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ORIGINAL INVESTIGATIONS

Novel Transcatheter Mitral Valve Prosthesis for Patients With Severe Mitral Annular Calcification

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ABSTRACT

BACKGROUND Treatment of mitral regurgitation (MR) in the setting of severe mitral annular calcification (MAC) is challenging due to the high risk for fatal atrioventricular groove disruption and significant paravalvular leak.

OBJECTIVES The objective of this study was to evaluate the potential for transcatheter mitral valve replacement in patients with severe MAC using an anatomically designed mitral prosthesis.

METHODS Nine patients (77 ± 6 years of age; 5 men) were treated with the valve, using transapical delivery performed under general anesthesia and with guidance from transesophageal echocardiography and fluoroscopy.

RESULTS Device implantation was successful with relief of MR in all 9 patients. There were no procedural deaths. In 1 patient, left ventricular outflow tract obstruction occurred due to malrotation of the prosthesis, and successful alcohol septal ablation was performed. During a median follow-up of 12 months (range 1 to 28 months), there was 1 cardiac death, 1 noncardiac death, no other mortality, and no prosthetic dysfunction, and MR remained absent in all treated patients. Rehospitalization for heart failure occurred in 2 patients who did not die subsequently. Clinical improvement with mild or no symptoms occurred in all patients alive at the end of follow-up.

CONCLUSIONS Transcatheter mitral valve replacement in severe mitral annular calcification with a dedicated prosthesis is feasible and can result in MR relief with symptom improvement. Further evaluation of this approach for these high-risk patients is warranted. (J Am Coll Cardiol 2019;74:1431–40) © 2019 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

EOA = effective orifice area

LVOT = left ventricular outflow tract

MAC = mitral annular calcification

MR = mitral regurgitation

NYHA = New York Heart Association

TMVR = transcatheter mitral valve replacement

Mitral annular calcification (MAC) is a vexing clinical condition in which chronic degeneration of the fibrous skeleton leads to mitral regurgitation (MR), stenosis, or a combination of these valvular lesions. For many patients, MAC can be severe and invade the myocardium, posing challenges for open surgical correction. These challenges include residual paravalvular regurgitation, as well as the potential for atrioventricular groove disruption, a surgical complication that is nearly universally fatal (1,2). Moreover, MAC frequently is accompanied by severe morbidities that significantly increase surgical risk, such as coronary atherosclerosis, inflammatory disorders, and renal failure. Thus, open mitral valve surgery for treatment of MAC is reserved only for select patients.

Transcatheter techniques for treatment of MAC have been developed to obviate the need for open surgical correction. These approaches have primarily entailed off-label use of balloon-expandable prostheses (e.g., Sapien valves, Edwards Lifesciences, Irvine, California), placed via transapical or transvascular access, or open surgery with a direct atrial approach (3–6). Although this off-label therapy has been successful in a majority of patients, there remains a high risk of left ventricular outflow tract (LVOT) obstruction, residual regurgitation, device embolization, and death (30-day mortality 25%) (4).

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We hypothesized that transcatheter therapy of severe MAC could be possible with use of a specifically designed prosthesis. The Tendyne prosthesis (Abbott Structural, Santa Clara, California) is anatomically shaped with an outer sealing cuff, and is anchored via an epicardial pad, with the ability to be fully retrieved and repositioned (7). In this study, we examined the outcomes of the first 9 patients who underwent transcatheter mitral valve replacement (TMVR) with the prosthesis for the treatment of mitral disease due to severe MAC.

METHODS

STUDY DESIGN AND POPULATION. Patients were recruited for the study at 5 hospitals (Abbott Northwestern Hospital, Minneapolis, Minnesota; Emory University, Atlanta, Georgia; HonorHealth, Phoenix, Arizona; University Heart Center, Hamburg, Germany; and Clinique Pasteur, Hopitaux de Toulouse, Toulouse, France). Each patient was evaluated by a complete heart team, consisting of cardiologists, interventionalists, and cardiac surgeons, as well as imaging with transthoracic echocardiography, transesophageal echocardiography, and gated, contrast-enhanced cardiac computed tomography (8). Enrollment criteria were: 1) symptoms of heart failure (i.e., New York Heart Association [NYHA] functional class ≥II); 2) severe MR; 3) presence of severe MAC; and 4) high or prohibitive surgical risk, as determined by a local heart team evaluation. Patients with severe left ventricular dysfunction (ejection fraction <30% or end-diastolic diameter ≥70 mm), severe tricuspid regurgitation, right ventricular dysfunction, or pulmonary hypertension (systolic pressure ≥70 mm Hg) were excluded. Severe MR was defined using standard American Society of Echocardiography criteria. Severe MAC was considered present when the mitral annular anatomy posed high or prohibitive risk for open surgical correction, and was defined as either the presence of myocardial invasion or an extensive severity with a total volume of ≥750 mm^3 measured on cardiac computed tomography imaging (**Figure 1**).

