Cardiovascular Revascularization Medicine 16 (2015) 381–385

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Coronary

Short-term outcomes in patients with acute coronary syndrome treated with direct bioresorbable scaffold deployment☆

Ayyaz Sultan, Varinder Randhawa, Anthony C. Camuglia, Shahar Lavi *

Division of Cardiology, Department of Internal Medicine, London Health Sciences Centre, Western University, London, Ontario, Canada

ARTICLE INFO

Article history:
Received 20 March 2015
Received in revised form 6 June 2015
Accepted 16 June 2015

Keywords:
Bioresorbable vascular scaffold
Direct coronary stenting
Myocardial infarction

ABSTRACT

Background: Direct coronary stenting is a validated therapeutic option for coronary lesions. We studied the feasibility of direct deployment with a bioresorbable vascular scaffold (BVS) in acute coronary syndrome (ACS).
Methods: Demographic, procedural, and survival data were obtained for patients who had direct scaffold deployment with BVS from 1 May 2013 to 1 April 2014.
Results: We performed a retrospective review of nine patients which included eight patients having ST-elevation myocardial infarction. There were no cases of worsening coronary flow, scaffold thrombosis, target lesion revascularization or death up to 30 days post intervention.
Conclusion: Direct BVS deployment in ACS appears safe and feasible.

1. Introduction

The long-term safety of the drug eluting stent (DES) [1–3], in particular the occurrence of very late stent thrombosis, raises concern over permanent metallic stenting in coronary arteries. The concept of the "short-term" vascular scaffold may offer a viable solution by providing temporary radial support by scaffolding that later becomes fully resorbed via endogenous cellular and metabolic pathways [4,5]. The everolimus-eluting bioresorbable vascular scaffold (BVS) has shown reasonable safety and efficacy in short-term follow-up in patients with de novo coronary lesions after appropriate lesion preparation [6,7]. There is limited evidence however, for the use of BVS technology in patients with acute coronary syndrome (ACS) [8]. The first case series of BVS use in the setting of ST elevation myocardial infarction was published in 2013 [9]. More recently, a 1-year outcome study demonstrated, similar outcome with BVS, DES or bare metal stents (BMS) [10].

In the setting of ACS, direct stenting has been advocated as a potentially preferred technique where clinically feasible. This technique has been utilized with metallic stents in appropriately selected lesions in patients with stable coronary artery disease [11–13], non ST-elevation ACS [14], and ST-elevation myocardial infarction (STEMI) [15,16]. Direct stenting may reduce ischemic time, distal edge stent dissection, and thrombus and/or plaque fragmentation with distal migration. Most importantly, it may also provide superior myocardial perfusion with less distal embolization and microvascular dysfunction with higher frequency of TIMI 3 flow post revascularization [17,18]. These attributes make this technique appealing in the setting of ACS, particularly in primary percutaneous coronary intervention (PCI) for STEMI. It is plausible that direct scaffold deployment with BVS would be technically feasible in select patients [19–21]. Our case series aims to report the safety, feasibility, and short-term performance of BVS deployed without predilatation for ACS in a tertiary academic center in Ontario, Canada.

2. Methods

Thirty-seven patients underwent PCI with BVS implantation from June 2013 to March 2014, of which 30 had ACS. Baseline demographics, ECG and cardiac biomarker data, coronary angiography, BVS deployment details, and use of adjunctive coronary imaging were recorded. American College of Cardiology (ACC) Guidelines for Coronary Angiography was used to classify lesion type [22]. Oral antiplatelet therapy, intravenous unfractionated heparin and/or glycoprotein infusion were administered according to consensus guidelines. The scaffold used at our center, Absorb (Abbott Vascular, Santa Clara, CA, USA) is a second generation BVS composed of a poly L-lactide (PLLA) backbone with a strut thickness of 150 μm. It is coated with a polymer of poly DL-lactide (PDLLA) and the mammalian target of rapamycin (mTOR) inhibitor everolimus, which is slowly released over 30 days. Two platinum markers at each scaffold end aid fluoroscopic identification. Scaffold degradation begins by hydrolysis of esterified bonds by water, which generates lactic acid that is then rapidly metabolized through the Kreb's and pyruvic acid cycles.

Device success was defined by fluoroscopic evidence of ≤20% residual stenosis of the target lesion covered by the BVS. Procedural success was defined additionally by the lack of major peri-procedural coronary complications. Major adverse cardiac events included cardiac death, scaffold thrombosis or clinically driven target lesion revascularization

☆ The authors report no financial relationships or conflicts of interest regarding the content herein.

* Corresponding author at: Division of Cardiology, The University of Western Ontario, 339 Winderemere Road, PO Box 5339, London, ON N6A 5A5. Tel.: +1 519 6633611; fax: +1 519 6633117.
E-mail address: shahar.lavi@lhsc.on.ca (S. Lavi).

http://dx.doi.org/10.1016/j.carrev.2015.06.007
1553-8389/

at 30 days and 3 months. Descriptive statistics were provided for all variables. Continuous variables were presented as mean and standard deviation or as median and interquartile range when appropriate, whereas categorical variables were presented as counts and percentages.

This study has been approved by Western University's Research and Ethics Board (REB).

3. Results

3.1. Patients

Nine (mean age 55.6 ± 12.4 years) of 30 patients with ACS were treated with BVS deployment without pre-dilation. Less than half were female, diabetic, and actively smoking (all 44%), whereas 56% had hypertension and 67% had dyslipidemia (Table 1).

