

Long-term Safety and Effectiveness of Transcatheter versus Surgical Aortic Valve Replacement: A Pilot Study

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Background

Severe aortic stenosis is one of the most prevalent and clinically consequential valvular heart diseases in adults, associated with morbidity and mortality in the absence of timely intervention.¹ Supported by landmark randomized controlled trials and current clinical practice guidelines, the indication for transcatheter aortic valve replacement (TAVR) has progressively expanded to include patients at low surgical risk.^{1–4} Multiple randomized trials have demonstrated non-inferior or superior short- to intermediate-term outcomes of TAVR compared with surgical aortic valve replacement (SAVR) in this population.^{2,3} However, as TAVR increasingly reaches younger, lower-risk patients, long-term valve durability has emerged as an unresolved concern. The Evolut Low Risk trial recently reported no significant difference in the 6-year composite of all-cause mortality or disabling stroke between TAVR and SAVR (23.3% vs. 20.4%; $P=0.43$). Nevertheless, an exploratory analysis of available 7-year data identified a statistically significant higher reintervention rate in the TAVR arm (9.8% vs. 6.0%; sHR: 1.68 [95% CI: 1.10–2.58]; $P=0.02$).⁵ These findings, derived from a single trial evaluating a specific self-expanding device under controlled conditions, necessitate validation in real-world clinical settings. This study conducted a single-center pilot analysis to establish the methodological foundation for a planned multi-center real-world investigation of long-term outcomes of TAVR versus SAVR in low-risk patients, using the nationwide Korean Health Insurance Review and Assessment Service (HIRA) database.

Methods

This observational study utilized clinical data from Severance Hospital (2006–2025) standardized to the OHDSI Common Data Model (CDM) format.

Study Population & Outcomes

We employed a new-user cohort design targeting adult patients with severe aortic stenosis who underwent their first TAVR or SAVR procedure. The index date was defined as the date of the initial valve replacement procedure. TAVR included those implanted with balloon-expandable (SAPIEN 3, SAPIEN 3 Ultra; Edwards Lifesciences) or self-expanding (Evolut R, Evolut PRO, Evolut PRO+; Medtronic) devices. Index procedures occurred between January 2016 and December 2025. Patients aged 80 years or older were excluded to reflect Korean national reimbursement criteria for TAVR and to minimize age imbalance between treatment groups. Additionally, patients with prior aortic valve replacement of any type were excluded to ensure a new-user design. No minimum prior-observation period was required: in a tertiary referral centre such a requirement removes more than half of the eligible patients, who are referred shortly before the procedure.

The primary outcomes were (1) a composite of all-cause mortality or disabling stroke and (2) aortic valve reintervention. Secondary outcomes included all-cause mortality, any stroke, inpatient stroke, atrial

fibrillation (AF), new permanent pacemaker implantation (PPM), myocardial infarction, inpatient heart failure, and aortic valve hospitalization. Because analyses were run without removing subjects who had the outcome before index, the AF outcome captures any occurrence rather than new onset. Time at risk ran from the day after the index procedure to the end of observation, up to 9 years.