Eight of the 9 patients were treated on a compassionate use basis with approvals obtained from national governmental agencies (Food and Drug Administration in the United States, Federal Institute for Drugs and Medical Devices in Germany, or Agence Nationale de Sécurité du Médicament et des produits de santé in France). One other patient had undergone treatment as part of the Tendyne Global Feasibility Study, had qualifying clinical and MAC anatomy criteria, and was included in the present investigation (7). A procedural description with 30-day outcomes for the first patient treated as compassionate use has been previously published and is included in this

Boston Scientific, Edwards Lifesciences, and Medtronic. Dr. Tchetche has been a consultant for Abbott Vascular, Boston Scientific, Edwards Lifesciences, and Medtronic. Dr. Blanke has been a consultant to Tendyne/Abbott Vascular, Edwards Lifesciences, Neovasc, Gore, and Circle Cardiovascular Imaging; and his institution has provided computed tomography core lab services for Tendyne/Abbott Vascular, Edwards Lifesciences, Medtronic, and Neovasc. Dr. Cavalcante has received research grants and support from Abbott Vascular, Siemens, Medtronic, and Circle Cardiovascular Imaging; and has been a consultant and served on Speakers Bureaus for Siemens and Medtronic. Dr. Sun has been a consultant for Abbott Vascular. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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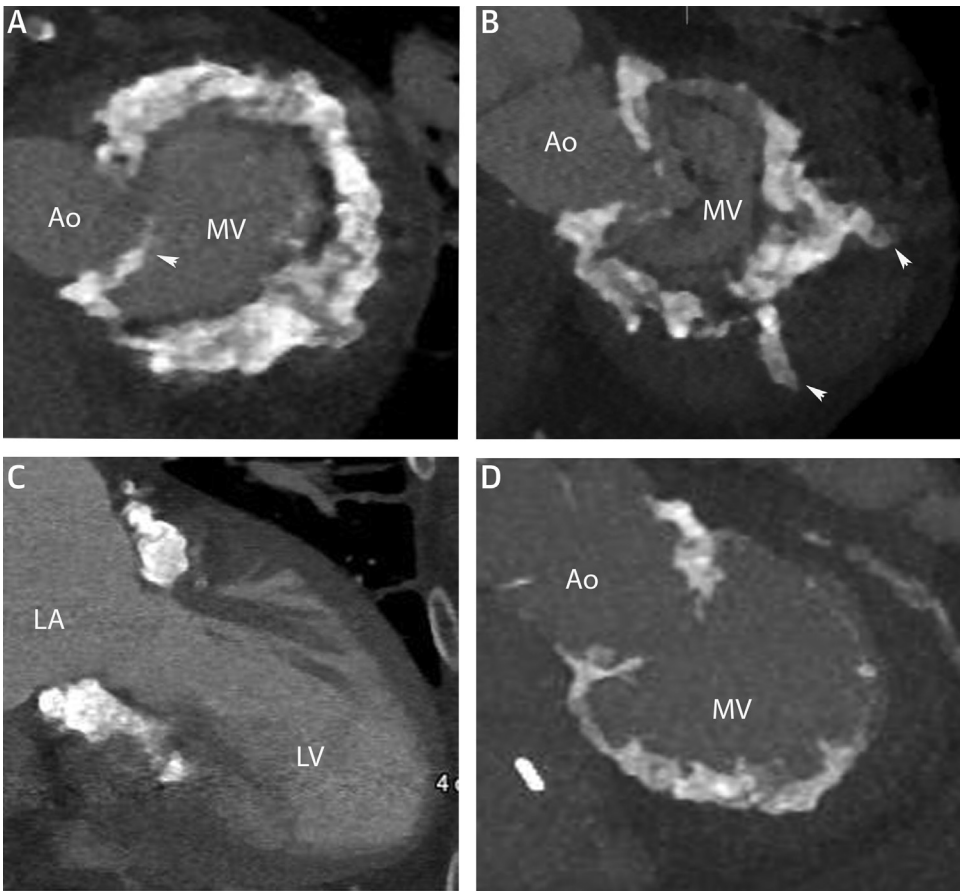
FIGURE 1 Representative Patterns of Severe MAC in Patients With Symptomatic MR



Images from gated, contrast-enhanced cardiac computed tomography are shown. **(A, B, D)** are from unique patients, whereas **(A)** and **(C)** are from the same patient. Some patients had large spicules arising from the anterior horn of the mitral annulus **(A, arrowhead)** or invading the myocardium **(B, arrowheads)**. Ao = aorta; LA = left atrium; LV = left ventricle; MAC = mitral annular calcification; MR = mitral regurgitation; MV = mitral valve.

report (9). All patients provided informed consent for participation in the study, which was approved by the local institutional review boards.

TRANSCATHETER MITRAL VALVE REPLACEMENT. The Tendyne prosthesis consists of 2 self-expanding nitinol frames that house a trileaflet porcine pericardial valve. Importantly, the outer frame is contoured to the fit of the mitral annulus, facilitating sealing and preventing regurgitation without the need for significant prosthesis oversizing or expansion of the native mitral annulus. The prosthesis is secured via a braided polyethylene tether, which is attached to an epicardial pad. The prosthesis has 2 configurations, standard (effective orifice area [EOA] 3.2 cm^2) and low profile (EOA 2.2 cm^2). Following pre-procedural planning with cardiac computed tomography, the prosthesis is deployed transventricular via a left lateral thoracotomy, and without the need for cardiopulmonary bypass, rapid ventricular pacing, or hemodynamic support (Figure 2). For placement of the prosthesis in severe MAC, pre-dilatation of the mitral valve apparatus with a balloon valvuloplasty catheter was used in some patients according to the preference of the local heart team, typically when there was concern regarding optimizing expansion of the prosthesis due to calcific spicules (Figure 3). Following the procedure, anticoagulation with warfarin was used for ≥6 months for all patients and then discontinued unless they had other indications for such therapy (e.g., stroke prevention for atrial fibrillation).

