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VALVULAR HEART DISEASE

CASE REPORT: CLINICAL CASE

Structural Degeneration of a 9-Year-Old Tendyne

Treatment by Transfemoral Transseptal SAPIEN in Tendyne

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ABSTRACT

An 83-year-old woman presented 9 years after Tendyne transcatheter mitral valve replacement with acute severe decompensated heart failure. Transesophageal echocardiography reported severe transvalvular mitral regurgitation caused by degenerated Tendyne leaflets. A transfemoral transseptal valve-in-Tendyne procedure using a 26-mm SAPIEN device resulted in significant mitral regurgitation reduction and symptomatic recovery. (JACC Case Rep 2024;29:102447) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

HISTORY OF PRESENTATION

An 83-year-old woman with previous mitral valve (MV) repair (38-mm Carpentier-Edwards Physio 2 ring in 2012) re-presented in 2014 with recurrent mitral regurgitation (MR). She was not a candidate for redo surgery and was anatomically unsuitable for transcatheter edge-to-edge-repair; therefore, she underwent compassionate-use transcatheter transapical mitral valve replacement (TMVR) with a size 2 Tendyne (Abbott) device (32.5 mm anteroposterior, 37.5 mm intercommissural, perimeter 118 mm). The procedure was complicated by periprocedural dynamic left ventricular outflow tract obstruction (LVOTO) (**Figure 1**) due to a combination of hyperdynamic basal septum, small left ventricular outflow tract (LVOT), and long anterior mitral valve leaflet (Video 1). The patient developed cardiogenic shock, necessitating intra-aortic balloon pump insertion and subsequent venoarterial extracorporeal membraneous oxygenation support. Five days later, a compassionate-use 22-mm CP Stent (Numed) was placed in the LVOT under fluoroscopic and 3-dimensional (3D) transesophageal echocardiography (TEE) guidance, and the LVOT peak gradient decreased to 25 mm Hg (Video 2). The length of hospital stay was 65 days due to venoarterial extracorporeal membraneous oxygenation wean and frailty. By discharge, the patient was in NYHA functional class I. She remained well at annual follow-up with normal Tendyne function on transthoracic echocardiography (TTE): no MR, mean Tendyne gradient

LEARNING OBJECTIVES

- To make a differential diagnosis of acute decompensated heart failure in a patient with previous Tendyne transcatheter mitral valve replacement.
- To understand preprocedural planning and steps in executing a safe SAPIEN-in-Tendyne procedure to relieve severe transvalvular mitral regurgitation.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

LV = left ventricular

LVOT = left ventricular outflow tract

LVOTO = left ventricular outflow tract obstruction

MR = mitral regurgitation

MV = mitral valve

TEE = transesophageal echocardiography

TMVR = transcatheter mitral valve replacement

TR = tricuspid regurgitation

TTE = transthoracic echocardiography

3D = 3-dimensional

2 mm Hg, peak LVOT gradient 20 mm Hg, mild tricuspid regurgitation (TR), and pulmonary systolic arterial pressure 33 mm Hg (**Figure 2**). Annual computed tomography was therefore not performed.

Almost 9 years later, the patient presented suddenly with acute decompensated heart failure and peripheral edema. She was apyrexial, with a pulse of 72 beats/min, blood pressure of 94/65 mm Hg, a jugular venous pulse visible at +5cm, and peripheral edema to the mid-thigh. Admitting medications included bisoprolol, ramipril, and warfarin.

PAST MEDICAL HISTORY

The patient was on lifelong anticoagulation for atrial flutter/fibrillation and had a cardiac resynchronization pacemaker and thrombocytopenia (presumed secondary to myelofibrosis).

DIFFERENTIAL DIAGNOSIS

Differential diagnosis included recurrent MR, recurrent LVOTO, paravalvular leak with hemolysis, and infective endocarditis.

