

## Long-term outcomes with new generation prostheses in patients undergoing transcatheter aortic valve implantation

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**Background:** Transcatheter Aortic Valve Implantation (TAVI) is today the first option for older patients with aortic valve stenosis (AS) at intermediate or high risk for surgery. Constant development of bioprosthetic valves and delivery systems have reduced complications and improved outcomes over the years. The 3rd generation Edwards Sapien 3 Valve (S3) and the 2nd generation Medtronic Evolut R Valve (ER) are currently the most frequently used worldwide. There is a paucity of published data regarding long term outcomes in these new generation TAVI patients.

**Methods and results:** In our retrospective, single-center analysis we included patients with severe Aortic Stenosis who underwent transfemoral TAVI with a new generation prosthesis between 2014 and 2016. Peri- and postprocedural outcomes of these patients were analyzed according to the VARC-2 criteria.

The study population consisted of 359 patients (mean patient age  $82 \pm 7$  years, 47% male, mean EuroSCORE II  $8.0 \pm 8$ ). The S3 group included 215 patients, the ER group 144 patients. Median follow-up period was 3.8 years (IQR 3.3 to 4.4 years, maximum follow-up in living patients 5.1 years).

Device Success rates were equal in both groups (93.0% vs. 92.4%,  $p=0.812$ ). We report a 30-day mortality of 2.8% in the S3 group, 2.1% in the ER group, respectively ( $p=0.674$ ). There was no difference in stroke rate, conversion to open heart surgery, major vascular complications, life-threatening or disabling bleeding or myocardial infarction. Implantation of a

new permanent pacemaker was lower in the S3 group (S3: 27.4% vs. ER: 44.5%,  $p=0.002$ ). While prosthesis mean gradients were higher in the S3 group (12.0 mmHg vs. 8.2 mmHg,  $p<0.001$ ), there was a tendency to less paravalvular leaks (PVL  $\geq 2$ : 1% vs. 3.6%,  $p=0.088$ ).

All-Cause Mortality up to 5 years did not show a difference between both patient groups (mean survival S3 3.5 years, ER 3.3 years,  $p=0.895$ ). Independent predictors of death were impaired left ventricular function (HR 1.61,  $p=0.007$ ), chronic kidney injury (HR 1.55,  $p=0.032$ ), peripheral artery disease (HR 2.10,  $p=0.003$ ), malignant tumor (HR 2.40,  $p<0.001$ ) and periprocedural stroke (HR 3.95,  $p=0.007$ ).

**Discussion:** We present a comparison of the new-generation aortic valve prostheses Edwards Sapien 3 and Medtronic Evolut R concerning long-term as well as periprocedural outcomes. The analyzed cohort consisted of patients at intermediate to high surgical risk. Yet, 30-day mortality was very low both in S3 and ER patients. Device success and periprocedural outcomes in both groups were comparable and are in line with previous studies using VARC-2 definitions.

**Conclusion:** New generation TAVI valves offer an excellent implant and outcome success rate compared to early transcatheter Aortic valve replacement. Long-term survival was independent of prostheses choice and mainly attributed to pre- and intraprocedural comorbidities and complications.

