Transcatheter Mitral Valve Replacement for Native and Failed Bioprosthetic Mitral Valves

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ABSTRACT: Transcatheter mitral valve replacement (TMVR) is a novel approach for treatment of severe mitral regurgitation. A number of TMVR devices are currently undergoing feasibility trials using both transseptal and transapical routes for device delivery. Overall experience worldwide is limited to fewer than 200 cases. At present, the 30-day mortality exceeds 30% and is attributable to both patient- and device-related factors.

TMVR has been successfully used to treat patients with degenerative mitral stenosis (DMS) as well as failed mitral bioprosthesis and mitral repair using transcatheter mitral valve-in-valve (TMViV)/valve-in-ring (ViR) repair. These patients are currently treated with devices designed for transcatheter aortic valve replacement. Multicenter registries have been initiated to collect outcomes data on patients currently undergoing TMViV/ViR and TMVR for DMS and have confirmed the feasibility of TMVR in these patients. However, the high periprocedural and 30-day event rates underscore the need for further improvements in device design and multicenter randomized studies to delineate the role of these technologies in patients with mitral valve disease.

INTRODUCTION AND BACKGROUND

The prevalence of moderate or severe mitral regurgitation (MR) in the United States is between 2 and 2.5 million and is expected to reach 5 million by 2030.¹ The 2013 American College of Cardiology/American Heart Association and 2012 European Society of Cardiology guidelines recommend mitral valve (MV) surgery for severe symptomatic MR or asymptomatic MR with left ventricular (LV) dysfunction.^{2,3} However, large surveys in western populations⁴ have documented that only a small percentage of patients undergo potentially curative mitral surgery, whereas patients with advanced age, severe LV dysfunction, and comorbidities are typically denied surgery.⁵

The swift metamorphosis of transcatheter aortic valve replacement (TAVR) from an investigational technique for inoperable patients^{6,7} to an established therapy for severe aortic stenosis (AS)^{8,9} in intermediate- and high-risk subgroups has stimulated efforts to develop transcatheter approaches for treating MV disease. In addition, patients with degenerative mitral stenosis (DMS),¹⁰ a failed surgical mitral bioprosthesis,¹¹ and prior mitral repair also represent cohorts that may benefit from less-invasive alternatives to high-risk redo MV surgery. As a result, transcatheter MV replacement (TMVR) is the latest iteration of catheter-based strategies that attempts to fulfill the unmet need for percutaneous treatment of MV disease.

This review highlights the current nascent state of TMVR and summarizes relevant insights from the limited contemporary experience with this procedure in three patient cohorts: those with severe degenerative or functional MR, failed mitral bioprostheses or repair, and DMS.

TMVR FOR MITRAL REGURGITATION

An ideal transcatheter treatment for MR should accomplish the following objectives: (1) expand the patient population that can be offered a viable treatment, including patients with unacceptable risk for open surgery; (2) successfully treat the pathophysiology, including both primary and secondary MR; (3) provide lasting reduction and elimination of MR with no recurrence; (4) ideally be performed percutaneously without needing protracted general anesthesia or extracorporeal circulatory support (ECC); and (5) deliver the device with relatively simple access and closure to minimize the risk of major cardiac or vascular complications.

The fact that MV disease is undertreated worldwide along with the potential broad applicability of this new technology (in contrast to transcatheter mitral repair, which is feasible in only a limited number of patients) is driving interest in TMVR. However, a number of formidable challenges must be overcome in designing a device that targets the MV complex. Figure 1 enumerates some of the constraints in developing a successful TMVR device. At the time of this writing, at least

Figure 1.

