Interactive CardioVascular and Thoracic Surgery 31 (2020) 461–466
doi:10.1093/icvts/ivaa142 Advance Access publication 8 September 2020

ORIGINAL ARTICLE

Cite this article as: Bastos Filho JBB, Sampaio RO, Cividanes FR, Rosa VEE, da Costa LPN, Vieira MLC *et al.* Double transcatheter balloon-expandable valve implantation for severe valve dysfunction in high-risk patients: initial experience. Interact CardioVasc Thorac Surg 2020;31:461–6.

Double transcatheter balloon-expandable valve implantation for severe valve dysfunction in high-risk patients: initial experience

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Received 26 February 2020; received in revised form 15 May 2020; accepted 6 July 2020

Key question

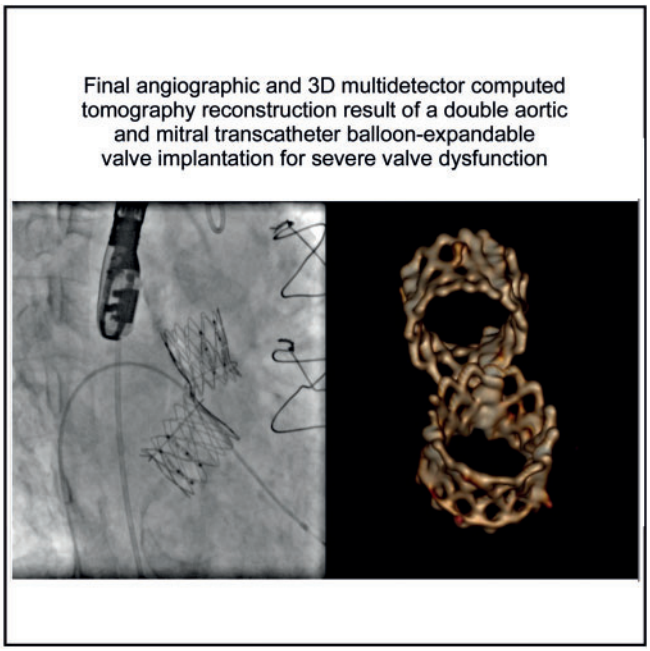
Is double transcatheter bioprosthesis implantation for severe valve dysfunction safe and viable?

Key finding(s)

Transcatheter double valve implantation is a reasonable alternative to redo operations in selected patients.

Take-home message

Clinical and echocardiographic outcomes of double transcatheter procedures show promising results, although larger studies are warranted.



Abstract

OBJECTIVES: Concomitant valvular heart valve disease is a frequent finding, with higher morbidity and mortality among patients undergoing redo surgical procedures. Our goal was to report our initial experience with combined transcatheter Inovare bioprosthesis implants for severe valve dysfunction.

METHODS: Among 300 transcatheter procedures, a total of 6 patients had concurrent simultaneous transcatheter bioprosthesis implants for severe mitral bioprosthesis failure (valve-in-valve), with a second valve procedure that included native aortic ($n = 2$) or degenerated bioprostheses in the aortic position ($n = 4$). During the procedures, all patients were treated with a balloon-expandable Inovare transcatheter valve, using the transapical approach.

RESULTS: Patients were highly symptomatic [New York Heart Association (NYHA) functional class IV: 100%], with a mean age of 62 ± 5 years, yielding a mean European System for Cardiac Operative Risk II (EuroSCORE II) of 24.0 ± 10.1%. There was a mean of 1.6 ± 0.4 prior valve operations/patient, with a median time from prior mitral bioprosthesis surgery of 13.0 (9.2–20.0) years. Device success was 100% according to the Mitral Valve Academic Research Consortium and the Valve Academic Research Consortium-2 criteria. During the hospital stay, only 1 patient required dialysis, and the median intensive care unit and hospital lengths of stay were 5.0 (3.2–6.7) days and 16.0 (12.2–21.2) days, respectively. No deaths occurred at 30 days; at a median follow-up of 287 (194–437) days, 1 patient died of a non-cardiac cause and the rest of patients were in NYHA functional class I or II, with normofunctioning bioprostheses.

