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# The impact of walking impairment, cardiovascular risk factors, and comorbidity on quality of life in patients with intermittent claudication

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**Objective:** The objective of this study was to assess the impact of walking impairment, cardiovascular risk factors, and comorbidity on quality of life (QOL) in patients with intermittent claudication (IC).

**Material and methods:** The prospective observational study was conducted in the setting of a vascular outpatient department of a teaching hospital. QOL was assessed in 200 consecutive patients with IC, with a reduced version of the World Health Organization Quality of Life Assessment Instrument-100. The reduced instrument assesses 17 facets of QOL within five domains (Physical and Psychological Health, Level of Independence, Social Relationships, and Environment). Age, gender, degree of IC, risk factors, comorbidity, as recommended by the Society for Vascular Surgery/North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS), and the presence of back, hip, or knee symptoms were analyzed as possible predictors of QOL. Multiple regression analyses were run with each of the QOL facets and domains as dependent variable. A probability value of less than .05 was considered to be statistically significant.

**Results:** Male gender was found to be a predictor of better scores for Energy and Fatigue and for Sleep and Rest. Women had more Negative Feelings. The presence of back, hip, or knee symptoms was a significant predictive value for many aspects of QOL. With more concomitant diseases, patients had lower scores on the facets of Overall QOL and General Health and of Energy and Fatigue and showed more dependence on medication and treatments. The degree of IC, as expressed in the SVS/ISCVS classification, was a statistically significant predictor of QOL on the domain Level of Independence and its facets Mobility, Activities of Daily Living, and Working Capacity and the facets Pain and Discomfort, Sexual Activity, and Transport. Hypertension was the second most important single predictor of QOL in patients with IC.

**Conclusion:** QOL in patients with IC is only partially determined by the severity of walking limitation as expressed in the SVS/ISCVS classification. The significant impact of cardiovascular risk factors and comorbidity and the presence of back, hip, or knee symptoms on QOL should be recognized and taken into account in the treatment policy. (J Vasc Surg 2002; 36:94-9.)

Intermittent claudication (IC) is a frequently occurring expression of peripheral arterial occlusive disease (PAOD), usually with a benign course for the legs.<sup>1</sup> Although the presenting symptom may seem innocent, concomitant coronary disease and cerebrovascular disease are serious threats to the patient's life.<sup>2</sup> Treatment results in patients with IC are traditionally expressed as changes in ankle blood pressures and walking distance.<sup>3</sup> Because arteriosclerosis is a chronic progressive and incurable disease, for a long time, relief of symptoms was the main goal of treatment. However, during the last years, quality of life (QOL) has become an accepted measure of disease impact and therapeutic

outcome in patients with vascular disease.<sup>4-7</sup> Accordingly, the goal of treatment of patients with IC has shifted from mere palliation of symptoms to the preservation or improvement of QOL. The impact of IC on QOL has been highlighted in several studies.<sup>8-10</sup> However, in these studies, the role of cardiovascular risk factors and the impact of concomitant disease on the QOL of these patients are generally not included as variables. Therefore, the aim of this study was to assess the relative impact of age, gender, degree of claudication, cardiovascular risk factors, comorbidity, and the presence of back, hip, or knee symptoms on QOL in patients with IC.

## MATERIAL AND METHODS

Between January 1999 and June 2000, QOL was assessed in patients with IC who agreed to participate in the study at the vascular unit of the St Elisabeth Hospital in Tilburg, The Netherlands. Two hundred patients were included in the study: 135 men and 65 women, with a mean age of 63 years (range, 42 to 83 years). Diagnosis was suspected on history and physical examination in 215 patients and could be confirmed with treadmill performance and ankle blood pressure in 207 patients. Seven of the patients refused or were not capable of participation.

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**Table I.** Characteristics of 200 patients with IC who underwent study for QOL

	<i>Mild claudication</i>	<i>Moderate claudication</i>	<i>Severe claudication</i>
No. of patients	37	81	82
Gender (male/female)	31/6	53/28	51/31
Mean age (years)	60.6	63.7	62.8
ABI	0.70 (0.52-0.95)	0.68 (0.33-0.93)	0.53 (0.24-0.88)

*Mild claudication:* Completion of standard treadmill exercise (5 minutes at 2 mph on 12% incline); ankle pressure after exercise >50 mm Hg, but at least 20 mm Hg lower than resting value. *Moderate claudication:* Between mild and severe. *Severe claudication:* Completion of standard treadmill exercise not possible; ankle pressure after exercise < 50 mm Hg.

