

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

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±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**.

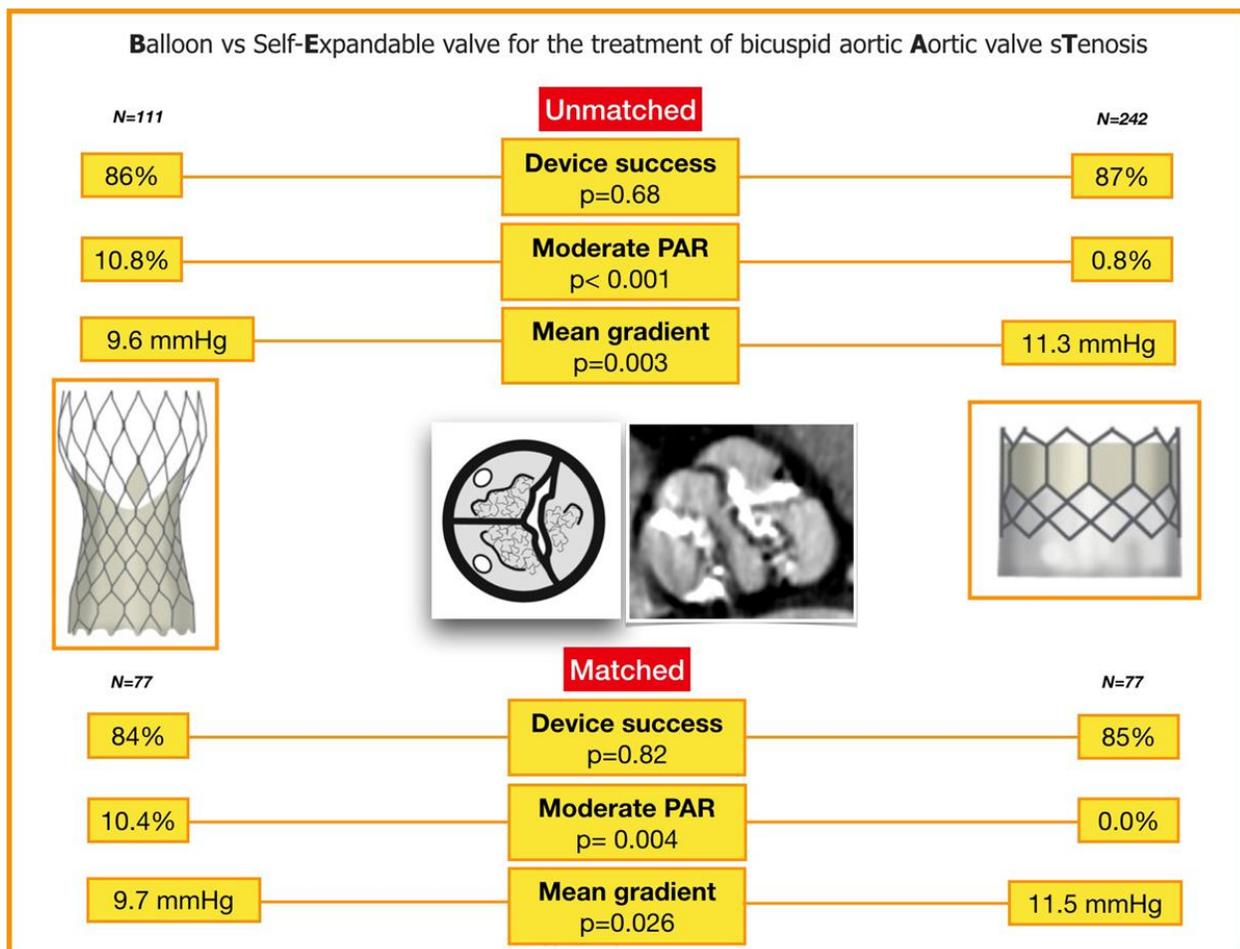
After propensity score matching, Valve Academic Research Consortium-2 device **success was similar between both groups** (Sapien 3=85.7% versus Evolut R/Pro=84.4%; P=0.821).

