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First experience in Turkey with Meril's MyVal™ transcatheter aortic valve-in valve replacement for degenerated PERCEVAL™ bioprothesis valve

CASE REPORT

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INTRODUCTION

Transcatheter aortic valve replacement (TAVR) procedures have extensively increased in the last decades thanks to the introduction of new generation transcatheter heart valves (THVs) in the clinical market, improvements in valve design, improvements in deployment techniques, and increased operator experience. Thus, TAVR has been the treatment of choice even in patients with aortic stenosis (AS) with a low surgical risk (1). Furthermore, TAVR has become a therapeutic option for patients who need a redo intervention for failed bioprosthetic heart valve with a high or prohibitive surgical risk. This procedure is defined as the valve-in-valve (ViV) technique and is considered as a valuable treatment strategy owing to its lower rate of complications and mortality compared with that of redo surgery in patients with a degenerated bioprosthetic aortic valve (2).

MyVal™ (Meril Life Science, Vapi, India) is a recently approved newer generation balloon expandable bioprosthetic THV whose safety and efficacy were tested in patients with severe symptomatic native AS with intermediate or high surgical risk in a MyVal-1 study (3). MyVal™ is commercially available in Turkey at present, and a case study including a small number of patients with severe AS from the Turkish population reported positive feedback after implantation (4). In this case report, we present a patient with a failed Perceval™ (Liva Nova, Milan, Italy) sutureless bioprosthetic aortic heart valve who was treated with MyVal™ through a ViV-TAVR procedure.

CASE REPORT

A 70-year-old woman was admitted to our clinic with a complaint of new-onset dyspnea. She had a history of well-controlled hypertension, chronic obstructive pulmonary disease (COPD), and surgical aortic valve replacement with a sutureless Perceval™ large size prosthesis in 2016 because of severe AS. On admission,

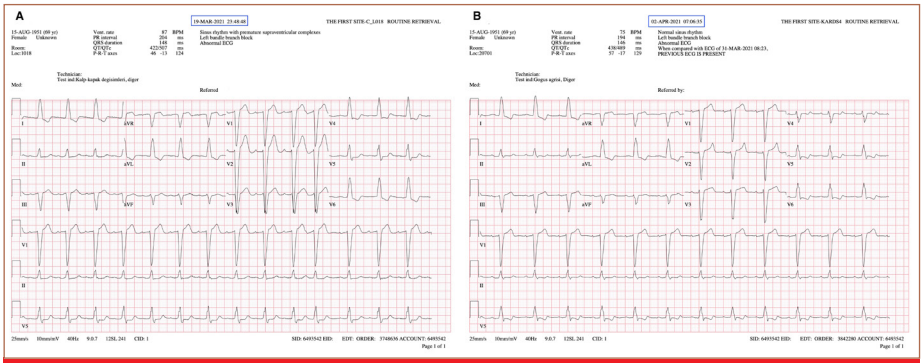

Figure 1. Twelve-lead electrocardiography of the patient (a) before and (b) after the procedure

