Stent Placement versus Balloon Angioplasty for the Treatment of Obstructive Lesions of the Popliteal Artery: A Prospective, Multi-centre, Randomized Trial

Running title: Rastan et al; Stent versus PTA in Popliteal Artery Treatment

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Abstract:

**Background**—Stenting has been shown to improve patency after femoral artery revascularization in comparison to balloon angioplasty (PTA). Limited data are available evaluating endovascular treatment for obstructive lesions of the popliteal artery (PA).

**Methods and Results**—This prospective, randomized, multi-centre trial compares primary nitinol stent (NS) placement to PTA in patients with peripheral artery disease Rutherford-Becker class (RC) 2-5 who had a de-novo lesion in the PA. The primary study endpoint was 1-year primary patency defined as freedom from target lesion restenosis (luminal narrowing of ≥50%) detected with duplex ultrasound. Secondary endpoints included target lesion revascularization (TLR) rate and changes in RC. Provisional stent placement was considered as TLR and loss of primary patency. Two-hundred-forty-six patients were included in this trial. The mean target lesion length was 42.3mm. One-hundred-ninety-seven patients were available for the 1-year follow-up. The 1-year primary patency rate was significantly higher in the NS group (67.4%) than in the PTA group (44.9%, P=0.0002). TLR rates were 14.7% and 44.1% (P=0.0001). However, when provisional NS placement was not considered as TLR and loss in patency no significant differences prevailed between the study groups (67.4% vs. 65.7%, P=0.92 for primary patency). Approximately 73% of patients in the PTA group and 77% in the NS group showed an improvement of at least one RC (P=0.31).

**Conclusions** Primary NS of obstructive lesions of the popliteal artery achieves superior acute technical success and higher 1-year primary patency, only if provisional stenting is considered as TLR. Provisional stenting, as part of a PTA strategy has equivalent 1-year patency, and should be preferred over primary stenting.

**Clinical Trial Registration Information**—www.clinicaltrials.gov. Identifier: NCT00712309.

**Key words:** peripheral artery disease, stent, angioplasty
Greater 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 (PAD). Intermittent claudication and critical limb ischemia are the most common symptoms in patients with lower extremity PAD.1,3

Besides conservative therapy and bypass surgery, endovascular therapy has been established as a treatment option for femoro-popliteal obstructive disease.2,3 During the last decade randomized trials revealed that with increasing lesion length nitinol stent placement (NS) provides frequently better patency, target lesion revascularization (TLR) rates, and clinical improvements compared to percutaneous transluminal balloon angioplasty (PTA) alone after treatment of superficial femoral artery (SFA) lesions including the proximal segment of the popliteal artery (PA).4-6 None of these trials, however, address true PA lesions beyond the proximal (P1) segment. To date, limited evidence exists concerning any kind of endovascular treatment for isolated PA obstructive disease. Due to excessive mechanical forces applied to the PA during motion the PA is considered as 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.7-9

The goal of this prospective, multi-centre, randomized trial was to investigate the efficacy and safety of nitinol stent placement compared to 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 centres 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 (CEC) adjudicated major adverse events, and core laboratories provided independent analyses for duplex ultrasound (DU) and radiographic imaging Laboratory (coreLab Bad Krozingen; Bad Krozingen, Germany).

Patients were eligible for the study if they were at least 21 years old, were not pregnant, and suffered from peripheral artery disease with a Rutherford category (RC) 2 to 5. Angiographic eligibility required the presence of a single primary de-novo target lesion (occlusion or stenosis) in the PA (4 mm to 7 mm in diameter) with a stenosis of at least 70%, estimated by angiography. The lesion was not allowed to involve the SFA (arterial intersection with the femur in an A-P view), and to extend into the infrapopliteal arteries (origin of the anterior tibial artery or tibio-peroneal trunk). Major exclusion criteria were subintimal recanalization of the target lesion, restenosis of the PA, known systemic coagulopathy, renal failure requiring dialysis, life expectancy less than 2 years or other factors making follow up impossible, and/or intolerance to aspirin, clopidogrel, and heparin.

