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Predictors of Conduction System Disturbances Resulting in a New Permanent Pacemaker Implantation Within the LANDMARK Trial

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BACKGROUND The need for permanent pacemaker implantation (PPMI) after transcatheter aortic valve implantation (TAVR) is a serious complication that adds additional risk for the patient. It also lengthens the hospitalization and increases costs. Unknown is the PPMI rate of the new balloon expandable Myval transcatheter heart valve (THV) series in comparison to the current-generation balloon- and self-expandable THVs. We investigated the conduction disturbances and PPMI rates within the LANDMARK trial, a prospective randomized trial comparing the Myval THV series with contemporary THV series (the balloon-expandable Sapien and the self-expanding Evolut THV series) in patients with severe and symptomatic native aortic valve stenosis.

METHODS All preprocedure and postprocedure electrograms (ECGs) up to 30 days postimplantation were analyzed, and the need for PPMI was independently assessed within both randomization arms, as well in the patient subsets receiving balloon-expandable and self-expandable THVs. Rates of PPMI among the groups according to preprocedural conduction disturbances, arrhythmia's, patient (age, diabetes mellitus, valve calcification, membranous septum length) and procedural (preimplant and postimplant dilatation) characteristics were compared and predictors for PPMI according to the regression model evaluated.

RESULTS After excluding patients with preprocedure PPMI, crossover, or no THV recipients, 706 patients with THV remained (352 patients in the Myval arm and 354 patients in the contemporary arm). The balloon- and self-expandable THV groups consisted of 533 and 173 patients, respectively. Within 30 days post-THV implantation, 55 of 352 (15.6%) in the Myval arm and 65 of 354 (18.4%) in the contemporary arm received a PPMI ($P = 0.39$). In the balloon- and self-expandable THV subsets, these numbers (%) were 88 of 533 (16.5%) and 32 of 173 (18.5%); $P = 0.63$. Among the ECG, patient, and procedural baseline variables, patients with right bundle branch block (RBBB) with or without left anterior or posterior fascicular block had the highest PPMI rates (ranging between 30% and 57%) with no significant differences between the groups. Regression model identified RBBB at baseline as a borderline significant predictor for PPMI in the Myval THV arm ($P = 0.059$), whereas this was a significant predictor for PPMI in the Sapien ($P = 0.02$) and Evolut ($P = 0.002$) THV groups. Presence of moderate or severe calcification were significant predictors for PPMI in the Myval (both $P = 0.03$) and Sapien (both $P = 0.01$) THV groups. Presence of atrial fibrillation was also a significant predictor for PPMI in the overall THV group ($P = 0.02$).

CONCLUSION Compared with contemporary THVs, the new Myval THV has a similar PPMI rate postprocedure. The presence of baseline RBBB with or without fascicular blocks has the highest rate of postimplant PMMI, irrespective of the type of THV. The regression model identified RBBB as a significant predictor for the Sapien and Evolut THV series groups and borderline for the Myval THV series group.

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MÉTIS Study: Modification of Neurological Outcome After TAVR Using Sentinel Protection Device

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AIM The study aimed to prove a clinical benefit from routine usage of the Sentinel cerebral protection during percutaneous aortic valve replacement (TAVR).

METHODS This is a prospective, randomized, nonblind trial performed in 2 Czech centers. The primary endpoint was detection of small cerebral injuries indicated by the elevation of neuron-specific enolase (NSE). This enzyme is localized within neurons and is released when neurons are injured. Secondary endpoints were detection of neurological injury using the NIH stroke scale (NIHSS), and detection of cognitive deterioration using the Montreal Cognitive Assessment (MoCA).

RESULTS Between March 2021 and May 2024, a total 211 patients undergoing TAVR were included. They were randomized (in 1:1 ratio) either into the cerebral protection arm, or into the conservative arm. The femoral approach was used in all TAVR cases. The mean age of patients was 79.8 ± 5.0 years; the number of female individuals was 100 (47.6%); the number of patients with atrial fibrillation was 79 (40%); bicuspid anatomy was found in 22 patients (10.4%); the mean aortic pressure gradient was 42.8 mm Hg ± 14.6; and, the mean indexed aortic valve area was 0.46 ± 0.11. A self-expanding valve was implanted in 189 cases (91.3%), predilatation was used in 96 cases (46.6%), and cerebral protection (Sentinel, Boston Scientific) was used in 107 patients (50.7%). The mean implantation time for the Sentinel device was 6.5 ± 0.5 min, and technical difficulties were found in 10 (0.9%) Sentinel cases. The mean elevation of NSE was lower in the group with Sentinel cerebral protection than in the conservative arm (−0.05 ± 9.73 vs 3.64 ± 12.49 μg/L; $P = 0.028$). Two-fold increase of NSE was less frequent on Sentinel group: 4 (4.3%) vs 15 (15.3%) patients; $P = 0.01$. Neither NIHSS nor MoCA differed between the conservative and Sentinel arms: NIHSS (0.1 ± 0.7 vs 0.09 ± 0.57; $P = 0.93$, MoCA (0.65 ± 4.15 vs 0.76 ± 3.38; $P = 0.86$) . The number of new neurological findings (2 control patients, 2.08% vs 5 Sentinel patients, 5.26%; $P = 0.24$) and new stroke (1 control patient, 1.04% vs 2 Sentinel patients, 2.023%; $P = 0.58$) was too small for statistical analysis. Univariant predictors for the level of elevation of NSE were female sex ($P = 0.039$) and bicuspid aortic valve anatomy ($P = 0.034$). Univariant for predictors of NSE elevation as a categorical value were atherosclerotic lesions in the right internal carotid artery ($P = 0.0026$) and in the left internal carotid artery ($P = 0.0003$).