INVESTIGATIONS

Chest radiography reported a moderate right-sided pleural effusion. Admitting blood labs were the following: white cell count 6.8 $\times$ 10^9/L, hemoglobin 10^9 g/L, platelet count 19 $\times$ 10^9/L, C-reactive protein 6 mg/L, international normalized ratio 2.2, and 3 sets of negative blood cultures. TTE reported normal left ventricular (LV) size with ejection fraction 50% to 55%, severe transvalvular MR, mean Tendyne gradient 6 mm Hg, peak LVOT gradient 7 mm Hg, moderate TR, and pulmonary systolic arterial pressure 57 mm Hg. TEE confirmed severe transvalvular MR (Video 3) due to degenerated prolapsing Tendyne leaflets (Video 4), no evidence of vegetation or paravalvular leak, and stable position but crushed/fractured LVOT stent (Video 4), confirmed on fluoroscopy (Video 5).

MANAGEMENT

Multidisciplinary team discussion felt the patient unsuitable for redo MV surgery due to frailty and thrombocytopenia and suggested a valve-in-Tendyne-in-ring procedure. Preprocedural 3D TEE measured Tendyne inner-ring dimensions of 2.3 cm $\times$ 2.6 cm, confirmed by computed tomography and 3D printing (**Figure 3**), suggesting use of a 26-mm SAPIEN device (Edwards Lifesciences). Surgical skirt modification was performed to prevent para-SAPIEN leak (**Figure 4**).

After attaining right femoral venous and arterial access, right femoral access was upsized to a 26-F Gore DRYSEAL sheath. Following a single-pass transseptal puncture, the opening left atrial pressure was V 70 mm Hg, with a mean of 31 mm Hg, and LV end-diastolic pressure was 18 mm Hg. An AL1 catheter via an SL0 transseptal sheath was used to cross the Tendyne into the LV, then exchanged for a Safari wire positioned at the LV apex. Following atrial septostomy using a 14 x 40 mm Atlas Gold balloon (Video 6), a 26-mm SAPIEN was deployed at nominal volume under rapid ventricular pacing (140 beats/min) on the LV wire within the Tendyne inner frame (Videos 7 and 8). The expanded SAPIEN implant was canted slightly with leaflet over-hang but was well-apposed within the Tendyne frame (Video 9). Transvalvular MR decreased to mild (Video 10) with reduction in LA pressure (V 30 mm Hg, mean 22 mm Hg) and no change in LV end-diastolic pressure (19 mm Hg). A 21-mm atrial septal defect was closed using a 24-mm Amplatzer ASD occluder and there were no immediate postprocedural complications.

