

COMPARISON OF POSTOPERATIVE ATRIAL FIBRILLATION, STROKE, MORTALITY, AND ECONOMIC OUTCOMES IN LOW-RISK TAVR PATIENTS

A Systematic Review Using the PARTNER 3 Trial as a Comparator to Real-World Evidence

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Background

- Transcatheter aortic valve replacement (TAVR) is a standard alternative to surgery (SAVR) for severe aortic stenosis.
- Indications expanded to low-risk patients in 2019 following the PARTNER 3 trial.

Gap

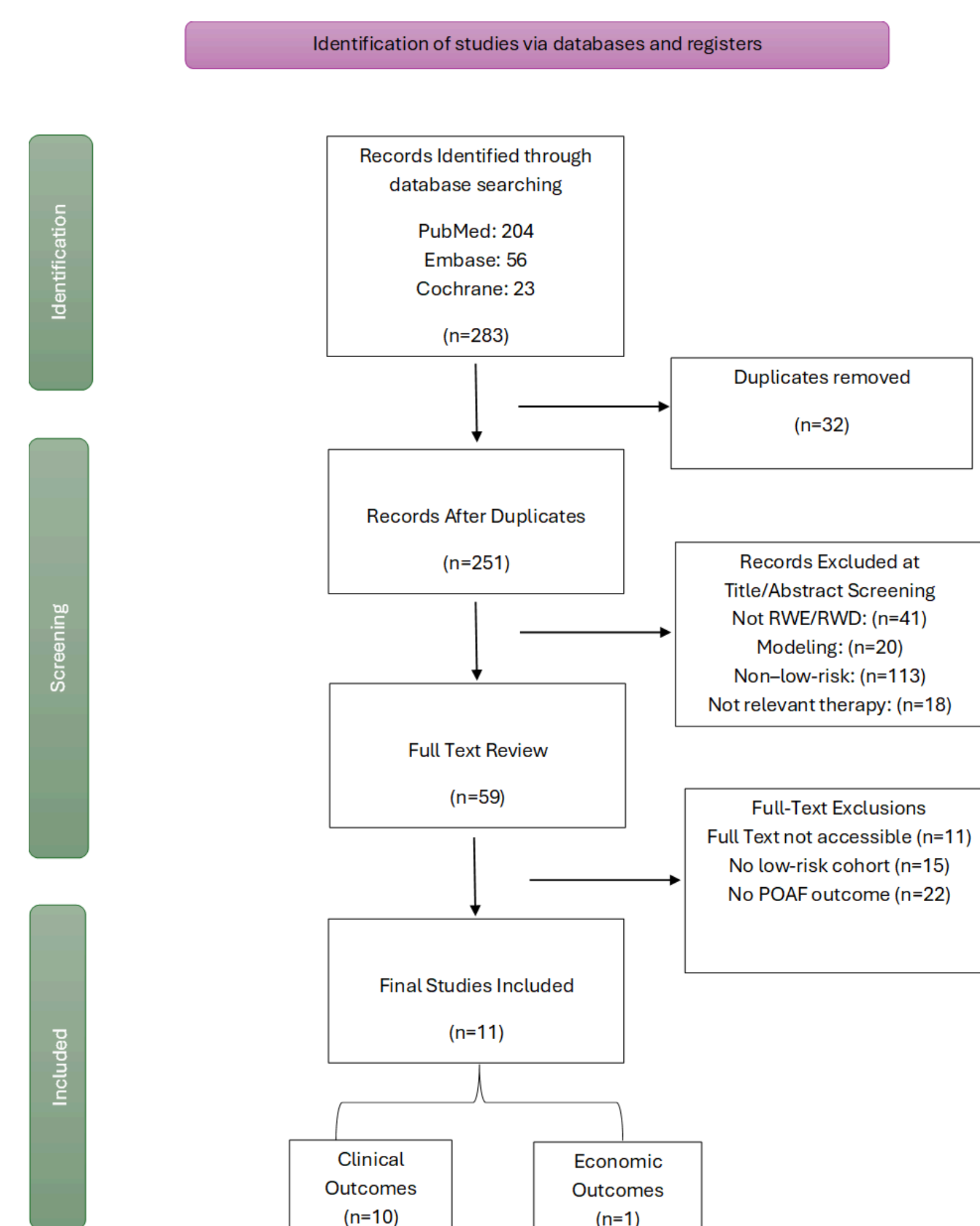
Limited evidence comparing real-world outcomes of Post Operative (POAF) and economic impacts after TAVR with RCT findings in low-risk populations.

Objective

To systematically evaluate real-world evidence (RWE) on postoperative atrial fibrillation (POAF), stroke, mortality, and economic outcomes in low-risk TAVR patients, and compare findings with the PARTNER 3 randomized trial.

Methodology

- Review Type: Systematic literature review (PRISMA 2020 guidelines).
- Search Period: Jan 1, 2019 – June 30, 2025.
- Data Sources: PubMed, Embase, Scopus, Cochrane, and clinical registries.



