Stent Placement Versus Balloon Angioplasty for the Treatment of Obstructive Lesions of the Popliteal Artery
A Prospective, Multicenter, Randomized Trial

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Background—Stenting has been shown to improve patency after femoral artery revascularization compared with balloon angioplasty. Limited data are available evaluating endovascular treatment for obstructive lesions of the popliteal artery.

Methods and Results—This prospective, randomized, multicenter trial compared primary nitinol stent placement to percutaneous transluminal balloon angioplasty in patients with peripheral artery disease Rutherford-Becker class 2 to 5 who had a de novo lesion in the popliteal artery. The primary study end point was 1-year primary patency, defined as freedom from target-lesion restenosis (luminal narrowing of ≥50%) as detected by duplex ultrasound. Secondary end points included target-lesion revascularization rate and changes in Rutherford-Becker class. Provisional stent placement was considered target-lesion revascularization and loss of primary patency. Two hundred forty-six patients were included in this trial. The mean target-lesion length was 42.3 mm. One hundred ninety-seven patients were available for the 1-year follow-up. The 1-year primary patency rate was significantly higher in the group with primary nitinol stent placement (67.4%) than in the percutaneous transluminal balloon angioplasty group (44.9%, P=0.002). Target-lesion revascularization rates were 14.7% and 44.1%, respectively (P=0.0001); however, when provisional nitinol stent placement was not considered target-lesion revascularization and loss in patency, no significant differences prevailed between the study groups (67.4% versus 65.7%, P=0.92 for primary patency). Approximately 73% of patients in the percutaneous transluminal balloon angioplasty group and 77% in the nitinol stent group showed an improvement of ≥1 Rutherford-Becker class (P=0.31).

Conclusions—Primary nitinol stent placement for obstructive lesions of the popliteal artery achieves superior acute technical success and higher 1-year primary patency only if provisional stenting is considered target-lesion revascularization. Provisional stenting as part of a percutaneous transluminal balloon angioplasty strategy has equivalent 1-year patency and should be preferred over primary stenting.


Key Words: angioplasty ■ arteries ■ peripheral vascular diseases ■ stents

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creater life expectancy and the increasing prevalence of diabetes mellitus in the developing world have led to a progressive rise in the number of patients with peripheral artery disease. Intermittent claudication and critical limb ischemia are the most common symptoms in patients with lower-extremity peripheral artery disease.1–3

Besides conservative therapy and bypass surgery, endovascular therapy has been established as a treatment option for femoropopliteal obstructive disease.2,3 During the past decade, randomized trials revealed that with increasing lesion length, nitinol stent (NS) placement frequently provides better patency, target-lesion revascularization (TLR) rates, and clinical improvement than percutaneous transluminal balloon angioplasty (PTA) alone after treatment of superficial femoral artery (SFA) lesions, including the proximal segment

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of the popliteal artery (PA). None of these trials, however, addressed true PA lesions beyond the proximal (P1) segment. To date, limited evidence exists concerning any kind of endovascular treatment for isolated PA obstructive disease. Because of excessive mechanical forces applied to the PA during motion, the PA is considered a no-stent zone, and stent placement is currently reserved for suboptimal results after PTA, such as significant recoil, flow-limiting dissection, or significant residual stenosis. The goal of this prospective, multicenter, randomized trial was to investigate the efficacy and safety of NS placement compared with PTA for the treatment of obstructive lesions in the PA.

Methods

Study Design

The ETAP study (Endovascular Treatment of Atherosclerotic Popliteal Artery Lesions—Balloon Angioplasty Versus Primary Stenting) is a prospective randomized trial performed at 9 medical centers in Germany, Austria, and Switzerland in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the ethics committee at each participating institution, and patients gave written informed consent. The study was overseen by an independent Data Safety Monitoring Board. A clinical events committee adjudicated major adverse events, and core laboratories provided independent analyses for duplex ultrasound and radiographic imaging (CoreLab Bad Krozingen; Bad Krozingen, Germany). Patients were eligible for the study if they were ≥21 years old, were not pregnant, and had peripheral artery disease with a Rutherford-Becker classification (RC) of 2 to 5. Angiographic eligibility required the presence of a single primary de novo target lesion (occlusion or stenosis) in the PA (≥4 mm in diameter) with a stenosis ≥70%, estimated by angiography. The lesion was not allowed to involve the SFA (arterial intersection with the femur in an anteroposterior view) or to extend into the infrapopliteal arteries (origin of the anterior tibial artery or tibioperoneal trunk). Major exclusion criteria were subintimal recanalization of the target lesion, restenosis of the PA, known systemic coagulopathy, renal failure requiring dialysis, life expectancy <2 years or other factors that made follow-up impossible, and intolerance to aspirin, clopidogrel, or heparin.