**Study Device**

Patients randomized to the stent group received a CE marked and FDA-approved self-expanding NS (LifeStent Vascular Stent, Bard Peripheral Vascular; Tempe, AZ). Stents were available in diameters of 6mm, 7mm, and 8mm and in lengths up to 170mm. Stent selection was based on the manufacture’s recommendation that stent diameter should be 1 to 2mm above reference diameter of the target lesion. Appropriate stent length was visual estimated with the aid of a radiopaque
ruler. The intent of the study was to treat isolated atherosclerotic lesions of the PA with one single stent. Placement of two or more stents was only allowed as bail-out indication in cases of geographical 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 6 French introducer sheath, an initial dose of 5000IU heparin was administered. Randomization to either the PTA with provisional stenting or primary NS group was completed following successful crossing of the target lesion with a guide-wire. Patients were allocated to one of two treatment groups using a computer generated random sequence, set in blocks for each participating centre. 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 pre-dilating the lesion before NS placement in order to avoid geographical miss (i.e. the stent does not cover the entire pre-dilated vessel segment). A residual stenosis of \( \leq 30\% \) of the vessel lumen diameter (visual estimate by the investigator) following 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 a flow-limiting dissection needed 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 the visual estimate of the size of the vessel and the morphology of the vessel and/or lesion. A residual stenosis of \( \leq 30\% \) vascular lumen diameter by visual estimation following 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 \( > 30\% \)
following repeated and prolonged PTA, or a flow-limiting dissection, a study stent should be placed at the target lesion.

After final intervention the runoff status was re-assessed to evaluate possible periinterventional distal embolization.

All patients were received 100mg acetylsalicylic acid (ASA) daily. If the patient was not taking ASA prior to the procedure, a 500mg ASA loading dose was administered before the intervention. In additional, a loading dose of clopidogrel (1 x 300mg p.o.) was administered on the day of the intervention, followed by a daily dose of 75mg for a minimum duration of 4 weeks.

Follow-up
The pre-interventional work-up 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 DU. In case of NS placement during index procedure radiographs (two orthogonal views using 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 in type 1 to 4.\textsuperscript{10}

Study endpoints
The primary study endpoint was primary patency rate after 1 year, defined as freedom from target lesion restenosis (luminal narrowing of $\geq 50\%$) detected with DU. The definition of a 50% restenosis was based on the peak systolic velocity ratio (peak systolic velocity within the target lesion divided by peak systolic velocity proximal of the target lesion in a healthy vessel segment) $>2.4$.\textsuperscript{11,12}

Secondary endpoints included primary patency rate after 6 months and secondary patency
rate, defined as patency following successful TLR after 1 year, the change in ABI and the
median change of the RC class after 6 and 12 months. In addition, limb salvage rates and stent
fracture rates were documented.

Death, major- 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 endpoints and major
adverse events were adjudicated by an independent clinical-events committee.

**Statistical analysis**

Based on 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 two-sided p<0.05. Considering a dropout rate of 25% we obtained a total sample size of
250 patients.

Data for all endpoints were evaluated in the “intention-to-treat” analysis. Concerning the
primary endpoint the non-responder imputation model was used and the “treatment received”
analysis was performed additionally. For the analyses based on the “intention-to-treat” set,
patients who were randomized to the PTA group and who received a stent during procedure for
any reason (so called crossover patients) were analyzed in two 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 ±standard deviation (SD). Categorical variables
were compared with the use of the two-sided chi-square test and continuous variables were
compared with the use of the two-sided Student’s t-test. Changes in RC were expressed as
median with interquartile range and group comparisons were performed using the Mann-Whitney U test. To control for unbalanced data changes in RC and ABI were modeled using repeated measures analysis. The stent fracture rate calculation based on a per stent analysis.

