83193 | Sapien 3 Ultra Compared with Sapien Ultra Resilia Over 2 Years

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Background: The Sapien 3 Ultra Resilia (S3UR) valve incorporates a novel anti-calcification process, updated leaflet suspension in 20 and 23-mm sizes, and a 40% taller PET sealing skirt compared to the Sapien 3 Ultra (S3U). We evaluated gradients and perivalvular leak (PVL) in patients undergoing TAVR with S3UR versus the prior-generation S3U at our center.
Methods: Data were collected at 1 day, 30 days, 1 year, and 2 years. Clinically significant PVL was defined as moderate or greater. Gradients were compared by valve size and PVL rates between groups overall (χ^2; $p<0.05$).
Results: Data on 20- and 29-mm valves were limited and excluded. S3UR (n=39) showed lower peak and mean gradients than S3U (n=75) at all time points, persisting in 23-mm valves but only at 30 days in 26-mm valves. Notably, 23-mm S3UR had gradients comparable to 26-mm S3U. PVL rates were lower with S3UR at all time points.
Conclusion: S3UR demonstrated lower gradients than S3U, with 23-mm S3UR achieving gradients comparable to 26-mm S3U despite larger EOA. This likely reflects enhanced leaflet mobility, with sustained benefit over 2 years. PVL was also reduced with S3UR, consistent with its more robust sealing skirt. Further study is needed to define clinical impact and durability.

		23 mm S3U (mmHg)	23 mm S3UR (mmHg)	P value	26 mm S3U (mmHg)	26 mm S3UR (mmHg)	P value	S3U PVL (%)	S3UR PVL (%)	P value
1 Day	Peak Mean	22.71 12.18	16.73 9.47	**0.01** **0.04**	18.73 9.78	16.59 8.18	**0.12** **0.06**	14.67	0	**0.03**
30 Day	Peak Mean	26.88 14.65	18.80 10.27	**< 0.01** **< 0.01**	22.24 12.00	18.23 9.81	**0.01** **0.02**	26.67	0	**<0.01**
1 Year	Peak Mean	28.37 15.18	21.33 11.6	**0.02** **0.03**	20.96 11.66	18.76 9.76	**0.13** **0.09**	26.67	0	**<0.01**
2 Year	Peak Mean	28.31 15.16	21.49 11.2	**0.03** **0.02**	19.60 10.13	17.71 9.50	**0.16** **0.27**	28.00	7.69	**0.02**

Table 1. Gradients ($\bar{x}$) are lower with S3UR in 23-mm valves and comparable between 23-mm S3UR and 26-mm S3U ($p<0.05$), while there was no difference between 23-mm S3UR and 26-mm S3U valves. PVL was significantly less in the S3UR group by two sample T test.

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83204 | Predictors of Conduction System Disturbances Resulting in a New Permanent Pacemaker Implantation: A Sub-study of the LANDMARK Trial