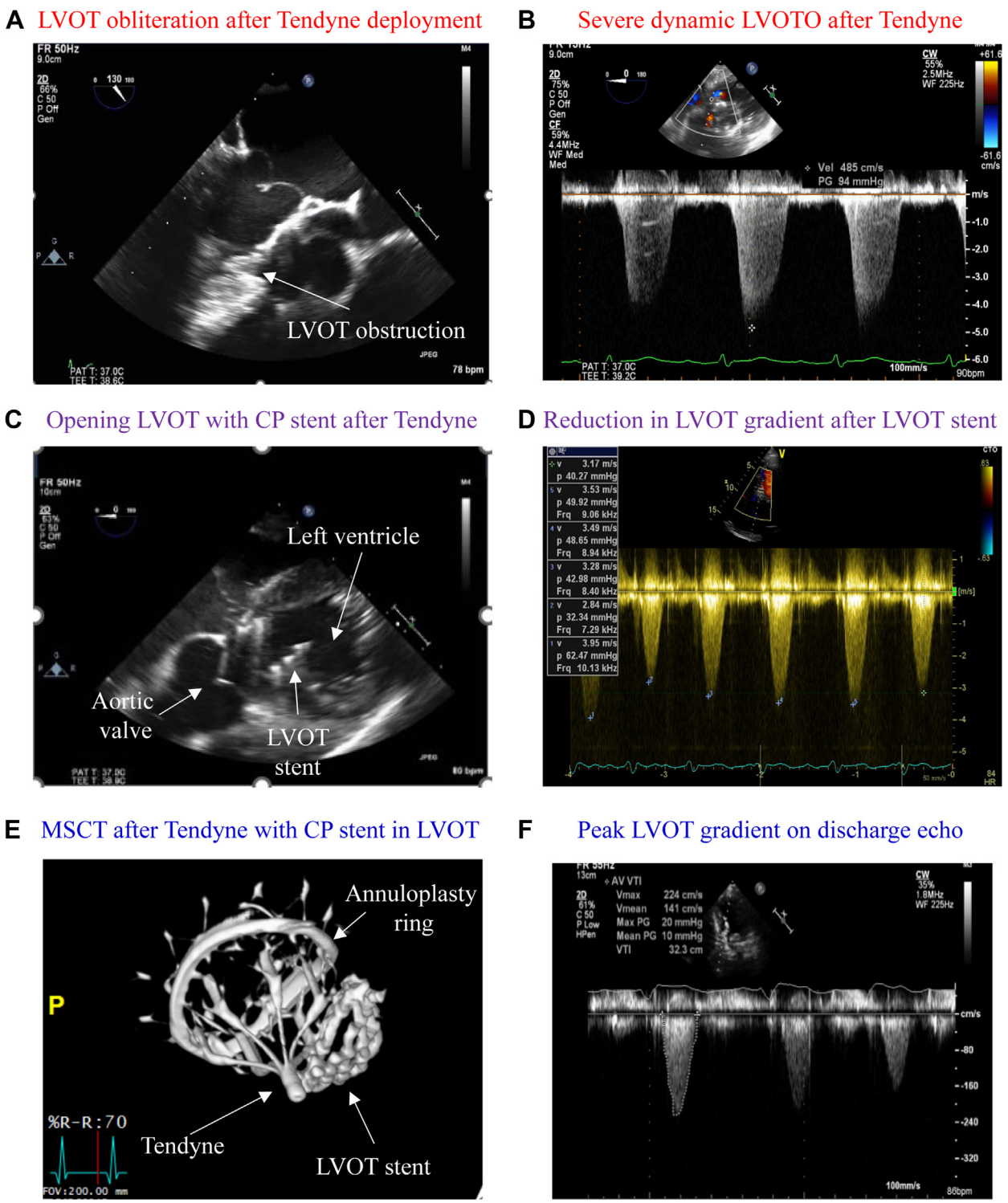
The patient reported immediate improvement in breathlessness, though required 6 weeks of intravenous diuretics for continued offloading. Thrombocytopenia improved (platelet count 100 $\times$ 10^9/L). She was discharged home, independent of all activities of daily living, on bendroflumethiazide, bisoprolol, candesartan, dapagliflozin, furosemide, spironolactone, and warfarin (target international normalized ratio 2.0). Discharge TTE reported a LV ejection fraction of 40% to 45%, mild transvalvular MR, mean Tendyne gradient 3 mm Hg, LVOT gradient 7 mm Hg, mild-moderate TR, and pulmonary artery systolic pressure of 39 mm Hg (**Figure 5**).

DISCUSSION

Tendyne TMVR has the largest cohort of patients undergoing transcatheter mitral valve replacement for native MR[1] with the longest follow-up.[2] Our team implanted the first Tendyne in man in 2014, and the device achieved CE mark in 2020. We present the first case of structural leaflet degeneration of a Tendyne device, 9 years after implantation.