Study Device

Patients randomized to the stent group received a CE-marked and Food and Drug Administration–approved self-expanding NS (LifeStent Vascular Stent, Bard Peripheral Vascular; Tempe, AZ). Stents were available in diameters of 6, 7, and 8 mm and in lengths up to 170 mm. Stent selection was based on the manufacturer’s recommendation that stent diameter should be 1 to 2 mm greater than the reference diameter of the target lesion. Appropriate stent length was estimated visually with the aid of a radiopaque ruler. The intent of the study was to treat isolated atherosclerotic lesions of the PA with a single stent. Placement of ≥2 stents was only allowed as a bailout indication in cases of geographic miss of the first study stent.

Study Procedures

Arterial access-site selection was left to the discretion of the investigator. After arterial puncture and placement of a 6F introducer sheath, an initial dose of 5000 IU of heparin was administered. Randomization to either the group with PTA with provisional stenting or the primary NS placement group was completed after successful crossing of the target lesion with a guidewire. Patients were allocated to 1 of 2 treatment groups by use of a computer-generated random sequence, set in blocks for each participating center. Patients were randomly assigned to the groups in a 1:1 ratio.

A strict definition of primary NS implantation was followed with the goal of not predilating the lesion before NS placement, to avoid geographic miss (ie, the stent does not cover the entire predilated vessel segment). A residual stenosis of ≤30% of the vessel lumen diameter (visual estimate by the investigator) after NS implantation was considered successful treatment of the target lesion. The use of an additional NS was permitted if the target lesion was longer than the longest available stent, if the first NS did not completely cover the target lesion, or if a flow-limiting dissection required treatment proximal or distal to the primary NS.

Patients randomized to the PTA arm of the study received an angioplasty procedure in the standard manner. Balloon size selection was based on a visual estimate of the size of the vessel and the morphology of the vessel or lesion. A residual stenosis of ≤30% vascular lumen diameter by visual estimation after PTA was considered successful treatment of the target lesion. If there was a residual stenosis of >30% or a flow-limiting dissection, an additional, prolonged (5 minutes) PTA had to be performed. If there was a persistent stenosis of >30% after repeated and prolonged PTA or a flow-limiting dissection, a study stent was to be placed at the target lesion. After final intervention, the runoff status was reassessed to evaluate possible peri-interventional distal embolization.

All patients were given 100 mg of acetylsalicylic acid daily. If the patient was not taking acetylsalicylic acid before the procedure, a 500-mg loading dose was administered before the intervention. In addition, a loading dose of clopidogrel (1×300 mg PO) was administered on the day of the intervention, followed by a daily dose of 75 mg for a minimum of 4 weeks.

Follow-Up

The preinterventional workup and the follow-up visits after 6 and 12 months included clinical examination, calculation of the ankle-brachial index (ABI), determination of the stage of disease according to the RC, and target-lesion evaluation by duplex ultrasound. In case of NS placement during the index procedure, radiographs (2 orthogonal views with a standardized protocol) of the target lesion were taken at 1 year for assessment of stent fractures by the angiographic core laboratory. Stent fractures were classified as types 1 to 4.

Study End Points

The primary study end point was primary patency rate after 1 year, defined as freedom from target-lesion restenosis (luminal narrowing ≥50%) detected with duplex ultrasound. The definition of a 50% restenosis was based on peak systolic velocity ratio (peak systolic velocity within the target lesion divided by peak systolic velocity proximal to the target lesion in a healthy vessel segment) >2.4. Secondary end points included primary patency rate after 6 months and secondary patency rate, defined as patency after successful TLR after 1 year; the change in ABI; and the median change in RC class after 6 and 12 months. In addition, limb salvage rates and stent fracture rates were documented.

