

no differences were found in terms of TLR (3.3% vs. 3.3%; $p=0.98$), and DOCE (4.3% vs. 3.4%, $p=0.4$) and its singular components (cardiac death: 0.8% vs. 0.2%, $p=0.1$; TV-MI: 2.7% vs. 1.3%, $p=0.07$; ID-TLR: 2.8% vs. 2.5%, $p=0.682$) between ACS and stable CAD groups respectively. The rate of definite/probable Sct was numerically higher, albeit not statistically significant in ACS vs. stable CAD patients (1.3% vs. 0.8%, $p=0.2$).

Conclusions: Our data from a real-world population of consecutive patients suggest that the use of BVS in patients presenting with ACS is associated with good clinical outcome at one-year follow-up compared to stable CAD patients.

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Bioresorbable vascular scaffolds versus metallic stents in patients with ST-segment

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Background: In patients with ST-segment elevation myocardial infarction (STEMI) patients, temporary vascular sealing with bioresorbable vascular scaffolds (BVS) might reflect a promising approach. We evaluate the utility of BVS in STEMI patients, we performed a systematic review and meta-analysis.

Methods: MEDLINE, EMBASE, and the Cochrane Register of Controlled Trials were searched from 1983 to December 2016. Studies comparing performance of BVS and MS in STEMI patients and providing data about clinical outcomes for more than 30 days after index event were considered. Data were combined using random-effects models.

Results: Of 8,393 citations, 6 studies (N=2,280) were included; 1 randomized trial (N=191). Procedure success was high with BVS and MS (96.78% versus 97.33%, $p=0.79$) Median follow up was 11.8 (8.5–16.5) months. Comparing rates of major adverse cardiovascular events (MACE) between STEMI patients treated with either BVS or MS, we found no significant differences, but there was a significant heterogeneity (BVS: 36/746 (4.8%) versus MS: 97/1,530 (6.3%) events; Odds ratio (OR) 0.81 [95% confidence interval (CI) 0.40–1.63], $p=0.56$; I²=48%; Figure A). Regarding target lesion revascularizations, there were no significant differences between BVS and MS (21/746 (2.8%) versus 42/1,530 (2.7%); OR 1.06 [95% CI 0.58–1.93], $p=0.85$; I²=0%). Overall, rates of definite stent thrombosis (ST) were higher among STEMI patients receiving BVS compared to MS (16/746 (2.1%) versus 13/1,530 (0.8%); OR 2.44 [95% CI 1.14–5.18], $p=0.02$; I² 0%, Figure B).

Figure Forest plots for the comparisons of bioresorbable vascular scaffolds (BVS) versus metallic stents (MS) in STEMI patients: (A) Major adverse cardiovascular events (MACE); (B) Rates of definite stent thrombosis.

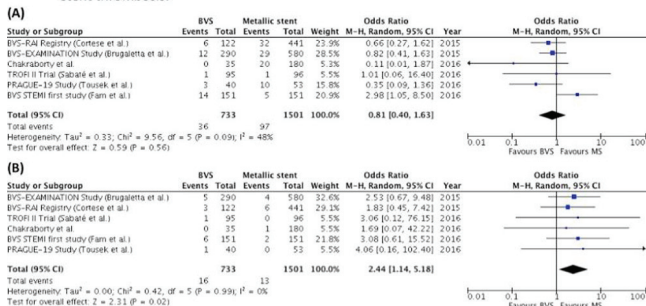


Figure A and B

Conclusions: To date, there is limited randomized data supporting the use of BVS in STEMI patients. According to mostly observational studies, usage of BVS in STEMI might be safe with regards to MACE rates. But there is also a signal for higher rates of ST with BVS.

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Quantitative angiographic analysis in patients with de novo native coronary artery lesions treated with novel poly-L-lactide based sirolimus-eluting bioresorbable vascular scaffold: MeRes-1 Trial

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Thiruvananthapuram, India; ¹¹Trivandrum Medical College, Thiruvananthapuram, India; ¹²Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, India; ¹³Max Super Speciality Hospital, New Delhi, India; ¹⁴Fortis Flt.Lt.Rajan Dhall Hospital, New Delhi, India; ¹⁵G.B. Pant Hospital, New Delhi, India

Background: BioResorbable vascular scaffolds (BRS) are a novel approach to the treatment of coronary artery disease in that BRS provide transient vessel support and drug delivery to the vessel wall. The aim of this first-in-man study was to report the six-month angiographic results of a MeRes100 BRS applied for the treatment of de novo native coronary artery lesions.

