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Are BVS suitable for ACS patients? Support from a large single center real live registry

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ABSTRACT

Objectives: To investigate one-year outcomes after implantation of a bioresorbable vascular scaffold (BVS) in patients presenting with acute coronary syndrome (ACS) compared to stable angina patients.
Background: Robust data on the outcome of BVS in the setting of ACS is still scarce.
Methods: Two investigator initiated, single-center, single-arm BVS registries have been pooled for the purpose of this study, namely the BVS Expand and BVS STEMI registries.
Results: From September 2012–October 2014, 351 patients with a total of 428 lesions were enrolled. 255 (72.6%) were ACS patients and 99 (27.4%) presented with stable angina/silent ischemia. Mean number of scaffold/patient was 1.55 ± 0.91 in ACS group versus 1.91 ± 1.11 in non-ACS group (P = 0.11). Pre- and post-dilatation were performed less frequent in ACS patients, 75.7% and 41.3% versus 89.0% and 62.0% respectively (P = 0.05 and P = 0.001). Interestingly, post-procedural acute lumen gain and percentage diameter stenosis were superior in ACS patients, 1.62 ± 0.65 mm (versus 1.22 ± 0.49 mm, P < 0.001) and 15.51 ± 8.47% (versus 18.46 ± 9.54%, P = 0.04). Major adverse cardiac events (MACE) rate at 12 months was 5.5% in the ACS group (versus 5.3% in stable group, P = 0.90). One-year definite scaffold thrombosis rate was comparable: 2.0% for ACS population versus 2.1% for stable population (P = 0.94), however, early scaffold thromboses occurred only in ACS patients.
Conclusions: One-year clinical outcomes in ACS patients treated with BVS were similar to non-ACS patients. Acute angiographic outcomes were better in ACS than in non-ACS, yet the early thrombotic events require attention and further research.

1. Introduction

Drug-eluting stents (DES) are the first choice devices in percutaneous coronary interventions (PCI). Despite recent advantages, shortcomings related to the use of DES still are present such as delayed arterial healing, late stent thrombosis (ST), neo-atherosclerosis and hypersensitivity reactions to the polymer [1,2].

To overcome these limitations, coronary devices made of fully bioresorbable material were developed to provide mechanical support and drug-delivery within the first year, followed by complete resorption. The first bioresorbable vascular scaffold (BVS) was commercially introduced in September 2012 as the Absorb BVS (Abbott Vascular, Santa Clara, CA). The BVS provides transient vessel support and gradually elutes the anti-proliferative drug everolimus. After degradation of the polymer (after approximately two to three years) no foreign material remains and need for late reintervention triggered by foreign material should thus be reduced [3].

First-in-man trials have proven the safety of the BVS up to five years [4,5] with a fully completed bioresorption process, a late luminal enlargement due to plaque reduction and a persistent restoration of vasomotion [6–8]. The 1-year results of the larger ABSORB II, ABSORB Japan, ABSORB China and ABSORB III randomized controlled trials comparing BVS with DES (Xience V), confirmed the safety in relatively simple coronary lesions with similar clinical event rates for both devices [9–12].

In all these early studies, ACS patients were largely excluded while BVS would comprise a more attractive choice in this setting as ACS patients are in general younger with a longer life expectancy, less previous

Abbreviations: ACS, acute coronary syndrome; BMS, bare metal stent; BVS, bioresorbable vascular scaffold; BRS, bioresorbable scaffold; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CEC, clinical events committee; DES, drug-eluting stent; ITT, intention-to-treat; IVUS, intravascular ultrasound; LM, left main; MACE, major adverse cardiac events; MI, myocardial infarction; MLD, minimal lumen area; Non-TVR, non-target vessel revascularization; NSTEMI, non-ST elevation myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; PT, per-treatment; QCA, quantitative coronary angiography; RVD, reference vessel diameter; ST, scaffold thrombosis; STEMI, ST elevation myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TVR, target vessel revascularization; UA, unstable angina pectoris; %DS, percentage diameter stenosis.

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MI and revascularizations with implantation of metallic stents, that would conflict with a therapy aiming at maximal recovery and restoration of normal anatomy of both the coronary artery and myocardium. Furthermore, lesions primarily consisting of soft plaque would be conceptually easy to expand thus facilitating BVS implantation in ACS population. On the other hand, ACS patients are in a much higher prothrombotic state which might accelerate thrombus formation on the larger struts of the BVS impacting much more on shear stress compared to the thinner struts of current metallic DES.

Few registries focused on the performance of the BVS in patients presenting with ACS, mainly ST-elevation myocardial infarction (STEMI). BVS STEMI First examined the procedural and short-term clinical outcomes of 49 STEMI patients, revealing excellent results: procedural success was 97.9% and only 1 patient suffered an event (non-target vessel MI) [13]. Kočka et al. reported similar results in the Prague-19 study [14]. Extending the initial Prague-19 study, the BVS Examination is currently the largest registry on BVS in STEMI with encouraging MACE rates (Device oriented clinical endpoint: 4.1% at one year for both the BVS and the DES), although with a not negligible definite/probable scaffold thrombosis rate (2.4% at one year for the BVS) [15].

