVA * $p < 0.01$, ** $p < 0.05$. (■) mild claudication; (▨) moderate claudication; (▩) severe claudication; (▧) rest pain; (□) tissue loss.

the Mann-Whitney U-test. Throughout the statistical analysis a p value of < 0.01 was taken to represent statistical significance unless otherwise stated.

Results

Increasing lower limb ischaemia is associated with a reduction in the male to female ratio of patients affected, a significant increase in patients' age, and a significant fall in ABPI.

Quality of life results

Increasing lower limb ischaemia results in a significant deterioration in SF36-measured QOL domains of physical functioning, physical role, pain, general health, vitality, social functioning ($p < 0.01$) and mental health ($p < 0.05$) and all NHP-measured QOL domains, i.e. physical mobility, pain, energy, emotional reaction, sleep and social isolation ($p < 0.01$). These results are shown in Figs 1 and 2. Increasing lower limb ischaemia also results in a statistically significant increase in the reported severity of the EQ-5D pain, and an increase in both the reported frequency and the severity of the domains of mobility, self-care, usual activities and anxiety/depression (Fig. 3). The only domain analysed by the three instruments which is not significantly adversely influenced by increasing lower limb ischaemia is the SF36-measured emotional role.

Validity

Using the analysis method outlined above, the demonstration of validity requires the correlation between "like" domains measured by different instruments to be greater than the correlation between non-like domains, i.e. the correlation between EQ-5D-measured pain and SF36-measured pain should be closer than the correlation between EQ-5D-measured pain and the other SF36-measured domains. The Spearman rank convergent and divergent correlation coefficients are summarised in Table 3.

Short Form 36. The SF36, when correlated with the NHP, would seem a valid measurement of pain, physical abilities and psychological status, with convergent correlation coefficients exceeding divergent. However, when correlated with the EQ-5D the convergent correlation coefficient for pain is not as great as the divergent correlation coefficient for usual activities, and the SF36 domain of physical functioning correlates more closely with usual activities and self-care than with mobility. The correlations with the EQ-5D's psychological domains do, however, lend further support to the validity of the SF36 in the assessment of psychological status.

Nottingham Health Profile. The validity of the NHP in the measurement of pain, physical ability and psychological status are supported by high convergent correlation coefficients. The NHP domain of physical mobility correlates more closely with usual activities

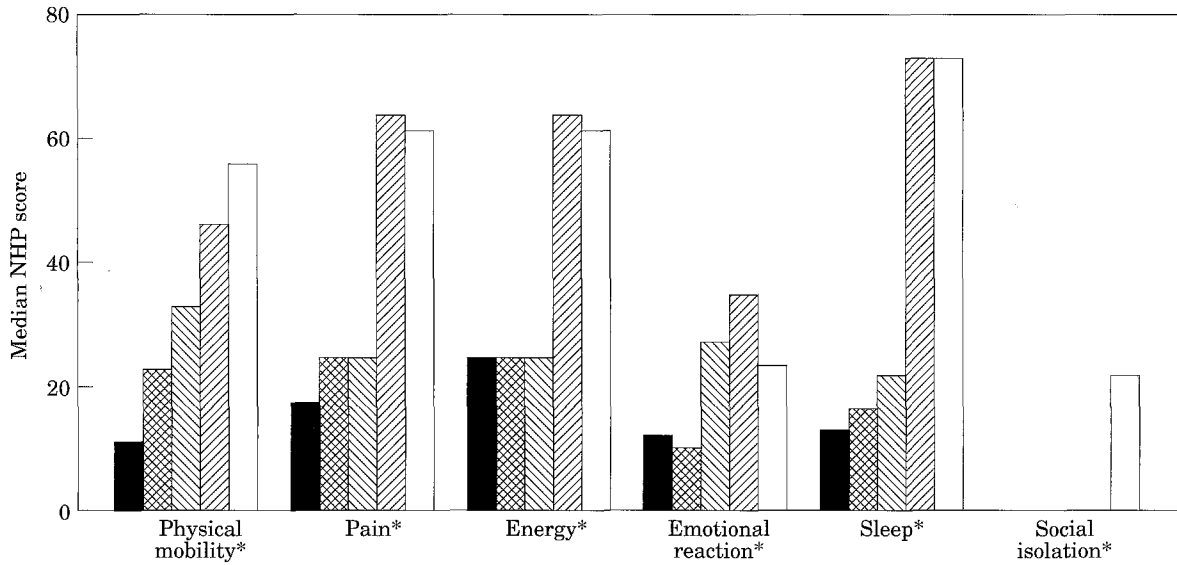


Fig. 2. Variation in Nottingham Health Profile (NHP) quality of life domains with increasing lower limb ischaemia. Kruskal Wallis ANOVA * $p < 0.01$. (■) mild claudication; (▨) moderate claudication; (▩) severe claudication; (▧) rest pain; (□) tissue loss.

