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Quality of Life in Patients with Intermittent Claudication Using The World Health Organisation (WHO) Questionnaire

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Objective: to assess quality of life (QOL) in patients with intermittent claudication.

Design: a prospective, open study.

Material and method: one hundred and fifty-one consecutive claudicants (100 men, 51 women), and 161 healthy controls (70 men and 91 women) completed an adapted version of the World Health Organisation Quality of Life Assessment Instrument-100.

Results: patients scored significantly worse on the domains Physical health and Level of independence, as well as on the facets Pain and discomfort, Energy and fatigue, Mobility, Activities of daily living, Dependence on medication and treatments, Working capacity, Negative feelings, Recreation and leisure and Overall QOL and general health. Increasing disease to incapacitating claudication affected only the facet Mobility and the domain Level of independence.

Conclusion: QOL in patients with intermittent claudication is reduced in many aspects. Where co-morbidity seems to affect QOL strongly, the effect of walking distance on QOL might be small. These findings may justify a reserved attitude towards invasive, even minimally invasive treatment of these patients.

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

Introduction

The severity of intermittent claudication is usually assessed by means of treadmill walking distance or ankle brachial pressure index (ABPI).¹ However, neither of these variables correlate well with patient reported functional impairment.^{2–4} An alternative means of assessing disability is therefore required.

Quality of life (QOL) is increasingly recognised as an important measure of disease impact and therapeutic outcome in patients with vascular disease.^{8,9} However, the interpretation and comparison of QOL studies is hampered by the range of different instruments used.^{10–13} In the literature, QOL is often used as a comprehensive concept: i.e. concepts like functional status and health status are labelled as QOL. However, functional status refers to physical functioning; for instance, walking distance in claudicants. Health status assesses the influence of disease on physical, social and emotional functioning; it measures restrictions in functioning. QOL as defined by the World Health Organisation (WHO) is a broader

concept, comprising the personal evaluation of functioning with regard to physical health, psychological state, level of independence, social relationships, personal beliefs and relationships to salient features in the environment. QOL assesses functioning in relation to the patients' own criteria.

The aim of this present study was to measure QOL in claudicants using the World Health Organisation (WHO) instrument.

Materials and Methods

Patients

Between January 1999 and 31 December 1999 QOL was assessed in 151 consecutive patients (100 men, 51 women, mean age 63 years, range 43–83 years) presenting with intermittent claudication. The diagnosis was based on history, physical examination, treadmill-walking distance and ankle pressure. Impairment was recorded as: mild, 26 patients; moderate, 72 patients; severe, 53 patients.¹⁴ Risk factors and co-morbidity are presented in Table 1.

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Table 1. Distribution of risk-factors and co-morbidity, specified into "none", "mild", "moderate" and "severe", according to the SVS/ISCVS¹⁴ in 151 patients with intermittent claudication, studied for QOL.

	None	Mild	Moderate	Severe
Diabetes mellitus	127 (84%)	9 (6%)	11 (7%)	4 (3%)
Tobacco use	27 (18%)	27 (18%)	52 (34%)	45 (30%)
Hypertension	82 (54%)	41 (27%)	20 (13%)	8 (5%)
Hyperlipidaemia	77 (51%)	28 (19%)	15 (10%)	31 (21%)
Cardiac status	99 (66%)	35 (23%)	16 (11%)	1 (1%)
Carotid disease	124 (82%)	8 (5%)	14 (9%)	5 (3%)
Renal status	146 (97%)	3 (2%)	1 (1%)	1 (1%)
Pulmonary status	135 (89%)	9 (6%)	6 (4%)	1 (1%)

Measure

QOL was assessed using the World Health Organisation Quality of Life Assessment Instrument-100 (WHOQOL-100).¹⁵ This is a generic, multidimensional, self-report QOL measure that is easy to score.¹⁶ It has been used in a wide variety of patient populations,^{17,18} most recently in sarcoidosis.^{19,20} The instrument has been developed simultaneously and cross-culturally in 15 centres around the world.²¹ It consists of 100 items assessing 24 facets of QOL within six domains (Physical health, Psychological health, Level of independence, Social relationships, Environment, Spirituality/religion/personal beliefs) and a generic evaluative facet (Overall QOL and General health). Each facet is represented by four items. The responses are expressed in 5-point scales. Scores on each facet and domain can range from 4 to 20. The reliability and validity of the instrument are high,¹⁸ also in healthy elderly.¹⁷

In a preceding pilot-study the instrument was reduced for vascular patients to 17 relevant facets, including Overall QOL and general health. The patients completed the questionnaire and a research assistant was available for help, if needed. The QOL scores of the examined patient population was put into perspective by comparing them with an age-matched, community-based sample of 161 healthy persons, without co-morbidity (70 men, 91 women, mean age 62 years, range 40–91 years) from the validation study of the Dutch version of the WHOQOL-100.¹⁶

All data were collected by one research assistant.

