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◆CLINICAL INVESTIGATION ◆

German Multicenter Real-World Registry of Stenting for Superficial Femoral Artery Disease: Clinical Results and Predictive Factors for Revascularization

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Purpose: To investigate nitinol stent treatment of superficial femoral artery (SFA) lesions and the impact of different risk factors on the need for clinically driven target lesion revascularization (TLR) in a large, real-world population of claudicants.

Methods: Patients presenting with symptomatic SFA stenosis >70% were consecutively enrolled in the 13-center MARIS prospective registry (*ClinicalTrials.gov* identifier NCT01067885). There was no restriction on lesion length, thus leading to the inclusion of a real-world as well as high-risk patient cohort. The 998 participating patients (657 men; mean age 67.4±9.2 years) had 1050 lesions treated with the same nitinol stent type. The mean lesion length was 9.5±9.6 cm (range 0.5–44; median 8.0); more than a third of the lesions (450, 42.9%) were total occlusions. The primary endpoint was the need for clinically driven target lesion revascularization (TLR) at 12 months.

Results: Acute technical success was achieved in 1042 (99.2%) lesions. Restenosis occurred in 187 (23.7%) and reocclusion in 79 (10.0%) lesions at 12 months. The primary endpoint of TLR at 12 months was reached by 136 (17.2%) patients. The periprocedural complication rate was 5.4%. Independent predictors of TLR were female gender [odds ratio (OR) 0.5, 95% confidence interval (CI) 0.3 to 0.7, p<0.001] and lesion length >20 cm vs. 10 cm (OR 2.7, 95% CI 1.1 to 6.6, p=0.029) and 10–20 cm vs. 10 cm (OR 1.9, 95% CI 1.0 to 4.1, p=0.047).

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The authors declare no association with any individual, company, or organization having a vested interest in the subject matter/products mentioned in this article.

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Conclusion: Stent implantation in the SFA is safe and associated with favorable acute and midterm results in a real-world setting. Lesion length and female gender were identified as independent risk factors for TLR.

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Key words: angioplasty, peripheral artery disease, stent, superficial femoral artery, restenosis, reocclusion, target lesion revascularization, lesion length, gender

Percutaneous balloon angioplasty has been available as a treatment for superficial femoral artery (SFA) disease since the 1970s. However, procedural and long-term results of standard angioplasty are unsatisfactorily limited, especially in patients with moderate to high lesion complexity or disease burden.[1]

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The use of stents has revolutionized the management of coronary artery disease, improving success rates and long-term outcomes. Accordingly, stenting has been proposed also for SFA disease.[2] Whereas early generation balloon-expandable stainless steel stents were not associated with favorable results, randomized trials have suggested that routine stenting with self-expanding nitinol stents confers durable benefits in comparison to standard balloon angioplasty.[3–7] However, the available randomized trials are fraught with stringent selection criteria and limited sample sizes. Observational registries, if carefully planned and prospectively conducted, can provide important and complementary insights into the risk-benefit balance of medical interventions. Accordingly, we conducted a prospective multicenter observational registry to appraise early and midterm outcomes of routine SFA stenting.

METHODS

Study Design

Patients were eligible for enrollment in the prospective observational MARIS registry if they were at least 21 years of age and had a SFA lesion located at least 1 cm from the SFA origin in order to avoid any compression of the deep femoral artery due to stent implantation. Target lesion diameter stenosis had to be at least 70% by visual estimate, but there was no restriction on lesion length, thus leading to the inclusion of a real-world as well as high-risk patient cohort. The popliteal artery as well as one of the infrapopliteal (below-the-knee) vessels had to be continuously patent for sustained distal runoff. Clinically, the patients had to suffer from symptomatic chronic limb ischemia (Rutherford category 1–5). Major exclusion criteria were permanent treatment with oral anticoagulants, coagulation disorder, thrombolytic therapy within 72 hours before the intervention, active gastrointestinal bleeding, hyperthyroidism, allergy to contrast agents or antiplatelet agents, acute or subacute ($\leq$4 weeks) thrombotic occlusion, and an untreated ipsilateral iliac artery stenosis. Renal insufficiency was defined as estimated glomerular filtration rate (eGFR) $<$60 mL/min. All patients were informed about the nature of this study and the interventional procedures involved and gave their written consent. The study was approved by the ethics committees at all participating centers and was registered on the National Institutes of Health website (*ClinicalTrials.gov*; identifier NCT01067885).