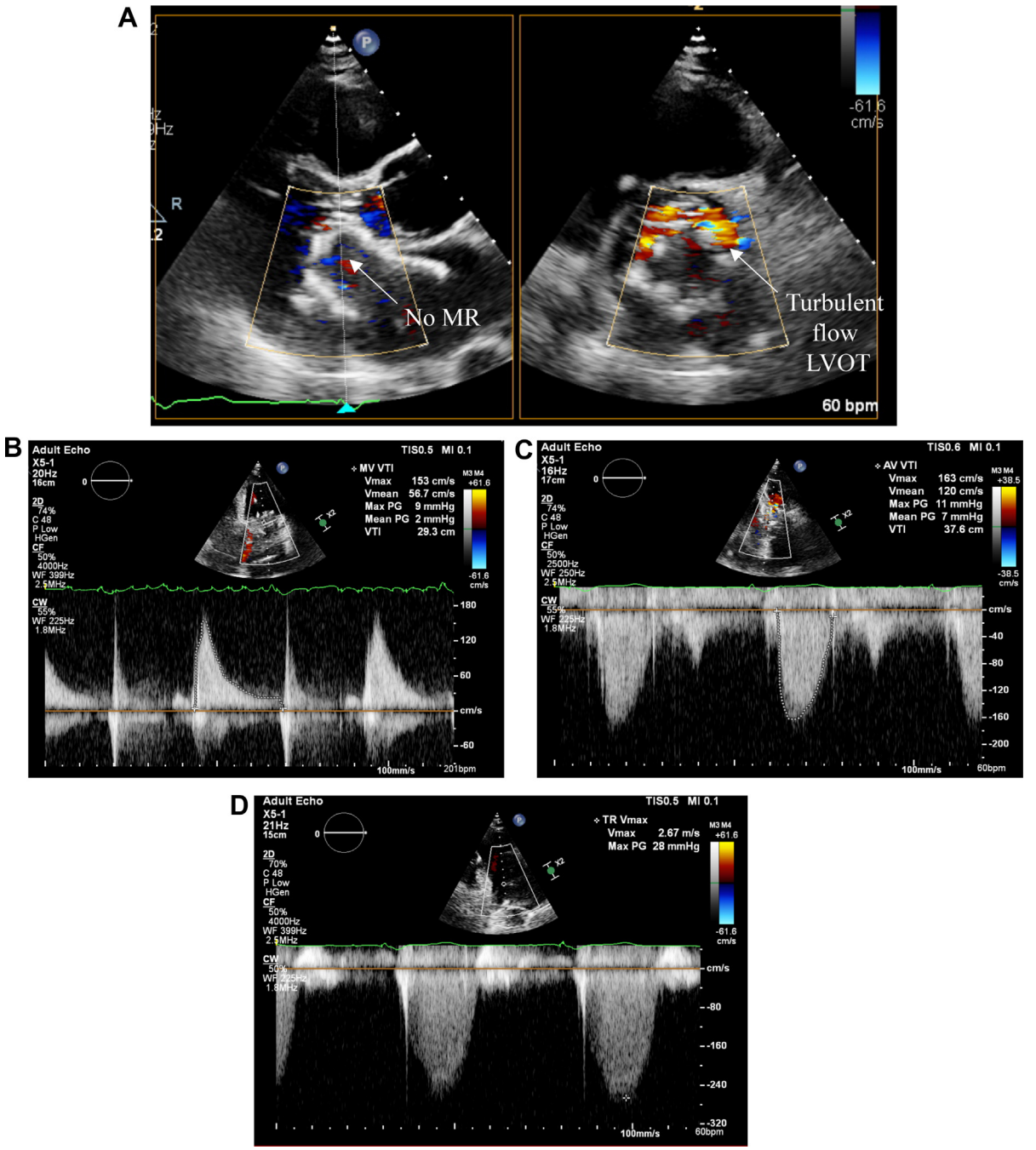
In the absence of infection or nontherapeutic anticoagulation, the mechanism of structural degeneration may have been the Tendyne natural durability, constraining forces caused by the annuloplasty ring (though Tendyne gradients were never elevated on annual follow-up), or obstruction caused by the