Death, major amputation and minor amputation, TLR (including need for surgical revascularization), and myocardial infarction were defined as major adverse events. All major events were determined cumulatively for the 370 days after index procedure. All clinical end points and major adverse events were adjudicated by an independent clinical events committee.

Statistical Analysis

On the basis of the published data, we assumed a patency rate of 50% with PTA after 1 year. The study was designed to have a power of 80% to detect an elevation of the patency rate by the NS to 70% with a 2-sided P<0.05. Estimating a dropout rate of 25%, we obtained a total sample size of 250 patients.

Data for all end points were evaluated in the intention-to-treat analysis. For the primary end point, the nonresponder imputation model was used, and a treatment-received analysis was performed additionally. For analyses based on the intention-to-treat set, patients who were randomized to the PTA group and who received a stent during the procedure for any reason (so-called crossover patients) were analyzed in 2 ways. Using the first analysis (type 1), provisional stent
placement was regarded as a TLR and loss of primary patency. In a post hoc analysis (type 2), provisional stent placement did not constitute a TLR or immediate loss of primary patency.

Continuous data are expressed as mean±SD. Categorical variables were compared with a 2-sided χ² test and continuous variables with a 2-sided Student’s t test. Changes in RC are expressed as median with interquartile range; group comparisons were performed with the Mann-Whitney U test. To control for unbalanced data, changes in RC and ABI were modeled by repeated-measures analysis. The stent fracture rate calculation was based on a per stent analysis. Event-free survival was compared by Kaplan-Meier analysis with the Mantel-Cox log-rank test constructed by Statistical Analysis Plan (SAP) software version 3.0. A 2-sided P<0.05 was considered to indicate statistical significance. To adjust for any remaining imbalance between study groups, we performed Cox regression analyses. The multivariable models included demographic, clinical, and interventional variables (Table 1), with a difference between the 2 study groups at a value of P≤0.1.

Results

Patient Characteristics

Between February 2007 and October 2010, 119 patients were randomly assigned to receive the NS and 127 to receive PTA. Both groups were similar with respect to all baseline variables. Overall, 64.2% of the patients were men; the mean age was 72 years (range, 41–89 years). One hundred ninety-five patients (79.3%) had intermittent claudication, and 51 patients (20.7%) had critical limb ischemia. The mean target-lesion length was 42.3±30 mm (range, 5–180 mm). Eighty-one occlusions (32.9%) were treated (Table 2).

Table 1. Baseline Characteristics of Each Treatment Group

<table>
<thead>
<tr>
<th></th>
<th>Stent (n=119)</th>
<th>PTA (n=127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (range), y</td>
<td>72 (42–89)</td>
<td>73 (41–89)</td>
</tr>
<tr>
<td>Males</td>
<td>63.9</td>
<td>64.6</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>27±4</td>
<td>26±4</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>36.1</td>
<td>37.8</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>75.6</td>
<td>81.9</td>
</tr>
<tr>
<td>Hypertension</td>
<td>82.4</td>
<td>88.2</td>
</tr>
<tr>
<td>Current smoker</td>
<td>21.8</td>
<td>24.4</td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>42.9</td>
<td>43.3</td>
</tr>
<tr>
<td>Carotid artery disease</td>
<td>17.6</td>
<td>13.4</td>
</tr>
<tr>
<td>Location of lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Popliteal (I)</td>
<td>29.4</td>
<td>29.1</td>
</tr>
<tr>
<td>Popliteal (II)</td>
<td>40.3</td>
<td>42.5</td>
</tr>
<tr>
<td>Popliteal (III)</td>
<td>5.9</td>
<td>4.7</td>
</tr>
<tr>
<td>Popliteal (I+II)</td>
<td>16.8</td>
<td>18.1</td>
</tr>
<tr>
<td>Popliteal (I+II+III)</td>
<td>5.9</td>
<td>4.7</td>
</tr>
<tr>
<td>Popliteal (I+II+III)</td>
<td>1.7</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Values are percentages unless otherwise indicated. There were no significant differences between the treatment groups. (I) indicates proximal part of the popliteal artery, pars I; (II), middle part of the popliteal artery, pars II; (III), distal part of the popliteal artery, pars III; and PTA, percutaneous transluminal angioplasty.

