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Stroke after transcatheter aortic valve implantation: incidence, temporal trends and predictors

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ABSTRACT

Background Stroke remains one of the most serious complications of transcatheter aortic valve implantation (TAVI). This study evaluated temporal trends in 30-day stroke after TAVI, explored potential contributors to these trends and examined associations with mortality.

Methods All patients undergoing TAVI in Sweden between 2008 and 2023 were identified from the SWEDEHEART registry. The primary endpoint was 30-day ischaemic or haemorrhagic stroke. Temporal trends were analysed using Bayesian binomial regression. To investigate potential contributors to the observed trends, sequential models were fitted, adjusting for patient case-mix and centre-level procedural volume. Predictors of 30-day stroke were explored using a hierarchical Bayesian logistic regression with a centre-level random intercept. Mortality was assessed using Kaplan-Meier estimates and a multivariable Bayesian Cox model with a 30-day landmark.

Results Among 11 957 patients, 374 (3.1%) experienced a stroke within 30 days and 310 during index hospitalisation. The incidence of 30-day stroke declined from 5.3% in 2008 to 3.2% in 2023 (OR 0.97 per year; 95% credible interval 0.95–1.00; probability of direction 98.2%). The temporal decline was partly explained by changes in patient case-mix, particularly declining EuroSCORE (European System for Cardiac Operative Risk Evaluation) II. Centre procedural volume did not modify temporal trends as this trend was similar across low-volume, medium-volume and high-volume centres. In exploratory analyses, prior stroke, female sex, porcelain aorta and self-expanding valves were associated with a higher probability of 30-day stroke, whereas TAVI-in-SAVR (transcatheter aortic valve implantation in surgical aortic valve replacement) procedures were associated with a lower stroke risk. Stroke within 30 days was associated with markedly higher 30-day and 1-year mortality.

Conclusions In this nationwide cohort, the incidence of early stroke after TAVI declined over time, partly reflecting changes in patient selection towards lower-risk profiles, with additional improvements in TAVI practice likely contributing. Despite this, early stroke remains strongly associated with excess mortality, underscoring the need for continued refinement of procedural strategies and targeted risk mitigation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Stroke after transcatheter aortic valve implantation (TAVI) is uncommon (~2–5%) but often disabling, and prior registry data show little change in short-term stroke rates despite growing TAVI volumes and younger, lower-risk patients.

WHAT THIS STUDY ADDS

⇒ In a nationwide cohort spanning 16 years, 30-day stroke incidence after TAVI declined modestly over time.
⇒ This reduction was partly explained by evolving patient selection towards lower-risk profiles, while exploratory analyses identified prior stroke, female sex, porcelain aorta, valve type and TAVI-in-SAVR (transcatheter aortic valve implantation in surgical aortic valve replacement) as factors associated with early stroke risk.
⇒ Stroke within 30 days remained strongly associated with excess 1-year mortality.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These findings highlight the continued clinical impact of early stroke after TAVI despite declining incidence.
⇒ Improved risk stratification may help identify patients at the highest risk, informing future studies of targeted neuroprotective strategies and procedural refinements, rather than broad, unselected interventions.

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has revolutionised the treatment of severe symptomatic aortic stenosis (AS) since its introduction. Initially reserved for inoperable patients or those at high surgical risk,[1] TAVI has progressively gained wider indications following evidence from pivotal randomised trials.[2 3] Current European guidelines now recommend TAVI as the preferred treatment in patients aged 70 years or older with tricuspid aortic valve anatomy and suitable vascular access, regardless of their surgical risk profile.[4] As a result, the number of TAVI procedures performed worldwide has increased substantially, and the procedure is increasingly being offered to younger and healthier patients.[5]