Between April 2006 and December 2008, 1000 consecutive patients were enrolled at 13 German centers; the majority were from 3 sites (44.7%, 21.5%, and 15.9%, respectively). Two patients withdrew their consent prior to the intervention, resulting in an overall number of 998 patients (657 men; mean age 67$\pm$9 years). A third of patients were diabetics and 43% were current smokers (Table 1). The prevalence of hypertension, hypercholesterolemia, and renal insufficiency was 86.4%, 66.5% and 10.5%, respectively. The majority of patients suffered from moderate to severe claudication. A total of 1050 lesions were treated. The mean lesion length was 9.5$\pm$9.6 cm [range 0.5–44; median 8.0 cm (IQR 4–15)]

TABLE 1
Baseline Characteristics of the 998 Study Patients

Age, y	67.4±9.2
Male gender	657 (65.8%)
Diabetes mellitus	320 (32.1%)
IDDM	140 (43.8%)
NIDDM	180 (56,2%)
Hypertension	861 (86.4%)
Hypercholesterolemia	664 (66.5%)
Current smoking	425 (42.6%)
Statin use	561 (56.2%)
Renal insufficiency*	105 (10.5%)
Rutherford category	
0	9 (0.9%)
1	240 (24.1%)
2 or 3	688 (68.9%)
4	23 (2.3%)
5 or 6	38 (3.8%)

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).
IDDM: insulin-dependent diabetes mellitus, NIDDM: non-insulin-dependent diabetes mellitus.
* Estimated glomerular filtration rate <60 mL/min using Cockroft-Gault formula.

with a length of 10 to 20 cm in 282 (26.9%) lesions and >20 cm in 204 (19.4%) lesions. More than a third of the lesions (450, 42.9%) were total occlusions. Lesion characteristics are listed in Table 2.

Study Stent and Interventions

The study stent was the Maris Vascular Stent (Medtronic Inc., Santa Rosa, CA, USA). This self-expanding open-cell nitinol stent (Fig. 1) was available in nominal diameters of 4 to 14 mm (in 1-mm increments) and lengths of 20 to 120 mm (in 20-mm increments) at the time of enrollment. In the context of this study, only stents with a 5- to 7-mm diameter were implanted.

All patients had to be premedicated with aspirin (100 mg/d) and clopidogrel (75 mg/d) for at least 10 days. Patients not on this regimen were given an intravenous bolus of 500 mg of aspirin immediately before the intervention plus 300 mg of clopidogrel within 1 hour of the final digital subtraction angiography (DSA).

TABLE 2
Characteristics of the 1050 Lesions Treated and Details of the Procedures

Lesion type	
Stenosis	553 (52.7%)
Occlusion	450 (42.9%)
Restenosis/reocclusion	47 (4.5%)
Mean lesion length, cm	9.5±9.6
Lesion length, cm	
<10	564 (53.7%)
10–20	282 (26.9%)
>20	204 (19.4.%)
Lesion involvement	
Proximal SFA	312 (29.7%)
Mid SFA	495 (47.1%)
Distal SFA	630 (60.0%)
Popliteal artery	65 (6.2%)
Calcification*	
None	142 (13.5%)
Mild	238 (22.7%)
Moderate	343 (32.7%)
Severe	327 (31.1%)
Stents per patient	1.5±0.8
Stents per lesion	
1	755 (71.9%)
2	161 (15.3%)
3 or more	134 (12.8%)
Reference vessel diameter, mm	5.5±0.6
Total stented length, mm	114.2±95.1
Distal runoff (number of open lower leg arteries)	2.4±0.8

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).
SFA: superficial femoral artery.
* Category of calcification based on investigator's assessment.

