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Transcatheter mitral valve replacement with Tendyne valve: The first two cases in Slovakia

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Transcatheter mitral valve replacement (TMVR) with the Tendyne mitral valve has emerged as a novel potential therapy for patients with severe mitral valve disease who are unsuitable candidates for conventional surgery and transcatheter mitral repair with MitraClip. In this communication we present the first two cases that were performed in Slovakia and the V4 countries. Two surgically high risk female patients 78 and 79 years old respectively (EuroScore II 7.8% and 7.4% respectively) also unsuitable candidates for transcatheter mitral repair with MitraClip, underwent transapical TMVR with the Tendyne valve. Both procedures were successful: one of the patients two months after the procedure is doing well, the other patient had a complicated postoperative course and died on postoperative day 4. Moreover we present a brief description of the valve, and of the deployment technique, and an overview of the major clinical studies. Fig. 3, Ref. 7, on-line full text (Free, PDF) www.cardiologyletters.sk

Key words: mitral valve regurgitation – transcatheter mitral valve replacement – Tendyne valve prosthesis

Mitral valve regurgitation (MR) is a very common occurring valvular disease in developed countries, with approximately 3.5 million people in the United States having above moderate-to severe MR (1). Surgical repair or replacement is the gold standard therapy for patients with symptomatic MR, whereas transcatheter edge-to-edge repair with MitraClip (Abbott Structural, Santa Clara, California) has proved of clinical benefit in selected patients (2).

This report presents our initial experience which is the first in V4 countries, and the potential role for transcatheter MV replacement (TMVR) with the Tendyne valve (Abbott Structural, Santa Clara, California) for patients with severe MV disease who are unsuitable candidates for conventional surgery and transcatheter mitral repair with MitraClip.

The Tendyne valve prosthesis

The tendyne valve is a self-expanding, nitinol prosthesis with a double-frame design that contains a trileaflet porcine pericardial valve and has an effective orifice area of greater than 3.2 cm^2 (standard size) or 2.0 cm^2 (low profile size). The prosthesis is anatomically shaped for the mitral annulus. The outer frame contains a cuff that extends above the plane of the annulus to abut the anterior atrial wall and aortic-mitral continuity for the purposes of preventing diastolic paravalvular MR. The implanted valve is selected to be larger than the native mitral orifice. The prosthesis, which is delivered via a 34F-36F transapical sheath, is uniquely anchored with a tether connected to an epicardial hemostatic pad at the apex **(Figure 1A, 1B)**. The Tendyne prosthesis is retrievable and repositionable after full deployment, an ability that minimizes the need for bailout open surgery (3).

Technique for deployment

The deployment procedure is performed under general anesthesia using a transapical approach via a left anterolateral minithoracotomy. A pigtail catheter is inserted through the

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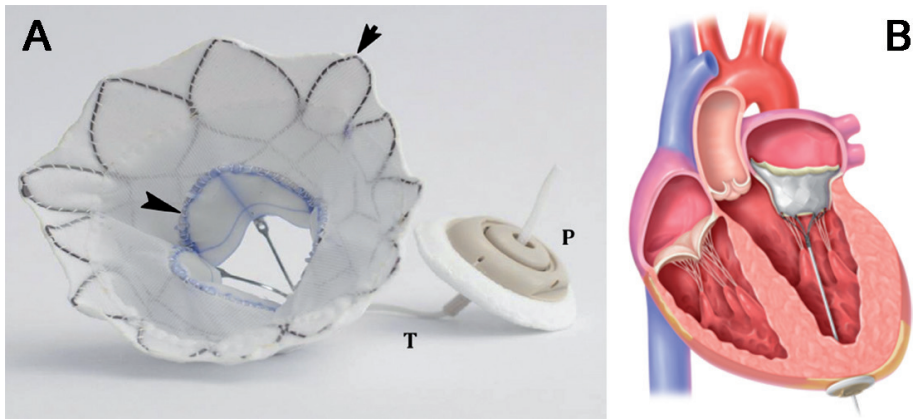

