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 irretrievably wedged in the tricuspid valve apparatus. 2) Valve damage included: 1) torn leaflet or chordal tissue irretrievably wedged in the tricuspid valve apparatus; 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

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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

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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 2.9% 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