Efficacy and Safety of Bioresorbable Vascular Scaffold (BVS) - Absorb in Acute Myocardial Infarction – A 45 Month Follow Up Study

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Abstract

Aim: Bioresorbable vascular scaffolds (BVS) over the years have emerged as a new treatment option in coronary revascularization. There is a limited data on the use of these novel devices in patients with acute myocardial infarction (AMI). The purpose of this study was to evaluate the safety feasibility and efficacy of BVS implantation in patients with AMI.

Methods and Results: 61 patients diagnosed for AMI underwent Absorb BVS device implantation. The mean age of the patients were 56.6 years with 86.89 % males. 34 patients has history of hypertension (HTN, 55.7%), 3 patients had history of myocardial infarction (MI, 4.91 %), 7 patients were diagnosed with unstable angina (UA, 11%), 34 patients had anterior wall ST elevation myocardial infarction (AWSTEMI, 55.73%), 13 with ST segment elevation myocardial infarction (STEMI, 21.31%), with Killips class 2 (39.34%), 6 patients had Non ST segment elevation Myocardial Infarction (NSTEMI, 9.83%). Procedural success was achieved in 93% patients with thrombolysis in myocardial infarction flow (TIMI) 3. During the follow up period of minimum 44±16 months no peri-procedural MACE were reported. Incidence of TLF (22.95%), definite probable ScT (11.47%) and TLR was 8 %. Average duration of DAPT was 17.57 months and 8 days. Cardiac death occurred in 4 patients (6.5%) after discharge from the hospital.

Conclusions: The study results suggest that BVS implantation is feasible and safe in AMI. Specific device implantation technique is critical step towards success of BVS devices.

Introduction

Coronary Artery Disease (CAD) is the most common condition amongst heart ailments and is the leading cause of death. Interventional management of CAD involves balloon angioplasty, stent placement and coronary artery bypass surgery. Percutaneous transluminal coronary angioplasty (PTCA) using a balloon is a minimally invasive procedure used to open blocked coronary arteries to improve blood flow and allow blood to circulate to the heart muscle. Balloon angioplasty results in a dissection forming inside a diseased vessel, which can lead to an overgrowth of scar tissue, and in turn can result in restenosis of a previously treated section. Evolution of drug eluting stents have also reported risk of edge restenosis and late thrombosis. The development of biodegradable and bio absorbable stents or bio absorbable vascular scaffolds (BVS) present a promising future in cardiovascular medicine.¹ The long-term advantages of BVS include: possibility of using non-invasive follow-up imaging (such as multiple detector computed tomography, MDCT), restoration of vasomotion, and positive remodelling.² Clinical trials have shown the use of the BVS as a safe and feasible modality with acceptable short and mid-term clinical outcomes.³ ⁵ However, registries performed in more complex patients and lesions reported higher rates of early and late scaffold thrombosis.⁶ ⁸ Studies on BVS in AMI are limited and there is a need for more data on the efficacy of BVS in the setting of PCI for AMI cases. The aim of our study was to evaluate the feasibility, efficacy and safety of bioresorbable vascular scaffold in patients presenting with acute myocardial infarction. To the best of our knowledge this study is the single longest follow up from India.

Methods

Study Center

This single center retrospective study was undertaken between June 2013 to April 2017. Study was conducted in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Ethics approval was obtained from the Institutional Ethical Committee. Based on the selection criteria, 84 patients were enrolled for percutaneous coronary intervention (PCI) and Absorb BVS (Abbott Vascular, Santa Clara, CA). The remaining 3 patients were treated with drug-eluting stent (DES). Prior written informed consent was obtained from all the patients for the study and the required follow-up.

Selection Criteria

Inclusion criteria: patients presenting with acute coronary syndrome (ACS) and acute myocardial infarction (AMI); presence of one significant coronary artery stenosis with no restrictions as to the number; severity or lesion location; target vessel reference diameter (2.3 mm - 3.7 mm) by visual estimate.
Exclusion criteria: Non ACS / MI condition; known intolerance to: acetylsalicylic acid, heparin, poly-L-lactide, everolimus contrast material; active bleeding; coagulopathy or patients on chronic anticoagulation therapy; poor compliance; cardiogenic shock; comorbidity with limited expected survival (<1 year); inaccessible vessel conditions: severe tortuosity, calcification or angulated coronary anatomy; fibrinolysis prior to PTCA.

Study Parameters

Demographic variables, angiographic findings, clinical outcome (hospital stay and subsequent follow up), lesion and procedural characteristics.

Study endpoints

The primary endpoint of the study was cumulative rate of major adverse cardiovascular events (MACE) including cardiac death, myocardial infarction (MI) and ischemia-driven target lesion revascularization (TLR) TLR was defined as the need for subsequent intervention of the target lesion due to the presence of a symptomatic >50% diameter stenosis during follow-up. Cardiac deaths were defined as death resulting from an acute MI, heart failure and cardiac procedures. All deaths were deemed cardiac unless proven otherwise.

