Health-Related Quality of Life After Angioplasty and Stent Placement in Patients With Iliac Artery Occlusive Disease: Results of a Randomized Controlled Clinical Trial

Johanna L. Bosch, Yolanda van der Graaf and Maria G. M. Hunink

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Health-Related Quality of Life After Angioplasty and Stent Placement in Patients With Iliac Artery Occlusive Disease
Results of a Randomized Controlled Clinical Trial

Johanna L. Bosch, PhD; Yolanda van der Graaf, MD, PhD; Maria G.M. Hunink, MD, PhD; for the Dutch Iliac Stent Trial Study Group*

**Background**—To assess the quality of life in patients with iliac artery occlusive disease, we compared primary stent placement versus primary angioplasty followed by selective stent placement in a multicenter randomized controlled trial.

**Methods and Results**—Quality-of-life assessments were completed by 254 patients in a telephone interview. Assessment measures consisted of the RAND 36-Item Health Survey 1.0, time tradeoff, standard gamble, rating scale, health utilities index, and EuroQol-5D. The interviews were performed before treatment and after 1, 3, 12, and 24 months. When the 2 treatments were compared, no significant difference was observed ($P>0.05$). All measurements showed a significant improvement in the quality of life after treatment ($P<0.05$). The RAND 36-Item Health Survey measures physical functioning, role limitations caused by physical problems, and bodily pain and the EuroQol-5D were the most sensitive to the impact of revascularization.

**Conclusions**—Health-related quality of life improves equally after primary stent placement and primary angioplasty with selective stent placement in the treatment of intermittent claudication caused by iliac artery occlusive disease. *(Circulation. 1999;99:3155-3160.)*

**Key Words:** quality of life ■ arteries ■ claudication ■ stents ■ angioplasty

Intermittent claudication caused by stenoses or occlusions in the iliac arteries is a lifestyle-limiting condition. For the majority of patients with intermittent claudication, the initial treatment consists of risk factor modification and exercise training. If initial noninterventional options fail and percutaneous intervention is feasible, patients are generally treated with percutaneous transluminal angioplasty (PTA) and, more recently, with stent placement. Stents can be placed as either a primary or adjutant therapy after suboptimal results are achieved with PTA.1,2

In presenting the results of percutaneous interventions, investigators generally report initial hemodynamic and long-term patency outcomes. Although these outcomes are of interest to the physician, patients are concerned mainly with their walking distance and quality of life. In the evaluation of interventions that have little or no impact on long-term survival, such as in peripheral percutaneous interventions, quality-of-life assessment is essential to demonstrate effectiveness.3

The purpose of this study was to assess the impact of percutaneous treatment on patients’ quality of life in the treatment of intermittent claudication. In a randomized controlled trial that compared stent placement with PTA,2 we measured and compared quality-of-life outcomes.

**Methods**

**Patients and Interviews**

All patients with intermittent claudication or critical ischemia caused by stenosis or occlusion in the iliac arteries and who were seen by vascular surgery departments in 1 of 6 participating hospitals in the Netherlands from November 1993 through November 1996 were considered for enrollment in the Dutch Iliac Stent Trial (DIST). Two hundred seventy-nine patients were enrolled and assigned to undergo either primary stent placement (group 1, n=143) or primary PTA (group 2, n=136) with selective stent placement for unsatisfactory angioplasty results, which was defined as a residual transstenotic mean pressure gradient of $>10$ mm Hg with vasodilatation. Randomization was performed for each hospital with a computer-generated randomization table to limit imbalances between treatment assignments to 4. Given the nature of the procedure, patients and physicians were not blinded to the assigned treatment. The study protocol was approved by the institutional review boards of the participating hospitals. All patients were informed of the treatment background and procedures, and their written informed consent was obtained. The treatment protocol remained unchanged throughout

