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Transcatheter valve-in-valve or valve-in-ring implantation with a novel balloon-expandable device in patients with bioprosthetic left side heart valves failure: 1-year follow-up from a multicenter experience

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Highlights

- Transcatheter aortic and mitral ViV implantation is an appealing treatment option for patients with failed BHVs.
- We evaluated mid-term outcomes of patients with aortic or mitral BHV deterioration treated with Myval THV.
- Technical success was achieved in 95 (98%) of the patient.
- Patients undergoing mitral ViV/ViR had a relatively worse survival compared with those undergoing aortic ViV implantation.
- Myval THV for failed BHVs can be performed safely with a high success rate and low mid-term mortality and morbidity.

Abstract

Background

Transcatheter aortic and mitral valve-in-valve (ViV) or valve-in-ring (ViR) implantation into failed bioprosthetic heart valves (BHVs) or rings represents an appealing, less invasive, treatment option for patients at high surgical risk. Nowadays, few data have been reported on the use of balloon-expandable Myval (Meril Life Science, Vapi, India) transcatheter heart valve (THV) for the treatment of degenerated BHVs or rings. We aimed at evaluating the early and mid-term clinical outcomes of patients with left side heart bioprosthesis deterioration treated with transcatheter ViV/ViR implantation using Myval THV.

Methods

97 consecutive patients with symptomatic, severe aortic(n=33) and mitral(n=64) BHVs/ring dysfunction underwent transcatheter aortic ViV and mitral ViV/ViR implantation with Myval THV.

Results

Technical success was achieved in 95 (98%) of the patients. Two cases of acute structural trans-catheter mitral ViV/ViR dysfunction requiring a second THV implantation were reported. At 30-day, a significant reduction in prosthetic trans-valvular pressure gradients and increase in valve areas were seen following both aortic and mitral ViV/ViR implantation. Overall survival at 15 months (IQR 8-21) was 92%. Patients undergoing mitral ViV/ViR had a relatively worse survival compared with those undergoing aortic ViV implantation (89% vs. 97% respectively; HR:2.7,CI:0.33-22.7;p=0.34). At longest follow-up available a significant improvement in NYHA functional class I and II was observed in patients with aortic and mitral ViV/ViR implantation(93.8% and 92.1%).

Conclusions

Despite high surgical risk, transcatheter ViV/ViR implantation for failed left side heart bioprosthesis can be performed safely using Myval THV with a high success rate and low early and mid-term mortality and morbidity.

Introduction

Valvular heart disease is a growing health problem associated with high morbidity and mortality. There is a significant increase in the use of bioprosthetic heart valves (BHVs) to replace severely diseased native valves either by conventional surgery or by trans-catheter interventions. Compared to mechanical valves, BHVs are advantageous as they do not need long-term anticoagulation therapy; however, their durability is limited, and they usually degenerate and fail between 10 and 20 years [[1], [2], [3]]. Structural valve deterioration is due to intrinsic permanent structural changes resulting in bioprosthetic valve stenosis, regurgitation, or a combination of both [4]. Given the constant increase in life expectancy, the number of patients with BHVs failure requiring reintervention is expected to increase in the next few years. Since most of these patients may not be surgical candidates due to various factors like old age, frailty and comorbidities, transcatheter heart valve (THV) implantation inside failed BHVs (valve-in-valve [ViV]) or valve-in-ring [ViR]) represents an appealing, less invasive, treatment option. Previous reports have demonstrated the feasibility and safety of treating aortic and mitral degenerated bioprosthesis with THV implantation [[5], [6], [7]]. Currently, the most commonly used THVs for ViV technique are the Evolut self-expanding (SE) family (Medtronic, Minneapolis, MN, USA) and Sapien balloon-expandable (BE) family (Edwards Lifesciences, Irvine, California) THVs in aortic position while the BE Sapien family THV is the only used in case of mitral BHVs or rings failure.

To date, the use of the BE Myval THV (Meril Life Science, Vapi, India) for the treatment of degenerated bioprosthesis is still off-label and only few data, with short-term results, have been reported on its safety and efficacy in this subset [8]. The aim of the current investigation is to evaluate the early and mid-term clinical outcomes of patients with left side heart BHVs (or ring in case of the mitral valve) deterioration treated with transcatheter ViV (or ViR) implantation using Myval THV.

