Original Article

First Percutaneous Orthotopic Tricuspid Valve Implantations using the LuX-Valve Plus Device in Latin America: Report of the First Three Cases

Fernanda Esteves,[1,2] Vinícius Esteves,[3] Marcio Mendes Pereira,[4] Frederico José Neves Mancuso,[2,5] Marden Tebet,[1,2,6] Sergio Kreimer,[1,2,6] Edmur Carlos de Araújo,[7] Francisco Monteiro de Almeida Magalhães[1]

Hospital Vila Nova Star,[1] São Paulo, SP – Brazil
Hospital e Maternidade São Luiz,[2] São Paulo, SP – Brazil
Rede D'Or,[3] São Paulo, SP – Brazil
UDI Hospital,[4] São Luis, MA – Brazil
Universidade Federal de São Paulo,[5] São Paulo, SP – Brazil
Hospital e Maternidade Brasil,[6] Santo André, SP – Brazil
Hospital do Coração do Brasil,[7] Brasília, DF – Brazil

Abstract

Background: Severe tricuspid regurgitation (TR) is associated with high morbidity and mortality, especially in patients with contraindications for surgery. Transcatheter tricuspid valve replacement has emerged as a minimally invasive alternative for this population, with the LuX-Valve Plus device designed for orthotopic implantation via the transjugular route.

Objective: To report the first 3 cases of transcatheter tricuspid valve replacement using the LuX-Valve Plus device in Latin America, assessing the feasibility, safety, and immediate clinical outcomes.

Methods: The study included 3 female patients with torrential TR and high surgical risk. Pre-procedure assessment included transesophageal echocardiography, 3-dimensional transthoracic echocardiography (3D TEE), computed tomography, and cardiac catheterization. The procedure was performed via transjugular access, under general anesthesia, with 3D TEE and fluoroscopy guidance. Implant efficacy was assessed as resolution of TR, transprosthetic gradient, and post-procedure complications.

Results: The implants were successful in all cases, with complete resolution of TR, absence of paravalvular leaks, and adequate transprosthetic gradient. Right ventricular function was preserved, and all patients were discharged 3 to 4 days after the procedure with no significant complications.

Conclusion: Transcatheter tricuspid valve replacement using the LuX-Valve Plus was shown to be a viable and safe alternative for patients with severe TR and high surgical risk. The use of 3D TEE was essential to the planning and execution of the implant. Further studies are needed to assess durability and long-term clinical outcomes.

Keywords: Tricuspid Valve; Tricuspid Valve Insufficiency; Transcatheter Aortic Valve Replacement; Transesophageal Echocardiography.

Introduction

Tricuspid regurgitation (TR) is frequently functional, resulting from dilation of the tricuspid annulus in conditions such as valvular heart disease, cardiomyopathy, and pulmonary hypertension. Primary cases may be associated with rheumatic disease or post-surgical complications. When severe and untreated, TR leads to right ventricular dysfunction, worsening prognosis and increasing morbidity and mortality.[1] Tricuspid valve replacement surgery is characterized by high risk in patients with comorbidities, such as right heart failure and pulmonary hypertension. Transcatheter replacement has emerged as a promising alternative, but there are still challenges related to the complex anatomical characteristics of the tricuspid valve.[2]

The LuX-Valve Plus device (Figure 1) is a self-expandable prosthesis implanted via a transjugular approach that was designed to overcome these limitations. This article reports the first 3 cases of transcatheter tricuspid valve replacement using the LuX-Valve Plus in Latin America, assessing the feasibility, safety, and immediate clinical outcomes.[3]

Methods

Three female patients with torrential TR were treated. Two had atrial functional TR, and the third had mixed

