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Endovascular Therapy for Infrainguinal Artery Disease With Coronary Devices: A Retrospective Observational Study Comparing Drug-Eluting Stents Versus Bioresorbable Vascular Scaffolds

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Abstract

Several devices are available for infrainguinal endovascular therapy, with drug-eluting stents (DES) among the most promising. Bioresorbable vascular scaffolds (BVS) may further improve outcomes. We have liberally used in our practice coronary DES and BVS for infrainguinal endovascular therapy and hereby report our preliminary results. We conducted an observational study by retrospectively identifying characteristics of patients undergoing infrainguinal implantation of coronary DES or BVS. We compared the risk of major adverse events (MAE: death, amputation, or target vessel revascularization [TVR]) and components of MAE in the overall sample and after propensity matching. We included a total of 204 patients (207 limbs), 148 (72.5%) treated with DES and 56 (27.5%) with BVS. Bivariate analysis showed that TVR was less common in the DES group (41.9% vs 18.4%, $P = .014$). However, propensity-matched analysis showed nearly identical risks of MAE, amputation, TVR, or symptom burden with DES and BVS (all $P > .05$). In conclusion, the present pilot experience with coronary BVS suggests that they could provide acceptable results for infrainguinal endovascular procedures, comparable to those obtained by their metallic counterpart.

Keywords

bioresorbable vascular scaffold, drug-eluting stent, endovascular therapy, peripheral artery disease, superficial femoral artery

Introduction

Peripheral artery disease remains a common cause of morbidity, and revascularization is indicated whenever symptoms cannot be adequately controlled with medical therapy or other noninvasive means (eg, exercise training).[1] While surgical bypass grafting remains the gold standard revascularization means, endovascular therapy has become a favorable alternative to surgery, especially in less complex lesions or patients at high surgical risk.[1-3]

There is a very wide range of alternative techniques and devices suitable for the endovascular therapy of infrainguinal artery disease, which include atherectomy, cryoplasty, laser, standard balloons, bare-metal stents, drug-eluting balloons, and drug-eluting stents (DES).[4-7] In particular, drug-eluting balloons have antirestenotic properties and leave nothing behind at long term but lack altogether scaffolding properties, which are crucial for stiff or calcific lesions.[8] Conversely, self-expanding metallic DESs, while combining antirestenotic properties with persistent scaffolding, constitute a permanent prosthesis, thus prone to long-term risk of fracture, restenosis, and/or thrombosis.[9] Indeed, most operators would agree that self-expanding devices are the default choice for the infrainguinal district, but balloon expandable devices can still provide reasonably favorable results, especially for nondiffuse disease.

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In such scenario, the presence of balloon-expandable drug-eluting bioresorbable vascular scaffolds (BVS) may represent an interesting adjunct for the endovascular specialists, even if the lack of self-expanding features and the limited range of sizes available are key limitations.[10] Bioresorbable vascular scaffolds represent a very recent innovation in revascularization technologies, but they have already entered successfully the clinical practice for the management of patients with coronary artery disease.[8] Yet, their role for infrainguinal artery disease remains, while promising, largely speculative.[11,12]

In our clinical practice, we have adopted the strategy of using coronary drug-eluting devices for infrainguinal artery disease, including the superficial femoral artery and proximal popliteal artery, under the premise that they offer a very effective tool to minimize restenosis and maximize patency while enabling a minimally invasive procedure.[5,6] The main caveat of the lack of large diameter devices remains, in our strategic view, a minor issue, as a 4.0 to 5.0 mm postprocedural minimum lumen diameter (such as the one achievable with systematic postdilation of coronary devices with large noncompliant balloons) still represents a very satisfactory results in terms of angiographic success and distal flow.

Most recently, and concomitantly with the adoption of BVS in our coronary interventional practice, we have shifted almost completely from using coronary DES for infrainguinal endovascular therapy to coronary BVS. The main premise for this choice is that BVS may offer the same protection from restenosis but disappearing after 1 to 2 years may provide much more room for subsequent repeat endovascular therapy or surgery.[8]

We hereby present our experience with infrainguinal endovascular therapy with both coronary DES and coronary BVS to inform practitioners and researchers on their potential noncoronary role.

Methods

This work is a retrospective observational study stemming from our larger institutional retrospective registry of cardiovascular procedures, which encompasses 2 different catheterization laboratories where the same interventional team operates on alternate days, with patient, procedural, and outcome details being collected in a single database, which has received approval by the institutional ethical committee and administration. All patients provided written informed consent for the procedure, including off-label use of coronary devices, data collection, and analysis. Specifically, consent to data collection and use for research purposes in anonymized fashion is provided in a specific written informed consent form during the index admission.

