B-LBCT01
Late-Breaking Clinical Trials and Registry

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B-LBCT01-01
SAFETY AND EFFICACY OF PERIPROCEDURAL DIRECT ORAL ANTICOAGULANT VERSUS ASPIRIN USE FOR REDUCTION OF THE RISK OF CEREBROVASCULAR EVENTS IN PATIENTS UNDERGOING VENTRICULAR TACHYCARDIA RADIOFREQUENCY CATHETER ABLATION (STROKE-VT)

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Introduction: Ablation of the left ventricle (LV) during ablation of ventricular tachycardia and premature ventricular contraction (PVC) can cause significant endocardial denudation and become a source systemic thromboembolization. So we studied if Direct Oral Anticoagulants (DOACS) are better than Aspirin (ASA) in reducing cerebrovascular events (CVE) in patients undergoing left ventricular arrhythmia (LVA - ventricular tachycardia (VT) or premature ventricular contraction (PVC)) using radiofrequency ablation (RFA).

Methods: 246 patients (from 4 centers) scheduled for LVA-RFA were 1:1 randomized post procedurally to receive DOAC or ASA. VT ablation was performed under moderate sedation or general anesthesia through retrograde aortic (n=98) or transseptal (n=148) approach. The study drug was administered 3 hours after hemostasis. A brain MRI was done within 24 hours and at 30 days. NIH stroke scale was used to assess neurological changes before, after, and at 30 days follow-up.

Applications: The baseline characteristics, in-room ablation characteristics and procedural times were similar between the two groups. There were significantly lower procedure-related complications in the DOAC arm than the ASA arm (24% vs. 3.7%; p<0.001). Post-procedure CVE (TIA and stroke) were lower in the DOAC arm versus ASA arm (4.5% vs. 19.6%, p<0.001 and 0 vs. 7.1%, p<0.001; respectively). Similarly, asymptomatic CVE (at 24 hours and 30 days) on MRI were lower in DOAC arm versus ASA arm (11.2% vs 25%, p=0.006 and 6% vs 19.6%, p=0.001; respectively). There was no significant difference in terms of in-hospital mortality between the two groups.

Next Steps/Future: DOAC utilization following endocardial/epicardial ablation for LVA-RFA was associated with reduced risk of a cerebrovascular event (both transient ischemic attack or stroke), and MRI detected asymptomatic cerebrovascular event. This risk seems to be significantly higher in patient undergoing VT ablation, retrograde aortic access, long procedural time and low EF.

B-LBCT01-02
A RANDOMIZED PILOT STUDY OF PERIOPERATIVE SPINAL CORD STIMULATION TO PREVENT POST-CABG ATRIAL FIBRILLATION: 30-DAY SAFETY AND EFFICACY OUTCOMES

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Introduction: Spinal cord stimulation (SCS) has been shown to be effective in the treatment of chronic pain and intractable angina pectoris. Recently, animal studies have demonstrated that SCS can also suppress atrial fibrillation (AF).

Methods: Fifty two patients with indications for coronary artery bypass grafting (CABG) and history of paroxysmal AF were randomized to 2 groups: CABG plus standard medical therapy (MED) with beta-blockers (n=26, Control group) and CABG plus MED plus percutaneous lead placement for temporary SCS (n=26, SCS group). In the SCS group under local anesthesia and with fluoroscopic guidance, temporary leads were placed at C7-T4 level according to patient’s sense of paresthesia and connected to a SC stimulator externally fixed on patient’s chest. Temporary SCS was begun 3 days before elective CABG, deactivated during surgery, reactivated in the intensive care unit after CABG, and continued for 7 days at which time the leads were removed. Continuous external ECG monitoring was performed for 30 days after CABG in all patients. These primary objectives were
tested over the 30-day postoperative period: 1) occurrence of adverse events, including death, stroke or TIA, myocardial infarction and kidney injury; and 2) occurrence of AF or any atrial tachyarrhythmia lasting ≥ 30 seconds.

Applications: Percutaneous lead placement for temporary SCS was successfully performed in all 26 patients before CABG without any complications. There were no adverse events related to temporary SCS in any patient throughout follow-up. There were no adverse events related to temporary SCS in any patient throughout follow-up. There were no significant differences in CK-MB and creatinine levels between groups (p=0.1 and 0.2, respectively) as well as other typical CABG-related complications (p>0.05). Postoperative AF occurred in 8 (30.7%) of 26 patients in the Control group versus only 1 (3.8%) of 26 patients in the SCS group (p=0.012, log-rank test, Figure).