Challenges in the successful development of a transcatheter mitral valve replacement (TMVR) device. Multiple interrelated factors influence the optimal positioning and performance of a TMVR device. PVL: paravalvular leak; LVOT: left ventricular outflow tract; LCx: left circumflex artery. Adapted from De Backer et al.¹²

six devices have been implanted in human patients.¹² These devices are based on nitinol alloy platforms enclosing bovine or porcine leaflets, and they employ diverse mechanisms to anchor and stabilize them in the mitral annulus (Table 1). All TMVR devices are implanted using transapical (TA) access except the CardiAQ device (Edwards Lifesciences Corporation), which has been successfully implanted using antegrade transseptal (TS) as well as TA access.¹³ The current clinical experience and status of the clinical program is summarized in Table 2.¹⁴

Procedure

The preparation for TMVR requires a detailed multimodality evaluation with both 2- and 3-dimensional (2D/3D) transesophageal echocardiography (TEE) and multiplanar computed tomography imaging with overlay and/or cardiac magnetic resonance imaging. These imaging technologies help ascertain (1) the mechanism and severity of mitral dysfunction, (2) accurate measurements of the left ventricle, mitral annulus, interatrial septum, left ventricular outflow tract

	Device Manufacturer	Device Features	Design	Anchoring Mechanism	Implantation Approach	Delivery System
1	CARDI-AQ	Self-expanding; nitinol frame; trileaflet valve; bovine pericardium leaflets		Does not rely on radial force; two sets of anchors grasping mitral leaflets from atrial and ventricular aspect for fixation.	Transfemoral, transapical	32-34F
2	TIARA	Self-expanding; nitinol frame; trileaflet valve; bovine pericardium leaflets		D-shaped atrial portion to match mitral orifice; atrial flange; 3 anchors on ventricular aspect (2 anterior and 1 posterior) for 3-point anchor	Transapical	32F
3	TENDYNE	Self-expanding; nitinol frame; trileaflet valve; porcine pericardium leaflets		Atrial flange; ventricular fixation system with a tethering string attached to the stent	Transapical	30F
4	MEDTRONIC (INTREPID)	Self-expanding; nitinol frame; trileaflet valve; bovine pericardium leaflets		Dual stent design; cork effect produced by variable stiffness along outer stent; radial interference; small cleats; frictional elements; tissue ingrowth	Transapical, transatrial	NA
5	ENDOVALVE	Self-expanding; nitinol frame; trileaflet valve; bovine pericardium leaflets		Specially designed grippers to attach with native valve leaflets; spares subvalvular apparatus	Transapical	NA
6	GORMAN-TMV	Self-expanding; nitinol frame; trileaflet valve; bovine pericardium leaflets		Combination of radial expansion and grasping arms on the ventricular aspect of the stent; these arms insert themselves around the leaflets and chordae when the device is exposed to LV systolic pressures.	Transatrial	30F
7	EDWARDS-FORTIS	Self-expanding; nitinol frame; trileaflet valve; bovine pericardium leaflets		Atrial flange with paddles located in the outflow of the central valve body, allowing capture of mitral leaflets.	Transapical	42F

Table 1.

Salient features of current transcatheter mitral valve replacement (TMVR) platforms. Comparison of relevant features pertaining to device design, anchoring mechanism, delivery approach, and sheath size.

(LVOT) and predicted neo-LVOT diameter after TMVR, and (3) the location and course of the left anterior descending and diagonal arteries relevant to TA access and myocardial thickness at the apex.

Transapical TMVR

In transapical TMVR, the patient is under general anesthesia, and the procedure is performed in a hybrid operating suite under 3D TEE and fluoroscopy guidance. A TA approach typically involves a minithoracotomy with purse-string sutures for access site management. The LV apex is accessed with a standard puncture needle, and a 6F sheath is introduced inside

the left ventricle. A J-tip guidewire is then advanced into a pulmonary vein and exchanged for a stiff guidewire. The access site is predilated, and the TMVR device delivery system is positioned and deployed under fluoroscopic and TEE guidance during rapid ventricular pacing (Figure 2).

