Case Report

Transcatheter Bicaval Valve System in the Treatment of Torrential Tricuspid Regurgitation and Refractory Systemic Hypervolemia: 12-Month Outcome

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Abstract

Severe isolated tricuspid regurgitation (TR) is associated with limiting symptoms, negative impact on quality of life, and poor prognosis. The TricValve® device is a transcatheter self-expanding biological valve system designed to mitigate systemic volume overload, improve quality of life, and improve congestive symptoms. We report a 12-month follow-up of a 61-year-old woman with signs of refractory systemic hypervolemia and torrential TR who underwent the procedure. The treatment resulted in significant weight loss, improvement in signs of hypervolemia, and improvement in functional class (FC).

Introduction

Tricuspid regurgitation (TR) is often underestimated and undertreated. Evidence in the literature indicates that isolated significant TR increases mortality, regardless of left ventricular ejection fraction, pulmonary pressures, or right ventricular (RV) dysfunction.[1] Clinical management typically involves escalating doses of diuretics, though efficacy remains limited due to the progressive nature of the disease and structural changes caused by systemic hypervolemia. Surgery for isolated TR is associated with a high mortality rate, ranging from 4% to 20%.[2] As a result, interventional therapies, especially percutaneous treatments, have gained attention due to their less invasive profile. The TricValve® system, a bicaval valve prosthesis, was developed to mitigate reflux responsible for volume overload in patients with severe TR. Studies have demonstrated that the device effectively reduces systemic congestion, leading to improved quality of life and better functional status.[3]

Case report

A 61-year-old female patient with a history of rheumatic mitral valve disease who had undergone mitral valve replacement with a metal prosthesis 16 years prior presented with progressive dyspnea, leg edema, abdominal discomfort, and asthenia. On physical examination, she exhibited an irregular heart rhythm, jugular vein distension, lower limb edema, a systolic murmur along the lower left sternal border, and a metallic click in the first heart sound.

Electrocardiography revealed atrial fibrillation with a controlled heart rate. Echocardiography demonstrated torrential TR due to annular dilation and leaflet tethering, with significant leaflet separation and a 6.6-mm gap, resulting in a regurgitant volume of 119 mL (Figure 1). The metallic mitral prosthesis displayed preserved opening with mild reflux. Left ventricular and RV systolic function were normal, while both the left atrium and right atrium (RA) were significantly enlarged. Cardiac catheterization revealed a prominent "V" wave in the RA and vena cava.

Given the presence of isolated TR, worsening symptoms despite high-dose diuretic therapy, and a high surgical risk (TRI-SCORE = 5), percutaneous treatment was selected. The available transcatheter option at the time was heterotopic implantation of a bicaval prosthesis. The procedure was performed under conscious sedation with primary access through the right femoral vein. Due to significant vena cava dilation at its junction with the RA, the superior vena cava prosthesis was implanted high, with its crown positioned entirely within the brachiocephalic vein. The inferior vena cava device was deployed below its junction with the RA, sealing at the level of the hepatic vein (Figure 2).

The patient recovered well from the procedure; however, on the third postoperative day, she developed a large hematoma at the main access site. Surgical drainage was performed successfully, and she was subsequently discharged from the hospital. At the 12-month follow-up, the patient demonstrated significant improvement in functional class (FC) and quality of life. Physical examination showed no hepatomegaly or lower limb edema. Follow-up imaging confirmed proper prosthesis positioning and effective vena cava sealing (Video 1). Additionally, the patient experienced significant weight loss and had no hospitalizations during this period (Table 1).

Discussion

Torrential TR with right heart failure presents a therapeutic challenge due to the complex and heterogeneous anatomy of the tricuspid valve, as well as the clinical profile of affected patients. Therefore, evaluation by a multidisciplinary cardiac

Keywords

Tricuspid Valve Insufficiency; Edema; Heart Valve Diseases; Cardiac Catheterization.

