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Early Outcomes of Percutaneous Transvenous Transseptal Transcatheter Valve Implantation in Failed Bioprosthetic Mitral Valves, Ring Annuloplasty, and Severe Mitral Annular Calcification

Mackram F. Eleid, MD,[a] Brian K. Whisenant, MD,[b] Allison K. Cabalka, MD,[a] Mathew R. Williams, MD,[c] Mohammed Nejjari, MD,[d] David Attias, MD,[d] Neil Fam, MD,[e] Nicholas Amoroso, MD,[c] Thomas A. Foley, MD,[a] Peter M. Pollak, MD,[a] Oluseun O. Alli, MD,[f] Sorin V. Pislaru, MD,[a] Sameh M. Said, MD,[g] Joseph A. Dearani, MD,[g] Charanjit S. Rihal, MD, MBA[a]

ABSTRACT

OBJECTIVES The aim of this study was to examine 1-year outcomes of transseptal balloon-expandable transcatheter heart valve implantation in failed mitral bioprosthesis, ring annuloplasty, and mitral annular calcification (MAC).

BACKGROUND Immediate outcomes following transseptal mitral valve implantation in failed bioprostheses are favorable, but data on subsequent outcomes are lacking.

METHODS Percutaneous transseptal implantation of balloon-expandable transcatheter heart valves was performed in 87 patients with degenerated mitral bioprostheses (valve in valve [VIV]) (n = 60), previous ring annuloplasty (valve in ring) (n = 15), and severe MAC (valve in MAC) (n = 12).

RESULTS The mean Society of Thoracic Surgeons risk score was 13 ± 8%, and the mean age was 75 ± 11 years. Acute procedural success was achieved in 78 of 87 patients (90%) in the overall group and 58 of 60 (97%) in the VIV group, with a success rate of 20 of 27 (74%) in the valve in ring/valve in MAC group. Thirty-day survival free of death and cardiovascular surgery was 95% (95% confidence interval [CI]: 92% to 97%) in the VIV subgroup and 78% (95% CI: 70% to 86%) in the valve in ring/valve in MAC group (p = 0.008). One-year survival free of death and cardiovascular surgery was 86% (95% CI: 81% to 91%) in the VIV group compared with 68% (95% CI: 58% to 78%) (p = 0.008). At 1 year, 36 of 40 patients (90%) had New York Heart Association functional class I or II symptoms, no patients had more than mild residual mitral prosthetic or periprosthetic regurgitation, and the mean transvalvular gradient was 7 ± 3 mm Hg.

CONCLUSIONS One-year outcomes following successful transseptal balloon-expandable transcatheter heart valve implantation in high-risk patients with degenerated mitral bioprostheses are excellent, characterized by durable symptom relief and prosthesis function. Although mitral valve in ring and valve in MAC have higher operative morbidity and mortality, 1-year outcomes after an initially successful procedure are favorable in carefully selected patients. (J Am Coll Cardiol Intv 2017;10:1932–42) © 2017 by the American College of Cardiology Foundation.

From the [a]Department of Cardiovascular Medicine, Mayo Clinic, Rochester, Minnesota; [b]Intermountain Heart Institute, Salt Lake City, Utah; [c]New York University Medical Center, New York, New York; [d]Centre Cardiologique du Nord, Saint-Denis, France; [e]St. Michael's Hospital, Toronto, Ontario, Canada; [f]University of Alabama, Birmingham, Alabama; and the [g]Department of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota. Dr. Whisenant has received honoraria and consulting income from Edwards Lifesciences and Boston Scientific. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Structural degeneration requiring repeat intervention in the first 10 years following mitral valve surgery may be required in up to 35% of patients (1,2). Given the high risk of redo mitral valve surgery, particularly in patients with severe medical comorbidities, alternative, less invasive therapies are needed. Nonrheumatic mitral stenosis or regurgitation due to mitral annular calcification (MAC) presents unique challenges and carries a higher procedural mortality with mitral valve replacement (3,4). Transcatheter valve-in-valve implantation is a promising therapy for such patients, with emerging evidence suggesting feasibility of this approach (5–7). We have recently reported a series of patients undergoing transvenous transseptal implantation of balloon-expandable transcatheter heart valves (THVs) showing high procedural success rates and rapid recovery, particularly in patients with degenerated mitral bioprostheses (8). However, the 1-year durability of balloon-expandable THVs designed for the treatment of aortic stenosis in the mitral position is unknown.

