Quantifying Improvement in Symptoms, Functioning, and Quality of Life After Peripheral Endovascular Revascularization

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Background—Patients with peripheral arterial disease often undergo peripheral endovascular revascularization (PER) to alleviate symptoms. Despite the growth of PER, little information exists quantifying the health status benefits after the procedure.

Methods and Results—From February 2001 to August 2004, 477 consecutive patients underwent PER for symptomatic peripheral arterial disease. Of these, 300 consented to participate in a longitudinal follow-up study of their health status. Health status was quantified with the disease-specific Peripheral Artery Questionnaire and the generic Short Form-12 and the EuroQol 5 Dimensions (EQ5D) questionnaire. Scores range from 0 to 100; higher scores represent fewer symptoms and better health status. The average age of the cohort was 68±11 years (mean±SD); 186 (62%) were male, 288 (96%) were white, and 118 (39%) were diabetic. Clinical follow-up was attained in 99% of patients; health status assessments were made in 86%. Mean Peripheral Artery Questionnaire summary scores improved significantly after revascularization from 31±19 to 62±27 at 1 year (P<0.0001). Generic health status scores also improved significantly (P<0.001 for all). Despite a technically successful procedure in 98% of patients, 21% of patients did not achieve the minimal clinically important improvement of an 8-point change in Peripheral Artery Questionnaire Summary score after PER (35±19 at baseline versus 31±16 at 1 year; P=0.09).

Conclusions—For most patients, significant and sustained improvements in symptoms, functioning, and quality of life occur after PER. Identifying and counseling patients less likely to benefit from PER is an important future research direction. (Circulation. 2007;115:569-575.)

Key Words: angioplasty ■ claudication ■ peripheral vascular disease ■ health status

Intermittent claudication is a common manifestation of peripheral artery disease (PAD), often leading to significant functional limitations. At least 20% to 25% of persons >55 years of age have PAD, and the prevalence is expected to increase. Among these patients, only a small minority have evidence of ischemic tissue damage, such as rest pain, nonhealing ulcers, or gangrene. Management of persons with PAD is multifaceted, including medications to improve symptoms and to modify vascular risk, smoking cessation, walking regimens, and revascularization.

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The cornerstone of PAD therapy is the treatment of associated cardiovascular risk factors and the alleviation of symptoms. Although medical strategies decrease cardiovascular risk, many patients experience little or no alleviation of physical limitations or symptoms with medical therapy alone, resulting in referral for revascularization. This phenomenon has led to a rapid increase in endovascular procedures. However, evidence that peripheral endovascular revascularization (PER) leads to a measurable and sustained improvement in patients’ functional health status is lacking.

Although no large-scale studies of health status recovery among patients undergoing PER have been performed using a disease-specific questionnaire, modest-sized studies have used both disease-specific and generic questionnaires. Some have reported significant improvements in health status 6 months after surgical revascularization. Others found no difference in health status between peripheral balloon angioplasty and a medical therapy. In the longest reported follow-up (mean, 9.3 years), no difference in health status existed among 77 patients who underwent peripheral balloon angioplasty.

The Assessment of Lower Extremity Revascularization Outcomes (ALEVE) study was designed explicitly to quan-
tify the health status recovery (symptoms, function, and quality of life) of individuals undergoing modern-day PER.

Methods

Study Patients

ALEVE is a single-center, prospective cohort study of patients undergoing PER. All consecutive patients >18 years of age who had a life expectancy of ≥1 year, were able to provide informed consent, and were undergoing PER were screened for enrollment. The majority of patients had intermittent claudication, but a minority of enrollees presented with critical limb ischemia, defined as nonhealing ulcer on the treatment limb, gangrene, or atrophy. Eligible patients underwent PER for atherosclerotic infra-aortic PAD. The local institutional review board approved the protocol, and all patients provided written informed consent for participation in the baseline and follow-up interviews.

