B-LBCT02
Late-Breaking Clinical Innovations

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CONTINUOUS ECG MONITORING VERSUS MOBILE TELEMETRY: A COMPARISON OF ARRHYTHMIA DIAGNOSTICS BETWEEN HUMAN AND ALGORITHM DEPENDENT SYSTEMS

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Introduction: A myriad of long-term (>48 hour) cardiac rhythm monitors are available for use. Clinicians rarely scrutinize the full disclosure and thus rely on manufacturers to detect and report relevant rhythm abnormalities using processes that are opaque to most providers. This study compares the diagnostic accuracy between human oversight-dependent continuous ECG monitoring and algorithm-dependent mobile cardiac telemetry (MCT).

Methods: In an outpatient arrhythmia clinic, we enrolled 50 sequential patients who were to simultaneously wear MCT and a long-term continuous ECG monitor. Periods of concomitant wear of both devices were examined for the purposes of this study as patient-application and removal of each device may have differed. Each study and the associated report were reviewed by two electrophysiologists and categorized according to whether significant clinical arrhythmias were identified and correctly diagnosed.

Applications: Of the 50 patients enrolled, 4 failed to wear both monitors simultaneously and were excluded. The remaining 46 wore both monitors simultaneously for at least some time period: 10.3 ± 4.4 days (range: 1.2-14.8 days). The mean age was 58 ± 16 (21-83), 15 (30%) were males and 31 (62%) were females. During simultaneous recording, significant arrhythmias were diagnosed by MCT in 11/46 patients (24%) compared with 23/46 (50%) patients by long-term continuous ECG monitoring, a 209% increase, p=0.018. Thus, in 12 of 46 patients (26%), a significant arrhythmia finding was missed by MCT but captured by long-term continuous human read ECG. In 2 patients, AV node re-entrant tachycardia, captured by long-term ECG, was missed by MCT. In 3 patients, second degree AV block was unreported by MCT but captured by long-term continuous ECG monitoring. In 7/46 (15%), VT was reported by MCT, compared to 13/46 (28%) patients by long-term continuous ECG monitoring. Atrial fibrillation was documented by both types of monitors in 2 patients however long-term continuous ECG monitoring captured 4 additional AF episodes missed by MCT.

Next Steps/Future: In a time-controlled, paired analysis of two disparate rhythm monitors worn simultaneously, human-oversight dependent continuous ECG recordings significantly outperformed algorithm-dependent MCT recordings in detecting significant arrhythmias by 209%.

B-LBCT02-02
LEADLESS LV STIMULATION WITH WISE-CRT SYSTEM - INITIAL EXPERIENCE IN NEW US CENTERS: RESULTS FROM PHASE I OF SOLVE-CRT STUDY (NON-RANDOMIZED, ROLL-IN PHASE)

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Introduction: Leadless left ventricular (LV) endocardial pacing is a promising pacing modality to deliver cardiac resynchronization therapy (CRT). WiSE-CRT is a wireless LV endocardial pacing system that delivers ultrasonic energy to a passive LV endocardial electrode; the system is currently being evaluated in the pivotal trial, SOLVE-CRT. This report summarizes results from Phase I of this study, which included roll-in patients from centers who did not have prior implanting experience.

Methods: Patients included had either lead failures with conventional CRT or were non-responders to conventional CRT. Data were prospectively collected from 19 centers where WISE-CRT systems were implanted during the roll-in phase of the SOLVE-CRT clinical trial. Patients were followed at 1, 3, and 6 months with Core lab adjudicated transthoracic echo (TTE) at baseline and 6 months.

Applications: The WiSE-CRT was successfully implanted in all 31 cases, and 30 patients completed the 6-month follow-up. One patient underwent heart transplantation 1 month after implantation, and was excluded from the analysis. Fourteen (46.7%) patients demonstrated ≥1 NYHA class improvement. TTE data were available in 29 patients. LV ejection fraction, LV end-systolic volume, and LV end-diastolic volume improved from 28.3 ±6.7% to 33.5 ±6.9% (p<0.001), 134.9 ±51.3 ml to 111.1 ±40.3 ml (p=0.0004), and 185.4 ±58.8 ml to 164.9 ±50.6 ml (p=0.0017), respectively. There were 3 (9.7%) device-related type 1 complications: 1 insufficient LV pacing, 1 embolization of an un-anchored LV electrode and 1 incisional skin infection.

