Journal of the Chinese Medical Association Publish Ahead of Print

DOI: 10.1097/JCMA.0000000000001390

Reimbursement policy and outcomes after transcatheter aortic valve implantation

Wei-Ting Wang[a,b,c], Hsiao-Huang Chang[d,e], I-Ming Chen[c,d], Hsin-Bang Leu[a,c,f], Tzu-Ting Kuo[c,d], Su-Man Lin[c,g], Ying-Hwa Chen[a,c,*]

[a]*Division of Cardiology, Department of Internal Medicine, Taipei Veterans General Hospital, Taipei, Taiwan, ROC*

[b]*Institute of Clinical Medicine, National Yang-Ming Chiao-Tung University, Taipei, Taiwan, ROC*

[c]*School of Medicine, National Yang-Ming Chiao-Tung University, Taipei, Taiwan, ROC*

[d]*Division of Cardiovascular Surgery, Department of Surgery, Taipei Veterans General Hospital, Taipei, Taiwan, ROC*

[e]*Department of Surgery, School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan, ROC*

[f]*Division of Healthcare and Management, Healthcare Center, Taipei Veterans General Hospital, Taipei, Taiwan, ROC*

[g]*Department of Anesthesiology, Taipei Veterans General Hospital, Taipei, Taiwan, ROC*

Received date: July 15, 2025. **Accepted date: April 29, 2026.**

ORCID: 0000-0002-2064-9523 (Wei-Ting Wang)

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

***Address correspondence.** Dr. Ying-Hwa Chen, Division of Cardiology, Taipei Veterans General Hospital, 201, Section 2, Shi-Pai Road, Taipei 112, Taiwan, ROC. Tel: +886-2-2871-2121 Fax: +886-2-2871-2121 E-mail: yhchen@vghtpe.gov.tw

Abstract

Background: Transcatheter aortic valve implantation (TAVI) is an established treatment for severe aortic stenosis. While reimbursement policies significantly expand access, the impact of Taiwan's National Health Insurance (NHI) coverage introduced in February 2021 on patient characteristics and outcomes remains unclear. This study evaluates changes in patient profiles and clinical outcomes before and after NHI reimbursement.

Methods: We compared patient profiles, procedural variables, and clinical outcomes, including 30-day complications and 1-year all-cause mortality, cardiovascular death, and rehospitalization for heart failure (HF). Risk was stratified using the Society of Thoracic Surgeons (STS) score.

Results: We analyzed 467 patients undergoing TAVI at a tertiary referral center between May 2010 and April 2024. Patients were divided into pre-reimbursement (n=258) and post-reimbursement (n=209) groups. Reimbursement was associated with a shift toward higher-risk patients, reflected by an increase in median STS scores (5.9% to 7.2%, p=0.002) and a greater proportion of patients with STS score ≥8% (44.0% vs. 31.8%, p=0.019). Post-reimbursement patients had higher prevalence of dialysis (17.7% vs. 7.6%, p=0.001) and more commonly underwent valve-in-valve TAVI for degenerated bioprosthetic valves (8.4% vs. 2.7%, p=0.007). Despite of this higher-risk profile, hospital stay was significantly shorter post-reimbursement (7.0 vs. 12.0 days, p<0.001). Valve Academic Research Consortium-3 (VARC-3) defined thirty-day outcomes were similar, except for reduced acute kidney injury in post-reimbursement patients (1.0% vs. 6.6%, p=0.021). One-year mortality was unchanged, but HF rehospitalization decreased significantly (2.9% vs. 8.1%, p=0.017). After multivariable adjustment, high STS risk (≥8%) independently predicted worse one-year outcomes.

Conclusion: In this single-treatment group experience, NHI reimbursement in Taiwan expanded TAVI access to higher-risk patients without compromising short- or mid-term mortality, and was associated with reduced heart failure readmission, especially among high-risk patients.

Keywords Aortic valve stenosis; Death; Heart Failure; Transcatheter aortic valve replacement.

Lay Summary: This study examined how Taiwan's National Health Insurance reimbursement policy affected access to transcatheter aortic valve implantation (TAVI), a minimally invasive treatment for severe aortic stenosis. After reimbursement was introduced, more elderly and higher-risk patients with multiple medical conditions were able to receive TAVI. Despite treating more complex patients, procedural safety and one-year survival remained stable. Importantly, rehospitalization for heart failure decreased after reimbursement. These findings suggest that broader insurance coverage, together with improvements in valve technology, patient selection, and operator experience, may allow more patients to benefit from TAVI without worsening clinical outcomes.

1. Introduction

Transcatheter aortic valve replacement (TAVI) is an established treatment for severe aortic stenosis, with robust clinical trial evidence demonstrating improved survival and functional capacity across all surgical risk categories.[1-4] Advances in valve technology, procedural techniques, and operator experience have further enhanced its procedural safety and clinical consistency.

Healthcare funding and reimbursement are crucial in facilitating the adoption of innovations such as TAVI. In Asia, its uptake has been slower than in Western countries, owing primarily to high device costs and limited reimbursement.[5,6] Following its inclusion in public insurance in 2013, Japan now reports the highest TAVI procedural volume in Asia[5]. In Taiwan, TAVI was initiated in 2010[7] and its utilization has increased rapidly—from approximately 300 cases in 2020 to more than 1,000 annually by 2024—following the introduction of the National Health Insurance (NHI) coverage for patients having severe aortic stenosis with high surgical risk in February 2021.

Reimbursement policies have broadened access to TAVI, particularly for older and frail patients with comorbidities who have previously been unsuitable for surgery. Although these patients pose higher procedural risks, advancements in TAVI technology, including next-generation valves, improved delivery systems, and increased experience of operators, have offset complications.[8-10] However, the effect of reimbursement-driven expansion on outcomes in Taiwan remains unclear. This study analyzes a longitudinal TAVI cohort from a high-volume tertiary center to evaluate changes in patient profiles, procedural characteristics, complications, and one-year outcomes, including all-cause mortality, cardiovascular death, and rehospitalization for heart failure (HF).