ABI, Ankle brachial index.

**Table II.** Distribution of risk factors and comorbidity, specified according to SVS/ISCVS, in 200 patients with IC who underwent study for QOL

	<i>None (0)</i>	<i>Mild (1)</i>	<i>Moderate (2)</i>	<i>Severe (3)</i>
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%)

SVS/ISCVS grading system for cardiovascular risk factors and comorbidity<sup>3</sup>:

*Diabetes mellitus:* 0, none; 1, adult onset, controlled with 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 less than 1 year), less than 1 pack/day; 3, current, greater than 1 pack/day.

*Hypertension:* 0, diastolic usually lower than 90 mm Hg; 1, controlled with 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 with diet; 2, requiring 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 either remote myocardial infarction with history (>6 months), occult myocardial infarction with electrocardiogram, or fixed defect on dipyridamole thallium or similar scan; 2, any one of stable angina, no angina but significant reversible perfusion defect on dipyridamole thallium scan, significant silent ischemia (≥1% of time) on Holter monitoring, ejection fraction 25% to 45%, controlled ectopy or asymptomatic arrhythmia, history of congestive heart failure that is now well compensated; 3, any one of unstable angina, symptomatic or poorly controlled ectopy/arrhythmia (chronic/recurrent), poorly compensated or recurrent congestive heart failure, ejection fraction less than 25%, myocardial infarction within 6 months.

*Carotid disease:* 0, no symptoms, no evidence of disease; 1, asymptomatic but with evidence of disease determined with 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 drops or elevations in response to intravenous medication, hydration, or contrast media) 0, no known renal disease, normal serum creatinine level; 1, moderately elevated creatinine level, as high as 2.4 mg/dL; 2, creatinine level, 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 radiograph film, pulmonary function tests within 20% of predicted; 1, asymptomatic or mild dyspnea on exertion, mild chronic parenchymal radiograph 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, partial pressure of carbon dioxide greater than 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension.

Apart from patients with dementia and those who were blind or deaf, no patients were excluded from the study. In all patients, degree of walking impairment, risk factors (smoking and hyperlipidemia), and comorbidity (hypertension, cardiac, carotid, renal and pulmonary status, diabetes mellitus) were recorded according to the Society for Vascular Surgery/North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS;<sup>3</sup> Tables I and II). Because of the impact on mobility, the presence of back, hip, or knee symptoms unrelated to vascular disease also were recorded. QOL was assessed with a reduced version of the World Health Organization Quality of Life Assessment Instrument-100 (WHOQOL-

100).<sup>11</sup> The WHOQOL-100 is a generic, multidimensional, self-report QOL measure that is easy to score and has good psychometric properties.<sup>12</sup> The WHOQOL-100 has been used in a wide variety of patient populations.<sup>10,13,14</sup> The instrument has been developed simultaneously and cross-culturally in 15 centers around the world.<sup>15</sup> It consists of 100 questions for assessment of 24 facets of QOL within six domains (Physical Health, Psychological Health, Level of Independence, Social Relationships, Environment, and Spirituality/Religion/Personal Beliefs) and a generic evaluative facet, Overall QOL and General Health. Each facet is represented by four questions. The response scales are 5-point scales. Scores on each

facet and domain can range from 4 to 20. A higher score indicates that respondents evaluate their functioning on the respective domains and facets of QOL as being better, except for the facets Pain and Discomfort, Negative Feelings, and Dependence on Medication/Treatments, which have an inverse score. To adapt the instrument for patients with IC and to limit patient burden of completion of 100 questions, the original WHOQOL-100 was reduced to the facets and domains that were relevant to this patient group. After a pilot study in 40 patients, with criteria for the distribution of answers (*kurtosis*, which describes the peakedness of the distribution, and *skewness*, which means that the length of one of the tails of the distribution, relative to the central section, is disproportionate to the other) and internal consistency (*Cronbach's*  $\alpha$ , a measure for the reliability of the instrument), the instrument could be reduced to 17 facets (68 questions). Because the original instrument was reduced with the elimination of only entire facets, which are independent components, the validity and reliability of the WHOQOL-100 were preserved.

**Statistics.** Age, gender, risk factors, comorbidity, and SVS/ISCVS classification of IC were tested as possible predictors of QOL. Multiple regression analyses (MRAs) were run with each of the QOL facets and domains as dependent variables. Each MRA (stepwise method) consisted of four blocks of variables.

