

## Feasibility of Coronary Balloon-Expandable Drug-Eluting Stent Implantation for Focal Superficial Femoral Artery Disease

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### ABSTRACT

**AIM:** Despite important advances in techniques and devices, endovascular treatment of the superficial femoral artery (SFA) is still fraught with suboptimal early and long-term adverse events. Coronary drug-eluting stents (DES) are associated with favorable results in patients with ischemic heart disease. Under the hypothesis that coronary DES may be safe and effective also for focal SFA lesions, we have used them in selected patients in the last few years. We thus aimed to review our experience with this novel treatment approach.

**METHODS:** Patients undergoing coronary DES implantation in the SFA at our institutions were retrospectively identified. Baseline, procedural and outcome details were systematically collected. Outcomes of interest were duplex ultrasound-based primary patency, target lesion revascularization, target limb revascularization, and improvement in Fontaine class at the longest follow-up available.

**RESULTS:** A total of 51 patients (54 limbs) were treated with coronary DES for SFA disease. Specifically, 23 (42.6%) limbs were treated with biolimus-eluting stents, 8 (14.8%) with everolimus-eluting stents, and 25 (46.3%) with sirolimus-eluting stents. All lesions were TASC A, with 24 (44.4%) total occlusions. Technical and procedural success was achieved in all cases. Clinical and duplex ultrasound-based follow-up, after a mean of 15.4±18.4 months, showed primary patency in 95.6% (95% confidence interval 85.2%-

99.6%), target lesion revascularization in 3.8% (0.3%-13.3%), target limb revascularization in 5.8% (1.3%-15.7%), and improvement in Fontaine class in 84.9% (74.0%-93.5%). No case of stent thrombosis, fracture or crush occurred.

**CONCLUSION:** Use of coronary DES for focal SFA lesions is feasible and safe, and associated with favorable clinical results at mid-term follow-up. Further controlled studies are warranted to define more precisely the risk-benefit ratio of these devices in comparison to SFA-dedicated DES and drug-eluting balloons.

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**Key words:** Coronary artery disease; Drug-eluting stent; Peripheral artery disease; Stent; Superficial femoral artery

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### INTRODUCTION

Endovascular therapy is now an established therapeutic means in patients with symptomatic peripheral artery disease (PAD) involving the superficial femoral artery (SFA)<sup>[1]</sup>. Several treatment options are available, from standard balloon angioplasty to nitinol stent implantation, drug-eluting stents especially devised for the SFA, drug-eluting balloons, and atherectomy<sup>[2]</sup>. There is however ongoing uncertainty on the best therapeutic strategy for transcatheter revascularization of the SFA, as each available treatment option has its own pros as well as cons. For instance, balloon-based approaches lack by definition scaffolding properties, whereas nitinol stents are associated with significant neointimal hyperplasia<sup>[3-6]</sup>.

Coronary DES, especially second-generation DES, have demonstrated momentous benefits in comparison to bare-metal stents (BMS), leading to a reduction in the risk of coronary restenosis and repeat revascularization<sup>[7]</sup>. Moreover, as recently demonstrated, novel coronary DES may even be associated with lower rates of stent thrombosis than BMS<sup>[8]</sup>. Indeed, off-label implantation of coronary DES in patients with PAD has already shown beneficial results for

infrapopliteal disease<sup>[9-10]</sup>. Yet, it is unclear whether they can be used effectively and safely in other locations.

Several years ago we hypothesized that coronary DES can be safe and effective for TASC A lesions in the SFA, and have since used them in selected patients. The hypothetical advantages of these devices include the superior antirestenotic efficacy and scaffolding properties, despite the theoretical risk of stent compression, and the limited range of sizes. We aimed thus to review our experience with this novel treatment approach.

