

## Dysfunctional Mitral Bioprosthesis Treated using Transapical Approach with Inovare Transcatheter Valve: A New Alternative to Conventional Surgery

Williams Roberto Lata Guacho, Jaime Paula Pessoa Linhares Filho, Henrique Barbosa Ribeiro, Roney Orismar Sampaio, José Onório Almeida Palma Fonseca, Márcio Silva Miguel Lima

Instituto do Coração, Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo (USP), São Paulo, SP – Brazil

### Introduction

Transcatheter aortic valve implantation (TAVI) developed over the last decade as a less invasive alternative to the conventional surgical procedure, for inoperable patients of medium and high operative risk.<sup>1,2</sup>

Considering its excellent results, the indication of the transcatheter procedure was extended to patients with a previous biological prosthesis, initially in the aortic position and, later, in the mitral position.<sup>3</sup> Transcatheter bioprosthesis valve-in-valve (ViV) implant procedures have been growing in the last decade in Interventional Cardiology and, today, it is considered an important alternative to reoperation in inoperable or high surgical risk patients, for the presence of major comorbidities.<sup>4-10</sup> Transthoracic (TTE) and Transesophageal (TEE) echocardiography are fundamental tools in the evaluation of the entire process of ViV valve prosthesis implantation, from the pre-procedure, intraoperatively and early and late postoperative follow-up.

We report an illustrative case from our institution, of a female patient, with previous surgical mitral valve replacement due to prolapse and major insufficiency. She evolved with degeneration and calcification of the bioprosthesis, in addition to signs of severe dysfunction, with significant functional class worsening (*New York Heart Association* – NYHA class IV), with significant limitation in the past few months. She was hospitalized with decompensated heart failure and significant pulmonary hypertension. She was considered to have a high surgical risk and had transapical transcatheter implant of an Inovare bioprosthesis via ViV, without requiring extracorporeal circulation.

### Case Report

A 47-year-old patient was referred to Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da

### Keywords

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**Mailing Address:** Williams Roberto Lata Guacho •

Rua Arruda Alvim, 111, apto. 2, Pinheiros. Postal Code 05410-020.

São Paulo, SP – Brazil.

E-mail: williams.guacho@incor.usp.br

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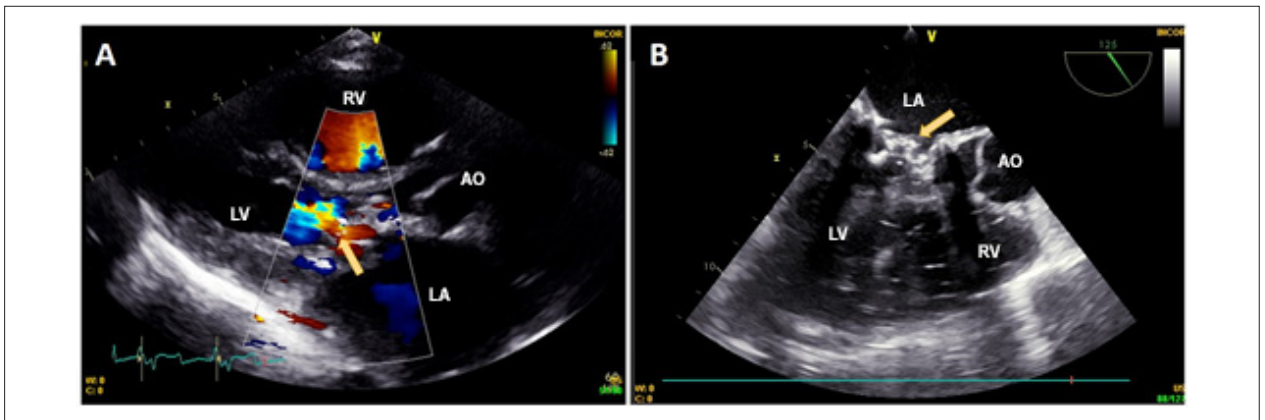
Universidade de São Paulo (USP) with symptoms of progressive dyspnea for two months, developing, in the past few days, severe functional limitation and dyspnea at rest. She had a Braille no. 28 mitral bioprosthesis implanted 5 years prior, for the treatment of symptomatic mitral valve prolapse due to severe insufficiency.

On admission, physical examination revealed dyspnea (respiratory rate: 20 ipm), hypoxemic (Blood Oxygen Saturation — SpO<sub>2</sub>: 88% in ambient air), sinus rhythm, tachycardia (115 bpm) and normal Blood Pressure (120/90 mmHg). Heart auscultation evidenced 3+/6+ regurgitant systolic murmur in tricuspid focus with an increase in intensity on inspiration; 3+/6+ holosystolic murmur in mitral focus irradiating to the axillary region, with decreased intensity on inspiration. Abdomen was distended, with evidence of severe ascites, diffusely painful on palpation and with discrete edema in the lower limbs.