Figure 1A The Tendyne mitral valve system. The nitinol self-expanding prosthesis has a double flame. An outer flame (arrow) contains a cuff and an inner flame has a trileaflet porcine pericardial valve (arrowhead). The prosthesis is anchored to an epicardial hemostatic pad (P) by a tether (T)
Figure 1B The Tendyne mitral valve system in place at the end of the procedure (Courtesy of Abbot, Inc, Santa Clara, CA)

femoral artery to the left ventricle, a myocardial access site is punctured with a multipurpose needle, a balloon-tip-catheter is advanced from the left ventricle to the left atrium and a 34F-36F delivery sheath is inserted into the left ventricle. The valve is deployed intrannularly under the guidance of transesophageal echocardiography and fluoroscopy. After deployment, anchoring is achieved by a tether connecting to an epicardial pad, which also provides hemostasis. The tension and length from the valve to the ventricular apex of the tether are adjusted after deployment to optimize the seating of the prosthesis without worsening of left ventricular filling pressures. If the function of the prosthesis is not acceptable or if LVOT obstruction occurs, the prosthesis can be repositioned or fully retrieved. The entire procedure is performed without cardiopulmonary bypass and without rapid ventricular pacing. Antiplatelet therapy with aspirin 100 mg or clopidogrel 75 mg and anticoagulant therapy with heparin followed by warfarin for greater than or equal to 3 months, with target international normalization ratio of 2.5 to 3.5, are used in general.

Patient selection

Patient evaluation by a multidisciplinary heart team is paramount to optimize procedural results and effectiveness of TMVR. Two surgically high risk (EuroScore II 7.8% and 7.4% respectively) and unsuitable candidates for transcatheter mitral repair with MitraClip female patients, 78 and 79 years old respectively, were indicated by our institutional multidisciplinary heart team for TMVR with the Tendyne valve.

Both patients underwent preprocedural multimodality imaging with transthoracic echocardiography, transesophageal echocardiography (TEE) and contrast-enhanced, gated--cardiac CT.

The procedures were performed in November 2020 under general anesthesia, using a transapical approach via a left anterolateral minithoracotomy without cardiopulmonary bypass and rapid ventricular pacing. Procedural success was 100%, with no or minimal paravulvular leak and without LVOT obstruction. The Tendyne bioprosthetic valves of 29 L LP and 35 M LP sizes were implanted. The first patient had a complicated postoperative course, where on the second postoperative day (POD) she underwent implantation of a peripheral venoarterial membrane oxygenation (VA-ECMO) due to cardiogenic shock. Later on POD 4 the patient died as a result of bleeding complications. The second patient had an uneventful postoperative course, she has long-term anticoagulation treatment with warfarin, and more than two months after the procedure is doing well **(Figure 2A, 2B, 3A, 3B)**.

Clinical outcomes

The Global Feasibility Study (4) was a prospective, open--label, non-randomized trial to establish the safety and efficacy of the Tendyne valve at 30-day follow-up. A total of 30 patients with grade 3 or grade 4 and mean Society of Thoracic Surgeons (STS) predicted mortality 7.3% ± 5.7% underwent TMVR using the Tendyne valve. Device implantation was successful in 28 of the 30 patients without procedural death or complications. The 30-day survival was 86.7% (26/30 patients).

Sorajja et al. (5) reported long-term results from the first 100 patients with mean STS predicted risk of operative mortality 7.9% ± 5.7% enrolled in the Global Feasibility Study. Successful valve implantation occurred in 97% of patients