CLINICAL EVALUATION. The clinical need for correction of MR, the potential role of TMVR,

FIGURE 2 Successful TMVR in a Patient With Severe MAC

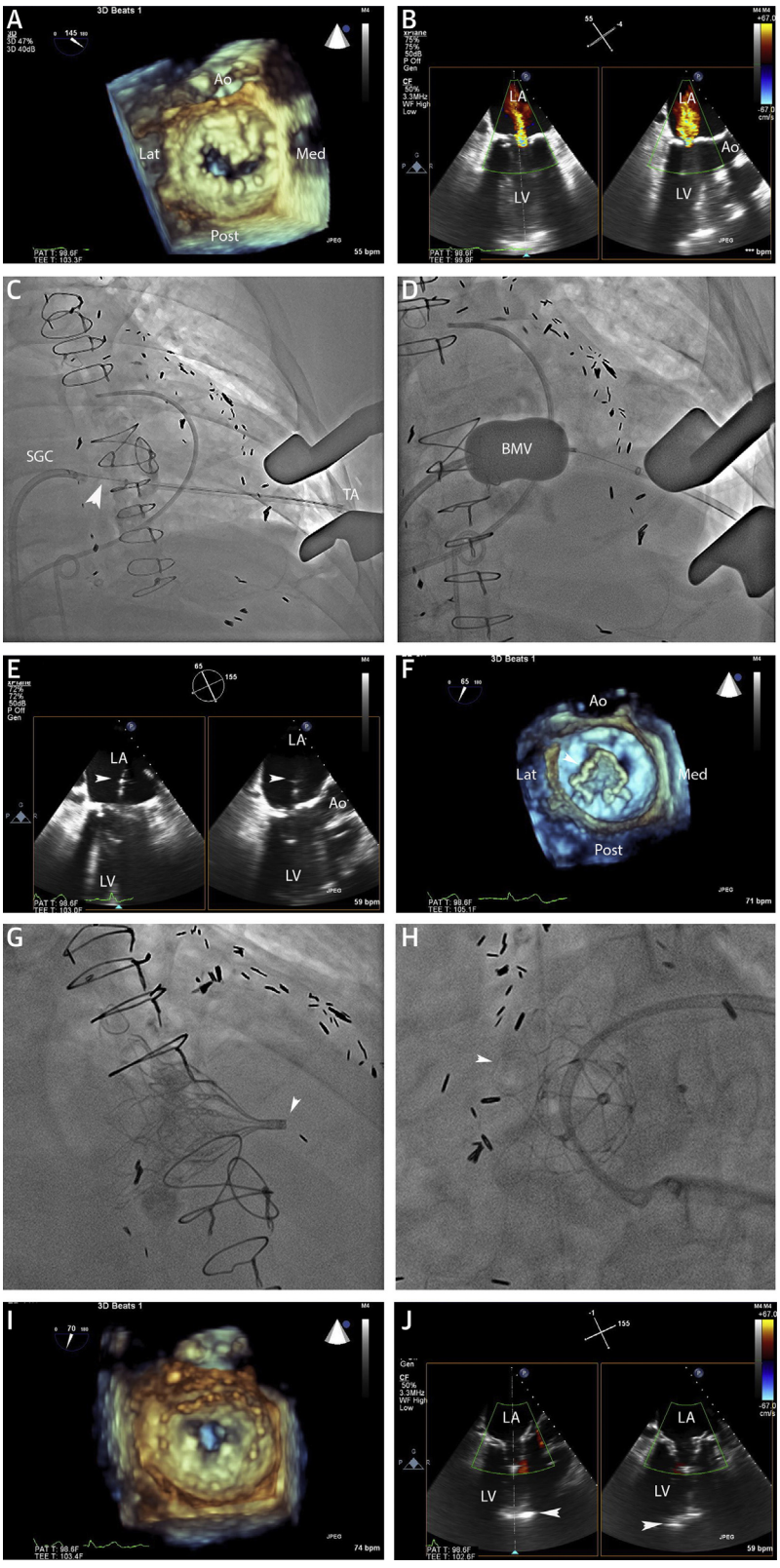


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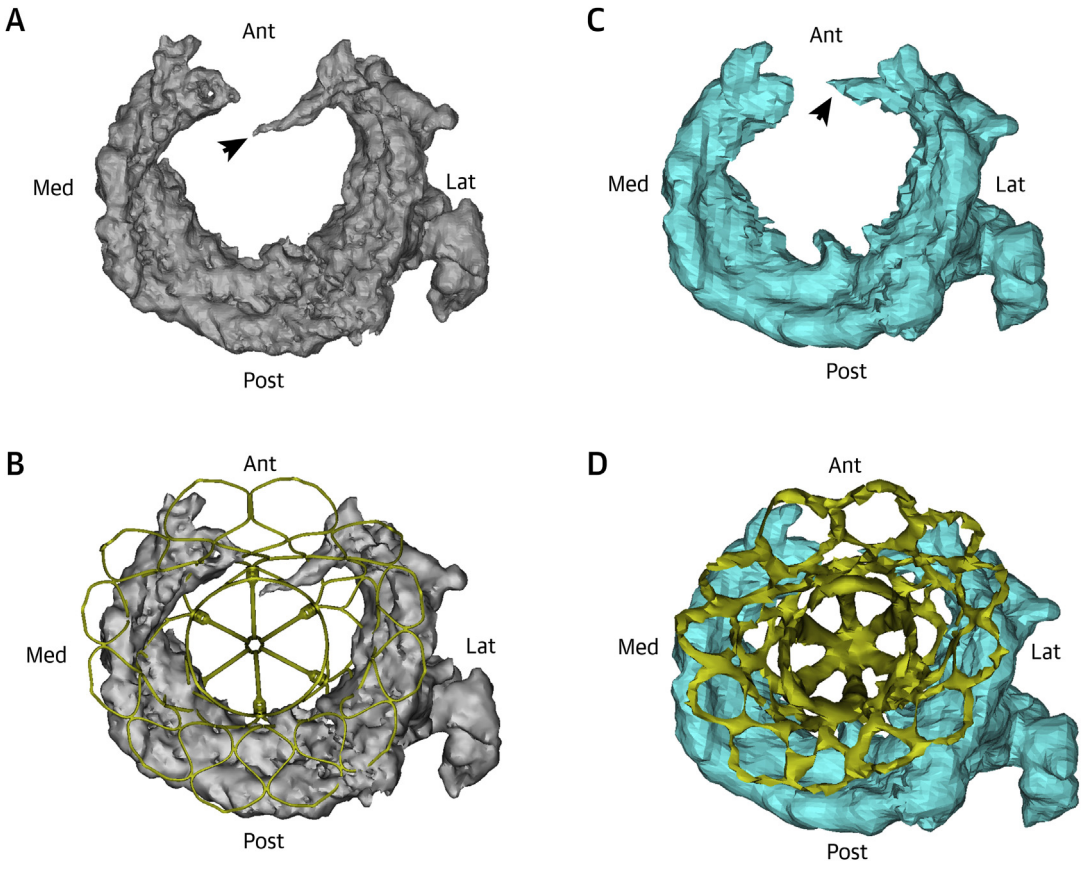
FIGURE 3 Predicted and Observed Implantation of Transcatheter Mitral Valve Prostheses in Patients With Severe MAC



(A) Pre-procedural imaging of the severe MAC shows large anterior spicule **(arrowhead)**. **(B)** Pre-procedural overlay of the prosthesis shows that the prosthesis **(yellow)** may not fully expand without mobilization of the large anterior spicule. The patient undergoes balloon mitral valvuloplasty and placement of the prosthesis. **(C)** Post-procedural imaging with subtraction of the prosthesis shows that the large anterior spicule had been successfully mobilized during the procedure **(arrowhead)**. **(D)** Post-procedural imaging shows fully expanded prosthesis **(yellow)**. Ant = anterior; Lat = lateral; Med = medial; Post = posterior; MAC = mitral annular calcification.

and surgical risk were determined through multidisciplinary heart team evaluations. Gated, contrast-enhanced cardiac computed tomography was performed in all patients for assessment of suitability for TMVR and for measurement of mitral annular dimensions, with data confirmed in a core laboratory (St. Paul's Hospital, Vancouver, British