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ABSTRACT WITHDRAWN



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Early Outcomes With Three TAVI Valves (Myval, Sapien, and Evolut Series) in Women - Substudy of Landmark Trial



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BACKGROUND Nearly 50% of severe aortic stenosis (AS) patients undergoing transcatheter aortic valve replacement (TAVR) are women, yet they are under-represented in clinical trials. SMART trial reported that in women with small annulus area, self-expanding transcatheter heart valve (THV) showed better hemodynamic outcomes than balloon-expandable THV. In the LANDMARK trial comparing three types of THVs, outcomes in women were investigated.

METHODS In a multicenter, non-inferiority LANDMARK trial (n=768), 369 women with severe AS were randomized to Myval THV series (n=193), Sapien THV series (n=86), and Evolut THV series (n=90). The primary endpoint at 30 days was a composite of all-cause death, all stroke, bleeding (types 3 and 4), acute kidney injury (stages 2-4), major vascular complications, moderate or severe prosthetic valve regurgitation (PVR), and new permanent pacemaker implantation as per the Valve Academic Research Consortium-3 consensus.

RESULTS Mean age (Myval: 81, Sapien: 81.7, and Evolut 79.8 years old) and median Society of Thoracic Surgeons scores (3.1%, 3.5%, 3.1%) were comparable in three arms. More than 50% of women had small aortic annuli (55.4%, 60.5%, 54.4%). In the Myval arm, 49% of patients received intermediate sizes (21.5, 24.5 and 27.5 mm). At 30 days, Myval had a lower aortic valve mean pressure gradient (MPG, Myval: 8.7mmHg; Sapien: 11.1mmHg, $p<0.001$) and a higher effective orifice area (EOA) compared to Sapien (1.88cm², 1.61cm², $p<0.001$), while having a higher MPG (Evolut: 5.4mmHg, $p<0.001$) and lower EOA than Evolut (2.37cm², $p<0.001$). Myval was non-inferior to Sapien (Myval: 19% vs Sapien: 20%, Risk difference [95%CI]: -0.6 [NA, 9.6], $P_{noninferiority}=0.01$) and Evolut (19% vs 30%; risk difference [95%CI]: -10.9% [NA, 0.1], $P_{noninferiority}<0.0001$) for the primary endpoint. There was no statistically significant difference between Myval versus Sapien for itemized events of the primary composite endpoint, whereas there were lower rates of moderate-severe PVR (Myval 2% vs. Evolut 9%, $p=0.01$) and major vascular complications (2% vs. 7%, $p=0.03$) in Myval than Evolut.

CONCLUSIONS In the women subset of the LANDMARK trial, Myval had a lower aortic valve mean pressure gradient and a higher effective orifice area than Sapien, whereas superior hemodynamics of Evolut to Myval entails a significantly higher risk of PVR at 30 days. TAVI with the Myval series in women patients with severe AS is non-inferior to both the Sapien and Evolut series for the primary composite endpoint at 30 days.

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Hemodynamic Differences and Disease Progression Among Patients Undergoing Surgical Versus Transcatheter Aortic Valve Implantation



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BACKGROUND Aortic stenosis (AS) is the most common valvular disease. The two main therapeutic interventions are Surgical (SAVR) or transcatheter aortic valve implantation (TAVI). Delay in identifying or treating AS leads to progressive cardiac damage that is associated with adverse outcomes. Hemodynamic characterization and the impact of delay in performing procedures among patients undergoing TAVI and SAVR are lacking.

METHODS In this prospective study (Jun-2020 to Jan-2022), patients undergoing TAVI/SAVR patients were investigated by a total body-impedance based Non-Invasive Cardiac System. Each patient's echocardiographic cardiac structural damage stages (stages 0 to 4) were assessed.

RESULTS 126 patients [mean age 81.1±7.9 yrs; 27% female] underwent TAVI and 33 patients [mean age: 66.2±10.2 yrs; 44% female] were treated with SAVR. Despite similar mean AVG (SAVR: 46.8±16.6 vs. TAVI: 43.5±16.8 mmHg; $p=0.32$), TAVI patients had low stroke volume index (29.7±6.9 vs. 39.1±8.8 ml/m²; $p<0.0001$; Panel B), low cardiac index (2.7±0.9 vs. 2.1±0.7 L/m²; $p=0.0002$; Panel C), and low cardiac power index (0.43±0.16 vs. 0.54±0.21 W/m²; $p=0.007$; Panel D). Pre-SAVR, most patients were in cardiac damage stages 0-2 (stages 0 to 4 respectively: 22.2%, 35%, 44.4%, 5.6%, 2.8%). The TAVI patients were mostly in stages 2-3 (Stages 0 to 4 respectively: 2.4%, 5.6%, 79.4%, 8%, and 4.8%). There were 17.5±11.2 months between the diagnosis of severe AS to undergoing the TAVI procedure. At this time there was further worsening of the structural damage state, so that 2.4%, 5.6%, 79.4%, 7.9%, and 4.8% of patients were in stages of 0 to 4, while no such deterioration was observed in patients undergoing SAVR.

CONCLUSION Despite similar gradients, TAVI patients are noted to have worse hemodynamics and progressive structural damage in comparison to SAVR patients.

