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Assessment of disease impact in patients with intermittent claudication: Discrepancy between health status and quality of life

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Objective: **To describe similarities and differences between health status and quality of life in patients with intermittent claudication.**

Methods: **This was an observational study in the vascular outpatient department of a teaching hospital; it concerned 200 consecutive patients with intermittent claudication. Health status was assessed with the RAND-36, and quality of life was assessed with a reduced version of the World Health Organization Quality of Life assessment instrument-100. Scores were compared with those of sex- and age-matched healthy controls. Mann-Whitney *U* tests were used to detect statistically significant differences ($P < .01$) between patients and healthy controls. Pearson correlations were calculated between health status and quality-of-life scores. Differences between correlations were examined by using Fisher *z* statistics. The upper and lower 10% of quality-of-life scores were compared with the response quartiles of the health status scores.**

Results: **Health status was significantly impaired in all domains. Quality of life was significantly worse with respect to aspects of physical health and level of independence and one global evaluative facets overall quality of life and general health. Quality-of-life assessment with the World Health Organization Quality of Life instrument disclosed patient-reported problems that had not been identified in health status. Conversely, patients did not regard all objective functional impairments as a problem. Pearson correlations ranged from 0.20 to 0.74. There were patients with excellent and very poor quality-of-life scores in nearly all the quartiles of the corresponding health status domains.**

Conclusions: **Health status and quality of life represent different outcomes in patients with intermittent claudication. In addition to functional restrictions as measured in health status, quality of life also permits a personal evaluation of these restrictions. Objective functioning and subjective appraisal of functioning are complementary and not identical. Combining these measures should direct treatment in a way that meets patients' needs. (J Vasc Surg 2005;41:443-50.)**

The importance of patients' perception of disease and the need for a patient-oriented evaluation of treatment modalities are increasingly recognized, especially in chronic illnesses.[1] Generally, the denominator of studies on these topics is quality of life (QoL). However, there is confusion about the terminology concerning QoL. The term is used in a comprehensive way for quantitative objective functional assessment of health dimensions, such as health status, and for concepts that also incorporate qualitative subjective appraisal of those dimensions.[2-5] The lack of consensus about the definition of QoL and the instruments that claim to measure them has resulted in a plethora of measures purporting to address QoL.[2] As a consequence, the use of these measures for the assessment of unclear concepts that ultimately might affect decisions made about ill people has been questioned.[6] Much of the semantic confusion in reports on QoL is caused by the erroneous use of health status measures in studies that claim to assess QoL.[2,7,8] For use in clinical practice, however, subjective appraisal should be incorporated in QoL measures to ensure that treatment plans and evaluations focus on the patient rather than on the disease.[5,9]

The World Health Organization (WHO) has defined health as a state of complete physical, mental, and social well-being—not merely the absence of disease or infirmity.[10] Accordingly, health status reflects the influence of disease on physical, emotional, and social functioning. It measures objective functional limitations as a result of disease, as reported by patients.[11] In contrast with health status, subjective appraisal of functioning is also incorporated in the measurement of QoL, which has been defined by the WHO as

> an individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives and in relation to his/her goals, expectations, standards, and concerns. It is a broad ranging concept incorporating in a complex way the individual's physical health, psychological state, level of independence, social relationships, personal beliefs, and relationships to salient features in the environment.[12]

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Table I. Patient characteristics in 200 patients with intermittent claudication

Variable	*Data*
No. patients	200
Sex (M/F)	135/65
Age, y, mean (range)	63 (42-83)
ABI, mean (range)	0.62 (0.33-0.83)
Median PFWD (m)	70
Median MWD (m)	240

ABI, Ankle-brachial index; *PFWD,* pain-free walking distance; *MWD,* maximum walking distance.

Intermittent claudication (IC) is a relatively mild expression of chronic progressive arteriosclerosis. Despite its benign course with respect to the threat to the lower extremities, IC has a large effect on daily life, and survival is threatened by concomitant cardiac and cerebrovascular disease.[13,14] Because treatment options are limited to relieving complaints and slowing down disease progression, the assessment of health status and QoL is of particular interest for patients with IC.[15] For patients with IC, practicing vascular surgeons are the target group for studies on these concepts and instruments and are the most eligible to implement results. The aim of this study was to illustrate the similarities and differences between health status and QoL in patients who present with IC.

