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Transcatheter mitral valve replacement: there is still work to be done

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Transcatheter mitral valve replacement (TMVR) is a novel therapeutic option for patients with severe mitral regurgitation (MR) at high or prohibitive surgical risk. Most TMVR technologies under investigation use either a trans-apical or a trans-septal approach via dedicated multistep anchoring systems. Transcatheter mitral valve replacement offers several potential advantages over transcatheter repair, notably a greater and more sustained MR reduction. At the same time, significant engineering challenges and potential disadvantages must be acknowledged. Preclinical and clinical studies have shown promising results, demonstrating TMVR feasibility. Nevertheless, further development, testing, and trials are needed before considering TMVR as a definitive therapeutic option for MR in a wide range of anatomical scenarios.

Introduction

Mitral regurgitation (MR) is the most prevalent form of moderate to severe valve disease in developed countries[1] affecting ~10% of people older than 75 years, and is associated with high morbidity and mortality.[2] Mitral valve intervention is indicated in patients with severe MR who develop symptoms or left ventricle (LV) dysfunction or dilatation. Nevertheless, many of these patients are being denied surgery because of advanced age, multiple comorbidities, impaired LV function and elevated or prohibitive surgical risk.[3] Mortality in untreated patients reaches 50% at 5 years, and up to 90% of surviving patients require heart failure (HF) hospitalization within 5 years after MR diagnosis.[3]

Transcatheter edge-to-edge repair (TEER) is a safe and effective technique to treat high-risk patients with primary MR (PMR) or secondary MR (SMR) who are symptomatic despite guideline-directed medical therapy.[4] However, it has been shown to reduce MR severity to a lesser degree than surgery. Specifically, moderate to severe residual MR after TEER has been reported in about 10% of patients and is associated with worse clinical outcome.[5] Additionally, as the experience with these technologies has expanded, it has become increasingly apparent that several patient characteristics and anatomical factors are associated with inability to perform TEER.

In the last years, transcatheter mitral valve replacement (TMVR) has emerged as a promising alternative approach to treat patients with limitations precluding TEER, with the added benefit of a more effective and durable reduction of MR.[6] Many TMVR technologies are still in early stages of development and face several challenges (*Table 1*) that are limiting their widespread adoption. Thus, the definitive clinical applicability of TMVR and the performance of a wide spectrum of devices is still under investigation.

The fundamental role of imaging in TMVR

Cardiovascular imaging is a key player in diagnosis, pre-procedural planning, procedural guidance, and follow-

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Table 1 Major TMVR challenges

The MV annulus: • has a dynamic D shape that changes throughout the cardiac cycle • is not located in a single plane but rather has a 3D elliptical saddle shape • is significantly larger that the aortic annulus requiring substantially higher retention forces and larger devices to obtain stable anchorage and sealing • has no fibrous calcified support in most cases
Given the lack of heavy annular calcification in most patients, fixation methods relying solely on radial force are unlikely to be successful and additional fixation elements are required
Mobilization of the AML towards the IV septum due to prosthetic valve implantation in the mitral position may cause LVOTO, which is a frequent cause of screen failure
The LV-LA pressure gradient is much greater than the LV-Ao gradient
Large (≥24 Fr) delivery systems are required for implantation
Need of a thoracotomy TA access in most cases

TMVR, transcatheter mitral valve replacement; MV, mitral valve; AML, anterior mitral leaflet; IV, interventricular; LVOTO, left ventricle outflow tract obstruction; LV, left ventricle; LA, left atrium; Ao, aorta; TA, transapical.