Continuous improvements in device technology, operator experience and procedural techniques have led to significant reductions in periprocedural complications and improved clinical outcomes,[6] establishing TAVI as the dominant therapy for severe AS in many countries.[5 7] Despite this progress, stroke remains one of the most serious and feared complications of the procedure. Although the reported incidence of stroke after TAVI is relatively low, typically ranging from 2% to 5%,[1 8–10] its consequences are profound. Patients experiencing stroke after TAVI have a substantially increased risk of both short- and long-term mortality.[11] Beyond survival, stroke frequently results in disability, loss of independence and reduced quality of life, with a significant proportion of patients requiring institutional care.[12 13] From a healthcare perspective, these events are associated with prolonged hospitalisations, intensive rehabilitation needs and considerable resource utilisation.[14]

Even small changes in stroke incidence over time are of major clinical and economic importance, as the absolute number of TAVI procedures continues to rise and increasingly involves younger, lower-risk patients for whom the consequences of stroke are particularly severe.

Against this background, we used nationwide registry data from Sweden to evaluate temporal trends in 30-day stroke following TAVI between 2008 and 2023 and to explore potential drivers of these trends. Secondary exploratory analyses examined associations with mortality and baseline and procedural characteristics.

METHODS

Study design and data sources

This observational study was based on data from the SWENTRY registry (SWEdish traNscatheter cardiac intervention regisTRY), a nationwide prospective multicentre registry that has consecutively enrolled all patients undergoing TAVI in Sweden since 2008. As part of the SWEDEHEART registry (Swedish Web-system for Enhancement and Development of Evidence-based Care in Heart Disease Evaluated According to Recommended Therapies),[15] SWENTRY ensures standardised reporting of procedural and clinical characteristics across all TAVI centres in Sweden.

Comorbidity data for all included patients were obtained through linkage with the National Patient Register (NPR),[16] which contains International Classification of Diseases (ICD)-coded diagnoses from all hospital admissions and outpatient visits across Sweden. Mortality and cause-specific death were ascertained from the Swedish Cause of Death Registry,[17] which captures all deaths occurring in Sweden.

Procedural, anatomical and device-related variables—including access route, valve type, procedural characteristics and aortic pathology—were obtained exclusively from the SWENTRY registry. Baseline comorbidities and prior medical history were ascertained from the SWENTRY as well as the NPR. When overlapping information was available from both data sources, registry-specific variables recorded in SWENTRY were prioritised, as these are prospectively collected in a procedure-specific clinical context (online supplemental table 1).

Patient population

The study population comprised all patients who underwent TAVI in Sweden between January 2008 and December 2023. Patients undergoing TAVI-in-TAVI procedures were excluded due to small numbers and because these represent repeat interventions in the same individual, requiring a separate analytical framework to account for within-patient correlation. The analysis was restricted to individuals treated with one of the four most used transcatheter heart valves in Sweden: CoreValve/Evolut, Sapien, Acurate and Portico/Navitor systems. Patients