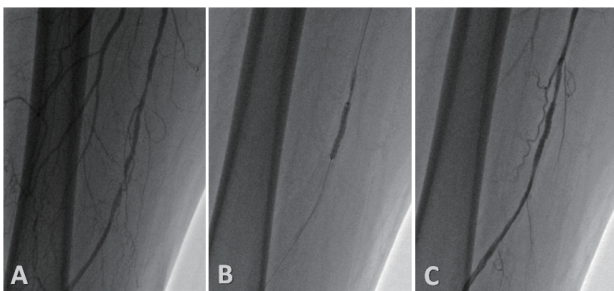
## METHODS

### Design

This was a retrospective observational study stemming from our multicenter experience in treating focal SFA disease with coronary DES. Ethical approval was waived and all patients provided informed consent.

### Patients and procedures

Patients in whom coronary DES implantation was attempted (being successful or not) were retrieved from our institutional database. No patient was excluded. Device choice, lesion preparation, and optimization, as well as ancillary medical therapy were all the physician's discretion. Typically, after contralateral femoral access and angiographic evidence of a TASC A lesion in the SFA (stenosis long  $\leq 10$  cm or occlusion  $\leq 5$  cm), this was crossed with a 0.014" guidewire and prepared with a suitably sized semi-compliant coronary balloon, dilated at 14-16 ATM and aiming for a 0.6-0.7 balloon-to-artery ratio. Afterwards, one or more coronary DES were implanted (Figure 1), trying to cover the most diseased part of the vessel, according to a spot stenting technique whenever the lesion was too long to be entirely covered with one or two stents. The largest and longest stent was chosen to achieve this, still aiming for a 0.7-0.8 balloon-to-artery ratio, and expanding the stent at 14-16 ATM. Post-dilation was at the physician's discretion. When performed, non-compliant balloons were inflated up to 30 ATM aiming for a 0.8 balloon-to-artery ratio. The following coronary DES were available for SFA implantation: biolimus-eluting stents (Biomatrix, Biosensors, Singapore; Nobori, Terumo, Tokyo, Japan), everolimus-eluting stents (Xience, Abbott Vascular, Santa Clara, CA, USA), and sirolimus-eluting stents (Cypher, Cordis, Miami, FL, USA). These are all 0.014" guidewire-compatible balloon-expandable stents, with everolimus-eluting stents having a cobalt-chromium metallic platform, while biolimus- and sirolimus-eluting stents have instead a stainless steel platform. Patients were pretreated with ticlopidine or clopidogrel for 3 or more days or front-loaded with 300 mg clopidogrel, continuing the same thienopyridine for 6 months after implantation. Aspirin was given before and indefinitely after the procedure in all.



**Figure 1** Coronary everolimus-eluting stent implantation in a patient with focal superficial femoral artery disease [A-baseline angiography, B-stenting with a Xience V (Abbott Vascular, Santa Clara, CA, USA) 3.5×28 mm device, C-final angiographic result]. The patient remained asymptomatic and devoid of duplex ultrasound-assessed restenosis up to 14 months after the index procedure.

### Follow-up

Clinical follow-up was based in all on duplex ultrasound, direct patient visits, and phone contacts. Outcomes of interest were death, repeat target limb revascularization, repeat target lesion revascularization, primary patency, amputation, and change in Fontaine class at the longest available follow-up. Specifically, duplex ultrasound exams were based on separate measurements of the maximum peak systolic velocity 2 cm proximally to the lesion, within the lesion, and up to 4 cm distally to the lesion. The ratio of the maximum intrastenotic peak systolic velocity to the maximum prestenotic peak systolic velocity was used to define the presence/absence of patency based on established cut-off values<sup>[11]</sup>. Bleeding was adjudicated in keeping with the Thrombolysis in Myocardial Infarction definitions.