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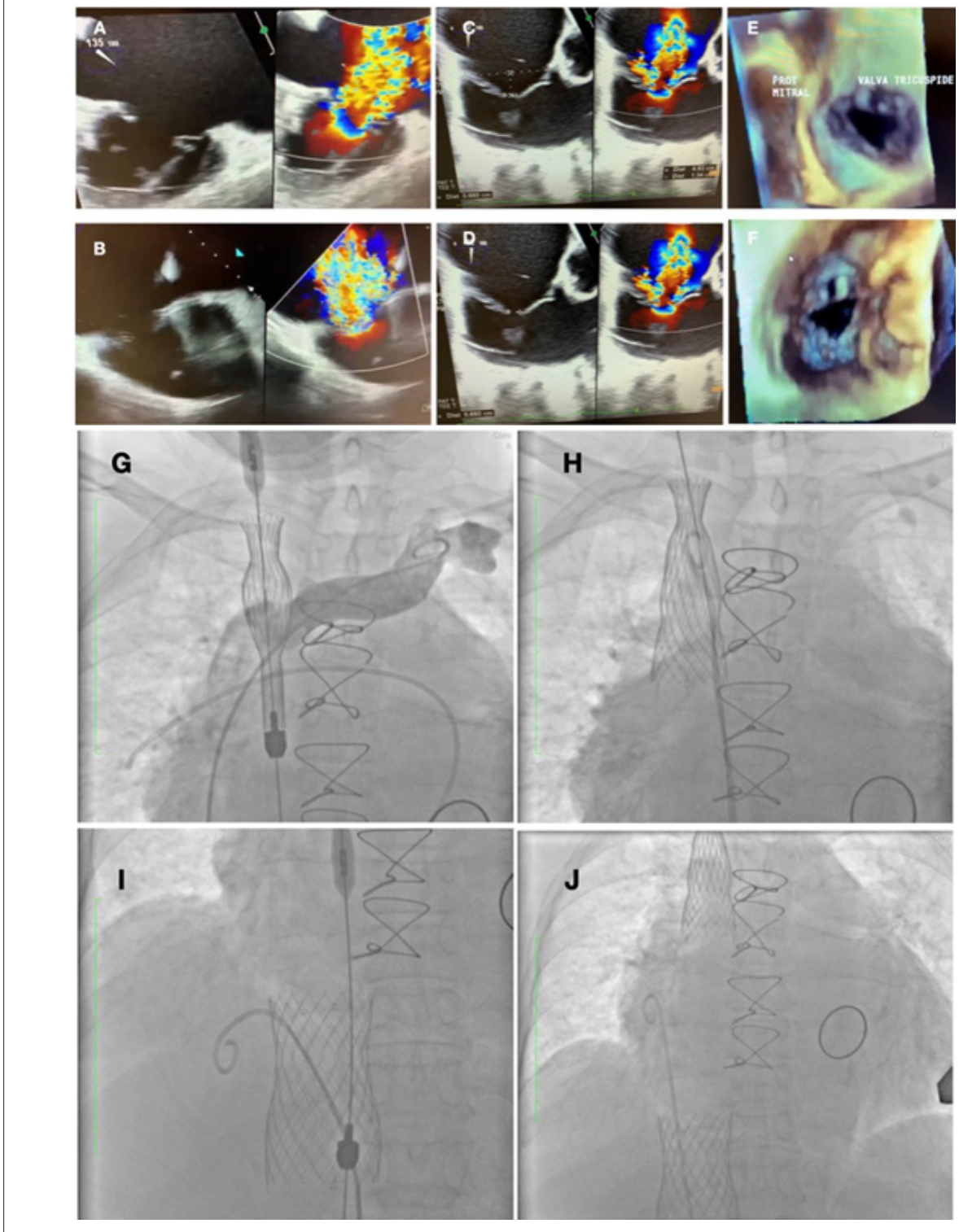


Figura 1 – *Images of the tricuspid valve obtained through 2D and 3D transesophageal echocardiography before implantation, as well as fluoroscopic images of the TricValve® device implantation procedure. A to D: Different views of torrential TR observed in the transesophageal echocardiographic evaluation. E and F: Three-dimensional assessment of tricuspid valve coaptation failure. G and H: Fluoroscopic images of the positioning of the self-expanding valve in the superior vena cava. I: Fluoroscopic images of the positioning of the self-expanding valve in the inferior vena cava. J: Final position of the valves after deployment.*