FIGURE 1 **Imaging at Time of Tendyne Implantation**



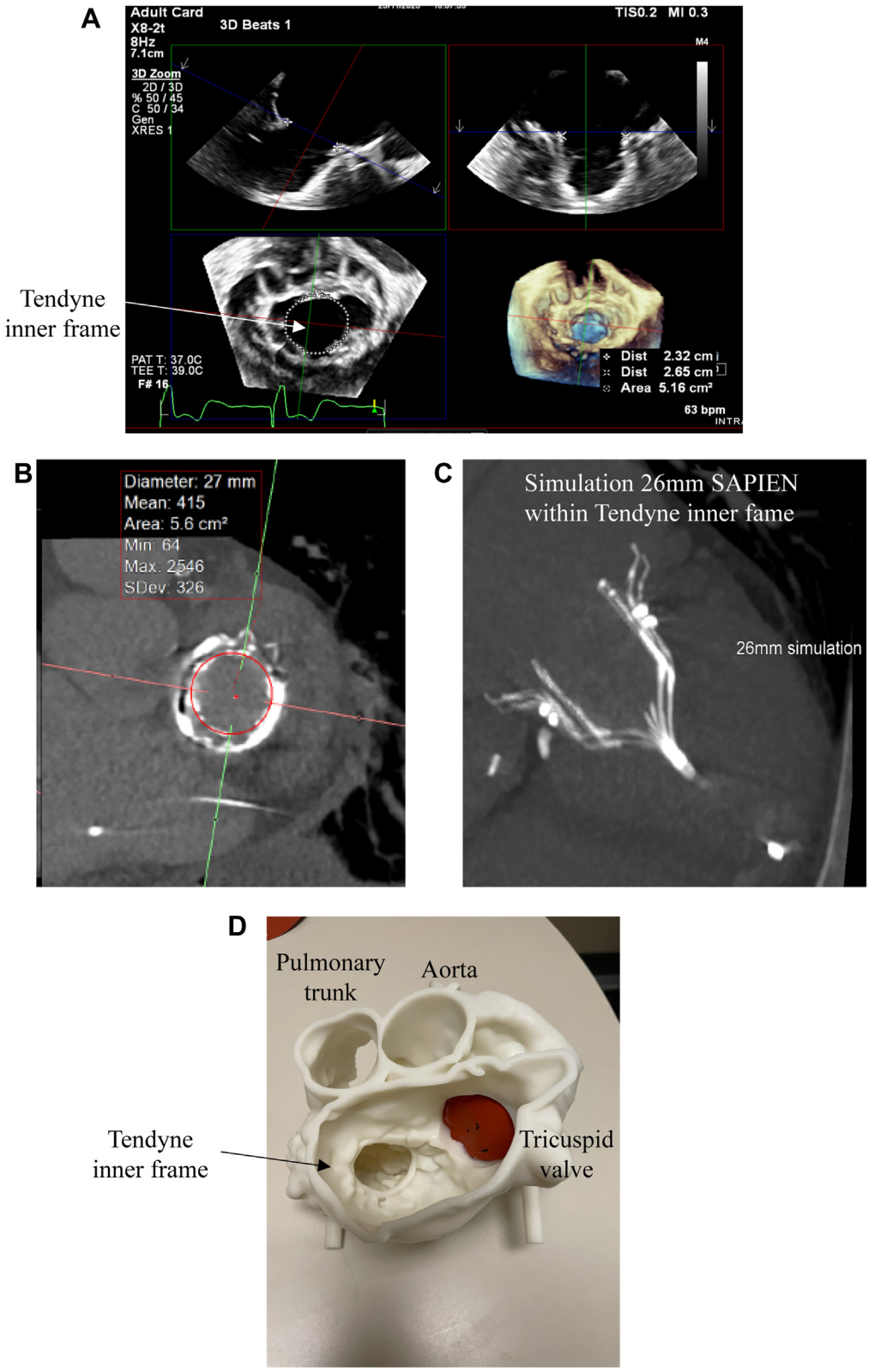
(A) Left ventricular outflow tract obstruction (LVOTO) immediately after Tendyne implantation (B) causing gradient 94 mm Hg. (C) Left ventricular outflow tract (LVOT) stenting (D) with reduction in LVOTO. (E) LVOT stent against anterior aspect of Tendyne and (F) stable LVOT gradient on discharge. MSCT = multislice computed tomography.

