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Correlating clinical indicators of lower-limb ischaemia with quality of life*

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The objectives of the study were to analyse the impact of increasing lower-limb ischaemia upon quality of life and to assess the correlation between clinical indicators of lower-limb ischaemia and such quality. A prospective observational study of a consecutive series of 235 patients (144 men and 91 women; median age 68 (range 41–87) years presenting with varying degrees of lower-limb ischaemia graded according to ISCVS criteria was performed. Data was collected at interview before any intervention. Clinical indicators of lower-limb perfusion included: intermittent claudication and maximum walking distance on standardized treadmill testing; ankle:brachial pressure indices and isotope limb blood flow. Quality of life analysis was performed using the EuroQol (EQ) questionnaire. This is a standardized generic instrument for describing health-related quality of life and consists of a descriptive system of five dimensions, each measured on three levels. Thus, a profile and two single indices of quality of life were derived using different methods. Increasing lower-limb ischaemia results in a statistically significant deterioration in both global quality of life and in all EQ-measured quality of life dimensions ($P < 0.01$ Kruskal–Wallis, ANOVA). The correlation between clinical indicators and quality of life is statistically significant but not sufficiently close (correlation coefficients < 0.6) to assume that variations in clinical indicators result in reciprocal variations in quality of life. In conclusion, as might be expected, a significant correlation exists between clinical indicators of lower-limb ischaemia and health-related quality of life. However, the low correlation coefficients emphasize how tenuous the association is. Thus, a significant improvement in the clinical indicators of lower-limb ischaemia cannot be assumed to impart a similar benefit on quality of life. The latter concept must therefore be analysed independently.

Keywords: lower-limb ischaemia, quality of life, vascular surgery

As vascular surgeons in this era of evidence-based medicine and limited resources, it has been suggested that we are required, on clinical and economic grounds, to demonstrate that we improve not only patient survival and lower-limb perfusion but also the quality of patients' lives [1, 2]. Thus, over recent years formal standardized quality of life analysis as an outcome measure in vascular surgery has become increasingly popular [3–5]. Several authors have analysed the impact of intermittent claudication or various treatments for lower-limb ischaemia upon quality of life, but no study has previously described the impact of increasing severity of lower-limb ischaemia upon such quality. This paper aims to analyse the impact of increasing ISCVS-graded lower-limb ischaemia upon patient-reported quality of life across the whole spectrum of the disease. Quality of life analysis itself, however, consumes time and

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

	Claudication			Rest pain	Tissue loss	*P*
	Mild	Moderate	Severe			(Kruskaal–Wallis ANOVA)
No. of patients	16	116	25	33	45	
Median age (years)	60	67	72	67	74	< 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 ankle:brachial pressure index	0.81	0.65	0.52	0.44	0.3	< 0.01
IQR resting ankle:brachial pressure index	0.6,0.85	0.57,0.75	0.44,0.58	0.19,0.58	0,0.4	
Median intermittent claudication distance (m)	100.7	31.3	20.8	0	0	< 0.01
IQR intermittent claudication distance (m)	62.5,141.9	20.8,44,5	15.6,34.7	0,17.4	0, 0	< 0.01
Median maximum walking distance (m)	208	57.3	36.5	0	0	< 0.01
IQR maximum walking distance (m)	208,208	38.2,78.1	31.2,64.2	0,27.8	0,0	
Median isotope limb blood flow (ml/100 ml/min)	6	5.8	3.9	3.3	1.9	< 0.01
IQR isotope limb blood flow (ml/100 ml/min)	4.7,8.1	3.9,7.4	2.8,5.6	2.3,4.8	1.4,3.4	

IQR, Inter Quartile Range

resources, and patients become tired with repetitive questionnaire completion. Routinely utilized objective clinical indicators of lower-limb ischaemia include intermittent claudication distance and maximum walking distance measured at standardized treadmill testing, ankle:brachial pressure indices, and lower-limb perfusion measured via an isotope influx technique. It may be appropriate to assume that the decreased treadmill measured mobility and reduced limb perfusion associated with increased lower-limb ischaemia must be associated with a deterioration in quality of life and that formal quality of life analysis may not be required. This paper also aims to analyse how closely the clinical indicators of lower-limb ischaemia reflect measured quality of life and thus comment upon whether formal standardized quality of life is really necessary.

