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Transcatheter Mitral Valve Replacement in Native Mitral Valve Disease With Severe Mitral Annular Calcification

Results From the First Multicenter Global Registry

Mayra Guerrero, MD,[a] Danny Dvir, MD,[b] Dominique Himbert, MD,[c] Marina Urena, MD,[c] Mackram Eleid, MD,[d] Dee Dee Wang, MD,[e] Adam Greenbaum, MD,[e] Vaikom S. Mahadevan, MBBS, MD,[f] David Holzhey, MD, PhD,[g] Daniel O'Hair, MD,[h] Nicolas Dumonteil, MD,[i] Josep Rodés-Cabau, MD,[j] Nicolo Piazza, MD,[k] Jose H. Palma, MD, PhD,[l] Augustin DeLago, MD,[m] Enrico Ferrari, MD,[n] Adam Witkowski, MD, PhD,[o] Olaf Wendler, MD, PhD,[p] Ran Kornowski, MD,[q] Pedro Martinez-Clark, MD,[r] Daniel Ciaburri, MD,[s] Richard Shemin, MD,[t] Sami Alnasser, MD,[u] David McAllister, DO,[v] Martin Bena, MD,[w] Faraz Kerendi, MD,[x] Gregory Pavlides, MD,[y] Jose J. Sobrinho, MD,[z] Guilherme F. Attizzani, MD,[aa] Isaac George, MD,[bb] George Nickenig, MD,[cc] Amir-Ali Fassa, MD,[dd] Alain Cribier, MD,[ee] Vinnie Bapat, MD,[ff] Ted Feldman, MD,[a] Charanjit Rihal, MD,[d] Alec Vahanian, MD,[c] John Webb, MD,[b] William O'Neill, MD[e]

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CME Objective for This Article: 1) appreciate the risks of mitral valve replacement in the setting of severe mitral annular calcification; 2) evaluate the clinical outcomes following transcatheter mitral valve replacement with balloon-expandable valves in high-risk patients; and 3) consider the significance of computed tomography for pre-procedural planning when transcatheter mitral valve replacement is the treatment of choice.

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ABSTRACT

OBJECTIVES This study sought to evaluate the outcomes of the early experience of transcatheter mitral valve replacement (TMVR) with balloon-expandable valves in patients with severe mitral annular calcification (MAC) and reports the first large series from a multicenter global registry.

BACKGROUND The risk of surgical mitral valve replacement in patients with severe MAC is high. There are isolated reports of successful TMVR with balloon-expandable valves in this patient population.

METHODS We performed a multicenter retrospective review of clinical outcomes of patients with severe MAC undergoing TMVR.

RESULTS From September 2012 to July of 2015, 64 patients in 32 centers underwent TMVR with compassionate use of balloon-expandable valves. Mean age was 73 ± 13 years, 66% were female, and mean Society of Thoracic Surgeons score was 14.4 ± 9.5%. The mean mitral gradient was 11.45 ± 4.4 mm Hg and the mean mitral area was 1.18 ± 0.5 cm^2. SAPIEN valves (Edwards Lifesciences, Irvine, California) were used in 7.8%, SAPIEN XT in 59.4%, SAPIEN 3 in 28.1%, and Inovare (Braile Biomedica, Brazil) in 4.7%. Access was transatrial in 15.6%, transapical in 43.8%, and transseptal in 40.6%. Technical success according to Mitral Valve Academic Research Consortium criteria was achieved in 46 (72%) patients, primarily limited by the need for a second valve in 11 (17.2%). Six (9.3%) had left ventricular tract obstruction with hemodynamic compromise. Mean mitral gradient post-procedure was 4 ± 2.2 mm Hg, paravalvular regurgitation was mild or absent in all. Thirty-day all-cause mortality was 29.7% (cardiovascular = 12.5% and noncardiac = 17.2%); 84% of the survivors with follow-up data available were in New York Heart Association functional class I or II at 30 days (n = 25).

CONCLUSIONS TMVR with balloon-expandable valves in patients with severe MAC is feasible but may be associated with significant adverse events. This strategy might be an alternative for selected high-risk patients with limited treatment options. (J Am Coll Cardiol Intv 2016;9:1361–71) © 2016 by the American College of Cardiology Foundation.

From [a]Department of Medicine, Division of Cardiology, Evanston Hospital, Evanston, Illinois; [b]Center for Heart Valve Innovation, St. Paul's Hospital, Vancouver, British Columbia, Canada; [c]Cardiology Department, Bichat-Claude Bernard Hospital, Paris, France; [d]Department of Cardiovascular Diseases, Mayo Clinic, Rochester, Minnesota; [e]Department of Medicine, Division of Cardiology, Henry Ford Hospital, Detroit, Michigan; [f]Department of Medicine, Division of Cardiology, University of California San Francisco, San Francisco, California; [g]Department of Cardiac Surgery, Leipzig Heart Center, Leipzig, Germany; [h]Department of Surgery, Aurora St. Luke's Medical Center, Milwaukee, Wisconsin; [i]Department of Cardiology, Rangueil University Hospital, Toulouse, France; [j]Quebec Heart and Lung Institute, Laval University, Quebec City, Quebec, Canada; [k]Department of Interventional Cardiology, McGill University Health Centre, Montreal, Quebec, Canada; [l]Department of Cardiovascular Surgery, Escola Paulista de Medicina, São Paolo, Brazil; [m]Department of Medicine, Division of Cardiology, Albany Medical Center Hospital, Albany, New York; [n]Cardiac Surgery Unit, Cardiocentro Ticino Foundation, Lugano, Switzerland; [o]Department of Interventional Cardiology & Angiology, Institute of Cardiology, Warsaw, Poland; [p]Department of Surgery, King's College Hospital, London, United Kingdom;