MATERIALS AND METHODS

Patients. Between January 1999 and June 2000, health status and QoL were assessed in all new patients who presented with IC at the vascular outpatient clinic of the St Elisabeth Hospital in Tilburg, The Netherlands. The diagnosis was suspected on history and physical examination in 215 patients and could be confirmed by treadmill performance and ankle-brachial pressure index in 207 patients. Seven patients refused participation or were not capable of participating. This left 200 patients in the study group, of which the characteristics, cardiovascular risk factors, and comorbidity, recorded according to the recommended standards (Appendix I[16]) for reports dealing with lower extremity ischemia, are presented in Tables I and II. All patients were matched with healthy controls for age and sex.

This study was approved by the local ethics committee. All patients provided written informed consent.

Instruments. The RAND 36-item health survey (RAND-36),[17,18] which is practically identical to the Medical Outcome Study/Short Form-36,[19] was chosen because of its proven applicability in peripheral arterial occlusive disease and compliance with the recommended standardization of reporting health status in vascular disease.[15,20,21] The RAND-36 is a 36-item generic multidimensional health status measure. It assesses health in eight dimensions: physical functioning, social functioning, limitations in usual role activities due to physical problems (role physical), limitations in usual role activities due to emotional problems (role emotional), mental health, vitality, bodily pain, and general health perception (Appendix II, online only). In addition to a score for each subscale on a scale from 0 to 100, a composite health status score is obtained. A high score indicates a good health status. The RAND-36 is short, is sensitive to intervening illness, and has a good reliability and validity.[22] The RAND-36 scores of 200 matched healthy controls in this study were collected from the database of the Northern Centre for Health Care Research, Groningen, The Netherlands.

QoL was assessed with the WHO QoL assessment instrument-100 (WHOQOL-100).[23,24] This instrument was chosen because it corresponds best with the subjective character of the WHO definition of QoL. The WHOQOL-100 is a generic multidimensional self-report measure with good psychometric properties.[25] The instrument has been developed simultaneously and cross-culturally in 15 centers around the world.[12] It consists of 100 questions that assess 24 facets of QoL in 6 domains (physical health, psychological health, level of independence, social relationships, environment, spirituality) and a generic evaluative facet (overall QoL and general health; Appendix III, online only). Each facet is represented by four questions that reflect the respondent's functioning and his or her personal evaluation of functioning. The response scales are five-point scales. Scores on each facet and domain can range from 4 to 20. A high score indicates a good QoL, except for the facets pain and discomfort, negative feelings, and dependence on medication and treatments: these have an inverse score. Reliability, validity, and sensitivity are high, also in healthy elderly persons.[3,26,27] In a preceding study, the instrument could be reduced to 17 facets that are most relevant for patients with peripheral arterial occlusive disease.[28] Because the original instrument was reduced by eliminating entire facets, which themselves are independent components, the validity and reliability of the WHOQOL-100 were preserved. The WHOQOL scores of 200 matched healthy controls were collected from the database of the Department of Psychology and Health, Tilburg University, Tilburg, The Netherlands.

The questionnaires were completed by the patients themselves, but occasionally questions had to be explained by a research assistant. To minimize bias related to differential attention between the questions in the first and the last half of the questionnaires, the sequence of completion was reversed halfway through the inclusion period.

Statistics. Data are expressed as means and standard deviations. Mann-Whitney *U* tests were used to detect statistically significant differences ($P < .01$) between patients and healthy controls.[29] Pearson correlations were calculated between the RAND-36 domains and the WHOQOL domains and facets.[29] Differences between correlations were examined with Fisher *z* statistics.[30] To illustrate the most apparent similarities and differences between health status and QoL, approximately 10% of the patients with the lowest and 10% with the highest scores on a WHOQOL facet or domain were selected. Their scores

Table II. Distribution of risk factors and comorbidity specified according to the Society for Vascular Surgery/International Society for Cardiovascular Surgery* in 200 patients with intermittent claudication

Variable	*None*	*Mild*	*Moderate*	*Severe*
Diabetes mellitus	168 (84%)	11 (6%)	15 (8%)	6 (3%)
Tobacco use	25 (13%)	43 (22%)	73 (37%)	59 (30%)
Hypertension	106 (53%)	50 (25%)	34 (17%)	10 (5%)
Hyperlipidemia	94 (47%)	38 (19%)	27 (14%)	41 (20%)
Cardiac status	136 (68%)	37 (19%)	25 (13%)	2 (1%)
Carotid status	172 (86%)	7 (4%)	15 (8%)	6 (3%)
Renal status	192 (96%)	3 (2%)	3 (2%)	2 (1%)
Pulmonary status	179 (90%)	12 (6%)	8 (4%)	1 (1%)

*See Appendix III, online only.