up in patients undergoing TMVR.[7,8] Pre-procedural transthoracic echocardiography (TTE) is the first examination, as it provides initial characterization of the magnitude and aetiology of mitral valve (MV) disease. Beyond TTE, transoesophageal echocardiography (TEE), and cardiac computed tomography (CCT) are the cornerstones for a successful TMVR. Screening with TEE is the primary step to assess TMVR indication and includes the characterization of MR mechanisms and regurgitation grading, as well as their impact on LV size and function. Moreover, it allows evaluation of right heart chambers and pulmonary hypertension that are important prognostic factors. Lastly, 3D-TEE with multiplane reconstruction is another key tool for correctly assessing native and prosthetic valve anatomy. During TMVR, close collaboration between the echocardiographer, who provides continuous TEE imaging, and the interventional team is of paramount importance for guiding all procedural steps. Bicaval, aortic short-axis, and four-chamber views may help to select the appropriate puncture site for trans-septal (TS) TMVR (the ideal position is usually slightly superior and posterior from the interatrial septum midpoint). Transoesophageal echocardiography may also guide prosthesis advancement and positioning within the native MV annulus. Simultaneous bicommissural and LV outflow tract (LVOT) and 3D views are highly valuable for final prosthesis positioning. Finally, after valve deployment, TEE may assess perivalvular leak (PVL), residual MR, and measure mitral and LVOT gradients.

Contrast-enhanced thin-sliced electrocardiography-gated CCT is essential for TMVR planning.[8] Dedicated acquisition protocol covering the entire cardiac cycle with 5–10% R-R interval reconstruction is highly recommended in order to include completely the systolic phase. This imaging tool offers isotropic sub-millimetre spatial resolution, facilitating accurate assessment of MV geometry and annular size, which is needed to assess patient suitability according to the official recommendations of TMVR systems. Although each valve technology has CCT-based device-specific measures leading to different evaluation algorithms, there are common anatomic structures routinely appraised for all devices. They include MV annulus dimensions (inter-commissural and anterior–posterior diameters, inter-trigone distance, perimeter, and area), calcification extent and severity, MV leaflet features (length, thickness, and calcification), interatrial septum, left atrium (LA) and LV anatomy and LVOT characteristics (aorto-mitral angle, baseline systolic and diastolic area and neo-LVOT assessment after virtual valve implantation). Mitral calcification assessment plays a key role in procedural planning and includes specific measures, such as trigone and leaflet involvement and the degree and distribution of mitral annulus calcification (MAC). Indeed, moderate and non-circumferential MAC may result in poor device sealing, leading to PVL, device migration or embolization, particularly in valve-in-MAC procedures. CCT can also predict optimal fluoroscopic angles to ensure coaxial TMVR deployment, while for transapical (TA) implantation it allows identification of optimal LV puncture site to facilitate perpendicular annular access. Left ventricular outflow tract obstruction (LVOTO) after TMVR is the result of MV anterior leaflet dislodgment toward the LV septum and is a feared and potentially fatal complication. CCT virtual valve implantation and evaluation of neo-LVOT area on a 3D dedicated software may predict the risk. The anticipated neo-LVOT is measured at mid-late systole as the narrowest area between the virtual valve and LV septum. Neo-LVOT area under 1.7 cm^2 identifies patients at risk of significant LVOTO. Other anatomical features play a role in LVOTO including septal hypertrophy (>15-mm thickness), long (>25 mm) anterior MV leaflet with redundant chordae, small LV (end-diastolic diameter <48 mm), aorto-mitral annular angle, and preserved ejection fraction. Strategies to reduce LVOTO risk have been developed, including pre-procedural alcohol septal ablation and intentional laceration of the anterior MV leaflet. Finally, CCT can provide an accurate evaluation of coronary anatomy even in challenging patients such as those with atrial fibrillation.

Delivery methods

Transcatheter mitral valve replacement designs are currently restricted to two delivery routes for reaching the MV, a surgical TA approach that gives large-bore access to the LV, and a TS approach through a femoral venous access that gives entry into the LA. Initial TMVR procedures have been performed with TA access, as this is the most direct route to the MV. However, it has several limitations (*Table 2*). Recently, coaxial alignment has