Access to the culprit SFA lesion was achieved at the investigator's discretion either by way of a retrograde approach from the contralateral femoral artery using a dedicated 6-F crossover sheath (e.g., Balkin; Cook Medical Inc., Bloomington, IN, USA) or via an antegrade (ipsilateral) approach with a standard 6-F sheath (e.g., Radifocus Introducer II; Terumo Medical Corp., Somerset, NJ, USA).

After sheath placement, an intravenous bolus of 3000 to 5000 units of heparin (70 U/kg) was administered. DSA was subsequently performed to assess the type of lesion (stenosis or total occlusion), its distance from the SFA origin, and its length (both deter-

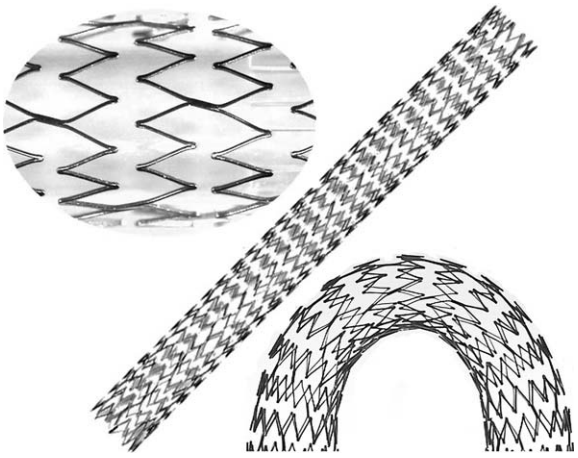

Figure 1 ◆ The Maris self-expanding nitinol stent has a zigzag open-cell design with reinforced connecting links.

mined by means of a radiopaque ruler placed below the patient's upper thigh), as well as the degree of calcification. Furthermore, the patency status of the ipsilateral iliac arteries, the popliteal artery, and the infrapopliteal arteries was documented. Protocol-mandated angioplasty of any ipsilateral iliac artery stenosis was performed prior to treatment of the culprit SFA lesion.

Following successful passage of the target lesion with a hydrophilic 0.018-inch or 0.035-inch guidewire, direct implantation without lesion predilation was preferably performed. In stenoses >80% and totally occluded lesions that precluded stent advancement, angioplasty with a balloon slightly undersized (~1 mm) in comparison to the study stent was done to enable stent placement. The Maris stent was implanted aiming at complete lesion coverage with a single stent. The stent dimensions were chosen such that the nominal diameter exceeded the reference vessel diameter by 1 mm and the length exceeded the lesion length by 5 to 10 mm proximal and distal. Deployment of additional study stents abutting the index stent was allowed in cases where the index lesion was too long for one stent, the first stent was positioned incorrectly, or a dissection extended beyond the stent margins. All stents were postdilated at moderate to high pressure (8 to 16 atmospheres) with a balloon-to-artery diameter ratio of 1:1. The intervention was concluded with a DSA to document the final outcome. Acute angiographic success was defined as a residual diameter stenosis <30% by visual estimate. Patients received both aspirin and clopidogrel after the procedure (aspirin 100 mg/d indefinitely, plus clopidogrel 75/d mg for at least 1 month).

Clinical Evaluation

The patient's clinical status was evaluated before the intervention and prior to discharge, as well as during outpatient hospital visits at 6 and 12 months independent of patient symptoms. Color duplex ultrasound examinations of the target SFA were performed within 1 week before the intervention and at the 6- and 12-month follow-up visits. Each examination comprised measurements of the maximum peak systolic velocity (PSV) 2 cm proximal to the culprit lesion ("prestenotic"), within the lesion ("intrastenotic"), and up to 4 cm distal to the lesion ("poststenotic"). The ratio of the maximum intrastenotic PSV and the maximum prestenotic PSV [proximal peak velocity ratio ($PVR_{proximal}$) = $PVS_{intrastenotic}/PVS_{prestenotic}$] determined the degree of percent stenosis by means of a validated reference table.[8] All stents were scheduled for biplanar radiography at 12 months to detect stent fractures.