Patients and methods

Patients

This study received approval from the ethics committee of St. James's and Seacroft University Hospitals. A consecutive series of 235 patients presenting with various grades of lower-limb ischaemia were invited to participate in the study. Those patients who were enrolled in the study gave informed written consent. The severity of patients lower-limb ischaemia was graded according to ISCVS criteria [6]. Patients underwent measurement of: ankle: brachial pressure indices; intermittent claudication distance and maximum walking distance on a treadmill at a speed of 2.5 km/h at a 10° incline and, limb perfusion measured by an isotope influx technique, described in detail previously, known as isotope limb blood flow [7]. Patient details are provided in *Table 1*. Patients then completed the EuroQol (EQ) quality of life questionnaire (*Table 2*) at interview. The EQ instrument was developed by a multi-disciplinary group of researchers from five European centres and is a standardized non-disease-specific instrument for describing health-related quality of life [8]. The EQ has been shown to be reliable and valid in both population studies and in patients with lower-limb ischaemia [9, 10]. Its responsiveness to changes in lower-limb ischaemia has also been demonstrated [11]. It consists of a descriptive system of five dimensions: mobility; self care; usual activities; pain; and anxiety/depression. Each dimension is measured on three levels with a score of 1 representing no problems, 2 moderate problems, and 3 severe problems or complete inability. The EQ thus produces a profile of health. The derivation of a single index of quality of life from the EQ can be performed by two different means. The first is by a simple 20 cm visual analogue scale on which the patient is asked to grade their quality of life on a scale from 0 (the worst imaginable) to 100 (the best imaginable). The second single index is derived using the time trade-off-derived matrix [12] (*Table 3*).

Table 2 The EuroQol instrument

Dimension	Level	Score
Mobility	I have no problems walking about	1
	I have some problems walking about	2
	I am confined to bed	3
Self care	I have no problems with self care	1
	I have some problems washing or dressing myself	2
	I am unable to wash or dress myself	3
Usual activities	I have no problems performing my usual activities (e.g. work, study, housework, family or leisure activities)	1
	I have some problems performing my usual activities	2
	I am unable to perform my usual activities	3
Pain/discomfort	I have no pain or discomfort	1
	I have moderate pain or discomfort	2
	I have extreme pain or discomfort	3
Anxiety/depression	I am not anxious or depressed	1
	I am moderately anxious or depressed	2
	I am extremely anxious or depressed	3

Table 3 Matrix to derive global quality of life index from time trade-off data using a regression model

EuroQol dimension	Level 2	Level 3
Mobility	0.069	0.314
Self care	0.104	0.214
Usual activity	0.036	0.094
Pain/discomfort	0.123	0.386
Anxiety/depression	0.071	0.236
Constant = 0.081		N3 = 0.269

Hence, the global time trade-off index for EQ health state 11223 = 1.0 − 0.081 − 0.036 − 0.123 − 0.236 − 0.269 = 0.255

Statistical analysis

All data were analysed using Microsoft Office Professional (Microsoft Ltd, Wharfdale Road, Winnersh Triangle, Wokingham, Berks, UK) with the Astute statistics add-in for Microsoft Excel (DDU Software, The University of Leeds, Old Medical School, Leeds, UK). Variation in quality of life dimensions and single indices of quality of life across the whole group was analysed using Kruskaal–Wallis analysis of variance (ANOVA). The Spearman rank test was utilized to analyse the correlation between single indices of quality of life and clinical indicators of lower-limb ischaemia. Throughout the study, a P value of < 0.01 was taken to represent statistical significance unless otherwise stated.

Results

With progressively increasing lower-limb ischaemia, there was a significant increase in the patients' age and a significant deterioration in all measured clinical parameters (intermittent claudication distance, maximum walking distance, ankle:brachial pressure index isotope limb blood flow) of lower-limb ischaemia (*Table 1*).

Quality of life analysis

Increasing lower-limb ischaemia resulted in a statistically significant increase in the severity of the reported domain of pain, and in both the frequency and the severity of the reported domains of mobility, self care, usual activities and anxiety/depression (*Figure 1*). Global quality of life as represented by the EQ visual analogue scale and time trade-off indices, demonstrated statistically significant ($P < 0.001$) deterioration with increasing lower-limb ischaemia (*Figures 2* and *3*).