Peripheral Endovascular Revascularization

PER was performed using standard techniques, and a broad range of interventional devices, including stents, were used at the discretion of the primary operator. No specific recommendations existed for stent use in this registry. Determination of the culprit lesion and completeness of revascularization also were at the discretion of the operator.

Data Collection

As described more completely below, disease-specific and generic health status measures were administered to eligible patients providing consent. On the day of PER, these assessments were administered by trained interviewers before or immediately after the procedure in the preprocedural or postprocedural care unit to establish baseline values. In addition, sociodemographic and medical history information was abstracted from patients’ charts and interviews. Information included cardiovascular risk factors and history of coronary artery disease, previous PER, congestive heart failure, diabetes mellitus, hypercholesterolemia, and hypertension. Renal insufficiency was defined as serum creatinine >1.5 mg/dL; current smoking was defined as tobacco use <1 year before the procedure.

Procedural details also were abstracted. Transatlantic Inter-Society Consensus definitions were used to classify iliac and femoropopliteal lesions as A, B, C, or D.12 A lesion was classified as a total occlusion if incomplete vessel opacification existed distal to the lesion on initial angiography or if the distal vessel filled via collateral circulation. Technical success was defined as dilatation of all attempted lesions with <40% residual stenosis in each lesion. Target vessels for revascularization were defined as occurring in the same segment of the proximal, mid, or distal superficial femoral artery or the popliteal artery above or below the knee. Otherwise, revascularization of the same anatomic vessel was analyzed as target vessel revascularization.

Follow-Up Procedures

Trained interviewers phoned participants at 1, 3, 6, and 12 months to elicit interim clinical events and to administer the follow-up questionnaires. Interviewers were blinded to baseline scores and treatment details at the time of follow-up. Questionnaire packets were mailed to patients who could not be reached by phone.

Health Status Measurements

The Peripheral Artery Questionnaire (PAQ) is a 20-item questionnaire that assesses PAD-specific health status (see the online Data Supplement). Each question asks about symptoms attributed to PAD over the 4 weeks before completion of the questionnaire.13 Scores are available for 6 domains, including symptoms, symptom stability (change in symptoms), physical limitation, treatment satisfaction, social functioning, and quality of life. A Summary score is calculated as the average of the physical limitation, symptoms, quality of life, and social functioning scores. Scores range from 0 to 100; higher scores indicate less functional limitation, fewer symptoms, better treatment satisfaction, higher social functioning, and better quality of life. A symptom stability score of 50 represents no change over the preceding 4 weeks, whereas scores >50 or <50 represent improvement or worsening of symptoms, respectively. This instrument has been previously described, validated, and shown to be reliable and responsive in patients undergoing PER.13

The Short Form-12 (SF-12) measures generic health status in 2 domains, the physical and mental component summary scores. A score of 50 represents the mean score of the US population, and a 10-point difference in scores reflects 1 SD from that mean.14 The EuroQol 5 Dimensions (EQ5D) also measures generic quality of life and can be converted into a “health utility” score, ranging from 0.0 (death) to 1.0 (“perfect health”).15,16 The Patient Health Questionnaire (PHQ) is a diagnostic instrument for depression. Each of the 9 Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition7 criteria for depression is scored as 0 (not at all) to 3 (nearly every day) and summed. Scores of <5 indicate no depression; scores of 5 to 14 are classified as mild to moderate depression; and scores >15 are considered to indicate severe depression.17

Definition of PER Responders

A prespecified aim of this study was to characterize responders and nonresponders after PER on the basis of a change in 1-year PAQ scores reflective of a moderate clinically important difference. The

<table>
<thead>
<tr>
<th>TABLE 1. Baseline Characteristics</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<td>Lesions, mean (SD), n</td>
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<td>Lesions treated, mean (SD), n</td>
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<td>Bilateral disease, n (%)</td>
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<td>Patients stented, n (%)</td>
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<td>Stent length, mean mm (SD)</td>
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<td>Stent diameter, mean mm (SD)</td>
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TASC indicates Transatlantic Inter-Society Consensus.
Statistical significance was considered as a clinically meaningful difference on the basis of the work of Sloan et al., who concluded that a medium effect size was represented by a change of 8% of the range of the instrument used to assess health status. This benchmark was found to represent the average change in questionnaire scores for patients reporting clinical improvements. In addition, Cohen defined a medium effect size as 50% of the SD of an instrument, which is estimated to be 16.7% of any scale on the basis of the fact that 99% of observations fall within 3 SDs of the mean. This leads to the use of a change of 8 points on the 100-point PAQ scale to represent a clinically meaningful change in this analysis.

