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Impact of number of run-off vessels on interwoven nitinol mesh stents patency in the femoropopliteal segment

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Abstract

Objective To evaluate the impact of run-off vessels number on the outcomes of Supera stent (Abbott Vascular, Santa Clara, Calif, USA) for treatment of femoropopliteal occlusive disease. **Methods** We retrospectively evaluated the medical records of 188 consecutive patients (mean age 68.2 ± 9.6 years, 100 males) undergone angiography and woven mesh stent implantation in femoral or popliteal arteries or both arterial segments, in our institution between January 1 2014 and January 1 2018. Target lesion revascularization and major adverse limb events at 12-month were evaluated comparing patients with 1-, 2- or 3-run-off vessels in the foot. **Results** Interventional success was achieved in 100%. Stent implantation involved in the femoral site in 56 patients (30.3%), the femoropopliteal in 92 patients (48.9%) and the popliteal site in 40 patients (21.3%). A significant improvement of ankle-brachial index (0.29 ± 0.6 *vs*. 0.88 ± 0.3, $P < 0.001$) and Rutherford class (5.3 ± 0.8 *vs*. 0.7 ± 1.9, $P < 0.01$) were observed before discharge. The median follow-up duration was 12.3 months (inter quartile range: 11.0 to 13.9). During the follow-up period, 52 patients (27.6%) had clinical events. Primary patency at 12 months was 72.4%. The primary patency significantly increased when the runoff status. Comparing the number of events among patients with different number of run-off vessels, a significant difference ($P < 0.001$) was observed for patients having one (24.0%) and two run-off vessels (15.0%). **Conclusions** The outcomes of Supera stent in femoropopliteal occlusive disease depend strictly on the number of run-off vessels.

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1 Introduction

The Supera stent (Abbott Vascular, Santa Clara, Calif, USA) is a self-expanding stent with six pairs of interwoven nitinol wires, in a closed-cell configuration which received Food and Drug Administration (FDA) approval for use in the femoropopliteal segment during 2014. Its design contributes to increase radial strength and compression-resistant conformability to biomechanical stress. This device has been developed to further improve the results of standard self-expandable stents at femoral and popliteal sites. As demonstrated by previous investigations, the implantation of the Supera stent resulted in an increased patency rate compared to standard laser-cut self-expanding stents,[1,2] and similar outcomes when compared to drug eluting stents (DES).[3]

Data about the performance of Supera stent in the treatment of femoropopliteal occlusive disease in respect of number of run-off vessels are still anecdotal. Our study is aimed to evaluate and compare, in a retrospective fashion, the outcomes of Supera stent for treatment of femoropopliteal occlusive disease in terms of primary patency, target lesion revascularization (TLR) and major adverse limb events (MALES) in respect of number of run-off vessels.

2 Methods

2.1 Population enrolled

We retrospectively evaluated the medical records of consecutive patients undergone angiography and woven mesh stent implantation of the femoral or popliteal arteries or both

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arterial segments, in our institution between January 1 2014 and January 1 2018. Patients were divided by number of patent vessels (vessels directly visible at the sheath injection including anterior tibial, posterior tibial and interosseal artery) at leg and foot which determined the run-off. Comparison among different grades of run-off has been performed as regards as primary patency at 12 months.

We excluded from the analysis those patients with acute or subacute thrombotic occlusions, prior use of stents, DES or covered stent, prior bypass graft anastomotic lesions, contraindications for aspirin or clopidogrel, life-threatening infections and a follow-up duration < 3 months. The local Committee approved the study and patients gave their informed consent for the indexed procedure.

2.2 Diagnostic assessment

The pre-interventional study included a complete clinical examination (presence of wound, and foot infection), hemodynamic evaluation (ankle or toe pressure, pulse volume recording, and duplex ultrasound), and anatomic assessments including computed tomographic angiography (CTA), magnetic resonance angiography, or diagnostic angiography. Toe pressures, pulse volume recording, and Doppler waveform patterns were obtained to measure hemodynamic changes in the patients with falsely elevated ankle-brachial index (ABI) values.