The demographic variables, gender and age, were entered in block 1. The second block consisted of the presence of back and hip/knee symptoms. Block 3 contained the risk factors smoking and hyperlipidemia. Two series of MRAs were run, with the fourth block containing the number of concomitant diseases in the first series and the nature of the concomitant disease (hypertension, cardiac, carotid, renal and pulmonary status, diabetes mellitus) and the SVS/ISCVS classification of IC in the second series. Before performing the MRAs, we examined the distributions of the variables involved. In the case of carotid, renal, and pulmonary status, exploration revealed extreme skewness and kurtosis scores that could not be improved satisfactorily with logarithmic transformations. Furthermore, additional data exploration pointed at violations of the linearity assumption. With these results of evaluation taken together, a decision was made to dichotomize the measures of these variables to absent or present. The degree of IC and the severity of the other risk factors and comorbidity are expressed as none, mild, moderate, or severe, so that the predictive value of these independent variables on QOL would correlate with the change and direction (increase or decrease) of the severity.

Differences in age, distribution of risk factors, and comorbidity between the three categories of claudication were tested with the Kruskal-Wallis test. A possible difference in gender between the three categories of IC was examined with a  $\chi^2$  test. For all calculations a probability value of less than .05 was considered to be statistically significant.

## RESULTS

No statistically significant differences were found in age and gender or in the distribution of risk factors and comorbidity between the three categories of IC. Back and hip or knee symptoms were present in 13% and 10% of the patients, respectively.

Male gender was a major predictor for higher scores on the domain Physical Health and its components of Energy and Fatigue and of Sleep and Rest. Female gender associated exclusively with more Negative Feelings.

From the first series of MRAs, patients with more concomitant diseases appeared to have lower scores on Overall QOL and General Health, Energy and Fatigue, and Dependence on Medication/Treatments. When patients had back, hip, or knee symptoms, their QOL scores were lower on all facets except for Sleep and Rest, Negative Feelings, Dependence on Medication/Treatments, Home Environment, and Opportunities for Acquiring New Information/Skills.

The second series of MRAs (Table III) showed that increasing IC, as expressed in the SVS/ISCVS classification, predicted a lower QOL on the domain Level of Independence and its facets Activities of Daily Living and Working Capacity. Moreover, the severity of IC was the only variable with a substantial predictive value for the facet Mobility (domain Level of Independence). In addition, more severe IC was associated with more Pain and Discomfort, lower scores on the facet Sexual Activity, and more problems with Transport. Hypertension emerged as an important factor for QOL with a significant predictive value for various aspects such as Overall QOL and General Health, Energy and Fatigue, the domain Level of Independence and its facets Dependence on Medication/Treatments and Working Capacity, and the facets Recreation/Leisure and Transport.

Specifically, nonsmokers, patients with mild smoking behavior, and patients with a compromised carotid or pulmonary status indicated that they felt more dependent on medication and treatments. Patients with pulmonary restrictions had higher scores for the facet Sleep and Rest, and patients with hyperlipidemia scored lower for Self-esteem.

Age and diabetes mellitus had no significant predictive value for any QOL aspects in patients with IC. Finally, no significant predictors of QOL were seen on the domain Social Relationships and the facets Personal Relationships and Home Environment.

## DISCUSSION

QOL scores in patients with IC are the result of influences of PAOD and of comorbidity. Because walking impairment is only one component of the clinical entity, other aspects should be evaluated as well to understand the impact of IC on patient's QOL. These results show that the predictive value of walking impairment, as expressed in the SVS/ISCVS classification, for the patients' QOL is limited to the physical aspects of QOL: Pain and Discomfort, Mobility, Activities of Daily Living, Working Capacity,

**Table III.** Results from stepwise multiple regression analysis with age, gender, nonvascular back, hip, and knee symptoms, risk factors, comorbidity (SVS/ISCVS classification), and degree of IC (SVS/ISCVS classification) as independent variables (predictors of QOL) and WHOQOL facets and domains as dependent variables

