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Transradial experience with bioresorbable vascular scaffolds: A case-matched study with metallic drug-eluting stents

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ABSTRACT

Background: Whether polymeric bioresorbable vascular scaffolds (BVS) implantation with transradial approach is feasible and safe is unknown. We compared the feasibility and safety of the transradial approach for BVS delivery with metallic drug-eluting stents (DES).
Methods: We identified 118 consecutive patients who underwent BVS implantation and we compared 30-days and 1-year results with 118 matched patients with DES. Patients were matched for age, sex, risk factors and clinical indication.
Results: Rates of transradial approach were 98% in the BVS group vs 95% in the DES group ($P = 0.16$) with 5Fr used in 38% and 32% ($P = 0.34$), respectively. The number of stents was similar in both groups, 2.6 ± 1.5 vs 2.4 ± 1.3 ($P = 0.23$). Although maximal pressure for stent deployment was identical in both groups (16 ± 3 atm), more lesions were pre-dilated (83% vs 52%, $P < 0.001$) and post-dilated (71% vs 33%, $P < 0.001$) in the BVS group. Contrast volume (217 ± 97 vs 175 ± 108 ml, $P < 0.001$), fluoroscopy time (16 [10–23] vs 13 [8–21] min, $P = 0.04$) and procedure duration (65 ± 31 vs 56 ± 47 min, $P = 0.045$) were significantly higher in the BVS group. Major adverse cardiac events, including death, myocardial infarction and target vessel revascularization remained similar in both groups, 1.7% vs 0.8% ($P = 0.56$) at 30 days and 10% vs 8.5% ($P = 0.66$) at 1 year. At 1 year, stent thrombosis occurred in 2 (1.7%) patients in the BVS group and 1 (0.8%) patient in the DES group ($P = 0.56$).
Conclusion: The use of transradial approach for BVS compared to DES implantation was feasible and safe in all-comers, although BVS implantation included more technical challenges. Outcomes up to 1-year remained comparable in both groups.

1. Introduction

Metallic drug-eluting stents (DES) have become the treatment of choice in the modern era of percutaneous coronary angioplasty but despite remarkable early efficacy, concerns remain on long-term efficacy and safety. The permanent presence of a metallic device and durable polymer inside the coronary artery make them susceptible to late stent thrombosis, restenosis, neoatherosclerosis and lack of normal vessel reactivity [1]. As a result, a number of patients remain confronted to repeat revascularization and/or prolonged dual anti-platelet therapy [2]. Large-scale trials have demonstrated that clinical events related to target lesion failure after metallic DES occur at a rate of 2–3% per year for at least 5 years [3,4]. Fully bioresorbable vascular scaffolds (BVS, Abbott Vascular) have been developed to provide drug release and temporary mechanical support, and then totally resorb within the next few years [5]. However, if initial data have shown similar procedural and early efficacy results between BVS and metallic DES [6,7], recent late follow-up data have suggested significant concerns with BVS [8,9]. It is yet to be determined whether sub-optimal late clinical results with BVS are related to procedural technical aspects or intrinsically linked to BVS design characteristics. Furthermore, there is no data yet on the use of radial access to deliver BVS. Since BVS have intrinsic differences in design and mechanical properties compared to DES, they might have been associated with specific technical challenges. Hence, we aimed 1) to evaluate our procedural results with BVS using transradial approach as default access-site and 2) to compare 30-day and 1-year results with BVS and DES using a case-matched design.

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2. Methods

2.1. Study Population

Consecutive patients undergoing percutaneous coronary intervention (PCI) with BVS were identified from our prospective catheterization data-base. All patients undergoing PCI are entered into this database and clinical follow-up is regularly updated by dedicated research professionals. Inclusion of patients into the Recherche Évaluative en Cardiologie InTerventionnelle (RECIT) registry was approved by our Institutional Review Board and to be enrolled, all patients gave their written and informed consent. By using coarsened exact matching [10,11] BVS patients were matched to patients treated with second-generation DES based on age, sex, diabetes, baseline serum creatinine, and indication for coronary angiography. For this analysis, we performed a 1:1 match and therefore included only one control patient for every case patient.

2.2. Definitions

Angiographic success was defined as successful completion of PCI procedure with Thrombolysis In Myocardial Infarction (TIMI) 3 flow and residual stenosis < 30%, while procedural success was angiographic success without major adverse cardiac events (MACE) during hospitalization. MACE were defined as any of the following: death, myocardial infarction (MI), or target vessel revascularization. All deaths were considered cardiac unless proven otherwise. The MI criteria for diagnosis was established according to the American and European definitions [12]. Target vessel revascularization was defined as any repeat percutaneous intervention or bypass surgery involving the initial target vessel. Stent thrombosis was defined according to the Academic Research Consortium guidelines [13].

2.3. Statistical analysis

All analyses were performed using JMP Pro version 12.0 (SAS Institute Inc., Cary, North Carolina). Continuous variables were expressed as mean ± standard deviation (SD) or median (interquartile range), and were compared using paired or unpaired Student *t*-test or Wilcoxon's rank-sum test as appropriate. Categorical variables were expressed as counts and percentages, and compared using Fischer's exact test or the χ^2 test. Event-free survival curves were constructed using Kaplan-Meier techniques, and comparisons were made using the log-rank test. A P value < 0.05 was considered statistically significant.

