S-LBCT04
Late-Breaking Clinical Trials
Session IV: Innovations

Saturday, May 11, 2019
10:30 a.m. - 12:00 p.m.

CHAIRS:
L. Hurwitz, MD, FHRS. North Texas Heart Center, Dallas, TX

George F. Van Hare, MD, FHRS, CCDS, CEPS-P. Washington University Medical School, Saint Louis, MO

S-LBCT04-01
FIRST-IN-HUMAN CHRONIC IMPLANT EXPERIENCE OF THE SUBSTERNAL EXTRAVASCULAR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

Ian G. Crozier, MBChB, MD, FHRS, Haris Haqqani, MBBS, PhD, FHRS, Emily Kotschet, David Shaw, Anil Prabhu, Nicholas Roubos, Jeffrey Alison, Iain Melton, Russell Denman, Tina Lin, Aubrey Almeida, Bridget Portway, Robert Sawchuk, Lou Sherefsee, Samuel Liang, BENG, Amy Thompson, Linnea Lentz, Paul Degroot and David O’Donnell. Christchurch Hospital, Christchurch, New Zealand, The Prince Charles Hospital, Brisbane, Australia, Monash Medical Centre, Melbourne, Australia, The Austin Hospital, Melbourne, Australia, Medtronic, Minneapolis, MN, Medtronic, Macquarie Park, Australia

Introduction: The Extravascular Implantable Cardioverter Defibrillator (EV ICD) is a novel defibrillator that offers both pacing and defibrillation therapies, including the potential for antitachycardia pacing (ATP), using a 40J device the size of a Transvenous ICD (TV ICD). Existing extravascular alternatives including the subcutaneous ICD remain limited by larger device size relative to TV ICDs, and inability to deliver ATP therapy. Previously reported proof of concept studies have demonstrated the feasibility of the EV ICD using a lead placed in the subternal space (anterior medias-tinum) to achieve pacing and defibrillation. The EV ICD Pilot study is the first human experience of an implanted extravascular system designed to characterize the system’s safety and efficacy.

Methods: The EV ICD Pilot Study is a prospective, non-randomized, chronic first-in-human study conducted in four centers in Australia and New Zealand. Patients with Class I or IIa indications for ICD were enrolled. A defibrillation lead was inserted into the subternal space under radiologic guidance via a tunnelling tool and peel-away introducer sheath. The device was placed on the left side of the chest close to the mid-axillary line. Defibrillation efficacy was characterized at implant by inducing, detecting, and converting ventricular fibrillation episodes. Implant required termination of VF with either a single 20J shock or on two consecutive episodes with a 30J shock. Patient follow-ups were conducted at 2 Weeks, 4-6 Weeks and 3-Months post-implant. Collected data include radiographic images, ambulatory device data, custom Holter monitor recordings including the ICD electrograms, and device electrical performance (sensing and pacing) in different postures and during exercise. The preliminary safety of the EV ICD was characterized as the freedom from major complications related to the EV ICD system and/or procedure at 3 months.

Applications: A total of 26 patients were enrolled and 21 underwent the EV ICD implant procedure. The cohort was 81% male with an average age of 54 years, with 43% having NYHA class II or III heart failure. The mean LVEF was 43 ± 18%. Patients’ BMI ranged from 22 to 38. Seven (33%) of those undergoing the procedure had ischemic cardiomyopathy, with 11 (52%) having non-ischemic cardiomyopathy including 6 with hypertrophic cardiomyopathy. Full results on procedure success, defibrillation efficacy and safety will be available for presentation at the time of the conference.

Next Steps/Future: This study is the first chronic human experience of the implanted extravascular defibrillator. The EV ICD is a novel platform for delivering high voltage therapy and ATP. This study will inform the further development of the extravascular ICD and the design and conduct of a large-scale pivotal study.