<i>Dependent variable</i>	<i>Predictor of QOL</i>	<i>β value</i>	<i>R<sup>2</sup> change</i>	<i>R<sup>2</sup> total</i>
Overall QOL and general health ( <i>P</i> < .001)	Hypertension	-.248	0.061	0.061
Physical health ( <i>P</i> < .000)	Male gender	-.306	0.089	0.089
	Back pain	-.206	0.037	0.126
Pain and discomfort ( <i>P</i> < .000)	Renal status	-.174	0.030	0.156
	Back pain	.312	0.087	0.087
	IC classification	.151	0.023	0.110
Energy and fatigue ( <i>P</i> < .007)	Male gender	-.173	0.034	0.034
	Hypertension	-.155	0.024	0.058
Sleep and rest ( <i>P</i> < .000)	Male gender	-.308	0.091	0.091
	Pulmonary status	.156	0.024	0.115
Psychological health				
Positive feelings ( <i>P</i> < .007)	Renal status	-.207	0.043	0.043
Thinking, learning, memory, concentration	-	-	-	-
Self-esteem ( <i>P</i> < .008)	Hyperlipidemia	-.205	0.042	0.042
Body image and appearance	-	-	-	-
Negative feelings ( <i>P</i> < .000)	Female gender	.297	0.088	0.088
Level of independence ( <i>P</i> < .000)	Hypertension	-.218	0.053	0.053
	IC classification	-.208	0.043	0.096
Mobility ( <i>P</i> < .000)	IC classification	-.290	0.084	0.084
Activities of daily living ( <i>P</i> < .008)	IC classification	-.204	0.042	0.042
Dependence on medication/treatments ( <i>P</i> < .000)	Smoking	-.161	0.036	0.036
	Hypertension	.254	0.073	0.109
Working capacity ( <i>P</i> < .000)	Pulmonary status	.170	0.032	0.141
	Carotid status	.165	0.026	0.167
	Back pain	-.255	0.040	0.040
	Hypertension	-.226	0.054	0.094
	IC classification	-.166	0.027	0.121
Social relationships	No significant predictors of QOL			
Personal relationships	No significant predictors of QOL			
Social support				
Sexual activity ( <i>P</i> < .006)	Carotid status	-.216	0.033	0.033
Environment	IC classification	-.195	0.037	0.070
	Physical safety and security	-	-	-
Home environment	No significant predictors of QOL			
Financial resources	-	-	-	-
Health and social care	-	-	-	-
Opportunities for acquiring new information/skills ( <i>P</i> < .023)	Cardiac status	-.175	0.031	0.031
Recreation/leisure ( <i>P</i> < .009)	Hypertension	-.201	0.041	0.041
Physical environment	-	-	-	-
Transport ( <i>P</i> < .003)	IC classification	-.192	0.041	0.041
Spirituality, religion, personal beliefs	Hypertension	-.162	0.026	0.067
	-	-	-	-

Scores on pain and discomfort, negative feelings, and dependence on medication/treatments are inverse. Higher scores indicate lower QOL.

*IC classification:* Mild, moderate, or severe IC according to SVS/ISCVS.<sup>3</sup>

*β value:* Indicates whether relation between predictor and facet of QOL is positive or negative. In Table, negative β value indicates that low scores on independent variables (mild claudication, absence of back, hip, or knee symptoms, absence of carotid, renal, and pulmonary comorbidity, less severe diabetes mellitus, tobacco use, hypertension, hyperlipidemia, and cardiac comorbidity) predict higher score on dependent variables (ie, respective domains or facets of QOL). Negative β value for gender indicates male gender to be predictor of QOL, and positive β value means that female gender is predictor of QOL facet or domain.

*R<sup>2</sup> change:* indicates proportion of variance of dependent variable (ie, facet or domain of QOL) that is explained by independent variable in that row.

*R<sup>2</sup> total:* reflects total proportion of variance of dependent variable that is explained by independent variables that are included in model up to that point.

*Significance:* of used model is expressed with *P* value. *P* value < .05 was considered statistically significant.

Sexual Activity, and Transport. This is in concordance with earlier reports,<sup>10,16</sup> which describe the limited effect of increasing IC on QOL as a whole.

The importance of risk factors and comorbidity for the development of PAOD and for the prognosis of patients

with it has been documented extensively.<sup>2,17,18</sup> For instance, IC has been shown to be a substantial predictor of cardiovascular morbidity and mortality, independent of associated coronary ischemia and other cardiovascular risk factors, in ambulatory elderly patients.<sup>19</sup> Although patients

seek help for a walking problem, the systemic risk of PAOD is the real threat to their lives. Facing this reduces IC to a relatively innocent ailment marking a more serious underlying disease.