3. Results

From June 3rd, 2013 to April 11th, 2016, we identified a total of 118 patients treated with BVS and a 1:1 case-control matching was performed with 118 patients treated with metallic DES. As shown in Table 1, both populations were very similar at baseline. Mean age was 59 ± 10 years and 83% of patients were male. Clinical presentation at admission was comparable in both groups and well balanced between patients with stable angina or acute coronary syndromes. The large majority of procedures were completed by radial approach in both groups (98% in BVS group vs 95% in DES group, P = 0.16) (Table 2). The rate of 5Fr procedures was similar in both groups, 38% vs 32% (P = 0.34), respectively. BVS were far more often used in left anterior descending artery (LAD) lesions than DES, 78% vs 27% (P < 0.001). Mean stent diameter was significantly larger in the DES group, 2.95 ± 0.46 mm vs 2.85 ± 0.35 mm (P = 0.03). More lesions were pre-dilated (83% vs 52%, P < 0.001) and post-dilated (71% vs 33%, P < 0.001) in the BVS group, although maximal balloon pressure was identical in both groups (16 ± 3 atm). Except for more balloons use with BVS compared to DES (3.2 ± 2.0 vs 2.2 ± 2.4, P = 0.01), there were no significant differences for wires 2.4 ± 2.0 vs 2.5 ± 3.2 (P = 0.78) or extension catheters 3.4% vs 4.2% (P = 0.75). Overall, BVS procedures lasted significantly longer (65 ± 31 vs. 56 ± 47 min, P = 0.045), required more fluoroscopy time (16 [10–23] vs 13 [8–21] min, P = 0.04) and used significantly higher contrast volume (217 ± 17 vs 175 ± 108 ml, P < 0.001). Angiographic success was 100% in both groups while procedural success was 98% in the BVS group vs 99% in the DES group (P = 0.56).

The rate of MACE remained similar in both groups at 30 days (1.7% vs 0.8%, P = 0.56) and at 1 year (10% vs 8.5%, P = 0.66), respectively (Table 3 and Fig. 1). There was no death in any group within 30 days

Table 1
Baseline demographic and clinical characteristics.

	BVS (n = 118)	DES (n = 118)	P
Age, yrs	59 ± 11	59 ± 10	0.43
Male	98 (83%)	98 (83%)	n/a
Diabetes	30 (25%)	30 (25%)	n/a
Hypertension	67 (57%)	69 (59%)	0.77
Dyslipidemia	88 (75%)	87 (74%)	0.87
Tobacco use (current and past)	33 (28%)	38 (32%)	0.22
BMI, kg/m^2	30 ± 5	29 ± 5	0.25
Family history of CAD	40 (34%)	29 (25%)	0.12
Previous MI	20 (17%)	15 (13%)	0.67
Previous PCI	41 (35%)	38 (32%)	0.67
Previous CABG	5 (4.2%)	7 (5.9%)	0.57
Creatinine, μmol/l	92 ± 19	95 ± 19	0.37
Hemoglobin, g/dl	14.3 ± 1.5	14.1 ± 1.5	0.31
Platelets, 10^9/l	225 ± 80	218 ± 59	0.41
Indication for procedure			
Stable CAD	43 (36%)	43 (36%)	n/a
Unstable angina	46 (39%)	46 (39%)	n/a
NSTEMI	18 (15%)	18 (15%)	n/a
STEMI	11 (9.3%)	11 (9.3%)	n/a

Data are presented as mean ± SD or number (percent of total). BMI: body mass index; CABG: coronary artery bypass grafting; CAD: coronary artery disease; MI: myocardial infarction; N/A: not applicable as variable was used in coarsened exact matching; NSTEMI: non-ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction.

Table 2
Procedural characteristics.

	BVS (n = 118)	DES (n = 118)	P
Radial access site	116 (98%)	112 (95%)	0.16
5Fr sheath	45 (38%)	38 (32%)	0.34
Total number of stents implanted	2.6 ± 1.5	2.4 ± 1.3	0.23
Contrast volume, ml	217 ± 97	175 ± 108	<0.001
Procedure duration, min	65 ± 31	56 ± 47	0.045
Fluoroscopy time, min	16 [10−23]	13 [8–21]	0.04
Dose area product, μGy·cm^2	8841 [5783–14,892]	6858 [4463–12,837]	0.03
Treated lesions	**BVS (n = 157)**	**DES (n = 233)**	
Stent length, mm	21.3 ± 6.1	20.8 ± 8.3	0.55
Stent diameter, mm	2.85 ± 0.35	2.95 ± 0.46	0.03
Target artery			
LAD	122 (78%)	63 (27%)	<0.001
LCX	15 (9.6%)	64 (28%)	<0.001
RCA	19 (12%)	104 (45%)	<0.001
LM	1 (0.6%)	2 (0.9%)	0.81
Bifurcation lesion	33 (21%)	43 (19%)	0.53
Ostial lesion	16 (10%)	25 (11%)	0.87
Pre-dilation	130 (83%)	122 (52%)	<0.001
Deployment pressure, atm	16 ± 3	16 ± 3	0.91
Post-dilation	111 (71%)	75 (33%)	<0.001
Non-compliant balloon	94 (60%)	55 (24%)	<0.001
1:1 non-compliant balloon	61 (55%)	41 (55%)	0.97
Non-compliant balloon > 1:1	46 (41%)	34 (45%)	0.60

Data are presented as mean ± SD or median (interquartile range), or number (percent of total).
LAD: left anterior descending artery; LCX: left circumflex artery; LM: left main artery; RCA: right coronary artery.

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