LBCT01-05

WIRELESS LV ENDOCARDIAL STIMULATION FOR CRT: PRIMARY RESULTS OF THE SAFETY AND PERFORMANCE OF ELECTRODES IMPLANTED IN THE LEFT VENTRICLE (SELECT-LV) STUDY

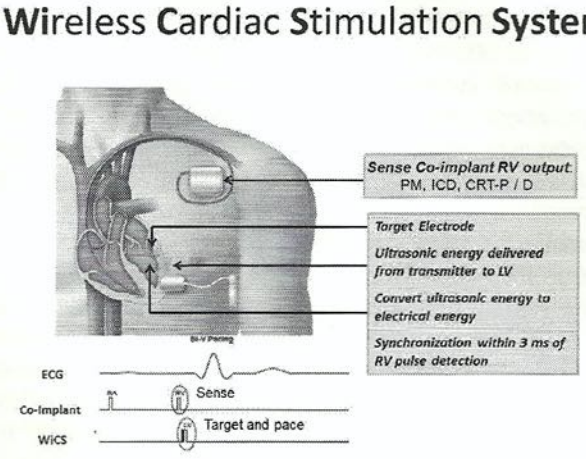
Vivek Y. Reddy, MD, Petr Neuzil, MD, Sam Riahi, MD, Peter Søgaard, MD, Christian Butter, MD, Thomas Schau, MD, Peter Paul Delnoy, MD, Lieselot van Erven, MD, Martin Schalij, MD and Lucas Boersma, MD. Mount Sinai School of Medicine, New York, NY, Homolce Hospital, Prague, Czech Republic, Aalborg University Hospital, Aalborg, Denmark, Heart Centre, Bernau bei Berlin, Bernau, Germany, Isala Hospital, Zwolle, Netherlands, Leiden University Medical Centre, Leiden, Netherlands, St. Antonius Hospital, Nieuwegein, Netherlands

Introduction: Indicated patients do not benefit from conventional CRT (ConCRT) because of lead issues such as an inability to place the CS lead or lack of clinical improvement with CRT. LV endocardial pacing has been proposed as a potential solution. We assessed the safety and performance of the novel Wireless Cardiac Stimulation System, WiCS-LV, to provide endocardial LV stimulation.

Methods: SELECT-LV is a non-randomized, 6 EU-center study of CRT-indicated pts with either a failure of ConCRT, or requiring an upgrade but unsuitable for ConCRT. The WiCS-LV includes a 9mm leadless pacing electrode implanted at the endocardial mid-lateral LV free wall, using a retrograde aortic approach with a steerable 12Fr sheath; fluoroscopy and TTE/ICE helped assess LV wall thickness at potential implant locations. The electrode is activated by a submuscular ultrasonic transmitter (Tx) synchronized to RV pacing pulse of a standard ICD / pacemaker. The Tx is connected to a battery implanted subcutaneously in the left mid-axillary line. The primary efficacy endpoint was successful CRT by 12 lead EKG at 1 mo post-implant. Primary safety events included device / procedure complications within 24 h and at 1 mo.

Application: Of 39 enrolled pts, 3 did not have an adequate acoustic window and 1 withdrew pre-implant. Implant was attempted in 35 (90%): age 65±8 yrs, 30 male, 15 ischemic CM (43%), EF 25.6±6.4%, NYHA 2.7±0.5 and baseline QRS 174±29 ms. Implantation was successful in 34 (97%); one pt had intra-operative VF precluding continuation. The most common indication for WiCS was the inability to perform CS pacing (24, 69%). Of the 27 pts followed for 1 mo, 96% achieved the primary endpoint, consistent CRT. At 1 month, the mean QRS reductions were 36.8ms and 52.7ms as compared with intrinsic and RV pacing, respectively; this was maintained in pts at 6 mo (n=19). Complications were separated into procedure-related (5, 15%), procedure and device related (1, 3%), unrelated (1, 3%), and as yet un-adjudicated (3 including 1 death 4 days after aborted implant, 9%).

Next steps / Future: This multicenter experience has demonstrated the feasibility of direct, wireless endocardial LV pacing to achieve CRT.



LBCT01-06

THE EVERA MRI STUDY

Michael R. Gold, MD, PHD, FHRS, Torsten Sommer, MD, PhD, Juerg Schwitter, MD, Ahmed Al Fagih, MD, Timothy Albert, MD, Béla Merkely, MD, Michael Peterson, MD, Allen Ciuffo, MD, Sung W. Lee, MD, Jeffrey Cerkvenik, MS, Lynn Landborg, BA and Emanuel Kanal, MD. Medical University of South Carolina, Charleston, SC, German Red Cross Hospital Neuwied, D-56564 Neuwied, Germany, Universit Hospial Lausanne, Lausanne, Switzerland, Prince Sultan Cardiac Center, Rayadh, Saudi Arabia, Central Coast Cardiology, Salinas, CA, Semmelweis University Heart Center, Budapest, Hungary, United Heart and Vascular Clinic, Minneapolis, MN, Sentara Norfolk General Hospital, Norfolk, VA, Washington Hospital Center, Washington, DC, Medtronic, Inc, Minneapolis, MN, University of Pittsburgh, Pittsburgh, PA

Introduction: Magnetic resonance imaging (MRI) of conventional implantable cardioverter-defibrillators (ICD) is contraindicated due to potential patient (pt) risks of MRI. We evaluated the safety and efficacy of an ICD system specially designed for full body MRI without restrictions on heart rate or pacing dependency.

Methods: The Evera MRI Study was a multicenter, randomized evaluation of pts with *de novo* eligibility for an ICD. Pts received an Evera MRI single or dual chamber ICD connected to pre-specified leads. Pts were assigned 2:1 to undergo MR imaging at 1.5 T of the cardiac, thoracic, cervical and head regions to maximize radiofrequency exposure up to 2W/kg specific absorption rate (SAR) and gradient field exposure to 200 T/m/s (MRI group, n=175) or a 1-hour waiting period without MRI (control, n=88). The composite primary safety objective was >90% freedom from MRI-related complication within 30 days post-MRI and sustained tachyarrhythmia occurring during MRI. The co-primary efficacy endpoints compared changes from the pre-MRI/waiting period to 1 month later between groups for ventricular pacing capture threshold (VPCT) (non-inferiority test, 10% margin) and