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Initial Experience of Transcatheter Mitral Valve Replacement With a Novel Transcatheter Mitral Valve

Procedural and 6-Month Follow-Up Results

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ABSTRACT

BACKGROUND There are scarce data available on transcatheter mitral valve replacement (TMVR), and these have been limited to procedural results, with no follow-up status reported.

OBJECTIVES The goal of this study was to evaluate the feasibility, procedural results, and 6-month follow-up outcomes after TMVR with a mitral transcatheter heart valve (Fortis, Edwards Lifesciences, Irvine, California).

METHODS We report a series of 3 patients (mean age 71 ± 9 years, 2 men) who had TMVR under a compassionate clinical use program. All patients treated had functional mitral regurgitation (MR) secondary to ischemic cardiomyopathy (prior bypass surgery in all cases; left ventricular ejection fraction between 25% and 30%) and were considered to be at very high surgical risk (mean Society of Thoracic Surgeons score: 9.3).

RESULTS The procedure was performed through the transapical approach, and the valve was successfully implanted in all cases, with no major complications. At hospital discharge, echocardiographic evaluation revealed trace residual MR in 2 patients and no MR in 1 patient. The mean transvalvular mitral gradient was ≤4 mm Hg in all patients. At the 3-month follow-up, the valve function remained unchanged, and transesophageal echocardiography and computed tomography showed no structural failures. All patients had improvements in functional status, in exercise capacity as evaluated by 6-min walk test, and in quality of life. At 6-month follow-up, all patients remain alive, without hospital readmission for heart failure and with New York Heart Association functional class ≤II.

CONCLUSIONS TMVR with this valve is feasible and is associated with good outcomes. Optimal valve functional results were obtained acutely and were sustained at 6-month follow-up in all patients. Further studies with a larger number of patients and longer follow-up are warranted. (J Am Coll Cardiol 2015;66:1011–9) © 2015 by the American College of Cardiology Foundation.

Severe mitral regurgitation (MR) represents the second most prevalent valvular heart disease in western countries (1). Although there is a consensus on the advisability of surgery in patients with symptomatic severe MR (3+/4), up to one-third to one-half of patients requiring mitral valve repair/replacement are deemed to be at too high risk for surgery (2,3). When the operative risk is unacceptable, percutaneous edge-to-edge mitral repair (MitraClip System, Abbott Vascular, Santa Clara, California) has emerged as a valid alternative to surgery with low procedural risk (4,5). However, specific anatomical

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Listen to this manuscript's audio summary by *JACC* Editor-in-Chief Dr. Valentin Fuster.

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ABBREVIATIONS AND ACRONYMS

6MWT = 6-min walk test

CT = computed tomography

DASI = Duke Activity Status Index

LVEF = left ventricular ejection fraction

LVOT = left ventricular outflow tract

MR = mitral regurgitation

NYHA = New York Heart Association

TEE = transesophageal echocardiography

TMVR = transcatheter mitral valve replacement

TTE = transthoracic echocardiography

conditions are required to obtain satisfactory results, with increasing rates of procedural failure and poorer clinical outcomes when these criteria are not taken into account (6–8). Therefore, a significant proportion of noncandidates for surgery for whom percutaneous mitral repair is not an appropriate option remain.

Transcatheter mitral valve replacement (TMVR) has recently emerged as a new therapeutic option for the treatment of mitral valve disease. However, current experience is limited to procedural results in very few cases worldwide (9–12), and follow-up status has not been reported. The objective of this study was to evaluate the feasibility, procedural results, and 6-month follow-up outcomes after TMVR with the mitral transcatheter heart valve (Fortis, Edwards Lifesciences, Irvine, California).

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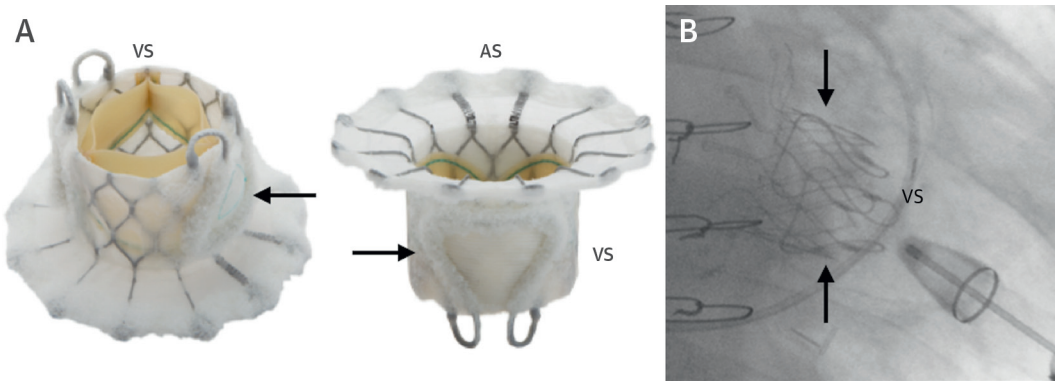
METHODS

A multidisciplinary team composed of cardiac surgeons, interventional cardiologists, echocardiographers, and radiologists evaluated all cases. Clinical inclusion criteria included the presence of isolated severe mitral regurgitation (3+ or 4) and New York Heart Association (NYHA) functional class III or IV, despite optimal medical treatment including cardiac resynchronization therapy, if indicated. Clinical exclusion criteria were moderate or greater mitral valve stenosis, untreated coronary artery disease requiring revascularization, chronic renal failure stage >III not receiving dialysis, other concomitant significant valve disease, and known hypersensitivity to nitinol. Anatomic suitably was evaluated using echocardiography and computed tomography (CT) scan criteria, as previously described (10).

After multidisciplinary team evaluation, all patients were considered to be at prohibitive risk for standard surgical valve repair/replacement. All patients were evaluated and treated under a Special Access Program approved by Health Canada. This is a clinically oriented program that evaluates, on a case-by-case basis, requests for access to nonmarketed drugs or devices for treatment, diagnosis, or prevention of serious or life-threatening conditions when conventional therapies have been considered and ruled out, have failed, are unsuitable, and/or unavailable. After Health Canada approval, all patients provided signed informed consent for the procedures and for retrospective data collection and reporting.

FORTIS MITRAL TRANSCATHETER HEART VALVE. The valve (Figure 1) comprises a self-expanding, nitinol frame, trileaflet Resilia bovine pericardial tissue, an atrial flange, and 2 opposing paddles that capture the native mitral leaflets and secure them to the frame, forming the primary attachment mechanism. The 29-mm prosthesis (the only available size to date) is crimped and loaded into a 42-F transapical delivery system. The 29-mm valve is suitable in patients with native annular diameter distance at the A2-P2 level between 30 and 44 mm.

FIGURE 1 The Fortis Transcatheter Heart Valve



(A) The Fortis mitral transcatheter heart valve has 3 different parts: the atrial flange, the ventricular side (or valve body), and 2 paddles **(black arrows)**. The paddles are opened once the prosthesis enters into the left ventricular cavity and are oriented using echocardiography guidance to capture the native mitral leaflets. **(B)** Fluoroscopic images of the Fortis valve after full deployment. AS = atrial side; VS = ventricular side.