Columbia, Canada) as previously described (8). As part of the risk determination, the Society of Thoracic Surgery Predicted Risk of Mortality (STS-PROM) score for mitral valve replacement was calculated using the online tool (10). Clinical follow-up was performed at

FIGURE 2 Continued

(A) Three-dimensional echocardiography at baseline shows severe MAC. **(B)** Severe mitral regurgitation and moderate stenosis was present. **(C)** In some patients, a rail was created by snaring a wire placed through the left ventricular apex into the left atrium. **(D)** Balloon mitral valvuloplasty performed using the rail. **(E)** The Tendyne prosthesis **(arrowheads)** is extruded in the left atrium with guidance from x-plane transesophageal echocardiography. **(F)** On 3-dimensional echocardiography, the prosthesis is oriented to fit the anatomy of the mitral valve. **(G)** Long-axis view of the deployed prosthesis **(arrowhead)**. **(H)** Short-axis view of the deployed prosthesis **(arrowhead)**. **(I)** Post-deployment transesophageal echocardiography. **(J)** With the prosthesis in place, there is no residual mitral regurgitation. The apical pad is visible on echocardiography **(arrowheads)**. BMV = balloon mitral valvuloplasty; Lat = lateral; Med = medial; Post = posterior; SGC = steerable guide catheter; TMVR = transcatheter mitral valve replacement; other abbreviations as in Figure 1.