Statistics

Data are expressed as mean and standard deviation. In order to detect statistically significant differences between patients and healthy people, data were analysed with the Mann–Whitney *U*-test. Due to the number of

facets in the WHOQOL-100 and thus the number of analyses examined, a probability value of less than 0.01 was considered to be statistically significant. The statistical differences between the three categories of intermittent claudication were analysed with the Kruskal–Wallis test.

The internal consistency of the facets and domains of the WHOQOL-100, which indicates that the responses to corresponding questions are comparable, were calculated with Cronbach's alpha, a measure of homogeneity.²² For the test-re-test reliability of the WHOQOL-100 facets and domains, Pearson correlations were used.

Results

Compared with healthy people, patients scored worse on several domains (Table 2).

There were no statistically significant differences in the distribution of risk factors and co-morbidity between the three categories of intermittent claudication. The three categories (mild, moderate and severe claudication) were comparable with regard to QOL, except for the facet Mobility and the domain Level of independence (Table 3).

On the domain level Cronbach's alpha ranged from 0.62 to 0.82 and on the facet level from 0.67 to 0.93, indicating an acceptable internal consistency (Table 4). Test-retest correlations are not very high, but acceptable. In a random sample with a smaller interval, test-retest reliability of the WHOQOL-100 at facet level ranged from 0.55 for Working capacity to 0.87 for Financial resources and at domain level from 0.72 for Level of independence to 0.86 for Physical health.¹⁷

Although the responsiveness of the WHOQOL-100 to discriminate between sick and healthy people has proven to be good,¹⁸ some facets might be less sensitive in a particular group of claudicants. We think that this is the case for all instruments assessing health status and QOL. The WHOQOL is a rather new instrument and only future studies will learn whether the instrument is sensitive in these patients or not.

Table 2. Scores on the reduced WHOQOL-100 in 151 patients with intermittent claudication.

	Healthy		Patients		U-value	Significance
	m	SD	m	SD		
Overall QOL and general health	16	2	14	3	6839.0	<i>p</i> <0.001
Physical health	16	2	13	3	5719.0	<i>p</i> <0.001
Pain and discomfort	9	3	12	3	5004.0	<i>p</i> <0.001
Energy and fatigue	15	3	12	3	5601.0	<i>p</i> <0.001
Sleep and rest	16	3	15	4		ns
Psychological health	—	—	—	—		
Positive feelings	14	2	14	2		ns
Thinking, learning, memory and concentration	—	—	—	—		
Self-esteem	15	2	15	3		ns
Body image and appearance	—	—	—	—		
Negative feelings	9	3	10	3	9220.0	<i>p</i> <0.005
Level of independence	17	2	13	3	2528.5	<i>p</i> <0.001
Mobility	17	3	11	3	1989.0	<i>p</i> <0.001
Activities of daily living	17	2	14	3	5070.0	<i>p</i> <0.001
Dependence on medication and treatments	7	3	11	4	3304.5	<i>p</i> <0.001
Working capacity	17	3	13	4	5187.0	<i>p</i> <0.001
Social relationships	16	2	15	3		ns
Personal relationships	16	2	17	3		ns
Social support	—	—	—	—		
Sexual activity	15	4	14	4		ns
Environment	—	—	—	—		
Physical safety and security	—	—	—	—		
Home environment	16	2	16	3		ns
Financial resources	—	—	—	—		
Health and social care	—	—	—	—		
Opportunities for acquiring new information and skills	15	2	15	3		ns
Participation in and opportunities for recreation/leisure	16	3	15	3	9709.0	<i>p</i> = 0.01
Physical environment	—	—	—	—		
Transport	17	3	16	4		ns
Spirituality, religion, personal beliefs	—	—	—	—		

m: mean.

SD: standard deviation.

ns: not significant.

The scores on the facets Pain and discomfort, Negative feelings and Dependence on medication and treatments are inverse. High scores, low QOL.

Table 3. Scores on the domain Level of independence and the facet Mobility of the WHOQOL-100 according to the grade of intermittent claudication in 151 patients.

	m	SD		m	SD	Significance
Facet mobility						
Mild claudication	13	3 compared with	Moderate	12	3	ns
			Severe	10	2	<i>p</i> <0.001
Moderate claudication	12	3 compared with	Severe	10	2	<i>p</i> <0.001
Domain Level of independence						
Mild claudication	14	2 compared with	Moderate	13	3	ns
			Severe	12	2	<i>p</i> = 0.025
Moderate claudication	13	3 compared with	Severe	12	2	ns

m: mean.