Mailing Address: Marcio Mendes Pereira •
UDI Hospital. AV. Prof. Carlos Cunha, 2000. Postal Code: 65076-820. Jaracti, São Luis, MA – Brazil
E-mail: marciomp50@hotmail.com
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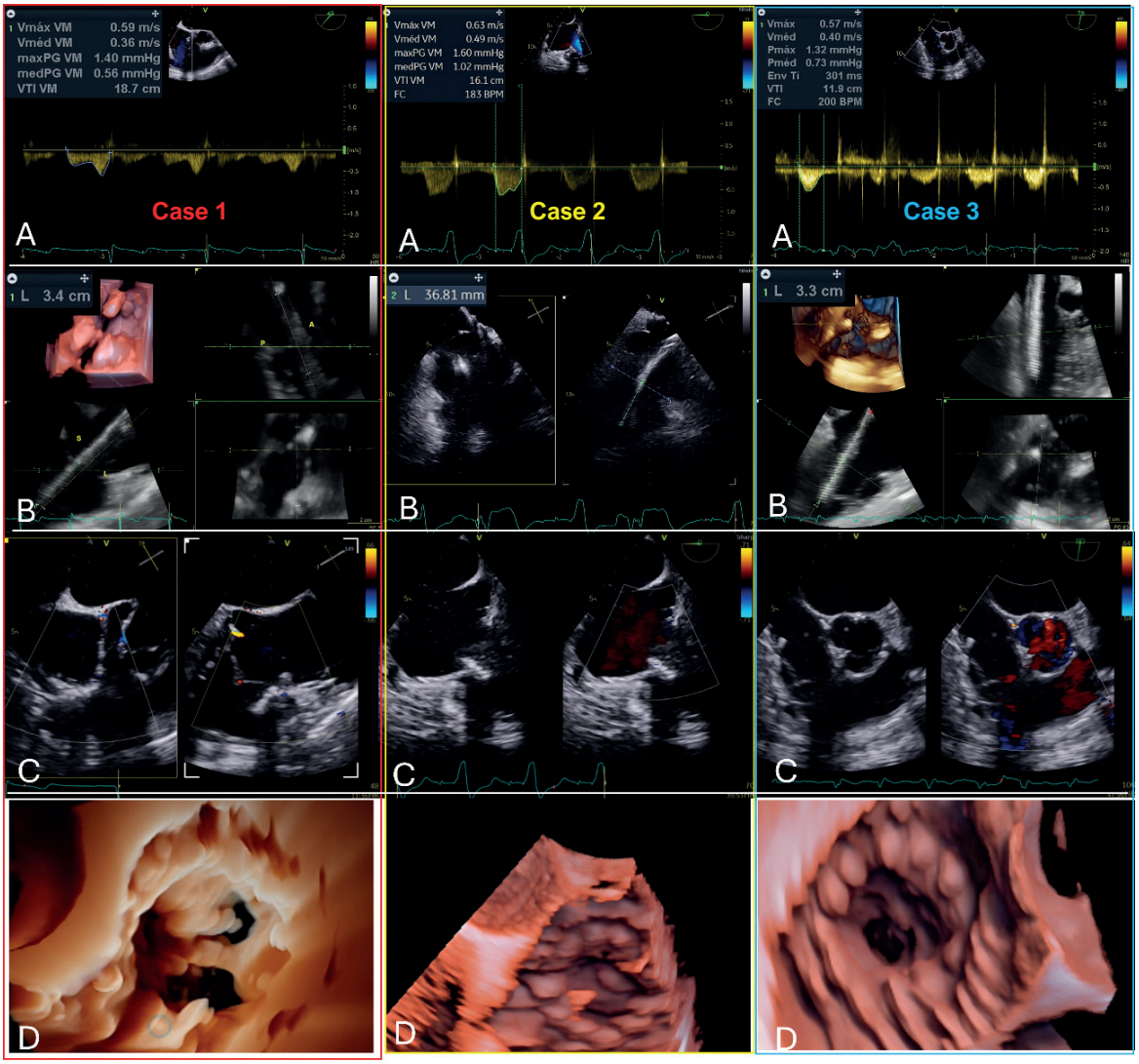
Central Illustration: First Percutaneous Orthotopic Tricuspid Valve Implantations using the LuX-Valve Plus Device in Latin America: Report of the First Three Cases



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Echocardiographic assessment after LuX-Valve Plus implantation in the 3 cases, illustrating the following: (A) the mean gradient, (B) the positioning of the delivery system, (C) the resolution of TR, and (D) 3-dimensional reconstructions of the implanted valve, demonstrating the efficacy of the transcatheter approach.

etiology related to mitral prosthesis and pacemaker leads. All patients had a history of decompensated heart failure, with predominance of systemic congestive symptoms.