2. Methods

2.1. Patients

From May 2010 to April 2024, 471 consecutive patients with severe aortic stenosis (AS) (valve area < 1.0 cm^2 or aortic valve area/body surface area < 0.6 cm^2 or mean aortic-valve gradient ≥ 40 mm Hg) underwent TAVI performed at our institution. All patients exhibited symptoms exceeding class II specified by the New York Heart Association. Since February 2021, Taiwan's NHI has reimbursed TAVI for patients satisfying specific inclusion criteria, not satisfying exclusion criteria, and regarded as unsuitable or high risk for surgical aortic valve replacement by the heart team. The inclusion criteria require either a high surgical risk—defined as a 30-d mortality >10% by the Society of Thoracic Surgeons (STS) risk score or > 20% by the logistic European System for Cardiac Operative Risk Evaluation—or the presence of conditions such as prior cardiac surgery, porcelain aorta, thoracic burning sequelae contraindicating open surgery, history of mediastinum radiotherapy, severe connective tissue disease, liver cirrhosis (Child class A or B), or severe pulmonary insufficiency with forced expiratory volume in 1 s < 1 L. The main exclusion criterion was a life expectancy of less than 12 months. This study defines procedures before March 2021 as the pre-reimbursement period and those from March 2021 onward as the post-reimbursement period. The study adhered to the Declaration of Helsinki and received approval from the Institutional Review Board of Taipei Veterans General Hospital (approval number 2020-11-002BC, granted on Dec 17, 2020) with a waiver of informed consent.

2.2. Devices

All procedures were performed using commercially launched transcatheter heart valves, including self-expanding valves (CoreValve, Evolut R/Pro/FX; Medtronic, Minneapolis, MN, USA, and ACURATE neo2; Boston Scientific, USA), balloon-expandable valves (Sapien XT/S3 S; Edwards Lifesciences, Irvine, CA,

USA, and MyVal; Meril Lifesciences, Gujarat, India), and mechanically expandable LOTUS valves (Boston Scientific, Natick, MA, USA). CoreValve and Sapien XT were classified as early-generation devices, while Evolut R/Pro/FX, Sapien 3, LOTUS, MyVal, and ACURATE neo2 were regarded as new-generation devices. Device selection and procedural planning were determined by a multidisciplinary heart team based on anatomical and clinical considerations.

2.3. Procedures

All TAVI procedures were performed in an equipped hybrid operating suite. At the beginning of our experience, TAVI procedures were performed under general anesthesia. Beginning from December 2013, local anesthesia with conscious sedation had been exclusively used for transfemoral TAVI at our institution. The standard approach is through the transfemoral route, if feasible. In patients whose anatomy does not allow for safe transfemoral access, alternative access routes such as trans-subclavian, direct aortic, transapical, trans-abdominal aortic, or transcarotid access are used.

Valve sizes were selected based on perimeter-derived annulus diameters measured via computed tomography. For patients with bicuspid aortic valve (BAV), supra-annular structures located 4–8 mm above the annulus were incorporated into valve-sizing algorithms. Both the intercommissural distance[11] and perimeter-derived diameter using supra-annular tracing, which delineated the edge of the aortic leaflets spanning across calcium deposits and included the commissures, were measured. The prosthesis size was selected based on the minimal perimeter-derived diameter of the annulus, supra-annular tracing, or the ICD. Balloon sizing was performed when necessary, particularly for patients classified under the "gray zone" between two valve sizes or those with BAV.[12]

2.4. Risk stratification and data collection

Baseline demographic characteristics, comorbidities, echocardiographic and computed tomographic data, and procedural variables were obtained prospectively. Risk was stratified using the STS score into three groups: low surgical risk (STS score < 4%), intermediate surgical risk (STS score 4–8%), and high surgical risk (STS score ≥ 8%).

2.5. Clinical follow-up and echocardiographic assessment

Clinical data were obtained prospectively. Patients underwent regular clinical evaluations every 3 months, along with transthoracic echocardiography prior to discharge, at 1 month, at 6 months, at 1 year, and annually post-TAVI, in accordance with VARC-3.[13] Patients who did not return to our center were followed up by phone or by inquiring referring hospitals. Echocardiograms were analyzed by an independent core laboratory. The post-procedural left ventricular outflow tract diameter was measured from the outer border to the outer border of a stent paired with a pulsed wave Doppler system placed apical to the stented valve indicated by Hahn et al.[14]

2.6. Study endpoints and definitions

The study endpoints were 1-year all-cause mortality, cardiovascular death, and rehospitalization for HF. According to VARC-3, cardiovascular death includes fatalities due to HF, cardiogenic shock, bioprosthetic valve dysfunction, myocardial infarction, stroke, thromboembolism, bleeding, tamponade, vascular complications, arrhythmias, conduction system disturbances, cardiovascular infections (e.g., mediastinitis, endocarditis), intraprocedural death, sudden death, or unknown causes. Rehospitalization for HF is defined as a ≥24-h admission primarily due to new or worsening HF, supported by clinical indicators, diagnostic

confirmation, and requirement for intravenous or mechanical HF therapies. Secondary endpoints were 30-d major clinical endpoints defined by VARC-3.

2.7. Statistical Analysis

Continuous variables were reported as mean ± SD or median [IQR], based on the Shapiro–Wilk test for normality. Categorical variables were summarized as counts and percentages. Between-group comparisons were performed based on the Student's t-test or Mann–Whitney U test for continuous variables, and the chi-square or Fisher's exact test for categorical variables. Comparisons across STS risk strata were performed using one-way ANOVA or Kruskal–Wallis tests with Bonferroni or Dunn's post-hoc corrections. Kaplan–Meier analysis with log-rank testing was performed to assess 1-year event-free survival. Clinical event rates were expressed per 100 person-years and compared using incidence-rate ratios or Poisson regression. For HF rehospitalization, all-cause death was regarded as a competing risk using the univariable Fine–Gray method. Multivariable Cox models identified independent predictors of 1-year mortality, with proportional hazards assumptions verified. Statistical significance was set at two-sided $p < 0.05$. Analyses were performed using SPSS v24.0 (IBM) and R v4.5.0 (R Foundation). A sensitivity analysis restricted to the last 100–150 pre-reimbursement cases was performed to mitigate potential confounding issues from the operator learning curve and device evolution.

3. Results

3.1. Patients' demographics and procedural characteristics

Among 471 consecutive patients undergoing TAVI, 4 were excluded owing to isolated aortic regurgitation, resulting in a cohort of 467 patients for analysis: 258 treated before and 209 treated after the implementation of NHI reimbursement. Among the 209 patients in the post-reimbursement era, 48 (23.0%) were self-paid.