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**.



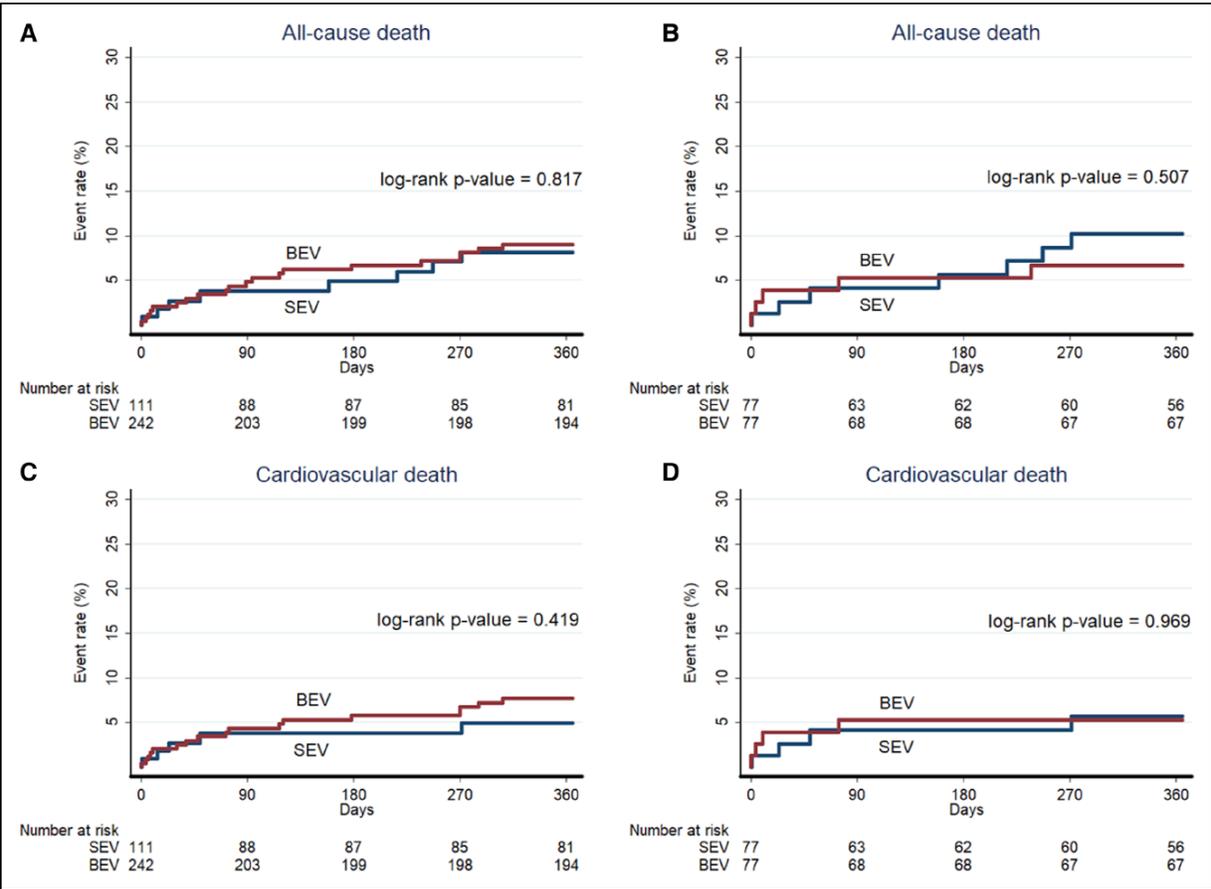


Figure. One-year outcome according to all cause of death and cardiovascular deaths in both matched and unmatched populations.

BEV indicates balloon-expandable valves; and SEV, self-expandable valve.