Tricuspid valve complications during leadless pacemaker implantation

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

Purpose: 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 closure; one patient 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 difficult or unsuccessful LPM recapture, and LPM interference with valve function.