CONCLUSIONS: Transcatheter double valve interventions using the Inovare bioprosthesis in this initial series were shown to be a reasonable alternative to redo surgical operations. The short- and mid-term clinical and echocardiographic outcomes demonstrate promising results, although future studies with a larger number of patients and longer follow-up are warranted.

Keywords: Transcatheter aortic valve implantation • Prior surgical bioprosthesis • Redo operation • Valve-in-valve

ABBREVIATIONS

CT	Computed tomography
LVOT	Left ventricular outflow tract obstruction
NYHA	New York Heart Association
VIR	Valve-in-ring
VIV	Valve-in-valve

INTRODUCTION

Concomitant valvular heart valve disease is a frequent finding, especially given the increasing age of the population. It may affect as many as 11% of patients undergoing valvular heart surgery [1]. Also, in countries where rheumatic valve disease is still prevalent, the incidence of simultaneous severe multivalvular disease requiring surgical intervention is even higher, representing ∼20% of the procedures [2, 3]. Importantly, these patients undergo multiple valvular procedures, which puts them at higher risk of morbidity and mortality. For instance, simultaneous aortic and mitral surgery mortality rates are between 5% and 13%, whereas an isolated aortic valve replacement generally causes severe complications in <4% of patients [4–6].

Transcatheter valve interventions have been established as an alternative to surgical interventions in recent years, initially for patients with severe aortic stenosis deemed inoperable or at high or intermediate surgical risk. More recently, this procedure has been evaluated in patients with bioprosthetic valve failure [valve-in-valve (VIV)] in aortic, mitral and tricuspid positions [7–9], as well as in those with pure native aortic regurgitation [10], among other indications. Therefore, although interest in simultaneous procedures during the same intervention has grown lately, experience is still limited and is restricted to case reports, small case series and only certain types of transcatheter valves [7, 9, 11–16]. Our goal was to report our initial experience with combined transcatheter Inovare bioprosthesis implants for severe valve dysfunction.

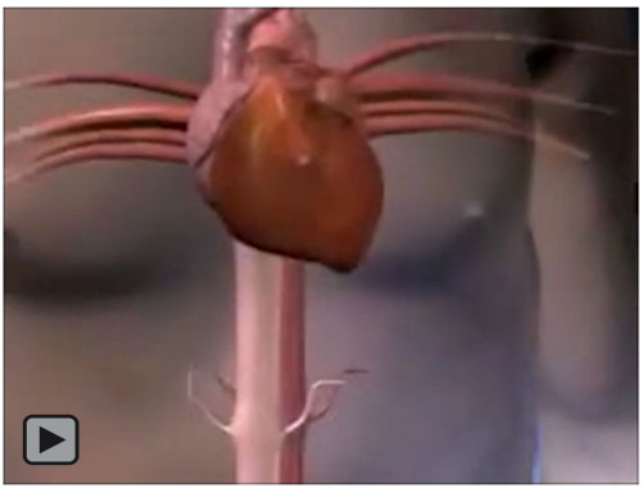
METHODS

Ours was a single-centre registry that included consecutive patients who had simultaneous transcatheter procedures from January 2015 to March 2019. A total of 300 transcatheter valves were implanted at our centre during this period, and 6 patients had concurrent combined transcatheter bioprosthesis implants for severe mitral bioprosthesis failure, with a second valve that included native or degenerated bioprostheses in the aortic position. During the procedures, all patients were treated with a balloon-expandable Inovare bioprosthesis (Braile Biomédica®, São José do Rio Preto, Brazil), made of a cobalt-chromium alloy and bovine pericardium, using the transapical approach [17]. The Inovare system includes a wide range of diameters; more vertices in the lozenge frame (for better force distribution and annulus accommodation); and a single pericardial sheet for all leaflets (reducing the number of pericardial sutures) [18, 19]. The main procedural steps are shown in the Video 1 [18, 19].

This study was approved by the institutional ethics committee; informed consent for the procedure was obtained from all patients.