The cohort had a median age of 82 years, with 56% being female and a median STS score of 6.4% (IQR 3.8–9.9). BAV was present in 11.5% of patients, and 5.1% underwent valve-in-valve procedures for degenerated surgical or transcatheter bioprostheses. The procedures were primarily transfemoral (92.5%) and performed under conscious sedation (78.1%) (Table 1). Baseline characteristics showed no significant differences in age, sex, body size, or major comorbidities across periods. However, the post-reimbursement patients had higher rates of peripheral artery disease (35.9 vs. 24.4%, $p = 0.006$), end-stage renal disease (ESRD) requiring dialysis (17.7 vs. 7.6%, $p = 0.001$), and valve-in-valve procedures (8.4 vs. 2.7%, $p = 0.007$). Reimbursement was associated with a shift toward higher patient risks: the median STS scores increased from 5.9 to 7.2 ($p = 0.002$), with more patients classified as high risk (44.0 vs. 31.8%) and fewer as low risk (22.0 vs. 29.8%, $p = 0.019$). The median STS scores for low- and intermediate-risk groups remained unchanged at 2.6 and 5.8%, respectively, while the high-risk group showed a trend toward higher scores following reimbursement (12.9 vs. 11.0%, $p = 0.055$).

Pre-TAVI echocardiography suggested earlier intervention in the post-reimbursement group, as reflected by a larger aortic valve area (AVA) (0.8 vs. 0.7 cm^2, $p = 0.004$), a higher AVA index (0.5 vs. 0.4 cm^2/m^2, $p < 0.001$), and lower mean gradients (34 vs. 39 mm Hg, $p < 0.001$). Moderate-to-severe aortic regurgitation was less common ($p = 0.011$). Following reimbursement, the patients received new-generation valves more frequently (100 vs. 45%, $p < 0.001$), used less contrast (65 vs. 90 ml, $p < 0.001$), and had shorter hospital stays (7 vs. 12 d, $p < 0.001$). The post-procedural AVA, pressure gradient, left ventricular ejection fraction, and occurrence of paravalvular leak were comparable. Medications at discharge were similar across periods.

3.2. Risk stratification and clinical outcomes

To provide a framework for analyzing the effect of reimbursement, we first validated the prognostic utility of the STS score within our entire study cohort. Patients were stratified into low-, intermediate-, and high-risk groups. Consistent with established models, survival analysis confirmed that patients in the high-risk STS group exhibited significantly higher rates of all-cause mortality (log-rank $p < 0.001$) and cardiovascular death ($p = 0.040$) compared with patients in the lower-risk groups (data not shown). Similarly, the incidence of HF rehospitalization increased progressively with risk ($p = 0.009$), as confirmed by competing risk analysis (Gray's test $p = 0.021$; data not shown). This confirmation of the STS score's validity provides a reliable baseline for interpreting the subsequent effect of the reimbursement policy. Regarding short-term outcomes (Table 1), the 30-d procedural complications defined in VARC-3 were comparable, except for a lower rate of stages 2–4 acute kidney injury in the post-reimbursement group (1.0 vs. 6.6%, $p = 0.021$). Before reimbursement, the 30-d mortality rates were 2.6% in the low-risk patients (median STS score: 2.6%), 3.0% in the intermediate-risk patients (median STS score: 5.8%), and 6.1% in the high-risk patients (median STS score: 11.0%), with observed-to-expected mortality ratios of 1.00, 0.52, and 0.55, respectively. After reimbursement, the 30-d mortality rates were 2.2, 2.8, and 5.4% for the abovementioned risk groups, respectively (median STS scores: 2.6, 5.8, and 12.9%, respectively), with corresponding ratios of 0.83, 0.49, and 0.42, respectively (Fig. 1).

One-year follow-up was available for all patients. Kaplan–Meier analysis showed all-cause and cardiovascular mortality rates of 13.7 and 4.1%, respectively, with no significant differences observed pre- and post-reimbursement (Fig. 2A and 2B). Rehospitalization for HF occurred in 5.8% of the patients and was significantly lower in the post-reimbursement group (2.9 vs. 8.1%, $p = 0.017$) (Figure 2C), i.e., approximately

a threefold reduction (3.0 vs. 8.9 events per 100 person-years, p = 0.020), as confirmed via univariable competing-risk analysis, where death was regarded as a competing risk (unadjusted sub-distribution hazard ratio [HR] 0.343, 95% confidence interval: 0.139–0.848, p = 0.015; Supplementary Fig. 1 http://links.lww.com/JCMA/A393).

3.3. STS risk-stratified outcomes before and after reimbursement

Supplementary Figures 2–4 http://links.lww.com/JCMA/A393 illustrate the 1-year Kaplan–Meier outcomes stratified by STS risk before and after reimbursement. In the low- and intermediate-risk groups, the rates of 1-year mortality, cardiovascular death, and HF rehospitalization showed no significant differences. As shown in Supplementary Table 1 http://links.lww.com/JCMA/A394, high-risk patients in the post-reimbursement period were younger, had a higher prevalence of dialysis-dependent ESRD (30.4 vs. 15.9%, p = 0.0237), and exhibited a trend toward higher STS scores (12.9 vs. 11.0%, p = 0.055), with comparable medications provided at discharge. While the 1-year mortality and cardiovascular death rates remained unchanged, rehospitalization for HF declined significantly (13.4 vs. 3.3%, p = 0.0227).

3.4. Predictors of 1-year mortality

The results of Cox regression analysis for the association between 1-year mortality and (i) demographics and (ii) procedural characteristics are presented in Table 2. The 1-year mortality was significantly higher in the intermediate- (HR = 3.88, 95% confidence interval [CI] = 1.32–11.36, p = 0.013) and high-risk patients (HR = 7.89, 95% CI: 2.82–22.07, p < 0.001) compared with that of the low-risk group. After multivariate adjustment, elevated risk persisted in the high-risk patients (HR = 5.39, 95% CI = 1.88–15.41, p = 0.002) (Table 2A). Additionally, atrial fibrillation and impaired renal function emerged as independent predictors of 1-year mortality (Table 2B). In the univariate Cox regression, the post- vs. pre-reimbursement status was not

associated with 1-year mortality (HR = 0.995, 95% CI = 0.607–1.630, p = 0.983) and was therefore excluded from the final multivariable model.