FIGURE 2 Imaging at Annual Follow-Up Thereafter



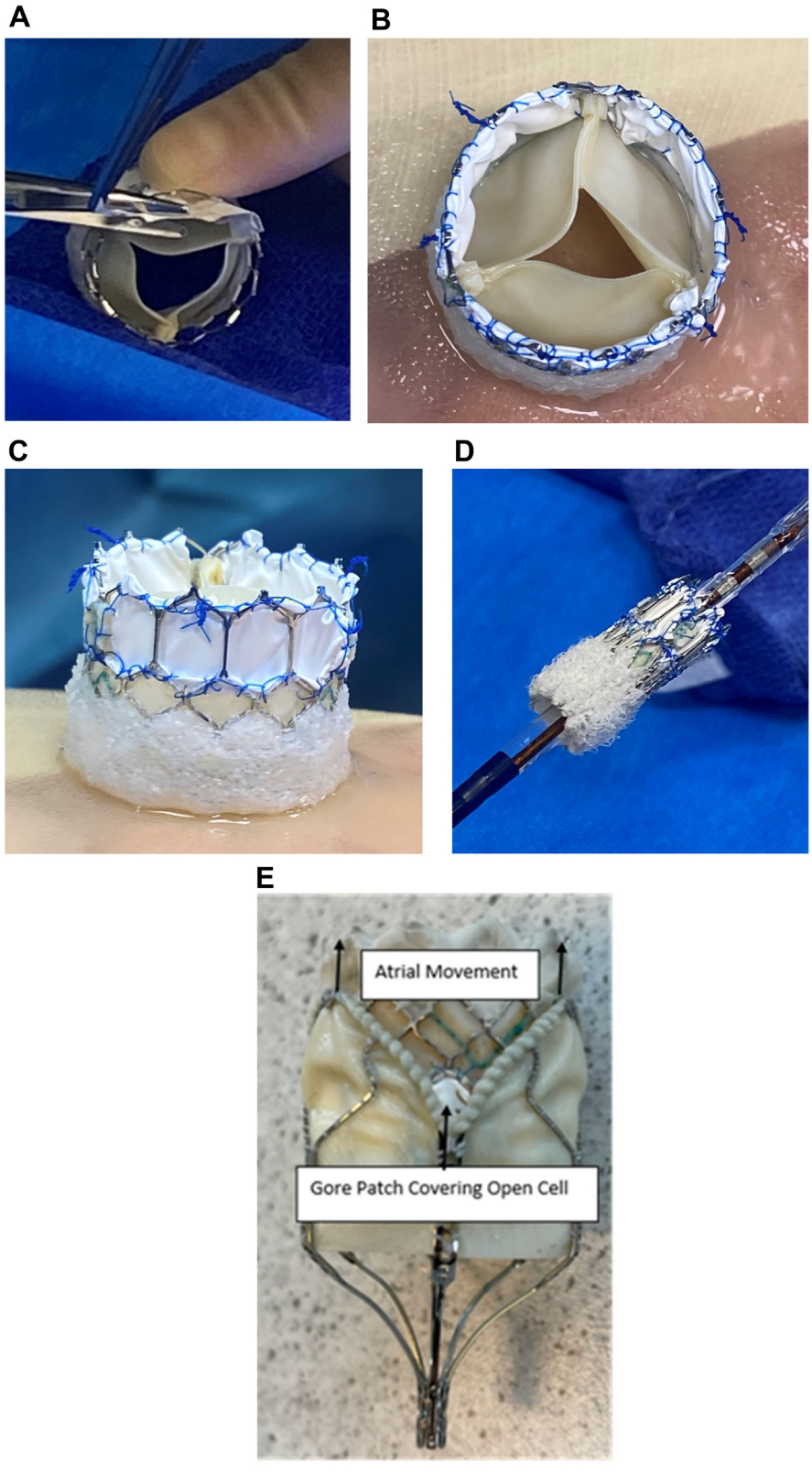
Well-functioning Tendyne on annual follow-up: (A) no mitral regurgitation, (B) mean mitral valve gradient 2 mm Hg, (C) peak left ventricular outflow tract (LVOT) gradient 11 mm Hg, (D) pulmonary systolic arterial pressure 33 mm Hg.

