Background: The implantation of a leadless right ventricular pacemaker (LPM) may be complicated by tricuspid valve injury or interference with tricuspid valve function.

Objective: Characterize the nature, causes, and outcomes of tricuspid valve injury and functional interference due to LPM implantation.

Methods: The Food and Drug Administration’s Manufacturers and User Facility Device Experience (MAUDE) database was queried for tricuspid valve adverse events involving the Medtronic Micra LPM that were reported by the manufacturer.

Results: From 2016-October 2021, 19 patients suffered a tricuspid valve adverse event, including damage to the leaflets, papillary muscle, or chordae tendineae (n = 14; 74%); interference with valve closure (n = 3; 16%); and 2 LPMs were irretrievably wedged in the tricuspid valve apparatus.

Damaged valves included: 1) torn leaflet or chordal tissue found in the delivery system (n = 6) after complicated or failed LPM recapture that necessitated removal without the LPM retracted into the delivery system; all patients developed tricuspid regurgitation, and one patient died. 2) valve damage by the delivery system either directly (n = 6) or during LPM recapture (n = 1) or removal by a snare (n = 1): all patients had new or worsening tricuspid regurgitation; one patient died, 2 had valve repair, and one valve was replaced. In three patients the LPM interfered with valve function; one had valve replacement, one underwent LPM removal, and one was treated medically. Of the 2 LPMs wedged in the tricuspid valve apparatus, one required surgical removal and one was abandoned.

Conclusion: Tricuspid valve trauma during LPM implantation may cause significant regurgitation that results in poor outcomes and requires medical or surgical intervention. Mechanisms include direct valve injury by the delivery system, complications of attempted LPM recapture, and LPM interference with valve function.

PO-632-02

GUIDELINE DIRECTED MEDICAL THERAPY AND THE RISK OF DEATH IN PRIMARY PREVENTION DEFIBRILLATOR RECIPIENTS

Mehek Dhande MD; Gautam Rangavajla MD; Ann Canterbury BS; Floyd Thoma BS; Suresh Mulukutla MD; Konstantinos N. Aronis MD, PhD; Aditya Bhonsale MD; Krishna Kancharla MBBS; Alaa Shalaby MD, FHRS; David Newhouse BS; Floyd Thoma BS; Suresh Mulukutla MD; Konstantinos N. Aronis MD, PhD; Aditya Bhonsale MD; Krishna Kancharla MBBS; Alaa Shalaby MD, FHRS; Mark Estes MD, FHRS, CCDS; Sandeep K. Jain MD, FHRS and Samir F. Saba MD, FHRS

Background: Primary prevention implantable cardiac defibrillators (ICD) are indicated in patients with heart failure and severely reduced ejection fraction (EF). Quadruple guideline-directed medical therapy (GDMT) with ACE inhibitors/ARB/ARNI, beta-blockers, aldosterone antagonists, and SGLT-2 inhibitors is indicated in this population.

Objective: To investigate the impact of number of GDMT medications prescribed at the time of device implantation on all-cause mortality at one year in primary prevention ICD recipients.

Methods: We analyzed data from 4,972 ICD and cardiac resynchronization therapy ICD (CRT-D) recipients at our institution, based on the sum of GDMT medications prescribed. We examined mortality using Cox multivariable models adjusting for age, EF, and the Elixhauser comorbidity score.

Results: Our cohort had 5%, 20%, 52%, 22%, and 1% of patients prescribed 0, 1, 2, 3, or 4 GDMT, respectively. In the multivariable models, use of each additional GDMT conferred a 41% reduction in the risk of death in ICD recipients (adjusted HR = 0.59, p < 0.001) (Figure 1A) and a 30% reduction in the risk of death in CRT-D recipients (adjusted HR = 0.70, p = 0.006) (Figure 1B). Among patients on quadruple GDMT, 1-year mortality was 2% in ICD and 0% in CRT-D recipients.

Conclusion: A higher number of prescribed GDMT at the time of device implantation is associated with better longevity in primary prevention ICD recipients with or without CRT. Initiation of maximum tolerated GDMT medications should therefore be the goal in these patients. In the setting of optimal GDMT, the survival benefit of primary prevention ICD warrants re-examination in future studies.

PO-632-03

COMORBIDITIES, CLINICAL OUTCOMES AND PREDICTORS OF COMPLICATIONS IN PATIENTS WITH LEADLESS PACEMAKER

Faris Haddadin MD; Monil Majmundar; Robert Pecha MD; Claire Scott; Marilyn Daher; Soufian AlMahameed MD, FHRS; Christopher V. DeSimone MD, PhD, FHRS; Yong-Mei Cha MD, FHRS; Siva K. Mulpu MD, FHRS; Kenneth A. Ellenbogen MD, FHRS; Mohammad Saeed MD; Mihail G. Chelu MD, PhD, FHRS and Abhishek J. Deshmukh MBBS, MD, FHRS

Background: Leadless pacemakers have emerged as a viable alternative for traditional transvenous pacemakers to reduce the risk of device-related complications.

Objective: This study aimed to examine the real-world clinical outcomes and complications associated with implantation of leadless pacemaker devices.

Methods: Using the National Readmission Database, we examined patient demographics, in-hospital, and 30-day procedural outcomes after leadless pacemaker implantation from 2016-2018. Our cohort was comprised of all adults (≥18 years) with an ICD-10 procedural code for leadless pacemaker implantation.