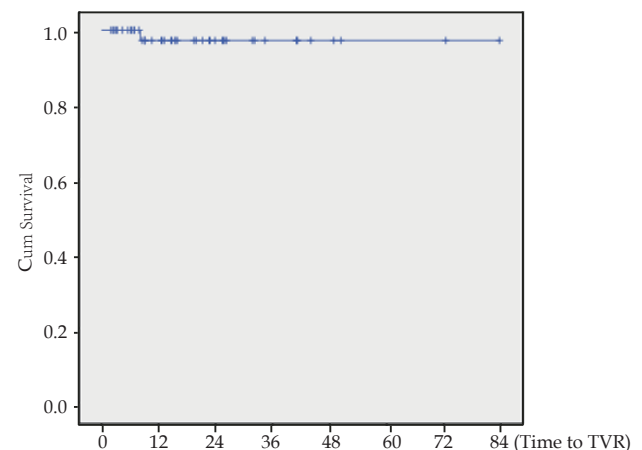
### Analysis

Continuous variables are reported as mean±standard deviation. Exploratory analyses to compare different DES were based on Kruskal-Wallis U test for continuous variables and on chi-squared test for categorical variables. Statistical inference was also based on the computation of 95% confidence intervals for dichotomous variables according to the adjusted Wald method. In addition, the Kaplan-Meier method was used for survival analyses. Statistical significance was set at the 2-tailed 0.05 level, and *p* values unadjusted for multiplicity are reported throughout. SPSS 20 (IBM, Armonk, NY, USA) was used for computations.

## RESULTS

A total of 51 patients were retrieved from database screening in whom coronary DES implantation was attempted (54 limbs) between 2006 and 2012. All lesions were TASC A, with 24 (44.4%) total occlusions. Specifically, 23 (42.6%) limbs were treated with biolimus-eluting stents, 8 (14.8%) with everolimus-eluting stents, and 25 (46.3%) with sirolimus-eluting stents. Technical and procedural success was achieved in all cases. No case of post-procedural TIMI major bleeding or local access site bleeding requiring surgical repair occurred (Table 1 and 2).

Clinical follow-up was available in all after a mean of 15.4±18.4 months, while duplex ultrasound-based follow-up was available in 49 (96.1%) patients (given the 2 fatalities). At such follow-up, primary patency had been obtained in 95.6% (95% confidence interval 85.2%-99.6%), target lesion revascularization in 3.8% (0.3%-13.3%), target limb revascularization in 5.8% (1.3%-15.7%), and improvement in Fontaine class from the baseline in 84.9% (74.0%-93.5%). No case of stent thrombosis, fracture or crush occurred. Survival analysis confirmed these favorable results, without any evidence of late catch up phenomenon (Figure 2, table 3).



**Figure 2** Cumulative survival free from target limb revascularization (in months).

**Table 1** Baseline characteristics.\*

	Total (Patients=51; Limbs=54)	BES only (Patients=15; Limbs=16)	EES only (Patients=7; Limbs=7)	SES only (Patients=16; Limbs=18)	P
Age (years)	66.9±9.2	66.9±9.2	68.9±10.7	67.1±10.5	0.909
Male gender	28 (54.9%)	9 (60.0%)	3 (42.9%)	6 (37.5%)	0.440
Obesity	7 (13.7%)	1 (6.7%)	2 (28.6%)	3 (18.8%)	0.386
Diabetes mellitus	35 (68.6%)	11 (73.3%)	5 (71.4%)	11 (68.8%)	0.961
Insulin-dependent diabetes mellitus	11 (21.6%)	2 (13.3%)	2 (28.6%)	6 (37.5%)	0.308
Dyslipidemia	33 (64.7%)	9 (60.0%)	5 (71.4%)	8 (50.0%)	0.618
Hypertension	37 (72.5%)	11 (73.3%)	5 (71.4%)	9 (56.2%)	0.570
Smoking status					0.590
Current	1 (2.0%)	0	0	1 (6.2%)	
Former	17 (33.3%)	5 (33.3%)	4 (57.1%)	5 (31.2%)	
Never	33 (64.7%)	10 (66.7%)	3 (42.9%)	10 (62.5%)	
Chronic renal failure	5 (9.8%)	1 (6.7%)	1 (14.3%)	3 (18.8%)	0.607
Prior myocardial infarction	12 (23.5%)	4 (26.7%)	2 (28.6%)	3 (18.8%)	0.826
Prior peripheral intervention or bypass	12 (23.5%)	3 (20.0%)	2 (28.6%)	5 (31.2%)	0.768
Fontaine class					0.113
I	0	0	0	0	
IIa	2 (3.9%)	1 (6.7%)	0	1 (6.2%)	
IIb	41 (80.4%)	12 (80.0%)	5 (71.4%)	13 (81.2%)	
III	2 (3.9%)	0	2 (28.6%)	0	
IV	6 (11.8%)	2 (13.3%)	0	2 (12.5%)	

\* reported as mean±standard deviation or n (%); BES=biolimus-eluting stents; EES=everolimus-eluting stents; SES=sirolimus-eluting stents.

