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2-Year Outcomes After Transcatheter Mitral Valve Replacement

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ABSTRACT

OBJECTIVES This study sought to determine late (2-year) outcomes following transcatheter mitral valve replacement (TMVR) with the FORTIS valve (Edwards Lifesciences, Irvine, California).

BACKGROUND No data exist on long-term clinical outcomes following TMVR in patients with severe native mitral regurgitation (MR).

METHODS This multicenter registry included consecutive patients with severe MR who underwent TMVR with the FORTIS valve under a compassionate clinical use program. Clinical and echocardiographic data were collected at baseline, 30-day, and 1- and 2-year follow-up.

RESULTS Thirteen patients (71 ± 8 years, 10 men, logistic European System for Cardiac Operative Risk Evaluation score = 23.7 ± 12.1%) with severe MR were included. MR was of ischemic origin in most (76.9%) patients, and the mean left ventricular ejection fraction was 34 ± 9%. Technical success was achieved in 10 patients (76.9%), and 5 patients (38.5%) died within the 30 days following the procedure. At 30-day follow-up, mean transmitral gradient was 3 ± 1 mm Hg, and there were no cases of moderate-severe residual MR or left ventricular outflow tract obstruction. Two patients died during the follow-up period due to terminal heart failure, leading to an all-cause mortality rate of 54% at 2-year follow-up. At 2-year follow-up, all patients but 1 were in New York Heart Association functional class II, and there were no cases of valve malfunction (increasing gradients or MR recurrence). Computed tomography exams performed at 2-year follow-up in 3 patients showed no valve prosthesis fractures or displacement.

CONCLUSIONS TMVR with the FORTIS valve was feasible. MR reduction after TMVR was maintained at 2-year follow-up and no late device-related events were observed. (J Am Coll Cardiol Intv 2017;10:1671–8)

Mitral regurgitation (MR) is one of the most prevalent forms of heart valve disease in Western countries (1). Mitral valve repair or replacement remains the gold standard for the treatment of MR (2), but a significant proportion of patients with severe symptomatic MR are not referred for surgery, mainly due to the presence of concomitant cardiac and noncardiac comorbidities leading to an excessive surgical risk (3).

Transcatheter therapies, and in particular mitral repair with the MitraClip system (Abbott Vascular, Abbott Park, Illinois), have been recognized as an alternative for treating patients with severe MR at high or prohibitive surgical risk (2). More recently,

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ABBREVIATIONS AND ACRONYMS

CT = computed tomography

LV = left ventricular

LVEF = left ventricular ejection fraction

MR = mitral regurgitation

TEE = transesophageal echocardiography

TMVR = transcatheter mitral valve replacement

transcatheter mitral valve replacement (TMVR) has emerged as another transcatheter option for treating MR. MR is a complex and heterogeneous disease, and TMVR may be associated with a more universal and predictable reduction in MR (4). At present, summaries of current TMVR experience are limited to initial in-human studies and report only periprocedural or short-term outcomes (5–9). To date, no information exists on long-term outcomes following TMVR. The objective of this study was to determine long-term outcomes following TMVR with the FORTIS transcatheter valve system (Edwards Lifesciences, Irvine, California).

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METHODS

This study included all patients undergoing TMVR with the FORTIS valve under a compassionate clinical use program between February 2014 and March 2015 in 5 centers in Europe and Canada. A multidisciplinary heart team composed of interventional cardiologists, cardiac surgeons, and echocardiographers evaluated all cases. TMVR was considered in patients deemed to be at very high or prohibitive risk for standard surgical valve repair or replacement. Anatomic suitability was determined using echocardiography and multislice computed tomography (CT) criteria, as previously described (6). A dedicated case report form was used for data collection that included baseline and periprocedural TMVR features, as well as in-hospital and follow-up outcomes. Adverse events were defined according to the Mitral Valve Academic Research Consortium (10).