The recently published TROFI II randomized trial investigated arterial healing in 90 STEMI patients treated with a BVS compared to those treated with an everolimus-eluting stent (EES). Based on OCT, arterial healing at 6 months after BVS implantation was non-inferior to that after EES implantation [16].

In general, the previous studies on BVS in ACS are limited in size and procedural details and there is a need for more data on the efficacy of BVS in the setting of PCI for ACS. The aim of this study was to compare the angiographic and clinical outcomes of BVS in ACS patients with stable patients.

2. Material and methods

2.1. Population

Two investigator-initiated, prospective, single-center, single-arm studies performed in an experienced, tertiary PCI center have been pooled for the purpose of this investigation. Patients presenting with NSTEMI, stable or unstable angina (UA), or silent ischemia caused by a *de novo* stenotic lesion in a native previously untreated coronary artery with intention to treat with a BVS were included in BVS Expand registry. Angiographic inclusion criteria were lesions with a Dmax (proximal and distal maximal lumen diameter) within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online quantitative coronary angiography (QCA). Complex lesions such as bifurcation, calcified (as assessed by angiography), long and thrombotic lesions were not excluded. Exclusion criteria were patients with a history of coronary bypass grafting (CABG), presentation with cardiogenic shock, bifurcation lesions requiring kissing balloon post-dilatation, ST-elevation myocardial infarction (STEMI) patients, allergy or contra-indications to antiplatelet therapy, fertile female patients not taking adequate contraceptives or currently breastfeeding and patients with expected survival of less than one year. As per hospital policy patients with a previously implanted metal DES in the intended target vessel were also excluded. Also, although old age was not an exclusion criterion, BVS were in general reserved for younger patients, and left to operator's interpretation of biological age.

Patients presenting with STEMI, were approached to participate in the BVS STEMI Registry, which started two months after the BVS Expand registry. The study design has been described elsewhere [13]. The most important inclusion criteria were presentation with STEMI and complaints <12 h. The remaining inclusion criteria were similar to the BVS-EXPAND registry.

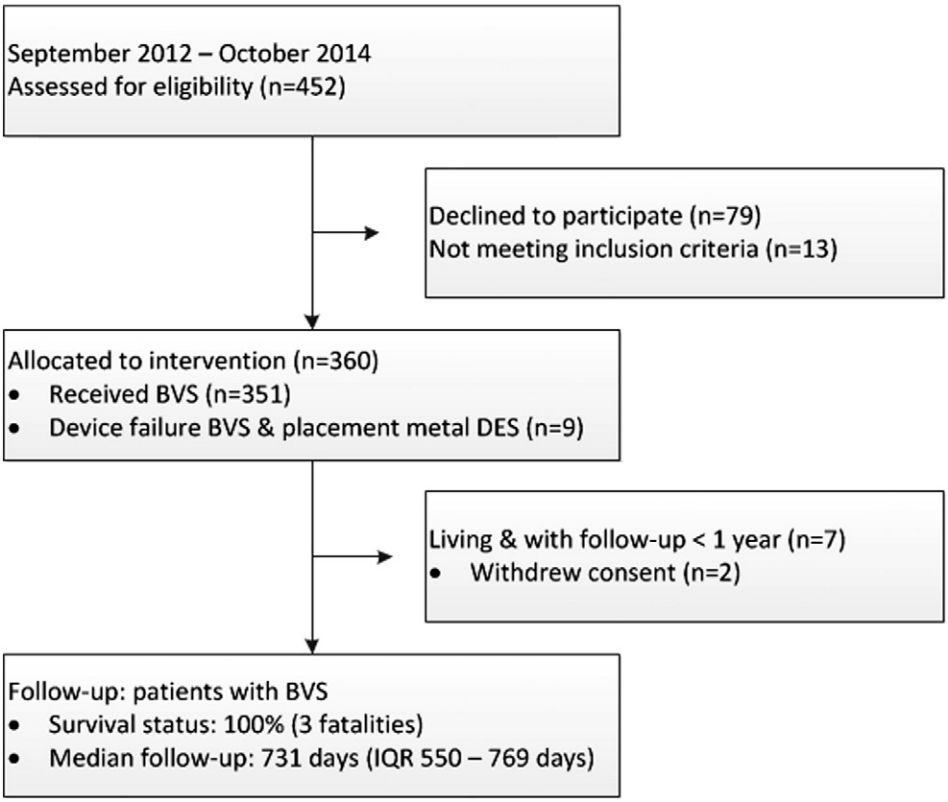

Fig. 1. Flowchart study.