**Table 2** Lesion and procedural characteristics.\*

	Total (Patients=51; Limbs=54)	BES only (Patients=15; Limbs=16)	EES only (Patients=7; Limbs=7)	SES only (Patients=16; Limbs=18)	P
Lesions per limb	1.1 (0.4%)	1.0 (0)	1.0 (0)	1.3 (0.6%)	0.085
Total occlusion	24 (44.4%)	6 (37.5%)	2 (28.6%)	6 (33.3%)	0.913
Run-off patent vessels	42 (77.8%)	12 (75.0%)	6 (85.7%)	12 (66.7%)	0.614
Lesion length (mm)	48.7 (29.3%)	40.2 (23.4)	26.7 (7.3)	43.1 (22.1)	0.225
Diameter stenosis (%)	92.3 (9.9)	89.9 (10.7)	88.4 (11.6)	92.5 (9.9)	0.633
Severe calcification	13 (24.1%)	5 (31.2%)	1 (14.3%)	5 (27.8%)	0.695
Thrombus	1 (1.9%)	0	1 (14.3%)	0	0.083
Predilation	36 (66.7%)	10 (62.5%)	2 (28.6%)	14 (77.8%)	0.072
Coronary drug-eluting stent					
BES	23 (42.6%)	16 (100%)	0	0	<0.001
EES	8 (14.8%)	0	7 (100%)	0	<0.001
SES	25 (46.3%)	0	0	18 (100%)	<0.001
Additional bare-metal stent implantation	11 (20.4%)	0	0	0	1.0
Postdilation	2 (3.7%)	0	0	1 (5.6%)	0.520
Total stent length per limb (mm)	49.4 (29.4)	41.3 (23.7)	28.7 (6.7)	42.3 (21.3)	0.323
Maximum balloon diameter (mm)	3.68 (0.38)	3.59 (0.33)	4.00 (0)	3.41 (0.19)	<0.001
Edge dissection	1 (1.9%)	0	0	0	1.0
Angiographic success	54 (100%)	16 (100%)	7 (100%)	18 (100%)	1.0

\* reported as mean±standard deviation or n (%); BES=biolimus-eluting stents; EES=everolimus-eluting stents; SES=sirolimus-eluting stents.

**Table 3** Outcomes.\*

	Total (Patients=51; Limbs=54)	BES only (Patients=15; Limbs=16)	EES only (Patients=7; Limbs=7)	SES only (Patients=16; Limbs=18)	P
1-month follow-up					
Death	0	0	0	0	1.0
Target limb revascularization	0	0	0	0	1.0
Target lesion revascularization	0	0	0	0	1.0
Amputation	0	0	0	0	0
Improvement in Fontaine class	48 (92.5%)	14 (100%)	7 (100%)	14 (93.3%)	0.487
Long-term follow-up					
Time to follow-up (month)	15.4±18.4	6.9±23.1	9.2±6.5	26.6±30.5	0.007
Death	1 (2.0%)	1 (6.7%)	0	0	0.455
Target limb revascularization	3 (5.8%)	0	0	2 (11.8%)	0.256
Target lesion revascularization	2 (3.8%)	0	0	1 (5.9%)	0.515
Primary patency	46/48 (95.6%)	15/15 (100%)	7/7 (100%)	13/15 (81.3%)	0.307
Amputation	1 (2.0%)	0	0	0	1.0
Improvement in Fontaine class	44 (84.9%)	14 (100%)	7 (100%)	13 (86.7%)	0.227

\* reported as mean±standard deviation or n (%); BES=biolimus-eluting stents; EES=everolimus-eluting stents; SES=sirolimus-eluting stents.