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*Study group members are listed in the Appendix.
Reprint requests to Maria G.M. Hunink, MD, PhD, Program for the Assessment of Radiological Technology (ART program), Department of Epidemiology and Biostatistics and Department of Radiology, Erasmus Medical Center Rotterdam, Room EE21-40a, PO Box 1738, 3000 DR Rotterdam, Netherlands. E-mail hunink@epib.fgg.eur.nl
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the study. Additional details in regard to the inclusion and exclusion criteria and treatment protocol have been reported previously.²

Ninety-one percent of the patients participated in the quality-of-life assessment (n=254). Nonparticipation was caused by logistical reasons (ie, the time between enrollment in the study and the procedure was too short to perform the interview or patients could not be reached by telephone). Quality of life was assessed by telephone before treatment and 1, 3, 12, and 24 months after treatment. Patients received the questionnaire by mail before each interview. One-year follow-up results were available in 198 (97%) of 204 patients eligible for follow-up. Two-year follow-up results were obtained in 101 (94%) of 108 patients eligible for follow-up. In 13 patients, no follow-up interviews were performed because of logistical reasons (n=3), noncompliance (n=6), or comorbidity (n=4). The mean follow-up was 14.7 months (range, 3 to 24 months). The interviews were performed by 3 trained interviewers who were blind to the subjects’ treatment assignments. The duration of an interview was ~30 minutes.

Clinical evaluation was performed before and 3, 12, and 24 months after the intervention and included treadmill exercises with measurement of ankle-brachial index.

Quality-of-Life Measures

The interview consisted of a generic descriptive health-status measure, the RAND 36-Item Health Survey 1.0 (RAND-36), and several evaluation measures, such as the time trade-off, health utilities index (HUI),⁶,⁷ rating scale, standard gamble, and EuroQol-5D.⁸ In the questionnaire, all measures were presented in the above order and in a written format. In the pilot feasibility study, intrainterviewer and interinterviewer reproducibility and test-retest reliability of the questionnaire were demonstrated in a similar patient group.⁹ In addition, construct validity and reliability of the telephone-based time-tradeoff and standard-gamble methods were demonstrated in patients with peripheral arterial occlusive disease.¹⁰

The RAND-36, which is equivalent to the Medical Outcomes Study Short Form 36,⁶,¹¹ includes 8 health dimensions. For each dimension, responses to items are summed and scores are converted to a 0 to 100 scale, in which 100 indicates best functioning or well being. With valuational measures, patients were assigned numerical values or utilities according to their present state of health averaged over the previous 4 weeks on a scale from 0 (death) to 1 (full health comparable to healthy contemporaries).¹² In the time-tradeoff patients were asked how many months or years they would trade in exchange for full health rather than living a full life expectancy in the current health state.⁹ In the standard-gamble patients were asked what risk of death they would willingly take to improve their current state of health to full health.⁹ In the rating scale, we asked patients to rate their current state of health on a scale from 0 (death) to 1 (full health).

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We tested for statistical significance of differences in quality-of-life values before and after treatment, differences in proportions of patients with values comparable to the reference values before and after treatment, and differences in quality-of-life values between the treatment groups with repeated-measures ANOVA (α=0.05). The statistical association of the change in ankle-brachial index and walking distance with the change in physical functioning (RAND-36) and bodily pain (RAND-36) and the valutational measures before and 2 years after treatment was assessed with the Spearman correlation coefficient. All analyses were performed with standard statistical software (SPSS for Windows version 6.01, SPSS). To demonstrate the degree of clinical improvement, we present figures with the cumulative frequency distribution of patients with the indicated quality-of-life score or higher (ie, better quality of life) at baseline and at 2-year follow-up.