Event-free survival was compared by Kaplan-Meier analysis with the use of the Mantel-Cox log-rank test constructed by the statistical analysis plan (SAP) software Version 3.0. A two-sided P value of less than 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 two 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 patients were assigned to receive PTA. Both groups were similar with respect to all baseline variables. Overall, 64.2 percent of the patients were men; the mean age was 72 years (range 41-89 years). Hundred-ninety-five patients (79.3%) suffered from intermittent claudication and 51 patients (20.7%) suffered from critical limb ischemia. Most frequently (65.4%, N=160) the middle part of the popliteal artery (pars II) was involved in the target lesion (Table 1). The mean target lesion length was 42.3±30mm (range: 5mm-180mm). Eighty-one (32.9%) occlusions were treated (Table 2).

Acute results

Due to flow-limiting dissections and residual stenosis (>30%) of the target lesion in the PTA group a cross-over to the NS group was needed in 25.2% (N=32). An average of 1.05 (Range 1-
2) stents were implanted per target lesion. Eight (4.9%) patients 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 concerning the residual stenosis of the target lesion and the number of patent infrapopliteal arteries after the index procedure (Table 2). Periinterventional complications (e.g. post procedural 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 (2.4%) patients died, 17 (6.9%) patients were lost during the follow-up period and 6 patients (2.4%) withdrew consent. Ninety-nine (83.2%) patients in the NS group and 98 (77.2%) patients 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 six-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 endpoint 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 over 60mm length [Odds ratio (OR): 0.26; Confidence interval (CI): 0.09-0.68; P=0.007], and total occlusions (OR: 0.39; CI: 0.18-0.87; P=0.02) as independent predictors of restenosis.

The median (interquartile range, IQR) RC decreased from 3 (3) in the NS group and 3 (3) in the PTA group (P=0.33) at baseline to 1 (0 to 2) and 1 (0 to 3; P=0.72) at 6 months and 1 (0 to 2) and 1 (0 to 2; P=0.95) at 1 year, respectively. The median (IQR) 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 to baseline (P=0.0001).

The overall stent fracture rate was 3.4%. All fractures were classified as type I or II. No correlation could be found between the incidence of stent fractures and neither restenosis nor 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: One patient deceased as a result of complications after intestine surgery; one patient suffered gallbladder cancer; one patient in consequence of a myocardial infarction, and one patient died because of a septic shock. In 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 events free survival for the two groups during follow-up is shown in Figure 3.

Discussion

To our best knowledge, this is the first randomized, multi-centre trial comparing NS placement with PTA for treatment of PA lesions. In the pre-specified intention-to-treat analysis (type 1) this trial reveals favourable technical outcomes for the NS compared to PTA. Similar to the SFA bed the use of NS resulted in significantly higher primary patency rates after 6 months and 1 year.\textsuperscript{5, 6}

Consistently, the number of TLR was significantly lower after 1-year in patients treated with NS. This difference is exclusively driven by intra-procedural cross-over from the PTA arm to stent placement that was classified as primary endpoint and TLR. After the initial procedure, however, no significant differences concerning the primary endpoint 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 and the ZILVER PTX trial investigating either bare nitinol stents or drug-eluting stents as compared to 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 in comparison to stent placement.\textsuperscript{6, 13}

To date, there are only a few studies exclusively addressing endovascular treatment options of PA lesions.\textsuperscript{14-18} Moreover, only of one prospective, non-randomized, single-center trial with a 32 patient cohort 1-year results after PA (bailout-) stent placement are available. The 1-year primary patency rate measured by DU and angiography was 81%.\textsuperscript{16} In a recent published
study Scheinert et al. performed a retrospective, single-centre analysis of 101 patients treated with a novel interwoven nitinol stent. Mean lesion length was 58.4 mm. Primary and secondary patency rates at 1-year were 87.7% and 96.5%, respectively.18 However, the performance of this particular stent was also investigated in another retrospective registry by Goltz et al. including 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%.17 The present study reveals comparable results in the NS group with a 1-year primary patency rate of 67.4% and TLR of 14.7%. Semann et al. compared PTA and atherectomy in a cohort of 56 patients with PA lesions. Due to residual stenosis or flow-limiting dissection bailout stenting was performed in 45% and 6% (P=0.005), respectively. However, 1-year primary patency rates show no significant differences between the study groups (73% versus 75%).15 In another study by Jahnke et al. 86 patients with PA lesions were treated using either conventional PTA or cryoplasty. 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.14 Noteworthy, the portion of bailout stenting procedures and the primary patency rate of the PTA arms in the mentioned studies are comparable with the results for the PTA arm in the present study.

