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Impaired health status and invasive treatment in peripheral arterial disease: A prospective 1-year follow-up study

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Objective: **It has been argued that health status and quality of life (QOL) should be taken into account in the treatment policy of patients with peripheral arterial disease (PAD). In cardiac patients, it has been shown that poor perceived health status is an independent predictor of mortality and hospitalization. We therefore examined (1) the role of health status, QOL, and clinical indices of disease severity as determinants of invasive treatment in patients with PAD and (2) the effect of invasive treatment on health status and QOL.**

Methods: **At their first visit, patients completed the RAND 36-item Health Survey and World Health Organization Quality of Life assessment instrument questionnaires to assess health status and QOL, respectively. During the 1-year follow-up period, data concerning hospitalization were derived from the patients' medical files. Furthermore, patients completed the RAND 36 and the World Health Organization Quality of Life assessment instrument again at 1-year follow-up. The setting was a vascular outpatient clinic of a teaching hospital in Tilburg, The Netherlands; participants were 200 consecutive patients newly diagnosed with intermittent claudication, a common expression of PAD. Diagnosis was based on history, physical examination, treadmill walking distance, and ankle-brachial pressure indices. Main outcome measures were (1) invasive treatment of PAD that took place during the 1-year follow-up, derived from the patients' medical files, and (2) health status and QOL after 1 year of follow-up.**

Results: **After 1 year of follow-up, 107 patients (53.5%) were event free, whereas 77 patients (38.5%) had been hospitalized for invasive treatment of PAD. Sixteen patients (8%) were hospitalized for other cardiovascular reasons. In a multivariate logistic regression model, age (odds ratio [OR], 0.95; 95% confidence interval [CI], 0.91-0.99; *P* = .024), pain-free walking distance (OR, 2.74; 95% CI, 1.05-7.17; *P* = .04), and physical functioning (OR, 4.46; 95% CI, 1.79-11.12; *P* = .001) were independent predictors of invasive treatment of intermittent claudication. After 1 year of follow-up, patients who were treated invasively experienced a significant improvement in their physical functioning (*P* = .004), role limitations due to emotional problems (*P* = .018), and bodily pain (*P* = .026).**

Conclusions: **Patients with poor self-reported physical functioning, limited walking distance, and a younger age were likely to be treated invasively. The physician's clinical judgment about when to intervene adequately reflects the patient's own opinion about his or her health status. Invasive treatment led to a significant improvement in patients' health status. These findings indicate the effectiveness of the strategy to include patients' perceived physical functioning into the process of clinical decision-making. (J Vasc Surg 2005;41:436-42.)**

Because of the chronic, progressive nature of atherosclerosis, self-reported health status and quality of life (QOL) have become increasingly important outcome measures for evaluating the effect of therapeutic interventions from patients' perspective.[1-3] Coronary artery disease, cerebrovascular disease, and peripheral arterial disease (PAD) are common expressions of atherosclerosis. Recently, it has been argued that health status and QOL should also be taken into account in the treatment policy of PAD patients.[4-6] In cardiac patients, it has already been shown that poor perceived health status is an independent predictor of mortality and hospitalization.[7-11] In PAD patients, preoperative health perceptions are related to surgical outcome.[12] These preliminary findings indicate the need to determine the predictive value of health status and QOL measures regarding invasive treatment of PAD.

The aim of this prospective study was twofold. First, we wanted to know whether the physician's clinical judgment in deciding when to intervene corresponds with the patient's health status and QOL. Therefore, we examined whether subjective reports of impaired health status and QOL are significant determinants of invasive treatment of PAD, in addition to clinical indices of PAD severity. Second, we wanted to know whether patients who underwent invasive treatment were better off in terms of health status and QOL. Therefore, we examined the effect of invasive treatment on patients' health status and QOL after 1 year of follow-up.

METHODS

Patients Between January 1999 and June 2000, baseline health status and QOL data were assessed in 200 consecutive patients presenting with intermittent claudication (IC; pain during ambulation), a common symptom of

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Table I. Baseline characteristics of 200 patients with intermittent claudication

Variable	*n*	*%*	*Mean (range)*	*Median*
Male/female sex	135/65	67.5/32.5		
Age (y)			62.8 (42-83)	
Unilateral/bilateral disease	130/70	65/35		
ABPI			0.62 (0.24-0.95)	
PFWD (m)			100.2 (0-1000)	80
MWD (m)			398.4 (40-1000)	245
Mild claudication†	37	18.5		
Moderate claudication‡	81	40.5		
Severe claudication§	82	41		
Diabetes mellitus	32	16		
Tobacco use	132	66		
Hypertension	94	47		
Hyperlipidemia	106	53		
Cardiac status	64	32		
Carotid status	28	14		
Renal status	8	4		
Pulmonary status	20	10		