SD: standard deviation.

ns: not significant.

Table 4. Internal consistency and test-retest correlations (interval six months) of the reduced WHOQOL.

	Cronbach's alpha	Pearson correlation
Overall QOL and general health	0.82	0.71
Physical health	0.64	0.73
Pain and discomfort	0.71	0.54
Energy and fatigue	0.80	0.67
Sleep and rest	0.93	0.74
Psychological health	—	—
Positive feelings	0.74	0.57
Thinking, learning, memory	—	—
Self-esteem	0.79	0.65
Body image and appearance	—	—
Negative feelings	0.82	0.60
Level of independence	0.82	0.67
Mobility	0.80	0.38
Activities of daily living	0.82	0.56
Dependence on medication and treatment	0.78	0.64
Working capacity	0.91	0.70
Social relationships	0.62	0.70
Personal relationships	0.67	0.63
Social support	—	—
Sexual activity	0.81	0.70
Environment	—	—
Physical safety	—	—
Home environment	0.79	0.57
Financial resources	—	—
Health and social care	—	—
Opportunities for acquiring new information and skills	0.72	0.42
Participation in and opportunities for recreation/leisure	0.77	0.66
Physical environment	—	—
Transport	0.87	0.51
Spirituality, religion, personal beliefs	—	—

Discussion

The present study highlights the personal and subjective evaluation of functioning in patients suffering from intermittent claudication. As we reduced the WHOQOL-100, by means of parameters for distribution of answers and internal consistency, the remaining questions are supposed to reflect those facets of life that are of particular importance to these patients.

Analogous to the health status studies, it appears that peripheral arterial occlusive disease (PAOD), even in its mildest expression, has a detrimental effect on QOL as experienced by the patient, compared with healthy persons. The main difference is found in the facets and domains evaluating physical functioning, as might be expected in these physically impaired patients. The significantly greater Dependence on medication and treatments in claudicants as expressed in the results is not directly related to an impaired walking distance and suggests an impact of co-morbidity on QOL. This is not surprising, since patients suffering from PAOD are known to be affected with important co-morbidity. There are several reports in the literature on health

status in patients suffering from intermittent claudication. Pell,²³ Currie²⁴ and Chetter,^{25,26} using the Short Form-36, the Euroqol and the Nottingham Health Profiles, found that patients were impaired in their physical, psychological and social functioning, deteriorating with the grade of claudication. This was especially the case in multi-level disease. The explicit Negative feelings as reported by the patients in this study did not emerge from the health status studies, because health status measures do not evaluate subjective feelings of patients. We feel that disregarding subjective feelings of patients is one of the important disadvantages of merely assessing health status in chronically ill patients, especially when treatment is mainly palliative.

Surprisingly, the three categories of claudicants differed only significantly with regard to Mobility. In addition, the patients with the mildest and the patients with the most severe form of claudication differed on the domain Level of independence. With regard to the other domains and facets of QOL the categories were comparable. This means that with increasing disease to incapacitating claudication patients' QOL only deteriorates on these two aspects. The grade of

claudication does not seem to be related to the level of QOL other than Mobility and Level of independence. Apparently the presence of intermittent claudication, irrespective of the severity, is enough to create a significant difference on the various domains and facets of QOL compared with the healthy population.

It is important to realise that the scores on QOL as presented in this study are the result of all influences of PAOD and co-morbidity. The relative impact of co-morbidity in addition to the impaired walking distance on QOL has not yet been elucidated. The observation that increasing claudication only affects Mobility and Level of independence suggests that successful treatment in terms of improving the walking distance may have a very limited effect on QOL on the whole.

Although not proven yet, it seems that co-morbidity may have a dominant effect on the QOL of patients suffering from intermittent claudication, whereas the impaired walking distance might be no more than the expression of a more complex underlying disease.

We think that the importance of walking distance as the principal factor in the assessment of patients with intermittent claudication should be questioned. Moreover, in our opinion the importance of co-morbidity is generally underestimated in the literature. That is why we feel that invasive therapy, even minimally invasive, is questionable in patients with intermittent claudication and serious co-morbidity. Future studies should determine the influence of all factors affecting QOL in patients with intermittent claudication, as it seems to depend on more than walking a few hundred metres more or less.

QOL and health status are considered complementary concepts²⁷ and should be assessed together in order to evaluate the impact of PAOD on the life of patients with intermittent claudication. Since this is the first study to evaluate QOL in patients with intermittent claudication with a true QOL questionnaire, further study is necessary to determine the complementary value of QOL on health status in these patients.

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