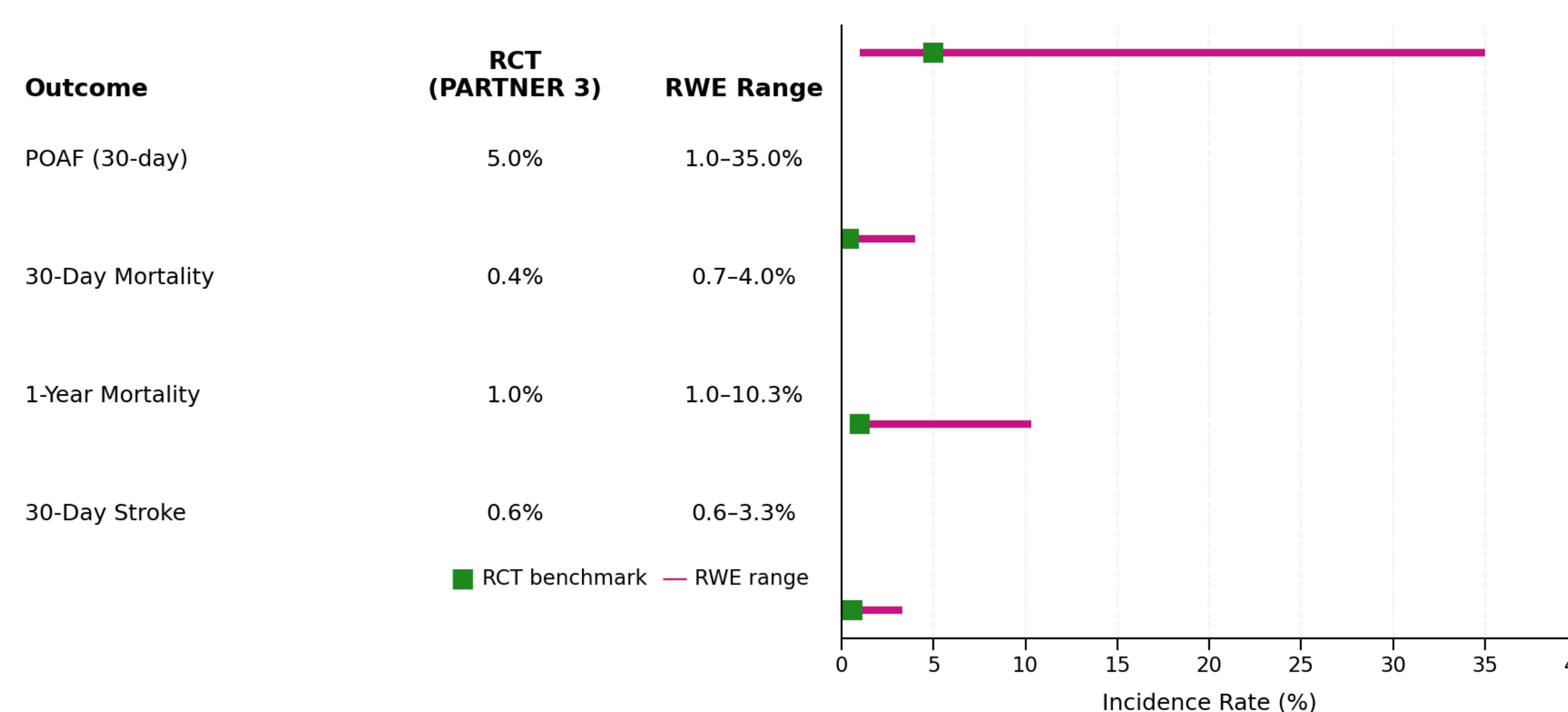
Baseline Characteristics: RCT VS RWE



■ RCT TAVR: PARTNER 3 trial ■ RWE 12–22: real-world studies as follows 12: Brízido et al., 2021; 13: García-Gómez et al., 2021; 14: Finkelstein et al., 2019; 15a: Hong et al., 2023, Bicuspid AS; 15b: Hong et al., 2023, Tricuspid AS; 16: Kaneko et al., 2021, VIV-TAVR; 17a: Kim et al., 2023, Asian TAVR; 17b: Kim et al., 2023, Non-Asian TAVR; 18: Kolar et al., 2023, TF-TAVI; 19a: Makkar et al., 2021, Bicuspid AS; 19b: Makkar et al., 2021, Tricuspid AS; 20: Shah et al., 2021; 21: Tagliari et al., 2021; 22: Virtanen et al., 2019.

Clinical Outcomes RCT Vs Real-World Evidence

RCT Benchmarks Compared with Observed Real-world Ranges



References

RCT Benchmark:
Shahim B, et al. JACC Cardiovasc Interv. 2021;14(14):1565-74.
Galper BZ, et al. Circulation. 2023;147(21):1594-605.

RWE Comparators:
Brízido C, et al. Catheter Cardiovasc Interv. 2021;98(7):E1033-43.
Finkelstein A, et al. Am J Cardiol. 2019;123(4):644-49.
García-Gómez M, et al. Catheter Cardiovasc Interv. 2022;99(3):889-95.
Hong N, et al. J Clin Med. 2023;12(1):387.
Kaneko T, et al. Circ Cardiovasc Interv. 2021;14(5):e010288.