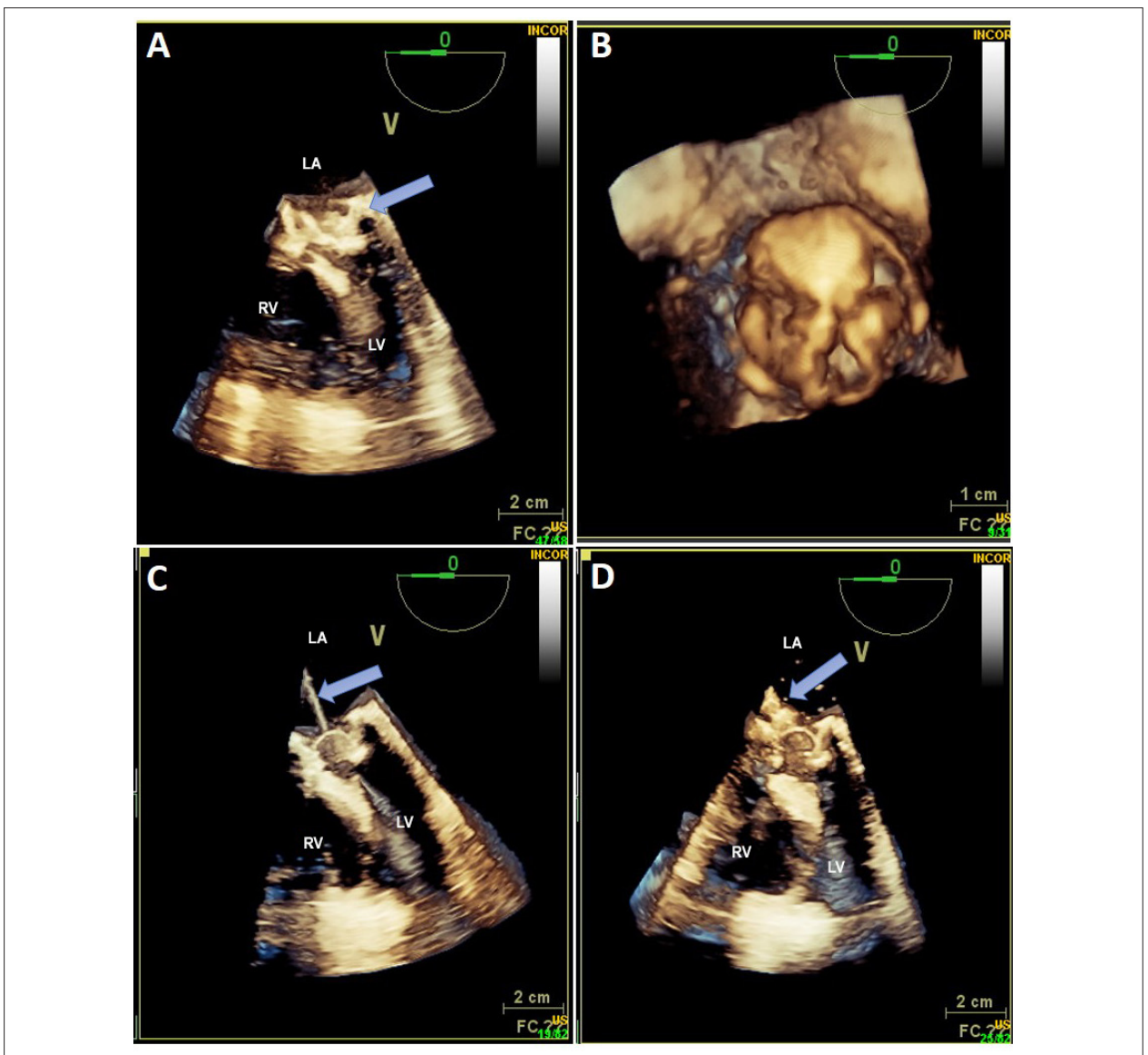
Pre-procedure TTE was performed, demonstrating significant increase of right chambers and discretely increased left atrium. Left ventricle had preserved systolic function and left ventricular ejection fraction was estimated at 68%. The right ventricle had moderate to major global hypokinesia. Bioprosthesis in the mitral position was thickened, calcified, with decreased mobility of its leaflets (Figure 1). Evaluation parameters of the prosthesis on Doppler: maximum velocity of the transprosthetic jet 3,4 m/s; maximum LA-LV diastolic gradient estimated at 30 mmHg and mean diastolic gradient estimated at 17 mmHg; E wave 2.7 m/s; mitral VTI 11 cm; Doppler index 4.4; mitral valve PHT 200 ms; effective valve orifice area 0.6 cm<sup>2</sup>. Color flow mapping by color Doppler showed mild to moderate insufficiency degree. There were clear signs of significant pulmonary hypertension, with marked tricuspid valve insufficiency. Pulmonary artery systolic pressure was estimated at 78 mmHg. In addition, a tomography scan was done to measure the mitral annulus and to assist in the choice of the transcatheter prosthesis to be used.