FORTIS MITRAL TRANSCATHETER VALVE AND PROCEDURAL STEPS. The characteristics of the FORTIS valve and the procedural steps have been described in detail elsewhere (7). Briefly, the valve is composed of a self-expanding nitinol frame, trileaflet bovine pericardial tissue, atrial flange, and 2 opposing paddles that capture the native mitral leaflets and secure them to the frame, forming the primary anchoring mechanism (**Figure 1**). The only size is 29 mm, and the valve is implanted through a transapical approach via a 42-F delivery system. The procedure is guided by fluoroscopy and transesophageal echocardiography (TEE). Following the apical puncture, a balloon-tipped catheter is used to cross the mitral valve, and a J-tip guidewire (Medtronic, Minneapolis, Minnesota) is positioned in the right superior pulmonary vein. The delivery system is advanced over the wire into the midventricular cavity. The paddles are partially exposed and oriented by TEE to engage the native mitral leaflets following full exposure. After leaflet capture, the atrial flange is released first, followed by the valve (**Figure 2**). Anticoagulation during the procedure is obtained with intravenous heparin to maintain an activated clotting time ≥300 s.

POST-PROCEDURE AND FOLLOW-UP. A transthoracic and TEE evaluation of the valve prosthesis was performed before hospital discharge. The antithrombotic regime post-procedure was not pre-specified, and it was left to the judgment of the physicians responsible for the patients at each center. Patients had a clinical visit and transthoracic echocardiography exams at 1- and 6-month follow-up, and yearly thereafter. In 1 of the participating centers, the patients had cardiac CT and TEE at 6- to 12-month follow-up and at 24-month follow-up.

RESULTS

A total of 13 patients (71 ± 8 years, 77% men) were included in the study (**Figure 3**). All patients had severe symptomatic MR of functional or mixed origin. The main baseline clinical and echocardiographic characteristics of the study population are shown in **Table 1**.

PROCEDURAL AND 30-DAY OUTCOMES. The main procedural and 30-day outcomes are shown in **Table 2**. Technical success according to Mitral Valve Academic Research Consortium criteria was achieved in 10 (76.9%) patients. There were no cases of left ventricular (LV) outflow tract obstruction. In 1 case, the presence of multiple papillary muscles, a septal bulge, and a thickened LV posterior wall impeded the proper placement of a wire after apical puncture. The procedure was converted to open-heart surgery and a mitral valve prosthesis was successfully implanted. The patient died 3 days after surgery as a consequence of intestinal ischemia. In another patient, an initial valve deployment attempt was unsuccessful and the valve was unstable due to incomplete posterior leaflet capture. The patient underwent open-heart surgery with mitral valve replacement and died 6 days after the procedure due to septic shock. In a third patient the transcatheter mitral valve prosthesis was implanted with no procedural complications. The patient died 4 days after the procedure due to multiorgan failure and the autopsy revealed the failure of posterior leaflet capture.

Device success defined according to Mitral Valve Academic Research Consortium criteria was obtained

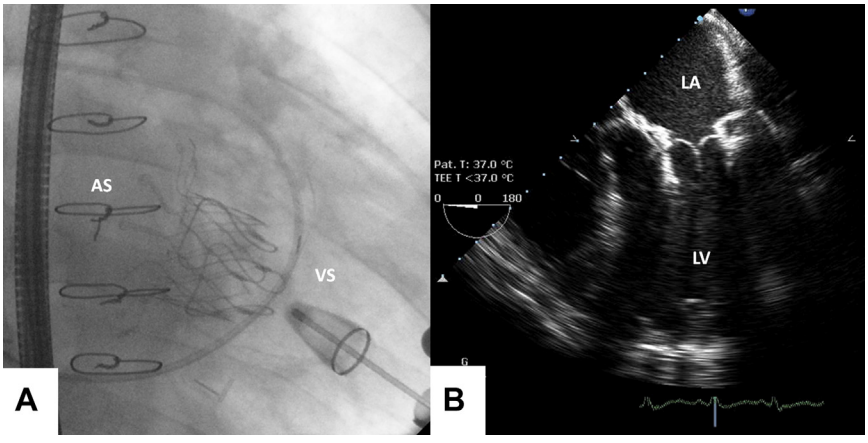
FIGURE 1 The FORTIS Transcatheter Mitral Valve