Results

Most patients were treated for intermittent claudication, and the majority had an iliac artery stenosis (Table 1).² The treatment groups demonstrated no significant differences with respect to descriptive variables, baseline quality-of-life measures, and baseline clinical measures (Tables 1 to 6). In group 1, 143 patients (187 lesions) were treated with a total of 208 stents. In group 2, 136 patients (169 lesions) were treated with PTA, which was followed by selective stent placement in 59 patients (43%; 65 lesions, 77 stents). Immediate postprocedural results demonstrated that both groups yielded similar initial hemodynamic success rates and complication rates (84% and 4% for group 1 versus 88% and 7% for group 2, respectively).² In addition, 2-year cumulative patency rates, with patency defined as a peak systolic velocity ratio of <2.5 found at duplex ultrasonography, were equivalent in both groups (ie, 71% and 70% for group 1 and group 2, respectively).² Table 2 shows mean ankle-brachial indices and walking distance over time. At 24-month follow-up, the proportion of patients with an ankle-brachial index of ≥0.90 or an improvement of ≥0.15 compared with pretreatment values was 80% when measured in rest and 92% when measured after exercise.

In both groups, scores of all RAND-36 dimensions showed significant improvement after revascularization (Tables 3 and 4,
At 24-month follow-up, the scores were still significantly higher than before treatment, with the exception of the dimension of general health perception in group 1 ($P < 0.20$) and group 2 ($P < 0.09$). The effect of treatment was highest for physical functioning, physical role functioning, and bodily pain. Figure 1 shows the cumulative distribution of patients who had the indicated RAND-36 score or better. For example, Figure 1a demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population demonstrates that before revascularization, ≈18% of patients had a score of ≥60 for physical functioning, whereas after revascularization, this proportion increased to ≈68%. The proportion of patients with values that exceeded the population
Reference was significantly higher after revascularization than before (Table 4) on most dimensions and in both groups (ie, except general health perception in group 1 \( P = 0.07 \) and group 2 \( P = 0.60 \) and social functioning in group 2 \( P = 0.10 \)). Scores on all RAND-36 dimensions were not significantly different between the groups.

All valuational quality-of-life measures demonstrated a significant improvement after treatment, with the exception of the standard gamble (group 1, \( P = 0.35 \); group 2, \( P = 0.40 \); Tables 5 and 6, Figure 2). At 24-month follow-up, the values were still significantly higher than before treatment, with the exception of the standard gamble and the time tradeoff in group 1 \( P = 0.35 \) and group 2 \( P = 0.08 \). The treatment effect was highest when measured with the EuroQol-5D. The cumulative distribution (Figure 2) of patients with the indicated value or higher demonstrates, for example, that before revascularization, 10% of patients had a EuroQol-5D value of \( \$0.60 \), whereas 24 months after treatment, this proportion had increased to 55%. The proportion of patients with values that exceeded the population-reference value was significantly higher after revascularization than before on most valuational measures (ie, except the time tradeoff in group 1 \( P = 0.10 \) and the standard gamble in group 1 \( P = 0.11 \) and group 2 \( P = 0.24 \)). The values were not significantly different between the groups.

Compared with the external patient group (ie, patients with intermittent claudication who participated in an exercise program\(^{17} \)), patients in the trial had lower quality-of-life values before revascularization and higher values after revascularization. The proportion of trial patients before revascularization

![Cumulative distribution curves of patients with indicated RAND-36 score or higher (ie, better) for the health dimensions physical functioning (A) and bodily pain (B) of patients assigned to either primary stent placement (solid line) or primary PTA followed by selective stent placement (dashed line) at baseline and at 24-month follow-up.](image)

**Figure 1.** Cumulative distribution curves of patients with indicated RAND-36 score or higher (ie, better) for the health dimensions physical functioning (A) and bodily pain (B) of patients assigned to either primary stent placement (solid line) or primary PTA followed by selective stent placement (dashed line) at baseline and at 24-month follow-up.