Kim H, et al. JACC Asia. 2023;3(3):376-87.
Kolar T, et al. Wien Klin Wochenschr. 2023;135:703-11.
Makkar RR, et al. JAMA. 2021;326(11):1034-44.
Shah KK, et al. Heart Lung Circ. 2021;30(12):1918-28.
Tagliari AP, et al. Am J Cardiol. 2021;149:64-71.
Virtanen MP, et al. JAMA Netw Open. 2019;2(6):e195742.

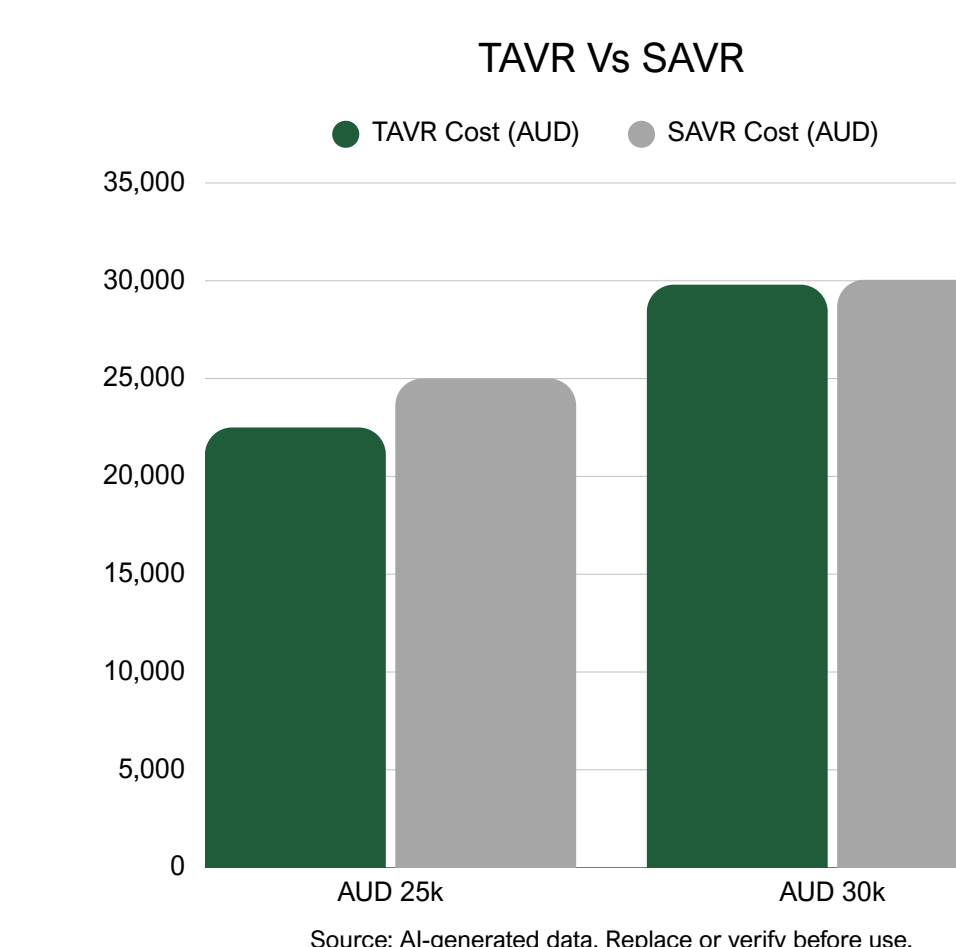
Economic Outcomes

RCT Based Dominance of TAVR Vs SAVR (PARTNER 3)

- USD 66,834 vs USD 68,864
- Shorter ICU LOS 0.8 vs 2.7 days
- Higher QALYs (+0.05).

Real World Evidence Sensitivity Analyses

- Efficiency: TAVR reduces hospital stay by 4.4 days vs. SAVR.
- Cost Savings: ~10% lower (Index + 30 days) at AUD 25k device price.
- Sensitivity: Savings cancelled out if device price exceeds AUD 30k.



Key Findings

- **The Risk Paradox:** "Low-risk" labels mask real-world frailty (NYHA Class, Diabetes status), and anatomical complexity (bicuspid/VIV) excluded from trials.
- **POAF Variability:** RWE rates are highly variable (1%–35%) vs. 5% in PARTNER 3. Trial results represent the "best-case" lower bound.
- **Safety Stability:** Mortality and stroke show minimal variation between RCT and RWE, confirming TAVR's robust safety profile.
- **Price Ceiling:** A 4.4-day LOS reduction drives savings, but economic dominance vanishes if device costs exceed AUD 30,000.

Conclusion

Real-world TAVR populations demonstrate greater clinical heterogeneity and variability in outcomes compared with RCT cohorts, highlighting limitations in generalizing trial findings to routine practice, while economic outcomes remain insufficiently characterized, representing an important gap for future studies.