The primary efficacy outcome of interest was target lesion failure. Secondary endpoints included cardiac death, all-cause death, MI, TLR, target vessel revascularization (TVR), stent thrombosis (ST), and very late stent thrombosis (VLST). Angiographic success was defined as successful scaffold deployment at the intended site with the residual stenosis of less than 30% (visual estimation), with thrombolysis in myocardial infarction (TIMI) flow grade 3. Procedure success was defined as angiographic success in the absence of in hospital major adverse cardiac events (MACE).

BVS implantation technique

Prior to implantation coronary angiograms were analysed with the CAAS 5.10 QCA software (Pie Medical BV, Maastricht, the Netherlands). PCI was performed using the radial or femoral approach using 6 or 7 french catheters. The recommended PSP technique was followed for device implantation in our study. This technique included: adequate lesion preparation (P), appropriate sizing (S) and post dilatation (P) with an objective to achieve final diameter stenosis of 10% with a +0.5 mm noncompliant balloon to high pressure (>16atm). (Figures 1, 2) After the procedure all patients received dual antiplatelet therapy (DAPT) loading and maintenance dose i.e. Aspirin - Clopidogrel or Aspirin - Ticagrelor or Aspirin - Prasugrel for at least 12 months. In patients with complex lesions or an acute presentation, the use of ticagrelor or prasugrel as a substitute for clopidogrel was preferred (at least for the first 3 months). Prolonged DAPT prescription (>12 months) was encouraged, if well tolerated with no bleeding events in the patient.

Follow-up

Minimum follow up duration was 4 years. This was conducted through telephonic contact or live status examination for reporting of: adverse events, subsequent coronary interventions, use and changes in concomitant medications.

Statistical analysis

The data was recorded on an electronic format, tabulated and analyzed Statistical Package for Social Sciences version 20.0.1 (IBM SPSS Statistics for Windows, Version 20.0.1 Armonk, NY: IBM Corp) Continuous variables are presented as mean ± standard deviation and categorical variables are presented as counts and percentages.

Results

Study patients

Out of the 64 patients, BVS device was implanted in 61 patients. The mean age of the study population was 56.6 years, 86.89% were males. 55.74% subjects had hypertension with 4.91% reported history of MI. 7 patients were diagnosed with unstable angina (11%), 34 with AWSTEMI (55.73%), 13 with STEMI (21.31%) with Killips class 2 (39.34%) (Table 1).

Lesion and procedural characteristics

During percutaneous coronary intervention (PCI) with BVS implantation, femoral artery catheterization was done in 60.66% cases. A total of 78 vessels were treated: left anterior descending artery (n=40) 65.57%, right coronary artery (n=11) 18.03%, left circumflex artery (n=12) 19.67%. Out of treated lesions (34.4%) were type B2 or C according to ACC/AHA classification. Pre-dilation was performed in (80.32%), mostly with non-compliant balloons and preferring 1:1 balloon-vessel ratio. Total scaffold length and breadth per lesion and per patient were 3.49±2.10 cm and 23.24±5.99 cm. Out of the studied subjects, 42 (68.8%) BVS were post-dilated with noncompliant balloon utilizing high-pressure, progressive and prolonged inflations. Thrombus aspiration was done in 49 patients. Angiographic success was achieved with a TIMI score of 3 in 93% of the cases. TIMI score of 2 was achieved in 4% of the patients (Table 2).
Our study reports efficacy of bioresorbable scaffold in AMI with a minimum follow up of 4 years. The use of bioresorbable scaffolds in AMI and ACS patients requires correct vessel and scaffold sizing. Aggressive vessel and scaffold sizing. Aggressive use of bioresorbable scaffolds in AMI with a minimum follow up of 4 years. The bioresorbable scaffold in AMI with a reported.

Probable thrombotic events were premature. 4 cases of definite and probable ScT occurred in 7 (11.47%) (Table 3). Adopting standardized device implantation technique is key to minimise the incidence of adverse events.

Type of treated lesions (34.42%) were type B2 or C in our study which is less than the largest randomized trial (68.7%) and the largest real-world registry (53.5%). Our study reported highest number of 100% thrombotic occlusion in 24 (39.34%) patients. The duration of DAPT is potentially associated with the occurrence of late scaffold thrombosis. The AIDA trial investigators recommended continuation of DAPT for all BVS patients until 3 years post index PCI. This recommendation is supported by the results from the DAPT trial: treatment with metallic drug-eluting stents and DAPT beyond 1 year compared with aspirin alone was associated with a significantly reduced risk of stent thrombosis and cardiovascular events.