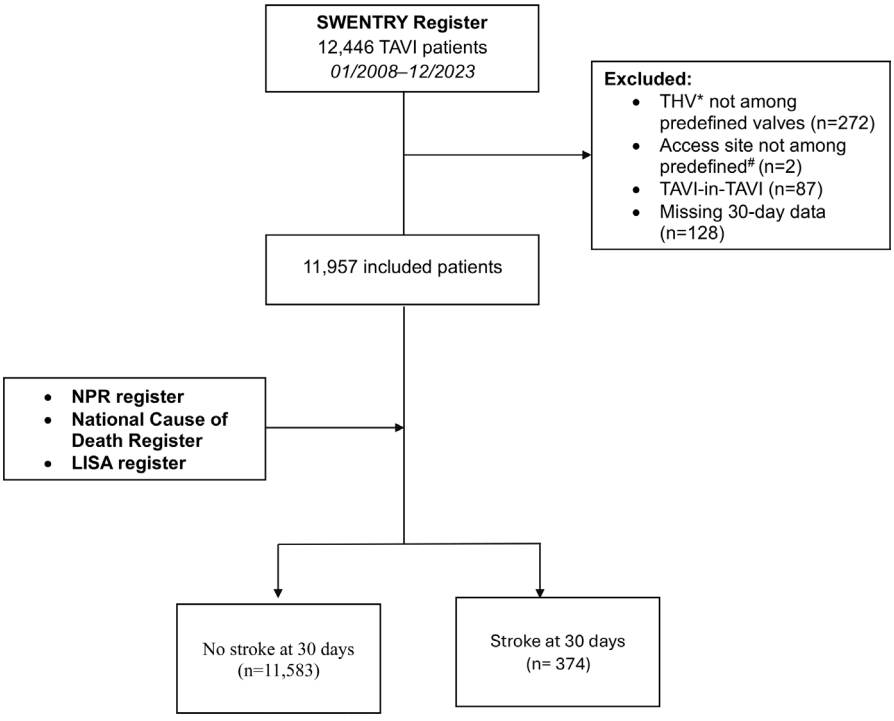

Figure 1 Flow diagram illustrating the patient selection process. *The study included patients who received one of the following transcatheter heart valves: CoreValve/Evolut, Sapien, Acurate or Portico/Navitor. #Access sites included the transfemoral, subclavian, apical and direct aortic access. LISA, Longitudinal integrated database for health insurance and labour market studies; NPR, National Patient Registry; SWENTRY, SWEdish traNscatheter cardiac intervention regisTRY; TAVI, transcatheter aortic valve implantation; TVH, transcatheter heart valve.

receiving TAVI via access routes other than transfemoral, subclavian, transapical or direct aortic, as well as those with missing 30-day outcome data, were excluded (figure 1).

Definitions and endpoints

Thirty-day stroke was defined as any ischaemic or haemorrhagic stroke occurring within 30 days after TAVI, including both in-hospital and post-discharge events. In-hospital stroke was identified exclusively from the SWENTRY registry and defined as any stroke occurring during the same hospital admission as the TAVI procedure, irrespective of whether the event occurred at the implanting centre or following transfer to another hospital. In SWENTRY, stroke is defined as a focal or global neurological deficit lasting >24 hours.

Because SWENTRY does not consistently record stroke subtype, information on ischaemic versus haemorrhagic stroke for in-hospital events was obtained from the NPR using ICD-10 codes. Post-discharge stroke events occurring between hospital discharge and 30 days were identified exclusively through the NPR using primary or secondary ICD-10 codes I60–I64. In addition, fatal strokes within 30 days were identified when stroke was recorded as the underlying cause of death in the Swedish Cause of Death Registry. Transient ischaemic attacks were excluded (online supplemental table 1 for data sources).

Theoretical device oversizing was defined as ([valve diameter−annulus diameter]×100)/annulus diameter. Porcelain aorta is recorded in SWENTRY as a binary variable based on the implanting operator's assessment, informed by CT and/or fluoroscopy, without nationally standardised imaging criteria.

The study endpoints included the incidence and temporal trends in 30-day stroke between 2008 and 2023, differences in 1-year all-cause mortality between patients with and without 30-day stroke and predictors of 30-day stroke.

Statistical analysis

Because this was a nationwide registry-based cohort study, the study size was determined by the number of patients meeting the predefined eligibility criteria during the study period rather than by a formal prospective sample size calculation.

Baseline characteristics are presented descriptively, with medians and IQRs for continuous variables and counts and percentages for categorical variables.

Missingness across candidate predictors ranged from 0.0% to 26.3%, and 45.7% of participants had at least one missing predictor included in the regression models. Missing data were assumed to be missing at random and were imputed using multiple imputation by chained equations with a random forest algorithm.[18] The imputation model included all variables used in the regression analyses, including demographic, clinical, echocardiographic and procedural predictors, as well as the outcome variable and the implanting centre identifier to preserve associations between predictors and outcomes. Ten imputed datasets were generated and combined according to Rubin's rules.