Endpoints

The primary study endpoint was the rate of target lesion revascularization (TLR) clinically driven by restenosis/reocclusion and symptoms at 12 months. Secondary endpoints and outcome measurements were acute technical success (<30% residual stenosis judged by visual estimation at the end of the intervention), periprocedural complications, binary restenosis (PSV ratio ≥2.4 or assessed by angiography prior to TLR) at 6 and 12 months, TLR at 6 months, number of stent fractures, vascular complications, amputation, and death within 12 months.

Statistical Analysis

Continuous variables are reported as mean ± standard deviation or median [interquartile

range (IQR)]. Categorical variables are presented as counts and percentages. Time to TLR was analyzed using the Kaplan-Meier method. The Cochrane-Armitage trend test was applied to binomial proportions across the levels of a single variable. In order to correct for center effects, hierarchical univariate and multivariable logistic regression analyses were performed to identify predictors of TLR. Results are presented as odds ratios (OR) and 95% confidence intervals (CI). All tests were 2 tailed; $p<0.05$ were considered the threshold of significance. No correction for multiple testing was done. Statistical analyses were performed using SPSS (version 19; IBM Corporation, Armonk, NY, USA) and SAS (version 9.2; SAS Institute, Inc, Cary, NC, USA).

RESULTS

Acute technical success was achieved in 1042 (99.2%) lesions including total occlusions. All periprocedural complications (5.4%, Table 3) were minor: no deaths, acute amputations, or conversions to vascular surgery were recorded.

Clinical follow-up was completed in 848 (85.0%) patients at 6 months and in 789 (79.1%) patients at 12 months, with duplex ultrasound in 796 and 754 patients, respectively. At 6 and 12 months, 791 (79.3%) and 448 (44.9%) patients, respectively, still received dual antiplatelet therapy. TLR was performed more frequently within the second than within the first half of the year after stenting (Fig. 2). Clinically driven TLR was performed in 21 (2.5%) patients at 6 months and in 136 (17.2%) patients at 12 months (Table 3, Fig. 2). The incidence of TLR was significantly associated with lesion length (9.3% for lesions <10 cm, 19.6% for lesions between 10 and 20 cm, and 25.1% for lesions >20 cm, $p<0.001$).

Univariate analysis (Fig. 3A) showed that TLR was associated with female gender (OR 0.5, 95% 0.3 to 0.7, $p<0.001$), occlusion (OR 1.8, 95% 1.2 to 2.6, $p=0.002$), proximal location (OR 2.2, 95% CI 1.5 to 3.2, $p<0.001$), lesion length (10–20 cm vs. <10 cm: OR 2.2, 95% CI 1.4 to 3.6, $p=0.001$; >20 cm vs. <10 cm: OR 3.3, 95% CI 2.2 to 5.1, $p<0.001$), stent length (>12 cm vs. ≤6 cm: OR 3.2, 95% CI 2.1 to 5.1, $p<0.001$; 6–12 cm vs. ≤6 cm: OR 1.8, 95% CI 1.1 to 2.9, $p=0.017$), and multiple stenting (OR 2.5, 95% CI 1.7 to 3.6, $p<0.001$). However, multivariate analysis (Fig. 3B) showed that only female gender (OR 0.5, 95% CI 0.3 to 0.7, $p<0.001$) and lesion length (>20 cm vs. 10 cm: OR 2.7, 95% CI 1.1 to 6.6, $p=0.029$; 10–20 cm vs. 10 cm: OR 1.9, 95% CI 1.0 to 4.1, $p=0.047$) were independent predictors of TLR at 12 months. Classical risk factors, such as age, diabetes, hypertension, hypercholesterolemia, or smoking, as well as lesion-related risk factors, such as calcification or vessel diameter, did not impact the 12-month TLR rate (Fig. 3).