3.5. Sensitivity analysis

When restricting the pre-reimbursement cohort to the last 100 and 150 cases, the 1-year all-cause and cardiovascular mortality remained comparable, while HF rehospitalization remained lower in the post-reimbursement group (Supplementary Tables 2 http://links.lww.com/JCMA/A394 and 3 http://links.lww.com/JCMA/A394).

4. Discussion

The increase in TAVI cases in Taiwan is associated closely with insurance coverage. Insurance coverage allows more patients, particularly elderly and high-risk individuals, to access TAVI without prohibitive out-of-pocket costs. This study provides comprehensive longitudinal evaluations of TAVI in Taiwan, where the procedural and clinical evolutions before and after the implementation of national reimbursement were captured. The main findings of this study are as follows: 1) The reimbursement was related to a shift toward higher-risk patients, with the median STS scores increasing from 5.9 to 7.2 and a greater proportion classified as high risk; 2) the procedural complications defined in the 30-d VARC-3 were comparable, except for a lower rate of stages 2–4 acute kidney injury after reimbursement. At 1 year, the all-cause and cardiovascular mortality rates remained unchanged, whereas rehospitalization for HF reduced significantly following reimbursement; 3) the 1-year outcomes deteriorated with increasing STS risk, with 70% of deaths beyond 30 d being non-cardiac, primarily due to infection or sepsis; and 4) the high STS risk (≥8%) independently predicted worse 1-year outcomes after multivariable adjustment.

In the USA, Medicare commenced TAVI reimbursements in 2012 for inoperable patients or patients with high surgical risk and later expanded the reimbursement to intermediate- and low-risk patients in 2016 and 2019, respectively, based on major clinical trials. Owing to the expansion of approved indications for TAVI, the median STS score reported by the national STS/ACC/TVT Registry of TAVI decreased steadily from 6.9% in 2013 to 4.4% in 2019.[15] In Taiwan, the reimbursement not only expanded access but also shifted the treated population toward higher-risk cohorts. Additionally, the patients presented more comorbidities, including ESRD and peripheral artery disease, and underwent valve-in-valve procedures more frequently. This shift indicates that the reimbursement expanded access to clinically indicated treatments previously limited by financial barriers.

The Japanese OCEAN registry (n = 2,588) reported 18.0% low-risk (STS < 4%), 46.4% intermediate-risk (STS 4–8%), and 35.6% high-risk (STS ≥ 8%) patients.[16] In a Korean registry (n = 581), low-risk patients predominated (62.5%), followed by intermediate- (29.8%) and high-risk (7.7%) patients.[17] By contrast, our post-reimbursement cohort demonstrated a significantly higher risk profile, i.e., 22% low, 34% intermediate, and 44% high risk, thus representing the highest proportion of high-risk patients among East Asian and Western TAVI studies to date.[15,17]

Despite the higher risk profiles following reimbursement, the procedural complications and 30-d mortality remained comparable to those in the pre-reimbursement period, with a significant reduction in stages 2–4 acute kidney injury. Considering the potential confounding effects of procedural learning and device evolution over the 14-year study period, in addition to recognizing that the steepest phase of the TAVI learning curve typically occurs within the first ~50 cases, we performed a sensitivity analysis restricting the pre-reimbursement cohort to the last 100–150 cases immediately preceding the policy change. This design aimed

to minimize the effects of accumulated operator experience and transcatheter heart valve advancements. The findings were consistent with those of the main analysis, thus indicating that the observed stability of the 1-year hard outcomes after reimbursement was not solely attributable to procedural experience or device evolution. Instead, these technological and procedural improvements—together with earlier intervention at a less decompensated stage, widespread adoption of newer-generation valves, optimized access routes and sedation protocols, and reduced contrast use—had likely contributed to the preservation of comparable early outcomes despite the inclusion of higher-risk patients.

Unplanned hospital readmissions after TAVI serve as key indicators of hospital performance and care quality,[18] as well as significantly increase healthcare costs. In the USA, the Centers for Medicare and Medicaid Services use readmission rates as a quality metric for reimbursement. Prior studies reported 1-year HF readmission rates of 13.6–24.1%.[19-22] Auffret et al. demonstrated that HF readmissions occurring 30 d to 12 months post-TAVI were independently associated with higher all-cause mortality at a median follow-up of 32 months (HR = 1.90; 95% CI = 1.30–2.78; $p = 0.001$).[22] In our study, HF rehospitalization occurred in 5.8% of the patients, with a reduction by approximately threefold in the post-reimbursement period despite their higher risk profiles. This improvement likely reflects earlier intervention (larger and higher indexed AVAs, lower gradients), decreased acute kidney injury from reduced contrast use, and increased procedural experience, as well as a trend toward fewer moderate-to-severe paravalvular leaks, all of which are established predictors of post-TAVI readmissions. [18,22,23]

In this study, the all-cause mortality was 3.3, 11.8, and 23.0% for the low-, intermediate-, and high-risk patients, respectively, whereas the cardiovascular mortality was 2.4, 2.4, and 6.9%, respectively. These results align with the Trans-Pacific TAVR registry from the USA and Korea. In our cohort, 70% of deaths beyond

30 d were noncardiac and primarily caused by infection or sepsis (58%), which is consistent with the STS/ACC/TVT Registry reporting 1-year all-cause and cardiovascular mortality rates of 12.2 and 3.0% in 2022, respectively, with two-thirds of deaths being noncardiac. Independent predictors of 1-year noncardiac death included the male sex, dialysis, current smoking, and in-hospital complications such as postprocedural atrial fibrillation, major bleeding, pacemaker implantation, and stroke.[24]

Study limitation

This study has several limitations. As a single-center observational cohort with a prolonged enrollment period, it is susceptible to temporal trends and operator learning effects. While sensitivity analyses limited to the last 100–150 pre-reimbursement cases mitigated these biases, residual confounding may remain. Among the post-reimbursement patients, approximately 20% were self-paying; because of the limited sample size, no further subgroup analysis was performed, which may have resulted in residual heterogeneity within the post-reimbursement era. Risk stratification was based on STS scores, which may not fully account for TAVI-specific prognostic factors such as frailty. Finally, as with all observational studies, unmeasured confounding cannot be excluded, and causal inferences should be made with caution.