in 9 of 13 patients (69.2%). The antithrombotic regime following hospital discharge was warfarin alone (n = 2), warfarin + aspirin (n = 5), warfarin + aspirin + clopidogrel (n = 1), and aspirin (n = 1). Two patients who had a successful valve implantation died within the 30 days following the procedure. One patient died 26 days after the intervention due to multiorgan failure. Another patient presented with chest pain and was rehospitalized 13 days after TMVR. The echocardiography exam showed a mass at the level of the valve leaflets linked to increased mitral gradients, and a diagnosis of probable valve thrombosis was made. The patient was under anticoagulation therapy with warfarin (+ aspirin). Anticoagulation with intravenous heparin was initiated but the patient experienced sudden death 15 days after the intervention. Overall, the all-cause mortality rate at 30 days was 38%. There was no evidence of any other valve-related dysfunction or any other complication related to the device within the first 30 days after the procedure. At 30-day follow-up, the echocardiography exams showed the lack of moderate-severe MR in all patients, and the mean transmitral gradient was 3 ± 1 mm Hg. All patients alive at 30 days were in New York Heart Association functional class ≤II.

2-YEAR FOLLOW-UP OUTCOMES. Clinical follow-up was available in all patients. Two patients died during the follow-up period, at 76 and 467 days after the procedure, respectively. Both patients were rehospitalized and died because of terminal heart failure and an echocardiographic exam confirmed the absence of valve dysfunction before death occurred. Overall, the mortality rate at 1- and 2-year follow-up was 46% and 54%, respectively. There were no other rehospitalizations due to cardiac causes at follow-up.

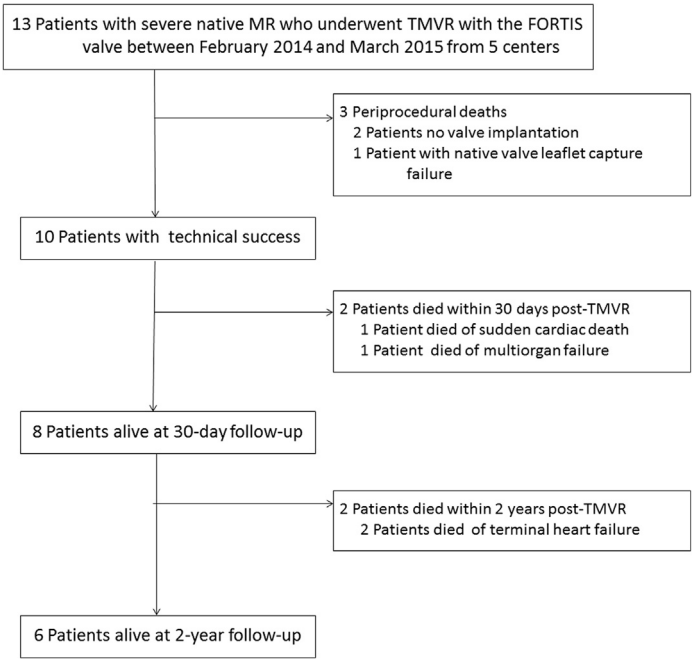
Functional status improvement persisted at 2-year follow-up with all patients but 1 in New York Heart Association functional class ≤II (Figure 4). There were no cases of device migration, embolization, or need for reintervention. An echocardiogram at 2-year follow-up was available in 5 patients and showed the absence of MR in all but 1 patient, who had mild (1+) paravalvular MR (Figure 5). Mean transmitral gradient was 3 ± 1 mm Hg (<4 mm Hg in all patients). Between

FIGURE 2 Immediate Post-Procedural Fluoroscopic and Transesophageal Echocardiographic Images



(A) Fluoroscopic and **(B)** transesophageal echocardiographic images of the FORTIS (Edwards Lifesciences, Irvine, California) valve after full deployment. AS = atrial side; LA = left atrium; LV = left ventricle; VS = ventricular side.

