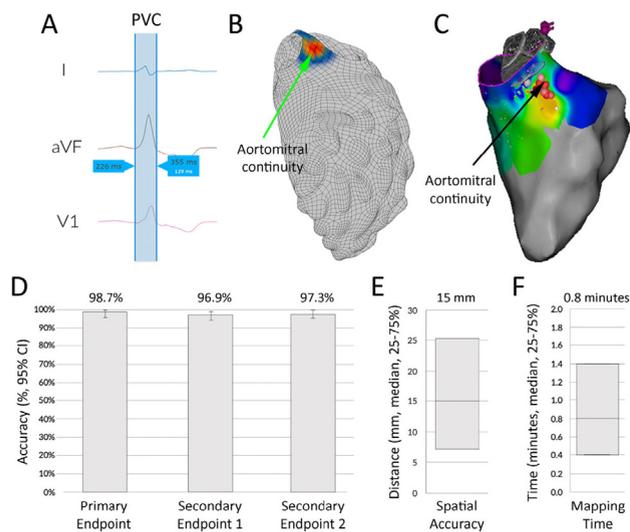


primary endpoint) was 98.7% (95% CI: 96.0-100%, $p < 0.001$ to reject study null hypothesis, panel D). Regional accuracy for all episodes (secondary endpoint 1) was 96.9% (95% CI: 94.7-99.0%, $p < 0.001$). Accuracy for the exact or neighboring segment for all episodes (secondary endpoint 2) was 97.3% (95% CI: 95.2-99.3%, $p < 0.001$). Median center-to-center spatial accuracy was 15 mm ($n = 255$, IQR: 7 - 25 mm, panel E). The mapping process was completed in a median of 0.8 minutes (IQR: 0.4 - 1.4 minutes, panel F).

Conclusion: Computational ECG mapping using a forward simulation approach exceeded prespecified accuracy goals for arrhythmia source and pacing site localization. Spatial accuracy analysis revealed clinically actionable results. This rapid, non-invasive mapping technology may facilitate catheter-based and noninvasive arrhythmia therapies.



ABSTRACT CI-523: Clinical Trials in CIEDs

Friday, April 29, 2022

9:15 AM - 10:15 AM

CI-523-01

CONDUCTION SYSTEM PACING VERSUS CONVENTIONAL PACING IN PATIENTS UNDERGOING AV NODE ABLATION: NON-RANDOMIZED, ON-TREATMENT COMPARISON

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Background: AV Node Ablation (AVNA) with right ventricular or biventricular pacing (Conventional Pacing-CP) is an effective therapy for patients with refractory atrial fibrillation. Conduction System Pacing (CSP) using His bundle pacing or left bundle branch area pacing preserves ventricular synchrony and may be associated with better clinical outcomes.

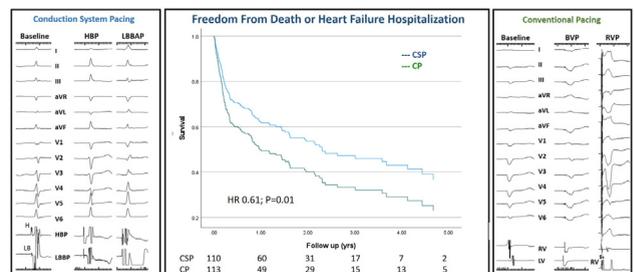
Objective: The aim of our study is to compare the clinical outcomes between CP and CSP in pts undergoing AVNA.

Methods: Patients undergoing AVNA at a large health system between Jan 2015 and Oct 2020 were included in this retrospective observational study. CP or CSP were performed at the operators' discretion. Procedural, pacing parameters and

echocardiographic data were assessed. Primary outcome was the combined endpoint of time to death or heart failure hospitalization (HFH) and analyzed using Cox proportional hazards. Secondary outcomes were individual outcomes of death and HFH.

Results: AVNA was performed in 223 patients (CSP 110; CP 113). Age 75 ± 10 years, men 52%, hypertension 67%, diabetes 25%, coronary disease 40%, LVEF 43 ± 15 % and baseline QRS duration 111 ± 30 ms. QRS duration increased from 103 ± 30 ms to 124 ± 20 ms ($p < 0.01$) in CSP and 119 ± 32 ms to 162 ± 24 ms in CP. During a mean follow up of 27 ± 19 months, LVEF significantly increased from 46.5 ± 14.2 % to 51.9 ± 11.2 % ($p = 0.02$) in CSP and 36.4 ± 16.1 % to 39.5 ± 16 % ($p = 0.6$) in CP. The primary outcome of death or HFH was significantly reduced in CSP compared to CP (48% vs 62%; HR 0.61, 95% CI 0.42-0.89, $p < 0.01$). There was no significant reduction in the secondary outcomes of HFH and death in the CSP group compared to CP.