Intraoperative TEE was requested to assist the entire ViV procedure, from the measurement of the mitral annulus through the choice of the transcatheter prosthesis size, passage of the guidewire and the transcatheter prosthesis sheath, monitoring of results and potential complications, in addition to confirming the absence of thrombi and masses in atria and appendices.

The procedure was uneventful, and Inovare n°. 26 transcatheter bioprosthesis was successfully implanted transapically pathway with left lateral thoracotomy (Figures 2 and 3). Immediate post endoprosthesis implantation TEE: maximum transprosthetic jet velocity 1.6 m/s; mitral valve VTI

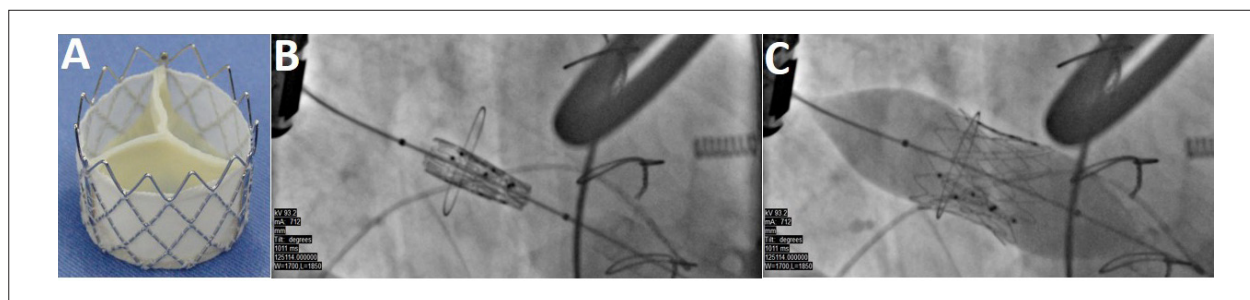


**Figure 1** – (A) Transthoracic echocardiography, long axis parasternal window showing thickening of mitral bioprosthesis with acceleration of the transprosthetic flow on Doppler, with color flow mapping. (B) Transesophageal echocardiography detailing thickening, calcification and restriction of mitral prosthesis mobility.



**Figure 2** – Three-dimensional echocardiography guiding the procedure. (A) Four-chamber window showing pronounced prosthesis thickening; (B) prosthesis zoom; (C) passage of guidewire through the prosthesis; (D) balloon insufflation for endoprosthesis implantation.

## Case Report



**Figure 3** – (A) Inovare transcatheter bioprosthesis (Braille biomédica) with external stent made of chromium-cobalt and bovine pericardial valve. Fluoroscopy in right anterior oblique projection showing (B) positioning of the Inovare valve through the mitral annulus of the dysfunctional bioprosthesis and (C) balloon insufflation for valve-in-valve implantation.

23 cm; LA-LV maximal diastolic gradient estimated at 8 mmHg and mean diastolic gradient estimated at 4 mmHg; effective valve orifice area estimated at 3.14 cm<sup>2</sup>. Color flow Doppler imaging showed mild periprosthetic regurgitation (Figure 3). In addition, slight protrusion of the transcatheter device was detected in the left ventricular outflow tract, causing small local flow acceleration (peak gradient of 20 mmHg).

After the surgery, the patient evolved with atrial fibrillation reversed with intravenous amiodarone and pneumonia treated with broad-spectrum antibiotic therapy. There was significant clinical improvement of dyspnea and anasarca with hospital discharge in functional class II. In the 6-month outpatient follow-up, the patient was well, referring dyspnea only on unusual exertion.