TABLE 1 Baseline Patient Characteristics (N = 9)

Age, yrs	77 ± 6
Men	5 (56)
NYHA functional class III or IV	6 (66)
Diabetes mellitus	6 (66)
Coronary artery disease	6 (66)
Prior myocardial infarction	1 (11)
Peripheral artery disease	0 (0)
Prior coronary artery bypass grafting	5 (56)
Prior valve intervention/surgery	4 (44)
Hospitalization for heart failure within 6 months	4 (44)
Glomerular filtration rate <60 ml/min	7 (78)
Hypertension	9 (100)
Chronic obstructive pulmonary disease	0 (0)
Current or prior smoker	2 (22)
Prior stroke or transient ischemic attack	0 (0)
Body mass index, kg/m^2	29.3 ± 4.3
Left ventricular ejection fraction, %	56 ± 8
Left ventricular end-diastolic volume, ml	147 ± 37
Left ventricular end-systolic volume, ml	58 ± 22
Left atrial diameter, cm	5.2 ± 0.6
Grade III or IV MR severity	8 (88)
Mean mitral gradient	6.3 ± 3.8
STS-PROM, %	7.4 ± 3.6
Medications	
ACE inhibitor, ARB, or vasodilator	6 (66)
Beta-receptor antagonist	6 (66)
Diuretic agent	7 (77)
Digoxin	0 (0)
Anticoagulant agent	5 (55)
Aspirin or antiplatelet agent	7 (77)

Values are mean ± SD or n (%).
ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; MR = mitral regurgitation; NYHA = New York Heart Association; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

TABLE 2 Gated, Contrast-Enhanced Cardiac Tomography Data

Volume of mitral annular calcification, ml	3,953 ± 5,527
Location of mitral annular calcification	
A1	8 (89)
A2	3 (33)
A3	7 (78)
P1	7 (78)
P2	9 (100)
P3	8 (89)
Invasion of myocardium by mitral annular calcification	7 (78)
Mitral valve dimensions	
Septal-lateral diameter, mm	28.8 ± 4.0
Intercommissural diameter, mm	36.7 ± 3.7
Perimeter, mm	111.5 ± 11.7
Area, cm^2	9.08 ± 2.01
Predicted Neo-LVOT, mm^2	417 ± 140
End-systolic aortomitral angle, °	55.8 ± 9.5
End-diastolic aortomitral angle, °	53.7 ± 9.5

Values are mean ± SD or n (%).
LVOT = left ventricular outflow tract.

TABLE 3 Procedure and In-Hospital Outcomes (N = 9)

Procedure time, min	130 ± 44
Mitral prosthesis perimeter, mm	128 ± 12
Device time, min	23 ± 7.9
Fluoroscopy duration, min	24.7 ± 10.0
Fluoroscopy dose, mGy	4,338 ± 7,800
Contrast volume, ml	37 ± 48
Implant rate	9 (100)
Cardiopulmonary bypass or ECMO	0 (0)
Intra-aortic balloon pump insertion	0 (0)
Procedural device-specific adverse events	
Bioprosthetic valve dysfunction	0 (0)
Embolization	0 (0)
Malposition	1 (11)
Device retrieval	0 (0)
Technical success	8 (89)
Discharge MR grade 0	9 (100)
Post-operative mean mitral gradient, mm Hg	3.4 ± 1.8
Re-intervention related to MV	1 (11)
BARC 2, 3, or 5 bleeding	1 (11)
Hemothorax	1 (11)
Cardiac tamponade	0 (0)
Major vascular complications	0 (0)
Stroke or transient ischemic attack	0 (0)
Post-operative cardiac arrest	1 (11)
New-onset atrial fibrillation	1 (11)
Acute kidney injury	2 (22)
Myocardial infarction	0 (0)
Hospital length of stay, days	9 ± 8