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Background: This sub-analysis of the LANDMARK trial compares the incidence of new permanent pacemaker implantation (PPI) after transcatheter aortic valve implantation (TAVI) between Myval and Contemporary (Sapien and Evolut) transcatheter heart valve (THV) series and THV types at 30-day and 1-year in patients with severe symptomatic native aortic stenosis. It also identifies pre- and peri-procedural predictors of PPI using multivariable regression models at 1-year.
Methods: The LANDMARK trial, a prospective, multinational randomized trial, was conducted across 31 sites in 16 countries. Patients were randomized 1:1 to Myval or contemporary (balloon-expandable [BE] Sapien THV series and self-expanding [SE] Evolut THV series) THV series. The as-treated population included 706 patients: Myval THV series (n=352) and Contemporary THV series (n=354) (Sapien [n=181] and Evolut [n=173]). BE (Myval and Sapien) THV series and SE (Evolut) THV groups included 533 and 173 patients, respectively. Electrograms were analysed and PPI events were adjudicated independently by clinical events committee. Predictors of PPI were evaluated using a combined multivariable regression model at 1-year.
Results: At 30 days and 1-year, PPI rates with Myval THV series (15.6% and 17.6%) were comparable to Sapien THV series (18.2% and 19.3%), Evolut THV series (18.5% and 19.1%), and Contemporary THV series (18.4% and 19.2%). Similarly, BE-THV vs SE THV groups showed comparable PPI rates at 30 days (16.5% vs 18.5%) and 1-year (18.2% vs 19.1%). Baseline right bundle branch block (RBBB), with or without fascicular block, was the most frequent indication of PPI. The combined multivariable regression model identified several significant predictors of PPI across all THV groups at 1-year: RBBB, left anterior fascicular block, atrial fibrillation, AV conduction delay > 200 m.sec, membranous septum length, implantation depth-non coronary cusp, and implantation depth-left coronary cusp.
Conclusion: Myval THV series demonstrated PPI rates comparable to contemporary THV series at 30 days and 1-year. Baseline conduction abnormalities, anatomical and peri-procedural factors were significant PPI predictors at 1-year.

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83207 | Win Ratio Analysis for the 1-Year Composite Endpoint: A Sub-study of the LANDMARK Trial

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Background: Traditional time-to-first event (Kaplan-Meier) analyses for composite endpoints consider only the first event and do not account for event severity and recurrence, whereas win-ratio analyses account for both severity and recurrence.
Methods: We performed a post-hoc win-ratio analysis of the 1-year composite endpoint in the LANDMARK trial, a prospective, multicentre, non-inferiority trial that randomized patients with severe native aortic stenosis to receive either the Myval transcatheter heart valve (THV) series (n=384) or contemporary (Sapien and Evolut series, n=192 in

each group) THVs (n=384). Win ratio analysis was performed using the Delphi method, involving 10 cardiologists. The 1-year composite endpoint included (hierarchically ranked) all-cause death, disabling stroke, non-disabling stroke, and procedure- or valve-related hospitalization. Win-ratio analysis was also conducted for an extended composite endpoint that included quality-of-life outcomes (defined as a ≥2.5-point decrease from baseline to 1-year follow-up in both the physical and mental domains of the Short-Form 12).

Results: Among 147,456 (384x384) unmatched patient pairs, the win ratio for the primary composite endpoint was 1.02 (95% CI: 0.68–1.51; p=0.94), with 17,870 (12.1%) wins for the Myval group and 17,599 (11.9%) for the contemporary group. The win difference was 0.18%, and the win odds were 1.00. For the extended composite endpoint, the win ratio was 1.13 (95% CI: 0.82–1.55; p=0.45), with 27,007 (18.3%) wins for the Myval group and 23,920 (16.2%) for the contemporary group. The win difference was 2.09%, and the win odds were 1.04. Comparisons of the primary composite endpoint between the Myval and Sapien groups, and between the Myval and Evolut groups, were also not statistically significant (Myval vs Sapien: win ratio=0.99; 95% CI: 0.61-1.60; p=0.98, Myval vs Evolut: win ratio=1.04; 95% CI: 0.64-1.68; p=0.88).

Conclusion: Win-ratio analysis demonstrated a comparable primary composite endpoint at 1-year between Myval and contemporary THVs, consistent with the primary time-to-first event analysis of the LANDMARK trial.

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83210 | Impact of Cardiac Damage on 1-Year Outcomes After TAVI in Severe Aortic Stenosis: Insights from the LANDMARK Trial Sub-Analysis

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Background: Previous studies demonstrated that the extent of cardiac damage in patients with aortic stenosis (AS) is associated with worse clinical outcomes. This study aims to report the incidence, temporal change, and clinical impact of cardiac damage in patients with severe AS who underwent transcatheter aortic valve implantation (TAVI) in the LANDMARK randomized trial (a non-inferiority trial of Myval vs. contemporary TAVI valves).