Vessel sizing is important prior to scaffold placement and optical coherence tomography (OCT) provides precise vessel and lesion measurements, optimal for sizing and positioning and also allows accurate assessment of scaffold apposition after completion of the procedure. In our study OCT and IVUS (intravascular ultrasound) was done in 32% and 42% patients respectively (Figures 3, 4).

Presence of thrombus increases the risk of late scaffold malposition. Post-dilatation, has been sought after step to correct scaffold malposition. Post-dilatation was performed in 68% of the cases in our study which is in concurrence to the study that states post-dilatation should be performed with short non-compliant balloons. Scaffold thrombosis (ScT) post implantation might be related to a combination of incompletely embedded and non-absorbed scaffold struts, (predominant amongst the 1st generation scaffolds when implanted in small vessels) and late discontinuity or device dismantling of malapposed struts. The results of our study with a minimum 4 year follow up revealed: ScT was reported in 5 cases (8.1%). Very late stent/scaffold thrombosis was found in 2 cases (3.2%). Cardiac mortality in 4 cases (6.1%) (Table 3). Adopting standardized device implantation technique is key to minimise the incidence of adverse events.

The duration of clinical follow-up was minimum 44±16 months. No peri-procedural MACE were reported. TLF occurred in 14 (22.95%) patients. Definite probable ScT occurred in 7 patients (11.47%) (Table 3). Cardiac death occurred in 4 patients (6.5%) after discharge from the hospital. Target-vessel myocardial infarction and target-vessel revascularization was 8% respectively. Average duration of DAPT was 17.57 months and 8 days. At discharge preferred second antiplatelet agent was: Clopidogrel (59.9%), Prasugrel (20.9%) Ticagrelor (19.2%). DAPT was not discontinued prematurely. 4 cases of definite and probable thrombotic events were reported.

Discussion

Our study reports efficacy of bioresorbable scaffold in AMI with a minimum follow up of 4 years. The use of bioresorbable scaffolds in AMI and ACS patients requires correct vessel and scaffold sizing. Aggressive use of bioresorbable scaffolds in AMI with a minimum follow up of 4 years. The bioresorbable scaffold in AMI with a reported.

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late ScT occurred in patients that were not on DAPT at the time of the event.\textsuperscript{15} Average duration of DAPT was 17.57 months and 8 days in our study. 60 % of the regular clinical follow up patients are still continuing the DAPT.

**Study limitations**

The main limitations of this study was the small sample size, single center and non-randomized nature. Patient and lesion characteristics could have led to possible biased outcomes. There is paucity in literature for the clear-cut guidelines for placement of BVS devices.

**Conclusions**

Despite high TLR rate as presented in our study of minimum 4 years follow up, we concluded that the implantation of bioresorbable vascular scaffold (BVS) is safe and feasible coronary revascularization alternative in ACS / AMI patient’s. Use of specific device implantation technique is crucial towards success of BVS devices. Advantages of BVS is well documented in terms of their superior ability to maintain the physiological vasomotion. Therefore, the BVS may become a very promising alternative to DES.

**Abbreviations**


**Table 3: Clinical Outcomes at minimum 4 years of follow up**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number (N)</th>
<th>Percentage (%)</th>
</tr>
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<tbody>
<tr>
<td>1. Cardiac Mortality</td>
<td>4</td>
<td>6.56</td>
</tr>
<tr>
<td>2. Target vessel MI</td>
<td>5</td>
<td>8.20</td>
</tr>
<tr>
<td>3. Target lesion revascularization</td>
<td>5</td>
<td>8.20</td>
</tr>
<tr>
<td>4. Target lesion failure (Cardiac Mortal+)</td>
<td>14</td>
<td>22.95</td>
</tr>
<tr>
<td>5. All other cause mortality</td>
<td>3</td>
<td>4.91</td>
</tr>
<tr>
<td>6. Stent/scaffold thrombosis</td>
<td>5</td>
<td>8.19</td>
</tr>
<tr>
<td>7. Very late Stent/scaffold thrombosis</td>
<td>2</td>
<td>3.27</td>
</tr>
<tr>
<td>8. Primary safety outcomes (Stent/scaffold thrombosis)</td>
<td>7</td>
<td>11.47</td>
</tr>
<tr>
<td>9. Ventricular arrhythmia</td>
<td>5</td>
<td>8.20</td>
</tr>
<tr>
<td>10. Major or clinically relevant bleeding</td>
<td>3</td>
<td>4.91</td>
</tr>
<tr>
<td>11. Acute renal failure</td>
<td>1</td>
<td>1.63</td>
</tr>
<tr>
<td>12. Stroke</td>
<td>1</td>
<td>1.63</td>
</tr>
</tbody>
</table>

**References**

16. Authors/Task Force m, S. Windecker, P Kolh, et al. ESC/EACTS guidelines on myocardial revascularization: the task force on myocardial revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J 2014; 35:2541–2619.