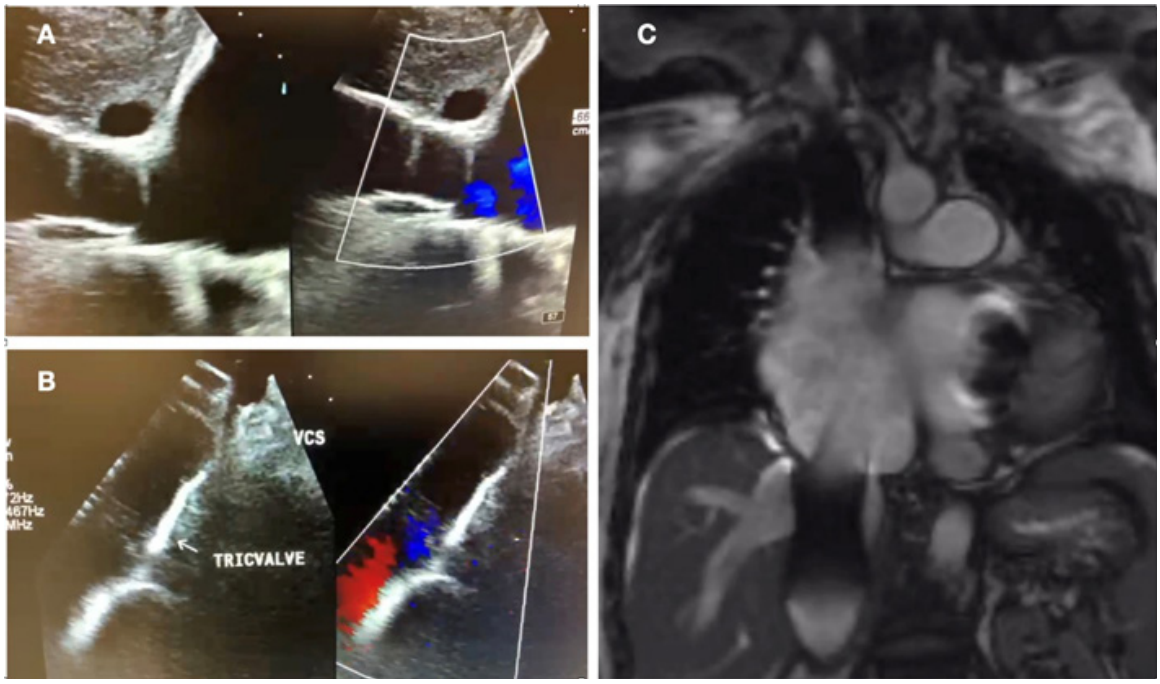
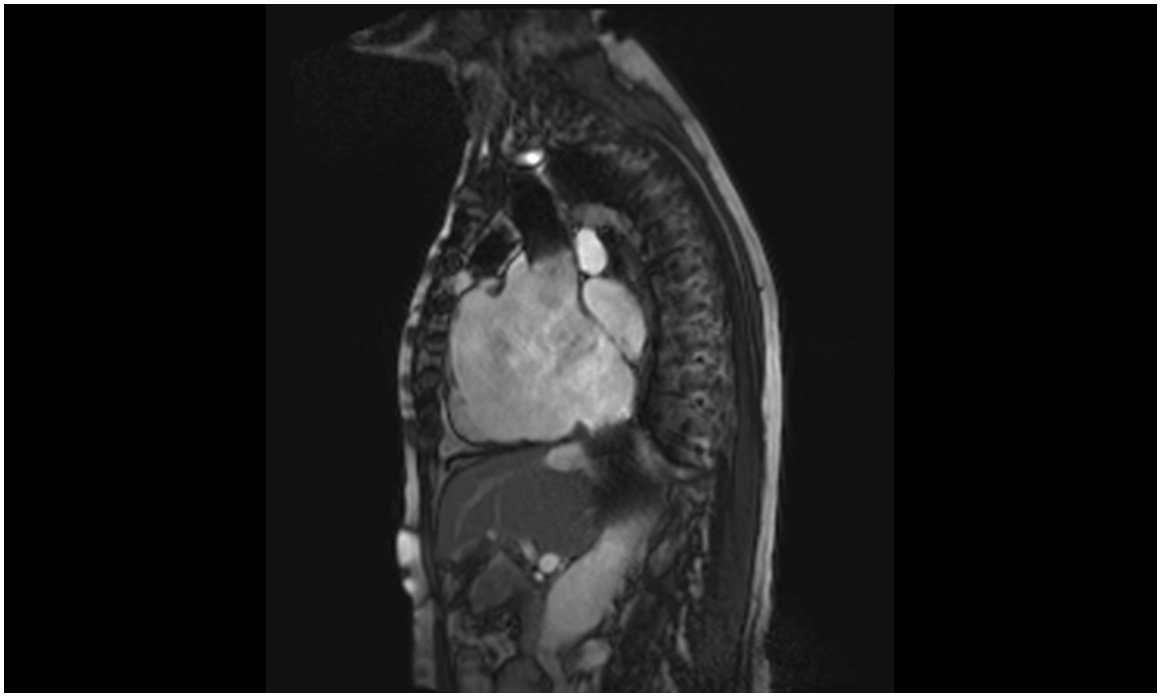


Figura 2 – *Post-procedure imaging assessment. A to C: Transthoracic echocardiography and cardiac magnetic resonance imaging demonstrating well-positioned prostheses in the inferior and superior vena cava.*



Video 1 – *Control cardiac magnetic resonance imaging demonstrating the prostheses well positioned in the superior and inferior vena cava. Link: https://ijcscardiol.org/supplementary-material/2025/38/2025-0035_Tricvalve.mp4*

