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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 adjuvant 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 con-

trolled 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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From the Departments of Epidemiology and Biostatistics (J.L.B., M.G.M.H.) and Radiology (M.G.M.H.), Erasmus Medical Center, Rotterdam, Netherlands; Julius Center for Patient Oriented Research (Y.v.d.G.), University Hospital, Utrecht, Netherlands; School of Medicine, Keio University (J.L.B.), Tokyo, Japan; and the Harvard School of Public Health (M.G.M.H.), Boston, Mass.

*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),⁴ and several evaluation measures, such as the time tradeoff, health utilities index (HUI),^{5,6} rating scale, standard gamble, and EuroQol-5D.^{7,8} 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,^{4,11} 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 valual 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 0.0 (death) to 1.0 (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 to 100, in which 0 represented death and 100 represented full health.⁹

To assess preferences for health states from a societal perspective, we included the HUI Mark I and EuroQol-5D.^{5-8,13} Both measures provided a framework to describe health states in terms of attributes and a model to estimate a community-based value for every health state that can be identified in the classification scheme.

Data Analysis

Data were analyzed in accordance with the intention-to-treat principle. This principle implies that values were assumed to be zero in the analysis if a patient died during follow-up. The Kolmogorov-Smirnov test was used to test the null hypothesis that a variable had an underlying normal distribution. In our study, most variables were not normally distributed. Therefore, we report the medians and the proportion of patients with values that exceeded a population-based reference value. For each measurement instrument, the reference value was defined as the lower 95% confidence limit of published data from a similar age group among the general population (Personal Communication, Sylvie Alary [Technical Research Officer, National Health Population Survey, Canada Statistics], e-mail, March 1998).^{11,14-16} In addition, the results were compared with health values measured with the same questionnaire in a comparable group of patients with intermittent claudication who participated in an exercise program (with a symptom-free walking distance of 150 m).¹⁷

TABLE 1. Baseline Characteristics

	Group 1, n=143	Group 2, n=136
Mean age, y (SD)	59 (11)	60 (10)
Male/female, n	102/41	99/37
Medical history, n (%)		
Cerebrovascular accident	20 (14)	9 (7)
Diabetes mellitus	13 (9)	15 (11)
Hypertension	40 (28)	37 (27)
Tobacco use	124 (87)	128 (94)
No. of lesions	187	169
Arterial segment, n (%)		
Common iliac artery	131 (70)	114 (67)
External iliac artery	56 (30)	55 (33)
Angiographic stenosis grade, n (%)		
<50% diameter reduction	21 (11)	19 (11)
≥50% diameter reduction	149 (80)	138 (82)
Total occlusion	17 (9)	12 (7)

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 ($\alpha=0.05$). 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 valual 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,

TABLE 2. Hemodynamic Data

	Group 1	Group 2
Ankle-brachial index*		
At rest		
Before treatment	0.74 (0.20)	0.73 (0.21)
3 mo	0.92 (0.25)	0.93 (0.22)
12 mo	0.92 (0.22)	0.94 (0.19)
24 mo	0.88 (0.24)	0.96 (0.20)
After exercise		
Before treatment	0.46 (0.23)	0.49 (0.23)
3 mo	0.80 (0.63)	0.81 (0.28)
12 mo	0.74 (0.32)	0.82 (0.27)
24 mo	0.77 (0.28)	0.91 (0.24)
Walking distance, m†		
Before treatment	190 (109)	204 (106)
3 mo	263 (57)	255 (64)
12 mo	261 (58)	263 (65)
24 mo	258 (68)	255 (68)

Values are mean (SD).

*Mean of the ratio of minimum left/right ankle pressure and brachial blood pressures.

†Measured during a 5-minute walking test with a maximum of 300 m.

Figure 1). 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

TABLE 4. Proportion of Patients With RAND-36 Scores Exceeding the Lower 95% Confidence Limit of RAND-36 Values Among the General Population

	Before Revascularization, %	After Revascularization, %			
		1 mo	3 mo	12 mo	24 mo
Group 1					
Physical functioning	5	60	62	49	51
Physical role functioning	18	54	63	57	53
Emotional role functioning	50	64	69	60	66
Social functioning	30	56	66	60	59
Bodily pain	17	58	64	59	57
General health perception	42	54	52	50	43
Mental health	54	61	66	56	57
Vitality	33	57	62	52	59
Group 2					
Physical functioning	9	56	63	66	60
Physical role functioning	28	53	61	65	67
Emotional role functioning	45	54	64	72	71
Social functioning	42	53	61	66	63
Bodily pain	17	48	58	58	69
General health perception	41	45	46	51	48
Mental health	50	56	63	57	63
Vitality	35	56	54	54	46