2.3 Procedural protocols

Quantitative angiograms were acquired using at least two orthogonal views at baseline and after the intervention. A radiopaque ruler was used to calibrate angiographic measurements, including the length and minimal luminal diameter (MLD) of the target lesion and the mean proximal and distal reference vessel diameters (RVDs). Percent DS was calculated [%DS = (1 – MLD/RVD) × 100] at baseline and after EVT. Dual antiplatelet therapy with aspirin 100 mg and clopidogrel 300 mg was recommended before EVT and continued for three months after the procedure. Antiplatelet therapy and anticoagulant regimens were used according to the physician's discretion based on the patient's condition. The revascularization procedure was considered anatomically and technically successful in cases with < 30% residual stenosis and in the absence of major complications, defined as adverse events occurring within 30 days after the procedure, requiring further medical, interventional, or surgical measures.

2.4 Supera stent implantation

The Supera (Abbott Vascular, Santa Clara, Calif, USA) is self-expanding, interwoven, nitinol stent: its stent delivery system underwent a series of modifications (three generations) during the course of the study period, but there were no changes to the stent construct itself. Lesion were prepared with standard balloon angioplasty uncoated PTA balloon (Sterling, Boston Scientific Corp, USA) sized 1: 1 with the RVD. Then an adequate Supera stent matching the RVD and 5 mm longer than the lesion length was deployed. A postdilation using a balloon angioplasty uncoated PTA balloon (Sterling, Boston Scientific Corp, USA) of the same stent diameter was performed only if a residual stenosis > 50% at any site of implanted stent was observed.

2.5 Definitions

We defined lumen gain as the change in MLD at each vessel before and after EVT. The severity of vessel calcification was graded according to the peripheral artery calcification scoring system. Clinically driven target lesion (TLR) revascularization was defined as a reintervention performed for > 50% DS within 5 mm of the target lesion after the documentation of recurrent clinical symptoms after the index procedure. Target vessel revascularization (TVR) was defined as a reintervention performed for > 50% DS in the target vessel after the documentation of recurrent clinical symptoms after the index procedure. Major adverse limb event **(**MALE) was defined as acute or chronic limb ischemia and, in this analysis, includes all major vascular amputations. Acute limb ischemia was defined as limb threatening ischemia that was confirmed by using limb hemodynamic parameters or imaging and led to an acute vascular intervention (pharmacological (heparin, thrombolysis), peripheral artery surgery/reconstruction, peripheral angioplasty/stent, or amputation) within 30 days of onset of symptoms. Chronic limb ischemia was defined as continuing ischemic limb, foot, or digit pain leading to hospitalization and intervention and not meeting the definition of acute limb ischemia; or participants with Fontaine classification III or IV at baseline who had a peripheral vascular intervention over the course of the trial. Major vascular amputation was defined as an amputation due to a vascular event above the forefoot.

Run-off vessel was defined as a vessel directly visible at the sheath injection before lesion predilation including anterior tibial, posterior tibial and interosseal artery filling the leg up to the foot.

2.6 Follow-up

Vessel patency after EVT was regularly assessed during the follow-up period with clinical examinations and non-in-

vasive studies, including ankle or toe brachial pressure index and duplex ultrasound at one and 6 months thereafter. The indication for a reintervention was clinically driven. The main events (death, amputation, any endovascular or surgical revascularization, or other vascular events) were documented at discharge and during follow-up visits. The alternate data sources used when office follow-up was not feasible were telephone interviews, data from medical records, local electronic medical databases and referring physicians.

2.7 Statistical analysis

Continues variables were expressed as mean ± SD and were compared by Student' *t*-test if the data had normal distribution, otherwise by Wilcoxon-Mann-Whitney *U* test. Categorical variables were compared by the Pearson's χ^2 test. To estimate the overall and different groups 1-year primary patency, the Kaplan–Meier method was applied, and the log-rank test was used to evaluate the differences between the two groups. Statistical significance was defined as $P < 0.05$. Statistical analyses were performed using SPSS package version 20.0 (SPSS, Chicago, IL, USA).

3 Results

3.1 Procedural outcomes

Interventional success was 100% of patients. A mean of 1.8 ± 0.8 stent for leg were implanted with a diameter of 4 mm (44/188, 23.7%), 5 mm (60/188, 31.9%), 6 mm (58/188, 30.8%), and 7 mm (26/188, 13.8%). Stent implantation involved in the femoral site in 56 patients (30.3%), the femoropopliteal in 92 patients (48.9%) and the popliteal site in 40 patients (21.3%). A significant improvement of ankle-brachial index (0.29 ± 0.6 *vs*. 0.88 ± 0.3, $P < 0.001$) and Rutherford class (5.3 ± 0.8 *vs*. 0.7 ± 1.9, $P < 0.01$) were observed before discharge.