All participants undergoing infrainguinal endovascular therapy between June 2006 and March 2015 were retrospectively identified by querying our institutional database. We shortlisted those undergoing implantation of one or more coronary DES or coronary BVS in the superficial femoral artery or in the proximal popliteal artery. For the purpose of this work, we excluded patients undergoing a hybrid procedure, that is, those receiving coronary DES and coronary BVS or those undergoing implantation of either of the 2 as well as a bare-metal stent.

Procedures were carried out as described previously.[6] Briefly, we gained contralateral femoral access with a 6F sheath, performed cross-over with a 0.035-in hydrophilic guidewire, completed angiography with a 6F JR^4 diagnostic catheter, and then deployed over a 0.035-in exchange guidewire a 6F JR^4 guiding catheter up to the distal external iliac artery or the common femoral artery. The infrainguinal lesion was then crossed with a 0.014-in standard or hydrophilic coronary guidewire and predilated when deemed necessary with a 2.5 $\times$ 20 mm semicompliant balloon. Coronary DES and coronary BVS were both deployed at 12 to 14 atmospheres. Postdilation was used at operator's discretion for both devices by means of noncompliant 0.014-in compatible balloons, with a typical 0.5 to 1.0 mm diameter upsizing for DES and a typical 0.5 mm diameter upsizing for BVS. Procedural success was defined as device implantation with final diameter stenosis <20% and conserved antegrade flow to the distal popliteal artery without major procedural complications (Figures 1 and 2).

In terms of device choice, we may disclose that in the pre-BVS era it was common for us to use coronary DES for infrainguinal disease, unless very severely calcific or diffuse disease was present (<5%).[5,6] As soon as coronary BVS became available at our center, we decided to liberally use them also for infrainguinal therapy, thanks also to specific discounts from the device manufacturer. Accordingly, most procedures in the early phase of our experience were conducted using DES, whereas in the subsequent phase we used more commonly BVS.

Periprocedural antithrombotic therapy relied on weight-adjusted intravenous heparin and tirofiban. Patients were also pretreated with aspirin and clopidogrel or received loading doses of these agents in the absence of pretreatment. Aspirin was then continued lifelong, whereas clopidogrel was recommended for 12 months, in keeping with established absorption kinetics for BVS and current recommendations for coronary drug-eluting devices.[13,14] Follow-up was based on periodic phone interviews and office visits, plus explicit recommendations to referring physicians to perform duplex ultrasound or computed tomographic angiography at 3 to 6 months. This being a retrospective registry, follow-up was based on both office visits and phone interviews conducted at our center as well as the routine follow-up procedures of referring physicians. Accordingly, no standardization of follow-up was possible throughout the study period. However, repeated attempts were performed by dedicated study personnel to contact the patients at least once and to refer them for duplex ultrasound scan at least once.

The events of interest were death, major amputation, minor amputation, target vessel revascularization (TVR), target lesion revascularization (TLR), and change in Fontaine class from baseline to follow-up. Moreover, we computed the rate of major adverse events, that is, the composite of death, amputation (either major or minor), or TVR. As this study stems from