Transseptal TMVR

The transseptal approach to TMVR is more nuanced due to the large profile of the CardiAQ device.¹³ After gaining transfemoral arterial and venous accesses, a transseptal puncture (TSP) is performed under TEE guidance. A second TSP is performed caudal to the first one to introduce a snare

DEVICE	N	OUTCOMES	STATUS OF PROGRAM
Fortis (Edwards)	16	Three patients in Canada. All survived until 6-month follow-up. Mean gradient on echo < 4 mm Hg. Thirteen patients in EU and Canada. The average left ventricular ejection fraction (LVEF) was 34%, and 12 of 13 patients (92%) had functional mitral regurgitation (MR). Procedural success was achieved in 10 patients, but 5 patients died within 30 days (multiorgan failure, septic shock, intestinal ischemia after failed valve implantation and conversion to open surgery, malnutrition leading to respiratory failure, and valve thrombosis). Among the 5 implanted patients who survived 30 days, all were still alive at 6 months, and echocardiography demonstrated no or trivial MR in 6 patients (80%) and mild regurgitation in 2 patients (20%); the average mitral gradient was 4 mm Hg.	Program is on hold as more data are collected.
Tiara	11	Eleven patients underwent implantation as part of either a Canadian registry or an international feasibility trial. Average STS Score was 15.6%. Nine patients had uneventful procedures and demonstrated no residual MR and no left ventricular outflow tract obstruction (LVOT). Two patients were converted to open surgery owing to valve malpositioning, and both of them died within 30 days. One patient who experienced a successful procedure suffered erosion of the septum and died on day 4.	Patients are being enrolled in phase 1 trials.
Tendyne	80	Twelve patients were enrolled in an early feasibility trial. Average LVEF was 40%, and 11 of the 12 patients had functional MR. Successful implantation was achieved in 11 patients, while one patient developed LVOT and the device was uneventfully removed. All patients were still alive at 30 days, and the 11 patients who still had a prosthetic valve did not have any residual MR.	Patients are being enrolled in phase 1 trials.
Intrepid	15	In a series of 15 patients, 11 had functional MR (with an average LVEF of 35%) and 4 had degenerative MR (with an average LVEF of 57%). ¹⁵ The device was successfully implanted in 14 patients, after which the average mitral valve gradient was 4 mm Hg. All patients but one were left with no regurgitation (the other patient had 1+ regurgitation).	Patients are being enrolled in phase 1 trials.
CardiAQ	12	Twelve patients were treated under compassionate use: eight had functional MR. Two died during procedure, three died of noncardiac complications within 30 days, and one more died of sepsis shortly thereafter; two patients with TS access were alive beyond 30-day follow-up.	Program on hold as data are collected and design changes undertaken.

Table 2.

Current experience and status of clinical programs with transcatheter mitral valve replacement platforms. Adapted from Krishnaswamy et al.¹⁴

catheter that helps navigate the device across the mitral annulus. An arteriovenous loop is established between the ipsilateral femoral artery and vein by using a customized nitinol guide wire in the descending aorta that is positioned from the venous side and snared out of the ipsilateral femoral artery (Figure 3, panel I).¹³

Under TEE guidance, the device capsule is inserted into the femoral vein over the nitinol wire, and the entire catheter delivery system (CDS) is tracked through the interatrial septum into the left atrium and across the mitral annulus. The capsule containing the loaded valve is directed toward the

LV with the help of the snare system. Once in position across the mitral valve, the capsule is retracted and the LV anchors deployed to capture the native mitral leaflets. The position of the LV anchors is confirmed with TEE before the left atrial anchors are exposed and deployed. After documenting optimal bioprosthesis performance under fluoroscopy and TEE, the valve is released from the CDS (Figure 3, Panel II).¹³ Finally, the CDS is removed via the femoral vein. Three-dimensional echocardiographic reconstruction is used to confirm the optimal position and valve function. The residual interatrial communication is closed with a patent foramen ovale occluder (Figure 3, Panel III).¹³

Figure 2.

Transapical (TA) transcatheter mitral valve replacement preprocedural planning and device deployment. Panel I (A-F) illustrates preprocedural planning with emphasis on computed tomography (CT) overlay and predicting device anchoring and effect on left ventricular outflow tract (LVOT) dimensions. Panel II (A-C) illustrates use of CT techniques to predict TA access site and sheath trajectory. Panel III (A-E) demonstrates TA access, device deployment, and postdeployment echo assessment.