### Discussion

We report the case of a patient with mitral bioprosthesis for 5 years, with a rapid early evolution to severe stenosis. There was significant clinical worsening with a great deal of functional limitation. Clinical examination and echocardiography showed severe dysfunction of the mitral bioprosthesis, so valve replacement surgery was indicated. However, due to the patient's clinical condition, with clear signs of heart failure, pulmonary hypertension, hypoxemia, voluminous ascites and pronounced peripheral edema, she was considered of very high surgical risk. She became refractory to intensive clinical treatment in the ward. The case was then discussed by the institution's Heart Team, who chose to conduct ViV percutaneous treatment, which was successfully performed. In this case, there was a discreet protrusion of the endoprosthesis in the left ventricular outflow tract with a slight local gradient, without hemodynamic repercussion. This fact may be technically due to the pronounced angulation of the outflow tract. At the end, there was an important clinical improvement of the functional class and shorter hospital stay (ward and intensive care unit), without any adverse events related to the prosthesis. The patient was discharged from the hospital and was followed up in an outpatient clinic with good evolution.

In the risk assessment prior to the surgical procedure, at least two risk scores are widely used for stratification of these patients, which estimate mortality risk: the European System

for Cardiac Operative Risk Evaluation (EuroSCORE) I or II and the Society of Thoracic Surgeons (STS). Patients with EuroSCORE I > 15, EuroSCORE II  $\geq$  6 and STS > 10 are considered of high surgical risk. ViV transcatheter implant is an alternative low-risk treatment for inoperable or high surgical risk patients.<sup>11,12</sup>

Currently, the Inovare transcatheter valve prosthesis is only available for transapical access and can be used for the treatment of various valvular diseases, such as native aortic stenosis (TAVI), and for various types of ViV, such as mitral, aortic, tricuspid and pulmonary procedures. It is a nationally developed balloon-expandable valve that is more affordable and has been used in many countries around the world. In the world today, transapical implantation procedures represent less than 10% of the total number of cases performed. It is still more used in the treatment of mitral valvular diseases, either for ViV, with balloon-expandable prostheses, or with new mitral transcatheter valves, in the treatment of native mitral diseases. In our institution, we have more than one hundred patients treated via this route with the Inovare prosthesis.

Regarding the technical details of the procedure, recent studies have shown that the transcatheter valve implantation through the femoral vein should always be chosen to the detriment of other alternative approaches such as transapical, because of the low rate of complications, such as bleeding, arrhythmia and myocardial injury, as well as due to reduced hospitalization time. On the other hand, transapical access makes it easier to treat mitral diseases with most transcatheter systems available today. In patients with concomitant coronary artery disease who require transcatheter therapy, there is still much controversy in the literature about when to treat. However, in those patients with critical disease in major epicardial vessels, we have been doing coronary percutaneous treatment before the transcatheter valve procedure, largely because of the contrast volume and the complexity of the combined procedure.

TTE is the test of choice for initial morphological evaluation of the prosthesis, but it presents an important imaging limitation due to acoustic artifacts from the bioprosthesis or inadequate acoustic windows, which may also mask or prevent the detection of color Doppler signal. The high jet velocity and the mean gradient through the high prosthesis are important aspects in the suspicion of bioprosthesis dysfunction.

Tomography is normally used to better measure the mitral annulus, helping to choose the endoprosthesis to be used, and is considered to be better than echocardiography.

TEE is recommended to assist the ViV procedure intraoperatively, which is particularly important for the anatomic assessment and detailing of prosthesis dysfunction (site of regurgitation and stenosis), and to systematically evaluate all of its components. It has the advantage of better image resolution because it uses high frequency transducers greater than 7 MHz and its proximity between the esophagus and the heart, as well as the multiple incidences and angulations compared to TTE. The estimation of the size of the prosthesis to be used by measuring the internal annulus (preferably using three-dimensional ECHO) and positioning the catheter insertion, monitoring and immediate post-implant evaluation of prosthesis functioning, as well as the search for complications (paraprosthesis reflux, perfusion or pericardial tamponade).

## Conclusion

The transapical mitral valve-in-valve implantation is a new, promising and less invasive alternative to conventional mitral valve replacement surgery in inoperable patients or patients at high surgical risk. In this brief report, we exemplify the pertinent indication of this relatively new procedure with balloon-expandable Inovare valvular endoprosthesis.

Imaging tests, such as tomography, but mainly two-dimensional and three-dimensional transthoracic and transesophageal echocardiography are fundamental tools in the whole valve-in-valve procedure, as these tests help choosing the prosthesis to be used and, as for the echocardiography, it helps monitoring the outcomes and the complications of the procedure.

## Authors' contributions

Creation and design: Lata WRC, Lima MSM; Data acquisition: Lata WRC, Filho JPPL, Ribeiro HBR, Sampaio RO, Fonseca JHAP, Lima MSM; Manuscript writing: Lata WRC, Ribeiro HB, Lima MSM; Revision of the manuscript as for important intellectual content: Lima MSM, Ribeiro HB.

## Potential Conflicts of Interest

This study has no relevant conflicts of interest.

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## Academic Association

This study is not associated with any graduate programs.

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