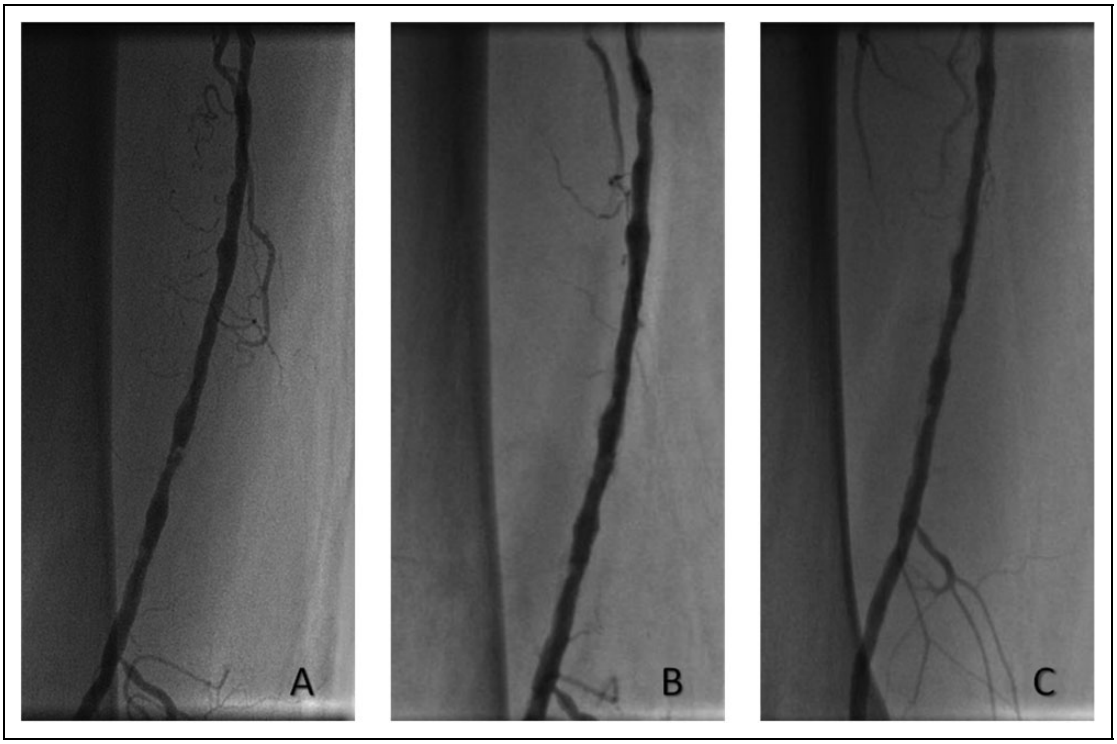

Figure 1. A successful case of infrainguinal endovascular therapy with a bioresorbable vascular scaffold. This patient presented with Fontaine class IIb claudication, despite maximal medical therapy. Angiography disclosed a focal but significant lesion of the distal superficial femoral artery (A). Angioplasty was performed with the implantation of a 3.5 × 28 mm bioresorbable vascular scaffold, postdilated with a 4.0 × 15 mm noncompliant balloon, achieving a satisfactory angiographic result (B). Twelve months later, the patient was admitted for an acute coronary syndrome, before coronary angiography, lower limb arteriography was performed, despite the lack of claudication symptom, highlighting a patent superficial femoral artery and patency of the bioresorbable vascular scaffold (C).

our administrative database, which collects all patient baseline and procedural and outcome details for clinical, reporting, and billing purposes, the likelihood of missing data or information bias for core baseline, procedural, and outcome details is low. However, no formal monitoring or data quality checking was enforced, thus leaving room for potential sources of bias. Nonetheless, in such an administrative database, it is unlikely that such bias acts systematically in favor or against a specific device or treatment. More specifically, we had no missing data for baseline features encompassing clinical indication, whereas 0.3% of procedural data (such as balloon size for postdilation) were missing. Conversely, clinical follow-up after at least 3 months after the procedure was available in 182 (89.2%) of 204 patients, whereas duplex ultrasound or angiographic follow-up was available in 110 (53.9%) of 204 patients. A complete case analysis approach was used to handle missing data, avoiding data imputation.

Descriptive analysis was based on reporting mean ± standard deviation or count (percentage). Inferential analysis was based on Student *t* test, Fisher exact test, log-rank test, and Cox proportional hazard analysis. Specifically, the following covariates were a priori selected for the multivariable Cox model and then shortlisted using a forward stepwise selection approach (probability of entry, .05): age, female gender, obesity, diabetes mellitus, dyslipidemia, hypertension, smoking, chronic renal failure, prior myocardial infarction, prior revascularization, Fontaine class, side, site, tandem lesion, lesion length, diameter stenosis, calcification, thrombus, predilation, postdilation, stents per limb, total stent length, use of BVS, use of everolimus-eluting stents, and maximum balloon diameter. For sensitivity analysis purposes and in order to further adjust for baseline and procedural differences, we also computed the propensity score to receive a coronary BVS and then matched patients 1:1 with 0.001 propensity score caliper.[15] Such propensity score-matched pairs when then analyzed reporting standardized mean differences and results of Student *t* test, Fisher exact test, log-rank test, and Cox proportional hazard analysis. Statistical significance was set at the 2-tailed .05 level, and all reported *P* values are unadjusted for multiplicity. Stata 13 (StataCorp, College Station, Texas) was used for computations.