Statistical Analysis

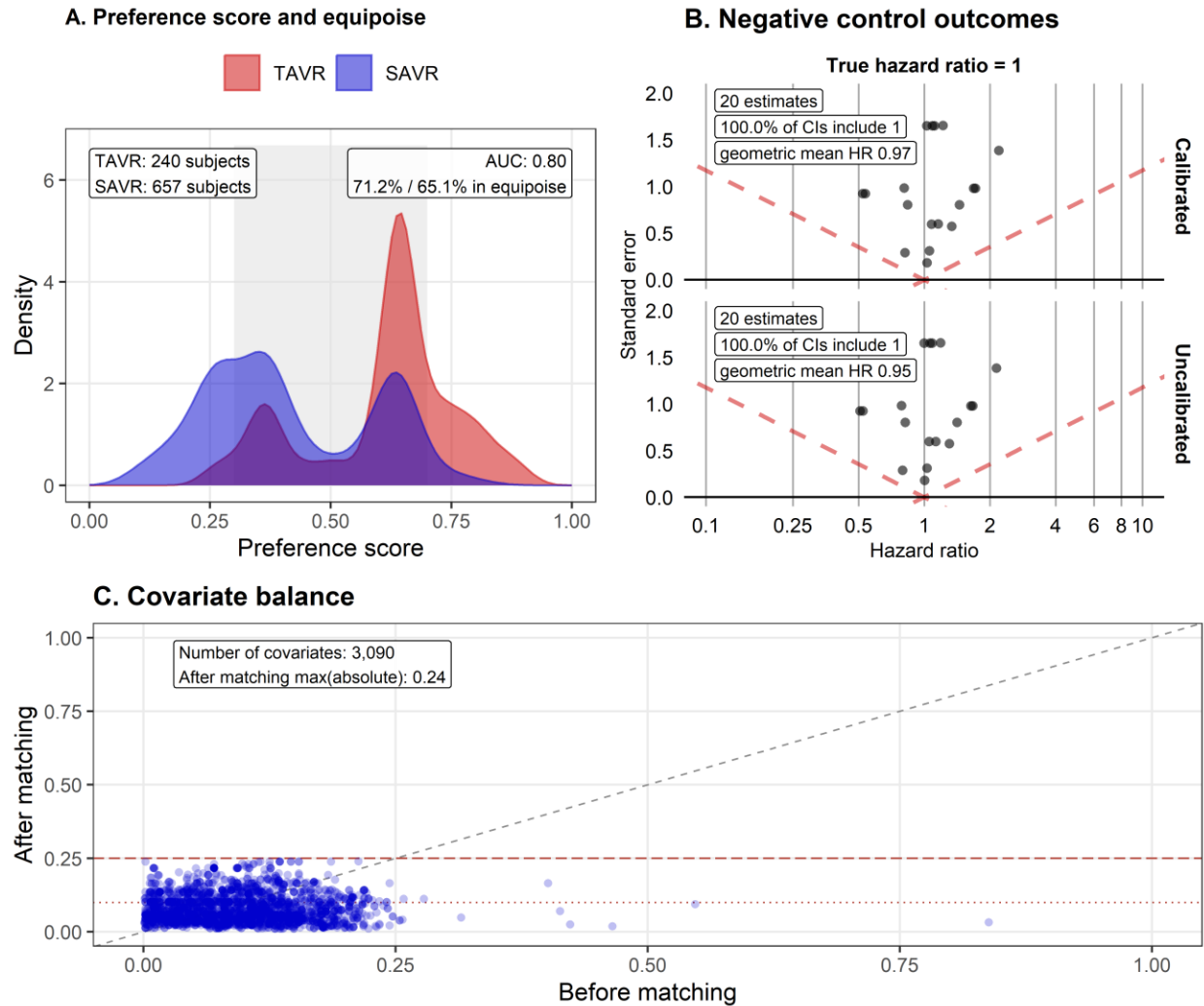
Confounding was addressed via large-scale propensity score estimation using regularized logistic regression over 3,090 baseline covariates, with 1:1 propensity score matching applied to balance baseline covariates between treatment groups. Clinical equipoise was assessed by evaluating the overlap in preference-score distributions between the TAVR and SAVR groups. The Cox proportional hazards model was used to estimate hazard ratios (HR) with 95% confidence intervals (CI). Residual systematic bias was assessed through empirical calibration using 89 pre-specified negative control outcomes. All 20 analysis specifications executed for this cohort pair were compared on these diagnostics before any outcome estimate was examined. Full-covariate 1:1 matching was the only specification that left no covariate above an absolute standardized mean difference (SMD) of 0.25, and its negative control outcomes were the closest to the null.

Results

Of 240 TAVR and 657 SAVR patients meeting eligibility criteria, 198 matched pairs were retained after 1:1 propensity score matching. Preference score distributions demonstrated adequate overlap between treatment groups, with 71.2% of the TAVR group and 65.1% of the SAVR group falling inside the equipoise range (preference score 0.3–0.7); the propensity model had an area under the receiver operating characteristic curve of 0.80. After matching, no covariate among 3,090 exceeded an absolute SMD of 0.25 (maximum 0.24), and the proportion above 0.10 fell from 38.9% to 28.9%. Of the 89 pre-specified negative control outcomes, 20 accrued enough events to be estimated; all 20 confidence intervals encompassed the null and their geometric mean hazard ratio was 0.95, indicating no material residual systematic error. Median follow-up was 725 days in the TAVR group and 749 days in the SAVR group, with the longest follow-up 2,990 and 3,177 days respectively. Study diagnostics are presented in Figure 1.