In conclusion, in this single-center longitudinal study, the implementation of the NHI reimbursement in Taiwan significantly expanded access to TAVI, particularly for older, high-risk patients with comorbidities. Despite a shift toward higher-risk profiles, including more dialysis-dependent and valve-in-valve cases, procedural complications remained stable, and the 1-year all-cause and cardiovascular mortality rates remained unchanged. Notably, rehospitalization for HF decreased significantly post-reimbursement, particularly among high-risk patients. These findings highlight the pivotal role of reimbursement policies in

enabling broader access to TAVI without compromising safety while underscoring the necessity for continued optimization of care in high-risk populations.

References

1. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187-98.

2. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016;374:1609-20.

3. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019;380:1706-15.

4. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J. ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J* 2022; 43: 561–632.

5. Izumi C, Eishi K, Ashihara K, Arita T, Otsuji Y, Kunihara T, et al. JCS/JSCS/JATS/JSVS 2020 guidelines on the management of valvular heart disease. *Circ J* 2020;84:2037-119

6. Lee CH, Inohara T, Hayashida K, Park D-W. Transcatheter aortic valve replacement in Asia: present status and future perspectives. *JACC: Asia*. 2021;1:279-93.

7. Chen YH, Chang HH, Chen PL, Weng ZC, Chen IM, Leu HB, et al. Procedural characteristics and outcomes of transcatheter aortic valve implantation: a single-center experience of the first 100 inoperable or high surgical risk patients with severe aortic stenosis. *Acta Cardiol Sin* 2017;33:339.

8. Afilalo J, Lauck S, Kim DH, Lefevre T, Piazza N, Lachapelle K, et al. Frailty in older adults undergoing aortic valve replacement: the FRAILTY-AVR study. *J Am Coll Cardiol* 2017;70:689-700.

9. Amrane H, Porta F, Van Boven AV, Kappetein AP, Head SJ. A meta-analysis on clinical outcomes after transaortic transcatheter aortic valve implantation by the heart team. *EuroIntervention* 2017;13:e168-76.

10. Généreux P, Webb JG, Svensson LG, Kodali SK, Satler LF, Fearon WF, et al. Vascular complications after transcatheter aortic valve replacement: insights from the PARTNER (Placement of AoRTic TraNscathetER Valve) trial. *J Am Coll Cardiol* 2012;60:1043-52.

11. Tchetche D, De Biase C, van Gils L, Parma R, Ochala A, Lefevre T, et al. Bicuspid aortic valve anatomy and relationship with devices: The bavard multicenter registry: a European picture of contemporary multidetector computed tomography sizing for bicuspid valves. *Circ Cardiovasc Interv* 2019;12:e007107.

12. Patsalis PC, Al-Rashid F, Neumann T, Plicht B, Hildebrandt HA, Wendt D, et al. Preparatory balloon aortic valvuloplasty during transcatheter aortic valve implantation for improved valve sizing. *JACC Cardiovasc Interv* 2013;6:965-71.

13. Committee VW, Généreux P, Piazza N, Alu MC, Nazif T, Hahn RT, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *Eur Heart J* 2021;42:1825-57.

14. Hahn RT, Leipsic J, Douglas PS, Jaber WA, Weissman NJ, Pibarot P, et al. Comprehensive echocardiographic assessment of normal transcatheter valve function. *JACC Cardiovasc Imaging* 2019;12:25-34.

15. Carroll JD, Mack MJ, Vemulapalli S, Herrmann HC, Gleason TG, Hanzel G, et al. STS-ACC TVT registry of transcatheter aortic valve replacement. *J Am Coll Cardiol* 2020;76:2492-516

16. Ishizu K, Shirai S, Isotani A, Hayashi M, Kawaguchi T, Taniguchi T, et al. Long-term prognostic value of the society of thoracic surgery risk score in patients undergoing transcatheter aortic valve implantation (from the OCEAN-TAVI registry). *Am J Cardiol* 2021;149:86-94..

17. Kim H, Kang DY, Ahn JM, Kim JB, Yeung AC, Nishi T, et al. Race-specific impact of conventional surgical risk score on 1-year mortality after transcatheter aortic valve replacement. *JACC: Asia* 2023;3:376-87.

18. Goldsweig A, Aronow HD. Identifying patients likely to be readmitted after transcatheter aortic valve replacement. *Heart* 2020;106:256-60.

19. Nombela-Franco L, Trigo Md, Morrison-Polo G, Veiga G, Jimenez-Quevedo P, Abdul-Jawad Altisent O,et al. Incidence, causes, and predictors of early (≤ 30 days) and late unplanned hospital readmissions after transcatheter aortic valve replacement. *JACC: Cardiovascular Interventions* 2015;8:1748-57.

20. Durand E, Doutriaux M, Bettinger N, Tron C, Fauvel C, Bauer F, et al. Incidence, prognostic impact, and predictive factors of readmission for heart failure after transcatheter aortic valve replacement. *JACC: Cardiovascular Interventions* 2017;10:2426-36.

21. Holmes DR, Brennan JM, Rumsfeld JS, Dai D, O'Brien SM, Vemulapalli S, Edwards FH, et al. Clinical outcomes at 1 year following transcatheter aortic valve replacement. *JAMA* 2015;313:1019-28.

22. Auffret V, Bakhti A, Leurent G, Bedossa M, Tomasi J, Belhaj Soulami R, et al. Determinants and Impact of Heart Failure Readmission Following Transcatheter Aortic Valve Replacement. *Circ Cardiovasc Interv* 2020;13:e008959.

23. Franzone A, Pilgrim T, Arnold N, Heg D, Langhammer B, Piccolo R, et al. Rates and predictors of hospital readmission after transcatheter aortic valve implantation. *Eur Heart J* 2017;38:2211-7.

24. Kolte D, Marquis-Gravel G, Stebbins A, Vekstein AM, Vemulapalli S, Elmariah S. Temporal trends

in 1-year cause-specific mortality after TAVR: insights from the STS/ACC TVT registry. *JACC Cardiovasc Interv* 2025;18:1013-24.