Results

A total of 204 patients were included, treated on a total of 207 limbs. Specifically, 148 patients (150 limbs) were treated with DES and 56 patients (57 limbs) with BVS (Table 1). Demographic features and risk factors were similar in the 2 groups (all $P > .05$), with diabetes mellitus in 82 (55.4%) versus 25 (44.6%, $P = .209$) and Fontaine class 2b in 130 (86.7%) versus 52 (91.2%, $P = .863$), whereas prior revascularization was

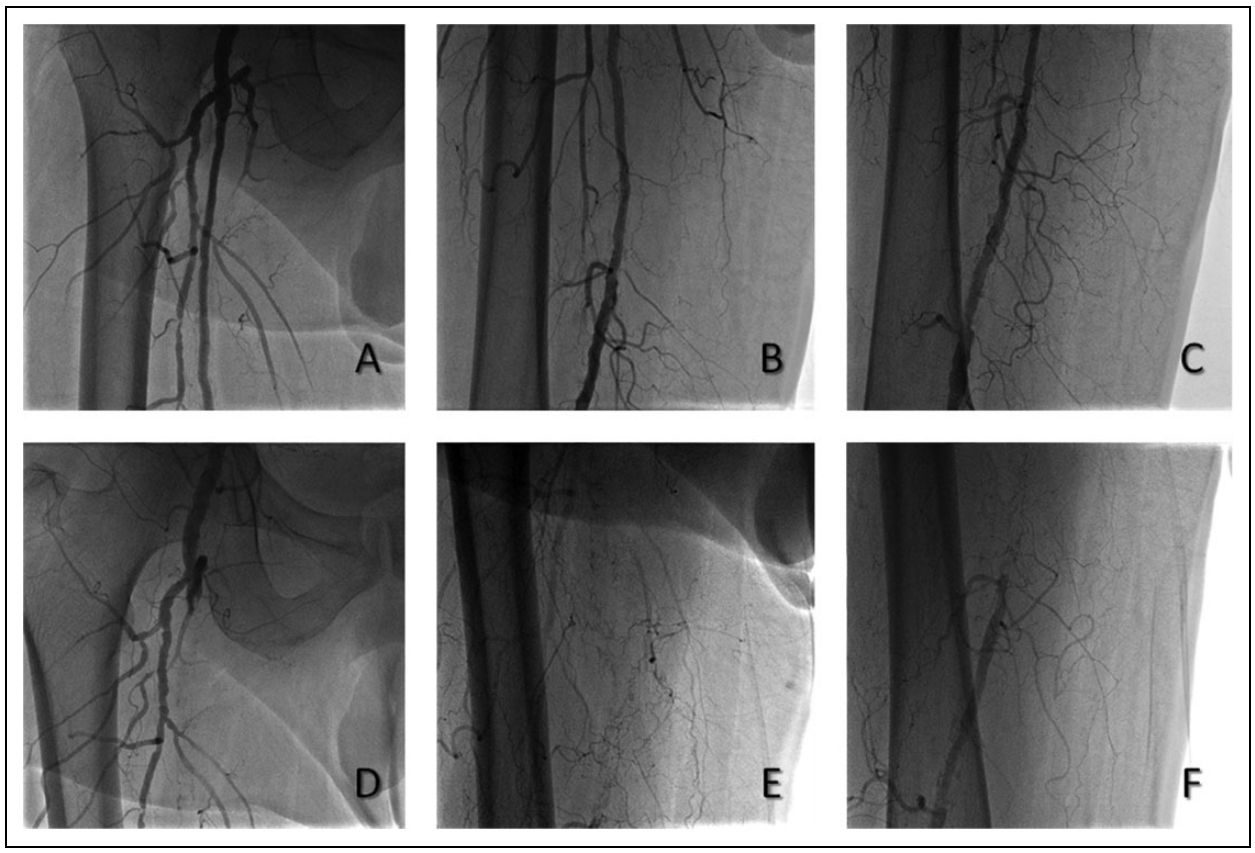

Figure 2. A failure of infrainguinal endovascular therapy with a bioresorbable vascular scaffold. This patient presented with Fontaine class IIb claudication, despite maximal medical therapy. Angiography disclosed a long occlusion of the superficial femoral artery from the ostium to the distal tract. Angioplasty was performed with the implantation of 9 3.5 × 28 mm bioresorbable vascular scaffolds, postdilated with a 4.0 × 30 mm noncompliant balloon, achieving a satisfactory angiographic result (A-C). After the procedure, the patient reported an improvement in claudication symptoms, but 9 months later claudication progressively recurred. Angiography confirmed a diffuse occlusive restenosis involving all the treated segments (D-F). The patient was then referred for bypass surgery.

more prevalent in patients treated with DES (12 [8.1%] vs 0, $P = .039$).