she was New York Heart Association functional class 3, and the 12-lead electrocardiography (ECG) revealed sinus rhythm with a heart rate of 87 beats per minute, left bundle branch block with a QRS duration of 148 ms, and first-degree atrioventricular block with a PR duration of 204 ms (Fig. 1a). Transthoracic echocardiography (TTE) demonstrated a degenerated bioprosthetic valve at the aortic position with an aortic velocity of 5.3 m/sec and peak and mean transvalvular gradients of 112 mm Hg and 62 mm Hg, respectively. The effective orifice area was calculated at 0.61 cm^2, and left ventricular ejection fraction (LVEF) was 46%. There were moderate mitral and moderate to severe tricuspid regurgitations owing to annular dilatation with a systolic pulmonary artery pressure of 77 mm Hg. Coronary angiography did not show a significant obstruction. The Society of Thoracic Surgeons Predicted Risk of Mortality score was calculated at 4.5%, and our heart team favored a ViV-TAVR procedure than a redo surgery. Multidetector computed tomography imaging obtained from diverse planes demonstrated degenerated sutureless bioprosthetic valve with limited expansion at the aortic position. Minimum, maximum, and mean diameters of the aortic annulus were measured at 20 mm, 25 mm, and 22.5 mm, respectively (Fig. 2). In addition, the perimeter and area of the aortic annulus was calculated 73 mm and 3.99 cm^2. Distance to coronary ostium was 1.1 cm for the right coronary ostium and 1.16 cm for the left coronary ostium (Fig. 3). There was no severe tortuosity and/or calcification in both femoral arteries, and the narrowest diameters were 8.5 mm and 8 mm in right and left femoral arteries, respectively. Implantation of a balloon expandable THV with an intra-annular design was planned through right femoral approach under conscious sedation and 26 mm MyVal™ THV was chosen for the procedure. Subsequent to predilation with 23×40 mm balloon using rapid pacing at a rate of 180 beats per minute, 26 mm MyVal™ THV was successfully implanted. There was no significant gradient and/or paravalvular regurgitation on control aortic root angiography after THV implantation, and both the coronary arteries were patent (Fig. 4, Videos 1-4). Follow-up ECGs and continuous monitorization with a temporary pacemaker did not reveal any significant deterioration from baseline, including PR and QRS interval (Fig. 1b). Control TTE before discharge on the seventh day demonstrated an LVEF of 51% with mild mitral and tricuspid regurgitation. There was trivial paravalvular regurgitation at the aortic bioprosthesis with an accompanying aortic velocity of 2.1 m/sec, peak and mean transvalvular gradients of 17 and 7 mm Hg, respectively, with a systolic pulmonary artery pressure of 45 mm Hg (Fig. 5, Videos 5, 6).

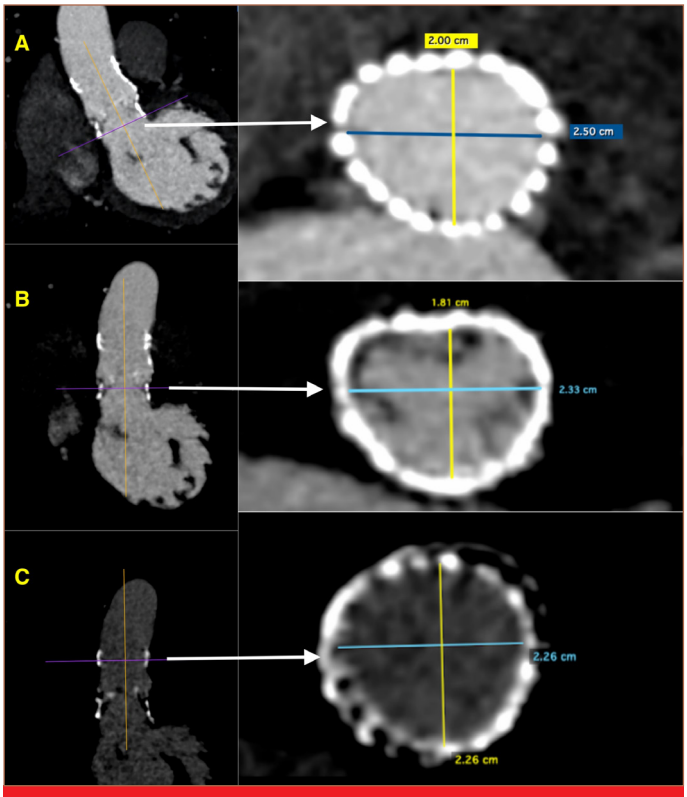

Figure 2. Computed tomography of the degenerated PERCEVALTM valve and annulus measurements from (a) basal level, (b) 5 mm above basal level, and (c) ascending aorta level

DISCUSSION

To the best of our knowledge, successful treatment of a failed Perceval™ with MyVal™ through ViV-TAVR procedure is the first in Turkey as well as one of the rarely reported cases in the world. There are significant issues that need to be discussed considering this case to improve our understanding

