Transeptal valve-in-valve transcatheter mitral valve replacement in patient with deteriorated mitral bioprosthesis

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ABSTRACT – Transcatheter mitral valve replacement is a new option to treat deteriorated surgical prosthesis in high surgical risk patients. The number of valve-in-valve mitral procedures has been growing in the last few years. This case reports an initial experience with this type of procedure, safely and effectively performed in an elderly female patient with high-risk for valve replacement.

Keywords: Mitral valve; Heart valve prosthesis; Heart valve prosthesis implantation; Prosthesis failure

INTRODUCTION

With the increased longevity currently observed for individuals with heart disease, there is an increased prevalence of patients with deteriorated mitral biological valves, associated with the presence of multiple comorbidities resulting from advanced age. Transcatheter mitral valve replacement (TMVR) has emerged as a therapeutic option for this clinical condition. Still with a limited number of dedicated devices currently under clinical research, transcatheter aortic valve prostheses, already approved for aortic valve-in-valve (ViV) treatment, have been used for mitral ViV. 1

The potential for incorporating this new technology is huge, especially when evaluating the need to meet the repressed demand of high surgical risk patients, whose clinical treatment is not sufficient to reduce mortality and improve quality of life. 2,3

In this case report, the objective was to give an example of a situation in which TMVR modified the prognosis, since advanced age and the coexistence of important comorbidities would pose high risk for conventional surgery. This article was evaluated by the Research Ethics Committee of Hospital Carlos Macieira and approved (protocol 5.375.346, CAAE 51505221.3.0000.8907).

CASE REPORT

A 74-year-old obese woman with hypertension, diabetes, dyslipidemia, and a history of mitral valve replacement in 2012, with a Braile porcine biological prosthesis...
In May 2019, she suffered a spontaneous fracture of the left femur, presenting acute pulmonary edema during hospital stay, followed by bilateral deep venous thrombosis, prompting the implantation of an inferior vena cava filter. In July, 2 months after hospital discharge, she sought a cardiologist, presenting New York Heart Association (NYHA) functional class IV heart failure. An echocardiogram performed on the day of the visit showed significant mitral regurgitation due to deterioration of the mitral valve prosthesis, in addition to moderate aortic regurgitation and mild tricuspid insufficiency.

With a Society of Thoracic Surgeons (STS) score of 5.5% and EuroSCORE II of 8.3%, the management was discussed at a Heart Team meeting. Due to the frailty and surgical risk, the team decided for TMVR, done on October 10, 2019. Two days before, the vascular surgery team unsuccessfully attempted to percutaneously remove the vena cava filter. The objective was to facilitate the passage of catheters and devices through the venous access, considering the option of transseptal approach to perform the cardiac procedure. Despite the presence of the vena cava filter, it was not difficult to pass devices through the inferior vena cava.

The procedure was conducted under mixed general anesthesia and with the aid of transesophageal echocardiography (TEE) (Figure 1). Initially, the transvenous pacemaker (St. Jude Medical, USA) was positioned through the right internal jugular vein. The primary and secondary accesses were obtained in the right femoral vein (8F) and left femoral artery (6F), respectively. Prophylaxis was conducted with 2g of intravenous cefazolin, followed by total heparinization with unfractionated heparin. A transseptal puncture was performed, followed by dilation of the interatrial septum with a Mustang 12x40mm balloon (Boston Scientific, Massachusetts, United States), to facilitate the passage of the 14F introducer. Activated clotting time (ACT) was checked, which was 390 seconds. A 0.035x275cm Safari guidewire (Boston Scientific) was positioned in the left ventricle, and a 26mm Sapien 3 valve (Edwards Lifesciences, CA, USA) was positioned in the left ventricle, and a 26mm Sapien 3 valve (Edwards Lifesciences, CA, USA) was implanted under rapid pacing at 150bpm. The choice of valve was based on measurement of the previous surgical prosthesis and on the TEE, since no computed tomography angiography (CTA) was conducted before the procedure (Figure 2). Echocardiographic control showed resolution of mitral regurgitation (Figure 3). Two Proglide 6F devices (Abbott Vascular, Chicago, IL, USA) were used for hemostasis of the vascular accesses.