ABPI, Ankle-brachial pressure index; *PFWD,* pain-free treadmill walking distance; *MWD,* maximum treadmill walking distance.
†Mild claudication: completes modified treadmill exercise;* ankle pressure after exercise is >50 mmHg but at least 20 mm Hg lower than resting value.
‡Moderate claudication: between mild and severe.
§Severe claudication: cannot complete modified treadmill exercise, and ankle pressure after exercise is <50 mm Hg.* 3.5 km/h on a 5% incline with a maximum of 1000 m.
*The Society for Vascular Surgery/North American Chapter of the International Society for Cardiovascular Surgery grading system[13] for cardiovascular risk factors is as follows (all risk factors were recoded into absent [0] or present [1, 2, or 3], except for smoking [absent, 0 or 1; present, 2 or 3]).
Diabetes: 0, none; 1, adult onset, controlled by diet or oral agents; 2, adult onset, insulin controlled; 3, juvenile onset.
Smoking: 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 one pack per day; 3, current, more than one pack per day.
Hypertension: 0, none, diastolic pressure usually lower than 90 mm Hg; 1, controlled with single drug; 2, controlled with two drugs; 3, requires more than two drugs or uncontrolled.
Hyperlipidemia: 0, cholesterol (low-density lipoprotein and total) and triglycerides within normal limits for age; 1, mild increase, controllable by diet; 2, requiring strict dietary control; 3, requiring dietary and drug control.
Cardiac status: 0, asymptomatic, normal electrocardiogram; 1, asymptomatic, 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 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, history of congestive heart failure that is now well compensated; 3, any one of unstable angina, symptomatic or poorly controlled ectopy or arrhythmia, poorly compensated or recurrent congestive heart failure, ejection fracture less than 25%, 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 increase in response to intravenous medication, hydration, or contrast media): 0, no known renal disease, normal serum creatinine; 1, moderately increased creatinine level, as high as 2.4 mg/dL; 2, creatinine level, 2.5 to 5.9 mg/dL; 3, creatinine >6.0 mg/dL, or on dialysis or with kidney transplant.
Pulmonary status: 0, asymptomatic, normal chest x-ray film, pulmonary function test within 20% of predicted; 1, asymptomatic or mild dyspnea on exertion, mild chronic parenchymal x-ray changes, pulmonary function test 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, P_{CO_2} greater than 45 mm Hg, supplemental oxygen use medically necessary, or pulmonary hypertension.

PAD, at the vascular outpatient clinic of the department of surgery at the St Elisabeth Hospital in Tilburg, The Netherlands. Patients were referred by their general practitioners for evaluation and diagnosis. All patients were newly diagnosed with IC on the basis of history, physical examination, treadmill walking, and ankle-brachial pressure indices (ABPI). IC was classified as mild, moderate, or severe according to the Society for Vascular Surgery/North American Chapter of the International Society for Cardiovascular Surgery.[13] The characteristics of the 200 participating patients are shown in Table I. The mean age of the total study population was 62.8 years (range, 42-83 years). Detailed descriptions of the study population have been published elsewhere.[6] In brief, IC was suspected in 215 patients and could be confirmed in 207 patients. Of these patients, seven refused participation or were not able to participate. After 1 year, the patients were asked to complete health status and QOL questionnaires again. Of the entire study group, 156 patients (78%) filled in the questionnaires after 1 year. Of the invasively treated patients, 22% refused to complete the questionnaires at follow-up, vs 23% of the event-free patients. No differences between the responders and the nonresponders were found in age, ABPI, pain-free treadmill walking distance (PFWD), maximum treadmill walking distance (MWD), cardiovascular risk factors, or baseline health status and QOL data. The study was approved by the local ethics committee, and all patients signed written informed consent.

Predictors

Disease severity. In all patients, the PFWD, MWD, ABPI were measured as indices of severity of PAD. The ABPI is defined as the ratio of the ankle systolic blood pressure to the brachial artery systolic blood pressure and has a normal resting value of approximately 1.0.[14] A value of <0.9 has been shown to be highly sensitive to detect PAD.[5]

Cardiovascular risk factors. Smoking, hyperlipidemia, diabetes mellitus, hypertension, and cardiac, carotid, renal, and pulmonary status were registered at baseline according to the Society for Vascular Surgery/North American Chapter of the International Society for Cardiovascular Surgery criteria.[13] In addition, the presence of back, knee, and hip symptoms unrelated to PAD was also recorded.