Lesion and procedural features were only partly similar (Table 2). In particular, the DES group had much shorter lesions (lesion length: 53.4 ± 34.9 mm vs 101.6 ± 75.0 mm, $P < .001$) and thus required significantly fewer devices per limb (1.9 ± 1.1 vs 3.8 ± 2.6, $P < .001$) and a shorter total device length per limb (55.3 ± 35.8 mm vs 102.4 ± 72.7 mm, $P < .001$). In addition, predilation was used in 129 (86.0%) versus 56 (98.3%) of procedures ($P = .010$), whereas postdilation was used in 67 (44.7%) versus 44 (77.2%) of cases ($P < .001$). Notably, 12 (20.7%) patients received as many as 7 or more (up to 9) BVS in the same vessel (with a total BVS length per limb ranging between 186 mm and 252 mm), in comparison to no patient in the DES group ($P < .001$). Finally, maximum balloon diameter appeared slightly larger in the DES group (3.73 ± 0.27 mm vs 3.66 ± 0.23 mm, $P = .067$).

Clinical outcomes appeared significantly different at unadjusted analysis (Table 3; Figure 1). Specifically, the 12-month rate of TVR was lower in the DES group (16 [18.4%] vs 13 [41.9%], $P = .014$), as was the rate of TLR (8 [9.2%] vs 11 [35.5%], $P = .001$), even if there was only a nonsignificant trend for major adverse events (20 [23.0%] vs 13 [41.9%], $P = .104$). In order to adjust for the evident baseline and procedural differences, we then compared outcome rates in propensity matched pairs of patients and limbs (Table 4; Figure 3). In such adjusted analysis, there was no longer any significant difference in the rate of TVR (6 [28.6%] vs 6 [28.6%], $P = 1$), TLR (4 [19.1%] vs 4 [19.1%], $P = 1$), or major adverse events (6 [28.6%] vs 6 [28.6%], $P = 1$).

Survival analysis confirmed prior results at cumulative follow-up for the main analysis (HR for major adverse events comparing BVS vs DES = 2.27 [1.09-4.73]; P at log-rank test = 0.021; P at Cox analysis = 0.028) as well as for the propensity matched patients (HR = 1.12 [0.37-3.32]; P at log-rank test = 0.839; P at Cox analysis = 0.845). Furthermore, exploratory multivariable analysis to identify predictors of major adverse events during follow-up showed that only dyslipidemia, chronic renal failure, need for postdilation, and maximum balloon diameter proved significantly associated with outcomes (all $P < .05$; Table 5).

Table 1. Patient Characteristics.

Characteristics	Drug-Eluting Stents	Bioresorbable Vascular Scaffolds	*P*
Patients	148	56	–
Limbs	150	57	–
Age, years	67.0 ± 10.5	66.8 ± 9.8	.934
Female gender	57 (38.5%)	14 (25.0%)	.099
Obesity	14 (9.5%)	5 (8.9%)	1
Diabetes mellitus	82 (55.4%)	25 (44.6%)	.209
Insulin-dependent diabetes mellitus	24 (16.2%)	6 (10.7%)	.382
Dyslipidemia	97 (65.5%)	40 (71.4%)	.505
Hypertension	122 (82.4%)	49 (87.5%)	.523
Smoking status			.802
Never	107 (72.3%)	39 (69.6%)	
Former	40 (27.0%)	17 (30.4%)	
Current	1 (0.7%)	0	
Chronic renal failure	9 (6.1%)	3 (5.4%)	1
Prior myocardial infarction	29 (19.6%)	7 (12.5%)	.305
Prior peripheral intervention or bypass	12 (8.1%)	0	.039
Fontaine class			.863
2a	2 (1.3%)	0	
2b	130 (86.7%)	52 (91.2%)	
3	5 (3.3%)	2 (3.5%)	
4	13 (8.7%)	3 (5.3%)	

Table 2. Lesion and Procedure Characteristics.

