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BACKGROUND Magmaris (DREAMS 2G - Biotronik AG, Bülach, Switzerland), a second generation drug-eluting absorbable metal scaffold, has proved to be safe and effective in the BIOSOLVE-II study up to 2 years follow-up. Recently, biodegradable polymer sirolimus-eluting stent, Orsiro (Biotronik AG, Bülach, Switzerland) has shown good clinical results in Bioflow-V study. This study aims to compare the unadjusted clinical outcomes of patients treated with Orsiro and Magmaris at 12 months.

METHODS The patients included in the Magmaris group (N=184) were taken from the BIOSOLVE-II and BIOSOLVE-III trials. While the Orsiro group (N=298) consist of patients previously enrolled in BIOFLOW-II trial. As exploratory analysis, unadjusted rates were compared at 12-month follow-up. The primary comparison was target lesion failure (TLF, a composite of death, myocardial infarction, or any revascularization).

RESULTS The following baseline and procedure characteristics were different between the two groups: mean age was 62.7±10.4 years in Osiro group vs 65.5±10.8 years in Magmaris group (p=0.004); male gender in Orsiro group was 78.2% and 63.6% in Magmaris group (p=0.005); unstable angina was 19.5% in Orsiro group vs 12.5% in Magmaris group (p=0.04). The lesion distribution according to ACC/AHA lesion characterization, Orsiro and Magmaris groups were 13.8% vs. 47.3% for Type B2 (p<0.001), respectively. The primary comparison showed that TLF in Magmaris group was 6.0% vs. 6.4% in Orsiro group (unadjusted p value 0.8607). The individual components of the TLF also presented similar results between the two groups (Table 1).

CONCLUSION Magmaris and Orsiro groups did not present any statistically significant differences in TLF rate or in the comparison of the individual components of TLF at 12 months. At the meeting, adjusted event rates will be presented.

Table 1. Unadjusted clinical outcomes of the patients treated with Magmaris or Orsiro at 12 months follow-up.

	Orsiro Group (n=298), ITT		Magmaris Group (n=184), ITT		
	N	%	N	%	P value
Events at 12 months					
Death	3	1.0	3	1.6	0.6788
Cardiac death	2	0.7	2	1.1	0.6383
MI*	9	3.0	8	4.3	0.4427
TVMI	8	2.7	6	3.3	0.7143
Clinically driven TLR	10	3.4	3	1.6	0.3869
Any TLR	11	3.7	11	6.0	0.2425
Clinically driven TVR	19	6.4	6	3.3	0.1341
Any TVR	22	7.4	13	7.1	0.8962
Death or MI	12	4.0	11	6.0	0.3289
Cardiac Death or MI	11	3.7	10	5.4	0.3623
Target-lesion failure	19	6.4	11	6.0	0.8607
Target-vessel failure	26	8.7	13	7.1	0.5163
Definite ST	0	0.0	0	0.0	-
Probable ST	0	0.0	0	0.0	-

Legend: ITT = intention to treat; MI = myocardial infarction; ST = stent thrombosis; TLR = target lesion revascularization; TVMI = Target Vessel Myocardial Infarction; TVR = target vessel revascularization.
* Myocardial infarction was reported following the Joint ESC/ACCF/AHA/WHF Task Force universal definition of myocardial infarction.

TECHNOLOGY

EMERGING DEVICES & INNOVATIVE THERAPIES

CRT-600.08

Transeptal Epicardial Puncture Haptic Feedback System

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BACKGROUND Transeptal and Epicardial Puncture (TEP) are necessary for ablation of cardiac arrhythmia, left atrial appendage occlusion, and valve repair. TEP can cause perforation, especially in inexperienced hands. Catheters do not reliably enable palpation of biophysical events. Tactile feedback is advantageous when auditory and visual channels are heavily loaded, providing faster reaction times than visual feedback and alerting operators to unexpected high priority events. Work by our group demonstrated that physicians were able to identify time of contact with and puncture of the septum using digitized pressure waveforms as input into a novel haptic system (HS), and react to palpation of tissue contact in less time than cardiac systole. We also demonstrated the HS enables real-time tactile appreciation of contact force amplitude during ablation in live swine.

