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Letters

RESEARCH CORRESPONDENCE

Mitral Valve-in-Ring Implantation With a Dedicated Transcatheter Mitral Valve Replacement System

Mitral valve-in-valve implantation can be performed in a reliable fashion with excellent short- and mid-term results (1). However, the outcome of transcatheter mitral valve-in-ring (TMVIR) replacement using transcatheter aortic valve replacement devices has been far less predictable (2,3). Problems specific to TMVIR have included left ventricular outflow tract obstruction (LVOTO), limited large transcatheter aortic valve sizes, valve malpositioning, embolization, and significant paravalvular leak in flexible and incomplete annuloplasty rings. We report 3 successful TMVIR cases using a novel TMVR system to treat failed mitral valve repair with annuloplasty rings.

The Tiara transapical mitral implantation (TAMI) system (Neovasc, Richmond, BC, Canada) is a transapical TMVR system for native mitral regurgitation (4,5). The saddle-shaped Tiara bioprosthesis is a nitinol, self-expanding, bovine pericardial device. Valve fixation by 2 anterior tabs and a posterior tab that anchor onto the fibrous trigone and posterior shelf of the annulus. The anterior tabs capture the anterior leaflet to prevent systolic anterior motion and LVOTO.

Table 1 summarizes patient demographics and preoperative data. All cases were reviewed by the heart team, and the Tiara devices were implanted under the Canadian Special Access and Italian Compassionate Use programs.

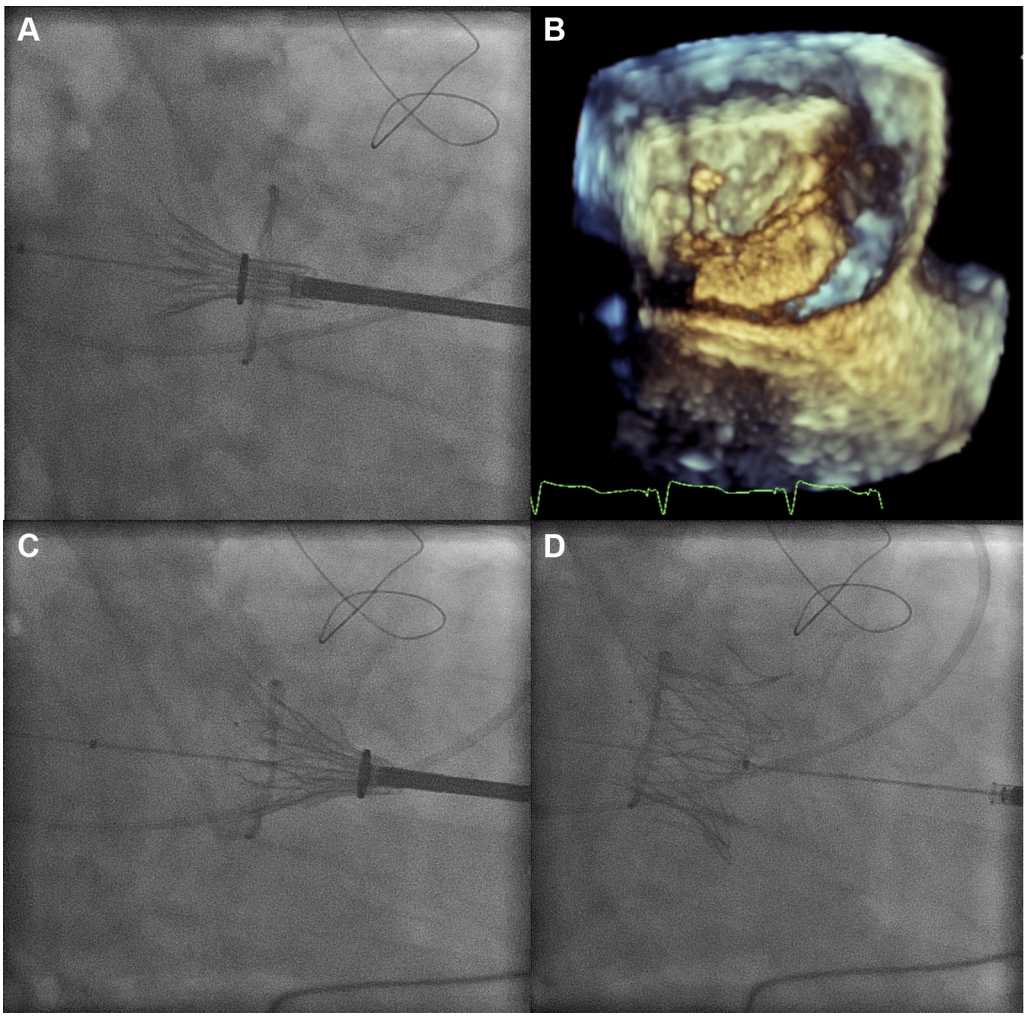
Tiara implants were performed in the hybrid room under general anesthesia with fluoroscopic and transesophageal echocardiographic (TEE) guidance. Pre-procedural cardiac computed tomography imaging provides invaluable information regarding sizing,