Acute Results

Because of flow-limiting dissections and residual stenosis (>30%) of the target lesion in the PTA group, a crossover to the NS group was needed in 25.2% of patients in that group (n=32). An average of 1.05 (range, 1–2) stents were implanted per target lesion. Eight patients (4.9%) needed an additional stent placement to cover the target lesion. The eventual procedure success was 100% in the entire study cohort. There was no significant difference between the study groups with regard to residual stenosis of the target lesion or the number of patent infrapopliteal arteries after the index procedure (Table 2). Peri-interventional complications (eg, postprocedural access site bleeding, abdominal wall hemorrhage, closure device–related stenosis) occurred in 2.4% of the patients in the PTA group and in 1.7% in the NS group (P=1). The mean ABI increased significantly from 0.67±0.42 at baseline to 0.98±0.35 at discharge (P<0.0001), with no significant difference between the groups (Table 2).

Results at 6 and 12 Months

Six patients (2.4%) died, 17 (6.9%) were lost to follow-up, and 6 (2.4%) withdrew consent. Ninety-nine patients (83.2%) in the NS group and 98 (77.2%) in the PTA group completed the 1-year follow-up (Figure 1).

In the intention-to-treat analysis (type 1), the rates of ≥50% target-lesion restenosis after 1 year were 32.6% (n=31) for the NS group and 55.1% (n=59) for the PTA group. Hence, the 1-year primary patency rates were 67.4% (n=64) and 44.9% (n=48; P=0.002), and 6-month primary patency rates were 76.3% (n=74) and 45.5% (n=50; P=0.0001), respectively. Using the intention-to-treat (type 2) and the treatment-received analyses, no significant difference concerning the primary end point could be demonstrated between the treatment groups. The 1-year primary patency rates were 67.4% and 69.2% for the NS group and 65.7% and 63% for the PTA group (P=0.92 and P=0.46; Figure 2), respectively. Secondary 1-year patency rates were 76.9% (n=70) for the NS group and 82.8% (n=77; P=0.42) for the PTA group. Multivariate logistic regression analysis revealed target-lesion length (<30mm versus >60mm lesion length; Odds ratio [OR]: 0.26; 95%-Confidence interval [CI]: 0.09–0.68; P=0.007), and total occlusions (stenosis versus occlusion; OR: 0.39; 95%-CI: 0.18-0.87; P=0.02) as independent predictors of restenosis.

The median (interquartile range) RC decreased from 3 (3) in the NS group and 3 (3) in the PTA group (P=0.33) at baseline to 1 (0–2) and 1 (0–3; P=0.72) at 6 months and 1 (0–2) and 1 (0–2; P=0.95) at 1 year, respectively. The median (interquartile range) change in RC was −2 (−3 to −1) at 1 year in both treatment groups (P=0.52).

The mean ABI increased from 0.63±0.38 in the NS group and 0.67±0.45 (P=0.51) in the PTA group at baseline to 0.92±0.27 and 0.93±0.39 (P=0.34) after 6 months and 0.89±0.27 and 0.93±0.32 (P=0.49) after 1 year, respectively. Hence, the mean ABI at 6 and 12 months in both groups remained significantly improved compared with baseline (P=0.0001).

The overall stent fracture rate was 3.4%. All fractures were classified as type 1 or 2. No correlation could be found between the incidence of stent fractures and either restenosis or TLR.
Adverse Events

Four patients (4%) in the NS group and 2 patients (2%; \(P=0.68\)) in the PTA group died during the follow-up period: 1 patient died as a result of complications after intestinal surgery, 1 developed gallbladder cancer, 1 died of a myocardial infarction, and 1 died of septic shock, whereas for 2 patients, the cause of death remained uncertain.

TLR was performed in 15 patients (14.7%) in the NS group and in 49 patients (44.1%) in the PTA group (\(P<0.0001\)). Three (3%) lower-leg minor amputations of the target limb were necessary in each treatment group (\(P=1\)). Hence, the limb salvage rate was 100% in both groups (Table 3). The Kaplan-Meier estimates of clinical event–free survival for the 2 groups during follow-up are shown in Figure 3.