The decision for transcatheter treatment was based on high surgical risk and favorable anatomy. Assessment included transthoracic and transesophageal echocardiography, computed tomography, and right chamber catheterization, allowing for detailed planning. Three-dimensional transesophageal echocardiography (3D TEE) was essential for analysis of regurgitation, valve anatomy, and right ventricular function.

Transcatheter procedure

Procedures were performed via transjugular access, under general anesthesia, with 3D TEE and fluoroscopy guidance. Critical steps included the following:

1. Positioning of the delivery system in the right atrium (Figure 2).
2. Centering and coaxiality in the tricuspid annulus (Figure 3).
3. Implantation and anchoring of the device in the interventricular septum (Figures 4 and 5).

4. Final assessment to rule out paravalvular leaks and obstructions (Figures 6 and 7).

Prosthesis sizes ranged from 30/50 mm, 30/55 mm, and 30/45 mm, adjusted to tricuspid anatomy. Intraoperative echocardiographic monitoring was crucial for successful implantation and rapid patient recovery.

Results

All 3 transcatheter tricuspid valve replacement procedures with the LuX-Valve Plus device were conducted successfully, by means of transjugular access with 3D TEE and fluoroscopy guidance. Implantation was performed without significant complications, with appropriate prosthesis positioning in all cases.

Following the procedure, complete resolution of TR was observed in all 3 patients, accompanied by preserved right ventricular function. The mean transvalvular gradient remained within physiological limits, with no evidence of relevant stenosis. Moreover, the patients showed rapid clinical recovery, without requiring hemodynamic support and no serious complications during the initial follow-up period.

Echocardiographic analysis demonstrated adequate adaptation of the prosthesis to the tricuspid annulus, without signs of displacement or valve dysfunction. These findings reinforce the safety and efficacy of the minimally invasive approach using the LuX-Valve Plus device in patients with high surgical risk (Central Illustration).

Discussion

Severe TR, previously considered of minor clinical relevance, has been associated with worse cardiovascular outcomes, including right ventricular dysfunction and increased morbidity and mortality. Multiple recent studies have demonstrated that the severity of TR is directly correlated with worse clinical outcomes, regardless of other parameters, such as pulmonary artery pressure and left ventricular ejection fraction.[4] Moreover, a large retrospective study found that even mild TR is associated with significantly worse clinical outcomes compared with the absence of any trace of regurgitation, reinforcing the need for early and effective therapeutic approaches.[5,6]

Transcatheter approaches, such as the LuX-Valve Plus, represent an important advance in cardiovascular medicine, offering new therapeutic perspectives for a challenging condition, with a substantial impact on patient quality of life and morbidity. Although conventional treatment, which includes medical therapy and open surgery, has shown limited benefits in many cases, transcatheter alternatives, such as implantation of tricuspid valve repair devices, have emerged as promising options, promoting a minimally invasive approach. These interventions have the potential to significantly expand therapeutic options for patients with refractory TR, especially those who are not ideal candidates for traditional surgery.[2,7,8]

A recent study including 76 patients undergoing LuX-Valve Plus implantation observed a significant reduction in TR to ≤ 2+ in 94.7% of cases and ≤ 1+ in 90.8%, with sustained results after 1 month. In-hospital mortality was 5.3%, and major events were infrequent, demonstrating the safety and efficacy of the transcatheter approach, even in complex anatomies.[9]