Table III. Scores on the RAND-36 in 200 patients with intermittent claudication and 200 sex- and age-matched healthy controls

	Healthy controls		*Patients*		
Variable	*Mean*	*SD*	*Mean*	*SD*	P *value*
Physical functioning	70.1	27.3	50.5	19.6	<.01
Social functioning	85.3	21.8	74.2	24.4	<.01
Role physical	73.0	39.9	46.3	42.1	<.01
Role emotional	86.7	28.6	70.4	66.1	<.01
Mental health	76.8	17.4	70.4	20.4	<.01
Vitality	65.5	21.6	56.6	20.8	<.01
Bodily pain	76.2	25.6	58.2	21.6	<.01
General health perception	63.7	23.7	56.3	20.3	<.01

SD, Standard deviation.

on corresponding RAND-36 domains were divided into quartiles and visualized in stapled histobars.

RESULTS

Compared with healthy controls, patients scored significantly worse on all RAND-36 domains (Table III). Concerning the WHOQOL, patients reported perceiving their functioning as significantly worse than healthy controls with regard to physical health and level of independence on the facets pain and discomfort, energy and fatigue, mobility, activities of daily living, and working capacity. In addition, patients felt more dependent on medication and treatments and were more bothered by negative feelings. The social domain was unaffected, but some impairments in the environmental domain were recorded. Finally, overall QoL and general health were significantly worse in claudicants compared with healthy controls (Table IV).

The magnitude of the correlations between the RAND-36 domains and the WHOQOL facets/domains ranged from 0.20 to 0.74, representing a maximal common variance of 55%. The strongest correlations were found between RAND-36 mental health and WHOQOL negative feelings; RAND-36 vitality and WHOQOL energy and fatigue; RAND-36 general health perception and WHOQOL energy and fatigue; RAND-36 role physical and WHOQOL level of independence, particularly the facet working capacity; and RAND-36 bodily pain and WHOQOL pain and discomfort (Table V).

Comparison of patients' best and worst 10% of WHOQOL scores with their scores on the corresponding domains of the RAND-36 showed that there were patients with excellent and very poor QoL in nearly all health status quartiles (Figs 1-6). Most similarities were found for the physical domains (Figs 1 and 2), whereas major discrepancies appeared regarding social functioning and bodily pain (Figs 3 and 4). The comparison of scores confirmed that RAND-36 mental health correlated more strongly with WHOQOL negative feelings (Fig 5) than with the other facets of the WHOQOL domain psychological health (Fisher z test: all $z > \pm 1.96$; $P < .01$). We were surprised to find that patients in both the upper and lower response quartiles of RAND-36 general health perception had excellent and very low scores on the WHOQOL global facet overall QoL and general health (Fig 6).

DISCUSSION

In patients with IC, health status and QoL are broadly affected, which may give the impression that the concepts measure the same problem with apparently similar results. The RAND-36 domains physical functioning and role physical show acceptable correlations with the WHOQOL domain level of independence. However, the common variance was far from 100%, thus indicating that the concepts only partially cover the same aspects and have a complementary value for the assessment of a patient's perception of disease. The congruence between the respective

Table IV. Scores on the reduced WHOQOL-100 in 200 patients with intermittent claudication and 200 sex- and age-matched healthy controls