Correlating quality of life with clinical indicators

The correlation between the two global indices of quality of life and all clinical indicators of lower-limb ischaemia reached statistical significance (*Table 4*). Overall, however, Spearman rank correlation coefficients were low ($r_s < 0.6$). Of the global indices of quality of life, the time trade-off-derived index correlated more closely than the visual trade-off-derived index with the clinical indicators. Measures of mobility correlated more closely with quality of life indices than measures of limb perfusion. In particular, maximum walking distance was the clinical indicator of lower-limb ischaemia which demonstrated the closest correlation with the time trade-off-derived global quality of life indices ($r_s = 0.55$; $P = < 0.0001$).

Discussion

Increasing lower-limb ischaemia results in a significant deterioration in all E2 measured domains of

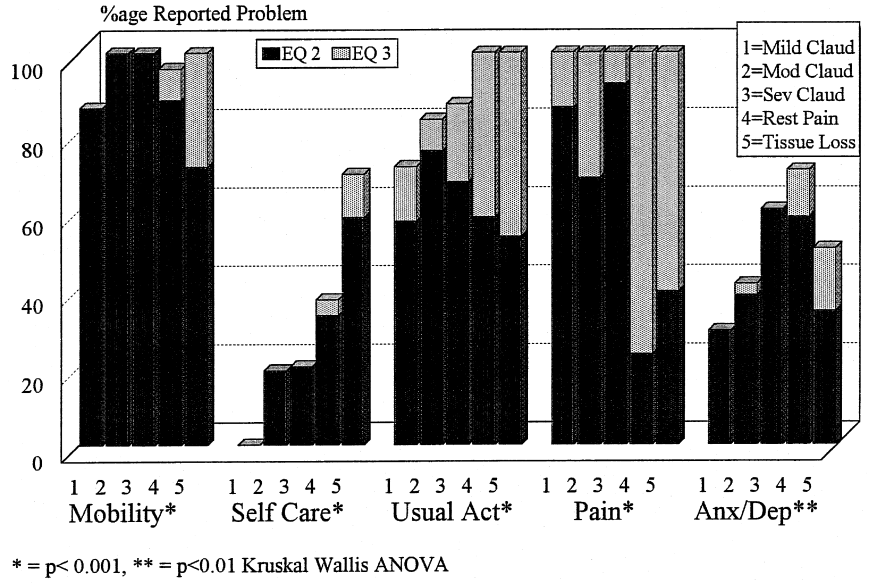

Figure 1 Variation in EuroQol-measured quality of life domains with increasing lower-limb ischaemia

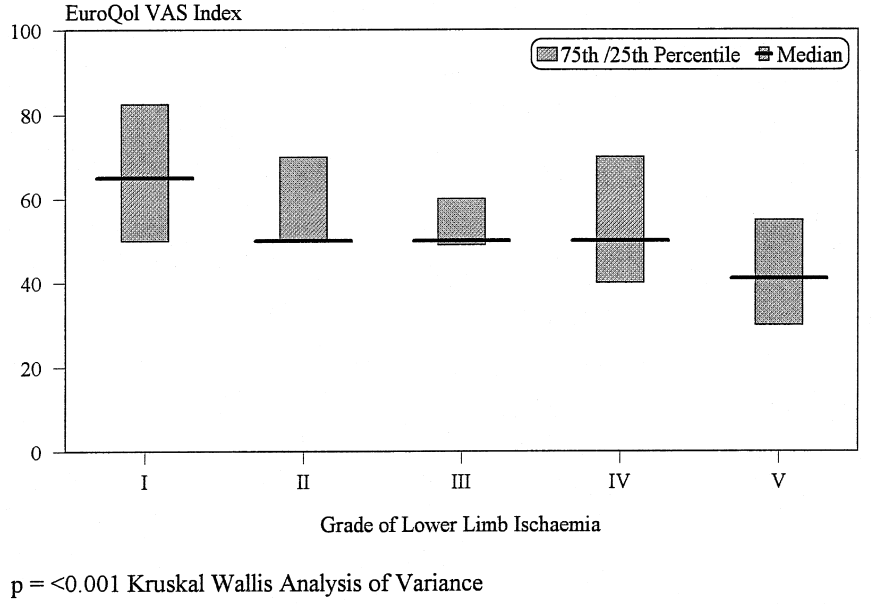

Figure 2 Variations in global EuroQol visual analogue score measured quality of life with increasing lower-limb ischaemia