METHODS We hypothesized physicians (P) familiar with TEP, as well as, non physicians (NP) blinded to any visual feedback will be able to palpate sensations due to catheter manipulation (M) and transeptal puncture (TP), differentiate a single attempt TP from one that required M, and identify tactile signals indicative of entry into the pericardial space. We prospectively tested the HS by storing and processing real time pressure signals (data) acquired during 13 consecutive TPs performed for atrial fibrillation ablation and a successful attempt at epicardial access (EP) and input the data into the HS. The HS delivered a TP haptic response to 6 P and 4 NP and EP haptic response to 8 P holding a Haptic Handle. Subjects were asked if they could palpate tangible sensations due to signals generated by M and TEP, differentiate a single pass TP from one that required M, and palpate needle localization within the pericardial space during EP. Results during TP were compared between P and NP subgroups to assess if the HS is intuitive.

RESULTS A total of 138 tests were performed. Tangible sensations of M and TP were palpated in 52 of 52 NP and 77 of 78 P tests (p = NS). All 10 subjects were able to differentiate a single attempt TP from one requiring M and all 8 subjects correctly identified time of access within the pericardial space.

CONCLUSION The HS provides P and NP subjects with a means to palpate and identify biophysical signals during M and TEP in the absence of visual cues and can be utilized as a tool to train inexperienced physicians. The HS may reduce complications associated with TEP. More work is required to evaluate the benefits of multi-sensory feedback inclusive of both visual and tactile feedback.

CRT-600.09

CardioHELP Support for High-Risk Percutaneous Coronary Intervention: A Single Center Case Series

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BACKGROUND Temporary extracorporeal membrane oxygenation (ECMO) support for high-risk percutaneous coronary intervention (PCI) has been described in select patient groups. Data is limited regarding outcomes using the CardioHELP device (Maquet, Inc.) for patients requiring high-risk PCI. We sought to assess clinical outcomes in consecutive patients undergoing high-risk PCI with CardioHELP support.

METHODS Baseline demographics and outcome were collected for 7 patients undergoing high-risk PCI with CardioHELP support. High-risk PCI was defined as unprotected left main disease (UPLMD), last remaining conduit or multi-vessel coronary artery disease (MV-CAD) and significantly reduced ejection fraction (EF<35%). All patients were deemed non-operative for surgical revascularization by the heart team. Primary outcome was in-hospital mortality. Secondary outcomes included freedom from hemodynamic compromise during PCI (defined as decrease in mean arterial pressure below 60 mm Hg for

>10 minutes), stent thrombosis, repeat revascularization, major bleeding (BARC definition), stroke and 30-day survival.

RESULTS Mean age was 68±12 years, 86% male with mean EF 31±14% (Table). MV-CAD was present in 6 (86%) and UPLMD in 4 (57%). Mean SYNTAX score was 37±14. CardioHELP was removed at the completion of PCI in 5 (71%). PCI was successful in all patients. In-hospital mortality occurred in 2 patients (mean SYNTAX score 51.5±9.2); the other 5 patients had a 30-day survival of 100%. No patient required repeat revascularization.

CONCLUSION Temporary use of ECMO with the CardioHELP device enables excellent hemodynamic support during high-risk PCI in patients with prohibitive surgical risk. The CardioHELP device may be a viable option for facilitating procedural success in patients with severe left ventricular dysfunction requiring high-risk PCI.

Table. Baseline risk scores, angiographic details, and clinical outcomes.

Baseline Risk	
Cardiogenic shock	3 (43%)
On vasopressor support during PCI	4 (57%)
STS score	8.8 ± 8.2
Euroscore II	6.5 ± 5.1
Logistic Euroscore	14.2 ± 14.7
Angiographic characteristics	
Multi-vessel disease	6 (86)
Bifurcation lesion	4 (57%)
Left main coronary artery stenosis	4 (57%)
Chronic total occlusion	3 (43%)
Total number stents	4.6 ± 1.7
SYNTAX Score	37 ± 14
Mean number of vessels treated	2.6 ± 0.97
Intra-aortic balloon pump use	5 (71%)
Rotational atherectomy	3 (43%)
Clinical outcomes	
Acute stent thrombosis	1 (14%)
Freedom from hemodynamic compromise	5 (71%)
Acute limb ischemia	1 (14%)
Stroke	0 (0)
Bleeding (BARC type 3a or greater)	1 (14%)
In-hospital mortality	2 (29%)

Categorical values are presented as number (%); continuous variables are presented as mean ± standard deviation.

