following failure. Automatic sensing and detection algorithms were used for the first ICD shock.
In Phase I (n=18), the EV-ICD system was removed following defibrillation testing. In Phase II (n=18), subjects were followed for up to 90 days with the EV-ICD System configured to *Monitor Only* and a concomitantly implanted TV-ICD system configured to deliver therapy (see Figure 1). This enabled both ICD systems to record spontaneous episodes for comparison purposes. Defibrillation success was reconfirmed with a single shock 10J less than the ICD maximum output at 30- and 90-day visits.
For analysis, the full study cohort (Phase I and II, n=36) was divided into low BMI (LBMI, n=23) and high BMI (HBMI, n=13) subgroups.
Results: Leads were placed in 21/23 LBMI (91%) and 12/12 HBMI attempts. Median time to placement was similar between the LBMI (11.5 min) and HBMI (10.3 min) groups. No intraoperative adverse events were seen in either cohort. Acute sensing and defibrillation of induced VF was 100% appropriate, with similar time-to-therapy (LBMI = 10.1 s vs HBMI = 11.5 s). Defibrillation was achieved in all patients (n=27), with mean energies of 16.2 J (n=19 LBMI) and 16.4 J (n=8 HBMI).
In the 16 subjects followed for 90 days, 2 Subjects required early EV-ICD System removal: 1 pneumothorax at 5 days and 1 sternal incision dehiscence at 22 days. Both events resolved without further sequalae.
Sensing and defibrillation were successful in all 23 chronic induced VF defibrillation tests (100%). By 90 days, 4 non-sustained VT/VF episodes in 3 subjects were appropriately sensed by both systems.
Application: This data shows a novel extravascular ICD lead placed with a parasternal approach feasibly senses and defibrillates using commercially available ICDs.
Next Steps/Future: These feasibility studies allow for further development of an EV-ICD lead via the anterior parasternal approach and lead iterations are underway to include pacing options.

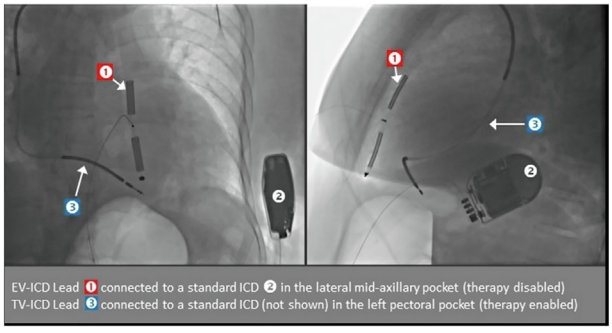

Figure: PA and Lateral Fluoroscopy

PO-05-213

INCREASE IN LEFT ATRIAL PRESSURE AFTER CRYOBALLOON ABLATION INDICATES WORSE ATRIAL FUNCTION: EVIDENCE FROM APPEARANCE-AF TRIAL

Zhongyuan Ren; Shubin Wu; Hui Sun; Yawei Xu and Dongdong Zhao

Introduction: Left atrial pressure (LAP) is a direct reflection of left atrial function, while LAP could fluctuate following left atrial procedure. The pattern of LAP change in response to pulmonary vein isolation (PVI) and its significance remain to be explored. The study aims to investigate the pattern of LAP change before and after PVI, and its correlation with other clinical profiles.
Methods: 28 patients from APPEARANCE-AF trial (NCT05106270) underwent PVI using cryoballoon ablation were included. Pre-ablation and post-ablation LAP were directly measured via catheter. The correlation of LAP change with demographics, biochemical measurements, and speckle traced echocardiographic indexes of left atrium (LA) were investigated.
Results: The included cohort has a mean age of 73.8±8.4 years old, with 12 male (42.9%). Instant PVI was achieved in all patients without complications. The average mean LAP (mLAP) measured before and after PVI was 8.2±4.5 mmHg (pre mLAP) and 14.0±6.5 mmHg (post mLAP), with a significant increment (ΔmLAP: 5.8±4.5 mmHg, P<0.001). The change in LAP significantly correlated with LA strain rate in reservoir (LASr, r=-0.58, P=0.001) and conduit phase (LAScd, r=0.63, P<0.001) and LA ejection fraction (r=-0.48, P=0.014). Correspondingly, patients with larger LAP increment (inc-mLAP, increment of mLAP>5 mmHg, n=14) presented significant worse atrial function indicated by LASr (17.3%±5.6% ninc-mLAP vs 11.5%±7.3% inc-mLAP, P=0.030), LAScd (-9.6%±2.2% ninc-mLAP vs -5.7%±3.6% inc-mLAP, P=0.003).
Application: PVI could significantly increase LAP, and a higher change of LAP could indicate worse atrial function. Measuring the change of LAP might be valuable in prediciting the prognosis of PVI.
Next Steps/Future: We aimed to 1. continue enrollment patients recieving PVI, in order to further validate the association between LAP and atrial function; 2. enroll patients recieving concomitant LAAC, to investigate the impact of LAAC on LAP; 3. complete follow-up and evaluate the prognositc value of LAP.