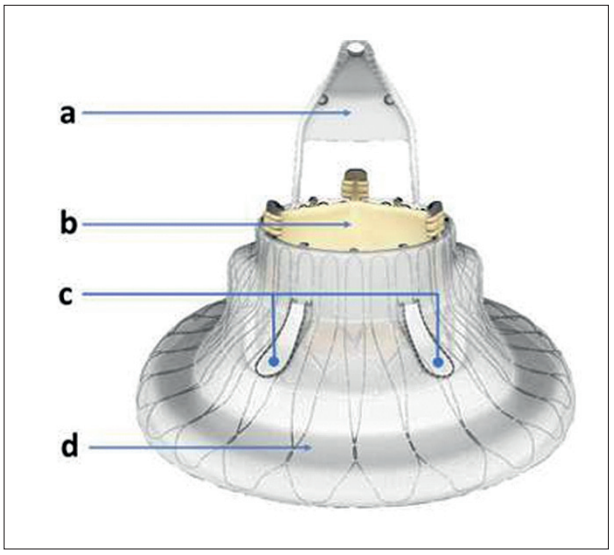

Figure 1 – *The LuX-Valve Plus device: (a) bird tongue-shaped ventricular septal anchor; (b) bovine pericardial prosthetic valve; (c) leaflet graspers; (d) a self-expanding nitinol valve stent consisting of an atrial disc.*

In this report, the device demonstrated safety and efficacy, with positive immediate outcomes, standing out as a promising option for the management of TR. The use of 3D TEE was essential to planning and execution, allowing detailed visualization of the tricuspid annulus and accurate guidance of the delivery system.

Compared to existing transcatheter alternatives, the LuX-Valve Plus offers benefits due to its anatomical adaptation and post-implant stability; however, long-term studies are needed to evaluate its durability and late clinical outcomes.

Conclusion

Transcatheter tricuspid valve replacement using the LuX-Valve Plus was shown to be an effective and safe alternative for patients with severe TR and high surgical risk. This pioneering report in Latin America reinforces the role of transcatheter therapies in managing complex valve conditions, highlighting the importance of echocardiography in planning and monitoring these procedures. Further studies are needed to consolidate its clinical application and establish criteria for patient selection.

Author Contributions

Conception and design of the research and acquisition of data: Esteves F, Esteves V, Pereira MM, Araújo EC, Tebet M, Mancuso FJN, Kreimer S, Magalhães FMA; Analysis and interpretation of the data, statistical analysis, writing of the manuscript and critical revision of the manuscript for intelectual content: Esteves F, Esteves V, Pereira MM.