Conclusion: CSP is a safe and effective option for pacing in patients with atrial fibrillation undergoing AVNA and may be associated with reduction in HFH or death compared to CP.



CI-523-02

A MULTICENTER RANDOMIZED COMPARISON BETWEEN ULTRASOUNDS AND FLUOROSCOPIC GUIDANCE FOR AXILLARY VEIN PUNCTURE FOR CARDIAC DEVICES IMPLANTATION

Sok-Sithikun Bun MD, PhD; Fabien Squara MD and Philippe TAGHJI

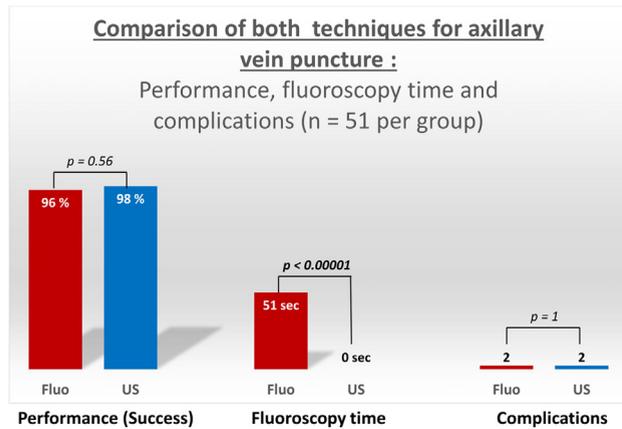
Background: Axillary vein (AV) puncture, an emerging route for cardiac implantable electronic devices (CIED), can be performed under ultrasounds (US) or fluoroscopic (Fluo) guidance.

Objective: To compare US to fluoroscopic-guided AV puncture in a multicenter randomized controlled trial.

Methods: Consecutive patients admitted for CIED (first implant or upgrade, including resynchronization therapy) intervention were prospectively randomized between US or Fluo guidance for AV puncture in the three participating centers. Access performances, radiation exposure and complications were compared in both groups.

Results: 102 patients were included ($n = 51$ patients per group). The two groups had similar characteristics concerning age (79.4 ± 10 years), and LVEF (47 ± 17 %). 92 leads were implanted in both groups. AV catheterization was successful in 50/51 (98 %) in the US group versus 49/51 in the Fluo group (96 %, $p = 0.56$). AV access time and procedure time were not different between the two groups, respectively (156 ± 274 in the US group versus 137 ± 151 sec, $p = 0.66$; 54 ± 24 versus 61 ± 26 min; $p = 0.13$). Total fluoroscopy time (FT) and dose-area product were respectively lower in the US group, but without reaching significance: 197 ± 231 versus 247 ± 293 sec, $p = 0.32$; 0.39 ± 0.95 versus 0.75 ± 1.58 mGy.m², $p = 0.14$. FT for AV access was significantly higher in the Fluo group (51 ± 55 sec versus 0, $p < 0.0001$). There were two complications in each group during the 9 ± 6 months follow-up.

Conclusion: Our study demonstrates that both US and fluoroscopy-guided AV catheterization for CEID are highly effective and safe techniques. Despite similar AV access time, compared to fluo guidance, US reduce time radiation exposure by 20 %.



CI-523-03

REDEFINE-EP: A PROSPECTIVE, RANDOMIZED EVALUATION OF THE CONTROLRAD SYSTEM TO REDUCE RADIATION EXPOSURE DURING CARDIAC ELECTRONIC IMPLANTABLE DEVICE PROCEDURES

Nishaki Mehta MD, FHRS; Joshua France BS; Kuldeep Shah MD; Ilana B. Kutinsky DO, FHRS; Brian D. Williamson MD; Anil K. Goel MD; Simon R. Dixon MBChB and David E. Haines MD, FHRS

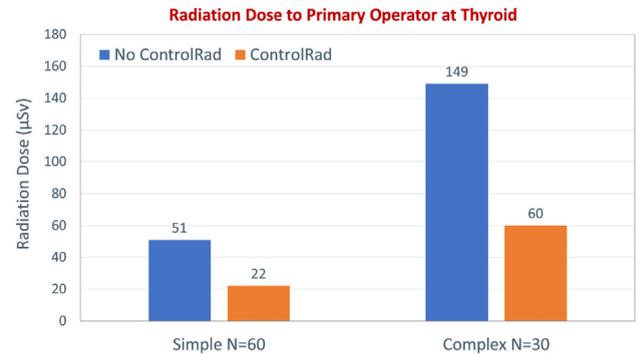
Background: The ControlRad (CR) system utilizes a dynamic collimator that allows high resolution imaging in an operator-selected region of interest, with significant radiation dose reduction for the remaining field of view.