TABLE 1 Patients' Baseline Pre-Operative Data

	Patient		
	#1	#2	#3
Clinical characteristics			
Age, yrs	81	74	68
Sex	Male	Male	Male
Body mass index, kg/m^2	29.1	24.4	24.8
Diabetes	No	No	No
Hypertension	Yes	No	No
Chronic obstructive pulmonary disease	No	No	No
Chronic atrial fibrillation/atrial flutter	Yes	Yes	Yes
Coronary artery disease	No	No	Yes
Previous coronary artery bypass grafting	No	No	No
Previous aortic valve replacement	No	No	Yes
Previous mitral valve repair/ring placement	Yes	Yes	Yes
Creatinine, mg/dl	1.1	1.43	1.9
NYHA functional class	III	III	III
Echocardiographic data			
LVEF, %	30	29	35
Mitral regurgitation	Severe	Severe	Severe
Pulmonary artery systolic pressure, mm Hg	63	55	55
Logistic EuroSCORE-II, %	16.2	6.4	9.4
STS risk score, %	7.2	4.8	5.8
Annuloplasty ring/size, mm	Medtronic Duran/29	Medtronic FutureBand/34	Sorin 3D Memo/34

Values are %. The manufacturers listed above are from Medtronic, Minnesota (Sorin Group, Saluggia, Italy).
LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

FIGURE 1 Tiara Implantation Procedure



(A) Transcatheter mitral valve-in-ring implantation (Tiara into a Medtronic Duran ring): opening of the atrial skirt. **(B)** Anatomic orientation to the native mitral valve with 3-dimensional transesophageal echocardiography. **(C)** Atrial skirt seating and deployment of ventricular anchors. **(D)** Full deployment. TAMI = transapical mitral implantation.

incision, LV access sites and implant projection. A left anterior mini-thoracotomy was performed followed by hemostasis sutures over the left ventricle. The delivery system was then advanced across the mitral valve into the left atrium over a guidewire, followed by the unsheathing of the atrial portion of the Tiara. The annuloplasty rings were well-defined by fluoroscopy and greatly aided the positioning and deployment process. TEE was used to guide the anatomic rotation of the saddle-shaped Tiara to match the native mitral anatomy. Following atrial skirt seating onto the mitral annulus, the ventricular tabs and skirt were then released on a beating heart without the aid of cardiopulmonary bypass. Ventricular tabs captured both the anterior and posterior mitral leaflets, and anchored the Tiara onto the mitral annulus (Figure 1).

All patients underwent uneventful TMVIR implantation with the 35-mm Tiara device. There was no surgical mortality, cerebrovascular accident, transfusion, or reintervention in any patient. At discharge, the echocardiogram demonstrated a well-positioned device with excellent function, a mean trans-mitral gradient of 2.3 ± 0.6 mm Hg, no LVOTO, and trace paravalvular mitral regurgitation in 1 patient. All patients were discharged home a few days post-implant

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with marked symptomatic improvement at 30-day follow-up.

Despite the impressive long-term results of MV repair, repair failure can occur. The morbidity and mortality associated with reoperative mitral surgery can be substantial. Transcatheter modality may well be the solution for some of these patients. However, the result of TMVIR is less encouraging, with frequent valve migration, embolization, paravalvular leak, and LVOTO. Experience with large, incomplete, flexible annuloplasty rings has been disappointing. A mitral-specific TMVR system might facilitate positioning, fixation, and sealing, while incorporating features designed to reduce the potential for LVOTO.

Our experience demonstrates the feasibility and excellent early clinical and hemodynamic outcomes that can be achieved in patients with failed repair with large, flexible and incomplete rings using the Neovasc Tiara TAMI system.

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Please note: Dr. Cheung has been a consultant to Neovasc Inc., and St. Jude Medical; holds stock options from Neovasc; and is a principal investigator for the Tiara Early Feasibility Trial. Dr. Denti has been a consultant to Abbott, 4Tech, and InnovHeart. Dr. Kiaii has been a consultant for Medtronic, Johnson & Johnson, and Boston Scientific; a proctor for Medtronic and Boston Scientific; and a speaker to Johnson & Johnson. Dr. Webb has been a consultant to Edwards Lifesciences and St. Jude Medical. Dr. Latib has been on advisory boards of Medtronic and Mitraltech. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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RESEARCH CORRESPONDENCE

Transcatheter Treatment of Severe Tricuspid Regurgitation Using the Edge-to-Edge Repair Technique in the Presence and Absence of Pacemaker Leads

Tricuspid regurgitation (TR) is associated with significant morbidity and mortality (1). Recently, transcatheter edge-to-edge repair has been shown to be an alternative treatment option in selected patients with severe TR (2). Heart failure patients are frequently treated with cardiac pacemakers including resynchronization and implantable cardioverter-defibrillator devices. Therefore, the aim of this study was to assess the feasibility and safety of the edge-to-edge repair technique in inoperable patients with severe TR in the presence and absence of pacemaker leads (PL).

We analyzed 41 consecutive patients treated for primarily secondary symptomatic severe TR from March 2016 to April 2017 at the Munich University Hospital. Results of the first 18 patients have been reported previously (2). In 13 out of these 41 patients a transtricuspid valve PL, including implantable cardioverter-defibrillator leads, was present. Patients with PL were included if the latter was not the predominant reason for TR.

Clips were implanted using a modified steering technique as previously described (2). A "triple orifice technique," where clips are placed between the septal and anterior as well as the septal and posterior tricuspid leaflet, was used in most patients. Alternatively, a "bicuspidalization technique" was used, where clips are placed between the septal and anterior tricuspid leaflet.

Mean patient age was 79 ± 7 years with a Society of Thoracic Surgeons score of 7 ± 6. Most patients experienced pulmonary hypertension as expressed by a transtricuspid gradient of 38 ± 14 mm Hg. Two-thirds of patients were treated simultaneously for severe TR and severe mitral regurgitation (MR). Baseline characteristics did not differ between both groups except for a lower left ventricular ejection fraction in the PL group (51 ± 14 in the no-PL group vs. 39 ± 13 in the PL group; $p = 0.008$). The triple orifice technique was applied in 46% and 77% of patients in the no-PL and the PL group, respectively.