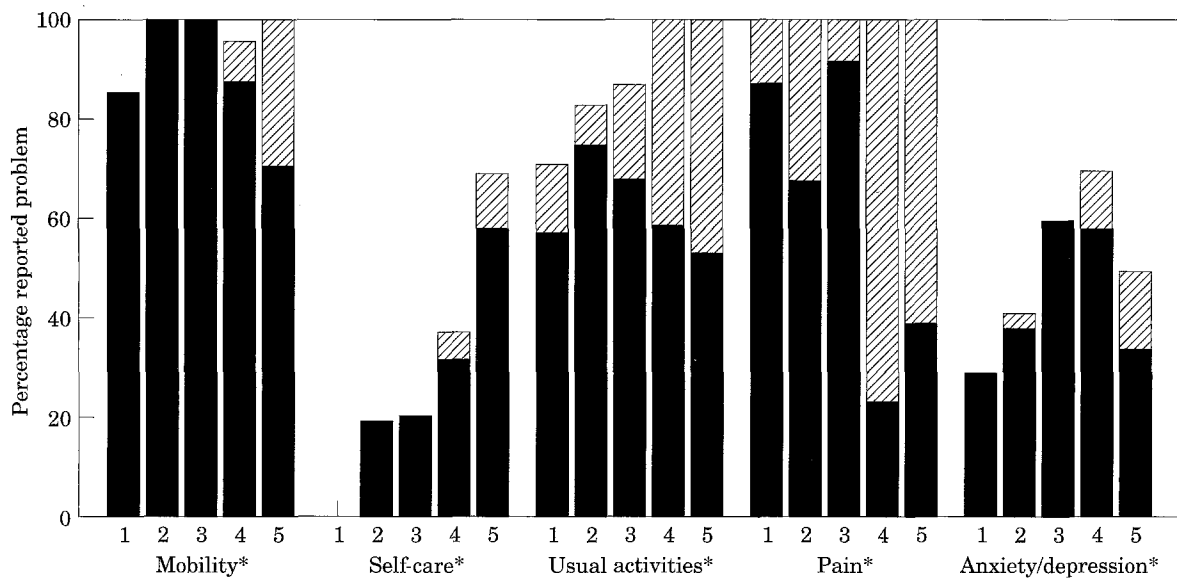


Fig. 3. Variation in EuroQol (EQ-5D) domains with increasing lower limb ischaemia. Kruskal Wallis ANOVA * $p < 0.01$. 1 = mild claudication; 2 = moderate claudication; 3 = severe claudication; 4 = rest pain; 5 = tissue loss. (▨) EQ 3; (■) EQ 2.

and self-care than mobility on the EQ-5D. However, NHP-measured social isolation has low convergent correlation with EQ-5D-measured usual activities and SF36-measured social functioning and has highest divergent correlation coefficients with EQ-5D-measured anxiety/depression and with SF36-measured mental health.

EuroQol. The validity of the EQ-5D in its measurement of pain, physical ability and psychological status

would seem to be supported with convergent correlation coefficients being greater than divergent for the domains of pain, mobility, self care and anxiety/depression. The EQ-5D domain of usual activities correlates best with the SF36 domains of pain, physical function and social functioning and with the NHP domains of pain and physical mobility. The convergent correlation coefficients of the EQ-5D are generally lower (-0.37 to -0.7) than for the SF36 and NHP (-0.5 to -0.78)

Table 3. Convergent (bold) and divergent correlation coefficients for domains measured by the three instruments.

