Journal of the American College of Cardiology
© 2012 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 60, No. 15, 2012
ISSN 0735-1097/$36.00

CORRESPONDENCE

Research Correspondence

Tiara: A Novel Catheter-Based Mitral Valve Bioprosthesis

Initial Experiments and Short-Term Pre-Clinical Results

To the Editor: Novel percutaneous transcatheter technologies are emerging as alternatives to surgery for high-risk patients (1). Transcatheter mitral valve (MV) implantation has the potential to become the preferred intervention to treat severe mitral regurgitation in these patients, because theoretically it can reduce mitral regurgitation to an extent similar to that of surgery while preserving the mitral apparatus. However, many challenges need to be addressed in the design and development of a device to be deployed across an asymmetric and multiplanar MV annulus (2). Transcatheter MV implants should restore unidirectional flow, spare chordal structures, and leave adjacent myocardium intact, while minimizing the risks associated with the procedure, allowing high-risk patients who are not candidates for surgery to receive definitive treatment. Herein we report our preclinical, short-term safety and feasibility experience with the Tiara valve (Neovasc, Inc., Richmond, British Columbia, Canada), a catheter-based, self-expanding mitral bioprosthesis.

The Tiara comprises a self-expanding frame and biological tissue leaflets fixed within this frame. Its atrial portion is designed specifically to fit the saddle-shaped mitral annulus. The Tiara orifice is D-shaped to match the natural shape of the mitral orifice, and when implanted, the flat side of the D is positioned anteriorly to prevent impingement of the left ventricular outflow tract (LVOT). The ventricular portion of the device comprises a covered so-called skirt structure that prevents paravalvular leak as well as 3 anchoring structures. The 2 anterior anchoring structures are designed to capture the fibrous trigones on both sides of the anterior mitral leaflet, whereas the posterior anchoring structure projects behind the posterior mitral leaflet, creating a 3-point anchor on the ventricular side that works in conjunction with the atrial flange to secure the Tiara within the mitral annulus. This securement prevents retrograde dislodgement during systole. The prosthetic valve leaflets are specially designed in a D configuration to match the valve frame orifice.

Tiara implantation is performed by a multidisciplinary team including 2 interventional cardiologists, a cardiac surgeon, and an echocardiographer. Before implantation, transesophageal echo (TEE) measurements of the left atrium, and mitral annulus dimensions are performed. Through a subxiphoid incision of less than 5 cm, an apical puncture is performed and a J-tipped 0.035-inch guidewire is advanced across the mitral apparatus into the left atrium. The Tiara valve loaded within a 30-F deployment catheter is advanced over the guidewire and is positioned in the left atrium. On angiographic and TEE confirmation of proper positioning of the Tiara delivery system, the guidewire is removed. A single thumbwheel retracts a sheath covering the device and controls the entire deployment process. Tiara deployment follows the sequence of first deploying and orienting the atrial flange portion. This is accomplished readily using fluoroscopy to visualize the device and radiopaque markers located at specific points on the structure, so that the flat aspect of the D-shaped prosthesis is aligned with the LVOT and the aorta. The valve then is pulled downward to seat the atrial flange firmly on the floor of the atrium, and the 3 ventricular anchor structures then are deployed to capture the fibrous trigones and posterior mitral leaflet. After these 3 anchors are deployed fully, the ventricular skirt and valve leaflets are released from the catheter, allowing the device to begin functioning in place of the native valve. In all stages of valve deployment until the final step of ventricular deployment, it is possible to recapture the partially deployed valve into the delivery catheter, reposition it, and restart the implantation process. Tiara implantation does not require rapid pacing and does not cause any hemodynamic instability.

Immediately after deployment, the delivery system is removed and hemostasis is secured with previously placed pledgeted apical sutures. Mitral and aortic valve function, presence of an LVOT gradient, valvular or paravalvular regurgitation, aortic valve gradient, and patency of the left circumflex coronary artery are ruled out by TEE, cardiac catheterization, or both.

All animals with successful implantation were monitored hemodynamically for a minimum of 90 min, and after an additional echocardiographic evaluation of the MV, all but 7 animals were killed. The surviving animals were extubated and allowed to recover from anesthesia and monitored clinically for 4 to 96 h (per protocol) before they were killed.

Tiara valves were implanted successfully in 29 (81%) of 36 domestic swine with fluoroscopic and 3-dimensional TEE guidance (Fig. 1). Follow-up varied from 90 min to 96 h. Total procedure time ranged from 17 to 26 min, and the prosthesis deployment time ranged from 5 to 13 min after the apical access. In the 29 successful implantations, TEE demonstrated excellent function and alignment of the Tiara, with no LVOT obstruction, no pericardial effusion, no encroachment on the aortic valve, and no transvalvular gradients. Significant paravalvular leak was seen only in cases of either MV annulus–prosthesis mismatch or failed implantation. Macroscopic evaluation of the explanted hearts demonstrated stable and secure positioning of the valves in all planes of the mitral apparatus. There was a steady increase in the rate of successful implantation as the series progressed, with the final 12 animals in the series all undergoing successful and uneventful implantations. All 29 animals that underwent successful Tiara implantation remained hemodynamically stable throughout the implantation procedure.

Our initial preclinical experience with the Tiara transcatheter self-expanding mitral bioprosthetic valve is encouraging. We demonstrated that the implantation of the Tiara valve is feasible, relatively straightforward, and results in a stable and well-functioning MV bioprosthesis. Successful completion of long-term preclinical trials of the Tiara valve will lead the way to human clinical trials.