Objective: The aim of this study was to evaluate the effectiveness of the CR system to reduce scatter radiation during cardiac electronic implantable device (CEID) procedures.

Methods: In a prospective, single center study, 90 patients undergoing simple (single or dual chamber CEID) or complex (left bundle pacing and biventricular CEID) procedures were randomly assigned to undergo the procedure with or without the CR system (CR= 43, No CR=47). The primary study endpoint was the scatter radiation dose to the primary operator measured using a standard aluminum oxide badge and a real-time radiation dosimeter badge. Secondary endpoints included the radiation dose to the secondary operator and nurse anesthetist, and dose-area product (DAP).

Results: Of the 90 patients, 60 (67%) underwent simple and 30 (33%) underwent complex CEID procedures. For the primary operator, the mean radiation dose at the thyroid position per case was 63% lower in the CR arm (standard badge: 56 vs. 23 μ Sv). For the second operator, the thyroid dose was also lower in the CR arm (9 vs. 2 μ Sv, 81% reduction). The cumulative radiation dose for the nurse anesthetist was too low to report meaningful data. The median DAP was 68% lower in the CR arm (622 vs 196 μ Gym²). Using the real-time radiation dosimeter badge, relative reduction in radiation dose for the primary operator was similar in simple (57%) and complex (60%) procedures (Figure 1). The mean procedure times were similar in CR vs. noCR (71 vs 66 mins, $p=0.6$). There was no difference in complications between study arms ($p=0.19$).

Conclusion: The ControlRad system effectively reduces scatter radiation exposure to the operators and patient during CEID procedures without prolonging procedure times or complications.



CI-523-04

CARDIAC RESYNCHRONIZATION THERAPY USING THE SYNCV ALGORITHM COMPARED TO CONVENTIONAL BIV PACING: PRELIMINARY RESULTS OF THE DOUBLE-BLIND, RANDOMIZED, MULTICENTER CLINICAL TRIAL "CRUSTY-TRIAL"

Jaume Francisco Pascual MD; Nuria Rivas-Gándara MD, PhD; Raquel Adelino; Aurelio Quesada MD, PhD; Inigo Sainz Godoy PhD; Pilar Cabanas; Emilce M. Trucco; Jordi Perez-Rodon; Begoña Benito MD, PhD; Jose Ferrando; Victor Exposito MD, PhD; Juan Fernández-Armenta MD; Alba Santos-Ortega and Ignacio Ferreira-Gonzalez; CRUSTY trial investigators

Background: Some of the devices for cardiac resynchronization therapy (CRT) have automatic algorithms to achieve ventricular fusion, such as the SyncAV™ algorithm (Abbott). There are few data on the possible clinical benefit of its use in clinical practice.

Objective: To assess whether cardiac resynchronization using the SyncAV™ algorithm achieves greater electrical resynchronization compared to a conventional biventricular pacing (CVP).

Methods: The CRUSTY trial is a multicenter, randomized, double-blind clinical trial to evaluate the superiority of CRT with fusion using the SyncAV™ algorithm over CVP (with optimization of AV and VV intervals) with a 6-month follow-up. (ClinicalTrials.gov Identifier: NCT03961399). This sub-study focuses on the data obtained at the inclusion and baseline visit to assess the acute electrical response.

Results: From January 2019 to April 2021, 54 patients were included in the 15 participating centers (mean age 66 \pm 9 years, 40% women). After 1: 1 randomization (Figure 1A), no significant differences were observed in their baseline characteristics (TABLE). After resynchronization, the duration of paced QRS in SyncAV group was lower (137 \pm 4 MS VS 118 \pm 17 ms, $p < 0.01$), as well as the absolute (deltaQRS) and relative (% deltaQRS) reduction of the QRS (29 \pm 23 ms Vs 52 \pm 19ms, $p < 0.01$; 17% vs 30%, $p < 0.01$ respectively) (FIGURE). The number of "super-resynchronizers" (QRS <120ms) was higher in the SyncAV group (19% vs 63%, $p < 0.01$). In the multivariate analysis, the use of the SyncAV™ algorithm was the only factor that predicted a "super-resynchronizer" response type (OR 7.8; 95% CI 2-26)

Conclusion: Fusion CRT using the SyncAV™ algorithm achieves greater electrical resynchronization compared to EBC in the short term. We remain awaiting the results of the follow-up