FIGURE 3 Flow Chart of the Study Cohort



MR = mitral regurgitation; TMVR = transcatheter mitral valve replacement.

TABLE 1 Baseline Clinical and Echocardiographic Characteristics (N = 13)

Age, yrs	71 ± 8
Male	10 (76.9)
Diabetes mellitus	5 (38.5)
Coronary artery disease	10 (76.9)
Prior coronary artery bypass surgery	7 (53.8)
Prior percutaneous coronary intervention	3 (23.1)
Atrial fibrillation	8 (61.5)
Prior stroke/TIA	3 (23.1)
Chronic obstructive pulmonary disease	5 (38.5)
eGFR, ml/min/1.73 m^2	43 ± 10
Cardiac resynchronization therapy	3 (23.1)
Heart failure hospitalizations*	9 (69.2)
NYHA functional class ≥III	13 (100)
STS PROM score, %†	7.2 ± 3.6
Logistic EuroSCORE, %	23.7 ± 12.1
LVEF, %	34 ± 9
<30%	4 (30.8)
30–50%	9 (69.2)
>50%	0 (0.0)
Mitral regurgitation mechanism	
Primary	0 (0.0)
Secondary	12 (92.3)
Mixed	1 (7.7)

Values are mean ± SD or n (%). *Hospitalizations during the year before the procedure. †Predicted periprocedural mortality for mitral valve repair.

eGFR = estimated glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; TIA = transient ischemic attack.

baseline and 2-year echocardiography the LV ejection fraction (LVEF) improved in 3 patients and was reduced in 2 patients (**Figure 6**).

CT scan images at 2-year follow-up were available in 3 patients. No fractures of the valve frame were detected, nor was there any erosion of the posterior aortic wall. There was no evidence suggesting obstruction of the outflow tract (**Figure 7**).

DISCUSSION

This study reported for the first time the long-term outcomes of TMVR for the treatment of native valve MR in patients at high risk for surgery. The reduction of MR after TMVR was maintained over time, with no significant recurrent MR at 2-year follow-up. No structural failures of the prosthesis or episodes of late thrombosis were observed. However, these results were limited to one-half of the study population, as about one-half of the patients had died within the 2 years following TMVR.

TMVR has emerged as a therapeutic option for the treatment of severe MR (5). Several TMVR devices are under preclinical or early clinical evaluation. Although evidence on clinical outcomes and valve performance after TMVR is available, the information has been limited to procedural or short-term outcome results (7–9).

Presently, multiple TMVR systems are being evaluated in a small number of highly selected patients (5). The 30-day mortality rate following TMVR ranges from 0% to 53% (5). The present report showed a high mortality rate at 2-year follow-up following TMVR with the FORTIS valve. However, most deaths occurred during the periprocedural period, and were partially related to a learning curve factor (first-in-human experience) in addition to the high risk of the study population, with a very high prevalence of cardiac and noncardiac comorbidities. The latter could have played a role particularly in those patients that survived the immediate procedure and died within the days following a successful uncomplicated TMVR. Also, the transapical approach has been associated with a higher rate of periprocedural complications (11), especially in patients with reduced LVEF such as those with functional MR. This factor could have increased the risk of

TABLE 2 Procedural and 30-Day Outcomes (N = 13)