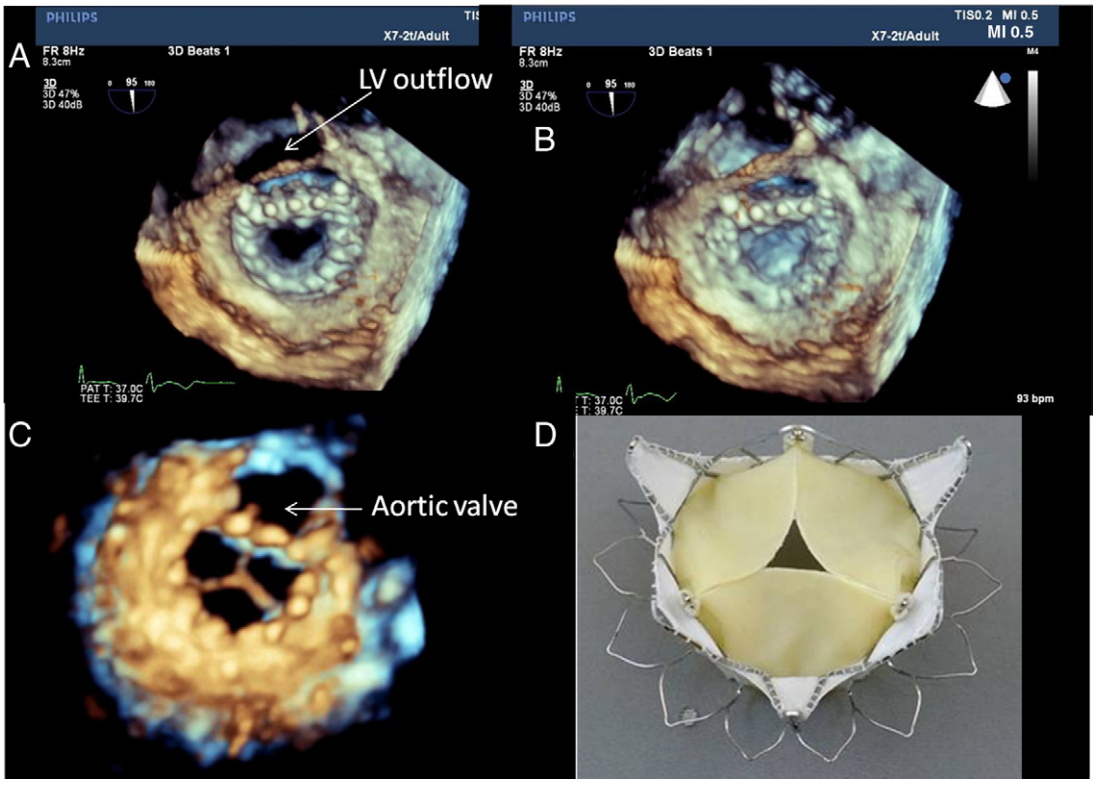

Figure 1 **Views of the Implanted Tiara Valve**

Three-dimensional (3D) transesophageal echo (TEE) atrial view of the implanted Tiara. Note the D-shaped prosthetic valve. **(A)** Diastole; **(B)** systole; **(C)** 3D TEE ventricular view of the implanted Tiara (note the trileaflet mitral bioprosthesis posterior to the aortic valve); and **(D)** ex vivo photography of the Tiara, ventricular view. LV = left ventricle.

***Shmuel Banai, MD**

*Interventional Cardiology
The Tel Aviv Medical Center
6 Weizman Street
Tel Aviv 64239
Israel
E-mail: shmuelb@tasmc.health.gov.il

E. Marc Jolicoeur, MD
Marc Schwartz, RCIS
Patrick Garceau, MD
Simon Biner, MD
Jean-Francois Tanguay, MD
Raymond Cartier, MD
Stefan Verheye, MD
Christopher J. White, MD
Elazer Edelman, MD, PhD

http://dx.doi.org/10.1016/j.jacc.2012.05.047

Please note: The research and development of the Tiara mitral bioprosthesis have been carried out by Neovasc, Inc. Dr. Banai is the Medical Director and Mr. Schwartz is Director of Clinical Affairs for Neovasc, Inc. Dr. Biner has received consulting fees from Neovasc Inc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Chiam PTL, Ruiz CE. Percutaneous transcatheter mitral valve repair: a classification of the technology. J Am Coll Cardiol Intv 2011;4:1–13.
2. Van Mieghem NM, Piazza N, Anderson RH, et al. Transcatheter interventions for mitral regurgitation anatomy of the mitral valvular complex and its implications for mitral regurgitation. J Am Coll Cardiol 2010;56:617–26.

Cardiac Arrest in a Long-Distance Ski Race (Vasaloppet) in Sweden

To the Editor: Physical training is generally regarded as beneficial for health. Heavy endurance exercises might, however, induce latent ischemic heart disease and acute cardiac arrhythmias. Kim et al. (1) recently reported on the incidence of cardiac arrest (CA) during long-distance running. Exercise in combination with a cold climate may be especially detrimental and trigger acute cardiac events (2). The incidence of CA during strenuous competitive exercise is uncertain. We aimed to investigate the absolute and relative risk for CA during long distance ski racing. Thus, we assessed the incidence of CA in Vasaloppet (90 km), the world's