TCT-414

Two-year outcomes of patients with acute coronary syndrome versus stable coronary disease undergoing bioresorbable scaffold implantation

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BACKGROUND There is a scarcity of data evaluating everolimus-eluting bioresorbable scaffold BRS implantation in the setting of acute coronary syndrome (ACS). We sought to evaluate clinical and angiographic outcomes of patients with ACS undergoing BRS implantation, in comparison to patients with stable coronary artery disease (CAD).

METHODS Consecutive patients undergoing implantation of everolimus-eluting BRS at two centers in Munich, Germany were enrolled and divided into 2 groups according to the indication for stenting: ACS vs. stable CAD. Angiographic surveillance was planned at 6-8 months. Clinical follow-up was performed up to 24 months. Primary endpoints of interest were the composite of death/myocardial infarction/target lesion revascularization, target lesion revascularization and definite scaffold thrombosis.

RESULTS A total of 419 patients were enrolled, of which 163 had ACS and 256 stable CAD. Complex lesion morphology (B2/C) was observed in a similar proportion of patients in both groups (50.8 vs. 47.9%; p=0.52). Minimal lumen diameter was significantly smaller (0.75 vs 0.99mm; p<0.001) and pre-dilatation was significantly more often utilized (99.5 vs. 96.6%; P0=0.04) in the ACS group. Post-dilatation was less frequently performed (62.3 vs. 77.1%; p<0.001) in the ACS group. Angiographic surveillance showed that in-stent late luminal loss was lower in the ACS group (0.17 vs. 0.31mm; p=0.01). After 2 years the rates of the composite endpoint (19.8 vs. 24.0%, p=0.50), target lesion revascularization (15.5 vs. 17.4%, p=0.62) and definite scaffold thrombosis was similar in both groups (4.3 vs. 3.8%, p=0.75).

CONCLUSION In selected patients with ACS undergoing BRS implantation clinical outcomes were similar to patients with stable CAD treated with BRS. In patients with angiographic surveillance data late lumen loss was lower in those with BRS implantation for ACS.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-415

Absorb Bioresorbable Vascular Scaffolds vs. XIENCE Everolimus-Eluting Stents: Are Clinical Outcomes Different for Men and Women?

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BACKGROUND Absorb bioresorbable vascular scaffolds (BVS) provide drug delivery and mechanical support functions similar to metallic DES, followed by resorption with recovery of more normal vascular structure and function, potentially improving very late clinical outcomes. In a prior patient-level meta-analysis of 4 randomized trials, Absorb BVS was not significantly different from XIENCE everolimus-eluting stents (EES) for 1-year target lesion failure (TLF). As women are under-represented in stent trials, we sought to assess the sex-specific relative safety and efficacy of BVS compared with EES.

METHODS The ABSORB II, ABSORB III, JAPAN, and CHINA trials were pooled (3389 total pts; 932 [28%] women). Baseline clinical, angiographic and procedural variables and 1-year outcomes including TLF, target vessel MI (TVMI), ischemic target lesion revascularization (TLR) and device thrombosis (ST; ARC def/pro) were analyzed stratified by sex and device.

RESULTS Women were older, more often diabetic (insulin-treated) and hypertensive, but had less prior PCI, 3-vessel disease and smoking (all p≤0.001). 1-year TLF and ST rates were similar in women and men (6.9% vs. 5.7%, P=0.20, and 1.2% vs. 1.0%, P=0.60, respectively). TLF rates were similar with BVS vs. EES (6.6% vs 5.2% respectively, p=0.17), with no interaction by sex (P=0.77). ST was non-significantly greater with BVS vs. EES (1.3% vs. 0.6%; p=0.08), more so in men than in women (Table), although Pinteraction=0.13).

	Gender	Absorb	Xience	RR [95% CI]
TLF	Male	6.2% (96/1558)	5.0% (44/877)	1.23 [0.87, 1.74]
	Female	7.6% (45/589)	5.7% (19/335)	1.35 [0.80, 2.26]
TVMI	Male	4.6% (72/1558)	3.1% (27/877)	1.50 [0.97, 2.32]
	Femal	6.5% (38/589)	3.9% (13/335)	1.66 [0.90, 3.08]
ID-TLR	Male	2.6% (40/1558)	2.2% (19/877)	1.19 [0.69, 2.03]
	Femal	2.9% (17/589)	2.7% (9/335)	1.07 [0.48, 2.38]
Det/Prob ST	Male	1.4% (21/1546)	0.3% (3/871)	3.94 [1.18, 13.18]
	Female	1.2% (7/584)	1.2% (4/333)	1.00 [0.29, 3.38]

CONCLUSION Despite differing demographic profiles, the relative effects of BVS and EES for 1-year TLF were similar in men and women. The trend toward greater ST for BVS (vs. EES) was driven by a low ST rate (0.3%) in EES-treated men.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-416

In vivo assessment of endothelial-dependent vasomotion in a coronary segment treated by the Second-Generation Drug-Eluting Absorbable Metal Scaffold (DREAMS 2G): Insights from the BIOSOLVE-II First-In-Man Trial

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BACKGROUND To analyse the vasomotion of a coronary segment in relationship to its intravascular ultrasound-virtual histology (IVUS-VH) composition. Coronary segments, transiently scaffolded by a fully absorbable sirolimus eluting Mg scaffold (DREAMS 2G), may in the long-term recover a normal vasomotor tone. Recovery of an endothelial-dependent vasomotion may be enabled by scaffold bioresorption, composition of the native vessel wall, or a combination of both mechanisms.

METHODS The prospective, international, multi-centre, first-in-man BIOSOLVE-II trial enrolled 123 patients with up to 2 de novo lesions with a reference diameter between 2.2 and 3.7 mm. All patients were scheduled for angiographic follow-up at 6 months. Quantitative coronary angiography (QCA) - based vasomotion was assessed at 6 months in one clinical center.

RESULTS At 6-month, the correlation between IVUS-VH necrotic core percentage and the change in QCA based minimum lumen diameter (MLD) in response to high dose of acetylcholine showed a Spearman estimate of -0.489 (p=0.055) and with fibrous volume of 0.53 (p=0.035). This means that the larger the necrotic core percentage the smaller the change in MLD in response to Ach and the contrary is true for fibrous volume, the larger the fibrous tissue the larger the change in MLD. There were no other significant correlations with fibro-fatty or dense calcium.

CONCLUSION Vasomotion signs were observed at 6-month following implantation of the drug-eluting metal absorbable scaffold DREAMS 2G and there was a relationship with underlying IVUS- VH plaque composition.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-417

Bioresorbable vascular scaffold in chronic total coronary artery occlusions: results from the RAI registry

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