Clinical Outcomes
Death, surgical access site repair, vascular bypass, and amputation of the treated limb during follow-up were recorded to assess the safety of PER. An in-hospital adverse event was recorded if an in-hospital death, peri-procedural myocardial infarction (elevation of creatine kinase-MB fraction to greater than twice the upper limit of normal), or major bleeding (requiring transfusion of ≥2 U of packed red blood cells) before discharge occurred after the index PER. One-year major adverse events consisted of target vessel revascularization (percutaneous or surgical), amputation, or all-cause mortality. Procedure-related renal insufficiency was recorded if creatinine increased to >1.5 mg/dL. Vital status was established through telephone follow-up and a query of the Social Security Death Master File, which has been shown to be equivalent to the National Death Index.

Study End Points
The primary end point was the change in the PAQ summary score 1 year after PER. This change was calculated as the 1-year score minus the baseline score. Generic health status outcomes (as measured by the SF-12, EQ5D, and PHQ) and clinical events were analyzed as secondary outcomes. Clinical outcomes included 1-year rates of death, target vessel revascularization, or amputation of the initially treated limb at the index procedure.

Statistical Methods
The primary analysis was to describe and compare over time changes in PAQ summary scores of patients undergoing PER. A repeated-measures ANOVA was used to determine whether a significant change over time occurred. This significant trend was demonstrated at the 0.05 level; therefore, paired t tests were performed. Three PAQ summary time intervals were compared: baseline to 30 days, baseline to 1 year, and 30 days to 1 year. Because 3 multiple comparisons were performed, statistical significance was considered at the level of \( P < 0.017 \), as suggested by Bonferroni.

To better characterize responders and non-responders to PER, the cohort was divided into those who did and did not improve by 8 points on the PAQ summary score at 1 year. Trends of PAQ summary scores at the index procedure. The range at each time point represents the 95% confidence interval. *P < 0.0001, baseline vs 30 days; †P < 0.0001, baseline vs 1 year; ‡P < 0.001, 30 days vs 1-year decrement.

| Table 2. Health Status Assessment Scores at Baseline and Changes at 1 Year After PER |
|-----------------------------------|-----|-----|-----|-----|
| Questionnaire                  | n   | Baseline | Change | P  |
| PAQ score, mean (SD)           | 258 | 31 (19)  | 31 (26) | <0.0001 |
| Quality of life                | 257 | 37 (22)  | 27 (31) | <0.0001 |
| Physical limitation            | 237 | 20 (21)  | 31 (32) | <0.0001 |
| Symptom stability              | 253 | 32 (23)  | 21 (30) | <0.0001 |
| Symptom                       | 255 | 35 (22)  | 27 (30) | <0.0001 |
| Treatment satisfaction         | 253 | 81 (18)  | 1 (26)  | 0.47  |
| Social functioning             | 242 | 32 (28)  | 37 (35) | <0.0001 |
| SF-12, mean (SD)               |     |         |        |      |
| Mental component               | 210 | 45 (7)   | 0 (8)  | 0.53  |
| Physical component             | 210 | 38 (7)   | 3 (8)  | <0.0001 |
| EQ5D, mean (SD)                | 250 | 0.71 (0.17)| 0.07 (0.23) | <0.0001 |
| PHQ, mean (SD)                 | 242 | 5.1 (6.0)| −0.2 (7.2) | 0.59  |

*Probability value for paired t test, baseline vs 30-day scores for each subgroup.