Procedural outcomes	
Technical success*	10 (76.9)
Immediate procedural mortality*	0 (0.0)
Greater than mild (1+) MR†	0 (0.0)
Mean transmitral gradient, mm Hg	2.6 ± 1.1
LVOT obstruction†	0 (0.0)
Device time, min‡	54 ± 22
Total procedure time, min§	123 ± 27
30-day outcomes	
Device success*	9 (69.2)
Procedural success*	9 (69.2)
All-cause mortality	5 (38.5)
Stroke	0 (0.0)
Life-threatening bleeding	0 (0.0)
Stage 2 or 3 acute kidney injury	2 (15.4)
Myocardial infarction requiring PCI or CABG	0 (0.0)
Sepsis	1 (7.7)
Arrhythmias or conduction disturbances	
New onset atrial fibrillation (or flutter)	1 (7.7)
New onset left bundle branch block	0 (0.0)
New onset ventricular tachycardia	1 (7.7)

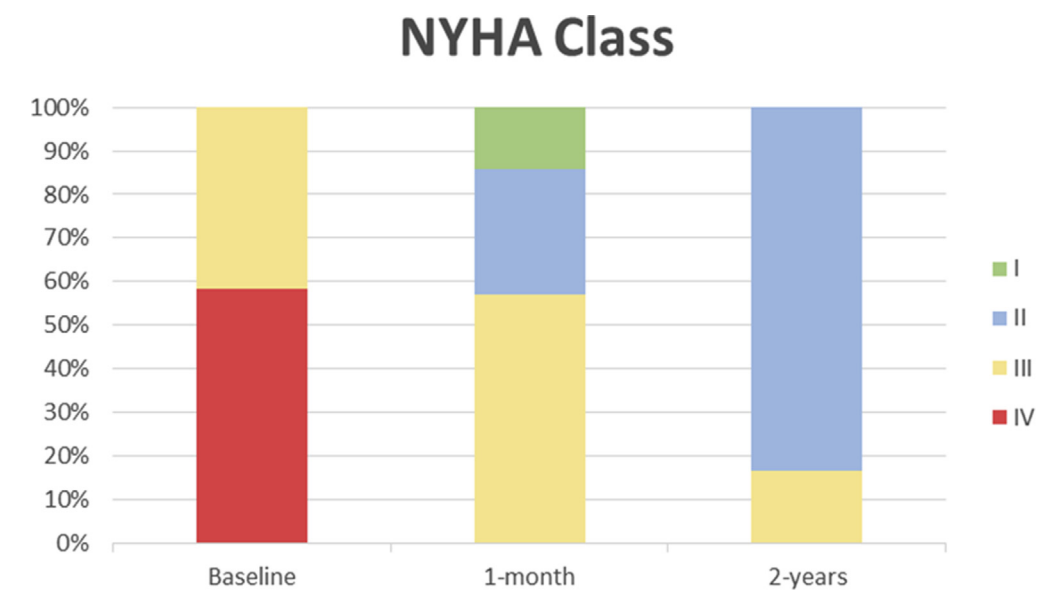
Values are n (%) or mean ± SD. *According to Mitral Valve Academic Research Consortium definition. †In the 11 patients with a transcatheter mitral valve prosthesis in situ. ‡Time from apical entry of the delivery sheath to retrieval of the delivery system. §Time from first skin incision to final wound closure.

CABG = coronary artery bypass graft surgery; LVOT = left ventricular outflow tract; MR = mitral regurgitation; PCI = percutaneous coronary intervention.

periprocedural mortality. On the other hand, the mortality rate during the follow-up period was limited to 2 patients who died because of terminal heart failure despite that valve performance was maintained over time. These 2 patients exhibited a very low LVEF before the procedure and appeared to have obtained no or marginal benefit from the TMVR procedure. Of note, most patients who survived the periprocedural period improved their functional status and had no rehospitalizations due to heart failure within the 2 years following the intervention. This compares favorably with the high rate of heart failure hospitalizations within the year before the procedure, and is consistent with previous studies in the surgical field (12). In addition to a learning curve factor and the transapical approach as factors that could explain post-TMVR mortality, patient selection may play a significant role. All patients that were included in the present study had functional or mixed severe MR with low LVEF and a high prevalence of noncardiac comorbidities. Future studies with a much larger number of patients are needed to provide definite safety and efficacy data after TMVR.