FIGURE 3 **Image Planning for SAPIEN in Tendyne**



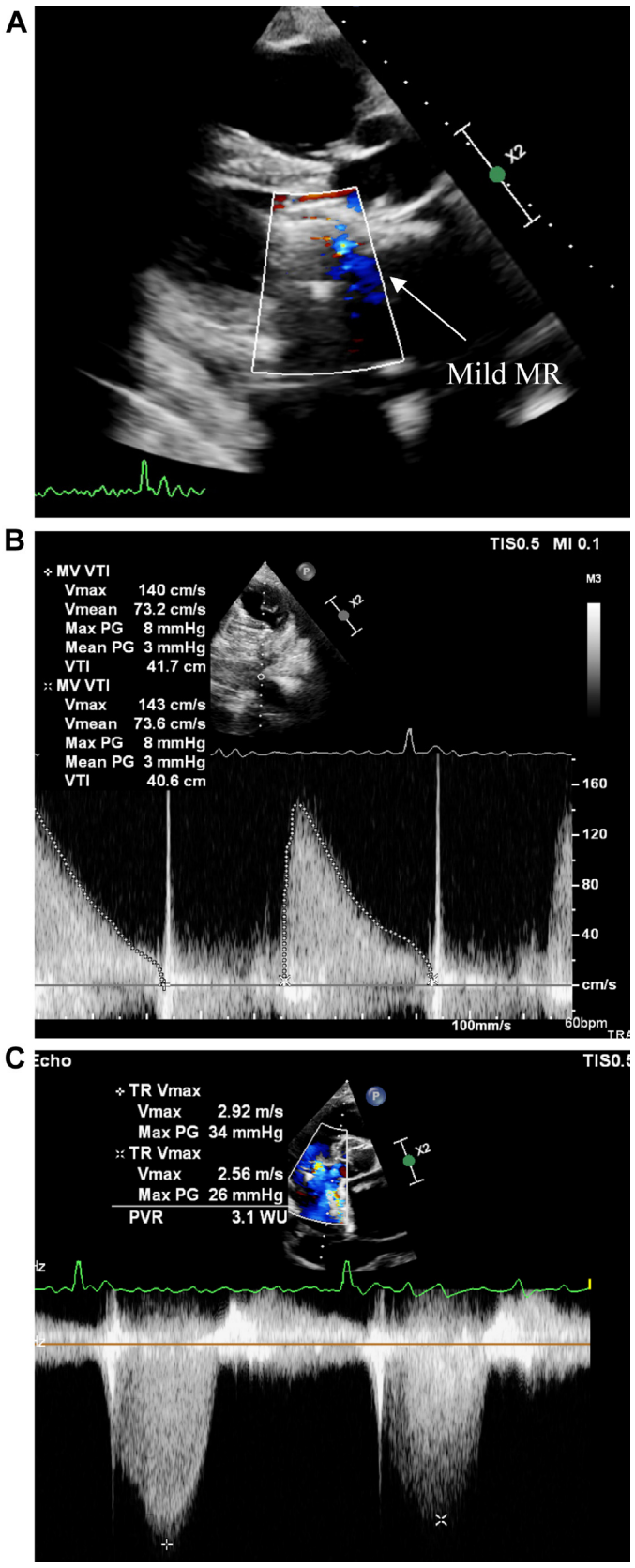
(A) The Tendyne inner frame measured 2.3 × 2.6 cm (area 5.2 cm^2) on 3-dimensional transesophageal echocardiography, (B) average diameter was 2.7 cm (area 5.6 cm^2) on computed tomography, (C) simulation of 26-mm SAPIEN-in-Tendyne on computed tomography and (D) confirmed on 3-dimensional printing.