Results: Our cohort included a total of 7,821 patients that underwent leadless pacemaker implantation. Pericardial effusion without the need for pericardiocentesis occurred in 1.9% of patients, while pericardiocentesis was performed in 1.0%. Vascular complications occurred in 2.3% of patients. The most significant predictor for procedural complications was end-stage renal disease (OR 2.36, 95% CI 1.56-3.56, P = 0.002), chronic liver disease (OR 2.08, 95% CI 1.32-3.28, P = 0.019), coagulopathy (OR 1.57, 95% CI 1.08-2.29, P > 0.001), and female gender (OR 1.45, 95% CI 1.07-1.97, P > 0.001). All-cause readmission occurred in 17.9% of patients within 30 days from implantation.
device implant, with 1.36% of readmissions being procedural related. At 30 days post-implant and after discharge, 0.25% of patients needed a new pacemaker and 0.18% had pericardial complications.

**Conclusion:** We found the rate of complications related to leadless pacemakers placement to be slightly higher than post-approval registry studies, but the rate of serious complications remained relatively low in a high-risk population with multiple comorbid conditions.

**PO-632-04**

**PATTERNS OF DEVICE-RELATED INFECTION IN DE NOVO TRANSVENOUS IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR MEDICARE PATIENTS WITH UNDERLYING RENAL DISEASE**

Mikhael F. El-Chami MD, FHRS; Yiyan Liu; Amy Brisben CCDS and Robert Griffiths

**Background:** Renal disease is a risk factor for device infection in transvenous implantable cardioverter-defibrillator (TV-ICD) implants.

**Objective:** Since chronic dialysis treatment for advanced renal disease creates a portal of entry for bacteria that can seed indwelling devices, we hypothesized that infection risk could accelerate after TV-ICD implantation in renal patients, especially dialysis dependent (DD) patients.

**Methods:** Medicare 100% administrative and claims data were used to identify patients who underwent de novo TV-ICD implantation (7/2016-12/2018). Patients were followed up to 540 days post implantation. Baseline characteristics, including renal disease (none; renal-non-DD; and renal-DD), and device infection during follow-up were identified using claims diagnosis and procedure codes. Statistical analysis consisted of Poisson regression with restricted cubic splines, followed by plotting predicted hazard ratios (HR) for TV-ICD infection in renal-non-DD and renal-DD patients to identify changes in infection risk over time.

**Results:** 42,200 TV-ICD patients were included (9,151 [22%] renal-non-DD; 1,832 [4%] renal-DD), with 809 (2%) leads infections. 64/82 leads that failed underwent explanation/extraction and replacement; we abandoned and replaced the other 18 (22%). Kaplan Meier survival curve shows an overall lead survival rate of 98.5% at 10 years, with no difference between manufacturers in unadjusted analyses. Multivariate analysis identifies younger patient age at implant as an increased risk of failure (OR = 1.03 per year younger age at implant, 95% CI 1.01-1.04).

**Conclusion:** The risk of infection following TV-ICD implantation is significantly higher in patients with underlying renal disease and increases over time, particularly in patients who are dialysis dependent.

**PO-632-05**

**LONG-TERM FOLLOW-UP ON PERFORMANCE OF SINGLE-CONNECTOR (DF4) IMPLANTABLE DEFIBRILLATOR LEADS: EXPERIENCE FROM A SINGLE TERTIARY CARE/REFERRAL CENTER**

Rand Ibrahim MD; Mounir Al-Gibbawi MD; Neal Kumar Bhatia MD; Soroosh Kiani MD, MS; Stacy B. Westerman MD, MPH; Anand D. Shah MD; Michael S. Lloyd MD, FHRS; David B. De Lurgio MD, FHRS; Anshul M. Patel MD, FHRS; Christine Tompkins MD, FHRS; Angel R. Leon; Faisal M. Merchant MD, FHRS and Mikhael F. El-Chami MD, FHRS

**Background:** Single-connector (DF4) defibrillator electrodes, introduced 10 years ago, eventually became the predominantly implanted trans-venous ICD leads. Assessment of their long-term performance comes primarily from manufacturer database analyses.

**Objective:** We describe the long-term performance of DF4 defibrillator leads in a cohort of patients implanted and followed in a single tertiary-care referral center.

**Methods:** A review of device interrogation reports in 5284 patients who received DF4 leads between 2011 and 2021 determined the frequency of lead-related abnormalities. We defined failure/malfunction as an electrical abnormality requiring revision to address a sudden increase (>2X) in stimulation threshold, a discrete jump in high-voltage impedance, or sensing of non-physiologic intervals or noise. We documented time to failure and the management for electrodes supplied by Boston Scientific, Medtronic, and St. Jude/Abbott.

**Results:** The cohort included 33.8% women with a mean age at implant 60.6 years [95% CI 46.3-74.8]. The patients received an average of 2.0 ICD leads. We followed them for 3.0 years [0.2-5.9]; 30% of them for > 5 years. 82 (1.6%) leads demonstrated electrical abnormalities requiring revision. 64/82 leads that failed underwent explanation/extraction and replacement; we abandoned and replaced the other 18 (22%). Kaplan Meier survival curve shows an overall lead survival rate of 98.5% at 10 years, with no difference between manufacturers in unadjusted analyses. Multivariate analysis identifies younger patient age at implant as an increased risk of failure (OR = 1.03 per year younger age at implant, 95% CI 1.01-1.04). Cox-regression models adjusted for age at implant, gender, and the presence of additional leads, identifies Abbott leads as developing a