CRT-600.10

Local Delivery of a Bioinspired Proteoglycan Mimetic SB-030 Ameliorates In-Stent Thrombogenicity and Inflammation in an Ex Vivo Swine Shunt Model

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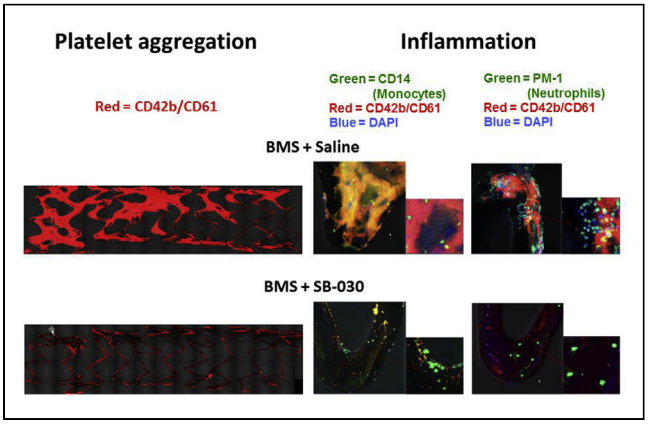
BACKGROUND Symic Bio has developed a novel bioinspired molecule (SB-030) designed to mimic native proteoglycans capable of binding exposed collagen thereby providing a localized barrier to platelets and inflammatory cells at the vessel wall. In this preliminary proof-of-concept study, the anti-thrombogenic property of SB-030 in acute stent thrombosis in a porcine low-dose heparin extracorporeal shunt model was assessed.

METHODS Bare metal coronary stents (BMS: Omega®) coated with Bovine collagen I were deployed in custom fabricated Sylgard tubing, which was connected to an extracorporeal AV- carotid shunt of porcine in an acute (0 to 1 hour) setting (Otsuka F et al, JACC Cardiovasc Interven 8: 1248-1260, 2015). Stents were initially primed with saline (BMS-Sa) or SB-030 (BMS-SB) for 3 to 5 min before exposure to circulating blood. At the conclusion of each run, stents were fixed in 4% paraformaldehyde, bisected in half and dual immunostained using platelet cocktail (CD61/CD42b) and inflammatory marker for neutrophils (PM1) or monocytes (CD14). Antibody staining was visualized by confocal microscopy and quantified by histomorphometry.

RESULTS Preliminary analysis of BMS-SB showed a lower percentage of adherent platelets on struts as compared to BMS-Sa (36.2 ± 0.8% vs. 116.5 ± 15.5%) (Figure). Moreover, inflammatory cell density (positive cells/mm^2) was lower for BMS-SB as compared with BMS-Sa for both neutrophils (163.5 ± 51.6 vs. 1243.0 ± 921.4) and monocytes (136.0 ± 7.1 vs. 265.0 ± 161.2). Overall results will be reported on 12 stents (n=6) per group at the time of presentation.

CONCLUSION This study confirmed the potent effect of SB-030 to ameliorate thrombogenicity and inflammation of vascular stent in an acute model and may prove a beneficial adjunct treatment option, particularly in the setting of peripheral artery disease.



CRT-600.11

Uncoupling Cardio-renal Hemodynamics in Heart Failure: Effects of an Intra-aortic Micro-axial Flow Pump in a Swine Model of Ischemic Heart Failure

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BACKGROUND Heart failure complicated by renal hypo-perfusion is a major cause of global morbidity and mortality. Increasing cardiac output, reducing cardiac workload, and increasing renal perfusion are major objectives for heart failure management. We explored the hemodynamic effect of a micro-axial flow pump positioned in the abdominal aorta above the renal arteries in a model of ischemic heart failure.

METHODS Five adult swine underwent 120 minutes of left anterior descending artery occlusion followed by reperfusion and recovery. After 28 days, animals underwent Aortix (Procyrion, Houston, TX) implantation and activation in the descending aorta via the left femoral artery. Aortic pressures, pulmonary artery catheter data, pressure-volume loop data, coronary flow and carotid pressures were obtained at baseline and at incremental ramp speeds: low (22-25K), med (28-30K), high (34-37K).

RESULTS Aortix activation increased distal aortic pressure, generating a trans-aortic gradient at all speeds ($p<0.01$) (Figure 1). Aortic root pressures were unchanged. LV volumes increased at low and med ($p<0.05$) speeds. At low speeds, thermodilution cardiac output (CO) increased from 5.3±0.9 L/min to 7.2±1.4 L/min ($p=0.046$). Transpulmonary gradient (TPG) increased at med and high speeds ($p<0.05$). PA compliance ($p=0.01$) decreased between low and high speeds. A trend towards increased urine output was observed. Cardiac filling pressures, carotid pressures, coronary flow, and left ventricular stroke work were unchanged.

CONCLUSIONS Aortix activation generates a trans-aortic pressure gradient and increases CO in a swine model of ischemic heart failure. Changes in PA Compliance, TPG, and LV volumes may reflect increased venous return to the right ventricle. Further investigation of the potential utility of the Aortix pump in heart failure is required.