Health status. The RAND 36-Item Health Survey (RAND 36)[15,16] is a 36-item generic health status measure that assesses eight concepts: (1) physical functioning, (2) social functioning, (3) role limitations due to physical problems, (4) role limitations due to emotional problems, (5) mental health, (6) vitality, (7) bodily pain, and (8) general health perception. The RAND 36 and the Medical Outcomes Study Short Form-36[17] are similar health status measures; however, concerning the dimensions bodily pain and general health perception, the scoring is somewhat different.[15] The RAND 36 has good reliability and validity.[18]

Quality of life. The World Health Organization QOL assessment instrument-100 (WHOQOL-100) is a generic QOL measure that consists of 100 questions assessing QOL with 24 facets in 6 domains.[19,20] In this study, an abbreviated version of the WHOQOL-100 was used that had previously been reduced for the specific patient population.[6] This version included three QOL-domains: (1) physical health, (2) level of independence, and (3) social relationships.[6] The WHOQOL-100 has good reliability and validity[20] and is sensitive to treatment-related change.[21]

Invasive treatment of PAD

Invasive treatment of PAD was used as an end point in this study. Although the general treatment policy for patients with IC is merely conservative—ie, 3 months of unsupervised exercise training, advice to quit smoking, and antiplatelet medication—this does not always lead to significant improvements in (pain-free) walking distance. Invasive therapy is then considered by the vascular surgeon. However, in case of severe impairment, or when conservative treatment is not expected to improve the patient's functioning, invasive treatment is considered sooner. During the 1-year follow up period, hospital admission was prospectively examined by using the patient records from the participating hospital. All patients who underwent invasive treatment were hospitalized. Invasive procedures were performed in the St Elisabeth Hospital. If a patient were admitted to another hospital or abroad, this information would be obtained from the patient records of the St Elisabeth Hospital. Patients who were not hospitalized at all during the 1-year follow-up period were considered to be event free. Patients were excluded if they were hospitalized for cardiovascular reasons other than invasive treatment of PAD (Table II). Furthermore, it was determined whether hospitalization was early or late. Patients were classified as being hospitalized early when invasive treatment occurred within 3 months after inclusion. They were classified as being hospitalized late if invasive treatment took place later than 3 months after inclusion. All 200 patients were followed up throughout the study period with regard to hospital admission.

Table II. Reasons for invasive treatment of IC (n = 77) and other cardiovascular-related hospitalizations (n = 16) in patients with intermittent claudication during 1 year of follow-up

Variable	*n*
Invasive treatment of IC	
Percutaneous transluminal angioplasty	56
Bypass	13
Percutaneous transluminal angioplasty and bypass	4
Endarterectomy	2
Amputation	2
Total	77
Other	
Myocardial infarction	4
Angina pectoris	1
Cardioversion	3
Coronary artery bypass grafting	1
Heart failure	2
Atrial fibrillation	1
Angina pectoris and myocardial infarction	1
Angina pectoris and endarterectomy (aorta)	1
Transient ischemic attack	1
Percutaneous transluminal angioplasty (renal artery)	1
Total	16
Total hospitalizations	93

IC, Intermittent claudication.

Statistical analyses

Univariate logistic regression analyses were used to examine the predictive value of clinical variables, health status, and QOL with regard to invasive treatment for IC. Therefore, ABPI, PFWD, and MWD were dichotomized into low scores (first quartile) vs average or high scores. This led to a cutoff score of 0.51 for ABPI, which is in accordance with previous studies.[14,22] Cutoff scores for PFWD and MWD were 40 and 130 m, respectively. In addition, the scores on the subscales of the RAND 36 and WHOQOL questionnaire were divided into low scores (first quartile) vs average or high scores. For example, scores on the RAND physical functioning scale were considered low if ≤35 (first quartile). Healthy elderly patients (55-64 years) have a mean score of 72.7 on this scale; this indicates far better health status.[16] The cardiovascular risk factors were dichotomized to absent or present. Significant

Table III. Independent predictors of invasive treatment of IC using multivariate logistic regression analysis