Variable	*Healthy controls*		*Patients*		P *value*
	Mean	*SD*	*Mean*	*SD*	
Overall QoL and general health	16.1	2.5	14.5	2.8	<.01
Physical health	15.3	2.4	13.4	2.4	<.01
Pain and discomfort*	9.4	2.8	12.1	2.6	<.01
Energy and fatigue	15.2	3.1	12.6	3.0	<.01
Sleep and rest	16.2	3.6	15.6	4.0	NS
Psychological health	—	—			
Positive feelings	14.4	2.0	14.2	2.4	NS
Thinking, learning, memory	—	—			
Self-esteem	14.7	2.2	14.5	2.7	NS
Body image and appearance	—	—			
Negative feelings*	8.9	2.8	10.1	3.1	<.01
Level of independence	16.8	2.4	13.1	2.6	<.01
Mobility	17.0	3.0	11.7	2.7	<.01
Activities of daily living	16.6	2.7	14.0	3.0	<.01
Dependence on medication/ treatments*	7.0	3.1	10.8	3.5	<.01
Working capacity	16.7	2.8	13.4	3.7	<.01
Social relationships	15.3	2.6	15.2	2.7	NS
Personal relationships	16.0	2.5	16.5	2.7	NS
Social support	—	—			
Sexual activity	14.2	4.0	13.8	3.5	NS
Environment	—	—			
Physical safety and security	—	—			
Home environment	15.9	2.5	16.1	2.9	NS
Financial resources	—	—			
Health and social care	—	—			
Opportunities for acquiring new information and skills	16.0	2.4	14.7	2.7	<.01
Recreation/leisure	15.9	2.7	14.9	3.1	<.01
Physical environment	—	—			
Transport	17.5	3.0	16.5	3.7	NS
Spirituality	—	—			

WHOQOL-100, World Health Organization Quality of Life Assessment Instrument-100; *QoL,* quality of life; *NS,* not significant.
*Scores on the facets pain and discomfort, negative feelings, and dependence on medication and treatments are inverse. High scores reflect low QoL.

RAND-36 response quartiles and the upper and lower 10% of the WHOQOL scores confirm that, with regard to the physical domains, both assessments comparably discriminate between better and worse performance (health status) and high and low satisfaction with performance (QoL). However, health status and QoL differed with respect to social functioning. Whereas patients reported significant limitations in the RAND-36 domain social functioning, it seemed that the upper 10% of the WHOQOL domain social relationships also represented patients from the second and third response quartiles of the corresponding RAND-36 domain, thus indicating that the suspected social limitations were not necessarily experienced as troublesome by all of these patients. This paradoxical finding may be explained by looking at the questions that assess health status and QoL. The social domain of the RAND-36 asks how often and to what extent physical health and emotional problems have interfered with social activities. Consequently, the frequency and the intensity of the events that have interfered with social activities will determine the score for social functioning. Patients with few social contacts will have a low score and therefore will be expected to have a poor social life or to function on a low social level. The social domain of the WHOQOL incorporates the facet personal relationships with questions about feeling lonely, satisfaction with relationships, and satisfaction with the ability to support and care for others. Because satisfaction with social contacts is not related to the size of someone's social network, few social contacts do not necessarily represent social deprivation, but may reflect a patient's preference.[31] Moreover, the feeling of being appreciated by others for providing care and support may contribute to social well-being as well. Practically, this means that attempts to improve social functioning in patients with IC based solely on health status assessments may not contribute to a better QoL per se, because patients may not feel socially impaired.

The pain scores show a similar pattern. All response quartiles of RAND-36 bodily pain contain patients with excellent scores on the corresponding WHOQOL facet pain and discomfort. This indicates that they perceive no problems in daily life as a result of pain. At least for patients with the best and worst QoL scores, this finding illustrates the difference between (1) recording only the frequency

Table V. Pearson correlations between the scores on the WHOQOL facets and domains and the RAND-36 domains in 200 patients with intermittent claudication

Variable	*PhysF*	*SocF*	*RoPh*	*RoEm*	*MentH*	*Vital*	*Pain*	*GH*
Overall QoL and general health	0.39	0.53	0.32	0.35	0.52	0.57	0.21	0.57
Physical health	0.47	0.50	0.46	0.39	0.56	0.57	0.48	0.53
Pain and discomfort	−0.45	−0.35	−0.40	−0.24	−0.42	−0.40	−0.57	−0.30
Energy and fatigue	0.44	0.44	0.41	0.42	0.43	0.67	0.31	0.64
Sleep and rest	NS	0.31	0.25	0.23	0.38	0.23	0.22	0.25
Psychological health								
Positive feelings	0.20	0.45	NS	0.33	0.56	0.52	NS	0.51
Thinking, learning, memory								
Self-esteem	NS	0.40	0.22	0.26	0.51	0.44	NS	0.40
Body image and appearance								
Negative feelings	−0.20	−0.43	−0.20	−0.38	−0.74	−0.49	NS	−0.36
Level of independence	0.59	0.50	0.60	0.37	0.39	0.52	0.50	0.57
Mobility	0.50	0.40	0.42	0.25	0.25	0.35	0.49	0.34
Activities of daily living	0.54	0.57	0.54	0.40	0.45	0.57	0.46	0.57
Dependence on medication/ treatments	−0.34	−0.22	−0.34	NS	−0.26	−0.25	−0.23	−0.42
Working capacity	0.49	0.40	0.60	0.41	0.28	0.47	0.42	0.47
Social relationships	0.28	0.44	NS	0.26	0.49	0.45	NS	0.37
Personal relationships	0.24	0.44	NS	0.21	0.52	0.44	NS	0.33
Social support								
Sexual activity	NS	0.34	NS	0.27	0.32	0.37	NS	0.29
Environment								
Physical safety and security								
Home environment	0.27	0.30	0.24	0.25	0.37	0.30	NS	0.33
Financial resources								
Health and social care								
Information/skills	NS	0.28	NS	NS	0.28	0.29	NS	0.28
Recreation and leisure	0.30	0.54	0.25	0.34	0.44	0.46	0.22	0.38
Physical environment								
Transport	0.24	0.36	0.20	NS	0.26	0.24	NS	0.22
Spirituality								