All of the included patients had severe double valve dysfunction that could include severe stenosis, regurgitation or both, and were in New York Heart Association (NYHA) functional class >2. They underwent gated computed tomography (CT) evaluation for annulus or bioprosthetic ring assessment and transoesophageal echocardiography for proper valve dysfunction analysis [20]. In addition, the potential for left ventricular outflow tract obstruction (LVOT) was also evaluated before the procedure as previously described [21, 22].

Gathered data included baseline clinical, echocardiographic and CT characteristics. Procedural data included the type and size of the transcatheter bioprosthesis and the approach, and the clinical events were defined according to the Mitral Valve Academic Research Consortium criteria and the Valve Academic Research Consortium-2 criteria, depending on the procedure



Video 1: Procedural steps for double transcatheter balloon-expandable valve implantation for severe valve dysfunction in aortic and mitral position, in a high-risk patients using the transapical approach.

[23, 24]. Finally, data regarding in-hospital and 1-year mortality were also included in the analysis.

Categorical variables were reported as *n* (%), and continuous variables as the mean ± standard deviation. All analyses were conducted using the statistical package SPSS (version 20.0. IBM Corp., Armonk, NY, USA).

RESULTS

The main baseline clinical, echocardiographic and procedural characteristics are presented in Table 1 (mean data) and Table 2 (individual data). All patients were highly symptomatic with NYHA functional class IV (100%). The mean age was 62 ± 5 years and half were men (50%). Only 1 patient had no definite aetiology, whereas the others had chronic rheumatic disease (83.3%).

Table 1 Baseline clinical, echocardiographic and procedural characteristics of the study population

Clinical variables	Values (*n* = 6)
Age (years), mean ± SD	62 ± 5
Male gender, *n* (%)	3 (50)
NYHA functional class IV, *n* (%)	6 (100)
Previous CABG, *n* (%)	1 (16.6)
Atrial fibrillation, *n* (%)	6 (100)
Rheumatic disease, *n* (%)	5 (83.3)
Previous operations, mean ± SD	1.6 ± 0.4
Post-mitral valve replacement (years), median (IQR)	13.0 (9.2–20.0)
EuroSCORE II (%), mean ± SD	24.0 ± 10.1
Echocardiographic variables	
LVEF (%), mean ± SD	59 ± 6
Mean aortic gradient (mmHg), mean ± SD	37 ± 12
Max aortic gradient (mmHg), mean ± SD	67 ± 17
Mean mitral gradient (mmHg), mean ± SD	13.5 ± 3.8
Moderate/severe mitral regurgitation, *n* (%)	3 (50)
Moderate/severe tricuspid regurgitation, *n* (%)	4 (66.7)
PSAP (mmHg), mean ± SD	78 ± 16
Procedural data, *n* (%)	
Simultaneous THV type[a]	
VIV aortic	4 (66.7)
Native aortic	2 (33.3)

[a]All patients underwent simultaneous mitral VIV procedure.

CABG: coronary artery bypass graft; EuroSCORE II: European System for Cardiac Operative Risk Evaluation II; IQR: interquartile range; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PSAP: pulmonary systolic arterial pressure; SD: standard deviation; THV: transcatheter heart valve; VIV: valve-in-valve.

There was a mean of 1.6 ± 0.4 prior valve operations/patient (ranging from 1 to 2); and for a degenerated mitral bioprosthesis, the median time from prior surgery was 13.0 (9.2–20.0) years (range 8–20 years). The mean European System for Cardiac Operative Risk II (EuroSCORE II) was 24.0 ± 10.1%.

In all patients the transapical access was used. The transapical approach was used for treatment of both mitral and aortic valves: 4 patients had double mitral and aortic VIV (Fig. 1), and 2 patients had native aortic stenosis and mitral bioprosthesis failure (Fig. 2 and Table 1).