Patient Population
From February 2001 to August 2004, 434 of 477 patients (91%) undergoing PER were screened. Three hundred patients consented to participate. Clinical follow-up was 99% complete, and sufficient health status information was available in 258 patients (86%) to generate PAQ summary scores, making them the primary cohort for this study. When the patients with complete health status follow-up were compared with those without, no significant differences in age, gender, number of lesions intervened on, lesion location, or stent characteristics were observed. Furthermore, no differences were observed in any of the baseline health status specified. All analyses were conducted on SAS version 9.1 (SAS Institute, Cary, NC). The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Figure 1. PAQ summary scores. The PAQ summary scores at baseline and 1, 3, 6, and 12 months are presented for the entire cohort. The range at each time point represents the 95% confidence interval.
questionnaire scores. The only difference between groups was that a significantly higher percentage of patients not providing follow-up were actively smoking at the time of their initial procedure (49% versus 26%; P=0.004).

Baseline clinical characteristics of the study cohort are shown in Table 1. Indications for revascularization included critical limb ischemia, defined as nonhealing ulcer, atrophy, or gangrene, in 19 patients (6.3%). Intermittent claudication was the indication for revascularization in the remainder. Iliac and femoral-popliteal lesions were Transatlantic Inter-Society Consensus type A or B in 95% of patients. The index PER was performed on a single lesion in 140 patients (46%). Two lesions were treated in 102 patients (34%), and ≥3 lesions were treated in 58 patients (20%).

**Clinical Outcomes**

Technical success was attained in 295 of 300 attempted lesions (98%). In-hospital adverse events were rare; 1 patient (0.5%) required surgical repair of a pseudoaneurysm at the arteriotomy site. The overall 1-year major adverse event rate was 10%. Eight patients (3%) died. Repeat revascularization was performed on 50 patients (16.7%), 7 of which (2.3%) were surgical. Sixteen of these (5.3%) were target vessel revascularization.

**Health Status Recovery**

Significant improvements in PAQ scores occurred on all domains except treatment satisfaction at 1 year. In addition, both SF-12 Physical Component summary and EQSD scores improved, although no difference in the SF-12 mental component summary was seen (Table 2). Figure 1 shows that most of the health status improvement was seen by 30 days, although a slight decrement between scores at 1 and 12 months was observed. Although this was a statistically significant decrement, the average PAQ summary score at 1 year remained significantly improved compared with baseline scores. Consistency of benefit existed in all clinical subgroups analyzed (Table 3).

In the overall cohort, patients undergoing PER did not report a significant improvement in depression symptoms as assessed by the PHQ at 1 year (PHQ, 5.1±6.0 at baseline versus 4.9±5.7 at 1 year) (Table 3).

**Responder Versus Nonresponder Analysis**

Twenty-one percent of the cohort failed to report improvements in health status or to respond to PER through the 1-year follow-up. Baseline demographic data of the responder and nonresponder cohorts are shown in Table 4. No significant differences existed in Transatlantic Inter-Society Consensus lesion classification. A statistically significant difference was observed in the prevalence of prior PER of the index segment (responders 13% versus nonresponders 26%; P=0.017). Technical success also was greater in responders (99.5% versus 94.4%; P=0.0007). No difference existed in overall major adverse events (responders 8.3% versus nonresponders 7.4%; P=0.8) or target vessel revascularization (responders 5.9% versus nonresponders 7.4%; P=0.68) that would explain the lack of improvement at 1 year among nonresponders.