WHOQOL, World Health Organization Quality of Life; *PhysF,* physical functioning; *SocF,* social functioning; *RoPh,* role physical; *RoEm,* role emotional; *MentH,* mental health; *Vital,* vitality; *Pain,* bodily pain; *GH,* general health perception; *NS,* not significant.
Correlations are significant at $P < .01$.

and intensity of pain, as reflected in health status, and (2) also asking the patient whether his or her life is actually affected by having pain. In other words, health status indicates whether there are limitations, and QoL also reflects to what extent these limitations are considered a problem in daily life. Because individual expectations regarding health, coping abilities, and the threshold for the tolerance of discomfort modulate objective health status scores into subjective values, two people with identical restrictions in functioning (health status) may evaluate these restrictions differently (QoL).[32]

The WHOQOL is more comprehensive than the RAND-36 and allows a more detailed appreciation of subjective feelings. For example, the RAND-36 scores show an impaired mental health status in patients with IC. The questions belonging to mental health explore the frequency of feeling nervous, down, calm, depressed, and happy. However, the aggregated score does not permit identification of which feelings are affected in particular. The facets of the corresponding WHOQOL domain psychological health specify the subjective content of those feelings. Table IV shows that IC patients are more bothered than healthy controls by negative feelings. Moreover, RAND-36 mental health correlates significantly more strongly with WHOQOL negative feelings than with the other facets of the corresponding WHOQOL domain, and all patients in the upper and the lower quartiles of RAND-36 mental health belong to the 10% of patients with the least and the most negative feelings, respectively. These findings confirm that impaired mental health in claudicants is caused by an excess of negative feelings. As a consequence, it might be speculated that therapy directed at reducing negative feelings would rather meet these patients' needs than efforts to increase self-esteem.

In general, health status measures assess disability rather than health and disregard the mutual influence of health-related and non–health-related aspects of life.[2,6,7,33] The present QoL results show that claudicants do not report fewer positive feelings or more negative self-esteem compared with healthy controls; this shows that positive evaluations of QoL remain despite a broadly deteriorated health status.

In addition to problems regarding common non–health-related aspects of everyday life, such as acquiring information/skills or participating in leisure activities, QoL measurement revealed a significant dependency on medica-