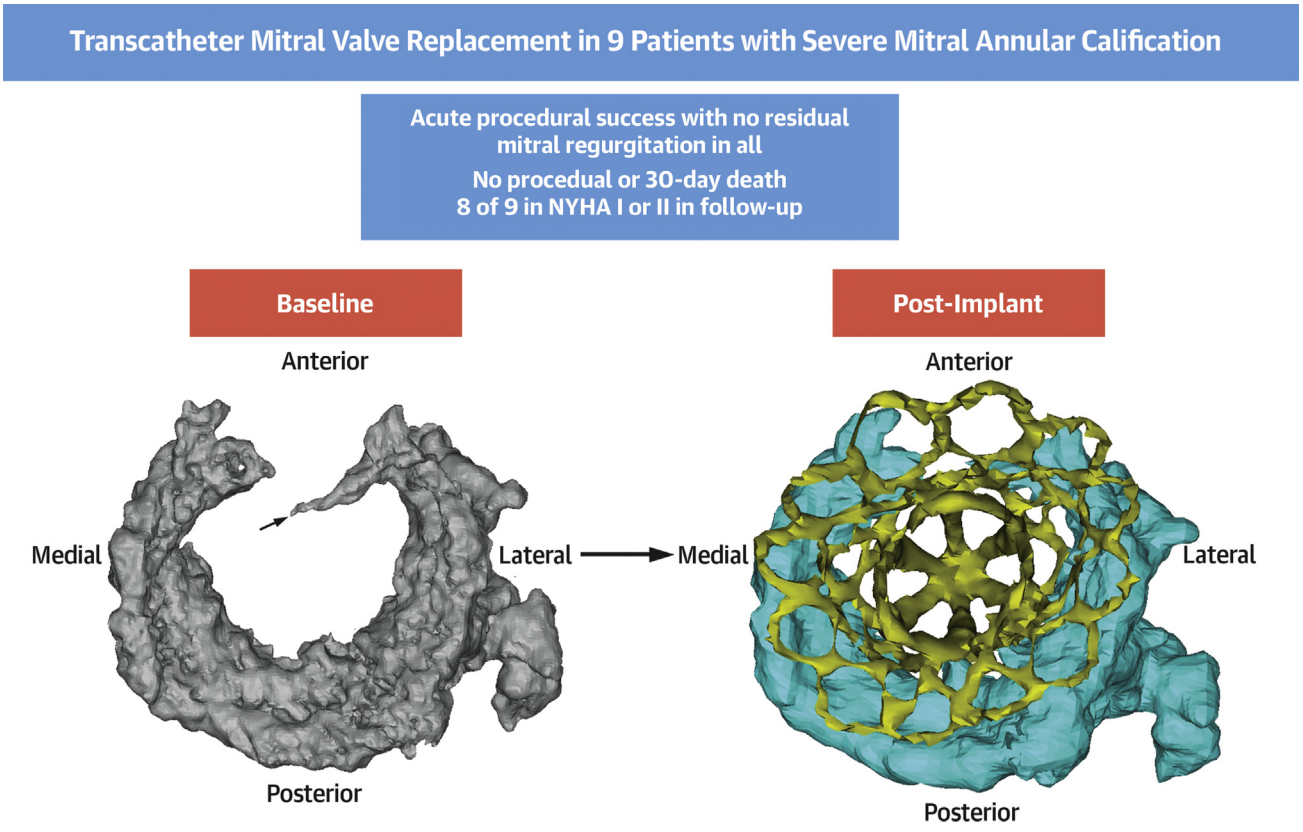
Values are mean ± SD or n (%).
BARC = Bleeding Academic Research Consortium, ECMO = extracorporeal membrane oxygenation; MR = mitral regurgitation; MV = mitral valve.

30 days and as part of routine care thereafter with serial echocardiography. Device and procedure success were defined using standard criteria. All patients were evaluated for occurrence of adverse clinical events (death, stroke, transient ischemic attack, bleeding, myocardial infarction, endocarditis, hemolysis), need for re-intervention (transcatheter or surgical), and recurrent hospitalization. Evidence of MR, device dysfunction (stenosis, degeneration, fracture), malposition (embolization or migration), and LVOT obstruction was determined from 2-dimensional and Doppler echocardiography. Where appropriate, Mitral Valve Academic Research Consortium criteria were used for endpoint definitions (11).

RESULTS

STUDY PATIENTS. The study patients were elderly (mean age 77 ± 6 years; 5 men), with severe symptoms and morbidities being common (STS-PROM 7.4 ± 3.6%) (Table 1). All patients had preserved left ventricular function (56 ± 8%) and severe MR. On cardiac computed tomography, the average volume of

CENTRAL ILLUSTRATION **Transcatheter Mitral Valve Replacement in Severe Mitral Annular Calcification**



(Left) Severe mitral annular calcification was assessed using gated, contrast-enhanced cardiac computed tomography. **(Right)** Post-implantation images showing a well-seated prosthesis **(yellow)**, which successfully relieved mitral regurgitation in all patients. NYHA = New York Heart Association.

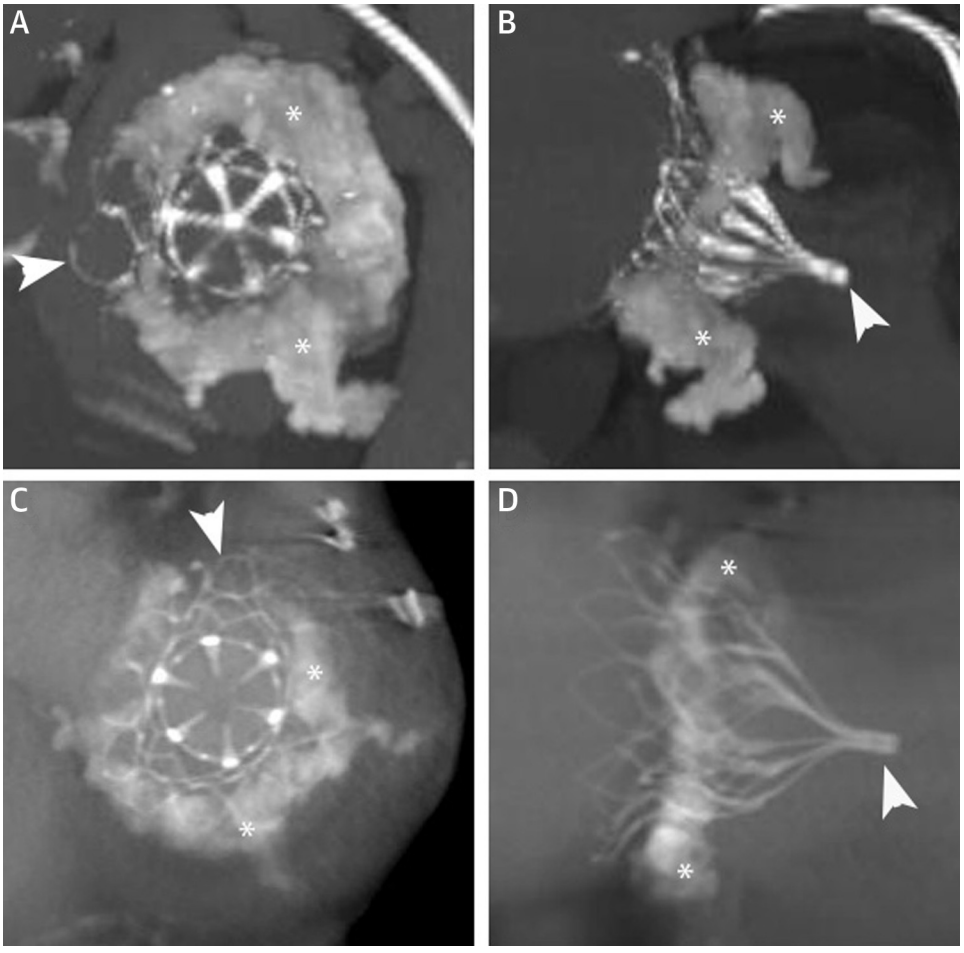
MAC was 3,953 ± 5,527 mm^3, with the most common location being in the posterior annulus (Table 2). Invasion of the myocardium with MAC was present in 7 of the 9 patients.