The health status recovery of responders and nonresponders is shown in Table 5 and diagrammed in Figure 2. The recovery of nonresponders differed in many ways from that of responders. First, the short-term gain in health status was attenuated. Although a measurable improvement existed in PAQ summary score at 30 days among nonresponders (35±19 at baseline versus 59±26 at 1 month; P<0.0001), this improvement was less than that achieved among responders (30±18 at baseline versus 72±25 at 1 month; P<0.0001). Second, there was a marked reduction in the durability of benefit between 30 days and 12 months among nonresponders when scores decreased from 59±26 to 31±16 (P<0.0001). This decrement in health status was not evident.
In contrast, responders experienced significant improvements in all measures of health status, including treatment satisfaction (81 ± 18 to 86 ± 18; \(P = 0.027\)) and general health status (SF-12 physical component, 38 ± 7 versus 43 ± 7, \(P < 0.001\); EQ5D, 0.7 ± 0.2 versus 0.8 ± 0.1, \(P < 0.001\)) and depression (PHQ score, 4.9 ± 5.9 versus 3.7 ± 5.1; \(P = 0.02\)).

### Discussion

We have shown that most patients report a significant, sustained improvement in health status through 1 year after PER. However, a significant minority report only an early improvement in health status, without a durable 1-year benefit. No significant clinical or procedural differences existed to further differentiate these 2 groups. This study has 3 major implications for the clinical management of persons undergoing PER. First, these data demonstrate that PER is associated with a significant and measurable improvement in symptoms, function, and quality of life in a substantial majority of persons. Second, the current data provide the basis to evaluate the appropriateness of PER. For example, although the nonresponders (21% of this cohort) did derive an improvement in health status at 30 days, it was not durable. Their improvement at 30 days paralleled that of the responders but deteriorated to the level of baseline PAQ scores by 1 year. There were no clinical or anatomic characteristics that differed significantly between PER responders and nonresponders. This lack of difference will limit an operator’s ability to identify this group before an endovascular procedure.

We believe that the benefit of PER should be sustainable to justify its use. Thus, the loss of this initial improvement in 21% of this cohort is concerning. The health status differences identified between the responder and nonresponder cohorts are certainly clinically meaningful. There was a significant 40-point difference in PAQ summary scores between these groups 1 year after PER, with no difference in major adverse events or target vessel revascularization. For these reasons, we believe that we have appropriately identified a group of patients who derived little, if any, health status benefit 1 year after PER. The reason for the lack of benefit is unclear but is likely related to procedural and anatomic characteristics rather than lack of baseline health status impairment. It also is possible that the treatment failure reflects a lack of complete revascularization of the culprit lesion(s). However, the early improvements noted would suggest otherwise. Nonresponders had substantial health status limitations at baseline (PAQ summary score, 35 ± 19), suggesting that potential for improvement existed. Our group has previously evaluated patients reporting no health status benefit after coronary revascularization. The lack of benefit group in that study had little preprocedural angina, suggesting minimal potential for health status improvement. However, nonresponders in the present study clearly had health status limitations but did not benefit from PER. Certainly, this lack of benefit needs to be investigated further in additional studies.

The third implication is that assessment of health status not only is an emerging strategy to evaluate effectiveness and appropriateness of PER but also may lead to improved