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We sought to evaluate the 1-year outcomes of percutaneous antegrade transvenous transseptal mitral valve implantation using commercially available balloon-expandable THVs in patients with failed mitral bioprostheses, ring annuloplasty, and mitral stenosis due to MAC.

METHODS

PATIENT POPULATION. From January 2014 through March 2017, 46 consecutive patients underwent percutaneous transvenous transseptal implantation of the balloon-expandable SAPIEN, SAPIEN XT, or SAPIEN 3 THV (Edwards Lifesciences, Irvine, California) into the mitral position at the Mayo Clinic (Rochester, Minnesota), 19 at Intermountain Heart Institute (Salt Lake City, Utah), 10 at New York University Medical Center (New York, New York), 6 at Centre Cardiologique du Nord (Saint-Denis, France), 4 at St. Michael's Hospital (Toronto, Ontario, Canada), and 3 at the University of Alabama (Birmingham, Alabama). Each center included in this study performed the procedure using the same technique (described later) and patient selection criteria. Patients who had significant bioprosthetic mitral valve or annuloplasty repair dysfunction (stenosis, regurgitation, or both) or severe mitral stenosis due to MAC, with comorbid conditions that would preclude a repeat sternotomy and valve replacement, were considered candidates for the procedure. Exclusion criteria for patients with bioprosthetic valve failure included the presence of active endocarditis or prosthetic valve thrombosis. Exclusion criteria for patients with annuloplasty rings included a high predicted risk for left ventricular outflow tract (LVOT) obstruction on the basis of pre-procedural imaging or the presence of an annular area too large to allow 5% to 10% oversizing with a balloon-expandable THV. Exclusion criteria for patients with MAC included insufficient circumferential calcification (<270° of annular circumference), a high predicted risk for LVOT obstruction on the basis of pre-procedural imaging (anticipated ≥50% reduction in LVOT area), or the presence of an annular area too large to allow 5% to 10% oversizing with a balloon-expandable THV. All patients were evaluated by a cardiovascular surgeon before proceeding with percutaneous valve therapy. All patients received detailed instruction on potential risks of the procedure and the off-label use of the THVs. Alternatives, including repeat open surgery and medical therapy, were carefully discussed. All patients provided informed consent for the procedure. Patients were counseled about the need for long-term anticoagulation with warfarin after valve implantation (in the absence of contraindications). All procedures were performed electively, with the exception of 2 urgent mitral valve implantations. Four procedures were performed using planned venoarterial extracorporeal membrane oxygenation; the remaining were performed without hemodynamic support devices. This retrospective study was approved by the Mayo Clinic Institutional Review Board.

PROCEDURAL PLANNING. In most cases, transcatheter valve size was selected on the basis of a combination of the manufacturer's reported internal dimension and true internal dimension as well as computed tomography–derived and transesophageal echocardiography (TEE)–derived measurements (9). The valve-in-valve app was consulted for each case to ensure proper valve size selection (Bapat V, Valve in Valve Mitral app, UBQO Limited, London, United Kingdom). We typically added 1 to 2 ml of additional volume to the deployment balloon and determined the amount of volume on the basis of the visual appearance of the valve, aiming to achieve mild flaring of the ends of the valve stent on the ventricular and atrial sides. For patients with calcific mitral stenosis or mitral annuloplasty rings, 3-dimensional computed tomographic evaluation of the mitral annulus and leaflets was essential to determine the presence of adequate calcification or ring coverage of

ABBREVIATIONS AND ACRONYMS

CI = confidence interval

LV = left ventricular

LVOT = left ventricular outflow tract

MAC = mitral annular calcification

MR = mitral regurgitation

MVARC = Mitral Valve Academic Research Consortium

NYHA = New York Heart Association

TEE = transesophageal echocardiography

THV = transcatheter heart valve