Discussion

To the best of our knowledge, this is the first randomized, multicenter trial comparing NS placement with PTA for treatment of PA lesions. In the prespecified intention-to-treat analysis (type 1), this trial revealed favorable technical outcomes for the NS compared with PTA. Similar to the SFA bed, the use of NS resulted in significantly higher primary patency rates after 6 months and 1 year. Consistently, the number of TLRs was significantly lower after 1 year in patients treated with an NS. This difference was driven exclusively by intraprocedural crossover from the PTA arm to stent placement, which was classified as a primary end point and TLR. After the initial procedure, however, no significant differences concerning the primary end point and TLR could be observed between the study groups, as shown by the intention-to-treat analysis (type 2) and the treatment-received analysis. These results are in line with the outcomes of the RESILIENT trial (Randomized Study Comparing the Edwards Self-expanding LifeStent vs Angioplasty Alone in Lesions Involving the SFA and/or Proximal Popliteal Artery) and the ZILVER PTX trial, which investigated either bare NS or drug-eluting stents compared with PTA in SFA lesions. In both trials, an optimal acute balloon angioplasty outcome resulted in either similar (RESILIENT) or slightly inferior (ZILVER PTX) long-term patency rates compared with stent placement.

To date, there are only a few studies that exclusively address endovascular treatment options for PA lesions. Moreover, only 1 prospective, nonrandomized, single-center trial with a 32-patient cohort has 1-year results after PA (bail-out) stent placement available. The 1-year primary patency rate measured by duplex ultrasound and angiography in that trial was 81%. In a recently published study, Scheinert et al performed a retrospective, single-center analysis of 101 patients treated with a novel interwoven NS. Mean lesion length was 58.4 mm. Primary and secondary patency rates at 1 year were 87.7% and 96.5%, respectively. However, the performance of this particular stent was also investigated in another retrospective registry by Goltz et al that included patients with critical limb ischemia. Primary and secondary patency rates at 1 year in the 34 patients eligible for follow-up were 68.4% and 79.8%, respectively, and the TLR rate was 17.5%. The present study revealed comparable results in the NS group, with a 1-year primary patency rate of 67.4% and
TLR of 14.7%. Semaan et al\textsuperscript{15} compared PTA and atherec-tomy in a cohort of 56 patients with PA lesions. Because of residual stenosis or flow-limiting dissection, bailout stenting was performed in 45\% and 6\% of patients (\(P=0.005\)), respectively; however, 1-year primary patency rates were not significantly different between the study groups (73\% versus 75\%).\textsuperscript{15} In another study by Jahnke et al,\textsuperscript{14} 86 patients with PA lesions were treated with either conventional PTA or cryo-plasty. Bailout NS placement was necessary in 39\% and 30\% (\(P=0.35\)), and 9-month primary patency rates were 66.7\% and 79.3\% (\(P=0.14\)), respectively.\textsuperscript{14} Of note, the proportion of bailout stenting procedures and the primary patency rate of the PTA arms in the abovementioned studies were comparable to results for the PTA arm in the present study.

As shown in former SFA trials, patients with occlusions and long lesions of the PA were also at higher risk for restenosis in the present trial.\textsuperscript{19–21} The lack of broad acceptance for PA stent placement is mainly attributable to the fear of stent fractures, with possible subsequent restenosis in this vascular bed with high biomechanical stress next to the knee joint.\textsuperscript{7,9,16,22,23} Published data support assumptions that stent design and technical aspects during stent deployment (eg, stent elongation, stent overlap) play major roles in the appearance of stent fractures.\textsuperscript{6,8,9} However, the incidence of fractures in second-generation stents was low and ranged between 0\% and 8.1\% during a 1-year follow-up.\textsuperscript{6,13,17,24,25} Whether the stent fracture rate in the PA location might increase with longer duration of follow-up is not yet known and should be studied separately. In the RESLIENT trial, which investigated patients with lesions in the SFA and the proximal segment of the PA, the stent fracture rate was 1.8\% compared with 3.4\% in the present trial; in both trials, the same stent type was used. Moreover, with regard to the results of previous trials and the present trial, a relationship between the incidence of stent fractures and an increase in the restenosis rate could not be postulated.\textsuperscript{6,17,25,26} Therefore, the role that stent fractures play in the overall risk of restenosis is probably overestimated.