Table 2 Advantages and disadvantages of the TA and TS approach for TMVR

TA advantages
Allows excellent coaxial alignment of the prosthetic valve
Can reduce the risk of valve migration, PVL, and possibly LVOTO
TA disadvantages
Thoracotomy with relatively high complication rates and longer hospitalization
Previous TAVR studies indicate less favourable outcome (increased mortality and delayed or reduced LV function improvement) after TA access, particularly in patients with LV dysfunction
Risk of significant access-related bleeding, particularly with large-bore access sites and post-procedural anticoagulation
TS advantages
Avoids cardiac surgery and LV compromise and reduces invasiveness, blood loss, morbidity
Faster recovery time demonstrated in TS vs. TA mitral ViV procedures
Recent experiences with TS TMVR suggest that coaxial alignment of the prosthetic valve is feasible also with this approach
TS disadvantages
SMR patients may have cardiomyopathy prevalence and an iatrogenic large ASD may increase LV overload and HF worsening
Residual ASD carries a potential risk of right-to-left shunting, which may lead to hypoxemia and paradoxical embolism
ASD closure may be needed (it was performed in 73% of patients treated with the Intrepid valve)
A large ASD occluder may hinder future LA access for PVL closure, AF ablation, and TS mitral ViV in the event of acute or chronic bioprosthetic valve failure

TA, transapical; TS, transseptal; TMVR, transcatheter mitral valve replacement; PVL, paravalvular leak; LVOTO, left ventricle outflow tract obstruction; TAVR, transcatheter aortic valve replacement; LV, left ventricle; ViV, valve-in-valve; SMR, secondary mitral regurgitation; HF, heart failure; ASD, atrial septal defect; LA, left atrium; AF, atrial fibrillation.

been demonstrated to be feasible also with the TS approach, eliminating a potential advantage of the TA route. Thus, the current focus on TMVR technology is on TS devices despite they are associated with engineering and procedural challenges due to the increased travel length and a higher number of turns. However, some concerns have been raised also for TS TMVR (*Table 2*). Nevertheless, most device manufacturers are currently focusing on developing TS systems and preliminary results with dedicated devices showed that this approach is effective, safe, and associated with less morbidity and reduced recovery time compared to TA access.

Prosthetic valve fixation and sealing

Valve fixation techniques cannot exclusively rely on radial forces similar to transcatheter aortic valve replacement (TAVR) due to the frequent absence of MV calcification and a shorter annular region. Moreover, the MV is subjected to high systolic pressure (~120 mmHg), so late valve migration is of concern. Additionally, the dynamic motion over the cardiac cycle should be considered, as a protruding anterior MV leaflet due to the implanted valve may create LVOTO or device dislodgement due to the high systolic pressures if the system utilizes a leaflet capturing technique. Thus, TMVR requires more advanced anchoring systems and several techniques have been proposed.[9] They include tethers to counteract axial forces, native leaflet grasping to fixate the prosthesis, docking systems to allow radial forces sufficient enough for fixation, LA and LV flanges for MV annulus and leaflet grasping, cages that occupy the entire LA to prevent valve migration, sub-annular hooks piercing native MV tissue, cork-like effects that produce radial forces for anchoring, and partial replacement devices that affix to the MV annulus (*Figure 1*, *Table 3*).

Anticoagulation treatment after TMVR

The risk of thrombosis seems to be relevant after TMVR. Clots usually form between the native leaflets and the implanted valve due to blood stagnation. In the initial Tendyne experience, thrombosis was seen in 6% of patients, resulting in mandatory anticoagulation for >3 months.[10] Similarly, in the EVOQUE and SAPIEN M3 experience, all patients were anticoagulated after the procedure. Thus, it is likely that all patients will need a period of anticoagulation after TMVR, a therapeutic approach similar to that currently used for surgical bioprosthetic valves. Nevertheless, there is lack of evidence on the optimal duration of anticoagulation and the potential use of direct oral anticoagulants.

Characteristics and outcome of patients undergoing screening for and treatment with TMVR

The role that TMVR will take among available treatment options for severe MR is yet to be defined. Several devices underwent first-in-man implantation or early clinical trials (*Table 3*). Valuable real-world data that may contribute to a more precise definition of TMVR results come from the **CH**oice of **O**pt**I**mal trans**C**atheter tr**E**atment for **M**itral **I**nsufficiency (CHOICE-MI), the largest multicentre, international registry to date aimed at investigating the outcomes of patients who underwent screening for TMVR with 10 different devices.[11] From May 2014 to March 2021, 746 patients with symptomatic MR (≥2+) considered suboptimal TEER candidates and at high or prohibitive surgical risk underwent TMVR screening at 26 centres within compassionate-use programs, clinical trials, or as commercial use. The primary combined endpoint included 1-year all-cause mortality or HF hospitalization. Secondary endpoints were all-cause and cardiovascular mortality at 1 year, residual MR on TTE and NYHA functional class at discharge and after 1

