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Original article

Latest-iteration balloon- and self-expandable transcatheter valves for severe bicuspid aortic stenosis: the TRITON study

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Summary

Introduction and objectives

The latest generation of balloon-expandable and self-expandable heart valves for transcatheter implantation have not been compared in bicuspid aortic valve disease (BAV).

Methods

Multicenter registry of consecutive patients with BAV and severe stenosis treated with balloon-expandable (Myval and SAPIEN 3 Ultra [S3U]) or self-expandable Evolut PRO+ (EP +) heart valves. Triplet analysis was performed using TriMatch *software* to minimize the impact of baseline differences. The primary objective of the study was to evaluate the 30-day device success rate and the secondary endpoints, the combined safety endpoint and its individual components, at 30 days.

Results

A total of 360 patients (mean age, 76.6 ± 7.6 years; 71.9% men) were included; 122 Myval (33.9%), 129 S3U (35.8%), and 109 EP + (30.3%). The mean STS score was 3.6 ± 1.9%. There were no cases of coronary occlusion, annular rupture, aortic dissection, or periprocedural mortality. The primary endpoint of 30-day device success was significantly higher in the Myval group (Myval, 100%; S3U, 87.5%; and EP + , 81.3%), mainly due to a higher residual gradient with S3U and a higher rate of at least moderate aortic regurgitation with EP + . The unadjusted rate of pacemaker implantation was not significantly different.

Conclusions

In BAV with severe stenosis and contraindicated surgery, Myval, S3U, and EP + had comparable safety, although Myval had a better residual gradient than S3U and both balloon-expandable devices resulted in less residual perivalvular leak than EP + . Therefore, based on patient-specific risks, any of the 3 devices can be selected with optimal results.

Abstract

Introduction and objectives

No comparisons have been published yet regarding the newest iteration of balloon- and self-expandable transcatheter heart valves for the treatment of bicuspid aortic valve (BAV) stenosis.

Methods

Multicenter registry of consecutive patients with severe BAV stenosis treated with balloon-expandable transcatheter heart valves (Myval and SAPIEN 3 Ultra, S3U) or self-expanding Evolut PRO+ (EP +). TriMatch analysis was carried out to minimize the impact of baseline differences. The primary endpoint of the study was 30-day device success, and the secondary endpoints were the composite and individual components of early safety at 30 days.

Results

A total of 360 patients (age 76.6 ± 7.6 years, 71.9% diseases) were included: 122 Myval (33.9%), 129 S3U (35.8%), and 109 EP + (30.3%). The mean STS score was 3.6 ± 1.9%. There were no cases of coronary artery occlusion, annulus rupture, aortic dissection, or procedural death. The primary endpoint of device success at 30 days was significantly higher in the Myval group (Myval: 100%; S3U: 87.5%; and EP + : 81.3%), mainly due to higher residual aortic gradients with S3U and greater ≥ moderate aortic regurgitation (AR) with EP + . No significant differences were found in the unadjusted rate of pacemaker implementation.

Conclusions

In patients with BAV stenosis deemed unsuitable for surgery, Myval, S3U and EP + showed similar safety but balloon-expandable Myval had better gradients than S3U, and both balloon-expandable devices had lower residual AR than EP + , suggesting that, taking into consideration the patient-specific risks, any of these devices can be selected with optimal outcomes.

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Section snippets

INTRODUCTION

Bicuspid aortic valve (BAV) is the most common congenital valvular disease, occurring in up to 1% of the general population and 50% of patients requiring aortic valve replacement, with large regional differences [1] . Given its complex anatomic considerations and risk of aortic complications, the major randomized controlled trials that have explored transcatheter aortic valve implantation (TAVI) have excluded BAV. Although many registries of the

Study design and population

A retrospective multicenter registry was conducted at 12 centers. The study protocol was approved by the research ethics committees of each participating center and was in accordance with the Declaration of Helsinki. All patients gave written informed consent for TAVI and inclusion in the registry.

Consecutive patients with symptomatic severe aortic stenosis and BAV morphology in real clinical practice were included.

Baseline clinical, electrocardiographic and imaging characteristics

Between January 2018 and January 2022, 360 consecutive patients with BAV and symptomatic aortic stenosis undergoing TAVI were included in the registry (Figure 2 of the supplementary material). The total study population was divided into 3 groups based on the implanted CPV: 122 patients (33.9%) with Myval, 129 (35.8%) with S3U, and 109 (30.3%) with EP+.

The mean age of the study population was 76.6 ± 7.6 years and 101 patients (28.1%) were

women. Most patients

DISCUSSION

The main results of our study are: *a)* the safety profile of TAVI performed with new-generation balloon-expandable devices and EA was excellent in patients with BAV stenosis, with no cases of coronary artery occlusion, annular rupture, aortic dissection, or intraprocedural death, and with better overall results than those recently described with previous versions of balloon-expandable devices and EA; *b)*

CONCLUSIONS

In this first real-world comparison of balloon-expandable VCPs and next-generation EAs in patients with BAV stenosis deemed unsuitable for surgery, the devices showed an excellent safety profile, with better residual failure rates with the balloon-expandable devices and better residual gradients with the EAs and Myval. The pacemaker implantation rate was similar regardless of the device used. The results

FINANCING

None to declare.

AUTHORS' CONTRIBUTION

I.J. Amat-Santos and M. García-Gómez should be considered first authors, as they designed the study and carried out the data collection, analysis, interpretation, and writing up. F. De Marco, K. Won-Keun, J. Brito, J. Halim, J. Jose, G. Sengotuvelu, A. Seth, C. Terkelsen, M. Protasiewicz, N. Bonilla, B. García, JP Sánchez-Luna, S. Blasco-Turrión, J.C. González, E. González-Bartol, A.J.J. Ijsselmuiden and A. San Román participated in data collection, analysis, and interpretation.

CONFLICT OF INTEREST

There was no private funding. IJ Amat-Santos is *a proctor* for Medtronic, Meril Life, and Boston Scientific. B. García has been *a proctor* for Edwards Lifesciences. The Hospital Clínico de Valladolid receives unconditional funding from Meril Life for the LANDMARK trial and from Medtronic for the EXPAND-II trial.

WHAT IS KNOWN ABOUT THE TOPIC?

- Bicuspid aortic valve stenosis is the underlying lesion in an increasing proportion of patients eligible for TAVI.
- The existing evidence on the most recent versions of

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