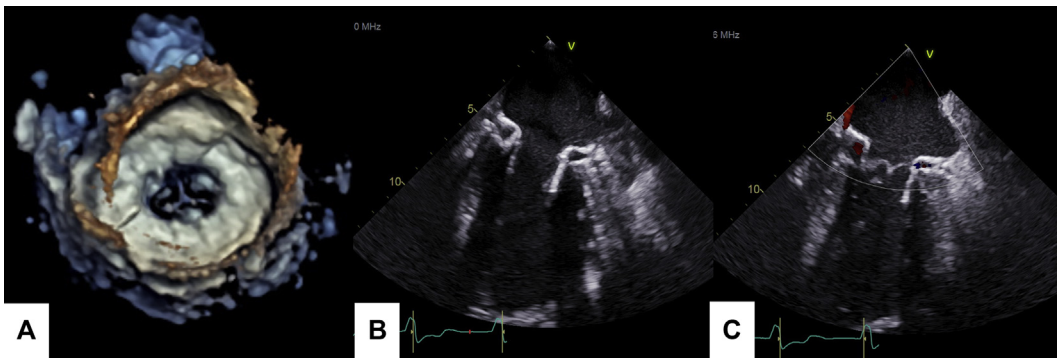
Ischemic heart disease with secondary MR was the main mechanism of MR in the present study. Although no strong evidence yet exists regarding the

FIGURE 4 2-Year Follow-Up NYHA Functional Class



Baseline, 1-month, and 2-year follow-up New York Heart Association (NYHA) functional class after transcatheter mitral valve replacement with the Fortis valve.

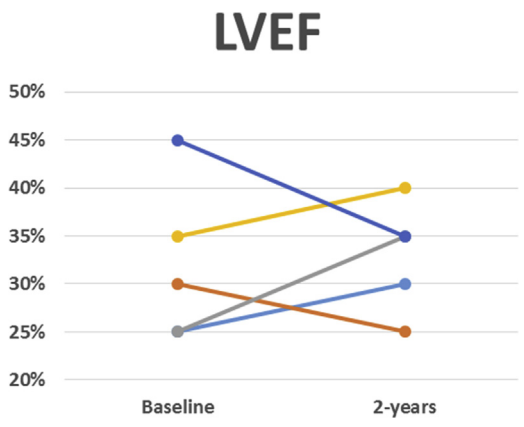
FIGURE 5 2-Year Follow-Up Transesophageal Echocardiographic Images



Two-year follow-up transesophageal echocardiographic images: **(A)** 3-dimensional view (from the left atrium), **(B)** 2-dimensional diastolic long-axis view, and **(C)** 2-dimensional systolic long-axis. The images reveal a trivial medial paravalvular leak following transcatheter mitral valve replacement with the FORTIS valve (Edwards Lifesciences, Irvine, California).

efficacy of any valve intervention in terms of survival or improvement of quality of life for patients with secondary MR, surgical mitral valve replacement has proven to be effective in reducing the degree of MR with a greater durability of correction when compared with surgical mitral valve repair (13). This suggests a better outcome for valve replacement compared with valve repair in this population. In our study we did not observe cases of MR recurrence in patients who survived the periprocedural period. This finding needs to be confirmed in further studies.