quality of life. As may be expected, high percentages of patients in all groups reported problems with mobility, and all patients in all groups reported some pain. However, other effects of lower-limb ischaemia on quality of life may not have been so easily predicted. For example, patients with claudication report a 15–20% incidence of problems washing and dressing, a 70% incidence of limitation of their usual activities, and a 40% incidence of feeling anxious or depressed. With critical ischaemia the percentage of patients reporting problems with self care, usual activities and anxiety/depression rises to 50%, 100%, and 50%, respectively. These figures are far in excess of those reported in an age-matched population survey [12] and thus are not easily explained by such phenomena as co-morbid features. Thus, all grades of lower-limb ischaemia result in a perhaps predictable impairment of several quality of life domains;

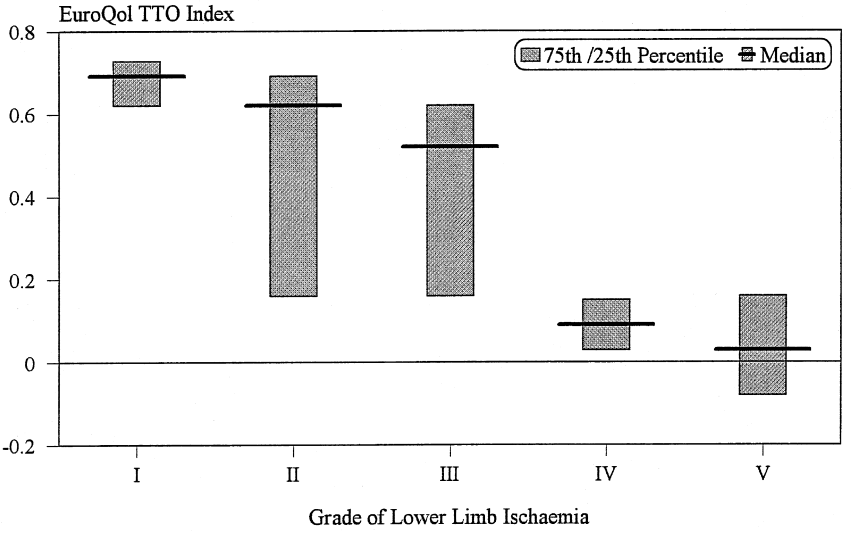

Figure 3 Variations in global EuroQol time trade-off measured quality of life with increasing lower-limb ischaemia

Table 4 Spearman rank correlation between global indices of quality of life and clinical parameters of lower-limb ischaemia

	Clinical indicators of lower-limb ischaemia							
	Ankle:brachial pressure index		Isotope limb blood flow		Intermittent claudication distance		Maximum walking distance	
	r_s	*P*	r_s	*P*	r_s	*P*	r_s	*P*
Global visual analogue scale index	0.19	< 0.01	0.17	< 0.05	0.31	< 0.001	0.3	< 0.001
Global time trade-off index	0.22	< 0.001	0.25	< 0.001	0.53	< 0.001	0.5	< 0.001

however, domains which one may not have expected to be affected by lower-limb ischaemia certainly appear to be compromised.

Patients' global quality of life estimates also demonstrate a significant deterioration with increasing lower-limb ischaemia. Those suffering with critical ischaemia demonstrate a dramatic deterioration in overall quality of life, especially on the time trade-off-derived index, with patients scoring close to the lowest possible scores. Thus, we may have previously underestimated the serious debilitating impact that this severity of disease plays on patients' lifestyles. This may lend some justification to the high levels of time and resources spent in the management of this condition. Also of particular note in *Figure 3* are the wide inter-quartile ranges of patients suffering with grade II and III claudication. This suggests that disease of similar severity has vastly different impacts upon patients' quality of life, and also highlights the uniquely subjective nature of quality of life reporting.

In analysing the group as a whole there is a significant correlation between the clinical indicators of lower-limb ischaemia and patient-reported quality of life. Maximum walking distance on treadmill testing would seem to be the clinical indicator which most closely reflects quality of life. However, as suggested by the relatively low correlation coefficients, this relationship is relatively tenuous. Thus, on an individual basis we would suggest that variations in clinical indicators of lower-limb ischaemia cannot be assumed to impart reciprocal variations in quality of life, and, if we are to claim quality of life improvements for our patients, its independent analysis would seem mandatory.

Acknowledgements

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