These values are based on comparisons with a similar age group.¹¹

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

TABLE 3. Median RAND-36 Scores at Baseline and During Follow-Up

	Before Revascularization	After Revascularization			
		1 mo	3 mo	12 mo	24 mo
Group 1					
Physical functioning	40 (5–79)	85 (10–100)	85 (10–100)	70 (7–100)	75 (5–100)
Physical role functioning	0 (0–100)	75 (0–100)	100 (0–100)	100 (0–100)	75 (0–100)
Emotional role functioning	100 (0–100)	100 (0–100)	100 (0–100)	100 (0–100)	100 (0–100)
Social functioning	63 (0–100)	88 (13–100)	100 (14–100)	100 (0–100)	88 (0–100)
Bodily pain	45 (3–100)	80 (4–100)	90 (20–100)	78 (4–100)	78 (2–100)
General health perception	55 (15–94)	65 (16–100)	65 (15–100)	63 (15–100)	55 (2–99)
Mental health	76 (13–100)	80 (28–100)	84 (28–100)	80 (6–100)	80 (30–100)
Vitality	50 (6–95)	65 (15–100)	70 (15–100)	65 (12–100)	70 (15–100)
Group 2					
Physical functioning	45 (10–85)	80 (15–100)	85 (10–100)	85 (20–100)	85 (5–100)
Physical role functioning	0 (0–100)	75 (0–100)	100 (0–100)	100 (0–100)	100 (0–100)
Emotional role functioning	67 (0–100)	100 (0–100)	100 (0–100)	100 (0–100)	100 (0–100)
Social functioning	75 (13–100)	88 (13–100)	88 (13–100)	88 (25–100)	94 (0–100)
Bodily pain	45 (0–99)	67 (0–100)	78 (10–100)	80 (22–100)	90 (20–98)
General health perception	55 (10–90)	60 (15–95)	60 (10–95)	65 (15–95)	60 (15–100)
Mental health	74 (20–100)	80 (24–100)	80 (28–100)	76 (30–100)	80 (24–100)
Vitality	50 (5–90)	65 (10–100)	70 (20–100)	65 (16–100)	60 (15–100)

Higher scores mean better functioning, fewer limitations, or less pain. Parenthetical values are 95% range.

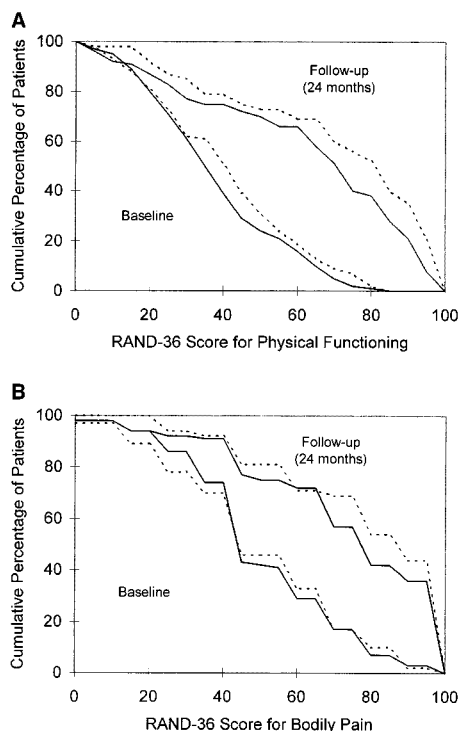


Figure 1. Cumulative distribution curves of patients with indicated RAND-36 score or higher (ie, better) for the health dimensions physical functioning (A) and bodily pain (B) of patients assigned to either primary stent placement (solid line) or primary PTA followed by selective stent placement (dashed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

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

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

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

Values are based on comparisons with similar age groups.¹⁴⁻¹⁶

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 program¹⁷), patients in the trial had lower quality-of-life values before revascularization and higher values after revascularization. The proportion of trial patients before revascularization

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

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

Parenthetical values are 95% range.

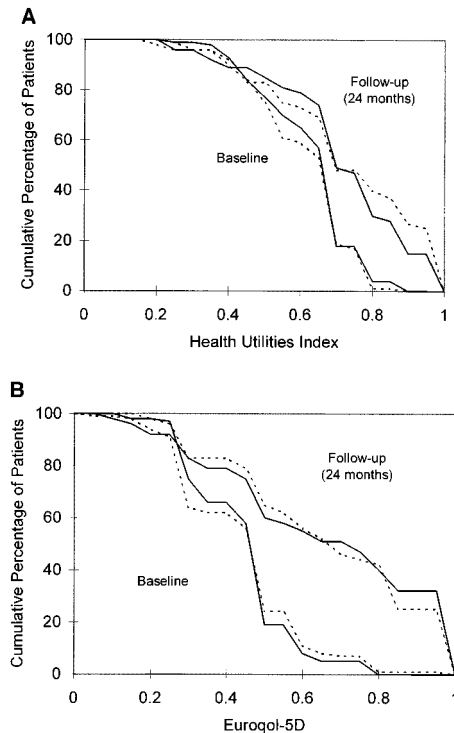


Figure 2. Cumulative distribution curves of patients with indicated value or higher (ie, better) for the HUI (A) and EuroQol-5D (B). Values indicate patients assigned to either primary stent placement (solid line) or primary PTA followed by selective stent placement (dashed line) at baseline and at 24-month follow-up.

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 valuations 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.² 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.^{9,10} 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.^{18,19} Quality-of-life assessment in this trial focused on valuations 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 valuations 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 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); JGJM van Iersel, MD; J Seegers, MD (vascular surgery). University Hospital Utrecht: BC Eikelboom, MD, PhD (vascular surgery); WPTM Mali, MD, PhD; JPJ 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). Twenteborg Hospital, Almelo: JJ Kouwenberg, MD; FHB Tuynman, 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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