		EuroQol measured					Nottingham Health Profile measured					
		Pain	Mobility	Usual activity	Self-care	Anxiety/depression	Pain	Physical mobility	Emotional reaction	Energy	Social isolation	Sleep
Short Form 36-measured	Pain	-0.54	-0.30	-0.60	-0.46	-0.30	-0.68	-0.64	-0.39	-0.40	-0.26	-0.46
	Physical function	-0.44	-0.37	-0.55	-0.59	-0.35	-0.65	-0.78	-0.44	-0.49	-0.38	-0.51
	Mental health	-0.31	-0.16	-0.33	-0.31	-0.70	-0.36	-0.34	-0.74	-0.59	-0.44	-0.41
	Vitality	-0.32	-0.26	-0.45	-0.39	-0.46	-0.57	-0.62	-0.58	-0.69	-0.40	-0.47
	Emotional role	-0.16	-0.27	-0.27	-0.16	-0.52	-0.18	-0.43	-0.50	-0.47	-0.33	-0.31
	Social functioning	-0.44	-0.08	(-0.53)	-0.36	-0.26	-0.5	-0.52	-0.44	-0.33	-0.32	-0.37
	General health	-0.26	-0.09	-0.29	-0.36	-0.36	-0.40	-0.44	-0.38	-0.40	-0.17	-0.37
Nottingham Health Profile-measured	Physical role	-0.31	-0.12	-0.27	-0.33	-0.30	-0.46	-0.49	-0.39	-0.44	-0.21	-0.43
	Pain	0.57	0.26	0.51	0.44	0.31						
	Physical mobility	0.38	0.38	0.52	0.61	0.30						
	Emotional reaction	0.25	0.16	0.34	0.33	0.64						
	Energy	0.22	0.22	0.38	0.36	0.49						
	Social isolation	0.16	0.18	0.27	0.39	0.43						
	Sleep	0.35	0.28	0.39	0.40	0.45						

Table 4. Test-retest reliability coefficients (r_s) for the three instruments.

Form 36 domains			Nottingham Health Profile		EuroQol domains			
	r_s	p	r_s	p	r_s	p		
Physical functioning	0.88	<0.0001	Energy	0.8	<0.0001	Mobility	0.83	<0.0001
Role physical	0.74	<0.0001	Pain	0.86	<0.0001	Self-care	0.82	<0.0001
Pain	0.82	<0.0001	Emotional reaction	0.87	<0.0001	Usual activities	0.74	<0.0001
General health	0.89	<0.0001	Sleep	0.86	<0.0001	Pain	0.80	<0.0001
Vitality	0.89	<0.0001	Social isolation	0.83	<0.0001	Anxiety/depression	0.78	<0.0001
Social functioning	0.81	<0.0001	Physical mobility	0.87	<0.0001			
Role emotional	0.7	<0.0001						
Mental health	0.88	<0.0001						

Reliability

Of the 80 patients requested to complete two sets of questionnaires, 59 patients, 33 men and 26 women, median age 71 years (range 44–87 years), fully completed both sets of questionnaires. The correlation between the two sets of responses reflects test-retest reliability and the results are summarised in Table 4. All domains measured by all three instruments are statistically reliable, with reliability coefficients >0.7. The NHP is perhaps the most reliable of the instruments tested, attaining reliability coefficients of >0.8 for all domains analysed.

Responsiveness

The ability to detect small but significant changes in pain and physical ability between the subgroups of patients is equally good for the SF36 and NHP. Both are able to detect changes between the majority of the subgroups. None of the three questionnaires are particularly responsive to changes in social functioning, but the SF36 and EQ-5D perform better than

the NHP. The SF36 domain of vitality is the most responsive of the "psychological" domains to changes in mood. Responsiveness of the instruments is shown in Table 5, and if an instrument has more than one measure of a domain the most responsive measure has been used.

Discussion

The changing male to female ratio with increasing lower limb ischaemia is an interesting finding which has not previously been documented and deserves further study. Regarding QOL analysis, the World Health Authority, in its definition of health, outlines the pivotal role of physical, social and psychological well being.²² These are the key dimensions analysed by the majority of generic QOL instruments, and form the basis of questioning in the three instruments under study here. There can be little argument that this study clearly demonstrates increasing lower limb ischaemia has a progressively detrimental impact on patient-reported QOL, with progressive deterioration in 18 of the 19 domains measured by the three instruments.

Table 5. Responsiveness analysis for "like" domains measured by the three instruments.