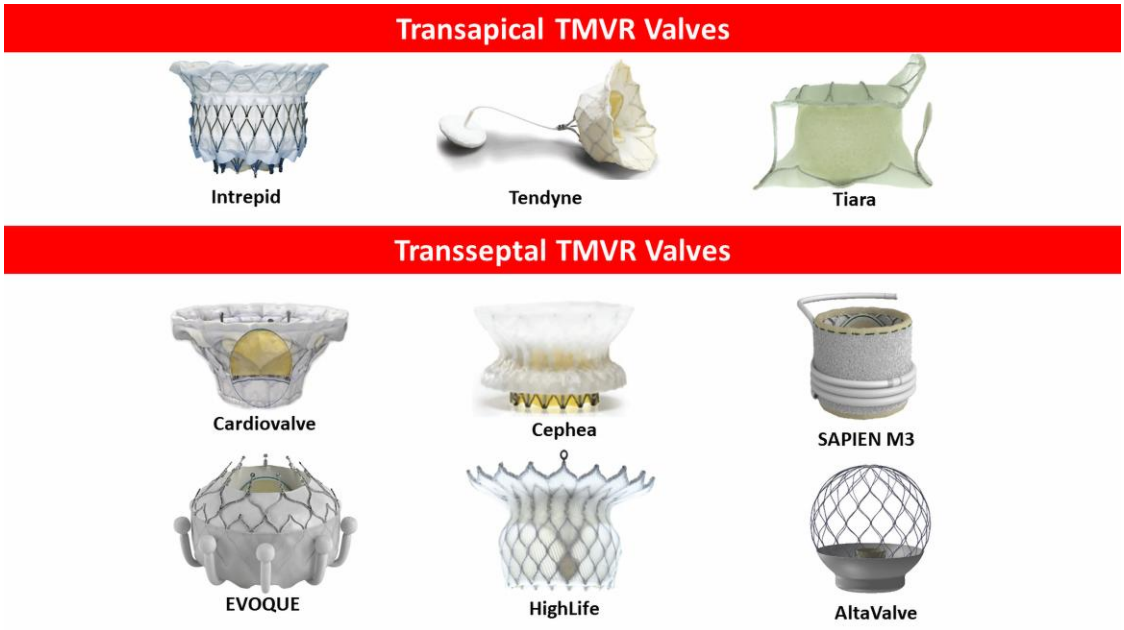

Figure 1 Transcatheter mitral valve replacement (TMVR) systems in clinical evaluation.

year. Among 746 patients, 517 were considered non-eligible mainly because of anatomical reasons (69.3%). The 229 (30.7%) TMVR-eligible patient [76 years (IQR 71.0–81.0), 36.7% female] had high rates of cardiac and non-cardiac comorbidities resulting in an elevated surgical risk [EuroSCORE II 6.3% (IQR 3.6, 13.2)]. Ninety-five (43%) patients had a previous myocardial infarction, while 82 (35.8%) previously underwent coronary artery bypass grafting and 22 (10%) surgical aortic valve replacement. MR aetiology was SMR or PMR in 58.4% and 28.8% of patients, respectively. Echocardiography showed LV dilatation [end-diastolic volume 153.4 mL (IQR 116.5–198.0)] and reduced ejection fraction [40.0% (IQR 35.0–54.0)], while tricuspid regurgitation (≥2+) was present in 111 (50.7%) patients. CCT showed moderate or severe MAC in 13%. Procedures were performed via TA or TS approach in 89.5% and 10.5%, respectively, yielding high (95.2%) technical success and low (1.8%) procedural mortality. Prosthesis malposition, LVOTO, and device migration occurred in 3.7%, 3.2% and 2.3%, respectively, while conversion to surgery was needed in 2.8%. Access site complications and reintervention for bleeding according to the Mitral Valve Academic Research Consortium (MVARC) criteria occurred in 9.6% and 7.5%, respectively. At 30 days, 22 patients had died, 19 from cardiovascular causes. At discharge, MR severity was ≤1 + in 95.1% and complete MR elimination was achieved in 83.9%. At 1 year, MR was ≤1 + in 95.2% and eliminated in 72.2%. At discharge and 1-year follow-up, NYHA functional class was I or II in 72.6% and 82.7%, respectively (both $P < 0.001$ compared to 14.4% at baseline). At 1 year, the primary combined endpoint occurred in 39.2%. In a landmark analysis for the primary endpoint excluding all events occurring within 30 days after TMVR, the 1-year rate decreased to 32.1%. All-cause and cardiovascular mortality after 1 year occurred in 28.2% and 19.3%, respectively. Kaplan-Meier estimated outcomes at 1 year comparing TS to TA access showed numerically lower rates of the primary combined endpoint (26.8% vs. 41.3%, $P = 0.22$) and all-cause mortality (17.3% vs. 29.6%, $P = 0.23$) for the TS approach. The high rate of 1-year all-cause and cardiovascular mortality may be partially explained by the high surgical risk of patients undergoing TMVR. Use of novel systems and devices in compassionate-use programs or early feasibility studies may have also played a role. Moreover, most patients were treated via large-bore delivery sheaths and TA access, which may partially account for the elevated 30-day mortality. Prospectively, complete transition from TA to TS access and better patient selection might reduce procedural risk and improve short- and mid-term outcomes (*Table 2*).