PROCEDURAL AND 30-DAY OUTCOMES. Device implantation with complete relief of MR occurred in all patients (Table 3, Central Illustration). Balloon valvuloplasty was utilized in 7 cases. The standard profile prosthesis was used in 4 patients; 5 others received the low-profile prosthesis. In all 9 cases, there were no instances of device embolization, significant mitral stenosis, or need for cardiopulmonary bypass or hemodynamic support (e.g., intra-aortic balloon pump or percutaneous ventricular assist device).

Technical success was achieved in 8 of the 9 patients. One patient without technical success had LVOT obstruction (peak gradient = 60 mm Hg) due to inadvertent rotation of a standard profile prosthesis and protrusion of the commissural segment of the prosthesis, which had been displaced anteriorly by calcification in the posterior annulus. Although this patient had no residual MR, the LVOT obstruction was recognized only after surgical closure, and successful alcohol septal ablation (final peak LVOT gradient 10 mm Hg) was performed. Post-operatively, he had cardiac arrest complicated by renal and liver failure, and ultimately pursued hospice care. Among all patients, including the one who had septal ablation, the peak LVOT gradient after implantation was 5.2 ± 2.9 mm Hg. One other patient had a hemothorax that required surgical drainage. Four patients were discharged to skilled nursing or rehabilitation facilities, whereas 5 went directly home.

Post-procedural, gated cardiac computed tomography with contrast was performed in 4 patients for routine assessment, in the absence of clinical concern (Figures 3 and 4). For each patient examined, the

FIGURE 4 Post-Implantation Images of Patients With Severe MAC Treated With TMVR



Imaging with gated, contrast-enhanced cardiac computed tomography performed on 3 representative patients 30 days after implantation are shown. **(A and B)** are from the same patient, whereas **(C and D)** are from separate individuals. The **asterisk** indicates severe mitral annular calcification. **Arrowheads** indicate the prosthesis. Abbreviations as in Figure 1.

outer frame fit the contour of the mitral annulus and symmetric expansion of the inner frame was evident. Among patients who had protruding spicules on pre-procedural imaging, mobilization of these calcific areas following TMVR with the dedicated prosthesis was evident (Figure 3).

CLINICAL FOLLOW-UP. Median follow-up for the study was 12.0 months (range 1 to 28 months). As described in the preceding text, 1 patient died in hospice on post-operative day 41. One patient, who had uncomplicated TMVR, normal prosthetic function, no recurrent MR, and no cardiac symptoms, committed suicide 8 months after the procedure. All other patients survived to the end of follow-up. MR remained absent (i.e., grade 0) in all treated patients. At last follow-up, 8 patients were ambulatory and had symptom improvement (i.e., NYHA functional class I or II). Two patients had hospitalization for recurrent heart failure. There was no evidence of prosthesis dysfunction, including no significant mitral stenosis (mean gradient 3.8 ± 1.9 mm Hg), hemolysis, thrombosis, as well as no major adverse clinical events in follow-up (Table 4).

DISCUSSION

The present investigation examined the potential of a novel therapy for the treatment of MR in patients with severe MAC. We demonstrate that safe treatment in this population is possible using a specifically designed TMVR prosthesis, with no procedural mortality, and with durable amelioration of MR in all

TABLE 4 Clinical Events in Follow-Up

Treated Population (N = 9)	30 Days	Last Follow-Up
Any mortality	0	1
Cardiovascular mortality	0	0
Stroke or TIA	0	0
Myocardial infarction	0	0
Heart failure hospitalization	0	2
Re-intervention for MV	0	0
BARC 2, 3, or 5 bleeding	1	1
Device-specific adverse events		
Bioprosthetic valve dysfunction	0	0
Hemolysis	0	0
Embolization	0	0
Thrombosis	0	0
Erosion, migration, malposition	0	0
Fracture	0	0
Endocarditis	0	0
New-onset atrial fibrillation	0	0
New permanent pacemaker	0	0

Values are n.
TIA = transient ischemic attack; other abbreviations as in Table 3.

patients, and relief of symptoms in most. These findings have implications for the field of TMVR, specifically with regards to the challenging anatomic subset of patients with severe MAC, in whom surgical correction is often prohibitive.