Overall, restenoses or reocclusions occurred in 165 (19.7%) lesions at 6 months and 266 (33.7%) lesions at 12 months, of which 187 (23.7%) were restenosed and 79 (10.0%) reoccluded. The incidence of restenoses/reocclusions at 12 months was significantly associated with lesion length: 21.7% for lesions up to 10 cm, 34.7% for intermediate

TABLE 3
Clinical Results

Acute technical success*	1042 (99.2%)
Periprocedural complications	54 (5.4%)
Dissection	25 (2.5%)
False aneurysm	12 (1.2%)
Hematoma	5 (0.5%)
Distal embolization	5 (0.5%)
Loss of delivery tip†	3 (0.3%)
Acute stent occlusion	2 (0.2%)
Perforation	2 (0.2%)
Bleeding	0
Death	0
Follow-up at 6 months	848 (85.0%)
TLR	21 (2.5%)
Restenosis or reocclusion	165 (19.5%)
Follow-up at 12 months	789 (79.1%)
Death	14 (1.8%)
Major amputation	1 (0.1%)
Minor amputation	3 (0.4%)
TLR	136 (17.2%)
Restenosis or reocclusion	266 (33.7%)
Vascular complications	7 (0.9%)

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).
TLR: target lesion revascularization.
* Residual angiographic stenosis <30%.
† Resolved by product improvement.

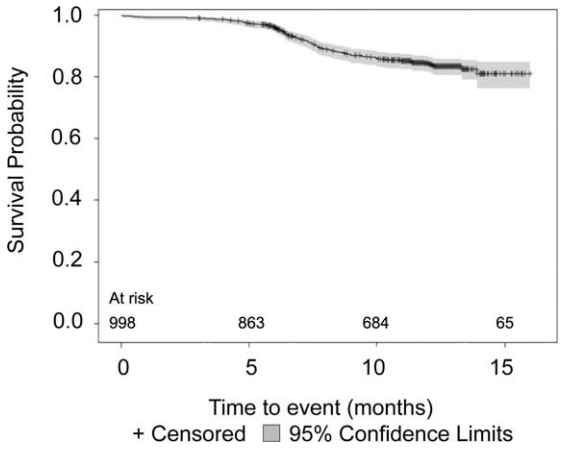

Figure 2 ◆ Freedom from target lesion revascularization after nitinol stent implantation for SFA disease in 998 patients.

lesions from 10 to 20 cm, and 51.2% for long lesions >20 cm ($p_{Trend}<0.001$). For occlusions, the restenosis/reocclusion incidence was 39.5% vs. 21.8% for stenosis at 12 months ($p<0.001$). Female gender was not associated with an increased restenosis/reocclusion rate (female 37.5% vs. male 30.8%, $p=0.142$). Vessel diameter did not impact the restenosis/reocclusion rate. Significantly more restenoses or reocclusions were seen in the left leg than in the right (37.5% vs. 28.9%, $p=0.031$).

Rutherford classification declined from 2.6 at baseline to 1.0 at 12 months on average. The mean ankle-brachial index rose from 0.7±0.3 at baseline to 0.9±0.2 and 0.8±0.2 at 6 and 12 months, respectively. The mean walking distance was 121.4±101.7 meters at baseline and 197.2±148.8 and 191.3±170.4 meters at 6 and 12 months, respectively.

In the 524 patients examined by biplanar radiography at 12 months, 49 (9.4%) had a stent fracture, which did not increase the 12-month restenosis/reocclusion rate significantly (28.5% and 21.6% in patients with and without stent fracture, respectively, $p>0.05$). During the 12-month follow-up period, 14 (1.7%) patients died; 4 (0.5%) patients had an amputation due to preexisting gangrene. No death or amputation was related to the index procedure.