Procedural results are shown in Table 3. Device success was 100% according to the Mitral Valve Academic Research Consortium criteria and Valve Academic Research Consortium-2 criteria. No deaths occurred intraprocedurally. Only 1 patient (16.7%) required postoperative dialysis; no other procedure-associated complications were recorded, including no cases of LVOT obstruction. The median intensive care unit and hospital lengths of stay after the procedure were 5.0 (3.2–6.7) days and 16.0 (12.2–21.2) days, respectively. No deaths occurred at 30 days; at a median follow-up period of 287 (194–437) days, 1 patient died of a non-cardiac cause (drug-induced fulminant hepatitis) and the rest of patients were in NYHA functional classes I–II. Individual patient follow-up days are shown in Supplementary Material, Table S1. Echocardiographic parameters at follow-up showed normofunctioning mitral bioprostheses with no mitral regurgitation and a mean gradient of 7.0 ± 2.3 mmHg; the aortic bioprostheses were also normofunctioning, with trace or no paravalvular leak, and mean gradients of 17.5 ± 5.1 mmHg. All patients received warfarin at hospital discharge because they had atrial fibrillation; no clinical leaflet thrombosis was noted during the follow-up period.

DISCUSSION

The main findings of this initial series were that implantation of a simultaneous double transcatheter Inovare bioprosthesis for severe valve dysfunction, performed in this high-risk population, may be an alternative to conventional redo surgery, with acceptable short- and mid-term clinical and echocardiographic outcomes.

The presence of multivalvular heart disease is a frequent finding, given the ageing population and the prevalence of rheumatic disease in some countries [3, 25]. Likewise, with comorbidities and repeated procedures, the rates of morbidity and mortality

Table 2 Individual data characteristics of the study population (*n* = 6)

Patient (*n* = 6)	Age (years)	Sex	Time since last surgery (years)	Previous CABG	Prior surgical valve procedures (*N*)	Euro SCORE II (%)	Approach	Order of intervention	Mitral bioprosthesis size	Simultaneous THV location	Other THV size
1	72	Male	17	Yes	2	14.8	TA	M→A	30	TAVI	28
2	63	Male	20	No	1	22.5	TA	A→M	30	Aortic VIV	26
3	48	Female	10	No	2	13.3	TA	M→A	28	Aortic VIV	20
4	60	Male	16	No	2	38.9	TA	M→A	30	Aortic VIV	22
5	62	Female	8	No	2	39.8	TA	A→M	24	Aortic VIV	20
6	67	Female	9	No	1	15.8	TA	A→M	26	TAVI	26

A: aortic; CABG: coronary artery bypass graft; EuroSCORE II: European System for Cardiac Operative Risk Evaluation II; M: mitral; T: tricuspid; TA: transapical; TAVI: transcatheter aortic valve implantation; THV: transcatheter heart valve; VIV: valve-in-valve.

