

Circulation: Cardiovascular interventions

Original Article

Balloon versus Self-Expandable Valve for the Treatment of Bicuspid Aortic Valve Stenosis:

Insights from the BEAT International Collaborative Registry

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Abstract

Background:

Large data comparing the performance of new-generation self-expandable versus balloon-expandable transcatheter heart valves in bicuspid aortic stenosis are lacking. We aim to compare the safety and performance of balloon-expandable and self-expandable transcatheter heart valves in the treatment of bicuspid aortic stenosis.

Methods:

The BEAT (balloon versus self-expandable valve for the treatment of bicuspid aortic valve stenosis) registry included 353 consecutive patients who underwent transcatheter aortic valve implantation using new-generation Evolut R/PRO or Sapien 3 valves in bicuspid aortic valve.

Results:

A total of 353 patients (n=242 [68.6%] treated with Sapien 3 and n=111 [68.6%] treated with Evolut R (n=70)/PRO [n=41]) were included. Mean age was 77.8 ± 8.3 years and mean Society of Thoracic Surgeons Predicted Risk of Mortality was $4.4 \pm 3.3\%$. Valve Academic Research Consortium-2 device success was similar between Sapien 3 and Evolut R/PRO (85.6%

versus 87.2%; $P=0.68$). In the Sapien 3 group, 4 patients experienced annular rupture whereas this complication did not occur in the Evolut R/PRO group. After propensity score matching, Valve Academic Research Consortium-2 device success was similar between both groups (Sapien 3=85.7% versus Evolut R/Pro=84.4%; $P=0.821$). Both in the overall and in the matched population, no differences in the rate of permanent pacemaker implant were observed. At 1-year follow-up, the rate of overall death and cardiovascular death were similar between the 2 groups. In the unmatched population, the 1-year echocardiographic follow-up demonstrated similar rate of moderate-to-severe paravalvular aortic regurgitation (Evolut R/PRO 10.5% versus Sapien 3 4.2%, $P=0.077$); however, after propensity matching, the rate of moderate-to-severe paravalvular leak became significantly higher among patients treated with self-expandable valves (9.3% versus 0%; $P=0.043$).

Conclusions:

Our study confirms the feasibility of both Sapien 3 and Evolut R/PRO implantation in bicuspid aortic valve anatomy; a higher rate of moderate-severe paravalvular aortic regurgitation was observed in the Evolut R/PRO group at 1-year follow-up in the matched cohort, although patients treated with balloon-expandable valve had a higher rate of annular rupture.

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