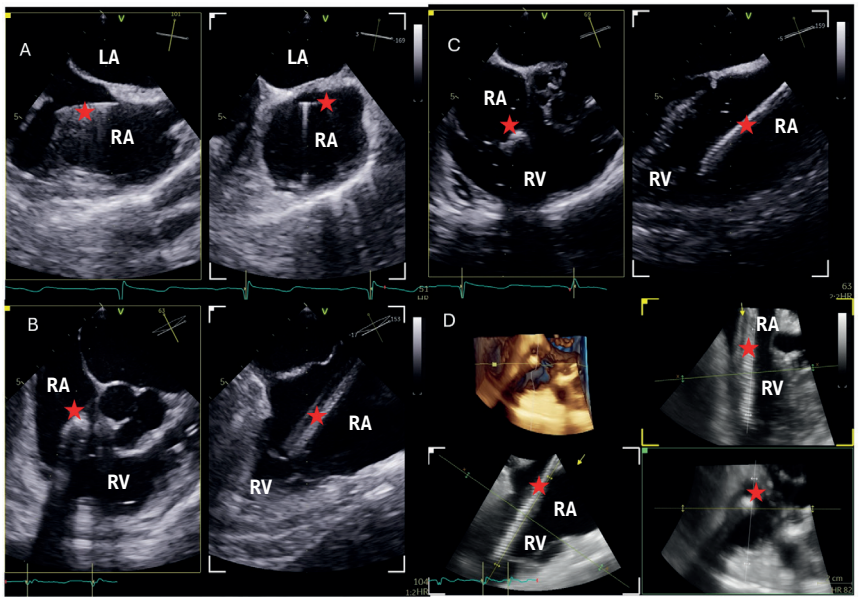

Figure 2 – *Two-dimensional transesophageal echocardiography with biplane images (multi-D or X-plane) based on the short-axis view, showing the process of guiding the delivery system (red star) through the valve and into the right ventricle. (A) The super stiff guidewire advancing into the right atrium (red star). (B) The delivery system has reached the tricuspid valve orifice. (C) The delivery system has crossed the tricuspid valve. (D) After crossing the tricuspid valve, 3-dimensional transesophageal echocardiography imaging with multiplane reconstruction to guide the coaxiality of the delivery system. LA: left atrium; RA: right atrium; RV: right ventricle.*

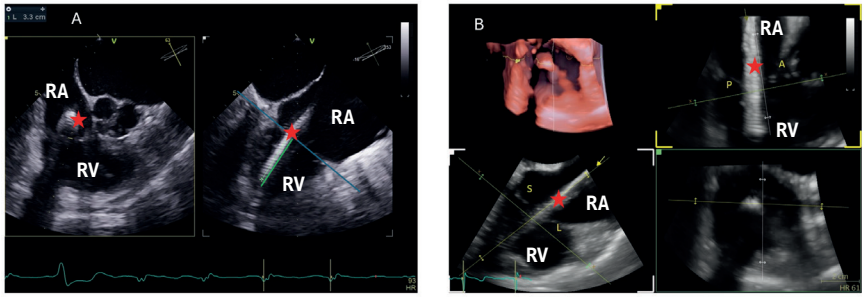

Figure 3 – *(A) Measurement of the insertion depth of the delivery system (red star). The implantation depth is 3.3 cm. (B) After coaxialization, the delivery system was positioned in the central axis of the tricuspid valve, perpendicular to the annular plane. RA: right atrium; RV: right ventricle.*

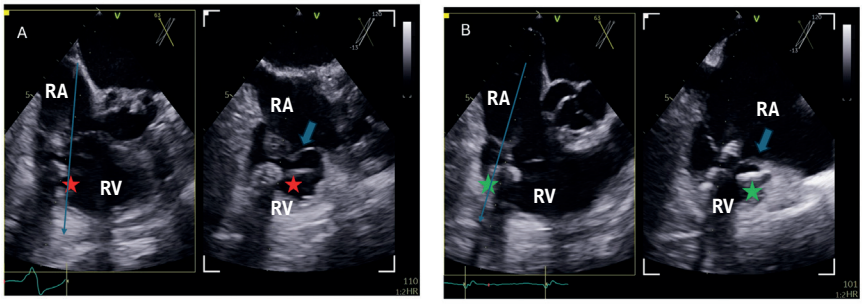

Figure 4 – *Confirmation of leaflet capture by grasper. In the short-axis view, two graspers (red and green stars) can be observed. (A) In the multi-D or X-plane in the RV inflow-outflow view, the sampling cursor is first positioned on the anterior grasper (red star) near the aorta. The grasper can be seen below the anterior tricuspid leaflet (blue arrow) in the corresponding orthogonal plane. (B) In the multi-D or X-plane in the RV inflow-outflow view, the sampling cursor is positioned on the posterior grasper (green star) away from the aorta. The grasper can be seen below the posterior tricuspid leaflet (blue arrow) in the corresponding orthogonal plane. RA: right atrium; RV: right ventricle.*