Temporal trends in 30-day stroke were assessed using a Bayesian binomial regression model with a logit link, with annual stroke counts and the total number of procedures specified as the outcome and calendar year modelled as a continuous predictor. To explore potential drivers of these trends, sequential models with increasing adjustment were fitted, incorporating patient case-mix (sex, age and EuroSCORE (European System for Cardiac Operative Risk Evaluation) II), and attenuation of the calendar-year effect was quantified. Effect modification by centre experience was assessed by including a year-by-volume interaction term, corresponding to interaction on the multiplicative scale, and by estimating calendar-year effects within strata of low-volume, mid-volume and high-volume centres.

Thirty-day all-cause mortality was summarised descriptively. Long-term outcomes were analysed using a 30-day landmark approach. For the survival analyses, time zero was defined as 30 days after the index TAVI procedure, and only patients alive at that time entered the risk set. Patients were followed until death, 1 year after TAVI or administrative end of follow-up (31 December 2023), whichever occurred first. One-year all-cause mortality was estimated using Kaplan-Meier methods, and associations were evaluated using a multivariable Bayesian Cox proportional hazards model. The proportional hazards assumption was assessed using Schoenfeld residuals. Covariates included in the Cox model were prespecified based on clinical relevance and prior literature, and no automated variable selection procedures were applied.

Predictors of 30-day stroke were assessed in a multivariable hierarchical Bayesian logistic regression, incorporating a centre-level random intercept to account for clustering and heterogeneity across implanting centres. Linearity of continuous predictors was assessed using restricted cubic splines and likelihood ratio tests comparing spline-based and linear specifications. No evidence of material non-linearity was observed; therefore, continuous predictors were retained as linear terms in the final models.

Weakly informative priors were specified for model parameters. Regression coefficients were assigned Normal(0,1) priors, the intercept was assigned a Normal(0,2) prior, and the SD of the centre-level random intercept was assigned a Student-t(3,0,2.5) prior. All Bayesian models were estimated using Markov chain Monte Carlo, and convergence was assessed using trace plots and the Gelman–Rubin statistic, with values <1.01 considered indicative of adequate convergence. All results are reported as posterior medians with 95% credible intervals (CrIs) and probability of direction (PD).

Statistical analyses were performed in R (V.4.3.2; R Foundation for Statistical Computing, Vienna, Austria).

Patient and public involvement

Patients and the public were not involved in the design, conduct, reporting or dissemination plans of our research.

RESULTS

Baseline patient characteristics

The analysis included 11 957 patients who underwent TAVI between January 2008 and November 2023. Among these, 374 patients (3.1%) experienced a stroke within 30 days.

Patients who experienced stroke were slightly older than those who did not (median age 82.0 years (IQR 77.0–86.0) vs 81.0 years (IQR 77.0–85.0)). Women accounted for 53% of patients with stroke and 46% of those without stroke. The median EuroSCORE II was similar in the two groups (3.5 (IQR 2.1–6.4) vs 3.6 (IQR 2.3–7.0)). Prior stroke was more common among patients with stroke (24% vs 11%), whereas previous cardiac surgery was less frequent (12% vs 17%).

Echocardiographic and anatomical characteristics were broadly similar between groups. The median preoperative mean aortic valve gradient was 47.0 mm Hg (IQR 40.0–57.0) among patients who experienced stroke and 45.0 mm Hg (IQR 40.0–54.0) among those who did not. Porcelain aorta was recorded in 8.2% of patients with stroke and 4.1% of those without stroke (table 1).

Table 1 Baseline characteristics of patients undergoing TAVI, overall and stratified by stroke within 30 days after the procedure