Methods: This is a post-hoc analysis. Preprocedural and 1-year transthoracic echocardiography (TTE) were evaluated by an independent core laboratory. Patients were classified into 5 stages (0-4) using modified cardiac damage classification (Genereux et al): stage 0 (no damage); stage 1 (Left ventricular damage/dysfunction: Left ventricular mass index >95 g/m^2 women, >115 g/m^2 men; Left ventricular diastolic dysfunction E/e' >14; or LV ejection fraction < 50%); stage 2 (Left atrial/mitral valve damage/dysfunction [Left atrial volume index >34 mL/m^2, atrial fibrillation, or ≥ moderate mitral regurgitation]); stage 3 (pulmonary artery vasculature/tricuspid valve damage: ≥ moderate tricuspid regurgitation and high probability of pulmonary hypertension per 2022 ESC/ERS combined criteria); stage 4 (right ventricular damage: tricuspid annular plane systolic excursion <17 mm, S' <9.5 cm/s, or right ventricular fractional area change <35%). The primary endpoint was 1-year all-cause mortality; the composite endpoint included death, stroke, and valve- or procedure-related re-hospitalisation.

Results: Among 596 patients, incidence of cardiac damage was: stage 0: 6%, stage 1: 15%, stage 2: 48%, stage 3: 14%, and stage 4: 17%; stages 0-2 and 3-4 accounted for 69% and 31%, respectively. 1-year mortality increased from stage 0 to 4: 0%, 1.1%, 4.7%, 7.2%, and 20.4% (log-rank p<0.001; AUC 0.739). Among patients with paired TTE, cardiac damage improved in 28.8%, remained unchanged in 49.8%, and worsened in 21.4%.

Conclusion: Preprocedural TTE-based cardiac damage stratified 1-year mortality post-TAVI. Stage 4 is associated with the highest mortality, highlighting the prognostic value of comprehensive echocardiographic assessment in severe AS.

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83219 | Permanent Pacemaker Recovery Post-Transcatheter Aortic Valve Implantation: Post-hoc Analysis from the LANDMARK Trial

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Background: Conduction disturbances are common after transcatheter aortic valve implantation (TAVI) and often require permanent pacemaker implantation (PPI). While some patients remain pacing-dependent, others recover conduction system over time. Data on pacemaker recovery (PMR) from randomized trials are limited. This study reports the incidence and predictors of PMR in the LANDMARK trial.

Methods: This post-hoc analysis of the LANDMARK trial (randomized [1:1 Myval vs contemporary THV series], non-inferiority trial) examined the 1-year incidence of PMR in 99 patients who received a PPI within 30 days post-TAVI (n=122 [15.9%]). Pacemaker follow-up data, including ventricular and atrial pacing rates, pacemaker mode, and lower rate setting, were collected retrospectively. Imaging data from echocardiography, 12-lead electrocardiogram (ECG), and preprocedural computed tomography (CT) were analyzed by core laboratories. Valve implantation depth was assessed by the CORRIB core lab using final procedural aortography. PMR was defined as a ventricular pacing rate of ≤1% at follow-up.

Results: Among 99 patients (mean age 80.7 ± 4.7 years), 1-year PMR occurred in 18% of patients. Patients with PMR were significantly younger than non-PMR patients (78.6 ± 3.0 vs. 81.1 ± 5.1 years, p=0.045). Baseline right bundle branch block (RBBB; 16.7% vs.27.2%, p=0.55) and left bundle branch block (LBBB, 0% vs. 8.6%, p=0.34) were numerically higher in the non-PMR group. Atrial fibrillation was significantly more prevalent in the non-PMR group (0% vs. 27.2%, p=0.01) and was identified as an independent predictor of lower odds of PMR on multivariable logistic regression (OR: 0.09, 95% CI: 0.00-0.77, p=0.02). Ventricular pacing rates were significantly lower in the PMR