Characteristics	Drug-Eluting Stents	Bioresorbable Vascular Scaffolds	*P*
Patients	148	56	–
Limbs	150	57	–
Side			.213
Right	68 (45.3%)	32 (56.1%)	
Left	82 (54.7%)	25 (43.9%)	
Site			.585
Superficial femoral artery	138 (92.0%)	51 (89.5%)	
Popliteal artery	12 (8.0%)	6 (10.5%)	
Tandem lesions	6 (4.0%)	0	.191
Lesion length, mm	53.4 ± 34.9	101.6 ± 75.0	<.001
Diameter stenosis (%)	89.6 ± 10.8	90.6 ± 11.3	.568
Severe calcification	36 (24.0%)	9 (15.8%)	.258
Thrombus	9 (6.0%)	7 (12.3%)	.149
Predilation	129 (86.0%)	56 (98.3%)	.010
Devices per limb	1.9 ± 1.1	3.8 ± 2.6	<.001
Seven or more devices in the same vessel	0	12 (20.7%)	<.001
Total device length per limb, mm	55.3 ± 35.8	102.4 ± 72.7	<.001
Stent type			–
Biolimus-eluting stent	60 (40.0%)	–	
Everolimus-eluting stent	25 (16.7%)	–	
Sirolimus-eluting stent	21 (14.0%)	–	
Zotarolimus-eluting stent	11 (7.3%)	–	
Maximum balloon diameter, mm	3.73 ± 0.27	3.66 ± 0.23	.067
Postdilation	67 (44.7%)	44 (77.2%)	<.001
Angiographic success	150 (100%)	57 (100%)	1

Table 3. Clinical Outcomes.

Characteristics	Drug-Eluting Stents	Bioresorbable Vascular Scaffolds	*P*
Outcomes in those eligible for at least 3-month follow-up or with earlier event			
Patients	126	56	–
Limbs	128	57	–
Follow-up duration, months	13.7 ± 12.7	8.9 ± 3.2	.006
Death	4 (3.2%)	0	.314
Target vessel revascularization	16 (12.5%)	13 (22.8%)	.083
Target lesion revascularization	8 (6.3%)	11 (19.3%)	.016
Major amputation	0	1 (1.8%)	.308
Minor amputation	1 (0.8%)	0	1
Major adverse event[a]	20 (15.9%)	13 (22.8%)	.298
Improvement in Fontaine class	97 (77.0%)	38 (67.9%)	.204
Outcomes in those eligible for at least 6-month follow-up or with earlier event			
Patients	122	55	–
Limbs	124	56	–
Follow-up duration, months	14.0 ± 12.8	9.0 ± 3.1	.005
Death	4 (3.3%)	0	.312
Target vessel revascularization	16 (12.9%)	13 (23.2%)	.124
Target lesion revascularization	8 (6.5%)	11 (19.6%)	.016
Major amputation	0	1 (1.8%)	.311
Minor amputation	1 (0.8%)	0	1
Major adverse event[a]	20 (16.1%)	13 (23.2%)	.299
Improvement in Fontaine class	95 (77.9%)	37 (67.3%)	.141
Outcomes in those eligible for at least 12-month follow-up or with earlier event			
Patients	87	30	–
Limbs	87	31	–
Follow-up duration, months	17.3 ± 13.9	11.5 ± 2.1	.026
Death	4 (4.6%)	0	.571
Target vessel revascularization	16 (18.4%)	13 (41.9%)	.014
Target lesion revascularization	8 (9.2%)	11 (35.5%)	.001
Major amputation	0	1 (3.2%)	.263
Minor amputation	1 (1.2%)	0	1
Major adverse event[a]	20 (23.0%)	13 (41.9%)	.061
Improvement in Fontaine class	63 (72.4%)	14 (46.7%)	.014

[a] The composite of death, amputation (either major or minor), or target vessel revascularization.

Finally, subgroup analysis according to popliteal versus nonpopliteal implantation suggested that even in the challenging popliteal setting DES and BVS provided equivalent clinical results, with major adverse events in, respectively, 2 of 12 (16.7%) and 1 of 6 (16.7%, $P = 1$).

Table 4. Clinical Outcomes in Propensity-Matched Patients.

Characteristics	Drug-Eluting Stents	Bioresorbable Vascular Scaffolds	*P*
Cumulative follow-up			
Patients	37	37	–
Limbs	38	38	–
Follow-up duration, months	8.9 ± 3.1	9.1 ± 3.2	.769
Death	0	0	1
Target vessel revascularization	6 (15.8%)	6 (15.8%)	1
Target lesion revascularization	4 (10.5%)	5 (13.2%)	1
Major amputation	0	0	1
Minor amputation	0	0	1
Major adverse event[a]	6 (15.8%)	6 (15.8%)	1
Improvement in Fontaine class	30 (81.1%)	29 (78.4%)	1
Outcomes in those eligible for at least 6-month follow-up			
Patients	36	36	–
Limbs	37	37	–
Follow-up duration, months	9.1 ± 3.0	9.3 ± 3.1	.757
Death	0	0	1
Target vessel revascularization	6 (16.2%)	7 (18.9%)	1
Target lesion revascularization	4 (10.8%)	5 (13.5%)	1
Major amputation	0	1 (2.7%)	1
Minor amputation	0	0	1
Major adverse event[a]	6 (16.2%)	7 (18.9%)	1
Improvement in Fontaine class	29 (80.6%)	28 (77.8%)	1
Outcomes in those eligible for at least 12-month follow-up			
Patients	20	20	–
Limbs	21	21	–
Follow-up duration, months	11.6 ± 1.5	11.7 ± 1.6	.836
Death	0	0	1
Target vessel revascularization	6 (28.6%)	6 (28.6%)	1
Target lesion revascularization	4 (19.1%)	4 (19.1%)	1
Major amputation	0	1 (4.8%)	1
Minor amputation	0	0	1
Major adverse event[a]	6 (28.6%)	6 (28.6%)	1
Improvement in Fontaine class	14 (70.0%)	13 (65.0%)	1