These data indicate that, in addition to walking impairment, concomitant disease plays an important role for most aspects of QOL in patients with IC. This does not detract from the value of improved walking for a better functional status, which will be appreciated by the patient, even in the presence of important comorbidity. However, the gains with respect to QOL may be small because the predictive value of walking impairment is limited to physical aspects. Concerning the finding that increasing IC only affects QOL with regard to the facet Mobility,<sup>10</sup> patients with IC and important comorbidity may gain some improvement in functional status but are unlikely to enjoy important QOL benefits from improving walking distance only. Optimizing their medical condition may be of greater importance for QOL.

Patients with pulmonary restrictions have better scores for Sleep and Rest. Because QOL assesses the personal evaluation of functioning, this subgroup of patients, with predominantly mild to moderate pulmonary impairments (Table II), appreciates sleep to compensate for the efforts of dyspnea.

Heavy smokers indicate less dependence on medication and treatments. Although this may seem contradictory, one might speculate that the perception of dependency of a person who is used to dependence on tobacco has been modulated. In other words, dependency as observed may not be experienced as such.

The importance of back and hip or knee symptoms for QOL in patients with IC is in concordance with Feinglass et al,<sup>20</sup> who reported on its negative predictive value for physical functioning. Nonvascular back, hip, or knee symptoms are relatively frequent in patients with IC and appear to be significant predictors for many aspects of QOL. If present in claudicants, these symptoms should not be ignored but treated. Relief of these symptoms promises a more profound influence on QOL than attempts to improve the peripheral vascular status.

No significant predictive value was seen for age. Except for the study by Barletta et al,<sup>16</sup> who found a relation between age and health status in patients with IC, this finding is concordant with most other studies. More surprising were the findings that diabetes mellitus did not have a predictive value for QOL and that hypertension appeared to be a major predictor. This may be explained by the fact that many of the risk factors and comorbidities that appeared to be of importance for the QOL in patients with IC are present in patients with diabetes as well. QOL in patients with IC and diabetes may be determined largely by the same factors. Moreover, the milder forms of diabetes can be treated with diet and lifestyle modification, with the purpose to keep glucose level within limits. This relatively small interference with daily life and the knowledge that severe complications of diabetes are not evident for 15 to 20 years after its onset may account for diabetes being not

a predictor of QOL in patients with IC. Although the severity of diabetes according to the SVS/ISCVS reporting standards<sup>3</sup> depends on the age of onset of the disease and the method of treatment, the severity of hypertension is rated according to the number of drugs needed for control. The number of antihypertension drugs needed every day directly confronts the patient with the severity of this condition, generally known to be associated with important implications for the vascular and cardiac status. The method of rating the severity of diabetes and hypertension may be responsible for the counterintuitive findings concerning the predictive value of these two variables for QOL in patients with IC.

Although convincing evidence exists that conservative treatment should be the first choice for patients with IC,<sup>21,22</sup> the increasing possibilities of minimally invasive percutaneous procedures have contributed to more active methods of treatment. Studies that focus on patients with IC have shown that percutaneous transluminal angioplasty (PTA) may produce favorable results with respect to patency, ankle-brachial indices, walking distance, and even health-related QOL in the short term.<sup>23-25</sup> However, mid-term and long-term results failed to show benefits from PTA over exercise training and sanitation of risk factors. A deterioration in QOL 12 months after a successful PTA has been attributed to the impact of increasing comorbidity.<sup>26,27</sup> These data show that risk factors and comorbidity also have an important impact on QOL in patients with IC at baseline, before treatment. Thus, successful treatment in terms of improving walking distance only will have a limited effect on patient QOL.

The clinical importance of the statistically significant predictors of QOL in this study may be questioned because of the modest strength of the association between dependent and independent variables. In the absence of an alternative method for assessment of the importance of these variables and facing the fact that patients with IC are known to have important comorbidity, the results of this study may help to direct treatment options in a way to satisfy patient needs.

In the Transatlantic Inter-Society Consensus document (TASC),<sup>6</sup> the statement is found that although the limitation in walking may be the only symptom of PAOD, the overriding issue in the management of patients with IC is their risk of development of severe and often fatal cardiovascular complications. In addition, this study indicates that the appraisal of risk factors and comorbidity in patients with IC is essential for the interpretation of QOL assessments. A challenge for those caring for patients with IC is to explain to them the importance of treating comorbidity and risk factors instead of only proposing attractive methods of palliation for their walking problem.

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