S-LBCT04-02
DIGITAL-AF II: RESULTS FROM A REAL-LIFE DIGITAL ATRIAL FIBRILLATION SCREENING AND OUTCOME REGISTRY IN THE GENERAL POPULATION

Tine Proesmans, MA Sc, Frederik Verbrugg, PhD, Pieter Vandervoort, MD, Mathieu Rutgers, MD, Peter Vanacker, MD, Geert Vanhoren, MD and Dieter Nuyens, MD, Mobile Health Unit, Hasselt University, Hasselt, Belgium, Department of Cardiology, Hospital Oost-Limburg, Genk, Belgium, Department of Neurology, Europe Hospital, Brussels, Belgium, Department of Neurology, AZ Groeninge, Kortrijk, Belgium, Department of Neurology, AZ Sint-Jan, Bruggen, Belgium, Gasthuisberg Univ Hospital, Leuven, Belgium

Introduction: Opportunistic screening for AF is recommended in a 65-years-and-older population. However, this remains a challenge because it is time-consuming, hampered by logistics and the use of additional healthcare resources. Novel technologies are emerging, among which smartphone apps that use pulse-plethysmography (PPG) through the camera. A real-life project evaluates the feasibility and impact of a digital, widespread population screening requiring only a smartphone. A follow-up registry will offer insights in the clinical care path of screening-positive participants.

Methods: Access to the app (CE/FDA-cleared) was gained by scanning a code distributed via different communication channels throughout Belgium. Users were instructed to measure twice daily and when experiencing symptoms, for an 8-day monitoring period. After symptom annotation, each measurement was classified as regular rhythm, possible AF, irregular rhythm or insufficient quality. To ensure high diagnostic accuracy, all irregular measurements were analyzed by medical technicians under supervision of cardiologists. After 8 days, all participants received a report with a conclusion and a copy of their rhythm traces. Follow-up questionnaires will map the decision making process of screening-positive participants and their physicians, and assess the impact of the screening at various time intervals.
after reporting.

**Applications:** During two weeks in December 2018, 62,821 participants enrolled in the screening. 61,730 participants completed the monitoring period resulting in a database of 588,282 60-second PPG-traces. The average age of the screened population was 48.5 ± 14.7 years, 57.6% was male. 791 participants (1.3%) performed measurements indicative for AF. The average age of the AF group was 61.9 ± 10.9 years, 75.9% was male. 72% of the AF patients did not experience symptoms. 210 patients (27%) had persistent AF, all were detected on first PPG-measurement. 581 patients (73%) had paroxysmal AF, 111 were detected on first measurement. By extending the period, the diagnostic yield more than tripled; from 0.53% to 1.75% after eight days.

**Next Steps/Future:** This supervised digital screening, targeting the general population and utilising only smartphones, demonstrates the feasibility to collect data in a scalable, controlled and cost-effective way. The results indicate a relevant yield of new AF patients without over-consuming healthcare resources. The registry will further disclose the clinical care path of screening-positive participants. As technology adoption will continue to grow in the elderly, these technologies become even more relevant and will aid to gain real-life evidence, outcome data and health-economic insights from screening-positive patients.

**S-LBTC04-03**

**NON-INVASIVE LOCALIZATION OF CARDIAC ARRHYTHMIAS USING ELECTROMECHANICAL WAVE IMAGING**


**Introduction:** Diagnosis and localization of arrhythmias are critical for decision making and treatment planning prior to cardiac ablation. The 12 lead ECG is the main noninvasive tool used to localize arrhythmias, however it can be limited in specificity and subject to interobserver variability. Electromechanical Wave Imaging (EWI) is a novel, high frame rate 3D rendered ultrasound technique that can noninvasively map the electromechanical activation of heart rhythm. This double blinded study evaluated the feasibility of transthoracic EWI to localize atrial tachycardia (AT), atrial flutter (AFL), premature ventricular complexes (PVC), and accessory pathways (AP) in Wolff-Parkinson-White syndrome prior to catheter ablation.

**Methods:** Patients presenting for catheter ablation of AT, AFL, PVCs, or an AP underwent transthoracic EWI and 12 lead ECG prior to the ablation. 67 patients were consented, 12 patients were excluded due to withdrawal of consent, poor imaging or not being in the arrhythmia at time of imaging. 55 patients underwent EWI (mean age 56.0±3 years, 71% male). 22% had WPW, 20% had PVCs, 13% had AT and 45% had AFL. 6 blinded clinical electrophysiologists predicted arrhythmia origins based on ECG alone. EWI isochrone processing was blinded to all clinical data except arrhythmia type. Operating physicians were blinded to EWI isochrones. EWI and ECG predictions were compared to arrhythmia location as determined by 3D electroanatomic mapping and ablation using a standardized 21 segment cardiac model.