Multivariate predictors of invasive treatment for IC	*OR*	*95% CI*	*P value*
Poor physical functioning	4.46	1.79-11.12	.001
PFWD ≤40 m	2.74	1.05-7.17	.040
ABPI ≤0.51	0.96	0.39-2.33	.924
Smoking	1.19	0.47-2.99	.716
Covariates			
Age*	0.95	0.91-0.99	.024
Sex	0.68	0.30-1.56	.366

IC, Intermittent claudication; *OR,* odds ratio; *CI,* confidence interval; *PFWD,* pain-free treadmill walking distance; *ABPI,* ankle-brachial pressure index.
*Age was entered as a continuous variable.

health status and QOL predictors derived from the previous analyses, age, sex, ABPI, and PFWD were included in multivariate logistic regression analyses (forward conditional method), with invasive treatment as the end point. The final multivariate logistic regression analysis (enter method) included age, sex, ABPI, PFWD, and the significant health status and QOL predictors. This model was tested separately for patients who were treated early and late. The event-free patients were used as the reference group. Analyses of variance for repeated measures were used to compare groups (invasively treated vs event free) over time on the eight subscales of the RAND 36 and the three QOL domains. Student *t* tests were performed to compare invasively treated patients with event-free patients on health status and QOL at 1 year of follow-up. All statistical analyses were performed with SPSS version 11.5 (SPSS Inc, Chicago, Ill).

RESULTS

After 1 year of follow-up, 77 patients (38.5%) had been hospitalized for invasive treatment of PAD (Table II). Of these patients, 11 had progressed to rest pain or pain at night, whereas 3 patients were treated for tissue loss. One hundred seven patients (53.5%) were event free. Furthermore, 16 patients (8%) were hospitalized for other cardiovascular reasons, such as coronary artery bypass grafting (Table II).

Disease severity and invasive treatment. Using univariate regression analyses, limited PFWD was found to be a predictor of invasive treatment, with an odds ratio (OR) of 3.51 (95% confidence interval [CI], 1.62-7.60; *P* = .001). Invasively treated patients had the shortest PFWD (mean, 86.8 m), whereas event-free patients had a mean PFWD of 113.7 m. Low ABPI and short MWD were not related to invasive treatment during follow-up. In addition, smoking (OR, 2.04; 95% CI, 1.06-3.92; *P* = .034) was the only cardiovascular risk factor that predicted invasive treatment in patients with IC. Patients who were treated invasively were more likely to be smokers as compared with event-free patients. Back, knee, and hip symptoms (unrelated to PAD) were unrelated to invasive treatment.

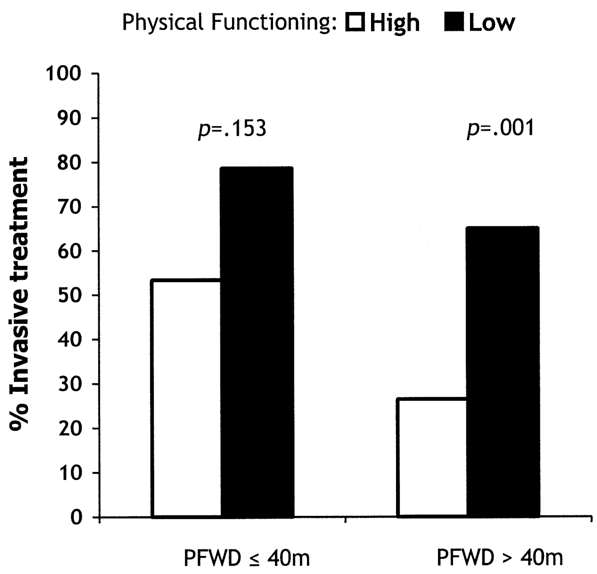

Fig 1. Invasive treatment as a function of pain-free treadmill walking distance *(PFWD)* and RAND 36-item Health Survey subscale physical functioning at baseline.

Health status, QOL, and invasive treatment. Poor physical functioning (OR, 4.32; 95% CI, 2.01-9.29; *P* = .001), role limitations due to emotional problems (OR, 2.09; 95% CI, 1.02-4.30; *P* = .045), and poor mental health (OR, 2.02; 95% CI, 1.01-4.02; *P* = .046) were univariate health status predictors of invasive treatment. Concerning QOL, poor physical health (OR, 2.09; 95% CI, 1.06-4.13; *P* = .034) was a predictor of invasive treatment. Multivariate logistic regression analysis, including the significant health status and QOL predictors, indicated that RAND 36 physical functioning remained as the only independent predictor of invasive treatment of IC (OR, 4.48; 95% CI, 1.98-0.12; P = .001).