### Table 4. Characteristics of Responders and Nonresponders

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Responders (n=204)</th>
<th>Nonresponders (n=54)</th>
<th>(P)</th>
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<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>68 (11)</td>
<td>70 (11)</td>
<td>0.16</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>197 (97)</td>
<td>52 (96)</td>
<td>0.92</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>126 (62)</td>
<td>31 (57)</td>
<td>0.56</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>133 (65)</td>
<td>29 (54)</td>
<td>0.12</td>
</tr>
<tr>
<td>Previous PER, n (%)</td>
<td>26 (13)</td>
<td>14 (26)</td>
<td>0.02</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>78 (39)</td>
<td>20 (37)</td>
<td>0.83</td>
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<td>High cholesterol, n (%)</td>
<td>141 (69)</td>
<td>30 (56)</td>
<td>0.06</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>139 (68)</td>
<td>36 (67)</td>
<td>0.84</td>
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<tr>
<td>Current smoking, n (%)</td>
<td>52 (26)</td>
<td>14 (27)</td>
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</tr>
<tr>
<td>Renal insufficiency, n (%)</td>
<td>7 (3)</td>
<td>0 (0)</td>
<td>0.17</td>
</tr>
<tr>
<td>Critical limb ischemia, n (%)</td>
<td>3 (6)</td>
<td>7 (3)</td>
<td>0.47</td>
</tr>
<tr>
<td>Lesions, mean (SD), n</td>
<td>2.0 (1.4)</td>
<td>2.2 (1.5)</td>
<td>0.43</td>
</tr>
<tr>
<td>Lesions treated, mean (SD), n</td>
<td>1.8 (1.0)</td>
<td>1.8 (1.1)</td>
<td>0.93</td>
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<td>Bilateral disease, n (%)</td>
<td>48 (24)</td>
<td>8 (15)</td>
<td>0.17</td>
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<tr>
<td>Multilevel disease, n (%)</td>
<td>92 (45)</td>
<td>28 (52)</td>
<td>0.38</td>
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<tr>
<td>Chronic occlusion treated, n (%)</td>
<td>42 (21)</td>
<td>10 (19)</td>
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<td>TASC lesion type, n (%)</td>
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<tr>
<td>A</td>
<td>140 (69)</td>
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<tr>
<td>B</td>
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<td>C</td>
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<td>1 (2)</td>
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<tr>
<td>D</td>
<td>1 (0.5)</td>
<td>0 (0)</td>
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<tr>
<td>Iliac</td>
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<td>2</td>
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<td>Patients stented, n (%)</td>
<td>167 (82)</td>
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<td>Lesions stented, mean (SD)</td>
<td>1.3 (1.0)</td>
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<td>1.5 (1.2)</td>
<td>1.4 (1.2)</td>
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<tr>
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<td>47.0 (41.0)</td>
<td>41.3 (27.5)</td>
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<td>Stent diameter, mean mm (SD)</td>
<td>6.6 (2.4)</td>
<td>6.6 (2.3)</td>
<td>0.91</td>
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TASC indicates Transatlantic Inter-Society Consensus.

among responders in whom a more sustained initial benefit was observed (72 ± 25 to 70 ± 23; \(P = 0.32\)). Accordingly, the final 1-year PAQ summary score differed by ~40 points between responders and nonresponders (70 ± 23 versus 31 ± 16; \(P < 0.001\)). In fact, nonresponders had no significant improvement in the PAQ summary score at 1 year and actually had slightly worse health status than what they reported at baseline (35 ± 19 versus 31 ± 16; \(P = 0.009\)).

Similarly, nonresponders had no measurable improvement in their overall health status at 1 year (Table 4). Nonresponders reported a deterioration in general health status (SF-12 physical component, 38 ± 5 versus 34 ± 5, \(P = 0.0009\); mental component, 44 ± 7 versus 41 ± 8, \(P = 0.03\); and EQ5D, 0.7 ± 0.2 versus 0.6 ± 0.2, \(P = 0.02\)). Their PAQ treatment satisfaction scores also deteriorated from 79 ± 18 to 58 ± 23 (\(P = 0.02\)). Additionally, symptoms of depression worsened among nonresponders. The mean PHQ score increased from baseline to 1 year (6.0 ± 6.3 versus 9.4 ± 6.0; \(P = 0.007\)).
evaluation of other new and existing therapies for PAD, such as exercise programs, medications, and novel devices and techniques for revascularization. Given the rapid increase in PER procedures, a pressing need exists for systematic evaluation of emerging devices and novel medical therapies. For example, PER use increased 6-fold from 2.53 per 100 000 in 1979 to 17.9 per 100 000 in 1996 (P < 0.001).5 More recent data from the US National Hospital Discharge Survey reveal a 500-fold increase in catheter-based interventions, from 1980 to 2000, to >160 000 noncoronary endovascular revascularization procedures (58.3 of 100 000).6 We believe that health status ought to be a benchmark in the evaluation of novel strategies and emerging technologies in the treatment of symptomatic PAD.