Characteristics	Overall N=11 957	No stroke N=11 583	Stroke N=374	Missing
Age (years)	81.0 (77.0, 85.0)	81.0 (77.0, 85.0)	82.0 (77.0, 86.0)	0 (0%)
Sex				0 (0%)
Male	6461 (54%)	6287 (54%)	174 (47%)	
Female	5496 (46%)	5296 (46%)	200 (53%)	
Body mass index (kg/m^2)	26.0 (23.4, 29.4)	26.0 (23.4, 29.4)	25.7 (23.2, 29.1)	−0.03, 0.17
Estimated glomerular filtration rate (mL/min/1.73 m^2)	59.8 (45.2, 77.0)	59.9 (45.2, 77.1)	58.0 (43.8, 73.9)	−0.01, 0.19
EuroSCORE II predicted mortality	3.5 (2.1, 6.4)	3.5 (2.1, 6.4)	3.6 (2.3, 7.0)	119 (1.0%)
Comorbidities				
Hypertension	10 736 (90%)	10 391 (90%)	345 (92%)	0 (0%)
Diabetes mellitus	3533 (30%)	3417 (30%)	116 (31%)	0 (0%)
Chronic pulmonary disease	2929 (24%)	2821 (24%)	108 (29%)	0 (0%)
Peripheral vascular disease	2565 (21%)	2463 (21%)	102 (27%)	0 (0%)
Atrial fibrillation	5122 (43%)	4956 (43%)	166 (44%)	0 (0%)
Moderate or severe liver disease	260 (2.2%)	251 (2.2%)	9 (2.4%)	0 (0%)
Rheumatic disease	478 (4.0%)	456 (3.9%)	22 (5.9%)	0 (0%)
Medical history				
History of myocardial infarction	3091 (26%)	2988 (26%)	103 (28%)	0 (0%)
History of PCI	3078 (26%)	2988 (26%)	90 (24%)	53 (0.4%)
History of cardiac surgery	2009 (17%)	1963 (17%)	46 (12%)	53 (0.4%)
History of congestive heart failure hospitalisation	4983 (42%)	4823 (42%)	160 (43%)	0 (0%)
History of stroke	1368 (11.4%)	1278 (11%)	90 (24%)	0 (0.0%)
Echocardiographic features and valve characteristics				
Left ventricular ejection fraction				105 (0.9%)
≥50%	8295 (70%)	8047 (70%)	248 (67%)	
31–49%	2672 (23%)	2576 (22%)	96 (26%)	
21–30%	703 (5.9%)	683 (5.9%)	20 (5.4%)	
<20%	182 (1.5%)	175 (1.5%)	7 (1.9%)	
Mean aortic valve gradient (mm Hg)	45.0 (40.0, 55.0)	45.0 (40.0, 54.0)	47.0 (40.0, 57.0)	141 (1.2%)
Annulus diameter (mm)	24.0 (22.7, 26.0)	24.0 (22.8, 26.0)	24.0 (22.0, 26.0)	83 (0.7%)
Aortic valve area (cm^2)	0.7 (0.6, 0.8)	0.7 (0.6, 0.8)	0.7 (0.6, 0.8)	3145 (26%)
Moderate/severe aortic valve insufficiency	1223 (10%)	1190 (11%)	33 (9.0%)	274 (2.3%)
Moderate/severe mitral valve insufficiency	1426 (12%)	1381 (12%)	45 (13%)	346 (2.9%)
Valve morphology				2155 (18%)
Tricuspid	8964 (91%)	8694 (91%)	270 (92%)	
Bicuspid	838 (8.5%)	814 (8.6%)	24 (8.2%)	
Porcelain aorta	458 (4.2%)	431 (4.1%)	27 (8.2%)	1003 (8.4%)
Thorax deformity	231 (2.1%)	221 (2.1%)	10 (3.0%)	995 (8.3%)
Complex thoracic anatomy*	344 (3.1%)	335 (3.2%)	9 (2.7%)	1002 (8.4%)

*Risk for injury of patent bypass grafts.
EuroSCORE, European System for Cardiac Operative Risk Evaluation; PCI, percutaneous coronary intervention; TAVI, transcatheter aortic valve implantation.

Procedural features

Aortic stenosis or mixed aortic valve disease (AVD) constituted the majority indication for TAVI (99%), whereas pure aortic insufficiency accounted for only 1.3% of procedures. Among patients who experienced stroke, all cases were performed for aortic stenosis/mixed AVD, compared with 99% in the non-stroke group. TAVI-in-SAVR (transcatheter aortic valve implantation in surgical aortic valve replacement) procedures accounted for 1.3% of procedures in patients who experienced stroke and 4.5% among those who did not. Cerebral protection devices were used in 2.2% of procedures (n=209), with similar proportions among patients with and without stroke. The transfemoral route was used in approximately 92% of procedures overall. Oversizing greater than 15% was observed in 35% of patients who experienced stroke and 30% of those who did not. Self-expanding valves were used in 62% of stroke cases and 56% of non-stroke procedures (table 2).