DISCUSSION

Treatment by stent implantation is a standard approach for SFA lesions today. However, the knowledge of safety and efficacy derives mainly from small trials with distinct inclusion criteria. This ~1000-patient registry allowed for detailed analyses to identify clinical results and independent patient and lesion-related risk factors. Given that long lesions in particular are still treated preferably by surgery, this study offers valid data to aid in the choice of the adequate approach on the basis of patient and lesion characteristics.

We have treated stenosed, occluded, or restenosed SFA lesions from 0.5 to 44 cm in length by implanting a self-expanding nitinol stent in a real-world setting. The only strict

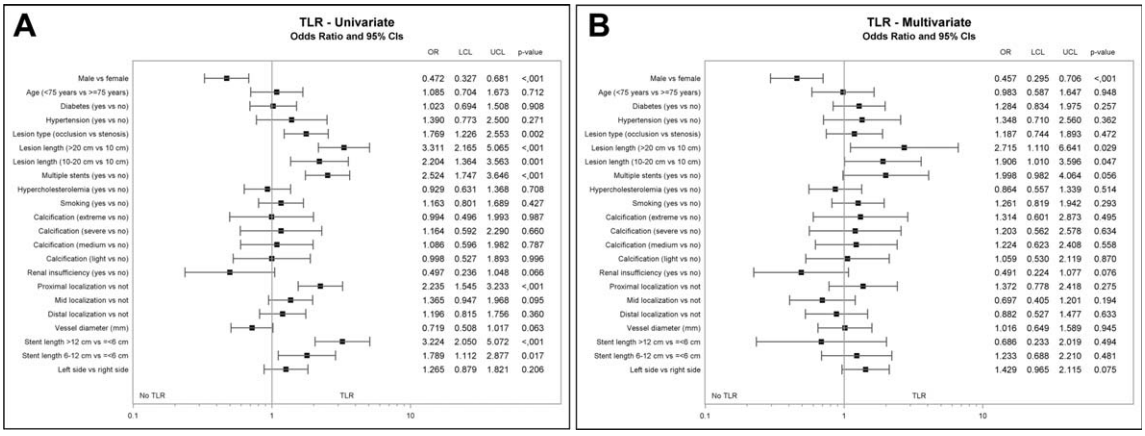

Figure 3 ◆ (**A**) Univariate and multivariate (**B**) analysis of factors influencing target lesion revascularization after nitinol stenting at 12 months. CI: confidence interval, LCL: lower confidence level, OR: odds ratio, TLR: target lesion revascularization, UCL: upper confidence level.

contraindication for enrollment was oral anticoagulation because in such patients the additional dual antiplatelet therapy mandatory after stent implantation would not have been appropriate.

Lesion Length

The overall 17.2% rate of TLR at 12 months for 9.5-cm SFA lesions on average confirms the results of previously published smaller studies. Bosiers et al.[9] and Diehl et al.[10] found TLR rates of 21% for 9.6-cm lesions and 23% for 9.4-cm lesions, respectively, treated with nitinol stents. Reflecting on our finding of lesion length as an independent predictor of TLR at 12 months, trials that addressed shorter SFA lesions showed lower TLR rates of 14.9% for 4.5-cm[4], 10.1% for 6.4-cm,[11] and 12.7% for 7.0-cm lesions.[5,6] Likewise, a meta-analysis of paclitaxel-coated balloon treatment with provisional stenting (crossover 4%–21%) for short SFA lesions of 5.7 to 8 cm on average led to a comparable TLR rate of 12.2%.[12] Accordingly, Bosiers et al.[13] found a 31.8% TLR rate for long lesions averaging 24.2 cm in length at 12 months. Slightly lower TLR rates resulted from studies assessing paclitaxel-eluting stents for SFA lesions. Dake et al.[14] showed a TLR rate of 9.5% for 10-cm SFA lesions and Bosiers et al.[15] recorded a 14.6% rate of TLR for SFA lesions averaging 22.6 cm in length. Clearly, the frequency of TLR corresponds with lesion length.