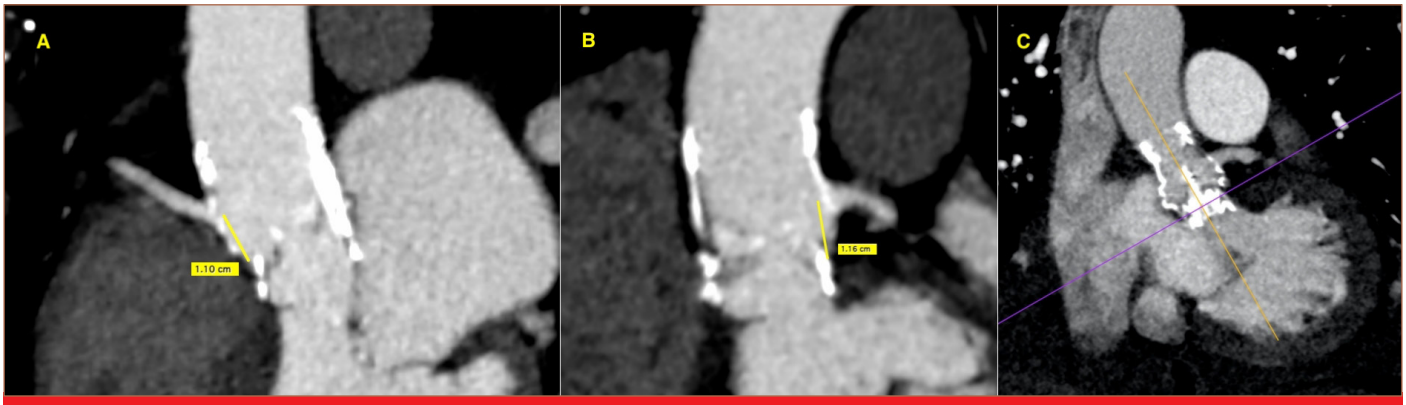

Figure 3. Computed tomography measurements between (a) aortic annulus and right coronary ostium, (b) aortic annulus and left coronary ostium, and (c) appearance of degenerated PERCEVAL™