Severe MAC has been an important boundary for therapy in patients with MR, whether performed via transcatheter or surgical means. For transcatheter approaches, key elements for a beneficial TMVR prosthesis are adequate sealing of the irregularly shaped mitral annulus to prevent paravalvular regurgitation, maintenance of antegrade flow for ventricular filling, and prosthesis stability to prevent migration or embolization. The presence of severe MAC in the mitral valve apparatus intensifies these technical requirements, with reduced, unpredictable valve compliance, irregular annular edges, restricted leaflets, and in some cases, protruding, immobile calcific spicules (**Figure 1**). Although off-label use of balloon-expanding prostheses for these patients has been pioneering, the procedures thus far have remained a high-risk endeavor (4,12). Successful direct implantation of these prostheses has been performed, though these approaches require cardiopulmonary bypass akin to traditional cardiac surgery. Open surgical mitral replacement for severe MAC, although successful in some reports, also can be difficult due to risk of atrioventricular groove disruption, circumflex artery injury, and residual paravalvular regurgitation (13,14).

In this study, we found reliable procedure success for treating severe MAC, with acute relief of MR in all patients, and without procedural mortality. This success was related, at least in part, to the anatomic configuration of the mitral prosthesis (i.e., Tendyne), which was suited for the irregular annular borders. Importantly, an epicardial pad serves as the anchoring mechanism, which obviates the need to aggressively oversize the prosthesis relative to the annulus. This feature thereby minimizes concerns regarding the need to circularize the calcified mitral annulus, whose compliance cannot be reliably predicted. The average intercommissural diameter in our study was 37 mm, which is larger than currently commercially available prostheses. Nonetheless, the use of an anatomically shaped prosthesis does require particular attention to proper device rotation, as incorrect positioning caused LVOT obstruction with life-threatening complications in 1 of our patients.

Our findings of the ability to successfully treat MR in patients with severe MAC is an important milestone for TMVR, which still remains under investigation as an alternative to surgery, particularly for high-risk patients. Due to its complex challenges, the presence of severe MAC has been an exclusion criterion in nearly all early feasibility and ongoing pivotal studies of TMVR. As a relatively unstudied area, this lack of insight into possible catheter-based therapy has been unfortunate due to the prevalence of MAC (15% to 30% of those >70 years of age), and the extent to which traditional open surgery may not be possible for some patients (15). We observed that TMVR with a dedicated prosthesis can obviate the need for surgical debridement of MAC for valve replacement, while using a large sealing cuff to prevent paravalvular regurgitation, with a large EOA that permits low transmitral gradients.

It is important to note that the present study was performed in a selected population of patients, with careful screening for potential LVOT obstruction. Although a reliable cutoff for neo-LVOT area has not been well defined, we did not pursue therapy in our study for patients with values <250 mm^2 detected on cardiac computed tomography (8,16). Risk of LVOT obstruction is not specific to patients with MAC, but has been more commonly reported for TMVR in this pathology (4). We did observe 1 case of LVOT obstruction due to malrotation of the prosthesis that could have been addressed with retrieval and device repositioning. Also, balloon valvuloplasty generally is not routine in clinical practice for complex mitral anatomy such as severe MAC, and was performed to help ensure complete expansion of the prosthesis in several cases. The absence of adverse events with balloon valvuloplasty was notable, but it is important

to note that these cases were performed in a facilitatory manner, with careful transesophageal echocardiography guidance in nonsurgical patients who were severely symptomatic. The mitral pathology in our treated cohort also was regurgitation, not stenosis, which remains an area in need of further investigation for the utility of TMVR.

Overall, clinical improvement with durable relief of MR occurred in all patients, with few adverse events in follow-up of 1 year. There were no instances of late malposition, embolization, or need for surgical reintervention. Certainly, our study is a case series that requires validation in a larger population and with scrutiny also given to other prostheses specifically designed for implantation in patients with mitral disease due to severe MAC. Nonetheless, as the first description of a novel therapy in severe MAC, our findings suggest that expansion of the study of TMVR into patients with high-risk, challenging anatomy is warranted.

STUDY LIMITATIONS. The present investigation represents the experience of TMVR in severe MAC in a series of patients, and further study on the generalizability of this therapy for this population is required. The current investigation describes 9 treated cases that were enrolled among 30 cases submitted for consideration. Reasons for rejection were small annular dimensions (n = 8), small predicted neo-LVOT (n = 7), consent withdrawal (n = 3), and concern for left ventricular access (n = 3). Nearly all patients had received therapy on the basis of compassionate use approval, and thus most data on clinical events are site-reported.

CONCLUSIONS

TMVR in severe MAC with a dedicated prosthesis is feasible and can result in MR relief with symptom improvement. Further evaluation of this approach for these high-risk patients is warranted.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: Transcatheter correction of mitral regurgitation in patients with severe mitral annular calcification is feasible with the Tendyne prosthesis.

TRANSLATIONAL OUTLOOK: Large clinical trials are needed to define the role of transcatheter mitral valve replacement for patients with severe annular calcification.

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