Incidence and trends of 30-day stroke

Among strokes occurring within 30 days, most occurred during the index hospitalisation for the TAVI procedure (n=311, 83.2%). Overall, 312 events (83.4%) were ischaemic, 29 (7.8%) were haemorrhagic, and the remainder were unspecified.

Annual TAVI volume increased from 77 procedures in 2008 to 1761 in 2023. Over the same period, the observed proportion of

Table 2 Procedural characteristics by 30-day stroke status after TAVI

Characteristics	No stroke N=11 583	Stroke N=374	Missing
Indication for TAVI			93 (0.8%)
Aortic stenosis/mixed AVD	11 347 (99%)	370 (100%)	
Pure aortic insufficiency	147 (1.3%)	0 (0%)	
Valve-in-valve			0 (0%)
Native	11 063 (96%)	369 (99%)	
TAVI-in-SAVR	520 (4.5%)	5 (1.3%)	
TAVI urgency			622 (5.2%)
Elective	9591 (87%)	290 (85%)	
Urgent	1305 (12%)	50 (15%)	
Emergency	96 (0.9%)	3 (0.9%)	
Cerebral protection device	209 (2.2%)	6 (2.1%)	2169 (18%)
Predilatation	6068 (55%)	204 (59%)	667 (5.6%)
Postdilatation	2698 (23%)	83 (22%)	54 (0.5%)
Rapid pacing	9171 (80%)	293 (79%)	57 (0.5%)
Prosthesis size	26.0 (25.0, 29.0)	26.0 (25.0, 29.0)	3 (<0.1%)
Oversizing by over 15%*	3470 (30%)	131 (35%)	86 (0.7%)
Access site			0 (0%)
Transfemoral	10 733 (93%)	341 (91%)	
Transapical	502 (4.3%)	13 (3.5%)	
Via subclavian artery	229 (2.0%)	16 (4.3%)	
Direct aortic access	119 (1.0%)	4 (1.1%)	
Expanding mechanism			0 (0%)
BEV	5086 (44%)	143 (38%)	
SEV	6497 (56%)	231 (62%)	
Valve group			0 (0%)
Sapien	5050 (44%)	141 (38%)	
CoreValve/Evolut	3727 (32%)	149 (40%)	
Acurate	2273 (20%)	67 (18%)	
Portico/Navitor	497 (4.3%)	15 (4.0%)	
Myval	36 (0.3%)	2 (0.5%)	
Radiation time (min)	14.3 (10.2, 21.0)	16.5 (11.2, 25.0)	75 (0.6%)
Contrast amount (mL)	57.0 (35.0, 80.0)	66.0 (40.0, 100.0)	55 (0.5%)
Radiation dose (Gy)	1079.0 (10.0, 3973.5)	1096.5 (10.0, 4366.0)	443 (3.7%)

*Theoretical device oversizing was defined using the following calculation: ([valve diameter−annulus diameter]×100)/annulus diameter.
AVD, aortic valve disease; BEV, balloon-expandable valve; CrI, credible interval; PCI, percutaneous coronary intervention; PD, probability of direction; SEV, self-expanding valve; TAVI, transcatheter aortic valve implantation; TAVI-in-SAVR, transcatheter aortic valve implantation in surgical aortic valve replacement.

patients experiencing a 30-day stroke ranged from 5.3% in 2008 to 3.2% in 2023 (figure 2). Posterior median estimates indicated a decline from 4.2% to 2.8%. Calendar year was associated with a lower odds of 30-day stroke (OR per year 0.970; 95% CrI 0.945–0.998; PD=98.2%), consistent with a gradual decline over time.

