

>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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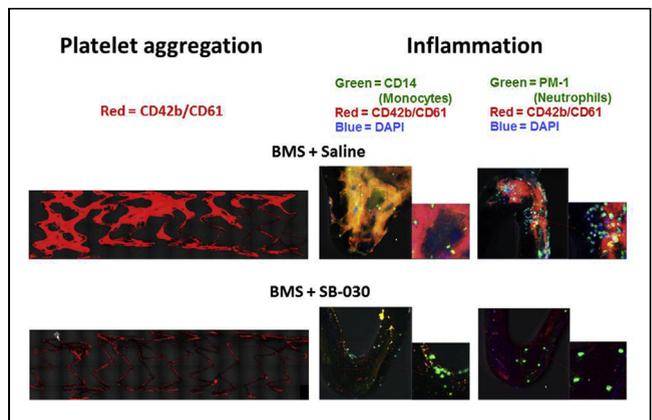
BACKGROUND Symic Bio has developed a novel bioinspired molecule (SB-030) designed to mimic native proteoglycans capable of binding exposed collagen thereby providing a localized barrier to platelets and inflammatory cells at the vessel wall. In this preliminary proof-of-concept study, the anti-thrombogenic 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 Intervent 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/mm²) 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



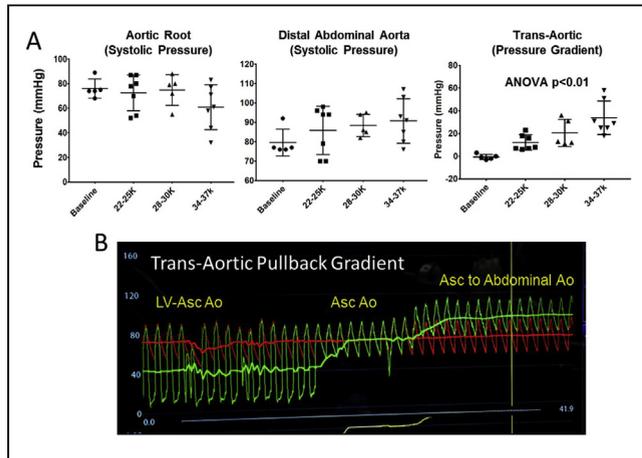
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BACKGROUND Heart failure complicated by renal hypo-perfusion is a major cause of global morbidity and mortality. Increasing cardiac output, reducing cardiac workload, and increasing renal perfusion are major objectives for heart failure management. 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 (Procyron, 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). Trans-pulmonary 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.



RENAL DENERVATION

CRT-600.15

Safety and Performance Of Diagnostic Electrical Mapping of Renal Nerves in Hypertensive Patients and/or Potential Candidates for a Renal Sympathetic Denervation (RDN) Procedure



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BACKGROUND As the exact location of renal nerves cannot be visualized, renal sympathetic denervation (RDN) remains a so-called blind procedure. The aim to the present study is to assess the safety and feasibility of renal nerve stimulation using the ConfidenHT™ mapping system. The technology could help to improve RDN procedures by providing: (1) better patient selection, and (2) intra-procedural guidance and feedback to optimize success rates.

METHODS The Confiden(HT) study is a prospective first-in-man multicenter study designed to assess the safety and feasibility of renal nerve mapping using the ConfidenHT™ system in 20 hypertensive patients with an indication for coronary angiography or a planned RDN. The Console delivers electrical energy to the catheter using a multi-channel stimulator, and a real time intra-arterial Blood Pressure (BP) monitor, which records, analyzes and displays the stimulation outcome (BP and/or heart rate changes) during the mapping phase. The flexible multi-electrode ConfidenHT™ catheter is compatible with an 8Fr guiding catheter and 0.014" guide wire. Stimulations were performed in left and right renal arteries at 3 to 4 sites per artery, including branches at 2 and 4 mA resulting in up to 8 mapped sites per patient. The primary efficacy endpoint was the change in systolic blood pressure during stimulation. All patients were followed up to 3 months.

RESULTS Mean age of the patients included was 58±12 years, 11/20 patients were female. Mean office blood pressure was 156±23mmHg and GFR was 78±13mL/min/1.73m². All procedures were performed under local anesthesia with mild conscious sedation. The use of the system appeared safe with no peri-procedural adverse events and no signs of angiographically visible spasms/thrombus or dissection post procedure. Creatinine levels remained within the normal range. Mean individual systolic BP responses varied between 3.5 and 18 mmHg while mean individual mean arterial pressure responses varied between 2.4 and 11.3 mmHg. The average time to maximal response was 45 seconds. The mean change in systolic BP response did not vary between proximal, mid, distal or branch sites when stimulating at 2mA.

CONCLUSIONS The results of the present study suggest that renal nerve mapping using the ConfidenHT™ system technology is feasible and safe and offers promising diagnostic electrical renal nerve mapping opportunities in hypertensive patients, which could help in optimizing the result of renal sympathetic denervation.

OTHER

CRT-600.13

Off- vs. On-hours Outcomes in Patients Receiving Acute Mechanical Circulatory Support



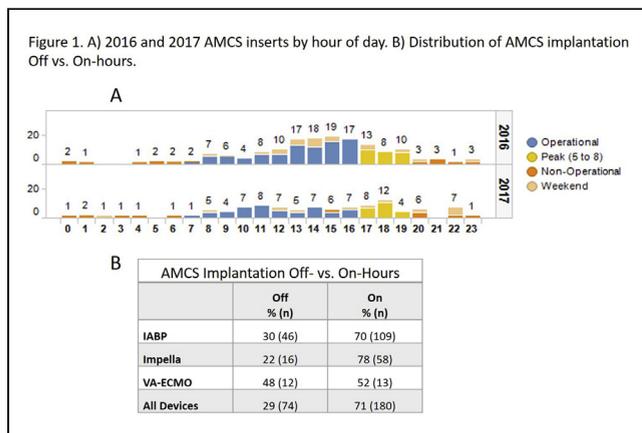
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BACKGROUND Acute mechanical circulatory support (AMCS) implantation is often performed urgently off scheduled operating hours. There is no available analysis comparing outcomes between off- vs. on-hours implantation of AMCS.

METHODS We retrospectively analyzed all patients (n=254) between 2016-2017 receiving VA-ECMO (n=25), Impella (n=74), or Intra-aortic balloon pump (IABP) (n=155) in our catheterization lab. Patients were stratified by time of implantation: on-hours (weekday operational hours: 7:30 AM to 5 PM and weekday peak hours: 5 PM to 8 PM) versus off-hours (weekends, holidays, and weeknights 8 PM to 7:30 AM). Primary outcomes were intra-procedural mortality, in-hospital mortality, and vascular complication requiring surgery. All categorical variables were analyzed using Fisher's exact test.

RESULTS A total of 180 devices were implanted during the study period (Figure 1A). 29% of devices were implanted during off-hours and 71% during on-hours (Figure 1B). There was no difference in intra-procedural mortality or vascular complications requiring surgery when comparing off- vs. on-hours implant. In-hospital mortality trended higher with IABP implantation off-hours (24% vs. 12%, p = 0.09).

CONCLUSIONS AMCS implantation occurs more frequently during regular working hours. Patients receiving AMCS during off-hours had similar outcomes to those presenting during regular hours.



VALVE & STRUCTURAL HEART

AORTIC VALVE

CRT-700.04

Impact of Discharge Home without Home Services on 30-Day Outcomes Following Transcatheter Aortic Valve Replacement with Contemporary Valves



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