Poor health-related quality of life in patients with peripheral arterial disease
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Peripheral arterial disease (PAD) is associated with cardiovascular mortality and impaired functional impairment in PAD patients. Although indexes of disease severity such as ankle-brachial index (ABI) and absolute claudication distance (ACD) may predict functional impairment in PAD patients, adjusting for ABI and ACD, invasive treatment and type D personality independently predicted all HRQOL domains, except for Physical Functioning. Overall, type D personality predicted increased risk for both poor General Health (odds ratio [OR], 3.70; 95% confidence interval [CI], 1.69 to 8.08; \( P = .001 \)) and poor Mental Health (OR, 6.01; 95% CI, 2.44 to 14.79, \( P < .0001 \)) at 1 year after the PAD diagnosis.

Conclusion: Despite an overall improvement, type D patients remained more impaired in 1-year HRQOL than other patients, adjusting for ABI and ACD. Type D personality is a psychologic risk factor that predicts poor patient-based outcomes in PAD and should be taken into account when HRQOL in PAD is evaluated. (J Vasc Surg 2007;46:507-12.)

**METHODS**

**Patients.** Between September 2001 and March 2004, 257 consecutive patients with PAD were referred to the vascular outpatient clinic of the Department of Surgery at the St. Elisabeth Hospital in Tilburg, The Netherlands. All patients are included in this study, and none were excluded. All patients completed the DS14 type D personality and RAND-36 questionnaires (all self-report). Clinical data were derived from patients’ medical files and included ankle-brachial index (ABI), initial and absolute claudication distance (ICD, ACD), and invasive treatment. The main outcome was HRQOL at 1-year follow-up.

Results: HRQOL improved between baseline and follow-up, and invasive treatment led to significant improvements in the subscales Physical Functioning (\( P = .005 \)) and Pain (\( P = .003 \)). Type D patients were severely impaired in their HRQOL compared with other patients at baseline (\( P < .01 \)) and at follow-up (\( P < .05 \)). ABI and ACD also predicted HRQOL at follow-up. After adjusting for ABI and ACD, invasive treatment and type D personality independently predicted all HRQOL domains, except for Physical Functioning. Overall, type D personality predicted increased risk for both poor General Health (odds ratio [OR], 3.70; 95% confidence interval [CI], 1.69 to 8.08; \( P = .001 \)) and poor Mental Health (OR, 6.01; 95% CI, 2.44 to 14.79, \( P < .0001 \)) at 1 year after the PAD diagnosis.

Conclusion: Despite an overall improvement, type D patients remained more impaired in 1-year HRQOL than other patients, adjusting for ABI and ACD. Type D personality is a psychologic risk factor that predicts poor patient-based outcomes in PAD and should be taken into account when HRQOL in PAD is evaluated. (J Vasc Surg 2007;46:507-12.)
patients were newly diagnosed with intermittent claudication from their history, physical examination, ABI, and treadmill-walking distance, and visited the vascular surgeon for the first time. Six patients were excluded from the study because of cognitive impairment (n = 2), recent myocardial infarction, visual problems, illness (influenza), and participation in another study. Of the remaining 251 patients, 203 (81%) agreed to participate and completed two questionnaires on type D personality and HRQOL. No significant differences were found in age, sex, ABI, ACD, initial claudication distance (ICD), cardiovascular risk factors, or comorbidity between participants and nonparticipants. The mean age was 64.5 years, and 63% were men. During the 1-year follow-up period, four patients (2%) died and seven were hospitalized for other reasons than invasive treatment of PAD. To prevent confounding of the results, these patients were excluded from follow-up analyses, leaving 192 patients for further analyses. After 1 year, the patients were asked to complete the HRQOL questionnaire again and 167 (87%) agreed. The study was approved by the Ethics Committee of the St. Elisabeth Hospital, and all patients signed informed consent.