Figure 3.

Transseptal (TS) transcatheter mitral valve replacement procedural steps. Panel I (A-H) shows dual transseptal puncture and balloon tracking. Panel II (A-F) shows device tracking and deployment. Panel III (A-D) shows device evaluation postdeployment.¹³

Figure 4.

(A) Transcatheter mitral valve-in-valve/valve-in-ring (ViV/ViR) fluoroscopic image of a 28-mm Edwards Physio 1 ring (Edwards Lifesciences Corporation). (B) Final fluoroscopic image after the implantation of a 23-mm Edwards SAPIEN XT transcatheter heart valve inside the ring (ViR procedure) via a transapical approach. (C) Fluoroscopic image of a failing 23-mm Mosaic valve (Medtronic) in the mitral position. (D) Postprocedural fluoroscopic image showing a 23-mm Edwards SAPIEN XT transcatheter heart valve implanted within the surgical heart valve through a transapical route.¹⁹

TMVR Outcomes

Worldwide experience with TMVR is limited to fewer than 200 cases. A number of devices are undergoing phase I trials at present. While detailed reports are still awaited, preliminary experience indicates a high 30-day mortality ranging from 25% to 40% that has been attributed to sepsis, multiorgan failure, device thrombosis, and the inability to recover from access site complications.¹⁵ This truly reflects the formidable challenges that exist in terms of patient selection, access management, device-related factors, and extensive comorbidities of patients currently undergoing this procedure. Incremental advances in all of these intertwined variables and data from evolving clinical experience are critical for defining the role of TMVR in the realm of transcatheter mitral therapy.

TMVR FOR FAILED SURGICAL MITRAL REPAIR AND REPLACEMENT: VALVE-IN-VALVE AND VALVE-IN-RING

Mitral valve repair and replacement with bioprosthetic valves is favored over mechanical MVR as they obviate the need for life-long anticoagulation, particularly in elderly patients with

bleeding risk factors.¹⁶ Bioprosthetic valves can often last between 10 and 20 years depending on the patient's age and comorbidities, with a risk for reoperation due to valve dysfunction of 4.1%, 13.6%, 18.8%, and 23.5%, at 5, 10, 15, and 20 years, respectively.¹⁷

Redo mitral surgery in patients older than 75 years of age is associated with high perioperative morbidity and mortality that often exceeds 15%.¹⁸ For patients who are at an acceptable surgical risk for redo surgery, transcatheter mitral valve-in-valve/valve-in-ring (TMViV/ViR) replacement has emerged as a feasible alternative. Current clinical experience with this procedure is based on TAVR/transcatheter pulmonary valves implanted in patients on a compassionate off-label basis.¹⁹

TMViV/ViR Procedure

Prior to performing any TMViV/ViR procedure, it is routine to secure both a multimodality evaluation that pinpoints the type of prosthetic valve dysfunction as well as an accurate evaluation of the size and type of prosthetic mitral valve (or ring). In particular, the native D-shaped annuloplasty ring may predispose to paravalvular regurgitation (PVR) following valve implantation. Since a circular-shaped device is critical to ensure efficient sealing and prevent significant postprocedural PVR, it is prudent to select deformable complete and rigid semilunar annuloplasty rings for this procedure. It is also important to achieve at least 10% oversizing of the transcatheter valve compared to the true internal diameter of the surgical device.²⁰ However, extreme oversizing can result in an underexpanded valve with impaired leaflet coaptation, elevated transvalvular gradient, and possibly limited durability. The general procedural principles involving a TA and TS approach are similar to those described for TMVR for native mitral valves, with a few technical details specific to TMViV/ViR: (1) Balloon predilation prior to implantation is generally avoided unless the crimped valve cannot be tracked across the bioprosthesis; (2) the transcatheter valve is positioned 3 to 5 mm atrially in relation to the sewing cuff of the surgical valve and deployed with a slow balloon inflation technique under rapid ventricular pacing²¹; and (3) for TMViR, the transcatheter valve is centered in the ring with equal portions in the left atrium and LV (Figure 4).¹⁹