Valve-in-valve, valve-in-ring, and valve-in-MAC procedures

Current results suggest that mitral valve-in-valve (ViV) and valve-in-ring (ViR), mainly using the SAPIEN family (Edwards Lifesciences, Irvine, CA, USA) of balloon-expandable aortic transcatheter heart valve (THV) are attractive options for patients with failing surgical valves or annuloplasty rings deemed at high-risk for redo surgery. Indeed, they demonstrated substantial haemodynamic and functional status improvement in selected high-risk patients. In particular, ViV might represent the first-line therapy for failing bioprosthesis,[12] while the oval shape and rigidity of most annuloplasty rings and the higher LVOTO risk may explain why ViR outcomes are less favourable. The largest experience comes

Table 3 TMVR devices with available clinical data

Device Characteristics	Study Patients	Study Outcomes
Tendyne TA access (34/36 Fr), self-expanding double frame (D-shaped outer stent, circular inner stent), adjustable LV apical tether, trileaflet porcine pericardial valve repositionable and retrievable	$n = 109$ Age: 75.4 (75.4-75.6) years STS risk score: 7.8 ± 5.7% SMR: 89%	**30 days:** 97.2% technical success, 0% conversion to surgery, 5.5% mortality, 1.8% stroke **23 (22.4-23.6) months:** 36.7% mortality, 4.6% stroke, 5.5% thrombosis, 4.6% endocarditis, 91.6% NYHA functional class I/II
Intrepid TA access (35 Fr), dual self-expanding stent design, outer stent engages the annulus, inner stent houses a trileaflet bovine pericardial valve	$n = 50$ Age: 73 ± 9 years STS risk score: 6.4%±5.5% SMR: 72%	**30 days:** 96% technical success, 0% surgery conversion, 14% mortality, 4% stroke **Mid-term (7 ± 7 months):** 36.7% mortality, 4.6% stroke, 0% thrombosis, 0% endocarditis, 79.1% NYHA functional class I/II
HighLife TA access (31 Fr), sub-annular ring as docking system with a prosthetic trileaflet THV sitting inside the ring	$n = 15$ Age: 69 (59-70) years STS risk score: NR SMR: 73%	**30 days:** 72.7% technical success, 18.2% surgery conversion, 20% mortality, 7.1% stroke **12 months:** 26.7% mortality
Tiara TA access (39 Fr), D-shaped, self-expanding nitinol frame, 1 anterior and 2 posterior ventricular anchors, atrial skirt, trileaflet bovine pericardial valve	$n = 79$ Age: 74 ± 9 years STS risk score: 7.9%±6.7% SMR: 62%	**30 days:** 92.4% technical success, 7% surgery conversion, 11.3% mortality, 8.5% stroke
SAPIEN M3 TS access (20 Fr), nitinol dock enclosing native MV leaflets and anchoring a PET-covered balloon-expandable SAPIEN 3 THV	$n = 35$ Age: 75 ± 11 years STS score: 7.1%±3.9% SMR: 60%	**30 days:** 88.6% technical success, 0% surgery conversion, 2.9% mortality, 8.6% stroke, 2.9% PVL closure, 2.9% ASD closure
EVOQUE TS access (28 Fr), self-expanding ventricular frame with 9 anchors attaching to mitral leaflets and chordae, atrial frame incorporates a sealing skirt and provides annular fixation, bovine pericardial leaflets	N = 14 Age: 84 years (median) STS risk score: 4.6% SMR: 21.4%	**30 days:** 92.9% technical success, 7.1% surgery conversion, 7.1% mortality, 7.1% stroke, 14.3% PVL closure, 78.6% ASD closure
Cephea TA/TS access, self-expanding, double disk assembly anchoring by axial compression forces with a trileaflet bovine pericardial valve with a surgical valve-like profile	N = 3 Age: 79 ± 13 years PMR: 100% Euroscore: 13.8 ± 2.4%	**6 months:** mortality 0%, stroke 0%, ASD closure in 1, mitral mean gradient ≤3, no moderate/severe PVL, no LVOTO, NYHA class II in all