3.2. Angiographic data

Eight patients had acute STEMI and underwent primary PCI. The infarct related artery was often the left anterior descending or right coronary artery (44%), and less often the left circumflex (11%). At index angiography, one-third of patients had no coronary flow in the infarct related artery and 55% had significant thrombus load. Most lesions were ACC type-B with relatively low median SYNTAX scores (Table 2). Aspiration thrombectomy and OCT-guided PCI (Figs. 1 and 2) were performed in 4 and 3 patients, respectively. Mean BVS length per-lesion was 19.6 ± 5.8 mm and mean BVS diameter per-lesion was 3.33 ± 0.11 mm. Post-dilatation was performed in all "direct" scaffold procedures using a mean inflation pressure of 16.4 ± 3.2 atm. There was no side branch occlusion in any of the patients who had bifurcation lesions (Table 2).

3.3. Follow-up

After direct BVS deployment, there were no cases of deterioration in TIMI flow. TIMI 3 flow was achieved in 88.9% of patients. Coronary flow remained unchanged in one patient. No residual thrombus was angiographically visible post-procedure. Device and procedural success were achieved in all nine patients. At the 30-day and 3 month follow-ups, no patients had clinically driven target vessel revascularization, cardiac death or a major adverse complication event.

4. Discussion

Our study demonstrates the short-term safety and efficacy of direct stenting of BVS in select patients with favorable clinical outcomes.

Table 1
Baseline characteristics of BVS treated patients.

Demographic data	Total BVS (n = 21)	Direct stent BVS (n = 9)
Age (years)	56.6	55.6
Female gender	23.8% (5)	44% (4)
Diabetes mellitus	28.6% (6)	44% (4)
Current smoker	28.6% (6)	44% (4)
Dyslipidemia	71.4 (15)	67% (6)
Hypertension	71.4% (15)	56% (5)
CABG	4.7% (1)	0
Vessels involved		
LMS	4.7% (1)	0
LAD	71.4% (15)	44.4% (4)
Proximal LAD	14.3% (3)	25% (1)
Mid to distal LAD	57.1% (12)	75% (3)
LCX	14.3% (3)	11.1% (1)
RCA	9.5% (2)	44.4% (4)
ACS presentation		
STEMI	33% (7)	89% (8)
NSTEMI	66.7% (14)	11% (1)

Table 2
Pre and post angiographic analysis.

Angiographic data	Total BVS (n = 21)	Direct stent BVS (n = 9)
Pre-procedure TIMI flow		
0	28.6% (6)	33.3% (3)
1	0	11.1% (1)
2	9.5% (2)	22.2% (2)
3	61.9% (13)	33.3% (3)
Lesion characteristic	n = 32	n = 11
Predominant thrombus	25% (8)	54.5% (6)
Predominant calcification	6.3% (2)	0%
Predominant plaque disease	68.8% (22)	45.5% (5)
Thrombus burden at culprit		
0	23.8% (5)	22.2% (2)
1	28.6% (6)	11.1% (1)
2	4.8% (1)	11.1% (1)
3	19% (4)	11.1% (1)
4	9.5% (2)	11.1% (1)
5	14.3% (3)	33.3% (3)
SYNTAX score (median)	15	7
ACC lesion type	N = 32	N = 11
A	9.4% (3)	9.1% (1)
B	71.9% (23)	72.7% (8)
C	18.8% (8)	18.2% (2)
Small side branch (bifurcation lesions)	42.8% (9)	44.4% (4)
Final TIMI flow 3 in side branches	100%	100%
Procedural data		
Manual thrombectomy	20% (2)	44.4% (4)
Post-dilatation	68.7% (22)	100% (9)
Total number of scaffolds (n)	32	11
Mean scaffolds per-patient (n)	1.52	1.22
Mean scaffold length per-lesion (mm)	20.5 ± 5.9	19.6 ± 5.8
Mean scaffold diameter per-lesion (mm)	3.03 ± 0.43	3.33 ± 0.11
Mean pressure (atm)	16.6 ± 3.5	16.4 ± 3.2
Post-BVS TIMI flow		
0	0	0
1	0	0
2	0	11.1% (1)
3	100% (21)	88.9% (8)
Post-BVS implant residual diameter		
>20%	0	0
<20%	100% (30/30)	100% (9/9)

Although, pre-dilation lesions are often required prior to stenting with BVS, it may be more important for calcified and fibrotic lesions. In younger patients, mainly those who did not have prior history of heart disease and present with STEMI, direct deployment with BVS seems feasible and is mechanistically attractive. One of the concerns with stenting in the setting of STEMI is stent malapposition (with the attendant risk of stent thrombosis) partly due to the presence of thrombus but probably more related to device under-sizing due to the vasoconstrictive milieu that predominates in the setting of acute myocardial infarction (despite repeated doses of intra-coronary nitrates) [23,24]. BVS addresses these issues by deploying a technology that is completely resorbed over the passage of two years. The gradual dissolution of BVS may further reduce the risk of late stent thrombosis, as well as help with restoration of coronary vasomotion [25,26], aid vessel remodeling [27,28], and evade lifelong caging of the vessel and permanent jailing of side branch. The risk of very late stent thrombosis may be reduced by avoiding the issue of acquired malapposition and delayed healing that can occur with metallic polymer coated stents [29–33].

The GHOST-EU registry included 1189 patients who received BVS. Only 16% of the cohort presented as a STEMI. 83.3% underwent pre-dilatation and 49.7% underwent post-dilatation.

The incidence of stent thrombosis was relatively high (2.1% at 6 months) compared to contemporary results of 2nd generation DES [34]. Brugaletta et al. have recently shown in the Bioresorbable Vascular Scaffold-A Clinical Evaluation of Everolimus Eluting Coronary Stents in