Next Steps/Future: The study demonstrated a high success rate of LV endocardial electrode placement in centers with no prior implanting experience, demonstrating broad applicability to different centers and implanting physicians. Favorable clinical responses in HF symptoms and significant LV reverse remodeling were observed in this patient cohort. Patient enrollment in the pivotal SOLVE-CRT trial is anticipated to be completed by early 2022 with 6 months results by mid-2022.
**B-LBCT02-03**

ULTRALOW TEMPERATURE CRYOABLATION FOR ATRIAL FIBRILLATION, PRIMARY OUTCOME RESULTS ON EFFICACY AND SAFETY. THE CRYOCURE-2 STUDY.

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**Introduction:** Ultra-Low Temperature Cryoablation (ULTC) that utilizes Near-Critical Nitrogen (-196⁰C) holds promise of improved outcomes in atrial fibrillation (AF) ablation, particularly persistent AF (PsAF) as it has been shown to produce durable contiguous and transmural lesions in the human atrium (Cryocure-1 Flutter study) as well as in animal models for left and right atrial targets.

**Methods:** The Cryocure-2 study (NCT02839304) was a European, multi-center, prospective, single-arm, clinical trial. Patients with paroxysmal AF (PAF) or PsAF received pulmonary vein isolation (PVI) plus additional ablation of the posterior wall, as well as linear left and right atrial (LA and RA) lesions at the discretion of the operator. Follow-up was done using Holter recordings at 3, 6 and 12 months. Primary endpoints included acute safety, procedural outcomes and freedom from AF at 12 months by Kaplan-Meier (K-M) analysis.

**Applications:** A total of 79 patients were enrolled, mean age 65±9 years old (68% male), 56% PsAF; 78 were treated. Acute success, defined as the achievement of PVI and confirmation of complete bidirectional conduction block across LA or RA lesions, was achieved in 252 out of 260 veins attempted for PVI (97%), 32 out of 32 LA posterior wall (100%), and 12 out of 13 RA lesions (92%). Average procedure time was 126 min and average catheter dwelling time was 82 min. Three cases of periprocedural phrenic nerve palsy were all resolved during the follow-up. No other major adverse events occurred. At 12 months, K-M estimate for freedom from AF was 85% and 76% in patients with PsAF and PAF, respectively.

**Conclusion:** The Adagio ULTC platform allows treatment of atrial fibrillation by PVI and additional LA and RA ablation. The Cryocure-2 data shows this approach to be safe and highly effective, with an observed 85% success rate for the persistent AF population, to be confirmed in larger ongoing cohorts.

**Next Steps/Future:** The European registry of Adagio ULTC technology and US IDE study are ongoing.

**B-LBCT02-04**

ANALYSIS OF BEHAVIOR OF AF SOURCES WITH ELECTROGRAPHIC FLOW MAPPING

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**Introduction:** Electrographic flow (EGF) mapping is a unique algorithm that employs Horn Schunck flow estimations to create temporospatial visualizations of atrial electrical wavefront propagation during atrial fibrillation (AF). Instead of attempting to define a specific arrhythmic mechanism of AF sources, this method finds the source location by identifying reproducible patterns of centrifugal EFG activation from those sites. Our purpose was to assess the patterns and prevalence of AF sources using EFG mapping.

**Methods:** Unipolar electrograms were recorded for 1-minute intervals with 64-pole basket catheters. Flow estimates were constructed by passing consecutive frames through an algorithm to learn typical wave direction patterns. Learning segments were compared with subsequent 2-second recordings to describe flow field evolution. During each 2-second segment, sites at the center of centrifugal activation patterns were defined as AF sources. A map of the location and duration of activity from each source over the 60-second recording was generated.

**Applications:** This method was applied to 405 prospective and retrospective patients with persistent or long-standing persistent AF who had basket mapping during AF with mean age 62.5 years; mean LA size 54 mm and mean AF duration 4.6 years. EGF mapping found 6.6 ± 2.4 AF sources/patient (55% LA, 45%RA). Dominant sources were defined as those observed during >20% of the recording and were demonstrated in 181 (44.7%) patients, but of 2,924 sources detected, only 312 (10.7%) crossed this threshold (figure). Among patients with complete data after catheter ablation (n=250), 113 had AF recurrence during follow-up of 12±2 months. The number of dominant sources recorded was 0.72 ± 0.09 (SE) in patients with versus 0.52 ± 0.06 (SE) in patients without recurrent AF (p=0.034).

**Next Steps/Future:** Complex AF conduction patterns make ablation challenging but with EGF mapping, time-dependent AF behaviors can be detected and summarized. Although low prevalence sources are detected, they may not be clinically relevant. A recording duration of 1 minute enables identification of dominant sources.
Focal Sources DS, ES Central Roof,
H3 Rotational Source Lateral – Simultaneously Active

Source Prevalence of All Analyzed

Number of Sources per Patient
>5% Prevalence