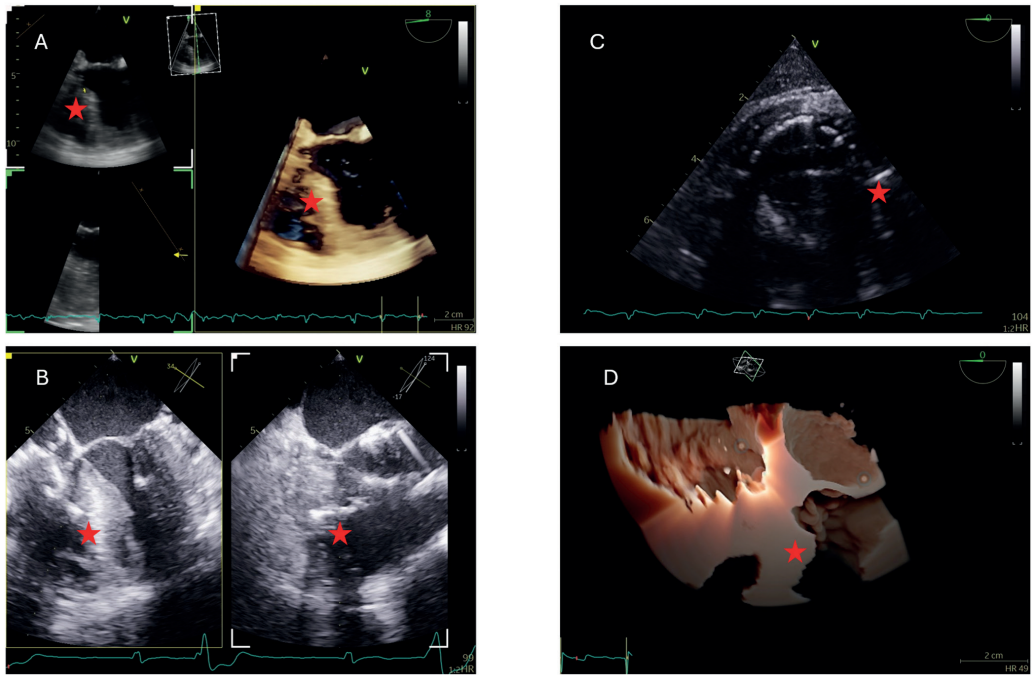

Figure 5 – *Different ways to analyze septal anchoring. (A) Real-time 3-dimensional transesophageal echocardiography imaging, mid-esophageal 4-chamber view, showing septal anchorage (red star). (B) Multi-D or X-plane 4-chamber view of the mid-esophagus. Left: the anchor aligns parallel and attaches to the septum (red star). Right: the anchor attaches to the septum (red star). (C) Short-axis view of the right ventricle through the transgastric window showing septal anchorage (red star). (D) Real-time 3-dimensional transesophageal echocardiography imaging, mid-esophageal 4-chamber view, showing septal anchoring (red star).*