In the immediate postoperative period, the patient remained on triple therapy with unfractionated heparin, acetylsalicylic acid (ASA) and clopidogrel, reinitiating Marven® on the second postoperative day. After 30 days, she

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**Figure 1.** Pre-procedural transesophageal echocardiography. (A) Evidence of fracture in previous mitral valve bioprosthesis. (B) Color-Doppler showing important mitral regurgitation.
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**Figure 2.** Steps of transeptal mitral valve implantation. (A) Transeptal puncture. (B) Stabilization of the Safari guidewire. (C) Positioning and deployment of Sapien 3 valve in the mitral position. (D) Final position.

**Figure 3.** Results by transesophageal echocardiography. (A) Before the procedure, malfunctioning mitral prosthesis and severe mitral regurgitation. (B) After valve implantation, absence of mitral regurgitation.

remained on dual therapy, with oral anticoagulant and ASA. She has been in clinical follow-up for 1 year and 8 months, in addition to maintaining functional class II. The patient sustains good echocardiographic and tomographic results.

**DISCUSSION**

The aortic ViV procedure presents as a clinically effective treatment tool for most elderly patients with deteriorated aortic bioprosthesis. TMVR, in turn, is in the initial trajec-
tery of evaluating its safety and efficacy, requiring a longer learning curve. The first transcatheter mitral ViV implant for treatment of deteriorated mitral valve prosthesis was published by the Vancouver group, in 2009, and followed by a series of publications confirming its feasibility.¹

In 2013, the same group reported a series of 23 cases of symptomatic patients with dysfunctional biological mitral prostheses, successfully managed by TMVR using balloon-expandable Sapien valves (Edwards Lifesciences), via the transapical approach.² All patients were symptomatic and of high surgical risk (mean STS score 12.2%), and 95.7% presenting NYHA functional class III/IV, with success achieved in 100% of cases, according to the definition by the Valve Academic Research Consortium (VARC-2). In this high-risk cohort, the results were quite encouraging, with no deaths reported within the first 30 days, and one-year survival of 91%. The hemodynamic performance was also sustained, with a mean residual gradient of 6.8mmHg, and little or no paravalvar leak during the 1-year follow-up.

In 2019, a systematic review of TMVR gathered 16 studies, which evaluated 11 devices dedicated to transcatheter mitral valve approach, in 308 patients with severe mitral regurgitation and high surgical risk.³ There was a predominance of patients in NYHA functional class III or IV (81.5%) and a mean STS score of 7.7%. Severe comorbidities were found in 70% of sample, such as coronary artery disease, kidney failure and atrial fibrillation. The mean ejection fraction was 42%, and the indication for TMVR was mainly functional or severe mixed mitral regurgitation (87.1%). Most procedures were conducted under general anesthesia, with the aid of TEE (81.5%) and via the transapical approach. Less than 20% were performed by transfemoral-transseptal approach, because only four out of 11 dedicated devices enabled this approach. Although this study describes the initial experience of different TMVR platforms, the success rate of the devices was high (92%), aligned with a low rate of moderate to severe residual regurgitation (1.5%) and a low mean transvalvar gradient (less than 4mmHg). However, the 30-day and one-year follow-up mortality was still high: 13.6% and 28%, respectively. The authors suggested a gradual migration from the transapical to the transeptal technique would be necessary to reduce complications and mortality rate in TMVR, and the consequent adoption of this technology as an alternative to conventional surgery.¹

Also in 2019, data were published from an observational, multicenter registry including 40 European and American organizations on TMVR, about deteriorated mitral prostheses (ViV), deteriorated annuloplasties (valve-in-ring) and valves with severe annular calcification, in high risk patients.⁴ Out of 521 patients, 322 underwent ViV, transapical access being used in 39.5%, and Sapien prostheses (including Sapien, Sapien XT and Sapien 3) in 90%. ViV procedures had technical and device success rates of 94.4% and 84.8%, respectively, in addition to only 6.2% and 14% mortality at 30 days, and at the end of 1-year follow-up, demonstrating mitral ViV is a feasible alternative to deteriorated prostheses in high surgical risk patients. However, the advantages and disadvantages of this procedure must be discussed case-by-case, and new literature data, as well as technical improvement, are necessary for its greater incorporation into clinical practice.

SOURCE OF FINANCING

None.

DECLARATION OF CONFLICTS OF INTEREST

Vinícius Borges Cardoso Esteves is proctor of Edward Lifesciences. Other authors declare having no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: TVLCCC, NOS and MJMF; data collection: TVLCCC, NOS, MJMF, RND and VBCE; data interpretation: TVLCCC, NOS, MJMF, RND and VBCE; text writing: TVLCCC and NOS; approval of the final version to be published: TVLCCC.

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