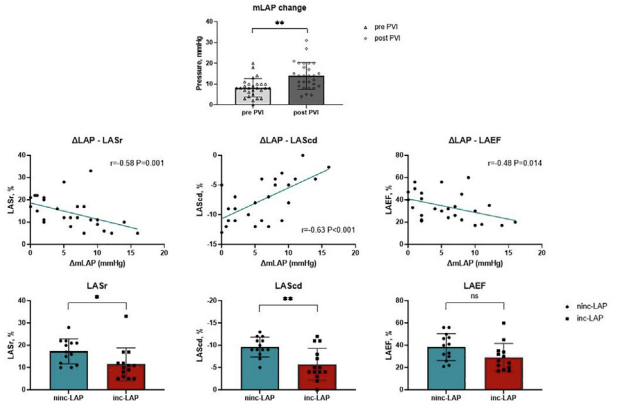

Figure: Change of left atrial pressure before and after PVI and its correlation with atrial function

PO-05-214

EVALUATION OF 3D CURVATURE AND LEAD STRESS OF TRANSVENOUS RIGHT VENTRICULAR LEADS: THE HUMAN USE CONDITIONS STUDY (HUCS)

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Introduction: Transvenous leads are meant to last the life of the patient, but they are at risk for conductor fatigue fracture from applied alternating stress. This stress depends on lead design and clinical use conditions. Present engineering standards for

preclinical testing do not relate test conditions to use conditions because stresses during clinical use are not well known. Stress is proportional to lead curvature (C, inverse radius of curvature). HUCS is the first large study to measure C in humans. Lead stiffness varies along each lead with changes in lead elements and transition points. HUCS was powered to examine the correlation between local lead stiffness and maximum alternating C ($C_{A\ max}$).
Methods: HUCS was a prospective, observational, multicenter clinical study. Four leads of widely varying stiffness (2 tachycardia and 2 bradycardia) were chosen with a target enrollment of 20 patients per lead. Leads were imaged with biplane cinefluoroscopy, and lead contours were traced for 3 regions: extravenous region (EVR, **Fig A**, in red), connector region (CNR), and intracardiac region (ICR). The EVR and CNR were imaged during arm motion. The ICR was imaged for multiple cardiac cycles. After 3-D reconstruction of images, $C_{A\ max}$ was determined as a function of distance along the lead. Stiffness was measured in bench testing for each lead element and transition point. **Fig B** plots $C_{A\ max}$ as a function of distance in the EVR of Fig A. We fitted a log-linear model, treating log ($C_{A\ max}$) as the outcome and stiffness as the predictor: log ($C_{A\ max}$) = a*stiffness + b+ normally distributed error.
Results: Across all 117 enrolled subjects, $C_{A\ max}$ was greatest in the EVR ($p<2x10^{-16}$, **Table**). On a per-subject basis, the region in which the greatest $C_{A\ max}$ occurred was EVR in 65.3%, CNR in 19.4%, and ICR in 15.3%. The correlation between $C_{A\ max}$ and stiffness was highly significant (a=-0.067, 90% CI [-infinity to -0.046], **Fig C**), but there is considerable scatter in the plot.
Application: HUCS is the first large study to measure alternating stresses applied to transvenous leads in clinical use. The greatest alternating stress occurs in the extravenous region. Alternating stress correlates inversely with local lead stiffness, but other factors (e.g., implant technique, anatomy, motion) also determine stress.
Next Steps/Future: The quantitative results of this study will be used to develop a new standard for preclinical testing of conductor fatigue-fracture based on human use conditions.

