A prospective, non-randomized comparison of SAPIEN XT and CoreValve implantation in two sequential cohorts of patients with severe aortic stenosis.

Abstract:
Few data is available comparing Edwards SAPIEN XT - SXT (Edwards Lifesciences, Irvine, California) with Medtronic CoreValve - CoV (Medtronic Inc., Minneapolis, Minnesota) in patients with severe aortic stenosis undergoing transcatheter aortic valve replacement (TAVR). We selected consecutive patients undergoing transfemoral TAVR with SXT or CoV at our Institution. Main outcomes were Valve Academic Research Consortium (VARC)-combined safety endpoints. A total of 100 patients (SXT, n=50 versus CoV, n=50) were analyzed. Both SXT and CoV showed good device success rates (98% versus 90%, p=0.20). SXT versus CoV reduced the occurrence of paravalvular regurgitation after TAVR (26% versus 90%, p<0.001), life-threatening bleedings (2% versus 4%, p<0.001), stroke (4% versus 6%, p=0.99) and death (6% versus 2%, p=0.99) did not differ between SXT and CoV. However, safety endpoints favored SXT (17% versus 34.6%, p=0.01), due to a numerically higher incidence of ischemic stroke and Acute Kidney Injury Stage 3 after CoV. At multivariate analysis, TAVR with SXT (odds ratio=0.21, 95% confidence intervals [0.05-0.84], p=0.03) was predictive of fewer adverse
Transcatheter valve implantation with Edwards SAPIEN XT was associated with lower VARC-combined safety endpoints as compared with Medtronic CoreValve. More extensive cohorts are needed to confirm these results.