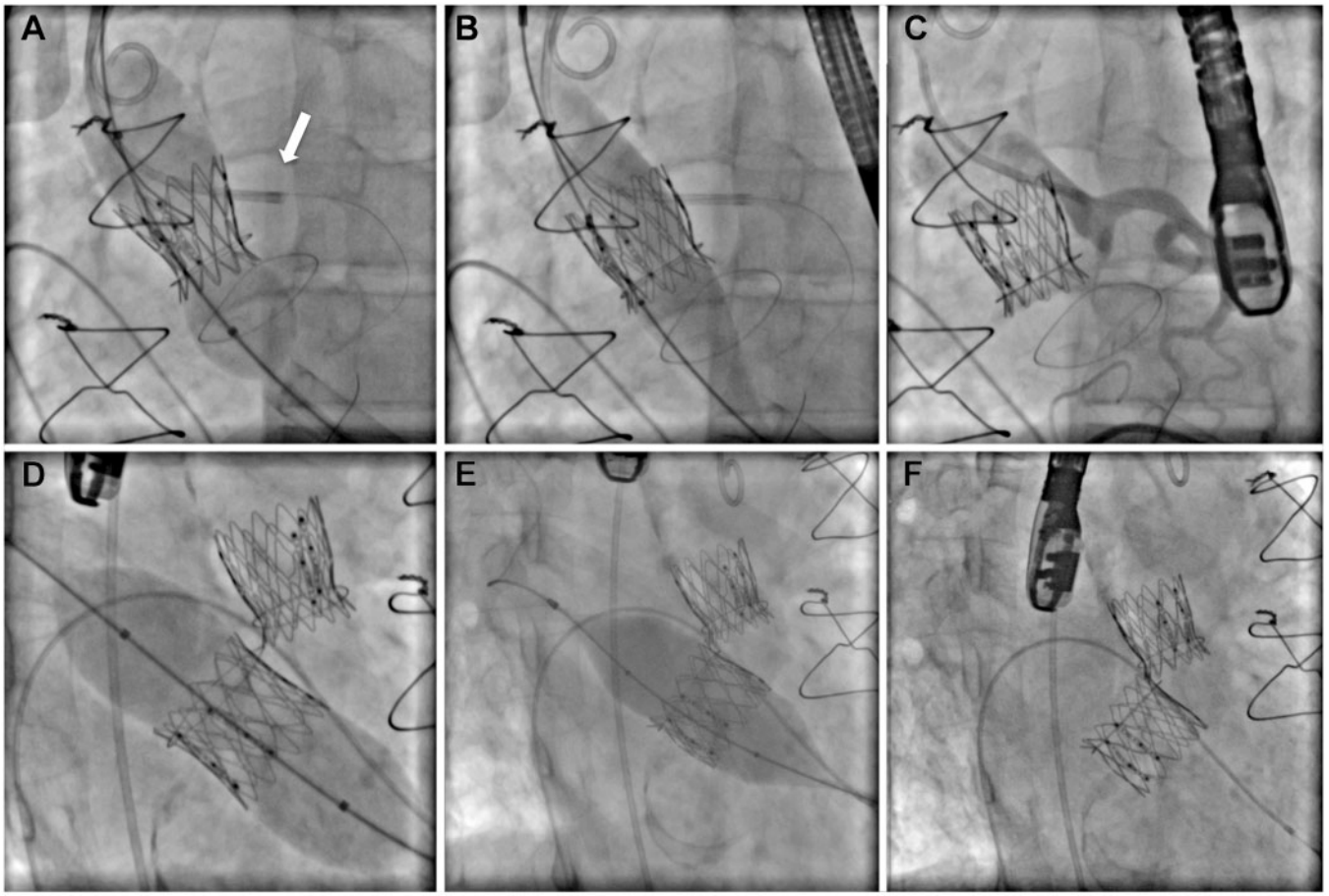


Figure 1: Case example of combined aortic and mitral valve-in-valve (VIV). Aortic VIV implantation with coronary wire protection (white arrow) (**A**). Non-compliant Atlas gold post-dilatation (**B**). Final result with normal coronary flow (**C**). Mitral VIV replacement (**D**). Non-compliant Atlas gold post-dilatation in the mitral position (**E**). Final result with both aortic and mitral transcatheter heart valve replacements (**F**).

are amplified up to five-fold compared to the replacement of a single valve [1, 3–5]. In this high-risk scenario, catheter-based valve implantation techniques have gradually become an alternative to standard redo surgical valve replacement for patients of different risk profiles, with good short- and mid-term results [8].

The so-called VIV procedures started in the aortic position and have rapidly expanded to mitral, tricuspid and pulmonary VIV procedures [7, 9]. The advantages of VIV implantation over conventional redo surgery are mainly related to the less invasive approach, which means shorter duration of the procedure and no need for mediastinal re-entry, cardiopulmonary bypass, aortic cross-clamping and removal of the failed valve [12]. The largest study to date evaluating VIV procedures is the Valve-in-Valve International Data Registry, which is a multinational comprehensive evaluation of transcatheter valve implants for failed surgical bioprostheses. In the aortic VIV subset of patients, the overall 30-day and 1-year mortality rates were 7.6% and 16.8%, respectively [8].

More recently, in a larger multicentre series including only transcatheter mitral valve replacements, a total of 521 patients were evaluated for mitral VIV and for failed annuloplasty rings [valve-in-ring (VIR)] [26]. The all-cause mortality was slightly higher for VIR versus VIV at 30 days (9.9% vs 6.2%) and at 1 year (30.6% vs 14.0%; adjusted hazard ratio 1.99, 95% confidence interval 1.27–3.12; $P = 0.003$). We have recently shown in a series of the first 50 cases of mitral VIV overall 30-day and 1-year mortality rates of 12.9% and 26.3%, respectively, including only the transapical approach and the Inovare bioprosthesis, which are comparable to those in previously published reports [27].