FIGURE 4 SAPIEN Skirt Modification



Dacron felt skirt (A) cut and (B, C) sutured onto 26-mm SAPIEN (D) before prepped in usual manner. (E) Final result with Gore patch covering open SAPIEN cells.

FIGURE 5 **Discharge Transthoracic Echocardiography**



Mild transvalvular mitral regurgitation (MR) (A), mean mitral valve gradient 3 mm Hg (B), pulmonary systolic arterial pressure 36 mm Hg (C).

compassionate-use atypical LVOT CP stent (though LVOT gradients had remained stable for almost 9 years and were lowest just before the SAPIEN-in-Tendyne procedure, possibly related to stent fracture some time prior to admission).

The Tendyne TMVR bioprosthesis comprises an outer D-shaped frame to conform to the native MV annulus, an inner circular stent containing 3 porcine leaflets, and a funnel-shaped ventricular portion. Benchtop testing suggested the possibility of SAPIEN-in-Tendyne,[3] which had recently been performed in vivo with additional surgical skirt adaptation to mitigate leak in the inner Tendyne stent fabric[4] but never for structural leaflet degeneration. The dimensions of the Tendyne inner circular stent in our patient suggested use of a 26-mm SAPIEN device. However, the narrowed funnel-shaped ventricular portion of the Tendyne bioprothesis could cause atrialization of the SAPIEN device, and "valleys" of the Tendyne inner sewing ring extend deep into the LV so that small "valley" gaps may be evident after SAPIEN-in-Tendyne even with perfect benchtop SAPIEN deployment. Furthermore, SAPIEN devices have short landing zones, so any imperfect implantation depth or malalignment decreases the effective skirt height and increases paravalvular leak risk. To mitigate against all these possibilities, a Dacron felt skirt (Ethicon) was sutured onto the SAPIEN prothesis to cover the large open cells on its outflow portion and lengthen the landing zone.[5] This off-label technique was particularly useful in our case in which complete coaxiality could not be achieved and atrialization was anticipated. Interatrial device closure was undertaken following creation of significant interatrial communication with bidirectional shunting on pre-existing moderate TR.

FOLLOW-UP

Three months postdischarge, the patient was in NYHA functional class II and TTE reported LV ejection fraction 39%, mild transvalvular MR, mean Tendyne gradient 6 mm Hg, LVOT gradient 9 mm Hg, moderate TR, and pulmonary artery systolic pressure 42 mm Hg.

CONCLUSIONS

Structural leaflet degeneration of Tendyne TMVR may occur several years after implantation. Annual follow-up with echocardiography/computed tomography is recommended to screen for this. Valve-in-Tendyne for a degenerated Tendyne using a modified SAPIEN device is safe and feasible.

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Dr Duncan has served as a consultant for and received honoraria from Abbott Laboratories, Medtronic, Edwards Lifesciences, and Neochord. Drs Quarto and Smith have served as a consultant for and received honoraria from Abbott Laboratories. Dr Denti has served as consultant for Approxima, Picardia, HVR, and InnovHeart; and received speaker honoraria from Abbott Laboratories and Edwards Lifesciences. Dr Heng has served as a consultant for and received honoraria from Abbott Laboratories and Edwards Lifesciences.

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KEY WORDS mitral regurgitation, transcatheter mitral valve replacement, valve-in-Tendyne

APPENDIX For supplemental videos, please see the online version of this paper.