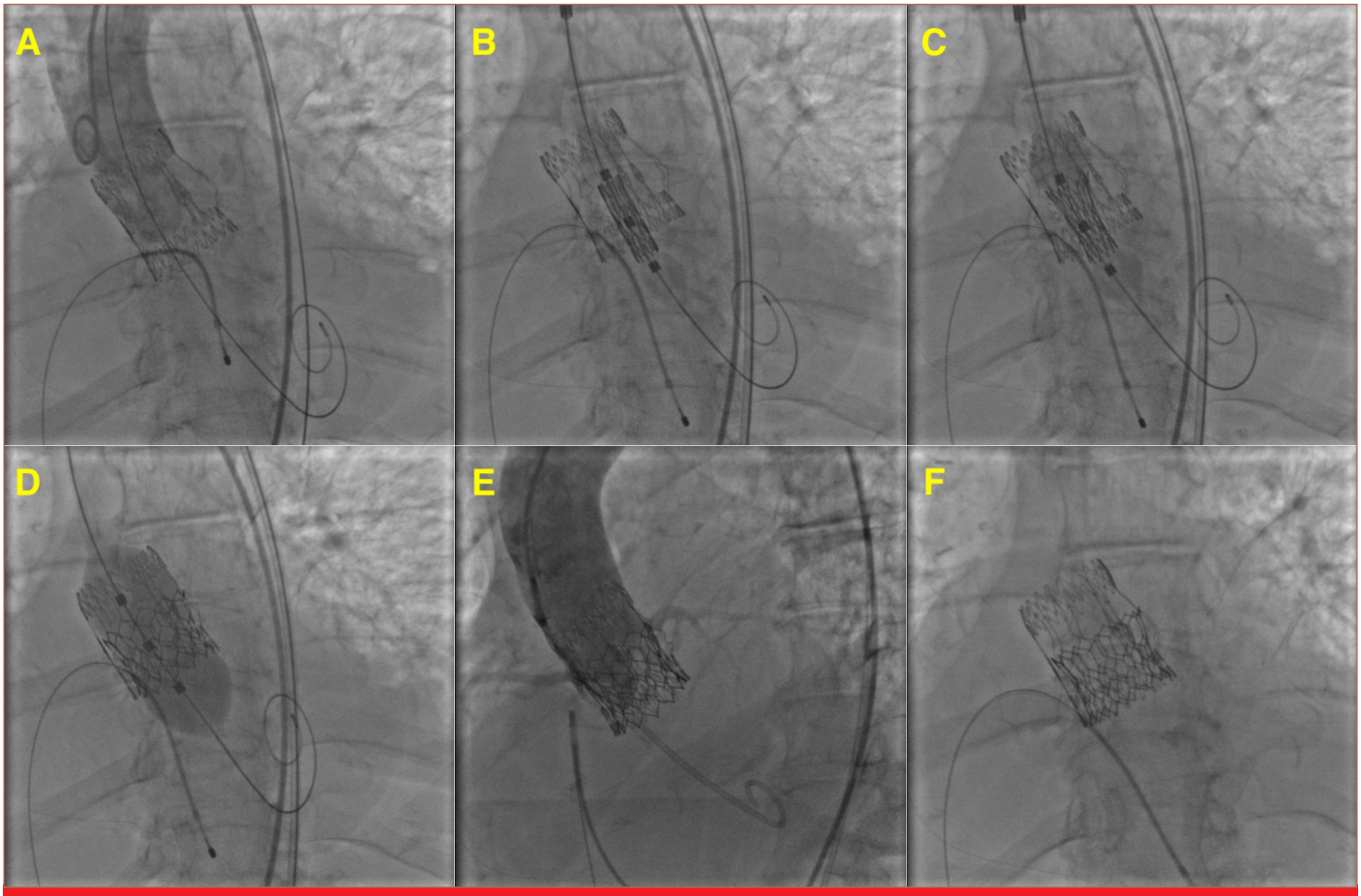

Figure 4. Angiographic images of the procedure. (a) Baseline aortic root angiography and structural appearance of the PERCEVAL™ (b) Positioning of MyVal™ at annular plane (c) Minimal inflation of the balloon of the transcatheter valve under rapid pacing and formation of dog-bone appearance (d) Complete inflation of the balloon of transcatheter valve under rapid pacing (e) Control aortic root angiography after MyVal™ implantation demonstrating patent coronary arteries and no paravalvular regurgitation (f) Structural appearance of overlapped PERCEVAL™ and 26 mm MyVal™ valves under fluoroscopy

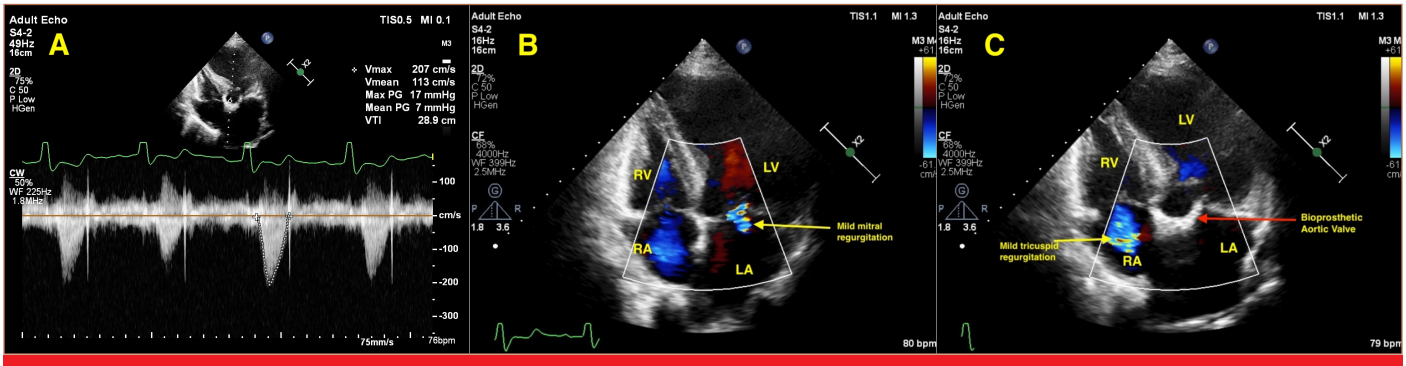

Figure 5. Transthoracic echocardiographic measurements after the procedure. (a) Transaortic velocity and maximum and mean gradients from apical five-chamber view, (b) Mild mitral regurgitation from apical four chamber, and (c) Mild tricuspid regurgitation from apical imaging.

about ViV-TAVR procedures, bioprosthetic THVs, and evolutionary process of the field.