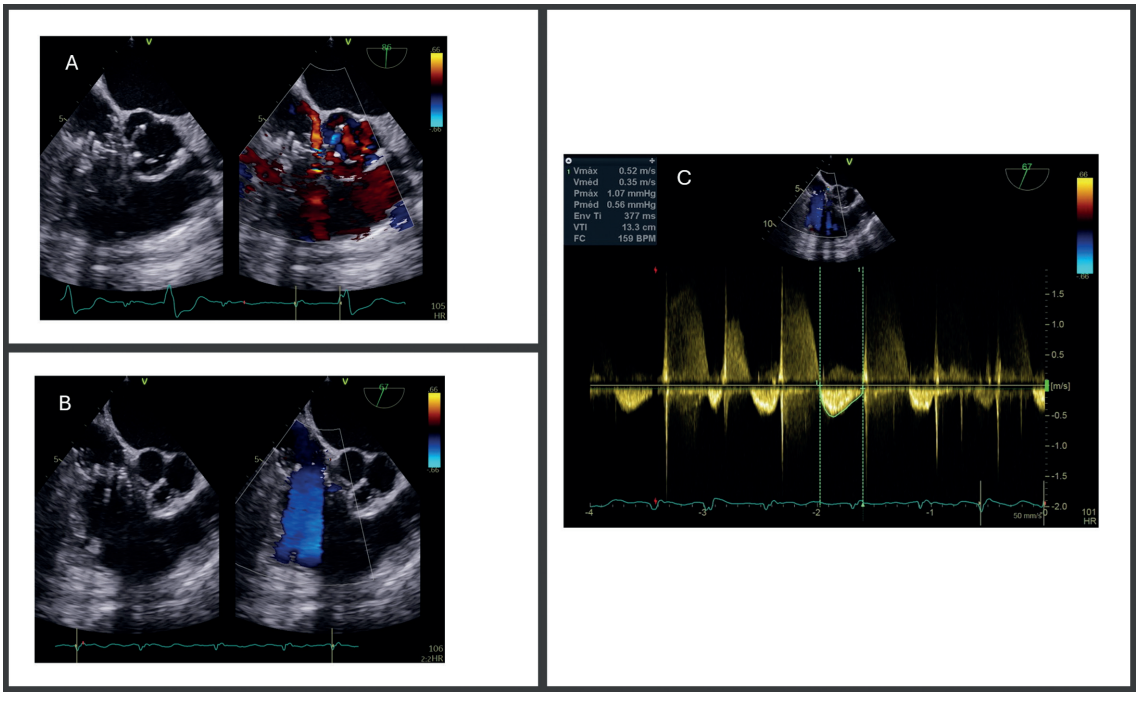

Figure 6 – *Assessment of prosthetic valve function. (A) Determination of the position and degree of paravalvular regurgitation. In the biplane RV inflow-outflow view, a mild paravalvular leak was observed, located in the anterior topography. (B) After fine adjustment and repositioning of the prosthesis, it was possible to correct the paravalvular leak with an excellent final result. (C) Analysis of transprosthetic gradients. RV: right ventricle.*

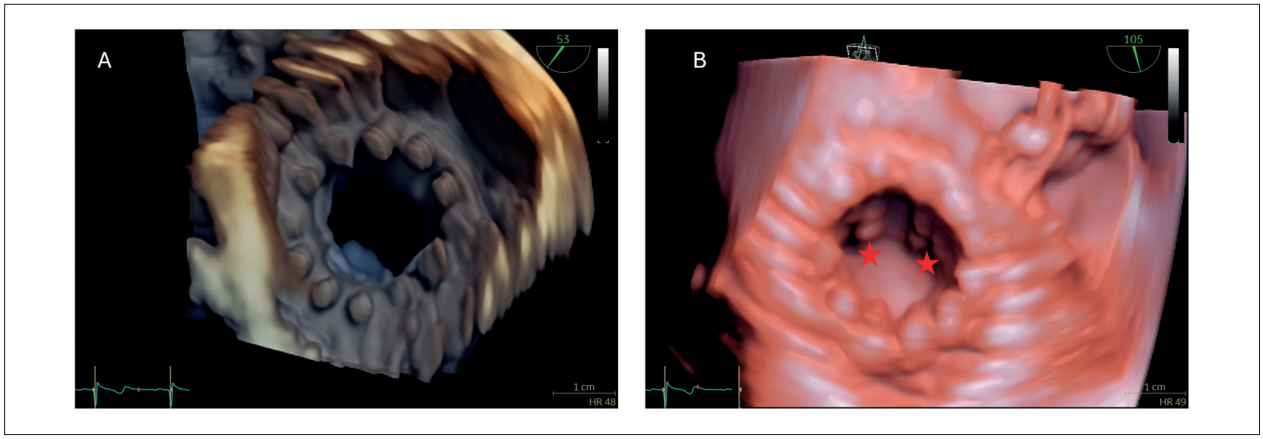

Figure 7 – *Assessment of prosthetic valve function. (A) Three-dimensional imaging of the atrial face of the LuX-Valve Plus, showing the right atrial disc (D-shaped) and stent (the circular structure in the middle). (B) Three-dimensional imaging of the ventricular face of the LuX-Valve Plus, showing 2 graspers, known as "rabbit ears" (red star).*

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any thesis or dissertation work.

Ethics Approval and Consent to Participate

This article does not contain any studies with human participants or animals performed by any of the authors.

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