Methods: A total of 108 patients with coronary artery lesion related to a single de novo lesion length up to 20 mm in length in native coronary artery or a maximum of two such lesions in different epicardial vessels with vessel diameter between 2.75 and 3.50 mm. The primary endpoint of the study was in-scaffold late lumen loss at six-months. The secondary endpoints include in-scaffold and in-segment restenosis and % diameter stenosis (DS). Angiographic follow-ups were scheduled at 6 and 24 months.

Results: The Quantitative Coronary Angiography (QCA) results were available in 37 patients (41 lesions) at six-months. QCA results post procedure showed an In-segment acute gain of 1.71 ± 0.50 mm and the late lumen loss was observed as 0.14 ± 0.22 mm at 6 month follow-up (FU). The In-scaffold acute gain was 1.86 ± 0.42 mm and the late lumen loss at 6 month FU was 0.15 ± 0.23 mm. In-scaffold RVD was observed as 3.14 ± 0.38 and 3.06 ± 0.39 at post-procedure and 6-months respectively while MLD was observed as 2.82 ± 0.32 and 2.67 ± 0.40 at post-procedure and 6-months respectively. Whereas, in-scaffold and in-segment % DS rates were 12.68% and 13.87%, respectively and angiographic binary restenosis rate at 6 months was 0 (0%).

Conclusion: The preliminary data from QCA reflects device feasibility in treating de novo native coronary artery lesions in terms of low late lumen loss and absence of restenosis at 6 month FU. Long-term QCA (24 month FU) results are awaited.

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Computed Tomography Coronary Angiography Long-term Results of Bioresorbable Vascular Scaffold in clinical practice. A BVS-Expand project

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Background: The Absorb Bioresorbable Vascular Scaffold (BVS) provides the unique opportunity to follow-up patients after Percutaneous Coronary Intervention (PCI) with Computed Tomography Coronary Angiography (CTCA). This might especially be valuable in patients usually not included in RCT's due to complexity of the lesions where otherwise only clinical follow-up is available.

Purpose: The objective of this study was to provide information on the long-term patency of BVS for PCI in a real-world setting.

Methods: The BVS Expand Registry is an investigator initiated, prospective, mono-center, single-arm study. In- and exclusion criteria have been described elsewhere.

Minimal eighteen months after the index procedure, eligible patients were invited for a CTCA. Main exclusion criteria for CTCA follow-up were: contrast medium allergy, severe renal insufficiency, TLR with metal stents before CTCA. Additional CT perfusion was indicated when a potential significant non-occlusive stenosis ($\geq 50\%$) in target vessel was seen on CTCA by an expert CTCA reader. Long-term BVS CTCA success was defined as: percentage diameter stenosis (%DS) of target vessel $< 50\%$ on CTCA or a CT perfusion without perfusion deficits. BVS CTCA failure was defined as: target lesion occlusion or restenosis $\geq 50\%$ in the target vessel on CTCA with ischemia on CT perfusion.

Results: Between September 2012 and September 2014, a total of 227 patients were included in the BVS Expand Registry. Eligible for CTCA were 179, 29 declined and 5 had previous TLR, resulting in a study population of 145 patients with a total of 202 lesions. Mean age was 60.0 ± 10.2 years, 77.9% were male and 12.1% were diabetic. 58.6% presented with ACS (NSTEMI and UAP). The following lesion characteristics were present: 37.5% calcified lesions, 46.8% long (> 20 mm) lesions, 35.4% AHA/ACC type B2/C lesions, 4.7% CTO. Average lesion length was 19.2 mm (IQR 15.2 – 28.5 mm) and number of scaffold per patient was 1.9 . In 4/145 (2.8%) patients CTCA images were of poor quality and for that reason excluded from analysis. Hundred thirty-four (95.7%) showed long term success with either no-luminal narrowing (70.7%), diameter stenosis $< 50\%$ (22.9%) or DS $> 50\%$ without ischemia on perfusion (2.1%). Six (4.3%) patients did not meet criteria for BVS CTCA success and might be considered as asymptomatic target lesions failure. Quantitative analysis on minimal lumen area and percentage area obstruction is ongoing and will be available before 1st of May 2017

Conclusions: CTCA was able to evaluate most BVS treated patients at follow-up, where additional perfusion imaging was a valuable addition, needed only in a small group of patients. BVS patency as assessed by CTCA in complex real-world patients was high. Detailed analysis using quantitative measurements will provide an additional insight in the lumen areas achieved at follow-up.

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