TMViV/ViR OUTCOMES

The largest data pool of TMViV procedures has been presented from the multicenter Valve-in-Valve International Data (VIVID) registry that included 349 patients who had TMViV and 88 patients who had TMViR.¹⁴ The following are key observations pertaining to outcomes after TMViV/ViR procedures from the VIVID registry:

Figure 5.

Transcatheter mitral valve replacement for degenerative mitral stenosis. (A) Images are for patients 1 to 4 in respective columns (1A, 2A, 3A, 4A). Computed tomography of mitral annular calcifications. (1B) Three-dimensional transesophageal echocardiography of valve implantation within the mitral annulus. (2B-4B) Fluoroscopy of valve implantation within the mitral annulus. (1C-4C) Computed tomography postimplantation. (1D) Three-dimensional echocardiography postimplantation. (2D-4D) Two-dimensional echocardiography postimplantation.²⁵

- These procedures have been performed in elderly patients with significant comorbidities. (Mean age 74 years and Society of Thoracic Surgeons' [STS] Online Risk Calculator score of 12.9%).
- Most ViV/ViR procedures have been performed using TA access, while transseptal and left atrial accesses have been used for the remaining 20%. General anesthesia was used in almost all cases (98.9%). Most procedures have been performed with a balloon expandable device (Edwards SAPIEN, SAPIEN XT, Melody).
- The mechanism of bioprosthetic valve failure included pure regurgitation (45%), pure stenosis (23%), and combined stenosis and regurgitation (32%).
- Balloon predilation was performed in 24% of cases. Valve malpositioning was reported in 6.6%.
- Postprocedure mean gradient was 6.3 mm Hg and significant (moderate or more) paravalvular leak (PVL) was reported in

3.5% of cases. LVOT obstruction was noted in 7% cases with a significantly higher incidence in ViR cases (8%) than in ViV (2.5%). A small valve size (< 25 mm) was a key predictor of significantly elevated gradient (> 10 mm Hg). Significant residual MR (> moderate) was more likely in ViR than in ViV cases.

- Overall 30-day mortality was 8.5% (7.7% and 11.4% in ViV and ViR procedures, respectively; $P = .15$) and the occurrence of stroke was 2.5% (2.9% and 1.1% in ViV and ViR procedures, respectively). Late mortality (beyond 12 months) was 20.5%.

TMVR FOR DEGENERATIVE MITRAL STENOSIS

The underlying pathological lesion in DMS is mitral annular calcification (MAC),²² which reduces anterior leaflet mobility and impairs diastolic dilatation of the annulus. Surgical