Sutureless aortic valves have been developed to decrease aortic cross-clamp and cardiopulmonary bypass times that result with improved hemodynamic performance and postoperative outcomes. They also have an advantage in minimally invasive surgeries particularly for older patients with increased surgical risk and in complex surgeries. Perceval™ is the most commonly used sutureless aortic valve currently; however, they are inherently prone to structural degeneration and may require reintervention (5, 6). Similarly, we observed clinically significant deterioration in our patient who

had a history of Perceval™ five years ago. Although redo surgery is the standard of care, except in high-risk patients, our heart team decided to perform a ViV-TAVR procedure owing to the relatively increased age of the patient, accompanying multivalvular disease including mitral and tricuspid regurgitation, pulmonary hypertension, and COPD. Thus, subsequent to the procedure, hemodynamic status of the mitral and tricuspid valves improved in addition to improvements in aortic valve hemodynamics and pulmonary hypertension.

MyVal™ THV has several advantages over its counterparts. First, owing to its dense and light banding pattern, it provides convenience for the landing zone and precise deployment. In addition to standard dimensions, various sizes including half-diameters are available allowing for accurate sizing that reduce the risk for annular rupture and paravalvular regurgitation. Moreover, the delivery system can be inserted through a 14 French expandable introduced sheath even with 29 mm valve. Short infra-annular depth and presence of open cells on the aortic part of the valve minimizes the risk of permanent pacemaker requirement and coronary obstruction risk. Furthermore, it is directly crimped and mounted on the balloon catheter system outside the body in contrast to other THVs (3, 4, 7). Therefore, we decided to perform the procedure with a 26-mm MyVal™ THV. There was no paravalvular regurgitation, coronary obstruction, stroke, and need for permanent pacemaker implantation after the procedure. The efficiency of MyVal™ in ViV-TAVR was also demonstrated in a small case series of failed bioprosthetic heart valves, which included a patient with a degenerated Perceval™ at aortic position (7). To the best of our knowledge, our case represents one of the rare cases in the world as well as the first in Turkey that demonstrates successful treatment of a failed Perceval™ with MyVal™. It should be noted that there is no study at present comparing MyVal™ and other THVs. However, the results of the LANDMARK trial, which aims to compare safety and efficacy of MyVal™ with other THVs in a randomized fashion, are highly warranted (8).

Because of the significant progresses in the era of TAVR and THVs, more patients are referred for transcatheter approaches instead of surgery; however, the durability of THVs and bioprosthetic valves is still an issue not yet solved. At this point, ViV-TAVR might be an alternative solution to redo surgery, especially in high-risk patients, although the lack of randomized clinical trials comparing ViV-TAVR and redo surgery hampers making firm conclusions. Observational studies seem to confer a clinical benefit of ViV-TAVR at short and mid-term, but data in terms of long-term follow-up are sparse. For instance, a recent meta-analysis study showed the superiority of ViV-TAVR in terms of 30-day mortality, major bleeding, and length of hospital stay with the cost of severe patient prosthesis mismatch and increased myocardial infarction rate. However, mortality benefit was lost at one-year follow-up (2). At this point, it is reasonable to conclude that randomized clinical trials with long-term follow-up are required to make more robust comparisons.

In conclusion, treatment of failed Perceval™ with MyVal™ through ViV-TAVR can be a safe and efficient procedure.

Informed consent: Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

Video 1. Baseline aortic root angiography

Video 2. Positioning of MyValTM at annular plane and inflation of the balloon of transcatheter valve under rapid pacing

Video 3. Control aortic root angiography after MyValTM implantation demonstrating patent coronary arteries and no paravalvular regurgitation

Video 4. Structural appearance of overlapped PERCEVALTM and 26 mm MyValTM valves under fluoroscopy

Video 5. Mild mitral and tricuspid regurgitation from apical four chamber

Video 6. Trivial paravalvular aortic regurgitation from apical five chamber

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