**TABLE 5. Median Values at Baseline and During Follow-Up**

<table>
<thead>
<tr>
<th></th>
<th>Before Revascularization</th>
<th>1 mo</th>
<th>3 mo</th>
<th>12 mo</th>
<th>24 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time tradeoff</td>
<td>0.88 (0.40–1.00)</td>
<td>0.94 (0.40–1.00)</td>
<td>0.96 (0.40–1.00)</td>
<td>0.98 (0.40–1.00)</td>
<td>0.93 (0.01–1.00)</td>
</tr>
<tr>
<td>Standard gamble</td>
<td>0.96 (0.40–1.00)</td>
<td>0.98 (0.51–1.00)</td>
<td>1.00 (0.50–1.00)</td>
<td>1.00 (0.50–1.00)</td>
<td>0.98 (0.02–1.00)</td>
</tr>
<tr>
<td>Rating scale</td>
<td>0.75 (0.29–0.96)</td>
<td>0.80 (0.50–1.00)</td>
<td>0.80 (0.40–1.00)</td>
<td>0.80 (0.40–1.00)</td>
<td>0.80 (0.28–1.00)</td>
</tr>
<tr>
<td>Health utilities index</td>
<td>0.68 (0.35–0.87)</td>
<td>0.70 (0.37–1.00)</td>
<td>0.76 (0.04–1.00)</td>
<td>0.70 (0.28–1.00)</td>
<td>0.70 (0.22–1.00)</td>
</tr>
<tr>
<td>EuroQol-5D</td>
<td>0.46 (0.20–0.75)</td>
<td>0.70 (0.15–1.00)</td>
<td>0.75 (0.15–1.00)</td>
<td>0.59 (0.19–1.00)</td>
<td>0.70 (0.09–1.00)</td>
</tr>
<tr>
<td>Group 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time tradeoff</td>
<td>0.88 (0.30–1.00)</td>
<td>0.91 (0.10–1.00)</td>
<td>0.96 (0.47–1.00)</td>
<td>0.95 (0.49–1.00)</td>
<td>0.95 (0.00–1.00)</td>
</tr>
<tr>
<td>Standard gamble</td>
<td>0.95 (0.48–1.00)</td>
<td>0.96 (0.47–1.00)</td>
<td>0.96 (0.51–1.00)</td>
<td>0.96 (0.40–1.00)</td>
<td>0.96 (0.00–1.00)</td>
</tr>
<tr>
<td>Rating scale</td>
<td>0.75 (0.20–0.99)</td>
<td>0.80 (0.50–1.00)</td>
<td>0.80 (0.50–1.00)</td>
<td>0.80 (0.40–1.00)</td>
<td>0.80 (0.40–1.00)</td>
</tr>
<tr>
<td>Health utilities index</td>
<td>0.69 (0.28–0.80)</td>
<td>0.70 (0.24–1.00)</td>
<td>0.70 (0.27–1.00)</td>
<td>0.77 (0.28–1.00)</td>
<td>0.70 (0.16–1.00)</td>
</tr>
<tr>
<td>EuroQol-5D</td>
<td>0.46 (0.15–0.75)</td>
<td>0.70 (0.20–1.00)</td>
<td>0.70 (0.20–1.00)</td>
<td>0.70 (0.15–1.00)</td>
<td>0.66 (0.15–1.00)</td>
</tr>
</tbody>
</table>

Parenthetical values are 95% range.

**TABLE 6. Proportion of Patients With a Utility or Value Exceeding the Lower 95% Confidence Limit of Values among the General Population**

<table>
<thead>
<tr>
<th></th>
<th>Before Revascularization, %</th>
<th>1 mo</th>
<th>3 mo</th>
<th>12 mo</th>
<th>24 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time tradeoff</td>
<td>58</td>
<td>71</td>
<td>70</td>
<td>71</td>
<td>65</td>
</tr>
<tr>
<td>Standard gamble</td>
<td>68</td>
<td>76</td>
<td>80</td>
<td>78</td>
<td>73</td>
</tr>
<tr>
<td>Rating scale</td>
<td>71</td>
<td>77</td>
<td>78</td>
<td>75</td>
<td>73</td>
</tr>
<tr>
<td>Health utilities index</td>
<td>0</td>
<td>15</td>
<td>19</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>EuroQol-5D</td>
<td>0</td>
<td>44</td>
<td>45</td>
<td>39</td>
<td>40</td>
</tr>
<tr>
<td>Group 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time tradeoff</td>
<td>56</td>
<td>69</td>
<td>74</td>
<td>76</td>
<td>60</td>
</tr>
<tr>
<td>Standard gamble</td>
<td>74</td>
<td>76</td>
<td>82</td>
<td>80</td>
<td>73</td>
</tr>
<tr>
<td>Rating scale</td>
<td>64</td>
<td>76</td>
<td>79</td>
<td>78</td>
<td>73</td>
</tr>
<tr>
<td>Health utilities index</td>
<td>0</td>
<td>17</td>
<td>18</td>
<td>22</td>
<td>25</td>
</tr>
<tr>
<td>EuroQol-5D</td>
<td>1</td>
<td>39</td>
<td>45</td>
<td>45</td>
<td>42</td>
</tr>
</tbody>
</table>