Table 1 – One-year follow-up after bicaval TricValve implantation

Heart failure symptoms			
	Baseline	**6-month follow-up**	**1-year follow-up**
NYHA FC	III	I	I
KCCQ score	37.5	-	100
Peripheral edema	+++	None	None
Jugular vein distension	+++	None	None
Weight, kg	78	65	67
Echocardiography			
TR severity	**Torrential**	**Torrential**	**-**
LVEF, %	69	66	-
RVBD, mm	63.1	57.5	-
RVMCD, mm	42.1	38.2	-
TAPSE	22.7	21	-
LAV, ml/m²	63	67	-
RAV, ml/m²	164	189	-
Cardiac MRI			
LVEDV, ml	-	93	106
LVEF, %	-	71	65
RVEDV, ml	-	352	287
RVEF, %	-	62	54
LAV, ml	-	353	294
RAV, ml	-	499	504

KCCQ: Kansas City Cardiomyopathy Questionnaire; LAV: left atrial volume; LVEDV: left ventricular end-diastolic volume; LVEF: left ventricular ejection fraction; MRI: magnetic resonance imaging; NYHA: New York Heart Association; RAV: right atrial volume; RVBD: right ventricular basal diameter; RVEDV: right ventricular end-diastolic volume; RVEF: right ventricular ejection fraction; RVMCD: right ventricular mid-cavity diameter; TAPSE: tricuspid annular plane systolic excursion; TR: tricuspid regurgitation; FC: functional class.

team is a crucial step in the decision-making process. In this report, we describe the 12-month follow-up results after implantation of the TricValve® system. The patient, a 61-year-old woman with isolated functional torrential TR, initially presented in FC III with systemic hypervolemia refractory to optimized medical therapy. Despite her relatively young age, surgery was deemed high-risk due to prior cardiac surgery, isolated tricuspid valve disease, and a TRI-SCORE-predicted in-hospital mortality of 14%.[3] Bicaval valve implantation has emerged as a viable option for patients unsuitable for direct tricuspid valve interventions and those with high or prohibitive surgical risk. At the 12-month follow-up, the patient had improved to FC I, experienced significant weight loss, and showed reduced signs of hypervolemia. This outcome aligns with existing literature, where nearly 80% of patients achieved FC I or II status at the 6-month follow-up.[4,5]

From a pathophysiological perspective, after device implantation in the vena cava, the RA effectively becomes part of the RV, leading to increased pressure in this chamber, which functions as a blood reservoir. Consequently, an increase in RA size is commonly observed during follow-up, as seen in the reported case. When comparing echocardiographic parameters, we noted a progressive increase in RA size, stability of RV function, and persistence of torrential TR. Regarding TR, studies suggest that while the TricValve® does not directly alter valve leaflet function, it may have a positive impact by relieving the RV from chronic volume overload. Up to the current follow-up period, cardiac magnetic resonance imaging demonstrated a reduction in RV volume between the 6-month and 12-month evaluations, with preservation of global systolic function. Structural changes may occur over longer follow-up periods, a phenomenon previously described in patients monitored for more than 6 months.

Vascular complications are reported in up to 20% of cases after the procedure and are associated with factors such as the large caliber of the device, anticoagulation use, and the clinical profile of these patients, all of which increase the risk of bleeding. The patient was using vitamin K antagonists due to a mechanical mitral prosthesis, and the hematoma occurred after reintroducing the medication. Another concerning complication is valve migration, which

may be attributed to variations in volume status, difficulty in anchoring the device due to vena cava dilation from chronic volume overload, and the absence of calcified structures.[6] In this case, echocardiography and cardiac magnetic resonance imaging demonstrated prosthesis stability, proper leaflet function, and the absence of significant paravalvular leakage during follow-up.

Conclusion

Percutaneous implantation of the TricValve® system resulted in a significant improvement in quality of life, as well as in signs and symptoms related to systemic hypervolemia, without compromising RV function at the 12-month follow-up after the procedure. Future studies with a larger patient population and long-term follow-up are needed to further validate this therapy and enhance the understanding of patient outcomes.

Author Contributions

Conception and design of the research: Torres RFA, Bozzi FPL, Grobe SF, Silva GBG; acquisition of data: Torres RFA, Kraemer A, Bozzi FPL, Grobe SF, Silva GBG; analysis and interpretation of the data: Torres RFA, Bozzi FPL, Balbi Filho EM, Torres RA; statistical analysis: Torres RFA; writing of the manuscript: Torres RFA, Bozzi FPL, Torres RA; critical revision of the manuscript for intellectual content: Torres RFA, Kraemer A, Balbi Filho EM.

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 study was approved by the Ethics Committee of the Pontifícia Universidade Católica do Paraná under the protocol number 83069924.2.0000.0020 / 7235893. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

Use of Artificial Intelligence

The authors did not use any artificial intelligence tools in the development of this work.

Availability of Research Data

The underlying content of the research text is contained within the manuscript.

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