CONCLUSION In this multicenter registry, robotic PCI was more commonly performed using radial rather than femoral access. Additionally transradial robotic PCI was found to be safe, with high rates of technical and clinical success.

CRT-700.06

Safety of Endovascular Therapeutic Hypothermia as an Adjuvant Therapy in Acute ST Segment Elevation Myocardial Infarction

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BACKGROUND Therapeutic hypothermia (TH) reduces the damage by ischemia and reperfusion cell syndrome in cardiac arrests, in which its application is already widely established and carried out in centers of excellence. However its role in patients with acute ST segment elevation myocardial infarction (STEMI) remains controversial.

OBJECTIVE Evaluation of safety in the development of a standard protocol for therapeutic hypothermia in STEMI patients, awaken and without the need for intubation or mechanical ventilation.

METHODS Patients admitted to the emergency department with up to 6 hours of the onset of chest pain, presenting STEMIs in anterior or inferior wall with ST segment elevation greater than 1mm in 2 or more contiguous leads, and eligible for percutaneous intervention procedures (PCI). Administration of anti-shivering drugs (buspirone and meperidine) and TH induced by the administration of 1L of cold saline solution at 4°C together with implant of Proteus® Endovascular System to induce therapeutic hypothermia as an adjuvant treatment to primary PCI, by cooling for at least 18 minutes before the recanalization of the occluded coronary artery at target temperature of 32°C before PCI. Maintenance of TH for 3 hours and active rewarming at rate of 1°C/h for 4h. The primary safety endpoints included death, reinfarction, need for target vessel revascularization (MACE), ventricular arrhythmias or major bleeding within 72 hours after infarct onset.

RESULTS TH induction was induced in 12 patients with a target temperature of 32°C, which was reached after a median of 29 min. There was successful cooling in all of them (100%). By administration of buspirone and meperidine, patients remained conscious and comfortable during the angioplasty procedure at all stages of HT and rewarming in intensive care unit (ICU). All patients received unfractionated heparin (100 IU/kg) and dual anti-platelet aggregation with 600mg of clopidogrel and 300mg of aspirin. The mortality rate was 8,3% (n = 1). Ventricular arrhythmias occurred in 16,7% of patients during TH (n = 2). Absence of bleeding or severe complications in 91,7% of patients (n = 11). In all patients, there was no delay in door-to-balloon time to primary angioplasty, which occurred in a timely manner (less than 90 minutes), and maintenance of TH successfully in the ICU (temperature of 32 ± 0.5°C).

CONCLUSION The therapeutic hypothermia protocol in awaken STEMI patients is feasible and safe. There were no delays in the door-to-balloon time in endovascular TH as an adjuvant therapy to primary PCI.

CRT-700.07

Nine-Month RESULTS Of The BIOHELIX-I Clinical Trial Study: Evaluation Of The PRO-Kinetic Energy Cobalt Chromium Bare-Metal Stent

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BACKGROUND Percutaneous Coronary Intervention (PCI) is one of the main stay treatments for symptomatic coronary artery disease. While drug-eluting stents (DES) constitute a majority of implants, bare-metal stents (BMS) remain important for a subset of patients with contraindications to longer duration of dual antiplatelet therapy (DAPT). Newer generation BMS offer advantages over older devices due to improved stent geometry and design, and decreased strut thickness.

METHODS The BIOHELIX-I study was a prospective, multicenter, non-randomized, single arm clinical trial designed to evaluate the safety and efficacy of the PRO-Kinetic Energy (PKE) Cobalt Chromium Coronary Stent System (BIOTRONIK AG, Switzerland). Thirty-three study centers (US, Columbia, Europe) enrolled 329 patients for treatment of one target lesion (≤ 31 mm). Eligible patients received a PRO-Kinetic Energy stent(s), at least one month of dual antiplatelet therapy and 36-months of follow-up. The primary endpoint was the 9-month rate of target vessel failure (TVF) which was compared with a pre-specified performance goal of 18.7% derived from prior BMS trials.

RESULTS The mean age of patients in the BIOHELIX-I study was 69 years, of which 28.6% had diabetes. 329 target lesions were treated, of which 99.4% were *de novo* (mean lesion length 13.7 ± 6.0 mm). The 9-month TVF rate was 9.06% ($p<0.001$) and met the primary endpoint. The TVF component rates were 0.95% cardiac death, 1.58% myocardial infarction, and 7.26% ischemia-driven TVR. The ischemia-driven target lesion revascularization (TLR) rate at 9-months was 6.62%.

CONCLUSION The 9-month TVF rate of the PRO-Kinetic Energy Cobalt Chromium Coronary Stent System was comparable to other bare metal stents and is a viable option for treating coronary artery disease. The low observed rate of ischemia-driven TVR supports the safety and efficacy of the novel BMS design.

CRT-700.08

ABSTRACT WITHDRAWN

CRT-700.11

Percutaneous repair and regeneration of native heart valves using a novel decalcification and bioelectric energy controlled stem cell homing and differentiation device

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BACKGROUND In the early 1990's our team developed and patented one of the first percutaneous heart valve systems working with Dr. Ivan Casagrande and Dr. Domingos Moraes in Brazil. We learned in this experience that a patient is nearly always better off keeping their own heart valve it they can.

AIMS The aim of this study was to evaluate the safety, technical feasibility and performance of a new trans-catheter heart valve repair system.

METHODS AND RESULTS Ten adult swine will be pre-conditioned with Cadherin-11 (Cad-11 upregulates RhoA and Sox9) to induce aortic valve calcification and will undergo transcatheter heart valve repair utilizing the Valvublator TM heart valve decalcification and regeneration system. The steerable transcatheter device will be introduced through a 14FR to 24FR sheath via minimally invasive access to the aortic valve with a beating heart. The Valvublator TM device will first use a vibrating burr at the end of the deflecting tip catheter under optical guidance to debulk the calcification followed by ultrasonic and bio safe solvent secondary cleanings. The brain is protected from stroke during this procedure with the Keystone Heart deflector or another FDA approved cerebral protection device. The decalcification procedure is followed by multiple sessions (4) of 40 minutes each of delivering bioelectric regeneration signals to the valve leaflets and orifice that recruits stem cells and differentiates them into healthy valvular tissue. Two sessions of bioelectric energy delivery are done via an endovascular catheter with an signal transmission array at the tip and two are done non-invasively with an external wireless signal transmitter focally pointed to the valve. Before and after images will be taken and functional assessment will be made before and after the procedure. Five of the swine (50%) will receive CoroStim TM vibrational energy via an external non-invasive transmitter to determine if this followup technology reduces re-calcification of the heart valve leaflets. All animals will be assessed at 3 months followup for valve calcification levels and functional status.