**Applications:** EWI was able to correctly predict 96% of arrhythmia locations as compared with 71% for 12-lead ECG analyses (unadjusted for arrhythmia type: OR: 11.8; 95% CI: 2.2-63.2; p=0.004; adjusted for arrhythmia type: OR: 12.1; 95% CI: 2.3-63.2; p=0.003). There was significant inter-observer variability amongst ECG reads.

**Next Steps/Future:** This study shows EWI is capable of localizing arrhythmias including AT, AFL, PVCs, and APs. Ongoing efforts include incorporating EWI isochrones into 3D anatomical maps prior to ablation to determine whether EWI can affect clinical outcomes e.g. procedure time and radiation dose, in addition to exploring EWI with transeophageal, intracardiac, and 3D ultrasound.
S-LBCT04-04

A NOVEL PERCUTANEOUS CAROTID COIL FILTER FOR STROKE PREVENTION IN ATRIAL FIBRILLATION: OUTCOMES OF THE FIRST-IN-HUMAN CAPTURE TRIAL

Vivek Y. Reddy, MD, Petr Neuziel, MD, PhD, Tom De Potter, MD, PhD, Jan Vanderheyden, MD, Selam Tromp, MD, Benno Rensing, MD, Eva Jiresova, MD, Libor Dujka, MD and Veronika Lekesova, MD. Icahn School of Medicine at Mount Sinai, New York, NY, Hospital of the Univ of Pennsylvania, Philadelphia, PA, Loyola Univ Medical Center, Maywood, IL, Beth Israel Deaconess Medical Center, Boston, MA, Texas Cardiac Arrhythmia, Austin, TX, Hospital of the University of Pennsylvania, Philadelphia, PA, Texas Cardiac Arrhythmia Insti, Austin, TX, BIDMC, Cardiology, Boston, MA, Mount Sinai Hospital, Brooklyn, NY, Icahn School of Medicine at Mount Sinai, New York, NY, Mount Sinai Medical Center, Icahn School of Medicine, New York, NY, University of Pennsylvania, Philadelphia, PA, Loyola Univ Medical Center, IL, Maywood, IL, Beth Israel Deaconess Medical Center, Boston, MA, Texas Cardiac Arrhythmia, Austin, TX, Hospital of the University of Pennsylvania, Philadelphia, PA, Texas Cardiac Arrhythmia Insti, Austin, TX, BIDMC, Cardioology, Boston, MA, Mount Sinai Hospital, Brooklyn, NY, Icahn School of Medicine at Mount Sinai, New York, NY, Mount Sinai Medical Center, Icahn School of Medicine, New York, NY, Hospital of the Univ of Pennsylvania, Cardio Electrophysiology, Bala Cynwyd, PA

Introduction: High stroke risk patients with AF who are unsuitable for oral anticoagulants (OAC) require other strategies for stroke prophylaxis. In a first-in-human clinical trial, we studied a novel permanent carotid coil filter designed to be transcutaneously placed directly into both common carotid arteries (CCAs) to prevent embolic stroke.

Methods: CAPTURE (NCT#03571789) is a multicenter, open label, non-randomized, first-in-human study of the Vine carotid coil filter (Javelin Medical Ltd, Israel): a single super-elastic helical nitinol wire, with 1 mm gaps between coils (Figure). Under ultrasound guidance, a 24G needle is used to transcutaneously puncture directly into the carotid artery in the neck; a motorized unit then exerts the filter to unfurl in the CCA. The post-procedure regimen included DAPT for 3 mo, and ASA thereafter. Eligible pts had AF, CHADS-VASc ≥ 2, OAC contraindications, CCA size 4.8 - 9.8 mm, and no carotid stenosis > 30%. Primary endpoints were: i) procedural success - bilateral, properly positioned filters in the CCAs without migration, fracture or entanglement, and ii) incidence of device/procedure related major AEs (death, stroke, major bleeding, CCA stenosis, filter migration, CCA thrombus) at 30 days. CCA ultrasounds and exams were at pre-discharge, 1 wk and 1/3/6/12 mo.

