Real-world comparison of the last generation balloon-expandable and self-expanding valves in patients undergoing TAVI

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Background/Introduction: The balloon expandable (BE) Edwards Sapien-S3/Ultra, and the self-expanding (SE) Medtronic Evolut-Pro represent the main volume of transcatheter aortic valve implantation (TAVI) procedures conducted worldwide.

Purpose: The present study represents the largest real-world comparison of periprocedural and short-term outcome between the aforementioned last generation devices.

Methods: Consecutive patients who had undergone TAVI with either the BE (S3/Ultra) or SE (Evolut-Pro/R-34mm if 34mm valve was required) device, in five centers were retrospectively studied. Periprocedural and short-term outcomes were recorded and compared.

Results: In total, 1341 patients (58.5% male) were treated with contemporary BE and SE valves (574 and 767pts with BE and SE respectively) and followed up for a median of 18.7 (IQR 30) months. Baseline demographics were similar between the two groups apart from severe left ventricle (LV) systolic impairment and extensive aorta calcification, being more prevalent amongst BE and SE groups respectively. Patients treated with the Evolut-Pro/R34mm device had significantly lower peak (16±9mmHg for SE vs 23.9±6mmHg for the BE valves, p=0.001) and mean (8.6±6mmHg SE vs 11.2±5.2mmHg BE, p=0.001) gradients at discharge.

Conversely, the BE group demonstrated significantly lower rates of at least moderate residual aortic regurgitation (AR) post-operatively (0.7% vs 5.2% for BE and SE valves respectively, $p<0.001$). Interestingly, the rate of new permanent pacemaker (PPM) required after the implantation in initially pacemaker-free patients, was higher for the S3/Ultra cohort compared to the self-expanding valve group (14.4% vs 12.3% respectively, p=0.001). No statistical difference was recorded between valve groups regarding cerebrovascular events (3.4% vs. 2.7% for SE and BE respectively, p=0.466), major vascular complications (4.2% vs. 3.0% for SE and BE respectively, p=0.251) and death to hospital discharge (1.6% vs. 2.9% for SE and BE respectively, p=0.117).

One-year Kaplan-Meier estimated survival was similar between the two groups (88.7% for BE vs. 91.4% for SE valves, plog-rank=0.093). When adjusting for age, extensive calcification of the aorta and baseline LV function all caused mortality hazard ratios were similar between patients treated with BE vs SE valves (HR 1.39; 95% CI 0.97 to 1.98, p=0.07).

Conclusions: Real life comparison of the last generation balloon expandable and self-expanding devices demonstrates superiority of the former in terms of residual PVL, at the expense of higher transvalvular gradients and higher need of new PPM implantation. The latter however may represent differences in center practices with regards to thresholds for permanent pacing. Long-term follow-up and future larger trials are required to establish any potential long-term difference in clinical outcomes and prognosis.