Exploratory comparative effectiveness analysis of the different type of coronary DES did not disclose any significant difference among biolimus-, everolimus-, and sirolimus-eluting stents in terms

of primary patency, target limb revascularization, target lesion revascularization, amputation, or improvement in Fontaine class (all  $p>0.05$ ).

## DISCUSSION

Our registry, reporting for the first time in the scholarly literature on the use of coronary DES in the SFA, suggest that use of these devices in this PAD location is feasible and safe, and apparently associated with favorable clinical outcomes. Accordingly, coronary DES can be considered a useful and promising adjunctive tool for carefully selected patients with PAD.

Despite ongoing refinements and notwithstanding the several treatment options available for SFA disease, no perfect approach or device has been identified to date. Balloon-based technology, either bare, drug-eluting, or based on cutting devices, do not provide adequate scaffolding or support<sup>[6,12]</sup>. Similar drawbacks apply to atherectomy devices. In addition, current nitinol-based stents have thick struts and thus at risk of significant neointimal hyperplasia. Self-expandable drug-eluting stents and covered stents also hold the promise of maintaining primary patency while providing mechanical support to avoid recoil, but the evidence on these devices largely stems from pivotal trials with limited external validity<sup>[13]</sup>.

Our registry provides favorable data in support of the feasibility, safety, and efficacy of implanting coronary DES for TASC A lesions in the SFA. The very low rate of adverse events is reassuring, and suggest that these devices, which have an established and favorable risk-benefit profile in the coronary vessels, can prove useful also elsewhere. Our study can be poignantly compared with the Femoral Artery Conformexx Trial (FACT), which was a multicenter prospective registry of TASC A or B lesions treated with self-expandable nitinol stents<sup>[4]</sup>. At 1-year follow-up, primary patency was achieved in 77% of lesions, while target lesion revascularization occurred in 7%, with 85% of patients achieving at least 1 class improvement in Rutherford class. Yet, we should bear in mind the peculiar anatomic, physiologic and pathophysiologic features of the SFA, which make it a very challenging disease location and prevent a single effective treatment strategy for all patients<sup>[14]</sup>. Focusing in particular on coronary DES, the main drawbacks of these devices in the SFA include the risk of compression, fracture, and deformation, as well as the risk of inadequate stent expansion or lesion coverage given the limited range of sizes (diameter and length). Accordingly, only SFA with a reference vessel diameter <6 mm and with focal lesions can be considered suitable targets for coronary DES.

This work has several limitations, mainly inherent to the retrospective design, and small sample. The retrospective feature of our work leave ample room for many types of bias, including, but not limited to, selection bias, performance bias, attrition bias, and adjudication bias. Given the few included patients, effect estimates are by definition imprecise, and thus our findings should be mainly viewed as exploratory. More importantly, no specific pre hoc criterion was stated for coronary DES implantation in the SFA, which was left at the operator's discretion and largely based on institutional practice. Accordingly, as we simply retrieved from our database patients in whom coronary DES had been used according to physician's preference, no formal inclusion or exclusion criteria could be identified. However, it may be speculated that coronary DES were used only after satisfactory recanalization with intra-luminal seating of the guidewire of prevalently short (<60 mm) SFA lesions with a proximal and distal reference diameter <5.5 mm. In addition, in keeping with the current focus on comparative effectiveness, clinical decision makers should base their decision on pragmatic randomized trials or carefully conducted observational cohort studies. Such studies are direly needed to clarify the risk-benefit balance of coronary DES for SFA treatment. However, such project was beyond

the scope of our present work, which is a pilot and preliminary experience aiming simply at showing the feasibility and, in second order, the possible safety and efficacy of this novel strategy<sup>[15]</sup>.

In conclusion, use of coronary DES for focal SFA lesions is feasible and safe, and associated with favorable clinical results at mid-term follow-up. Further controlled studies are warranted to define more precisely the risk-benefit ratio of these devices in comparison to SFA-dedicated DES and drug-eluting balloons.

## CONFLICT OF INTERESTS

There are no conflicts of interest with regard to the present study.

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