Figure legends

Fig. 1 Bar plots show the observed 30-day mortality rates stratified by STS risk category (low, intermediate, high) and insurance coverage status (Before NHI vs. After NHI). Solid points and connecting lines indicate the expected mortality based on STS prediction models. Observed-to-expected mortality ratios (O/E) are as follows: Low-risk: Before NHI = 1.00, After NHI = 0.83, Intermediate-risk: Before NHI = 0.52, After NHI = 0.49, High-risk: Before NHI = 0.55, After NHI = 0.42. These findings suggest a consistent reduction in observed mortality relative to expected risk after NHI reimbursement, especially in the high-risk group.

Fig. 2 Kaplan-Meier curves showing one-year (A) all-cause and (B) cardiovascular mortality and (C) freedom from rehospitalization for heart failure before and after reimbursement.

Supplementary Figure

Supplementary Fig. 1 Competing Risk Analysis of Heart Failure Hospitalization (HHF) by NHI Reimbursement Status

Cumulative incidence function (CIF) curves for 1-year hospitalization for heart failure (HHF) accounting for the competing risk of all-cause mortality, stratified by TAVR reimbursement status (Before vs. After National Health Insurance reimbursement implementation in March 2021). Gray's test $p = 0.015$. **Hazard ratios were estimated using a univariable Fine-Gray model.**

Supplementary Fig. 2 Clinical Outcomes Before and After Reimbursement in Low-Risk STS Patients

Kaplan–Meier curves showing 1-year (A) all-cause mortality, (B) cardiovascular death, and (C) Freedom from heart failure hospitalization in **low-risk STS patients (STS score <4%)**, comparing outcomes before versus after the implementation of Taiwan's National Health Insurance (NHI) reimbursement for TAVR in March 2021. Log-rank P values are displayed for each outcome. Curves were truncated at the 99.5th percentile of follow-up.

Supplementary Fig. 3 Clinical Outcomes Before and After Reimbursement in Intermediate-Risk STS Patients

Kaplan–Meier curves showing 1-year (A) all-cause mortality, (B) cardiovascular death, and (C) Freedom from heart failure hospitalization in **intermediate-risk STS patients (STS score 4–8%)**, comparing outcomes before versus after NHI reimbursement for TAVR. Log-rank P values are displayed for each outcome. Curves were truncated at the 99.5th percentile of follow-up.

Supplementary Fig. 4 Clinical Outcomes Before and After Reimbursement in High-Risk STS Patients

Kaplan–Meier curves showing 1-year (A) all-cause mortality, (B) cardiovascular death, and (C) Freedom from heart failure hospitalization in **high-risk STS patients (STS score >=8%)**, comparing outcomes before versus after NHI reimbursement for TAVR. Log-rank P values are displayed for each outcome. Curves were truncated at the 99.5th percentile of follow-up.

Table

Table 1 Baseline Characteristics, Procedural Profiles, and Clinical Outcomes Before and After National Health Insurance Reimbursement

	All (n=467)	Before (n= 258)	After (n=209)	*p*
Clinical characteristics				
Age, y	82.0 [76.0-87.0]	82.0 [78.0-87.0]	81.0 [74.0-86.0]	0.144
Female	259 (55.5)	143 (55.4)	116 (55.5)	1.000
Height, cm	156.0 [150.0-163.6]	156.8 [150.0-163.9]	155.6 [149.8-163.0]	0.426
Weight, kg	59.2 [52.1-66.7]	59.3 [52.4-67.5]	59.2 [52.0-65.5]	0.520
Body mass index, kg/m^2	24.1 [21.8-26.7]	24.3 [21.8-26.7]	23.9 [21.8-26.7]	0.862
Body surface area, m^2	1.6 [1.5-1.7]	1.6 [1.5-1.7]	1.6 [1.5-1.7]	0.661
Hypertension	347 (74.3)	194 (75.2)	153 (73.2)	0.702
Diabetes mellitus	169 (36.2)	94 (36.4)	75 (35.9)	0.979
Coronary artery disease	198 (42.4)	109 (42.2)	89 (42.6)	1.000
Prior PCI	167 (35.8)	89 (34.5)	78 (37.3)	0.591
Prior CABG	21 (4.4)	11 (4.3)	10 (4.8)	0.963
Prior MI	33 (7.1)	15 (5.8)	18 (8.6)	0.288
Cerebrovascular disease	73 (15.6)	44 (17.1)	29 (13.9)	0.471
Peripheral artery disease	138 (29.5)	63 (24.4)	75 (35.9)	0.006
NYHA class III or IV	288 (61.7)	167 (66.3)	121 (57.9)	0.079
Prior pacemaker	21 (4.4)	9 (3.5)	12 (5.7)	0.339
Atrial fibrillation	100 (21.4)	56 (22.0)	44 (21.1)	0.954
eGFR, mL/min	39.0 [24.0-55.0]	40.0 [26.0-55.0]	38.0 [22.1-54.8]	0.109
Bicuspid aortic valve	54 (11.5)	26 (10.1)	28 (13.4)	0.339
Valve-in-valve procedure	24 (5.1)	7 (2.7)	17 (8.4)	0.007
ESRD, undergoing dialysis	57 (12.2)	20 (7.6)	37 (17.7)	0.001
COPD	70 (15.0)	42 (16.3)	28 (13.4)	0.487
STS score	6.4 [3.8-9.9]	5.9 [3.4-9.0]	7.2 [4.4-11.0]	0.002
STS score stratification, %				0.019
Low (<4)	123 (26.3)	77 (29.8)	46 (22)	
Intermediate (between 4-8)	170 (36.4)	99 (38.4)	71 (34)	
High (≥8)	174 (37.3)	82 (31.8)	92 (44)	
Hospital length of stay, day	10 [6-19]	12 [7-20]	7 [5-16]	<0.001
Pre-TAVI Echocardiographic data				