In the past decade, prospective, randomized trials demonstrated a significant improvement in RC in patients after successful stent placement in SFA lesions.\textsuperscript{24–26} No data are available concerning the clinical impact after successful PA interventions. In the present trial, 77\% of patients in the NS group and 73\% of patients in the PTA group showed an improvement of \(\geq 1\) class in RC 1 year after the index procedure. However, because of the comparable secondary patency rates in both study cohorts, no significant differences in the clinical end points, including changes in RC, ABI, amputation rate, and mortality, could be detected between study groups. Minor amputations occurred in only 6 patients, and the limb salvage rate of 100\% in the study cohort was comparable to that of previous SFA and PA studies.\textsuperscript{6,15,17} 

### Study Limitations

Because of the study protocol, no statement can be made concerning possible 1-year results of patients with suboptimal PTA results (residual stenosis \(\geq 30\%) or flow-limiting dissection) without the opportunity for provisional stent placement. Although core laboratories were used for duplex ultrasound and stent fracture analysis, the nonblinded study design could not completely rule out possible bias. Furthermore, no quality-of-life evaluations and no functional measures of walking were performed.

<table>
<thead>
<tr>
<th>Table 3. Major Adverse Events and Limb Salvage at 1-Year Follow-Up</th>
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<tr>
<td><strong>Stent (n=99)</strong></td>
</tr>
<tr>
<td>TLR (type 1 analysis)*</td>
</tr>
<tr>
<td>TLR (type 2 analysis)†</td>
</tr>
<tr>
<td>TVR</td>
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<tr>
<td>Bypass surgery</td>
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<td>Minor amputation</td>
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<tr>
<td>Limb salvage</td>
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<tr>
<td>Death</td>
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<tr>
<td>Rehospitalization</td>
</tr>
<tr>
<td>Myocardial infarction</td>
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<tr>
<td>Heart failure</td>
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</table>

Values are n (%). PTA indicates percutaneous transluminal angioplasty; TLR, target-lesion revascularization; and TVR, target-vessel revascularization.

*For target-lesion revascularization type 1 analysis, bailout/provisional stent placement during the index procedure was regarded as target-lesion revascularization.

†For target-lesion revascularization type 2 analysis, bailout/provisional stent placement during the index procedure did not constitute a target-lesion revascularization.
Conclusions

This randomized, multicenter study demonstrated that in the treatment of PA lesions, primary NS placement achieved superior acute technical success and higher primary patency than PTA only if provisional stenting was considered TLR. However, provisional stenting as part of a PTA strategy has equivalent 1-year patency. Thus, a provisional stenting strategy should be considered over primary stenting for the treatment of PA lesions.

Sources of Funding

The trial was investigator-initiated and was secondarily supported by Bard Peripheral Vascular Corp in terms of study monitoring, data collection, and data evaluation, with no direct financial support.

Disclosures

None.

References


Stenting has been shown to improve patency after femoral artery revascularization compared with balloon angioplasty. Limited data are available evaluating endovascular treatment for obstructive lesions of the popliteal artery. This prospective, randomized, multicenter trial compared primary nitinol stent placement to percutaneous transluminal angioplasty in patients with peripheral artery disease Rutherford-Becker class 2 to 5 who had de novo lesions in the popliteal artery. Treatment of popliteal artery lesions with primary nitinol stent placement achieved superior acute technical success and higher primary patency at 1 year than percutaneous transluminal angioplasty only when provisional nitinol stent placement was considered target-lesion revascularization and loss of patency. However, optimal percutaneous transluminal angioplasty with provisional stent placement, if indicated, resulted in comparable technical and clinical 1-year outcomes. The results presented contradict the generally accepted opinion that stent placement in the popliteal artery bed might lead to unfavorable technical and clinical outcomes. The stent fracture rate was 3.4%. Moreover, these results prove that in this area of high biomechanical stress, nitinol stent placement is safe and effective and could be considered after suboptimal percutaneous transluminal angioplasty results. Whether the stent fracture rate in the popliteal artery location might increase with longer duration of follow-up is not yet known and needs to be studied separately.
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