### Severity and invasive treatment of peripheral arterial disease

The ICD, ACD, and ABI were measured in all patients as indices of PAD severity. The ABI is defined as the ratio of the ankle systolic blood pressure to the brachial artery systolic blood pressure and has a normal range of 0.9 to 1.3. A value of <0.90 is 95% sensitive to detect PAD and has been shown to be a strong predictor of cardiovascular disease and mortality. Treadmill-walking tests were performed to determine ACD and ICD. Treadmill tests are widely used to obtain objective information on walking ability of patients with PAD.

During the 1-year follow-up period, hospital admission was examined using the patient records from the participating hospital. All patients who underwent invasive treatment for PAD (either endovascular or surgical) were hospitalized. Invasive procedures were done in the St. Elisabeth Hospital. Information for patients who had been admitted to another hospital was obtained from the patient records. Patients who were not hospitalized at all during the 1-year follow-up period were considered to be event free.

Conservative treatment consisted of 3 months of unsupervised exercise training, the advice to quit smoking, and antiplatelet medication. All patients were followed up throughout the study period for hospital admission. Patients were excluded from follow-up analyses if they were hospitalized for other reasons than invasive treatment of PAD, such as coronary artery bypass grafting.

According to The Society for Vascular Surgery (SVS) and the North American Chapter of The International Society for Cardiovascular Surgery (ISCVS), recommended standards, comorbid medical conditions diabetes mellitus, smoking, hypertension, hyperlipidemia, and cardiac, carotid, renal and pulmonary disease were assessed at baseline in all patients.

### Type D personality

The 14-item Type D Scale-14 (DS14) was used to measure type D personality. All questions consist of a 5-point Likert-type scale (range, 0 to 4). The DS14 consists of two subscales that measure negative affectivity (the tendency to experience negative emotions) and social inhibition (the tendency to inhibit the expression of emotions in social interaction). High scores (≥10) on both scales indicate type D personality. Both subscales have good reliability; Cronbach α is .88 and .86, respectively. Type D personality is not mood-state dependent but remains stable over time. In cardiac patients, type D is an independent predictor of adverse outcomes. The role of type D in PAD is not clear yet, however. In the present study, type D personality was measured in all patients at baseline.

#### Health-related quality of life

HRQOL was measured at baseline and at 12 months of follow-up using the 36-item RAND-36 item health survey (RAND Health Communications, Santa Monica, Calif). The RAND-36 assesses eight concepts: (1) Physical Functioning, (2) Social Functioning, (3) role limitations due to physical problems (Role-Physical); (4) role limitations due to emotional problems (Role-Emotional); (5) Mental Health, (6) Vitality, (7) Bodily Pain, and (8) General Health Perception. The RAND-36 has good reliability and validity.

### Statistical analyses

Differences between patients were examined with χ² tests (dichotomous variables) and the Student t tests (continuous variables). Analyses of variance with repeated measures were used to compare between-group differences (type D vs nontype D, and invasive vs conservative treatment) over time on HRQOL. ACD and ICD were included in a regression analysis to determine which measure of walking distance was the best predictor of HRQOL. Stepwise multiple regression analyses were used to examine the influence of demographics (block 1), PAD severity, invasive treatment, and comorbidity (block 2), and type D personality (block 3) on the eight HRQOL domains at the 1-year follow-up. Multivariate logistic regression analyses (enter method) were conducted to determine the impact of type D personality on poor physical and psychologic HRQOL, adjusting for age, sex, ABI and ACD. For this purpose, the RAND-36 domains Mental Health and General Health were recoded into discrete variables, and the lowest quartile indicated poor HRQOL. All statistical analyses were performed with SPSS 12.0 software (SPSS Inc, Chicago, Ill).

### RESULTS

#### Changes in health-related quality of life

Between baseline and 1-year follow-up, there was an overall improvement in HRQOL. Patients experienced significant improvements in Physical Functioning and Bodily Pain (P < .0001); Social Functioning, Role-Physical, Role-Emotional, and Vitality (P < .01); and Mental Health (P < .05). Scores for General Health, however, did not improve significantly (P = .077).

During the follow-up period, 93 patients (48%) were treated invasively for their PAD condition, and 99 patients received conservative (noninvasive) treatment. Modes of invasive treatment were percutaneous transluminal angio-
vascular risk factors, or comorbidity (Table I). Type D demographics, disease severity (ABI, ICD, ACD), cardio-
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life.