Aortic valve area, cm^2	0.7 [0.6-0.9]	0.7 [0.6-0.9]	0.8 [0.6-0.9]	0.004
Indexed aortic valve area, cm^2/m^2	0.4 [0.4-0.5]	0.4 [0.4-0.5]	0.5 [0.4-0.5]	0.001
Mean PG, mm Hg	37.0 [25.9-49.8]	39.0 [29.1-52.8]	33.8 [22.9-43.5]	<0.001
LVEF, %	58.0 [52.0-62.0]	57.0 [52.0-62.0]	58.0 [53.0-62.5]	0.236
Moderate to severe AR	64 (13.7)	45 (17.4)	19 (9.3)	0.011
Moderate to severe MR	72 (15.4)	45 (17.4)	27 (12.9)	0.231
PAP, mm Hg	37.8 [30.0-48.9]	38.9 [31.3-49.2]	37.0 [28.2-47.8]	0.066
Device type				
Self-expanding	417 (89.1)	226 (87.6)	191 (90.9)	0.243
Balloon-expandable	44 (9.4)	26 (10.1)	18 (8.6)	0.704
Early generation	142 (30.4)	142 (55)	0	<0.001
New generation	325 (69.6)	116 (45)	209 (100)	<0.001
Procedural characteristics				
Conscious sedation	365 (78.1)	193 (74.8)	172 (82.3)	0.051
Transfemoral approach	432 (92.5)	235 (91.1)	197 (94.3)	0.263
Balloon pre-dilatation	268 (57.4)	174 (67.4)	94 (45.0)	<0.001
Balloon post-dilatation	24 (5.1)	10 (3.9)	14 (6.7)	0.244
Contrast volume, ml	80.5 [57.0-110.0]	90.0 [67.5-120.2]	65.0 [48.8-98.5]	<0.001
Post-TAVI Echocardiographic Data				
EOA, cm^2	1.8 [1.5-2.0]	1.7 [1.5-1.9]	1.8 [1.6-2.0]	0.112
Indexed EOA, cm^2/m^2	1.10± 0.24	1.08 ± 0.24	1.13 ± 0.24	0.074
Mean PG, mm Hg	7.3 [5.0-11.0]	7.8 [5.3-11.1]	7.0 [4.7-10.5]	0.061
LVEF, %	58.0 [53.0-62.0]	57.5 [53.0-62.0]	58.2 [52.1-61.5]	0.824
PAP, mmHg	35.7 [29.4-45.4]	36.6 [29.4-46.2]	33.5 [30.1-39.1]	0.112
Moderate/severe PVL, %	8 (1.7)	7 (2.7)	1 (0.5)	0.142
Medications After Discharge				
Warfarin or NOAC	104 (22.3%)	54 (20.9%)	50 (23.9%)	0.502
Single antiplatelet	187 (40.0%)	109 (42.3%)	78 (37.3%)	0.297
Dual antiplatelets	177 (37.9%)	100 (38.8%)	77 (36.8%)	0.702
ACEI or ARB	243 (52.0%)	134 (51.9%)	109 (52.2%)	1.000
ARNI	26 (5.6%)	10 (3.9%)	16 (7.7%)	0.103
β-blocker	182 (39.0%)	94 (36.4%)	88 (42.1%)	0.216
VARC-3 defined outcomes at 30 days				
All-cause mortality	18 (3.8)	10 (3.9)	8 (3.8)	0.793
Cardiovascular death	10 (2.1)	6 (2.3)	4 (1.9)	0.783
Stroke	9 (1.9)	6 (2.3)	3 (1.4)	0.487

Major vascular complication	5 (1.1)	3 (1.2)	2 (1.0)	0.619
Major cardiac structural complications	16 (3.4)	8 (3.1)	8 (3.8)	0.688
Coronary obstruction	4 (0.9)	3 (1.2)	1 (0.5)	0.749
Need for a second valve	5 (1.1)	3 (1.2)	2 (1.0)	0.571
Acute kidney injury, stage 2 -4[a]	19 (4.1)	17 (6.6)	2 (1.0)	0.021
New pacemaker implantation	16 (3.4)	8 (3.1)	8 (3.8)	0.688
Conversion to open surgery	6 (1.3)	6 (2.3)	0	0.090
Valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR)	0	0	0	NA
1-year study endpoints				
All-cause mortality	64 (13.7)	36 (14.0)	28 (13.4)	0.807
Cardiovascular death	19 (4.1)	12 (4.7)	7 (3.4)	0.909
Rehospitalization for heart failure	27 (5.8)	21 (8.1)	6 (2.9)	0.017
Incidence Rates of Clinical Outcomes Before and After Reimbursement (per 100 Person-Years)				
All-Cause mortality		14.50 (10.07–19.33)	13.86 (8.91–19.30)	0.858
Cardiovascular death		4.83 (2.42–7.65)	3.46 (0.99–6.43)	0.484
Rehospitalization for heart failure		8.91 (5.51–12.72)	3.02 (1.01–5.54)	0.020

Continuous variables are presented as mean ± standard deviation (SD) or as median (25th–75th percentile). Categorical variables are presented as numbers (percentages). ACEI= angiotensin converting enzyme inhibitors; AR= aortic regurgitation; ARB= angiotensin II receptor blocker; ARNI= angiotensin receptor-neprilysin inhibitor; BAV= balloon aortic valvuloplasty; CABG= coronary artery bypass graft surgery; eGFR= estimated glomerular filtration rate; EOA= effective orifice area; LVEF= left ventricular ejection fraction; MI= myocardial infarction; MR= mitral regurgitation; NA= not applicable; NOAC= novel oral anticoagulants; NYHA= New York Heart Association; PAP= pulmonary artery pressure; PCI= percutaneous coronary intervention; PG= pressure gradient; PVL= paravalvular leak; SAVR= Surgical aortic valve replacement; STS= the Society of Thoracic Surgeons; TAVI= transcatheter aortic valve implantation; VARC-3= Valve Academic Research Consortium-3.

[a]Excluding patients with pre-existing dialysis.