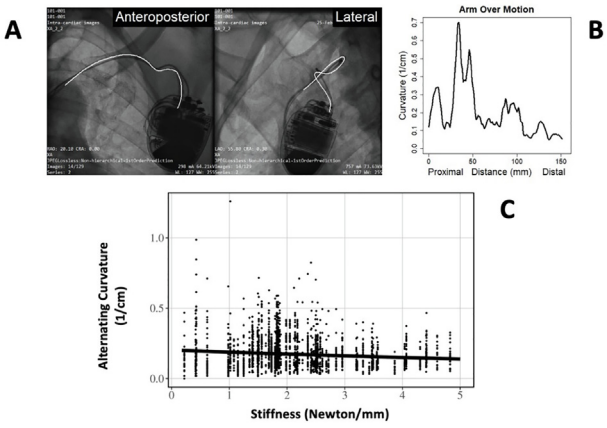

TABLE: Maximum Alternating Curvature (CA max) vs. Anatomic Region

Region	CA max (1/cm)
Connector	0.307 ± 0.202
Extravascular	0.645 ± 0.352*
Intracardiac	0.253 ± 0.155

* $p<0.0001$ vs. connector and intracardiac regions.

PO-05-215

RANDOMIZED COMPARISON OF RF ABLATION WITH ABLATION INDEX TECHNOLOGY AND ADENOSINE ADMINISTRATION VERSUS CRYOBALLOON ABLATION FOR PAROXYSMAL ATRIAL FIBRILLATION

Lisa W. Leung; Pavandeep Toor; Zaki Akhtar; Abhay Bajpai; Zia Zuberi; Anthony Li; Mark Norman; Manav Sohal and Mark M. Gallagher

Introduction: Prior scientific evidence shows that radiofrequency catheter ablation utilising Ablation Index (AI) technology and following the CLOSE protocol with ≤6mm inter-lesion distance achieved similar clinical outcomes to standard cryoballoon ablation for paroxysmal atrial fibrillation (AF). Adenosine administration following pulmonary vein isolation is associated with a greater freedom from atrial arrhythmias during post ablation follow up but this has not been previously studied or incorporated in randomized trials. Both methods of ablation are routinely used in standard care.
Methods: A single centre, prospective, single-blinded randomized trial was conducted to compare radiofrequency ablation with Ablation Index technology and adenosine administration versus 2nd generation cryoballoon ablation for the treatment of paroxysmal AF. Participants were randomized in a 1:1 manner to RF with AI and Adenosine or to receive cryoballoon ablation. In the RF group, ablation was point by point with Smart Touch Surround Flow (STSF) and Ablation Index targets (350-450), and an inter-lesion distance of ≤6mm. Adenosine was administered to assess dormant conduction and if further ablation lesions were to be applied for durability. In the cryoballoon group, ablation was with either the 23 or 28mm Arctic Front 2nd generation cryoballoon. There was no waiting period or adenosine provocation in the cryoballoon group. Patient and procedure metrics were measured. Acute and 12-month outcomes were recorded.
Results: At the time of writing, total recruitment is n=58, with 31 randomized to RF group and 27 to cryoballoon ablation. There was no significant difference in the patient baseline parameters including use of direct oral anticoagulants and anti-arrhythmic medications (p=ns). The RF group had significantly lower fluoroscopy time (14.1 +/-6.1 min vs 20.1+/-10.9 min; p=0.01) but increased procedure duration compared to the cryoballoon group; $p<0.0001$. Both methods were equally safe with low reattendance during the blanking period, repeat ablation rates and similar freedom from atrial arrhythmias at 12 months (p=ns).
Application: Further investigation is underway in this RF versus cryoballoon study to understand how current RF techniques perform compared to cryoballoon ablation for the treatment of paroxysmal AF.
Next Steps/Future: Further participant recruitment is expected to meet the power calculations of this study.