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invasive treatment did not influence the other
aspects of HRQOL.

Type D personality and health-related quality of
Thirty-four percent of the PAD patients were classi-
classified as type D. No significant differences were noted be-
between type D patients and the other PAD patients in
demographics, disease severity (ABI, ICD, ACD), cardio-
vascular risk factors, or comorbidity (Table I). Type D
patients were, however, more impaired in their HRQOL
than the other PAD patients at baseline (all
A

At 1-year follow-up, HRQOL remained significantly
more impaired in type D patients compared with nontype D
patients (P < .05), except for Physical Functioning (P = .454).
The interaction effect for time \times personality was
nonsignificant, indicating a stable adverse influence of type
D personality on HRQOL over time (Fig 1).

Predictors of health-related quality of life at 1-year
follow-up. Several baseline characteristics predicted HRQOL
at 1-year follow-up (Table II). With regard to disease severity,
a longer ACD was an independent predictor of better
HRQOL on all domains, whereas ABI predicted Mental
Health, Vitality, and General Health. In addition, invasive
treatment for PAD was an independent predictor of the
HRQOL domain Bodily Pain. Patients who were treated
invasively for their PAD reported less pain than patients
with conservative treatment (Table II).

After adjusting for all demographic and clinical vari-
ables, type D personality remained as an independent pre-
dictor of seven of eight HRQOL domains (Table II). In
general, type D patients had significantly poorer HRQOL
than other patients (Table II). Both disease severity and
type D personality independently predicted the 1-year level
of Social Functioning, Role-Physical, Mental Health, Vital-
ity, and General Health Perception. Invasive treatment or
the presence of risk factors did not influence these HRQOL
domains. However, Bodily Pain was affected by a combi-
nation of predictors, consisting of PAD severity, invasive
treatment, comorbidity, and type D personality.

Type D and impaired health-related quality of life
at 1-year follow-up. We then examined which subgroup
of patients was at increased risk of poor physical and psy-
chologic HRQOL. Of note, 46% (26/57) of type D patients
experienced a poor General Health versus only 18%
(20/110) of the nontype D patients (P < .0001). Likewise,
42% (24/57) of the type D patients had a poor Mental
Health score at follow-up vs 11% (12/110) of the nontype
D patients (P < .0001). Multivariable logistic regression
analyses showed that type D PAD patients were at a sub-
stantially increased risk for both poor General Health (odds
ratio [OR], 3.70; 95% confidence interval [CI], 1.69 to

<table>
<thead>
<tr>
<th>Characteristics*</th>
<th>Type D, % (n = 69, 34%)</th>
<th>Nontype D, % (n = 134, 66%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>62.7 ± 9.9</td>
<td>65.5 ± 9.8</td>
<td>.060</td>
</tr>
<tr>
<td>Male sex</td>
<td>60</td>
<td>66</td>
<td>.400</td>
</tr>
<tr>
<td>Disease severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ankle-brachial index</td>
<td>0.65 ± 0.16</td>
<td>0.61 ± 0.16</td>
<td>.098</td>
</tr>
<tr>
<td>Claudication distance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial (meters)</td>
<td>101 ± 87</td>
<td>122 ± 165</td>
<td>.329</td>
</tr>
<tr>
<td>Absolute (meters)</td>
<td>345.4 ± 289</td>
<td>385 ± 338</td>
<td>.417</td>
</tr>
<tr>
<td>Clinical factors</td>
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<tr>
<td>Diabetes mellitus</td>
<td>23</td>
<td>18</td>
<td>.437</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>62</td>
<td>49</td>
<td>.084</td>
</tr>
<tr>
<td>Hypertension</td>
<td>49</td>
<td>43</td>
<td>.390</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>55</td>
<td>52</td>
<td>.649</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>35</td>
<td>28</td>
<td>.299</td>
</tr>
<tr>
<td>Carotid disease</td>
<td>13</td>
<td>8</td>
<td>.263</td>
</tr>
<tr>
<td>Renal disease</td>
<td>6</td>
<td>3</td>
<td>.388</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>7</td>
<td>9</td>
<td>.700</td>
</tr>
</tbody>
</table>

*Categoric data are presented as percentages; continuous data are presented as mean ± standard deviation.