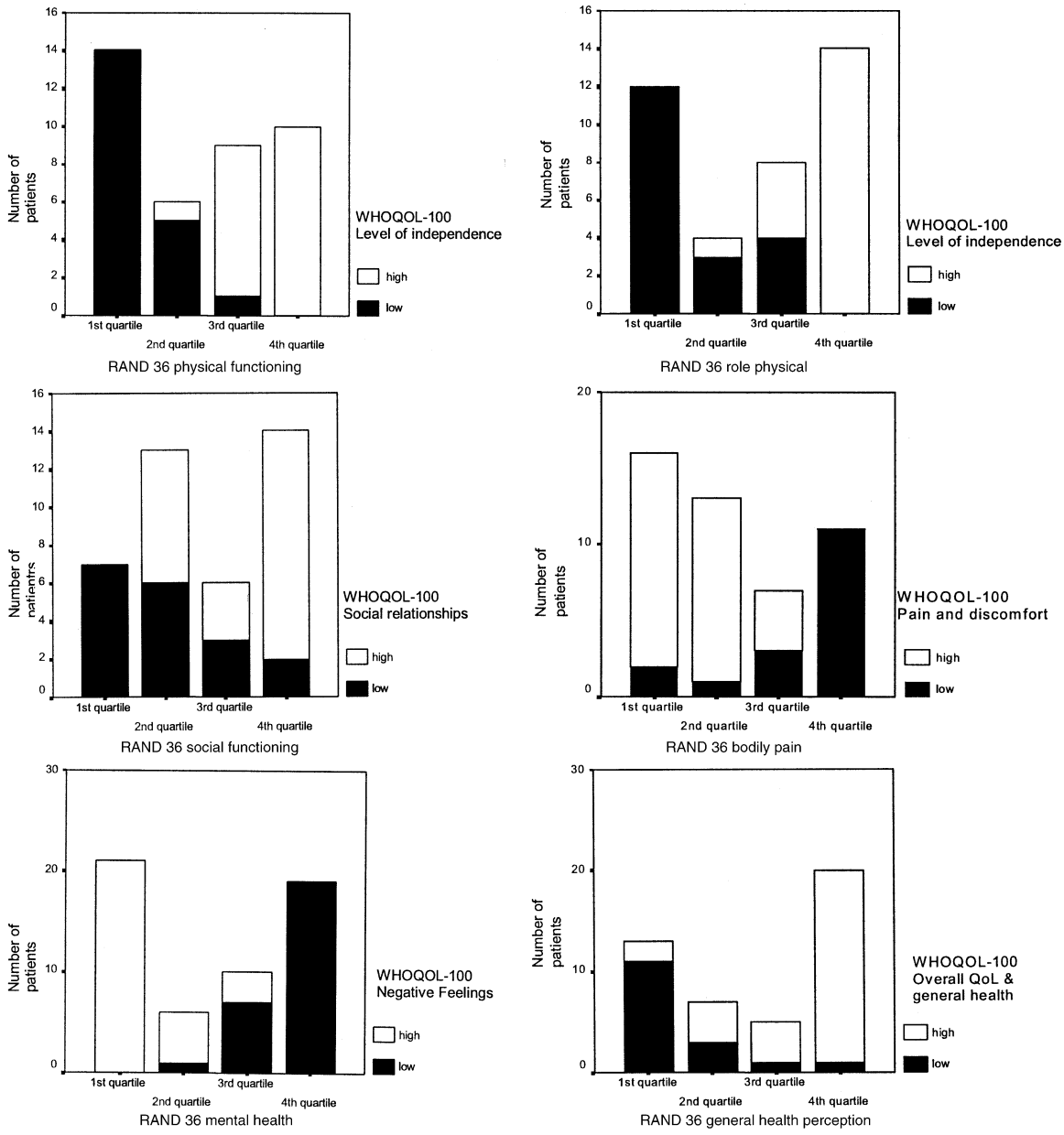

Fig 1. Stapled histobar showing the RAND-36 response quartiles against the upper and lower 10% of World Health Organization Quality of Life Assessment Instrument-100 *(WHOQOL-100)* scores for corresponding domains/facets in patients studied for health status and quality of life.

tion and treatments in claudicants that could not be traced in one of the RAND-36 domains. The relationship of this finding with the high incidence of cardiovascular risk factors and comorbidity in patients with IC has recently been made plausible and deserves attention in treatment strategy.[14,28] It shows that comorbidity and dependency on medical services moderate the relevance of the walking impairment for the claudicants' QoL and stresses the need for risk factor management and treatment of comorbidity.

It has been advocated that health status measures be supplemented with the assessment of global QoL to reflect individual values and preferences.[2] However, for the interpretation of impaired global QoL, it should be clear what the term represents. Table V shows that the WHOQOL overall QoL and general health and the RAND-36 general health perception correlate better with the RAND-36 domain vitality and the corresponding WHOQOL facet energy and fatigue, respectively, than with each other. In addition, in all response quartiles of the RAND-36 general health perception, there are patients with an excellent overall QoL and general health according to the WHOQOL. The bare fact that an unspecified term such as "global

QoL" is affected by a certain disease, is too vague to be interpreted, and does not contribute to the understanding of disease impact. Because patients with similar global QoL scores may have different underlying problems, this score will not provide relevant information for disease management. Knowledge of the causal relationships with aspects of life that actually determine general QoL and health perception may contribute to a better interpretation of these findings and may guide treatment appropriately.