As shown in former SFA trials, occlusions and long lesions of the PA were also at higher risk for restenosis in the present trial.19-21

The lack of broad acceptance concerning PA stent placement is mainly due to the fear of stent fractures with possible consecutive restenosis in this vascular bed with high biomechanical stress next to the knee joint.7, 9, 16, 22, 23 Published data support assumptions that stent design and technical aspects during stent deployment (e.g. stent elongation, stent overlap) play major roles in the appearance of stent fractures.6, 8, 9 However, the incidence of fractures in second-
generation stents is low and ranges between 0% and 8.1% during a 1-year follow-up.\textsuperscript{6, 13, 17, 24, 25}

If stent fracture rate in popliteal artery location might increase with duration of follow-up is not yet known and needs to be studied separately. In the RESLIENT trial investigating patients with lesions in the SFA and the proximal segment of the PA the stent fracture rate was 1.8% as compared to 3.4% in the present trial, considering that in both trials the same stent type has been used. Moreover, regarding the results of previous trials and the present trial, an evident relationship between the incidence of stent fractures and increase in restenosis rate could not be postulated.\textsuperscript{6, 17, 25, 26} Therefore, the part of stent fractures within the overall risk of restenosis is probably overestimated.

In the last decade prospective, randomized trials demonstrate a significant improvement in RC in patients after successful stent placement of 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 in 73% of patients in the PTA group showed an improvement of $\geq$1 class in RC 1-year after index procedure. However, due to the comparable secondary patency rates in both study cohorts, no significant differences in the clinical endpoints including changes in RC, ABI, amputation rate, and mortality could be detected between the study groups. Minor amputations occurred only in 6 patients and the limb salvage rate of 100% in the study cohort is comparable with previous SFA and PA studies.\textsuperscript{6, 15, 17}

\textbf{Limitations}

Due to the study protocol no statement can be made concerning possible 1-year results of the patients with suboptimal PTA results (residual stenosis $\geq$30% or flow-limiting dissection) without the opportunity of a provisional stent placement.

Although core labs were utilized for DU and stent fracture analysis, the non-blinded study
design could not completely rule out possible bias. Furthermore, no quality of life evaluations and no functional measures of walking had been performed.

Conclusion

This randomized, multi-centre study demonstrates that in the treatment of PA lesions primary NS achieves superior acute technical success and higher primary patency compared to PTA, only if provisional stenting is considered as 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.

Funding Sources: The trial was investigator initiated and was secondarily supported by Bard Peripheral Vascular Corp. in terms of study monitoring, data collection, and data evaluation without direct financial support.

Conflict of Interest Disclosures: None.

References:


12. Ranke C, Rieder M, Creutzig A, Alexander K. [A nomogram of duplex ultrasound quantification of peripheral arterial stenoses. Studies of the cardiovascular model and in


**Table 1.** Baseline Characteristics of Each Treatment Group*

<table>
<thead>
<tr>
<th></th>
<th>Stent (N=119)</th>
<th>PTA (N=127)</th>
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</thead>
<tbody>
<tr>
<td>Age (years, range)</td>
<td>72 (42-89)</td>
<td>73 (41-89)</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>63.9</td>
<td>64.6</td>
</tr>
<tr>
<td>Body-mass-Index (%)</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>
</tbody>
</table>

*Plus-minus values are means ±SD. There were no significant differences between the treatment groups.