Applications: Enrollment completed in Nov 2018 (n=25): mean age 72, CHADS-VASc = 4.4, prior stroke/TIA/SE in 48%. Procedure success was 92% (23/25 pts); 1 pt had unilateral deployment. The 30 d major device-related AE rate was 0%. Minor AEs (puncture site hematoma/edema) occurred in 5/25 (20%). During a median follow-up of 6 months, there was no evidence of in situ thrombus formation. The filter captured emboli in 4 patients (1 bilateral, 3 unilateral), none of which developed symptoms; in 3 of these 4 pts, the thrombi dissolved with SQ heparin (last pt ongoing). In 1 pt, 2 minor strokes occurred involving non-CCA territory (occipital lobe).

Next Steps/Future: In this first clinical experience, direct permanent carotid filter placement for AF stroke prophylaxis was technically feasible and safe. These promising data should prompt large prospective randomized trials.

S-LBCT04-05

BIPOLAR CATHETER ABLATION FOR THE TREATMENT OF REFRACTORY SCAR-RELATED VENTRICULAR TACHYCARDIA: A MULTICENTER, PROSPECTIVE FDA IDE STUDY

Srinivas R. Dukkipati, MD, FHRSA, Jacob S. Koruth, Pasquale Santangeli, MD, PhD, David J. Wilber, Alfred E. Buxton, MD, J. David Burkhardt, MD, FHRSA, Fermin C. Garcia, MD, Amin Al-Ahmad, Elad Anter, MD, Stephanie M. Harcum, BA, Betsy Eilsworth, Jonathan Williner, MD, Jalaj Garg, MD, Francis E. Marchlinski, MD, FHRSA, Andrea Natale, MD, FHRSA and Vivek Y. Reddy, MD. Mount Sinai Hospital, Mount Sinai Medical Center, New York, NY, University of Pennsylvania, Philadelphia, PA, Loyola Univ Medical Center, IL, Maywood, IL, Beth Israel Deaconess Medical Center, Boston, MA, Texas Cardiac Arrhythmia, Austin, TX, Hospital of the University of Pennsylvania, Philadelphia, PA, Texas Cardiac Arrhythmia Insti, Austin, TX, BIDMC, Cardiology, Boston, MA, Mount Sinai Hospital, Brooklyn, NY, Icahn School of Medicine at Mount Sinai, New York, NY, Mount Sinai Medical Center, Icahn School of Medicine, New York, NY, Hospital of the Univ of Pennsylvania, Cardio Electrophysiology, Bala Cynwyd, PA

Introduction: An intramural location of the VT circuit is a common cause of failed catheter ablation of VT. Despite the sequential application of unipolar RF ablation lesions on opposing surfaces of the target tissue, increased myocardial thickness is an important factor limiting success. With the benefits of increased lesion depth and higher rates of transmurality, bipolar RFA may be an alternative strategy in this setting.

Methods: In this multicenter (4 centers), non-randomized, prospective, investigator-initiated FDA IDE trial (NCT 02374476), bipolar RFA was evaluated in scar-VT patients with refractory VT planned for catheter ablation. Bipolar RFA was permitted if subjects underwent a failed unipolar ablation within the prior 6 months or failed unipolar ablation during the index procedure following study enrollment. If only unipolar RFA was used (i.e. bipolar RFA not needed or used), patients were followed in a Registry. Bipolar catheter ablation was performed using two externally-irrigated RF catheters (Thermocool ST-SF; Biosense-Webster Inc; max power = 35 W, 45 °C; 90 s) and custom software designed to simultaneously visualize both ablation catheters with real-time display of inter-catheter distance on the 3D mapping...
system (CARTO, Biosense Webster Inc.) (Figure). The primary endpoints were: (1) freedom from recurrent VT at 6 months; and (2) rate of procedure-related complications

Applications: A total of 105 patients (48 bipolar RFA, 57 Registry) were enrolled in the study. The baseline demographics are shown in the Figure. The mean LVEF was ~33%, most pts had an ischemic etiology, and ~1/3 received a combined epi/endo approach; the major difference from the Registry cohort was a much higher incidence of prior ablation procedures (87% vs 58%). Acute and final 6-month safety and outcome results will be presented.

Next Steps/Future: The acute and final 6-month safety and efficacy outcomes will be available for presentation in May 2019.