It could be argued that the differences between health status and QoL found in this study should be attributed to the differences in length between the questionnaires, rather than to the differences between the concepts. This might be true if health status and QoL were assessed in the same way. However, when looking at the questions regarding, eg, pain, social functioning, and general health and QoL, it becomes clear that the WHOQOL questions are almost identical to those in the RAND-36. In addition, the WHOQOL explores the subjective appraisal of these aspects by means of evaluating questions (Appendices I and II).

In conclusion, our data confirm the overwhelming effect of IC on health status and QoL. However, there is an important distinction between these concepts. Health status reflects health-related restrictions that are associated with a certain disease. QoL assessment offers patients the possibility to evaluate functional impairments and to indicate their perspectives on disease and treatment, their need for care, and their preferences for treatment and outcomes. Thus, reports on patients' perceptions of disease impact and treatment results that have been measured with health status instruments that do not reflect the respondents' subjective opinions may be misleading and may carry the risk of directing treatment efforts at the wrong targets.

The authors thank the Northern Centre for Health Care Research, Groningen, for providing the RAND-36 data for healthy controls.

APPENDIX I: Society for Vascular Surgery/ International Society for Cardiovascular Surgery (North American Chapter) Grading System for Cardiovascular Risk Factors and Comorbidity[16]

Diabetes mellitus: 0, none; 1, adult onset, controlled by diet or oral agents; 2, adult onset, insulin controlled; 3, juvenile onset

Tobacco use: 0, none or none for last 10 years; 1, none current, but smoked in last 10 years; 2, current (includes abstinence for less than 1 year), less than one pack per day; 3, current, more than 1 pack per day

Hypertension: 0, diastolic usually lower than 90 mm Hg; 1, controlled with a single drug; 2, controlled with two drugs; 3, requires more than two drugs or is uncontrolled

Hyperlipidemia: 0, cholesterol (low-density lipoprotein and total) and triglyceride levels within normal limits for age; 1, readily controllable by diet; 2, requires strict dietary control; 3, same as mild, but severe enough to require dietary and drug control

Cardiac status: 0, asymptomatic with normal electrocardiogram; 1, asymptomatic, but with remote myocardial infarction by history (>6 months), occult myocardial infarction by electrocardiogram, or fixed defect on dipyridamole thallium or similar scan; 2, any one of the following: stable angina, no angina (but significant reversible perfusion defect on dipyridamole thallium scan), significant silent ischemia (≥1% of the time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, or history of congestive heart failure that is now well compensated; 3, any one of the following: unstable angina, symptomatic or poorly controlled ectopy/ arrhythmia (chronic/recurrent), poorly compensated or recurrent congestive heart failure, ejection fraction less than 25%, or myocardial infarction within 6 months

Carotid disease: 0, no symptoms and no evidence of disease; 1, asymptomatic but with evidence of disease determined by duplex scan or other accepted noninvasive test or arteriogram; 2, transient or temporary stroke; 3, completed stroke with permanent neurologic deficit or acute stroke

Renal status (refers to stable levels, not transient decreases or increases in response to intravenous medication, hydration, or contrast media): 0, no known renal disease, normal serum creatinine level; 1, moderately increased creatinine level, as high as 2.4 mg/dL; 2, creatinine level of 2.5 to 5.9 mg/dL; 3, creatinine level greater than 6.0 mg/dL or on dialysis or with kidney transplant

Pulmonary status: 0, asymptomatic, normal chest x-ray film, pulmonary function tests within 20% of predicted; 1, asymptomatic or mild dyspnea on exertion, mild chronic parenchymal x-ray changes, pulmonary function tests 65% to 80% of predicted; 2, between 1 and 3; 3, vital capacity less than 1.85 L, forced expiratory volume in 1 second less than 1.2 L or less than 35% of predicted, maximal voluntary ventilation less than 50% of predicted, Pco_2 greater than 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension

REFERENCES

1. O'Boyle CA. Assessment of quality of life in surgery. Br J Surg 1992; 79:395-8.
2. Gill TM, Feinstein AR. A critical appraisal of the quality of quality-of-life measurements. JAMA 1994;272:619-26.
3. De Vries J, Van Heck GL. The World Health Organization Quality of Life assessment (WHOQOL-100): validation study with the Dutch version. Eur J Psychol Assess 1997;13:164-78.
4. Covinsky KE, Wu AW, Landefeld CS, Connors AF, Phillips RS, Tsevat J, et al. Health status versus quality of life in older patients: does the distinction matter? Am J Med 1999;106:435-40.
5. Schalock RL, Bonham GS, Marchand CB. Consumer based quality of life assessment: a path model of perceived satisfaction. Eval Program Plann 2000;23:77-87.
6. Hunt SM. The problem with quality of life. Qual Life Res 1997;6:205-12.
7. Leplege A, Hunt S. The problem of quality of life in medicine. JAMA 1997;278:47-50.
8. Bradley C. Importance of differentiating health status from quality of life. Lancet 2001;357:7-8.
9. Higginson IJ, Carr AJ. Using quality of life measures in the clinical setting. BMJ 2001;322:1297-300.