Independent predictors of invasive treatment. The final multivariate logistic regression analysis, with invasive treatment as the end point, included age, sex, PFWD, ABPI, smoking, and the RAND 36 domain physical functioning. Because the previous univariate analyses showed that none of the other cardiovascular risk factors or the presence of back, knee, and hip symptoms (unrelated to PAD) could predict invasive treatment in patients with IC, it was decided to exclude these variables from the final model. Results showed that younger age, limited PFWD, and poor physical functioning were independent predictors of invasive treatment of IC (Table III).

The previous analysis yielded both an index of disease severity and a measure of health status as determinants of invasive treatment. Therefore, patients were classified according to their scores on PFWD and the RAND 36 scale physical functioning (high vs low). This led to four patient subgroups (Fig 1). The percentages of invasive treatment were highest in patients with poor physical functioning, both with and without limited walking distance. In patients with a PFWD greater than 40 m, the percentages of hospitalization differed significantly between patients with good and poor physical functioning.

Early vs late invasive treatment. Within the group of invasively treated patients, 45 patients (58.4%) were hospitalized early. Thirty-two patients (41.6%) were hospitalized after the 3-month period after inclusion. To determine whether poor health status predicted both early and late invasive treatment, the final regression model was tested separately for patients who were hospitalized early and patients who were hospitalized late. Younger age (OR, 0.95; 95% CI, 0.90-0.99; P = .029) and poor physical functioning (OR, 4.6; 95% CI, 1.64-12.97; P = .004) were both independent predictors of invasive treatment within 3 months after inclusion, whereas short PFWD (OR, 4.8; 95% CI, 1.32-17.03; P = .017) and poor physical functioning (OR, 4.7; 95% CI, 1.30-16.98; P = .018) predicted late invasive treatment.

Effect of invasive treatment on health status and QOL. Regarding health status, there was a general significant improvement for all patients in physical functioning ($P < .0001$), role limitations due to physical problems (P = .013), and bodily pain ($P < .0001$, indicating less pain) between 0 and 12 months. The significant interaction effect for time × invasive treatment indicated that patients who were treated invasively experienced a significantly greater improvement in their physical functioning (P = .004), role limitations due to emotional problems (P = .018), and bodily pain (P = .026), as compared with patients who had conservative treatment (Fig 2).

Concerning QOL, a general improvement was found for all patients in physical health (P = .010) and level of independence (P = .016), whereas social relationships had deteriorated (P = .001) between 0 and 12 months. No significant effect was found for invasive treatment regarding the domains of the WHOQOL. At 12 months of follow-up, no significant differences remained in health status or QOL between invasively treated patients and event-free patients (all P values were >.22).

DISCUSSION

In this study, health status and QOL were examined in relation to invasive treatment in patients with PAD. The results demonstrated that IC patients with poor physical functioning (RAND 36), a short PFWD, and a younger age were likely to be treated invasively. It is important to note that invasive treatment led to significant improvements in patients' health status at 1 year of follow-up. These findings indicate the effectiveness of the strategy of including patients' perceived physical functioning into the process of clinical decision making.

Given the risk of possible complications and increasing health-care costs, invasive treatment for disabling IC remains controversial.[23] IC is generally a benign condition[24] that mostly requires conservative treatment and modification of risk factors.[25,26] However, previous studies have shown that IC causes significant impairments in health status and QOL.[27,28] It has been suggested that invasive treatment not only should be based on PFWD, but may also be considered when symptoms interfere with a patient's lifestyle or occupation,[24] thus causing poor QOL.[5,29,30] Patients who underwent invasive treatment were better off in terms of health status than patients who were treated conservatively, indicating that including self-reported health status in the decision to intervene was an effective strategy.