Values are based on comparisons with similar age groups.\(^{14–16}\)
with values below the 95% CI of the reference values among patients who underwent exercise therapy ranged from 21% (standard gamble) to 67% (RAND-36 physical functioning). After revascularization, these proportions decreased significantly. At 2-year follow-up, the proportion of trial patients after revascularization with health values equal to or higher than the upper 95% confidence limit of the reference values among patients who underwent exercise therapy ranged from 62% (EuroQol-5D) to 78% (RAND-36, bodily pain).

The Spearman correlation coefficient of changes from before treatment to 2-year follow-up that compared hemodynamic data with physical functioning (RAND-36) and bodily pain (RAND-36) and valutational measures ranged from −0.11 (ie, EuroQol-5D with ankle-brachial index after exercise) to 0.28 (ie, physical functioning with ankle-brachial index at rest).

**Discussion**

Health-related quality of life was assessed in a randomized controlled trial that compared primary stent placement and primary PTA followed by selective stent placement. Results demonstrated that both percutaneous treatment strategies significantly improved patients' quality of life. No significant difference in quality-of-life outcomes was demonstrated between the groups. Immediate hemodynamic results and clinical outcomes during follow-up were also similar in both groups. Thus, costs rather than effectiveness may be the decisive factor in the choice of percutaneous treatment.

Theoretically, it is possible that the outcomes were biased because of the interviews or interviewers. A placebo effect may have occurred because of the attention patients received from the interviewer or because of a learning effect. However, the demonstrated improvements in quality of life are not explainable with a placebo effect alone. In addition, previous studies evaluated construct validity, reliability, and feasibility of the measures in patients with peripheral arterial occlusive disease, and the measures were shown to be valid. Second, an order effect may have biased the quality-of-life values; however, because the same order was used in both treatment groups, a bias in the comparison between the groups was eliminated by randomization across treatments. Furthermore, a bias because of expectations of the interviewers is unlikely because the interviewers were blind to the assigned treatment.

Unfortunately, reference values from the Dutch population were not available for all instruments we used. Because quality-of-life values may differ across countries, the proportion of patients with values above the reference may have been overestimated or underestimated. In addition, bias may have occurred because a few reference values were obtained from a different version of a questionnaire than the version used in our study. Because we used the same reference values in both treatment groups, these biases did not influence the comparison between the groups.

A limitation of our study was the limited follow-up, and it thus remains unclear what the long-term efficacy, including quality of life, may be after PTA and stent placement. Also, a longer follow-up is needed to compare the outcomes with the efficacy of other treatments with demonstrated long-term benefits, such as exercise training or bypass surgery. Another limitation of our study was that most patients had intermittent claudication due to stenoses in the iliac arteries. The effect of PTA and stent placement on health-related quality-of-life outcomes in patients with critical ischemia caused by occlusions remains to be elucidated. Another limitation was the omission of a disease-specific questionnaire, such as the Walking Impairment Questionnaire. Quality-of-life assessment in this trial focused on valutational measures to enable a cost-effectiveness analysis and included a generic health-status measure to describe health on several dimensions. A disease-specific questionnaire might have detected a small difference between the groups, but given the large but equivalent effect sizes on the RAND-36 health dimensions physical functioning and bodily pain, a large undetected difference seems unlikely.