Table 2 Cox Proportional Hazards Analysis of One-Year All-Cause Mortality According to STS Risk Groups and Clinical Covariates

A. Association between STS risk categories and 1-year mortality

	STS Score Low (n=123)	STS Score Intermediate (n= 170)		STS Score High (n=174)	
		HR (95% CI)	***p***	**HR (95% CI)**	***p***
Univariate	Referent	3.88 (1.32-11.36)	0.013	7.89 (2.82-22.07)	<0.001
Multivariate*	Referent	2.72 (0.91-8.10)	0.072	5.39 (1.88-15.41)	0.002

B. Univariate and multivariate COX regression of 1-year all-cause mortality

	Univariate		Multivariate	
Variables	Hazard Ratio (95% CI)	*p*	Hazard Ratio (95% CI)	*p*
post-reimbursement vs. pre-reimbursement	0.995 (0.607–1.630)	0.983		
Clinical characteristics				
Age	1.034 (1.002–1.066)	0.035		
Male	0.680 (0.408–1.134)	0.139		
Height	0.971 (0.945–0.998)	0.035		
Weight	0.970 (0.949–0.992)	0.007		
Body mass index	0.954 (0.896–1.016)	0.142		
Body surface area	0.163 (0.043–0.614)	0.007		
Hypertension	0.796 (0.469–1.351)	0.397		
Diabetes mellitus	1.268 (0.772–2.083)	0.348		
Coronary artery disease	1.597 (0.977–2.609)	0.062		
Prior PCI	1.577 (0.964–2.580)	0.070		
Prior CABG	2.338 (1.009–5.419)	0.048		
Prior MI	1.022 (0.503–2.080)	0.951		
Cerebrovascular disease	1.530 (0.845–2.771)	0.161		
Peripheral artery disease	2.613 (1.600–4.266)	<0.001		
NYHA class III or IV	2.058 (1.137–3.723)	0.017		

Prior pacemaker	0.298 (0.041–2.151)	0.230	
Atrial fibrillation	3.180 (1.943–5.203)	<0.001	3.140 (1.911-5.159) <0.001
eGFR (every 15 decrease)	1.814 (1.474–2.234)	<0.001	1.901 (1.525-2.368) <0.001
Bicuspid aortic valve	0.811 (0.350–1.879)	0.625	
Valve-in-valve procedure	1.196 (0.435–3.291)	0.729	
ESRD, undergoing dialysis	2.317 (1.299–4.131)	0.004	
COPD	0.938 (0.463–1.899)	0.858	
STS score	1.070 (1.045–1.095)	<0.001	
Admission Duration	1.005 (1.001–1.008)	0.006	
Pre-TAVI Echocardiographic data			
Aortic valve area	0.453 (0.134–1.534)	0.203	
AVA index	0.883 (0.130–6.001)	0.898	
Mean PG	0.986 (0.971–1.001)	0.068	
LVEF	0.989 (0.968–1.010)	0.296	
Moderate to severe AR	1.046 (0.517–2.117)	0.900	
Moderate to severe MR	2.170 (1.259–3.743)	0.005	
PAP	1.024 (1.011–1.037)	<0.001	
Device type			
New generation Valve	0.757 (0.456–1.256)	0.281	
Conscious sedation	0.438 (0.262–0.731)	0.002	
Transfemoral approach	0.264 (0.143–0.487)	<0.001	
Balloon predilatation	0.998 (0.608–1.639)	0.993	
Balloon postdilatation	1.775 (0.711–4.433)	0.219	
Contrast volume	1.000 (0.995–1.005)	0.971	
Post-TAVI Echocardiographic Data			
EOA	0.277 (0.105–0.732)	0.010	

Indexed EOA	0.443 (0.115–1.701)	0.235
Post-TAVI Mean PG	0.956 (0.886–1.030)	0.238
Post-TAVI LVEF	0.972 (0.938–1.007)	0.120
Post-TAVI PAP	1.015 (0.992–1.040)	0.201

The relative risk was described by the HR, hazard ratio (for intermediate- or high-risk STS category compared with the low-risk category) and corresponding 95% CIs. ACEI= angiotensin converting enzyme inhibitors; AR= aortic regurgitation; ARB= angiotensin II receptor blocker; ARNI= angiotensin receptor-neprilysin inhibitor; BAV= balloon aortic valvuloplasty; CABG= coronary artery bypass graft surgery; eGFR= estimated glomerular filtration rate; EOA= effective orifice area; LVEF= left ventricular ejection fraction; MI= myocardial infarction; MR= mitral regurgitation; NYHA= New York Heart Association; PAP= pulmonary artery pressure; PCI= percutaneous coronary intervention; PG= pressure gradient; PVL= paravalvular leak; SAVR= Surgical aortic valve replacement; STS= the Society of Thoracic Surgeons; TAVI= transcatheter aortic valve implantation; VARC-3= Valve Academic Research Consortium-3. *includes variables that were statistically significant in univariate analysis ($p < 0.05$), specifically age, peripheral artery disease (PAD), atrial fibrillation (AF), NYHA III/IV and end-stage renal disease (ESRD) undergoing dialysis, moderate to severe mitral regurgitation, pulmonary artery pressure, and hospital stay duration.

Figure 1

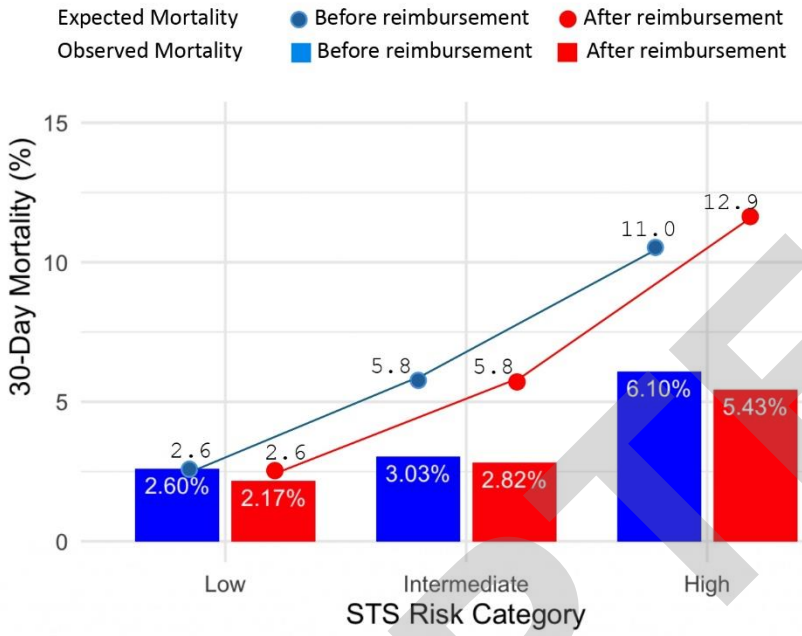

Figure 2

Figure 2. One-year study endpoints before and after reimbursement