Figure 1. Assessment of Methodological Validity

(A) Preference Score Distribution Demonstrating Treatment Equipoise, (B) Empirical Calibration of Systematic Bias Using Negative Control Outcomes, and (C) Absolute Standardized Mean Difference of 3,090 Baseline Covariates Before and After 1:1 Propensity Score Matching

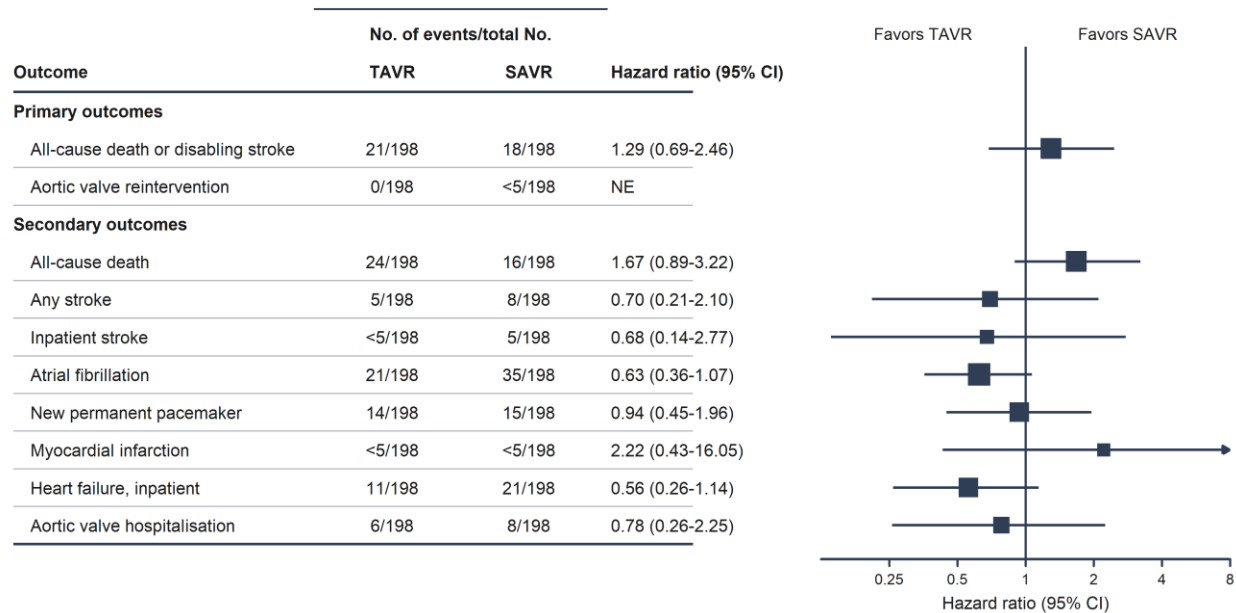


Primary Outcomes

Over up to 9 years of follow-up, TAVR was associated with similar rates of the composite primary endpoint of all-cause mortality or disabling stroke compared with SAVR (21 vs. 18 events; HR: 1.29; 95% CI: 0.69–2.46). Aortic valve reintervention could not be estimated: no event occurred in the TAVR arm and fewer than five in the SAVR arm, and none of the 20 executed specifications yielded an interpretable estimate. (Figure 2)

Figure 2. Hazard Ratios for All Outcomes

Hazard Ratios for the Primary and Secondary Outcomes in the 1:1 Propensity-Score-Matched Population (198 Pairs), From Cox Proportional Hazards Models. Squares are scaled by the precision of the estimate and the arrow marks an interval extending beyond the axis. NE, not estimable.



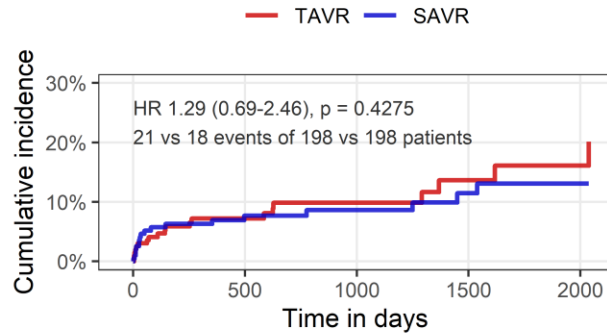
Secondary Outcomes

Among secondary outcomes, AF occurred less frequently in the TAVR arm (21 vs. 35 events; HR: 0.63; 95% CI: 0.36–1.07), as did inpatient heart failure (11 vs. 21 events; HR: 0.56; 95% CI: 0.26–1.14). All-cause mortality was numerically higher after TAVR (24 vs. 16 events; HR: 1.67; 95% CI: 0.89–3.22). New PPM implantation did not differ between groups (14 vs. 15 events; HR: 0.94; 95% CI: 0.45–1.96); across the six candidate specifications this estimate ranged from 0.94 to 1.54, so the present data do not resolve it. No outcome reached nominal statistical significance and all confidence intervals were wide. (Figure 3)