Fig: Health-related quality of life at baseline and at 1-year follow-up stratified by type D personality (solid circles) and nontype D personality (open squares). Univariate analysis was by analysis of variance for repeated measures. A higher score indicates better health status, with a high score on Bodily Pain representing the absence of pain.
DISCUSSION

Patients who were treated invasively for PAD improved in their physical functioning and pain. However, despite a general improvement in HRQOL, type D patients still had a significantly poorer HRQOL after 1 year of follow-up.

Accordingly, invasive treatment (positively) and type D personality (negatively) were both independent predictors of HRQOL, adjusting for ABI, ACD, and comorbidity.

HRQOL has become an important patient-based outcome measure in cardiovascular research.25,26 Impaired HRQOL has been shown to be an independent predictor of mortality and hospitalization in cardiac patients.26-28 Similarly, our previous research in another sample of PAD patients showed that impaired HRQOL predicted invasive treatment in these patients.29 However, most of the cardiovascular research on HRQOL has been conducted in patients with coronary artery disease or heart failure. Less is known about HRQOL in PAD patients and the way treatment affects this important patient-based outcome, even though these patients undergo many procedures. Therefore, identifying PAD patients at increased risk of poor HRQOL is very important.

The results of the present study confirm previous observations that walking-induced pain is associated with severe impairments in HRQOL.7,30 We found that ACD independently predicted HRQOL, in that patients who were less impaired in their walking distance reported better HRQOL. Consistent with our previous findings in another sample of PAD patients, invasive treatment did improve HRQOL in the present study29; however, these treatment-related improvements in Physical Functioning and Bodily Pain did not affect the other HRQOL domains. Hence, invasive treatment of PAD is associated with improvements in physical HRQOL, but other factors that may influence HRQOL are not fully understood.9

Table II. Predictors of health-related quality of life at 1-year follow-up*

<table>
<thead>
<tr>
<th>RAND-36 Domains</th>
<th>Predictors</th>
<th>R²</th>
<th>Standardized B</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>ACD</td>
<td>0.246</td>
<td>0.265</td>
<td>2.73†</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>ACD</td>
<td>0.242</td>
<td>−0.367</td>
<td>3.24‡</td>
</tr>
<tr>
<td>Role-Physical Problems</td>
<td>Type D personality</td>
<td>0.271</td>
<td>−0.287</td>
<td>3.48‡</td>
</tr>
<tr>
<td>Role-Emotional Problems</td>
<td>ACD</td>
<td>0.200</td>
<td>−0.240</td>
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</tr>
<tr>
<td>Mental Health</td>
<td>ABI</td>
<td>0.207</td>
<td>−0.188</td>
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<tr>
<td>Vitality</td>
<td>ACD</td>
<td>0.274</td>
<td>−0.404</td>
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<td>ABI</td>
<td>0.276</td>
<td>−0.160</td>
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ACD, Absolute claudication distance; ABI, ankle-brachial index.
*Analysis based on stepwise multivariate regression analyses with demographics as block 1; disease severity, risk factors, and invasive treatment as block 2; and type D personality as block 3.
†Significant at P < .01.
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Table III. Independent predictors of impaired health-related quality of life using multivariate logistic regression analysis

<table>
<thead>
<tr>
<th>Impaired HRQOL</th>
<th>Multivariate predictors</th>
<th>OR</th>
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<tbody>
<tr>
<td>Poor general health</td>
<td>Age*</td>
<td>1.02</td>
<td>0.97-1.06</td>
<td>.444</td>
</tr>
<tr>
<td>Male sex</td>
<td>2.12</td>
<td>0.90-5.01</td>
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<td>ABI*</td>
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<td>ACD†</td>
<td>0.77</td>
<td>0.65-0.92</td>
<td>.003</td>
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<td>3.65</td>
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<tr>
<td>Poor mental health</td>
<td>Age*</td>
<td>0.99</td>
<td>0.95-1.04</td>
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<td>Type D personality</td>
<td>5.97</td>
<td>2.43-14.71</td>
<td>&lt;.0001</td>
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HRQOL, Health-related quality of life; OR, odds ratio; CI, confidence interval; ABI, ankle-brachial index; ACD, absolute claudication distance.
*Age and ankle-brachial index were entered as continuous variables.
†Absolute claudication distance was entered as a discrete variable with increasing intervals of 100 meters.