3.2 Run-off status and related clinical events

The median follow-up duration was 12.3 months (inter quartile range: 11.0 to 13.9). Overall, during the follow-up period, 52 patients (27.6%) had clinical events over the follow-up period. The need for TLR, TVR and MALE decreased with the increasing of distal run-off (Table 3).

Primary patency at 12 months was 72.4%. A sub-analysis performed stratifying the patients according to the post-interventional run-off status demonstrated that the primary patency significantly increased when the runoff status increase (Figure 1 and Table 4). All causes mortality was 7.9% (15/188) at 12 months.

Table 1. General characteristics of the population enrolled.

	Supera stent, *n* = 188
Age, yrs	66.1 ± 14.2
Gender (males)	51 (49.0%)
Diabetes mellitus	38 (36.5%)
HT	32 (30.7%)
Dyslipidaemia	35 (33.6%)
Previous smoker	16 (15.3%)
CAD	26 (25.0%)
CKD	31 (29.8%)
ABI	0.29 ± 0.6
Rutherford class	5.4 ± 0.8
Presence of wound	42 (40.3%)
Foot Infection	11 (10.6%)

Data are presented as mean ± SD or *n* (%). ABI: ankle-brachial index; CAD: coronary artery disease; CKD: chronic kidney disease; HT: arterial hypertension.

Table 2. Procedural characteristics.

	Supera stent, *n* = 188
ABI	0.61 ± 0.16
RVD, mm	4.79 ± 0.76
MLD, mm	0.54 ± 0.66
Stenosis	89.0% ± 13.2%
Mean lenght lesion, mm	132.1 ± 32.6
Long lesion (≥ 15 cm)	44 (42.3%)
Total occlusion	49 (47.1%)
Severe calcification	58 (55.7%)
Side (right)	56 (53.8%)
*TASC	
A	6 (5.7%)
B	19 (18.2%)
C	45 (43.2%)
D	34 (32.6%)
Access	
Retrograde cross-over	32 (30.7%)
Antegrade femoral	72 (69.2%)
Sheath 6F	90 (86.5%)
Sheath 7F	14 (13.5%)

Data are presented as mean ± SD or *n* (%). ABI: ankle-brachial index; MLD: minimal luminal diameter; RVD: reference vessel diameters. *Jaff MR, White CJ, Hiatt WR, *et al*. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: A supplement to the inter-society consensus for the management of peripheral arterial disease (TASC II): the TASC steering committee. *Catheter Cardiovasc Interv* 2015; 86: 611-625.

4 Discussion

Our retrospective study suggests that the Supera stent had

Table 3. Follow up results for the entire study population.

Patent runoff vessels	Number of patients	Number of events	Type of events
0	39 (20.7%)	22 (56.4%)	10 TLR; 5 TVR; 4 surgical revascularization; 1endovascular revascularization; 3 amputation
1	49 (26.0%)	15 (30.6%)	6 TLR; 3 TVR; 3 surgical revascularization; 1 amputation; 2 hyperbaric oxygen therapy
2	43 (22.8%)	10 (23.2%)	3 TLR; 2 TVR; 4 endovascular revascularization; 1 Raynaud phenomenon
3	57 (30.3%)	5 (8.7%)	2 TLR; 1 TVR; 2 endovascular revascularization

TLR: target lesion revascularization; TVR: target vessel revascularization.

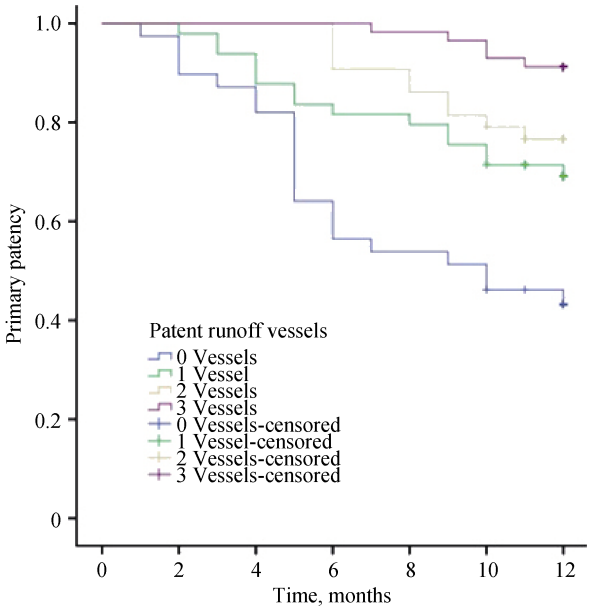

Figure 1. Global primary patency for the whole cohort of patients divided by run off number of vessels.

a good primary patency at 12 months when used to treat femoropopliteal occlusive disease. The primary patency as well as TLR, TVR and MALE resulted to be linked to the number of run-off vessels.