Figure 3. Cumulative Incidence of Selected Outcomes

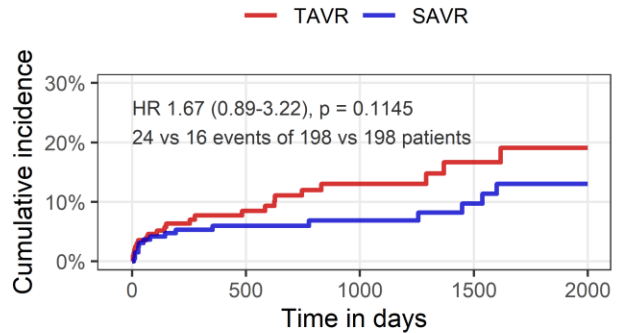
Cumulative Incidence in the Matched Population of (A) the Composite of All-Cause Mortality or Disabling Stroke, (B) All-Cause Mortality, (C) Atrial Fibrillation, and (D) New Permanent Pacemaker Implantation. Curves are truncated where the number at risk falls below five.

A. All-cause death or disabling stroke



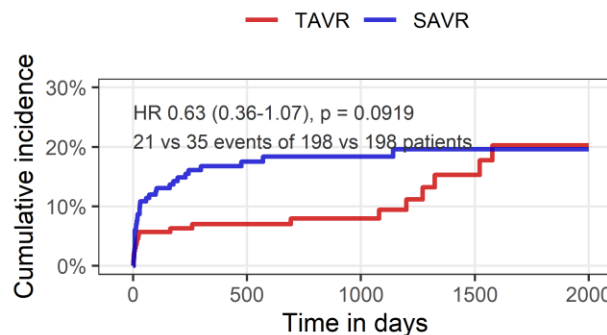
Number at risk					
TAVR	198	113	71	38	21
SAVR	198	124	85	55	35

B. All-cause death



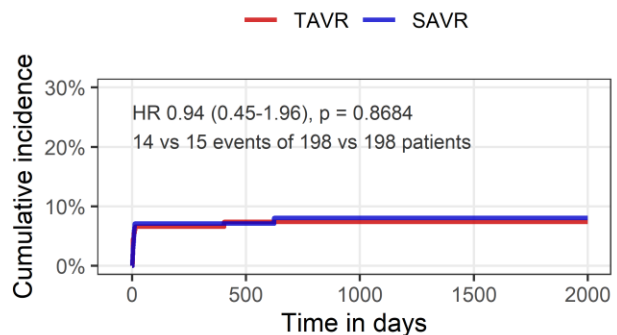
Number at risk					
TAVR	198	114	72	38	21
SAVR	198	127	88	56	36

C. Atrial fibrillation



Number at risk					
TAVR	198	108	66	34	19
SAVR	198	108	77	45	31

D. New permanent pacemaker



Number at risk					
TAVR	198	108	69	37	20
SAVR	198	119	81	51	32

Conclusion

This observational study demonstrated comparable rates of the composite of all-cause mortality or disabling stroke between TAVR and SAVR over up to 9 years, while aortic valve reintervention was too infrequent at this centre to be estimated; the limited matched sample size and wide confidence intervals preclude definitive conclusions. Among secondary outcomes, the directionally lower rate of AF after TAVR was consistent across every specification examined and is in line with established clinical priors, whereas new PPM implantation moved between 0.94 and 1.54 across specifications on 14 versus 15 events and is not resolved by these data. Equipose above 65% in both arms, no residual covariate imbalance above an SMD of 0.25, and negative control outcomes centred on the null support the validity of the study design, and the primary specification was selected on those diagnostics before any outcome estimate was examined.

This study has several limitations inherent to its pilot nature, including a small matched sample size, single-center data, outcome definitions derived from routinely collected records rather than adjudicated events, and residual confounding that cannot be fully eliminated in an observational setting. These estimates are descriptive of this cohort and are not interpreted causally. To address these limitations, a large-scale analysis utilizing the nationwide Korean Health Insurance Review and Assessment Service (HIRA) claims database is currently underway, with a federated analysis incorporating multi-institutional data planned to further validate and generalize these findings. Together, these efforts aim to provide robust real-world evidence on the long-term comparative effectiveness of TAVR versus SAVR in low-risk patients with severe aortic stenosis.

References

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