Few data in the literature evaluate transcatheter combined valve interventions; most are isolated case reports and small case series, restricted to self-expandable and Sapien valves [5, 7, 12–14]. In a recent systematic review of the literature, a total of 19 cases were reported: 6 patients with a transcatheter aortic valve implant combined with a transcatheter mitral VIV or VIR and 13 patients with combined aortic and mitral VIV or VIR procedures [11]. In this study the reported mortality rates at 30 days and in the follow-up period (range 13 days–6 months) for transcatheter aortic valve implantation in association with mitral VIV or VIR were 0% and 17%, respectively [11]. Importantly, no deaths occurred at 30 days or in the follow-up period (range 6–365 days) for combined aortic and mitral VIV [11]. These mortality rates are compatible with the present results, where no intraprocedural deaths and no procedure-associated complications were recorded.

It is important to note that in the study by Ando *et al.* [11], 2 patients had moderate/severe paravalvular leak in the mitral position and 2 other patients had LVOT obstruction. Neither of these complications occurred in our initial series, which was similar to the results in a recent report of mitral VIV using the

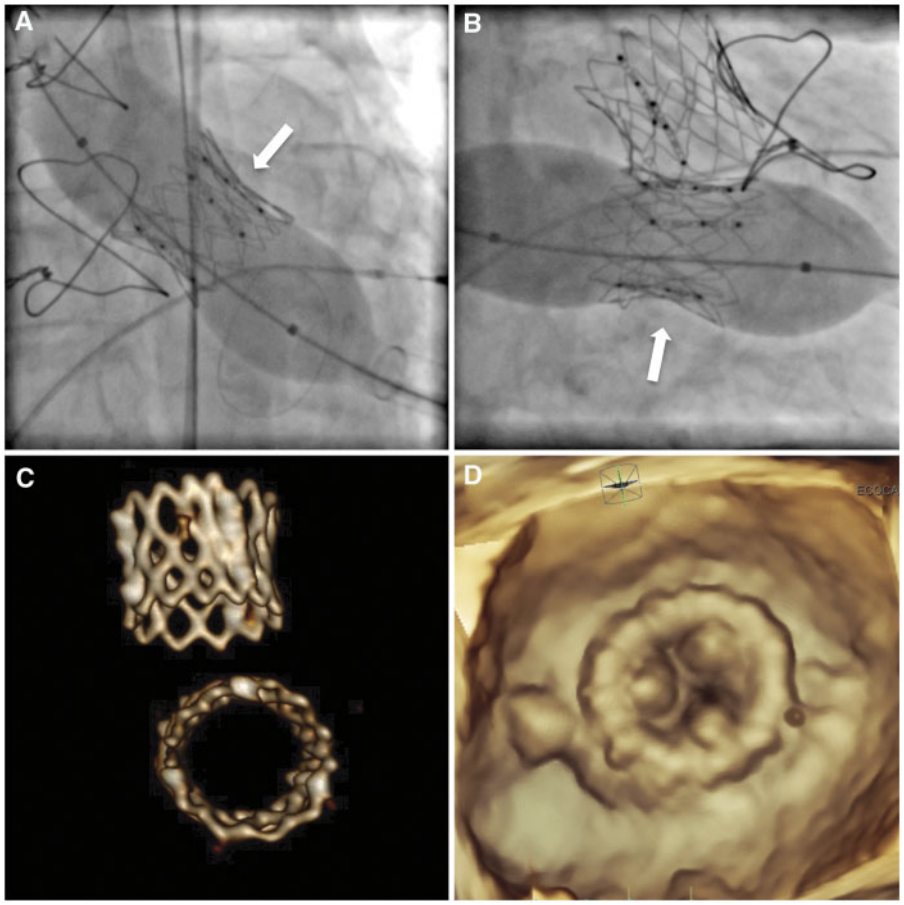


Figure 2: Case example of combined mitral valve-in-valve (VIV) and native aortic transcatheter aortic valve implantation (TAVI). TAVI was performed first (white arrow) (**A**), followed by the mitral VIV replacement (**B**). Three-dimensional multidetector computed tomography reconstruction showing both transcatheter heart valves implanted in aortic and mitral positions (**C**). Three-dimensional transoesophageal echocardiography reconstruction of the mitral transcatheter heart valve replacements (**D**).