Study Limitations

This is a prospective single-center study of health status recovery after PER. Given the design, participants also served as control subjects. No comparisons with other treatments such as medical therapy or exercise programs are possible given the study design. Although a medical control group was not included in this study, the PAQ has been shown to be valid and responsive and to have test-retest reliability.13 Likewise, a possible placebo effect cannot be adequately addressed. However, a randomized trial with sham-PER would not be feasible. Substantial effort was made to include all persons undergoing PER at our institution. However, many did not consent to participate. Few measurable differences existed between those with and without complete health status follow-up. Specifically, there were more smokers and higher baseline PAQ symptom stability scores among those without complete follow-up, which may have introduced bias into the analysis. However, we conducted a propensity analysis to identify a group of patients in the follow-up cohort who closely resembled the no follow-up group. This analysis did not identify any differences in the health status recovery after PER, suggesting that it was not an important source of bias. Our study addresses only the early and 1-year health status after PER. Durability beyond 1 year is not known and requires further study. Ankle/arm indices data were not systematically collected in this study. These data may have provided important insight into those patients without substantial improvement in health status. Therefore, our ability to differentiate between the possible causes in failure to improve after PER remains limited. The effects of comorbidities on PAQ scores cannot be assessed. We did not collect specific data on spinal stenosis. These data would have been helpful in understanding whether spinal stenosis and pseudoclaudication were major contributors in the nonresponder cohort. Finally, it remains unknown whether the health status of nonresponders would have worsened over time in the absence of intervention. Despite these limitations, this study quantifies the health status benefits of PER and lays a foundation for future clinical trials comparing PER with other treatments of PAD.

Conclusions

The present study assesses changes in health status after PER using the disease-specific PAQ. There were improvements in PAD-related quality of life, physical limitations, symptoms, and generic health status after PER. These improvements were sustained to 1 year in ~80% of patients. However, a cohort of patients improved initially but worsened by 1 year to a level of health status no better, and possible slightly
worse, than before PER. There were no clinical or anatomic differences identified between those reporting an improvement and those reporting no improvement after PER. Further study is warranted to more thoroughly characterize these nonresponders and to better predict who may benefit from PER.

Acknowledgments
We would like to thank Josh Murphy for editorial assistance and Jose Aceituno for preparation of graphics. This study would not have been possible without Margarita Miller, Jill Blake-Musick, and Lindsey Daniels, our study coordinators.

Source of Funding
The ALEVE Study was funded by an unrestricted research grant from Abbott Vascular (formerly Guidant). Abbott Vascular played no direct role in the study design, conduct, data collection, management or analysis, manuscript preparation, review, or approval for submission.

Disclosures
Dr Marso received an unrestricted research grant from Abbott Vascular to conduct the ALEVE registry. Dr Spertus owns the copyright to the PAQ. The other authors report no conflicts.

References

CLINICAL PERSPECTIVE
The cornerstone of peripheral artery disease therapy is to modify cardiovascular risk factors and to alleviate symptoms. Although medical strategies decrease cardiovascular risk, many patients experience little or no alleviation of physical limitation or symptoms with medical therapy alone. Thus, many patients undergo endovascular revascularization to improve symptoms of claudication. However, very few data exist to quantify the health status recovery after peripheral arterial revascularization. In the Assessment of Lower Extremity Revascularization Outcomes study, improvements in health status were sustained through 1 year in ~80% of patients. However, the remaining patients improved initially but returned to nearly baseline functioning at 1 year. No clinical or anatomic differences could be identified between those reporting an improvement compared with those reporting no improvement after peripheral endovascular revascularization. Given the rapid adoption of and emerging technology associated with endovascular revascularization, we believe that future research needs not only to focus on this nonresponder cohort but also to quantify further the health status among symptomatic patients undergoing peripheral endovascular revascularization.
Quantifying Improvement in Symptoms, Functioning, and Quality of Life After Peripheral Endovascular Revascularization

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*Circulation*. 2007;115:569-575; originally published online January 22, 2007;
doi: 10.1161/CIRCULATIONAHA.106.643346

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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