AUTHOR	YEAR	PATIENTS (N)	CLINICAL SCENARIO	PROCEDURE AND DEVICE DETAILS	PROCEDURAL OUTCOME	FOLLOW-UP: IMMEDIATE & LONG-TERM
Astarci	2013	1	62-y/o woman; severe AS and DMS (MVA 1;1 cm ²); extensive and deep mitral annular calcification not amenable to surgical repair/ replacement	Left atriotomy; 26-mm SAPIEN XT (Edwards Lifesciences) deployed under direct vision; additional bovine pericardial ring sutured around the device for PVL	Uneventful	NA/NA
Sinning	2013	1	75-y/o woman; STS score 13;8; NYHA IV dyspnea; severe DMS (MG 13 mm Hg) and moderate MR; severe MAC involving both leaflets; internal dimensions of annulus on CT (28 x 23 mm; perimeter 82 mm)	Transapical approach; 24-mm aortic valvuloplasty balloon for sizing at the time of LV gram; 26-mm SAPIEN XT deployed under fluoroscopy and TEE guidance; mild PVL after deployment	Uneventful	NYHA IV reduced to II/ NA
Hasan	2013	1	70-y/o woman with severe DMS (MVA 0.9 cm ² , MG 14 mm Hg); prior SAVR; heavy mitral calcification; maximum annular dimension 31 mm Hg (3D TEE)	Transapical approach; BMV with 24-mm AMPLATZER sizing balloon (St. Jude Medical) to demonstrate pliability; moderate MR post BMV; 29-mm SAPIEN deployed; post-dilation with same balloon with +1 cc; no PVL after deployment	Post-deployment gradient 9 mm Hg	No cardiac/NA
Guerro	2014	1	75-y/o man with history of severe rheumatic MS; history of successful BMV with 28-mm INOUE-BALLOON catheter (Toray Industries); presented with severe PH (PAP = 90 mm) and pulmonary edema; severe MS; BMV with 27-mm balloon aborted due to worsening MR	Percutaneous transapical and transseptal access; externalization of wire from the femoral vein; atrial septostomy with 14-mm balloon; BMV with 23-mm balloon; SAPIEN 26-mm valve deployed; TA site closed with a 4-mm VSD device	Post-deployment gradient 4 mm Hg; worsening renal failure and fluid overload; PEA arrest requiring CPR	Patient died 10 days after procedure from noncardiac causes
Ribiero	2014	1	55-y/o woman; prior history of TA TAVR due to porcelain aorta; severe MS (MG 14 mm Hg; MVA 0.9 cm ²); max and min CT diameter 30 mm x 15 mm; diameter derived area 428 mm ²	Transapical access; 26-mm SAPIEN XT; severe PVL after implantation; transcatheter heart valve (THV) in THV with second SAPIEN XT; mild PVL after implantation	Uneventful	3 months
Himbert	2014	4	NYHA III-IV; Inoperable MAC (2 with severe MS, 2 with severe MR)	Transseptal access in all patients; 26-mm and 29-mm SAPIEN XT deployed; THV in THV in one case; no LVOTO	Predischarge gradient < 5 mm Hg; MR 1+ in 3 patients and 2+ in 1 patient.	1-6 months
MAC Global Registry	2016	64	64 patients in 32 centers; 66% female; mean STS score 14.4, mean mitral gradient 11.45 +/-4.4; mean mitral area 1.18 ± 0.5 cm ² ; SAPIEN 7.8%, SAPIEN XT 59.4%, SAPIEN 3 28.1%, Inovare (Braile Biomédica) 4.7%	Transatrial access 15.6%, transapical 43.8%, transseptal 40.6%; technical success in 46 patients (72%); THV in THV in 11 patients (17.2%); Six (9.3%) had LVOTO with hemodynamic compromise	Mean mitral gradient 4 ± 2.2 mm Hg; PVL mild or none	30-day all-cause mortality was 29.7%; most survivors in NYHA I

AS: aortic stenosis; BMV: balloon mitral valvotomy; CPR: cardiac pulmonary resuscitation; CT: computed tomography; DMS: degenerative mitral stenosis; LVOTO: left ventricular outflow tract obstruction; LV gram: left ventriculogram; MAC: mitral annular calcification; MG: mitral gradient; MR: mitral regurgitation; MS: mitral stenosis; MVA: mitral valve area; PAP: pulmonary artery pressure; PEA: pulseless electrical activity; PH: pulmonary hypertension; PVL: paravalvular leak; STS score: Society of Thoracic Surgeons' score; TA: transapical; TEE: transesophageal echocardiography; VSD: ventricular septal defect

Table 3.

Published reports of transcatheter mitral valve replacement in degenerative mitral stenosis, including clinical presentation, device details, and follow-up.