Our finding of a 33.7% restenosis or reocclusion rate at 12 months is also comparable with published data from nitinol stent trials. Diehl et al.[10] and Bosiers et al.[9] found 28.3% and 27.8% binary restenosis rates, respectively, following nitinol stenting for lesions of 9.4 cm and 9.6 cm in average length, respectively. Moreover, we found a significantly increased 12-month restenosis/reocclusion rate of 51.2% for lesions >20 cm, consistent with the DURABILITY I findings of a 43% restenosis rate for lesions measuring 15 to 18 cm in length,[9] both confirming the impact of lesion length on SFA treatment results. The Zilver PTX drug-eluting stent registry[14,15] resulted in a comparatively high primary patency rate of 86.2% for 10.0-cm and 77.6% for 22.6-cm average lesion lengths at 12 months.

The higher restenosis/reocclusion rate of 39.5% found in occluded lesions compared to stenoses (21.8%) in our patients did not result from more frequent residual restenoses >30% in occluded lesions, as Scheinert et al.[16] and Bausback et al.[17] assumed to be causal. Possibly, the average stented length of 16.4 cm for occluded vs. 7.5 cm for stenosed lesions contributed to this result.

Female Gender

In addition to lesion length, female gender was predictive of TLR at 12 months, whereas vessel diameter as a possible causation was not, nor did it influence the restenosis/reocclusion rate itself. Previously, Suzuki et al.[18] identified female gender as an independent predictor of SFA restenosis within 4 years of nitinol stent implantation in a retrospective analysis of 432 patients (HR 0.39, 95% CI 0.22 to 0.71, p=0.002). In fact, they used smaller stent diameters for female patients, but they did not quantify the vessel diameter. Iida et al.[19] also found a positive association of early restenosis (occurring before the 369th day after stenting) and female gender (HR 1.79, 95% CI 1.17 to 2.73, p=0.0071). Whereas the TASC II (TransAtlantic Inter-Society Consensus) C/D classification remained a strong predictor of restenosis up to 6 years after stenting in their study, female gender did not. Lindgren et al.[20] identified female gender as an independent predictor of amputation at 12 months after SFA stenting. They assumed that this might have been attributed to more advanced ischemic damage at baseline in women. A causal connection of female gender and SFA restenosis is not known at present. Further investigations on the results of lesions in women are required.

Laterality

Left leg lesions were more frequently associated with restenosis/reocclusion than right leg lesions, in spite of equal interventional technique. Wang and Newell[21] found footedness to be a function of task asymmetry between the dominant and the non-dominant foot as found in the upper limbs. The non-preferred foot is mostly used for stabilizing

but not for mobilizing. Therefore, the poorer outcome of left leg lesions possibly reflects the fact that the majority of the people are right handed, with corresponding movement patterns of the distal extremities. Further investigations on the results of left leg lesions are required.

Stent Fractures

The 9.4% incidence of stent fractures detected in 49 of 524 patients is on the same order of magnitude as reported in other studies at 12 months.[4,9,18] A lower rate of stent fractures (1.5%) was reported from the Zilver PTX drug-eluting stent registry, with a 2.1% stent fracture rate in the 22.6-cm de novo lesion subgroup. This confirms that stent fracture is not only related to the length of the stented segment but also to stent design.[22] In accordance with other studies,[3–5,7,9] any impact of stent fracture on the 12-month restenosis/reocclusion rate was not noted in our registry.

Limitations

This work has several drawbacks, including the lack of a control group or a randomized design and the focus on a single technology. In addition, 12 months of clinical follow-up was not achieved in 195 patients.

Conclusion

The results of this large registry imply that SFA stenting with the self-expanding Maris nitinol stent is safe and associated with favorable acute and midterm results in a real-world setting, even for long and totally occluded lesions. However, these lesions were more often accompanied by restenosis/reocclusion. Female gender and lesion length were identified as independent predictors for TLR, whereas classical atherosclerotic risk factors did not influence the 12-month TLR rate independently.

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