

follow-up, a reduction in major adverse cardiac events (MACE) was observed with second-generation compared to first-generation DES (5.6 vs. 16.1%,  $p=0.20$ ), driven by a four-fold decrease in target vessel revascularization (2.9 vs. 14.8%,  $p=0.09$ ), although not reaching statistical significance. Only 1 patient (1.6%) in the first-generation DES and none in the second-generation DES had definite stent thrombosis (Table).

**Conclusion:** In this study of full metal jacket stenting for diffuse lesions, second-generation DES compared to first-generation DES demonstrated a favorable trend toward reduction in repeat revascularization and MACE at 1-year with acceptable safety profile.

**Clinical outcomes at 1-year between first and second generation DES**

	Second-generation DES (n=36)	First-generation DES (n=62)	P value
Major adverse cardiac events	2 (5.6%)	10 (16.1%)	0.20
Death	1 (2.8%)	1 (1.6%)	1.00
Q-wave myocardial infarction	0	0	-
Target vessel revascularization	1 (2.9%)	9 (14.8%)	0.09
Target lesion revascularization	1 (2.9%)	7 (11.5%)	0.25
Definite stent thrombosis	0	1 (1.6%)	1.00

**Emerging Devices & Innovative Therapies**

**CRT-126**

**Three Years Follow Up Data Demonstrate Safe And Effective Treatment Of De Novo Calcified Coronary Lesions By Orbital Atherectomy System**

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**Background:** Coronary Artery Disease continues to be a widespread and growing problem worldwide. Performing PCI on calcified lesions can lead to higher MACE rates and stent under expansion/malapposition. The Orbit I trial was conducted to evaluate the safety and performance of the Diamondback 360 Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc., St. Paul, MN, USA) for the treatment of calcified coronary lesions.

**Methods:** From May 2008 to July 2008, 33 patients were enrolled in ORBIT I study based on several criteria, including a de novo, coronary lesion with stenosis  $\geq 50\%$  and  $\leq 100\%$  and at least one quadrant of calcification via IVUS. The patients were treated with OAS prior to stent placement. The patients were followed for 36 months at Care Institute of Medical Sciences, Ahmedabad, India to evaluate the MACE rate.

**Results:** Of the 33 patients, 90.90% (n=30/33) were males with an average age of 54.9 years. The ACC/AHA lesion class was: Type A 6.06% (n=2/33); Type B1 33.33% (n=11/33); Type B2 60.60% (n=20/33). The % diameter stenosis was 85.75%; lesion length was 15.90 mm. The procedural success was 97% (32/33) with one case where IVUS/device was not able to cross the lesion due to severe calcification. All stents were successfully deployed with  $0.3\% \pm 1.8\%$  residual stenosis. The observed MACE rate was as follows: in-hospital 6.06% (n=2/33); 30 days 9.09% (n=3/33); 6 months 12.12% (n=4/33); 24 months 15.15% (n=5/33); and 36 months 18.18% (n=6/33). MACE rate comprised of 2 patients with a non Q-wave MI in-hospital; one patient with non Q-wave MI at 30 days that led to TLR; and one patient with cardiac death at 6 months, 24 months and 36 months, respectively.

**Conclusion:** This case series demonstrates that OAS safely and effectively modified calcified lesions and facilitated stent delivery in this difficult-to-treat plaque morphology, which continues up to three years post index procedure.

**CRT-127**

**Hyperinvasive Approach To Out-of Hospital Cardiac Arrest Using Mechanical Chest Compression Device, Prehospital Intraarrest Cooling, Extracorporeal Life Support And Early Invasive Assessment Compared To Standard Of Care. A Randomized Parallel Groups Comparative Study. "Prague Ohca Study". Results Of Presimulation And Simulation Phase**

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**Background:** Out of hospital cardiac arrest (OHCA) has a poor outcome. Recent non-randomized studies of ECLS (extracorporeal life support) in OHCA suggested further studies to define population that would benefit from ECLS. Ongoing prospective randomized study compares prehospital intraarrest hypothermia combined with mechanical chest compressions, intrahospital ECLS and early invasive assessment in refractory OHCA of presumed cardiac origin compared to a standard of care. This abstract describes methodology of the trial and results of presimulation and simulation phase.

**Methods:** Patients with witnessed OHCA without ROSC (return of spontaneous circulation) after a minimum of 5 minutes of ACLS (advanced cardiac life support) by emergency medical service (EMS) team are randomized to standard vs. hyperinvasive arm. In hyperinvasive arm, mechanical compression device together with intranasal evaporative cooling is instituted and patients are transferred directly to cardiac center under ongoing cardiopulmonary resuscitation. After admission, ECLS inclusion/exclusion criteria are evaluated and if achieved, veno-arterial ECLS is started. Invasive investigation and standard postresuscitation care follows immediately. Patients in standard arm are managed on scene. When ROSC is achieved, patients are transferred to cardiac center and further treated as per recent guidelines. During the presimulation phase mechanical chest compression device has been used routinely in all patients with OHCA, during the simulation phase patients were to practice the logistics of the study.

**Results:** Since January until October 2012 we enrolled 40 patients, 32 to presimulation and 8 to simulation protocol. Average age was 61 years (21-87), 85% were men. Acute coronary syndrome was the cause in 21 (53%) patients, STEMI 17 (43%), cardiac origin of OHCA was identified in 63% of patients. Average time until ROSC was 40 minutes, median 32 minutes (15-120). Twenty (50%) patients survived, CPC (Cerebral Performance Category) 1+2 during hospitalization reached 15 of 20 survivors (75%) and 1 of 20 nonsurvivors (5%). Survival in patients admitted under ongoing CPR was 5 of 17 (30%).

**Discussion:** A combined, hyperinvasive approach to refractory OHCA is a viable option with challenging preliminary results. The protocol is opened for sharing by other cardiac centers with available ECLS and cathlab teams trained to admit patients with refractory cardiac arrest under ongoing CPR. Supported by IGA NT 13225-4/2012, registered under ClinicalTrials.gov NCT01511666.

**Other**

**CRT-128**

**Renal Artery Denervation in Chronic Kidney Disease Patients**

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Renal Denervation Therapy (RDN) have been proven to be useful in resistant hypertension patients. The Symplicity Trials did not include patients with renal disease whereas, a significant number of end stage renal disease (ESRD) patients who have resistant hypertension despite being on multiple drugs and the benefits of RDN in such patients have not been reported.