[a] The composite of death, amputation (either major or minor), or target vessel revascularization.

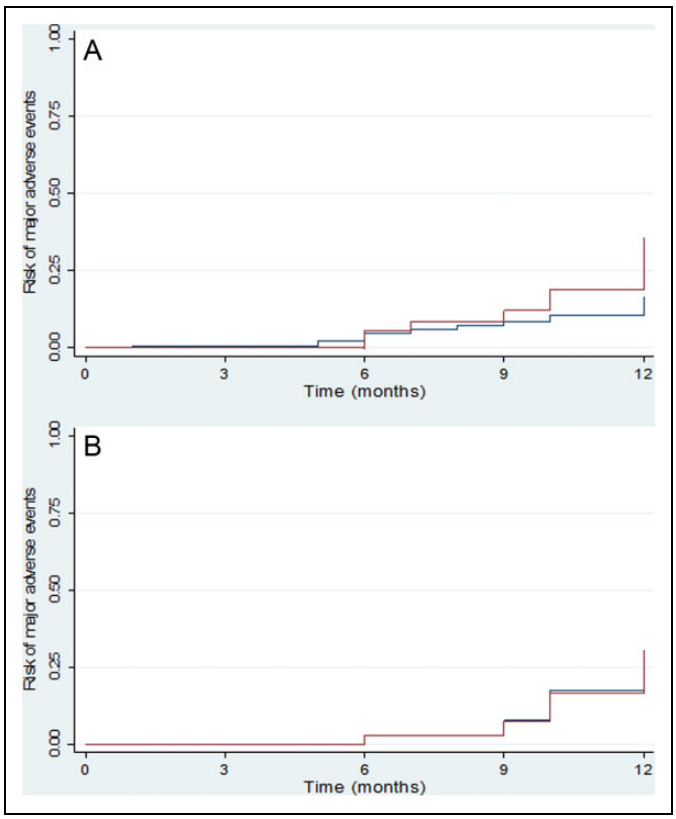

Figure 3. Risk of major adverse events (the composite of death, amputation [either major or minor], or target vessel revascularization) comparing bioresorbable vascular scaffolds (BVS; in red) versus drug-eluting stents (DES; in blue) in the overall cohort (A) and in propensity matched patients (B).

Table 5. Exploratory Multivariable Analysis for Predictors of Major Adverse Events (The Composite of Death, Amputation [Either Major or Minor], or Target Vessel Revascularization) During Follow-Up.[a]

Characteristics	Hazard Ratio		*P*
	Point Estimate	95% Confidence Interval	
Dyslipidemia	0.42	0.19-0.93	.032
Chronic renal failure	9.54	2.47-36.88	.001
Postdilation	7.40	2.78-19.67	<.001
Maximum balloon diameter, mm	11.36	2.55-50.62	.001

[a] With forward stepwise selection (probability of entry .05) from an initial model including age, female gender, obesity, diabetes mellitus, dyslipidemia, hypertension, smoking, chronic renal failure, prior myocardial infarction, prior revascularization, Fontaine class, side, site, tandem lesion, lesion length, diameter stenosis, calcification, thrombus, predilation, postdilation, stents per limb, total stent length, use of bioresorbable vascular scaffolds, use of everolimus-eluting stents, and maximum balloon diameter.

Discussion

This work presents our ongoing clinical experience with coronary DES and coronary BVS for infrainguinal endovascular therapy. We found apparently that BVS proved inferior to DES for infrainguinal revascularization in a group of patients with mostly moderately severe claudication, as BVS appeared associated with a higher unadjusted rate of repeat revascularization during follow-up. Yet, patients treated with BVS proved much more complex than those receiving DES, with particularly longer lesions. Adjustment for these and other key differences in baseline and procedural features lead no longer to significant differences between DES and BVS, thus calling for further

dedicated studies to more definitively compare the safety and efficacy of this devices.