(I), 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
### Table 2. Target Lesion Characteristics and Acute Results of Each Treatment Group*

<table>
<thead>
<tr>
<th></th>
<th>Stent (N=119)</th>
<th>PTA (N=127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of the lesion (mm)</td>
<td>41.3±31</td>
<td>43.2±28</td>
</tr>
<tr>
<td>Occlusion (%)</td>
<td>32.8</td>
<td>33.1</td>
</tr>
<tr>
<td>Target lesion diameter stenosis (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre intervention</td>
<td>92.9±7</td>
<td>92.5±7</td>
</tr>
<tr>
<td>Post intervention</td>
<td>12.9±24.8</td>
<td>11.6±12.5</td>
</tr>
<tr>
<td>Procedural success (%)</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Number of patent IPA after procedure (%)</td>
<td>58.5</td>
<td>50.6</td>
</tr>
<tr>
<td>2</td>
<td>39.0</td>
<td>47.1</td>
</tr>
<tr>
<td>3</td>
<td>2.4</td>
<td>3.8</td>
</tr>
<tr>
<td>ABI pre intervention</td>
<td>0.63±0.38</td>
<td>0.69±0.45</td>
</tr>
<tr>
<td>ABI post intervention</td>
<td>0.94±0.28</td>
<td>1.0±0.40</td>
</tr>
</tbody>
</table>

*Plus-minus values are means ±SD. There were no significant differences between the treatment groups.
IPA= infrapopliteal arteries
ABI= ankle-brachial index

### Table 3. Major Adverse Events and Limb Salvage at 1-Year Follow-up

<table>
<thead>
<tr>
<th></th>
<th>Stent (N=99)</th>
<th>PTA (N=98)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR</td>
<td>15 (14.7%)</td>
<td>49 (44.1%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>TLR†</td>
<td>15 (14.7%)</td>
<td>22 (21.4%)</td>
<td>0.29</td>
</tr>
<tr>
<td>TVR</td>
<td>3 (3%)</td>
<td>4 (4%)</td>
<td>1</td>
</tr>
<tr>
<td>Bypass surgery</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
<td>1</td>
</tr>
<tr>
<td>Minor Amputation</td>
<td>3 (3%)</td>
<td>3 (3%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Limb salvage</td>
<td>99 (100%)</td>
<td>98 (100%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Death</td>
<td>4 (4%)</td>
<td>2 (2%)</td>
<td>0.68</td>
</tr>
<tr>
<td>Rehospitalisation</td>
<td>9 (8.8%)</td>
<td>14 (14%)</td>
<td>0.35</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Heart failure</td>
<td>4 (4%)</td>
<td>2 (2%)</td>
<td>0.68</td>
</tr>
</tbody>
</table>

TLR*, target lesion revascularization (Type 1 analysis): bailout/provisional stent placement during index procedure is regarded as TLR.
TLR†, target lesion revascularization (Type 2 analysis): bailout/provisional stent placement during index procedure does not constitute a TLR.
TVR, target vessel revascularization
CAD, coronary artery disease
Figure Legends:

Figure 1. Study profile.

Figure 2. Rates of Primary Patency at 1-Year. Shown are the patency rates based on the “intention-to-treat” analysis (Typ 1: provisional stent placement was regarded as a loss of patency, and Type 2: provisional stent placement did not constitute a loss of patency), and the “treatment-received” analysis.

Figure 3. Event-free survivals in the two groups at 1-year [Type 1 analysis (A); Type 2 analysis (B)]. Survival free from target lesion and target vessel revascularization, major and minor amputation, myocardial infarction, and death was compared by Kaplan-Meier analysis with the use of the Mantel-cox log-rank test.
Figure 1

N = 246
Patients randomized

N = 127
PTA

Withdraw consent (N = 3)
Lost to FU (N = 11)
Death (N = 2)
On study:
No 1-year FU visit (N = 13)

N = 98
1-year FU performed

N = 119
Stent

Withdraw consent (N = 3)
Lost to FU (N = 6)
Death (N = 4)
On study:
No 1-year FU visit (N = 7)

N = 99
1-year FU performed
**Figure 3**

<table>
<thead>
<tr>
<th></th>
<th>No. at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stent</strong></td>
<td>119</td>
</tr>
<tr>
<td><strong>PTA</strong></td>
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