8.08; P = .001) and poor Mental Health (OR, 6.01; 95% CI, 2.44 to 14.79; P < .0001) after adjusting for demographics and disease severity (Table III).

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*Age and ankle-brachial index were entered as continuous variables.
†Absolute claudication distance was entered as a discrete variable with increasing intervals of 100 meters.
These findings indicate the need to study HRQOL in subgroups of PAD patients. Traditionally, age and sex have been included in research on PAD. Women with PAD may have greater walking impairment, a higher prevalence of leg pain, and poorer functioning than men with PAD, and PAD severity has been associated with QOL among older patients. In the present study, age and sex were not statistically significantly related to HRQOL at follow-up. However, other individual difference variables may affect the clinical course of PAD patients.

We found that type D personality had a major effect on HRQOL in PAD. This is in line with previous studies showing that type D predicted poor HRQOL and QOL after invasive treatment, including coronary artery bypass surgery, percutaneous coronary intervention, and heart transplantation. This adverse type D effect was also observed in cardiac rehabilitation and heart failure patients. Of importance are the findings of the present study that indicate the predictive value of type D personality regarding poor HRQOL in PAD over time. Type D patients reported significantly poorer HRQOL than nontype D patients across both baseline and follow-up assessments, and despite the relative improvement in HRQOL over time, type D patients still had a significantly impaired HRQOL at 1-year follow-up compared with the other patients.

This study has some limitations. First, patients with ischemic rest pain or tissue loss were not included. By including patients with critical limb ischemia, a more heterogeneous patient group could be obtained, possibly leading to a larger effect of ABI on HRQOL.

Second, 1 year may be a relatively short period to evaluate changes in HRQOL. However, the effect of type D personality on HRQOL was stable and in accordance with previous studies that used follow-up periods of 5 to 10 years.

Third, we did not assess type D personality at 1-year follow-up. Although type D remains stable over time in cardiac patients, future studies should look at the stability of type D in PAD.

Finally, ABI and walking impairment were not examined at follow-up. Future research should examine the relationship between patient-based outcomes and clinical improvement after treatment.

CONCLUSION

The findings of the present study have implications for further clinical research and practice. Recent guidelines emphasize the importance of assessing outcomes from the patient’s perspective. It is also argued that information on HRQOL should be included in treatment policy. The findings from the present study support this notion. Type-D patients had poorer HRQOL both at baseline and at 1-year follow-up. When evaluating outcomes such as HRQOL in the management of PAD, it is important not only to examine the total patient group but also to look at specific subgroups of patients. Type D personality should be accounted for in addition to age and sex to examine individual differences between patients. Identifying high-risk patients and providing more accurate treatment options for these patients, may help to improve their HRQOL.

These findings demonstrate the need to study risk factors that may predict poor HRQOL in patients with PAD in addition to indices of disease severity and invasive treatment. Despite the general improvement in HRQOL, type D patients remained more impaired in their HRQOL than nontype D patients, indicating the stable adverse effect of type D on HRQOL over time. Personality should be included when evaluating HRQOL in PAD. Hence, the present study provides evidence for the predictive value of type D personality in addition to traditional clinical indicators and invasive treatment with regard to HRQOL in PAD.

AUTHOR CONTRIBUTIONS

Conception and design: AA, JD, JV, JH
Analysis and interpretation: AA, JD, JV
Data collection: AA
Writing the article: AA
Critical revision of the article: JD, JV, JH
Final approval of the article: AA, JD, JV, JH
Statistical analysis: AA, JD
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Overall responsibility: AA

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