FIGURE 6 2-Year Follow-Up LVEF

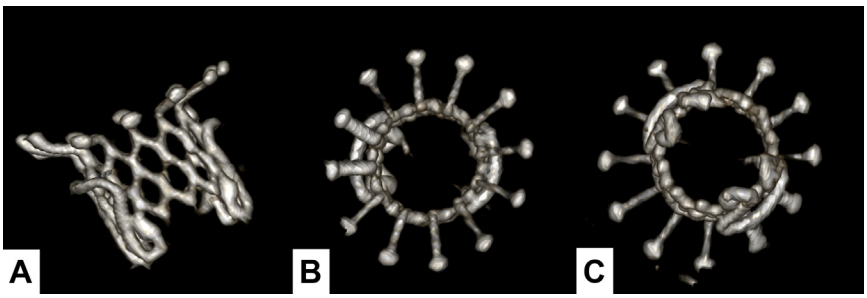


Baseline and 2-year follow-up left ventricular ejection fraction (LVEF) after transcatheter mitral valve replacement with the FORTIS valve (Edwards Lifesciences, Irvine, California).

Progression of LV dysfunction was observed in 2 patients at 2-year follow-up. The FORTIS valve was designed to preserve the subvalvular apparatus and although the influence of the valve prosthesis on LV function cannot be ruled out, the deterioration of LV function during follow-up may be more likely related to the myocardial injury secondary to transapical access or the progression of baseline cardiomyopathy.

Some studies have suggested a higher rate of valve thrombosis following surgical mitral valve replacement as compared with the aortic bioprostheses (14,15). This may be partially related to the slow flow conditions observed in the mitral valve as compared with the aortic side. The risk of valve thrombosis has also been a concern following transcatheter valve replacement therapies (8,15,16). In the present study, 1 patient developed a clinically significant episode of probable valve thrombosis within the days following successful TMVR. This highlights the importance of specific antithrombotic regimes in this setting, probably involving combined (anticoagulation + antiplatelet) therapies. Also, the international normalized ratio therapeutic levels may have to be higher (probably >2.5) within the weeks following the procedure. Importantly, no other episodes of valve thrombosis were documented during the 2-year follow-up period, suggesting that the risk of valve thrombosis is probably higher in the periprocedural period. Of note, Edwards Lifesciences halted the FORTIS valve program in May 2015 in response to issues of periprocedural valve thrombosis.

FIGURE 7 2-Year Follow-Up Cardiac Computed Tomographic Images



Computed tomography images showing no stent fracture after 2-year follow-up: **(A)** long-axis view, **(B)** short-axis view from the atrial side, **(C)** short-axis view from the ventricular side.

Studies in the surgical field have shown a very low rate of structural failure of valve prostheses requiring reintervention at very long-term (up to 20 years) follow-up (17,18). The present study is the first to provide data on valve durability following TMVR. No signs of valve structural failure or any hemodynamic deterioration were observed at 2-year follow-up. However, these features were evaluated only in one-half of the study population as a direct result of the high periprocedural mortality rate. Larger studies with a longer follow-up will be needed to confirm these results.

STUDY LIMITATIONS. This was a small-sized registry limited to 1 type of transcatheter mitral valve prosthesis. An early feasibility study of the FORTIS valve was performed in the United States, but we did not have access to these data. Data cannot be directly transferable to other transcatheter mitral valve prostheses. There was no centralized adjudication for echocardiographic data and clinical events.

CONCLUSIONS

This first long-term follow-up report of TMVR for treating severe MR in patients at high surgical risk showed that the reduction of MR after TMVR was maintained over time, with no significant recurrent MR at 2-year follow-up. No structural failures of the prosthesis or episodes of late thrombosis were observed. Larger and longer-term follow-up studies with currently available devices are warranted.

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PERSPECTIVES

WHAT IS KNOWN? Transcatheter mitral valve repair has been recognized as an alternative for treating patients with severe MR at high or prohibitive surgical risk. More recently, TMVR has emerged as another transcatheter option for treating MR.

WHAT IS NEW? This first long-term follow-up report of TMVR for treating severe MR in patients at high surgical risk showed that good valve performance and clinical improvements were sustained at 2-year follow-up, with no cases of late device-related events.

WHAT IS NEXT? Larger and longer-term follow-up studies with currently available devices are warranted.

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KEY WORDS heart failure, mitral regurgitation, transcatheter mitral valve replacement