Table 3 Main 30-day outcomes ($n = 6$)

Clinical outcomes	Number
Death	0
Pacemaker	0
Paravalvular leak	0
Vascular	0
Bleeding	0
Stroke	0
Dialysis, *n* (%)	1 (16.7)
ICU days, median (IQR)	5.0 (3.2–6.7)
Hospitalization days, median (IQR)	16.0 (12.2–21.2)
Echocardiographic variables	
LVEF (%), mean ± SD	59 ± 3.7
Mean aortic gradient (mmHg), mean ± SD	17.5 ± 5.1
Mean mitral gradient (mmHg), mean ± SD	7.0 ± 2.3
Moderate/severe MI, *n* (%)	1 (16.7)
Moderate/severe TI, *n* (%)	3 (50)
PSAP, mean ± SD	43.0 ± 15.6

ICU: intensive care unit; IQR: interquartile range; LVEF: left ventricular ejection fraction; MI: mitral insufficiency; PSAP: pulmonary systolic arterial pressure; SD: standard deviation; TI: tricuspid insufficiency.

Inovare bioprosthesis [27]. On the contrary, LVOT obstruction ensued in 2.2% and 5.0% after VIV and VIR, respectively, in a larger cohort of patients [26]. Finally, different strategies in the combined transcatheter heart valve implantation were used. The decision about the sequence in which the valve replacement should be performed in the first place was based on the type of dysfunction and on its severity; in general, the priority was to treat the more severe stenosis first. Yet, the best approach and order of implantation are unknown due to the limited number of cases in the literature.

Limitations

This study has several limitations. It was a single-centre registry that, although it included all consecutive patients, had a limited number of patients and a short follow-up period. Also, the small number of patients precludes an analysis of the different combinations of transcatheter procedures involving the different valves. The median procedural time was not available for this analysis. Finally, the transfemoral approach was recently shown to be associated with improved outcomes compared with alternative approaches such as the transapical, which was the only one used in the present study. Therefore, future studies should be performed using the transfemoral access in combined procedures.

CONCLUSION

In conclusion, transcatheter double valve interventions using the balloon-expandable Inovare bioprosthesis in this initial series

appear to be a reasonable alternative to redo surgical operations. The short- and mid-term clinical and echocardiographic outcomes show promising results, although future studies with a larger number of patients and longer follow-up period are warranted.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

Conflict of interest: José Honório Palma is proctor and consultant for Braile Biomédica. Henrique Barbosa Ribeiro is proctor and consultant for Edwards Lifesciences, Medtronic and Boston Scientific. All other authors declared no conflict of interest.

Author contributions

João Bosco Breckenfeld Bastos Filho: Conceptualization; Data curation; Formal analysis; Methodology; Project administration; Resources; Supervision; Validation; Visualization; Writing—original draft; Writing—review & editing. **Roney Orismar Sampaio:** Conceptualization; Data curation; Formal analysis; Methodology. **Felipe Reale Cividanes:** Investigation. **Vitor Emer Egypto Rosa:** Conceptualization; Investigation; Methodology; Supervision. **Leonardo Paim Nicolau da Costa:** Data curation; Formal analysis. **Marcelo Luiz Campos Vieira:** Project administration; Resources; Software; Visualization. **Fabio Biscegli Jatene:** Project administration; Resources; Supervision. **Flavio Tarasoutchi:** Formal analysis; Resources; Supervision; Validation. **José Honório Palma:** Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Supervision; Visualization; Writing—review & editing. **Henrique Barbosa Ribeiro:** Conceptualization; Data curation; Investigation; Methodology; Project administration; Supervision; Writing—original draft; Writing—review & editing.

Reviewer information

Interactive CardioVascular and Thoracic Surgery thanks Mizuki Miura, Stefano Salizzoni, Matheus Simonato and the other, anonymous reviewer(s) for their contribution to the peer review process of this article.

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