The management of patients with symptomatic claudication due to infrainguinal artery disease remains a common clinical conundrum.[2,4,7] Developments in pharmacologic and nonpharmacologic management strategies have confined revascularization to patients failing these noninvasive treatments.[1] While surgery has historically been the reference treatment, especially for complex lesions and patients at low or moderate surgical risk, endovascular therapy has come a long way by significantly improving over the years acute success rates and long-term freedom from reintervention or amputation.[1,2] Yet, it remains difficult to identify the best combination of techniques and devices for infrainguinal endovascular therapy.[7] A number of trials and meta-analyses suggest that self-expanding bare-metal stents, self-expanding DES, and drug-eluting balloons may represent the most attractive choices if operators wish to minimize the risk–benefit profile of their intervention.[4] However, none of these devices appears perfect or associated with completely satisfactory results. In particular, metallic stents are by definition permanent prostheses which may jeopardize future revascularization options or cause specific iatrogenic complications (eg, stent fracture), whereas drug-eluting balloons lack the favorable scaffolding properties of stents, which are clearly important to ensure high acute and subacute success rates in complex lesions.

Bioresorbable vascular scaffolds have been historically proposed as a noninvasive means to treat atherosclerotic lesions and offer short- to mid-term mechanical scaffolding while enabling complete absorption of all the device components over one or more years.[11,12] Despite several initial setbacks, the combination of a BVS design with a suitable polymeric coating and an antirestenotic drug has proved momentous, and BVS are now routinely used for coronary procedures and already provide remarkable clinical benefits to patients with coronary artery disease.[13]

For several years, it has been our routine practice to use coronary DES in patients with symptomatic lower limb artery disease involving the superficial femoral artery or the proximal popliteal artery.[5,6] Despite the counterintuitive choice of a relatively small device with balloon-expandable features, our clinical results have been rather satisfactory. Accordingly, as soon as BVS become available at our institution, we adopted them for infrainguinal endovascular therapy, under the premise that they could provide similar results to those afforded by coronary DES, while effectively disappearing from the patient within a few years after the procedure.

The present retrospective analysis suggests that coronary BVS for infrainguinal endovascular therapy could offer clinical results that are equivalent to those of coronary DES, thus providing further rationale for ongoing research and development of newer embodiments of BVS, with larger diameters and longer lesions, and possibly self-expanding features.[11,12,15] Nonetheless, our work remains a pilot experience based on our specific practice strategy of relying on coronary devices for infrainguinal revascularization, and we do not advocate or recommend other centers to adopt uncritically this approach. For instance, informal comparison with results of self-expanding paclitaxel-eluting stents suggest that the latter devices offer much higher freedom from adverse events than BVS.[9] In addition, as cost may indirectly guide decision-making as much as safety and efficacy data, it should be borne in mind that BVS may still be relatively expensive, at least in comparison to long self-expanding bare-metal stents and drug-eluting balloons dedicated for infra-inguinal disease, especially when multiple devices are needed.

This study has several limitations, as already clarified above. In particular, the retrospective design, administrative setting with pragmatic approach to data collection, and lack of follow-up imaging in all patients represent major drawbacks, as well as, most importantly, our choice for coronary BVS as based mostly (if not solely) on the favorable coronary results of these devices, making this work solely hypothesis generating. Moreover, as our practice shift from coronary DES to coronary BVS for infrainguinal endovascular therapy is rather recent, follow-up is ongoing and only mid-term events could be appraised in the vast majority of included patients. Moreover, reinterventions were at the operator's discretion and thus no pre hoc criteria were explicitly followed. However, per our clinical practice, only patients reporting recurrence of symptoms or subocclusive restenosis underwent repeat angiography. Notably, no patient refused as far as we are aware a repeat revascularization procedure. Yet, the lack of systematic imaging follow-up may leave room for residual bias. This is precisely why we provided cautious inferential statements relying on different analytical approaches. Finally, the use of propensity score matching in a small data set may lead to loss of statistical power.[16]

In conclusion, the present pilot experience with coronary BVS suggests that they could provide acceptable results for infrainguinal endovascular procedures, comparable to those obtained by their metallic and permanent counterpart. Further studies are needed with bioresorbable devices explicitly designed for infrainguinal vessels.

Declaration of Conflicting Interests

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Supplemental Material

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