Adapted from Guerrero et al.²⁶

treatment of DMS is technically challenging and associated with significant complications including intractable bleeding from the LV wall, posterior ventricular rupture, separation of the left atrium and LV, circumflex artery injury, and significant PVL post MVR.^{23,24}

TMVR has been performed on an off-label basis at multiple centers for DMS, with most cases using balloon expandable Edwards SAPIEN/SAPIEN XT valves (Edwards Lifesciences Corporation) (Figure 5).²⁵ Table 3 details relevant patient and procedural details from reported case series.²⁶ The largest accrued experience of TMVR for DMS has been documented in the Mitral Annular Calcification (MAC) Global registry²⁶ that enrolled 64 patients who underwent TMVR on a compassionate basis. Mean age of patients was 73 ± 13 years, 66% were female, and mean STS score was $14.4 \pm 9.5\%$. The mean mitral gradient was 11.45 ± 4.4 mm Hg and the mean mitral area was 1.18 ± 0.5 cm.

Access was transatrial in 15.6% of patients, transapical in 43.8%, and transseptal in 40.6%. Technical success was achieved in 46 (72%) patients, primarily limited by the need for a second valve in 11 (17.2%). Six (9.3%) had LV tract obstruction with hemodynamic compromise. Mean mitral gradient postprocedure was 4 ± 2.2 mm Hg, and PVL was mild or absent in all. Thirty-day all-cause mortality was 29.7% (cardiac: 12.5%, noncardiac: 17.2%); 84% of the survivors with available follow-up data were in New York Heart Association functional class I or II at 30 days ($n = 25$). These results highlight the feasibility of a transcatheter approach in this patient cohort. The high mortality on follow-up highlights the significant comorbidities of the patient population, which underscores the need for a more deliberate evaluation of the role of TMVR for DMS. Recently, the Mitral Implantation of Transcatheter Valves in Native Mitral Stenosis (MITRAL) trial

has been approved as a multicenter investigational device exemption pilot study to evaluate outcomes for mitral implantation of the Edwards SAPIEN XT transcatheter valve in patients with severe DMS who are not candidates for surgery.¹² The inclusion criteria specify patients with severe DMS (mitral valve area ≤ 1.5 cm²) who are symptomatic during a stress test or in New York Heart Association class II or greater. Exclusion criteria include patients with a history of recent myocardial infarction, complex coronary artery disease/hypertrophic obstructive cardiomyopathy, or those who received a permanent cardiac implant within the last 30 days. This study is expected to provide valuable insights into the role of TMVR for patients with DMS and the device improvements necessary to achieve optimal outcomes in these patients.

KEY POINTS

- Transcatheter mitral valve replacement (TMVR) is a novel approach in the treatment of severe mitral regurgitation (MR). It offers a potentially durable solution to the problem of severe MR in a wide spectrum of patients who are unsuitable for mitral valve surgery
- TMVR is presently being studied in patients with severe native MR, degenerated mitral bioprosthesis, or degenerative mitral stenosis. A number of devices are being evaluated in feasibility studies. Both transapical and transseptal routes have been used for delivering TMVR devices.
- Preliminary results with TMVR have demonstrated a high 30-day mortality rate. This is indicative of the prohibitive risk profile of patients currently being treated with TMVR and procedural challenges surrounding very bulky high profile devices.

CONCLUSION

TMVR is currently in the early stages of clinical evaluation. The role of this technology in the treatment of MVD will be influenced by the concurrent progress in three interrelated spheres, which include (1) technological developments in device design to address problems of truly percutaneous TA access and closure, TS deliverability, anchoring, thrombosis, and LVOT obstruction (this includes imaging algorithms to accurately predict the impact of a TMVR device in a dynamic environment such as the mitral annulus); (2) the development of novel transcatheter mitral repair technologies that replicate surgical annuloplasty (clinical results with follow-up data will reveal if the role of TMVR and TMV replacement will be competitive or complimentary); and most importantly, (3) the ability to identify patients who stand to benefit the most from these approaches, which is critical to the success of these procedures.

Conflict of Interest Disclosure:

The authors have completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and none were reported.

Keywords:

Transcatheter mitral valve replacement, mitral regurgitation, degenerative mitral stenosis, valve-in-valve repair, valve-in-ring repair

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