Methods: In a first-in-human multicenter single-arm trial of paroxysmal AF ablation, after informed consent and under general anesthesia, ICE-guided transseptal puncture was performed. Through a custom 19 Fr deflectable sheath, the multielectrode spherical array PFA catheter (Globe; Kardium Inc, Canada) was advanced into the left atrium and deployed to its full spherical shape. Using the custom mapping system (GPS; Kardium Inc), the PFA catheter rendered anatomic maps with ostial tags, using contact maps based on blood flow detection. The PFA catheter was positioned at each PV ostium for PVI (1.6-2 kV/application; typically ungated - 3 sec. PV entrance and exit block were assessed. Post-procedure endoscopy (EGD) and brain MRI occurred within 5 days.

Results: At a single center, a total 11 PAF pts (age 62.8 ± 13.0 yrs; M / F 5 / 6; LVEF 55 ± 8.1%; LA 41.5 ± 5.8 mm) underwent PVI. Using typically just one application per vein, PVI was acutely successful in 43 of 43 (100%) PVs in 11 of 11 pts (100%). The total pulse delivery period for each patient was 24 ± 5 seconds (range: 15 - 36 seconds). The PVI duration time (transpired from 1st to last lesion) was 30.6 ± 6.3 min (range 22.6- 42.5). The total LA catheter dwell time for the PFA catheter was 51 ± 7 min (range 42 - 66). There were no safety events - including no esophageal fistula, stroke/TIA, phrenic injury or tamponade. EGD in was normal in 4 of 4 pts. Brain MRI was normal in 6 of 7 pts; one pt had DWI+/FLAIR- lesions.

Conclusion: In this first-in-human study, the "single-shot" map-and-ablate spherical array PFA catheter was able to safely and effectively isolate PVs to treat paroxysmal AF.

PO-624-02

ELECTRIC CURRENTS IN PULSED FIELD ABLATION: IMPLICATIONS FOR CATHETER DESIGN, SAFETY AND EFFICACY

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Background: Various novel catheter designs are in development for Pulsed Field Ablation (PFA). It is unclear if they differ substantially in terms of safety and efficacy. We previously reported on circular catheters and balloons, but not on a nitinol cage sphere (9mm) nor a penta-spline basket-flower design.

Objective: To compare catheter designs using (1) efficacy: power delivered to a predefined atrial wall target, as a fraction of total delivered power; and (2) safety: electrode current density to achieve 90% transmurality, (a surrogate of bubble generation), given electrochemical laws relating electric current to electrolytic gas release.

Methods: Using a CT derived computer model, the following catheter designs were compared: penta-spline basket, 9 mm nitinol cage sphere, circular decapolar, balloon, and flex-circuit ball catheter. Energy magnitudes and delivery configurations were per publications. Target was a 6 x 47 mm circumferential slab of atrial wall at LPV antrum, with electrodes in contact with myocardium. 100% transmurality was defined conservatively as entire target having >600 V/cm electric field needed for irreversible electroporation.

Results: Efficacy ratios were 2.1, 0.6, 4.7, 12.1, and 9.8 % for the penta-spline basket, 9 mm nitinol sphere, decapolar, balloon, and flex-ball catheters, respectively. Regarding safety, the current densities (surrogate for bubble generation) were 434,140, 93, 33, and 42 Amps/sq cm, respectively, with lower values meaning less gas production.

Conclusion: The safest and most efficacious catheters were those with less electrode exposure to atrial blood, by factors of up to 20X compared to exposed ones.

PO-624-03

MAGNETIC RESONANCE IMAGING FEATURES OF VENTRICULAR LESIONS AFTER PULSED FIELD ABLATION: PRECLINICAL INSIGHTS

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Background: Magnetic resonance imaging of pulsed field ablation (PFA) lesions in the ventricular myocardium has not been well characterized.

Objective: To evaluate the characteristics of late gadolinium enhanced (LGE) MRI after PFA delivery in healthy and infarcted ventricles.

Methods: Seven swine (5 post-infarct [5 weeks after myocardial infarction induced by balloon occlusion of the LAD] & 2 healthy animals) underwent endocardial (5) or epicardial (2) ventricular PFA under general anesthesia. Pulses (2 kV) were delivered using an 8 Fr focal PFA catheter (Farapoint, Boston Scientific) in bipolar/biphasic mode to the: 1) endocardium over healed infarcts and adjacent healthy myocardium, and 2) over the epicardium in healthy swine. All animals underwent 3.0T MRI
ventricular summit VAs, and 7 had scar-mediated VAs. Double or triple balloons were used in the coronary veins. Advanced strategies for ethanol delivery include use of secondary balloons to (1) block collateral flow in a target vein (2) block collateral flow into a non-target vein (3) cannulate collaterals to reach a target vein that is not easily accessible via its ostium (4) serve as a distal mechanical block to facilitate more proximal vein cannulation and (5) occlude the coronary sinus to allow ostial delivery of ethanol in a branch vessel.

Results: Successful ethanol infusion was accomplished in the following target veins: LV annular (n = 2), septal (n = 6), lateral (n = 1), middle cardiac (n = 1), anterolateral (n = 2) and posterolateral (n = 3). At median follow up of 130.5 days, no patients experienced recurrences.

Conclusion: Utilization of collaterals between non-target and target veins can facilitate ethanol delivery with the multiple balloon technique. Understanding of CS venous anatomy and advanced approaches to balloon deployment may increase the efficacy of venous ethanol for treatment of VAs.

PO-624-05
MULTI-PROGRAMMABLE COHERENT SINE BURST ELECTROPORATION WAVEFORM FOR ATRIAL AND VENTRICULAR CATHETER ABLATION: A FEASIBILITY STUDY
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Background: Traditional pulsed field ablation (PFA) energy is typically delivered via a square wave. Direct current can cause muscle stimulation (MS) and electrolysis. Circuit designs also limit peak voltage, which may impact the ability to achieve transmurality throughout the atrium and ventricle.

Objective: Test the feasibility of using a multi-programmable Coherent Sine burst Electroporation (CSE) waveform to achieve a titratable range of lesion depths that address the variability of tissue thickness within the atrium and ventricle.

Methods: A PFA waveform using a sinusoidal delivery has been developed. The CSE waveform is designed to minimize muscle stimulation and increase peak voltage availability. The CSE waveform allows the user to select target voltage, number of sine waves/pulses, delay between pulses, cycle length (pulse + delay), number of cycles in a burst, and proportion of bipolar to unipolar energy delivered. Three (3) anesthetized swine underwent CSE PFA ablation in the left ventricle (LV) using a test catheter and generator capable of varying the parameters listed above. An accelerometer was secured around the diaphragm to measure MS. Lesions were delivered in discrete locations throughout the LV. An oscilloscope was used to confirm peak energy delivery. Animals were sacrificed 4-8d after ablation. Gross pathological exam and histology was performed. Depth