In *de novo* complex femoro-popliteal disease, interwoven nitinol stent showed excellent primary patency rate even in complex long femoropopliteal disease.[4,5] Data about the importance of number of run-off vessel are still scarce, somewhat confused and available mainly for conventional self-expandable stents. Inhat, *et al*.[6] found that a run-off score > 5 (HR = 2.6) significantly affected primary patency of nitinol stents in the femoral artery.

While some authors in different decades found a direct correlation among primary patency and number of run-off vessel, other did not. Davies, *et al*.[7] observed that at 5 years vessels with compromised and poor run-off had significantly lower freedom from recurrent symptoms and lower freedom from restenosis. Primary and assisted primary patency rates were significantly worse in patients with poor run-off. However, secondary patency was equivalent between the groups. Compromised or poor runoff was associated with incremental lower limb salvage.

Guo, *et al*.[8] in 2015 found that number of run-off vessels was a potential predictor of re-stenosis/occlusion in their series of 53 patients treated with self-expandable nitinol stents in the femoropopliteal vessels. More recently, Watanabe, *et al*.[9] observed using the same conventional stents that patients with > 2 run-off vessels had a significantly higher MALE free survival rate two years after PTA compared with patients with 1 run-off vessel (80.9% *vs*. 43.5%; $P < 0.001$). On the contrary, Lee, *et al*.[10] in their review of 289 patients found that while the number of runoff vessels decreased with worsening of the TASC classification ($P = 0.024$), overall ($P = 0.355$), and within individual TASC classes ($P \geq 0.092$ for each), there was no difference in the

Table 4. Log-rank (Mantel-Cox) comparison among patients with different run-off status.

Patent run-off vessels [Primary patency free-event period (95% CI)]	0 [chi-square], *P*	1 [chi-square], *P*	2 [chi-square], *P*	3 [chi-square], *P*
0 [8.2 ± 0.6 (7.0–9.5)]	-	[6.26], $P = 0.01$	[11.93], $P = 0.001$	[30.67], $P < 0.0001$
1 [10.2 ± 0.4 (9.3–11.1)]	[6.26], $P = 0.01$	-	[0.85], $P = 0.35$	[9.00], $P = 0.003$
2 [11.0 ± 0.2 (10.4–11.6)]	[11.93], $P = 0.001$	[0.85], $P = 0.35$	-	[4.35], $P = 0.03$
3 [11.7 ± 0.1 (11.5–11.9)]	[30.67], $P < 0.0001$	[9.00], $P = 0.003$	[4.35], $P = 0.03$	-

primary patency of stented segments with good runoff and those with compromised runoff. Limbs with poor runoff (one or no vessels) were no more likely to fail with occlusion than their counterparts with two or three patent tibial vessels (P = 0.383). The number of patent tibial vessels at the time of initial stenting did not impact ultimate limb salvage (P = 0.06).

Data about the role of run-off vessels on Interwoven Nitinol Mesh Stents are still lacking and our study is the first to correlate the stent patency with number of run-off vessel before the procedure. The stent confirmed also in our retrospective analysis to have an overall good primary patency rate but pointed out that a direct correlation does exist among follow-up adverse events, primary patency and pre-procedural run-off vessels number.

Our results suggests that Supera stent would be preferable implanted when at least two run-off vessel are visible at pre-procedural stage, reserving standard high-pressure balloon angioplasty for cases with very poor run-off or impossibility to achieve a final run off of at least two vessels.[11]

4.1 Study limitations

Our study obviously suffers of different limitations. Firstly, the retrospective fashion and the lack of any randomization; secondly the relatively small sample of patients; and thirdly the lack of a comparison with the prost-procedural number of run-off vessels. This last analysis was avoided because the difficult and non-homogeneous possibility to evaluate precisely the number and quality of run-off vessels after below the knee interventions because of diffuse dissection, incomplete treatment, angioplasty-related spasm.

4.2 Conclusions

Our retrospective single center study suggested that in femoropopliteal occlusive disease Supera stent had good primary patency excepted when pre-procedural run-off vessels number is less than two: the role of additional below-the-knee interventions on Supera patency should evaluated in ad hoc large study.

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