TMVR, transcatheter mitral valve replacement; TA, transapical; LV, left ventricle; STS, Society of Thoracic Surgeons; SMR, secondary mitral regurgitation; NYHA, New York Heart Association; THV, transcatheter heart valve; NR, not reported; PVL, paravalvular leak; ASD, atrial septal defect; TS, transseptal; PMR, primary mitral regurgitation; LVOTO, left ventricle outflow tract obstruction.

from the ViV International Data (VIVID) registry that included 1079 patients (857 ViV and 222 ViR, mean age 73.5 ± 12.5 years, 40.8% male) from 90 centres.[13] Overall MVARC-defined device success was 39.4% (41.3% ViV vs. 32.0% ViR, $P = 0.01$), mostly related to post-procedural mean gradients ≥5 mmHg in 61.4% of patients. Significant residual MR was more common in ViR patients (16.6% vs. 3.1%, $P = 0.001$) and associated with a 4-year lower survival (35.1% vs. 61.6%; $P = 0.02$). Four-year Kaplan-Meier survival rate was 62.5% in ViV vs. 49.5% in ViR ($P < 0.001$).

Valve-in-MAC is at a very early stage and important challenges exist with the currently available technologies developed for TAVR. The TMVR in MAC Global Registry enrolled 64 patients (92% NYHA class III or IV, mean age 73 ± 13 years, 66% female, mean STS score 14 ± 9.5) who underwent balloon-expandable THV implantation with a surgical transatrial (15.6%), TA (43.8) or TS (40.6%) approach and showed 72% procedural success, limited by the need of a second valve in 11 patients (due to migration in 5 and regurgitation in 6).[14] Post-procedural mean gradient was 4 ± 2.2 mmHg, mean MV area 2.2 ± 0.95 cm^2, and PVL was mild or absent in all. Four (6.25%) valves embolized in LA and 6 (9.3%) patients had severe LVOTO with haemodynamic compromise. In-hospital, mortality was 29.7% for cardiovascular (12.5%) and non-cardiac (17.2%) causes. Thirty-day echocardiograpy, available in 22 patients, showed mean MV gradient of 5.9 ± 2.1 mmHg and MV area of 2.3 ± 0.8 cm^2. Eighteen (81.8%) patients had zero/trace MR and four (18.2%) mild MR. Twenty-one (84%) of the 25 patients with 30-day follow-up were in NYHA class I or II, and 4 (16%) in NYHA class III.

Conclusions

Development of widely applicable TMVR systems poses many anatomic, patient-related, and engineering challenges. Although early experiences suggest that TMVR may offer better MR reduction compared with other transcatheter solutions, safer and more effective technologies are required. Currently, the low TMVR anatomical eligibility represents a major issue. Further technical and engineering advances, increased operator experience, better patient selection and procedural planning will be needed to improve technical success and long-term outcome. This is of special importance for patients who are inoperable or at high surgical risk and are not amenable to TEER because of unsuitable anatomical factors and may be better served by the TMVR option.

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