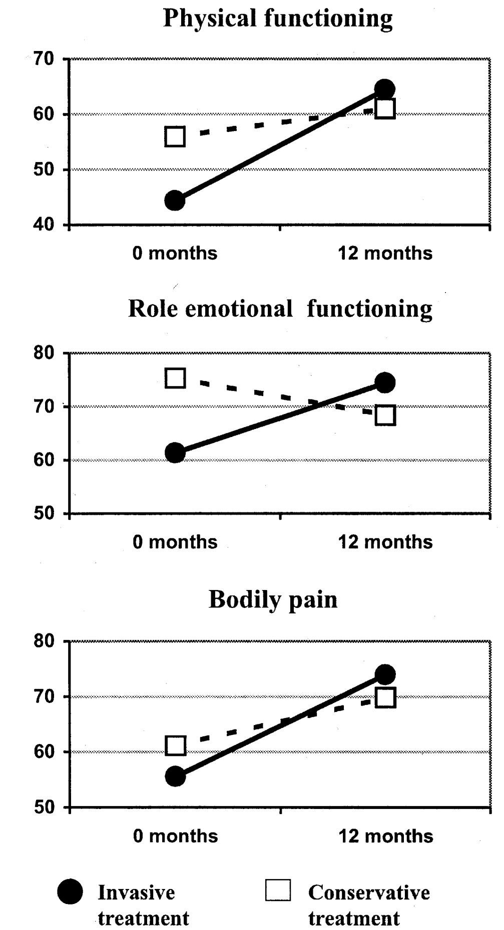

Fig 2. Health status at 0 and 12 months, stratified by invasive treatment.

A younger age and poor physical functioning, as reported by the patients themselves, were independent predictors of invasive treatment within 3 months. Younger claudicants often have more demanding lifestyles than older patients; invasive treatment could therefore be more suitable for these patients. Information regarding self-reported physical functioning could be very useful for vascular surgeons when deciding which patients need invasive treatment.

After 3 months, impaired PFWD and poor physical functioning were the main reasons for invasive treatment. This may indicate that some patients were treated conservatively at first but that, because of their impaired PFWD and their poor physical functioning, it was decided to perform invasive treatment after all. Although PFWD was a strong predictor, none of the other clinical variables, such as ABPI or MWD, could predict invasive treatment. Previous studies[31,32] have shown that a low ABPI was associated with cardiovascular mortality and morbidity in patients with PAD. In this study, only a few patients were hospitalized because of cardiovascular reasons other than invasive treatment of PAD; it was therefore not possible to determine the predictive value of ABPI regarding cardiovascular morbidity as a secondary end point. This could be due to the relatively short 1-year follow-up period, which is also one of the limitations of this study. A longer follow-up period would be better for obtaining more information on morbidity and mortality. Furthermore, McDermott et al[32] found that patients with an ABPI $\leq$0.3, indicating critical limb ischemia, had significantly poorer survival than patients with a higher ABPI. In this study, only patients with IC were included, which could make generalization of the results to other forms of PAD difficult. Because patients with chronic critical limb ischemia are often elderly and frail, their long-term survival is worse than in patients with IC.[33]

The findings of this study have implications for further clinical research and practice. Recent guidelines[2,5] emphasize the importance of assessing outcomes from patients' perspective. It is also argued that information regarding QOL and health status should be included in treatment policy. The findings from this study support this notion. Patients who reported low physical functioning were more likely to be treated invasively. It is therefore important to integrate patient-reported health status and QOL data with the clinical care of patients with PAD. Although it has previously been stated that surgeons predict the QOL of IC patients less accurately than patients do themselves,[29] this study showed that the physician's decision about when to intervene accurately reflects the patient's own opinion about his or her health status. Moreover, invasive treatment had a positive effect on patients' health status. For example, patients' physical functioning improved by more than 20 points after invasive treatment. By using objective patient-reported health status data in the management of PAD and subsequently detecting the patients who report low physical functioning, outcomes could be improved, and more accurate treatment options could be provided for this patient group in the future.

This study showed that physical functioning was an independent predictor of invasive treatment. The health status subscale physical functioning assesses functional limitations caused by disease. It is a measure of a patient's functioning. QOL assesses the patient's own evaluation of his or her physical functioning. In other words: is a patient satisfied or dissatisfied with his or her level of physical functioning? Only the health status subscale physical functioning, and not the QOL subscale, predicted invasive treatment in multivariate analyses. Therefore, we can conclude that the functional limitations caused by disease are the main determinants of intervention. The reporting of physical symptoms and impairments (health status)—not patients' perception of the symptoms and impairments (QOL)—determined invasive treatment.

In conclusion, these findings demonstrate that the physician's clinical judgment about when to intervene adequately reflects the patient's health status. Poor self-reported physical functioning predicted invasive treatment in patients with IC, even after controlling for clinical variables. The physician's decision about when to intervene is thus not based solely on clinical indicators such as PFWD or a younger age, but it also reflects the patient's own opinion about his or her health status. This may be an effective strategy, because invasive treatment led to significant improvements in patients' health status at 1 year of follow-up. Hence, this study provides evidence for the predictive value of perceived physical functioning in addition to traditional clinical indicators with regard to invasive treatment of IC. Self-reported physical functioning should be assessed in patients with PAD, in addition to traditional clinical measures.

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