As may be expected in the treatment of claudication, the health dimensions of physical functioning and bodily pain were the most sensitive to the impact of revascularization. Of the valutational quality-of-life measures, the EuroQol-5D demonstrated the highest treatment effect probably because it assesses only 5 health dimensions, of which 1 is mobility. Although an improvement in quality of life was demonstrated, many patients still had low quality-of-life values compared with a general-population reference group after treatment. The reason probably is that revascularization in patients with atherosclerotic disease does not cure the disease but rather is an attempt to improve symptoms. In addition, atherosclerosis is a systemic disease, and many patients may have had other manifestations of atherosclerosis, such as angina pectoris. Another outcome of our study was that at 2 years after revascularization, most patients demonstrated higher quality-of-life values than a comparable group of patients who underwent exercise therapy.
patients who participated in an exercise program, although before treatment, the quality-of-life values were similar or worse.17 Although we did not randomize between percutaneous revascularization and exercise, the large improvement in quality-of-life among the trial patients suggests that the revascularization procedure was efficacious. Finally, our study demonstrated a poor correlation between quality-of-life outcomes and hemodynamic data. This suggests that measurement of clinical parameters alone has limitations and measurement of health-related quality of life may provide extra information and is therefore important to include in clinical trials in addition to functional and clinical measures.

To the best of our knowledge, the results of quality-of-life assessments after stent placement have not been reported previously. A few studies have reported the effect of PTA on health-related quality of life and used measures such as the RAND-36 and EuroQol-5D.20–22 The results of these studies also demonstrated an improvement in quality of life after treatment. In addition, these studies reported quality of life measured at 1 point in time after revascularization. We included measurement of quality of life at 4 points during follow-up and found that most measures did not demonstrate a significant decrease to baseline values, although a trend could be seen. Additional research that analyzes long-term results is necessary to demonstrate the long-term effect of PTA and stent placement.

In conclusion, in the treatment of intermittent claudication caused by stenoses in the iliac arteries, health-related quality of life improves equally after primary stent placement and primary PTA, followed by selective stent placement. In addition, a recently performed cost-effectiveness analysis demonstrated that PTA with selective stent placement was a cost-effective treatment strategy compared with primary stent placement and with PTA alone.23 These results suggest that in the treatment of intermittent claudication due to iliac artery stenoses, the preferred treatment choice is primary PTA followed by selective stent placement.

Appendix

Centers That Participated in the Dutch Iliac Stent Trial Study Group
St Antonius Hospital Nieuwegein; TTC Overtoom, MD; JC de Valois, MD, PhD (radiology); FL Moll, MD, PhD; HDWM van de Pavoordt, MD, PhD (vascular surgery); Slingeland Hospital Doetinchem: JH Spithoven, MD (radiology); JOJM van Iersel, MD; J Jeegers, MD (vascular surgery); University Hospital Utrecht: BC Eikelboom, MD, PhD (vascular surgery); WPTM Mali, MD, PhD; IPI van Schaik, MD, PhD; FJA Beek, MD, PhD; E Tetteroo, MD, PhD; C Haaring, BA; and AD van Engelen, MD (radiology). University Hospital, Rotterdam: H Pieterman, MD (radiology); H van Urk, MD, PhD (vascular surgery); University Hospital, Utrecht: H de Vries, MD; PhD; FJ van Tol, MD, PhD; AD van Engelen, MD (radiology). University Hospital, Rotterdam: H Pieterman, MD (radiology); H van Urk, MD, PhD (vascular surgery); Twente Hospital, Almelo: JJ Kouwenberg, MD; FHB Tuyman, MD (radiology); JW van den Heuvel, MD; and JG van Baal, MD, PhD (vascular surgery). Catharina Hospital, Eindhoven: GHM Landman, MD, PhD; AV Tielbeek, MD, PhD (radiology); and J Buth, MD, PhD (vascular surgery). University of Groningen: EEE van Wijck, MSc (health sciences).

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