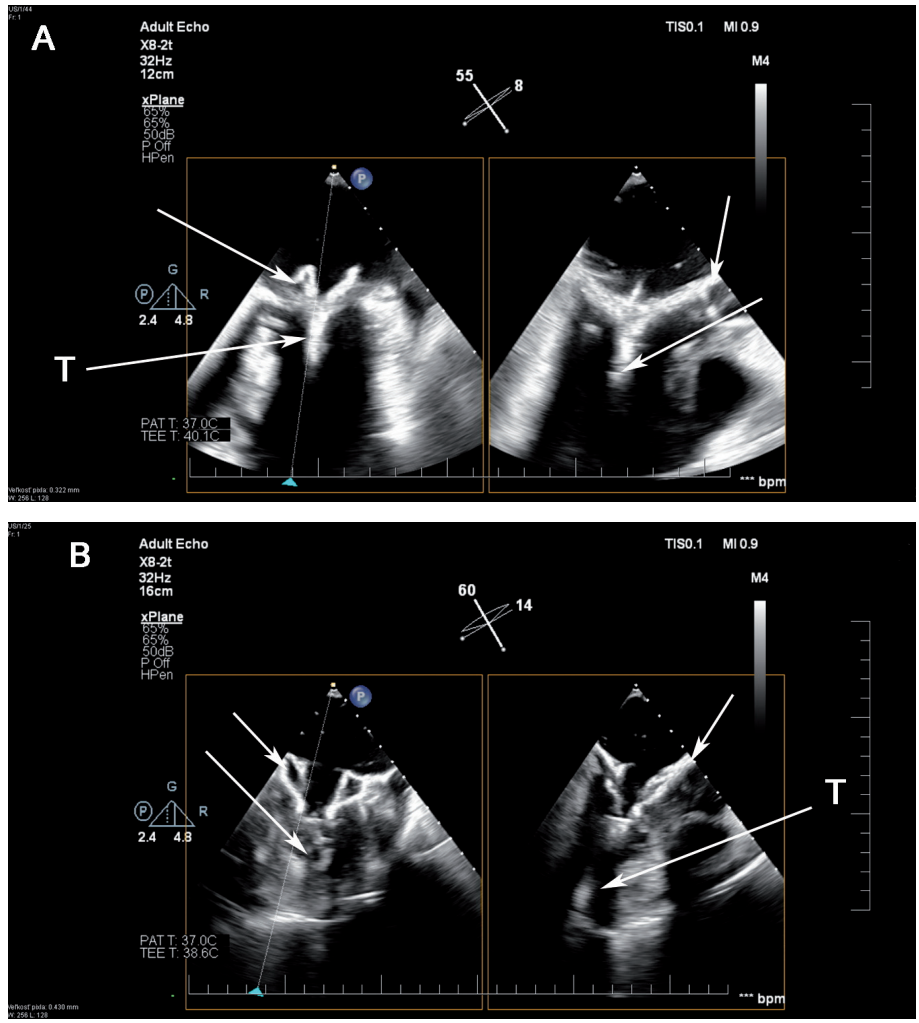

Figure 2A, 2B Intraoperative transesophageal images showing the Tendyne mitral valve prosthesis (arrows)
T – tether

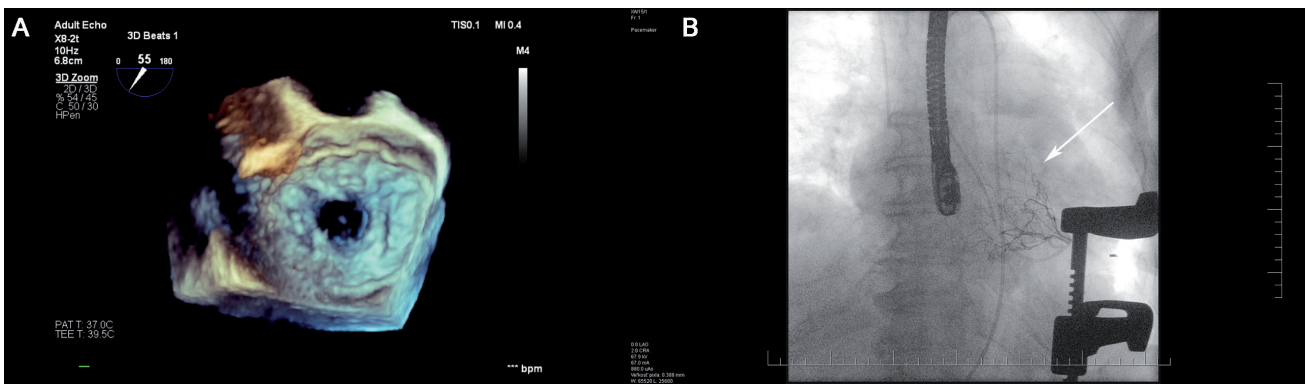

Figure 3A Intraoperative transesophageal 3D image showing the Tendyne mitral valve prosthesis fully extruded
Figure 3B Intraoperative fluoroscopy demonstrating placement of the Tendyne mitral valve prosthesis (arrow)

without procedural death or complications. The 30-day mortality was 6% and the rate of 1-year survival was 72% and 78% of the survivors had improved quality of life.

The SUMMIT (Tendyne Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation) trial (6) is a randomized 2:1 observational clinical trial that evaluates the safety and effectiveness of using the Tendyne mitral valve. The trial will enrol up to 1010 patients at 80 sites in the United States, European Union, and Canada. The trial design has a surgical (conventional surgery) and a nonsurgical arm (patients ineligible for MitraClip). The primary endpoint in both cohorts is a composite end point of death, cardiovascular hospitalization, stroke, or reoperation at 1 year.

The Tendyne mitral annular calcification (MAC) study is a feasibility study of the Tendyne valve use in patients with symptomatic MR and severe MAC not suitable for conventional surgery, which is currently recruiting patients. It is a single arm multicenter study that plans to include up to 30 patients at no more than 10 centers. The primary endpoint is procedural success and procedure-related adverse events at 30-day follow-up (7).

In conclusion, TMVR has emerged as a novel potential therapy for patients with severe mitral valve disease who are unsuitable candidates for conventional surgery and transcatheter mitral repair with MitraClip, and has shown potential as an effective and safe treatment alternative for high-risk patients at short-term follow-up.

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