10. World Health Organisation. The constitution of the WHO. WHO Chron 1947;1:29.
11. Bergner DK. Measurement of health status. Med Care 1985;23:696-704.
12. WHOQOL Group. Development of the WHOQOL: rationale and current status. Int J Ment Health 1994;23:24-56.
13. Breek JC, Hamming JF, De Vries J, Aquarius AEAM, Van Berge Henegouwen DP. Quality of life in patients with intermittent claudication using the World Health Organisation (WHO) Questionnaire. Eur J Vasc Endovasc Surg 2001;21:118-22.
14. Dormandy J, Heeck L, Vig S. Lower extremity arteriosclerosis as a reflection of a systemic process: implications for concomitant coronary and carotid disease. Semin Vasc Surg 1999;12:118-22.
15. TASC Working Group. Treatment of intermittent claudication. J Vasc Surg 2000;31:S77-89.
16. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
17. Hays RD, Sherbourne CD, Mazel RM. The RAND-36 item health survey 1.0. Health Econ 1993;2:217-27.
18. Van der Zee KI, Sanderman R. Measuring general health status with the RAND-36: a manual. Groningen: Northern Centre for Health Care Research; 1993.
19. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992; 30:473-83.
20. Chetter IC, Spark JI, Dolan P, Kester RC. Quality of life analysis in patients with lower limb ischaemia: suggestions for European standardisation. Eur J Vasc Endovasc Surg 1997;13:597-604.
21. McDaniel MD, Nehler MR, Santilli SM, Hiatt WR, Regensteiner JG, Goldstone J, et al. Extended outcome assessment in the care of vascular diseases: revising the paradigm for the 21st century. J Vasc Surg 2000;32:1239-50.
22. Bowling A. Measuring health. A review of quality of life measurement scales. Milton Keynes: Open University Press; 1991.
23. WHOQOL Group. The World Health Organization Quality of Life assessment (WHOQOL): position paper from the World Health Organisation. Soc Sci Med 1995;41:1403-9.
24. De Vries J, Van Heck GL. Dutch WHOQOL-100. Tilburg: Tilburg University; 1995.
25. WHOQOL Group. The WHOQOL assessment (WHOQOL: development and generic psychometric properties). Soc Sci Med 1998;46: 1569-85.
26. O'Carroll RE, Cossar JA, Couston MC, Hayes PC. Sensitivity to change following liver transplantation: a comparison of three instruments that measure quality of life. J Health Psychol 2000;5:69-74.
27. De Vries J. Beyond health status: construction and validation of the Dutch WHO quality of life assessment instrument [thesis]. Tilburg: Tilburg University; 1996.
28. Breek JC, Hamming JF, De Vries J, Van Berge Henegouwen DP, Van Heck GL. The impact of walking impairment, cardiovascular risk factors, and co-morbidity on quality of life in patients with intermittent claudication. J Vasc Surg 2002;36:94-9.
29. Gross Portney L, Watkins MP. Foundations of clinical research: applications to practice. 2nd ed. Upper Saddle River (NJ): Prentice Hall Health; 2000.
30. Runyon RP, Coleman KA, Pittenger DJ. Fundamentals of behavioral statistics. 9th ed. Boston: McGraw Hill; 2000.
31. Sarason BR, Sarason IG, Pierce GR. Traditional views of social support and their impact on assessment. In: Sarason BR, Sarason IG, Pierce GR, editors. Social support: an interactional view. New York: Wiley; 1990. p. 9-25.
32. Testa MA, Simonson DC. Assessment of quality of life outcomes. N Engl J Med 1996;334:835-40.
33. Swenson JR, Clinch JJ. Assessment of quality of life in patients with cardiac disease: the role of psychosomatic medicine. J Psychosom Res 2000;48:405-15.

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