Section snippets

Methods

This is a multicenter (n=17 centers), International registry that prospectively included consecutive patients with severe symptomatic aortic BHVs failure and mitral BHVs or annuloplasty ring failure undergoing transcatheter aortic ViV and mitral ViV or ViR implantation with BE Myval implantation from April 2019 to January 2022. BHV/ring failure was defined according to the European consensus statement [9]. Symptomatic patients with a significant increase in trans-prosthetic gradient or severe

Results

A total of 97 consecutive patients with symptomatic, severe aortic (n=33) and mitral (n=64) BHVs or ring failure underwent transcatheter aortic ViV and mitral ViV or ViR implantation, respectively.

Discussion

To the best of our knowledge, we present the first study reporting the outcomes of Myval THV implantation for the treatment of degenerated aortic and mitral bioprosthesis or ring. The main findings of our study can be summarized as follows:

- VARC-3 technical success was achieved in 98% of the patients.
- In patients undergoing aortic ViV procedure no differences were reported in terms of post-procedural or 30-day mean transvalvular gradient according to the size of the degenerated surgical valve.
- A

Conclusions

Our study shows that transcatheter ViV (or ViR) implantation for failed left side heart bioprosthesis can be safely performed with the use of the new BE Myval THV with a high success rate and low early and mid-term mortality and morbidity, despite high surgical

risk.

Declaration of Competing Interest

Ashok Seth is Proctor for TAVI and receives consulting fee from Meril Lifesciences and Medtronic. Matteo Montorfano receives consultanting fee from Abbott, Boston, Kardia and Medtronic.

References (23)

J. Forcillo *et al.*
Carpentier-Edwards pericardial valve in the aortic position: 25-years experience
Ann. Thorac. Surg. [Internet] (2013)

T.E. David *et al.*
Late results of heart valve replacement with the Hancock II bioprosthesis
J. Thorac. Cardiovasc. Surg. [Internet] (2001)

G. Gao *et al.*
Durability of pericardial versus porcine aortic valves
J. Am. Coll. Cardiol. [Internet] (2004)

J. Ye *et al.*
Transcatheter aortic and mitral valve-in-valve implantation for failed surgical bioprosthetic valves: an 8-year single-center experience
JACC Cardiovasc. Interv. [Internet] (2015)

M.Z. Khawaja *et al.*
Transcatheter aortic valve implantation for Stenosed and Regurgitant aortic valve bioprostheses: corevalve for failed bioprosthetic aortic valve replacements
J. Am. Coll. Cardiol. (2010)

A. Ielasi *et al.*
Transcatheter valve-in-valve implantation with a novel balloon-expandable device in patients with bioprosthetic heart valve failure: a case series
Cardiovasc. Revasc. Med. [Internet] (2021)

J.M. Khan *et al.*
Preventing coronary obstruction during Transcatheter aortic valve replacement: results from the multicenter international BASILICA registry
JACC Cardiovasc. Interv. (2021)

G.W. Stone *et al.*
Clinical trial design principles and endpoint definitions for Transcatheter mitral valve repair and replacement: part 2: endpoint definitions: a consensus document from the mitral valve academic research consortium
J. Am. Coll. Cardiol. (2015)

J. Ye *et al.*
Transcatheter aortic and mitral valve-in-valve implantation for failed surgical bioprosthetic valves: an 8-year single-center experience
JACC Cardiovasc. Interv. [Internet] (2015)

P. Blanke *et al.*
Computed tomography-based oversizing degrees and incidence of paravalvular regurgitation of a new Generation transcatheter heart valve
JACC Cardiovasc. Interv. [Internet] (2017)

View more references

Cited by (6)

BASELINE trial: update in study design
2024, American Heart Journal

Comparing two-year outcomes of balloon-expandable Myval and self-expanding Evolut R in severe aortic valve stenosis
2024, International Journal of Cardiology

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Another tool in the armamentarium for the percutaneous treatment of degenerated bioprosthetic valves and surgical rings
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2024, Expert Review of Cardiovascular Therapy

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2023, Frontiers in Cardiovascular Medicine

1 Equally contributed to the manuscript and join first author.