Next Steps/Future: Temporary SCS was effective in suppressing postoperative AF after CABG without any adverse events in this randomized pilot study (NCT 03539354). Further studies of SCS with larger samples are indicated to test its clinical value as a perioperative intervention.

CLINICAL OUTCOMES OF LEFT BUNDLE BRANCH AREA PACING COMPARED TO RIGHT VENTRICULAR PACING: RESULTS FROM THE GEISINGER-RUSH CONDUCTION SYSTEM PACING REGISTRY

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Introduction: Right Ventricular pacing (RVP) is associated with heart failure (HF), mortality and need for upgrade to biventricular cardiac resynchronization (CRT). Left bundle branch area pacing (LBBAP) has recently shown to be a safe and effective option for patients needing ventricular pacing. The aim of this study was to compare clinical outcomes between LBBAP and RVP among patients undergoing pacemaker implantation.

Methods: This observational registry included consecutive patients who underwent de novo permanent pacemaker implantations with LBBAP or RVP for bradycardia indications between April 2018 to Oct 2020 at the Geisinger Health System and Rush University Medical Center. Patients undergoing defibrillator, CRT implantation and those with an LVEF ≤ 35% were excluded. Patient and procedural characteristics, ventricular pacing burden, HF hospitalization, echocardiographic data, mortality and lead complications were assessed. The primary outcome was the composite endpoint of death from any cause, HF or upgrade to biventricular pacing. Secondary Outcomes included the composite endpoint among patients with higher burden of ventricular pacing and each component of the primary outcome.

Applications: A total of 693 patients met inclusion criteria (313 LBBAP and 380 RVP, Figure 1A). Mean age was 75 ± 12 yrs, female 48%, HTN 87%, DM 35%, CAD 48% and LVEF 59.3 ± 7%. LBBAP thresholds (V @ 0.4ms) were similar to RVP (0.63 ± 0.31 vs 0.6 ± 0.29, p = 0.3) at implant and remained stable during mean f/u of 21 ± 9 months (Figure 1B). Paced QRSd (ms) in LBBAP was similar to baseline (121 ± 23 vs 117 ± 31, p = 0.302) and significantly narrower compared to RVP (121 ± 23 vs 141 ± 36, p < 0.001). The primary composite outcome was significantly lower in the LBBP group (9.6%) vs RVP group (22.9%) (HR 0.55, p = 0.005) (Figure 1C). The secondary endpoints between the groups will be presented.

Next Steps/Future: LBBAP results in improved clinical outcomes when compared to RV pacing in this large cohort. Insights from this study will help understand the drivers for the differences between the 2 groups. Randomized controlled trials comparing LBBP to RVP will be necessary in this population.
Introduction: Randomized trials in early catheter ablation have not enrolled patients with nonischemic cardiomyopathy. There is a paucity of data on sudden cardiac death prevention strategies across Asia, where a lower prevalence of postinfarction ventricular tachycardia (VT) has been observed, amongst the most populous continent.

Methods: We conducted an international, multi-center, randomized controlled trial enrolling 121 patients with structural heart disease (ejection fraction <50%) and monomorphic VT with an indication for implantable defibrillator therapy to assess the impact of early first-line ablation therapy. Patients were randomly assigned (1:1) to ablation within 90 days of ICD implantation versus medical therapy. Use of antiarrhythmic therapy and epicardial approach were discretionary. Patients that refused ICD therapy were followed in a prospective registry after stand-alone ablation treatment. The primary outcome was a composite of VT recurrence, cardiovascular hospitalization, and death.

Applications: Randomized patients were 81% male, age 55 (IQR 46-64), EF 40% (IQR 30-49%) and the etiology of cardiomyopathy was 35% ICM, 30% NICM, 35% ARVC. Ablation was performed median 2 days prior to ICD implantation (IQR 5 days prior-14 days after). During a median 18 months follow-up, the primary outcome occurred in 49% of patients that underwent ablation and 66% in those managed with medical therapy (hazard ratio 0.59, 95% confidence interval, 0.35-0.97; P=0.036). No difference in amiodarone usage was observed between ablation and medical arms (33% vs. 36%; p=0.55). Ablation registry patients sans ICD had higher freedom from recurrent VT compared to medical therapy without significant differences in mortality. There were 8% procedural-related complications in the ablation group.

Next Steps/Future: In this randomized trial involving patients with structural heart disease of varied etiologies and monomorphic VT, early first-line catheter ablation significantly reduced the composite primary outcome of VT recurrence, CV hospitalization, and death. (PAUSE-SCD ClinicalTrials.gov number, NCT02848781)