Domain	Instrument	1v2	1v3	1v4	1v5	2v3	2v4	2v5	3v4	3v5	4v5	Total
Physical activity	SF36 Physical functioning	X	X	X	X	X	X	X	NS	X	NS	8/10
	NHP Physical mobility	X	X	X	X	NS	X	X	X	X	NS	8/10
	EQ-5D Usual activity	NS	NS	X	X	NS	X	X	NS	NS	NS	4/10
Pain	SF36 Pain	X	X	X	X	X	X	X	NS	X	NS	8/10
	NHP Pain	X	X	X	X	NS	X	X	X	X	NS	8/10
	EQ-5D Pain	NS	NS	X	X	NS	X	X	X	X	NS	6/10
Social activity	SF36 Social functioning	NS	NS	X	X	NS	X	X	NS	NS	NS	4/10
	NHP Social isolation	NS	NS	NS	X	NS	NS	X	NS	NS	NS	2/10
	EQ-5D Usual activity	NS	NS	X	X	NS	X	X	NS	NS	NS	4/10
Psychological status	SF36 Vitality	X	X	X	X	NS	X	X	NS	NS	NS	6/10
	NHP Energy	NS	NS	X	X	NS	X	X	NS	NS	NS	4/10
	EQ-5D Anxiety/depression	NS	NS	NS	NS	NS	X	NS	NS	NS	NS	1/10

X = $p < 0.01$, NS = not significant (Mann-Whitney U-Test). 1 = mild, 2 = moderate, 3 = severe claudication, 4 = rest pain, 5 = tissue loss. SF36 = Short Form 36; NHP = Nottingham Health Profile; EQ-5D = EuroQol.

This finding may lend justification to the time and resources consumed in the treatment of critical ischaemia.

The only domain not influenced by increasing lower limb ischaemia is the SF36-measured emotional role. Others have also found that this domain does not improve following successful treatment for lower limb ischaemia,⁷ and it has the poorest reliability coefficient of all domains analysed by the three questionnaires. Thus, in future studies concerning patients with lower limb ischaemia perhaps, in the interest of brevity, this domain could be omitted.

There would seem to be a "floor effect" in the SF36 analysis of physical role in patients with severe claudication, rest pain and tissue loss, i.e. they initially score the lowest possible score and thus further deterioration cannot be registered. Also, a "ceiling effect" is seen in the NHP analysis of social isolation in patients with mild, moderate and severe claudication and rest pain, i.e. their initial score is the highest possible, and thus any improvement will not be registered. There does not appear to be a simple solution to rectify these effects without major alterations to the questions posed by the instruments.

Closer inspection of the questionnaires reveals that the SF36 domain of physical functioning and the NHP domain of physical mobility analyse the physical activities of daily living rather than simple mobility. This being taken into account, the fact that these domains demonstrate better correlation with EQ-5D-measured usual activities and self-care than with mobility may actually support, rather than detract from, the validity of these domains.

The NHP domain of social isolation has a better correlation with psychological domains than with social domains measured by the other two instruments. This suggests that it is measuring psychological status rather than social activity. If this is the case, the NHP

does not contain a domain assessing social activity, and purists may argue that is therefore not comprehensively analysing generic QOL.

The EQ-5D narrowly escapes this argument due to the good correlation of its usual activities domain with the SF36 domain of social functioning. From the figures presented there can be little argument regarding the reliability of all three instruments in this specific patient group. The responsiveness to variations in physical activity and pain is excellent for both the NHP and the SF36. If ultra-critical, one may highlight the suggestion that lack of responsiveness to these dimensions is demonstrated by the NHP at the milder end of the disease spectrum and by the SF36 at the more severe end of the disease spectrum. The responsiveness of the EQ-5D to these dimensions seems acceptable between patients with claudication and critical ischaemia, but poor within these broad subgroups. The SF36 and EQ are the most responsive to changes of social activity, both only detecting differences between mild/moderate claudication and the other more severe degrees of lower limb ischaemia. This suggests that severe claudication, rest pain and tissue loss have a similar impact on social activity. The SF36 is clearly the most responsive to changes within the domain of psychological status. Also of interest was the fact that no significant differences were apparent between patients suffering rest pain and critical ischaemia in any of the 19 domains measured by the three instruments, suggesting both these conditions have an equally devastating impact upon health-related QOL.

Conclusion

There is no mystical enigma regarding QOL analysis: it should be treated as any other outcome measure.

That is to say, in order to facilitate the comparison of interventions for the same degree of ischaemia and the comparison of different centres, standardised methods of QOL analysis should be adopted in vascular surgery and interventional radiology. It is surprising, therefore, that unlike other outcome measures, no consensus statement is available to suggest which is the most appropriate instrument to use in this specific group of patients.^{2,4,9} We would suggest that on the evidence of validity, reliability and responsiveness analysis presented in this study, the SF36 should be adopted throughout Europe as a standardised instrument for reporting generic QOL and a benchmark against which other instruments may be gauged. Perhaps the only potential disadvantage with adopting the SF36 for widespread use is that, at present, no single useful index or tariff of QOL can be generated from it; however, I am assured this is under development (J.E. Brazier, personal communication).

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