Patient characteristics also changed over time. The median age declined from 84.0 years (IQR 79–87) in 2008 to 81.0 years (IQR 77–84) in 2023, corresponding to a posterior median decrease of 0.10 years per calendar year (95% CrI −0.13 to −0.06). The proportion of female patients declined modestly from 44% to 42% (OR per year 0.98; 95% CrI 0.97–0.99). The median EuroSCORE II decreased from 5.8 (IQR 4.2–10.4) to 2.6 (IQR 1.7–4.9), corresponding to an average relative reduction of approximately 5% per year. The mean transvalvular gradient also decreased over time (posterior median −0.27 mm Hg per year; 95% CrI −0.34 to −0.19, figure 3).

In hierarchical patient-level models, adjustment for age and sex resulted in modest attenuation of the calendar-year effect (5.8% and 5.1%, respectively), whereas adjustment for EuroSCORE II attenuated the effect by 15%.

Centre procedural volume did not materially modify the association between calendar year and 30-day stroke probability on the multiplicative scale. The year-by-volume interaction was small and highly uncertain (OR 1.02; 95% CrI 0.98–1.06; PD 19%). Calendar-year effects were directionally similar across low-volume, mid-volume and high-volume centres, with overlapping CrIs.

Independent predictors for stroke after TAVI

In the multivariable model, a history of prior stroke was associated with a higher probability of 30-day stroke (OR 2.42; 95% CrI 1.88–3.09; PD=1.00). Female sex (OR 1.33; 95% CrI 1.01–1.76; PD=0.98), porcelain aorta (OR 1.92; 95% CrI 1.32–2.75; PD=0.99) and the use of self-expanding valves (OR 1.44; 95% CrI 1.01–2.07; PD=0.98) were also associated with higher stroke probability. TAVI-in-SAVR procedures were associated with lower stroke probability (OR 0.38; 95% CrI 0.16–0.84; PD=0.99). Other patient comorbidities and procedural factors showed no convincing associations with the stroke risk (table 3).

Baseline and procedural characteristics of TAVI-in-SAVR and native TAVI procedures are presented in online supplemental table 2. Indication for TAVI was aortic stenosis in 99.5% of native TAVI procedures, whereas 18% of TAVI-in-SAVR procedures were performed for pure aortic insufficiency. The median age among patients undergoing TAVI-in-SAVR was 78 years, compared with 81 years among patients undergoing native TAVI. Male sex accounted for 60% of TAVI-in-SAVR procedures and 54% of native TAVI procedures, while atrial fibrillation was present in 60% and 42% of patients, respectively.

The median aortic valve gradient was 42 mmHg in TAVI-in-SAVR procedures and 45 mm Hg in native TAVI procedures. The median annulus diameter was 21 and 24 mm, respectively. Moderate-to-severe aortic insufficiency was recorded in 50% of TAVI-in-SAVR procedures and 8.7% of native TAVI procedures.

Procedurally, predilatation was performed in 12% of TAVI-in-SAVR procedures and 58% of native TAVI procedures. Oversizing greater than 15% occurred in 60% and 29% of procedures, respectively. The median prosthesis size was 23 mm in TAVI-in-SAVR procedures, and 26 mm in native TAVI procedures, and self-expanding valves were used in 68% and 56% of procedures, respectively.

Stroke and mortality

Thirty-day mortality was 2.1% (245/11 583) in patients without stroke compared with 11.8% (44/374) in those with stroke (figure 4).

In the 30-day landmark analysis, the Kaplan-Meier curves separated early and remained divergent. At 365 days, the survival probability was approximately 93% in the no-stroke group compared with 82% in the stroke group (figure 4). During follow-up, 10 874 patients were censored, of whom 9257 (85.1%) were administratively censored at 1 year and 1617 (14.9%) were censored at the end of the follow-up period. In the multivariable Bayesian Cox model, stroke within 30 days was associated with more than a twofold higher risk of mortality at 1 year (HR 2.34, 95% CrI 1.75–3.09; PD=1).

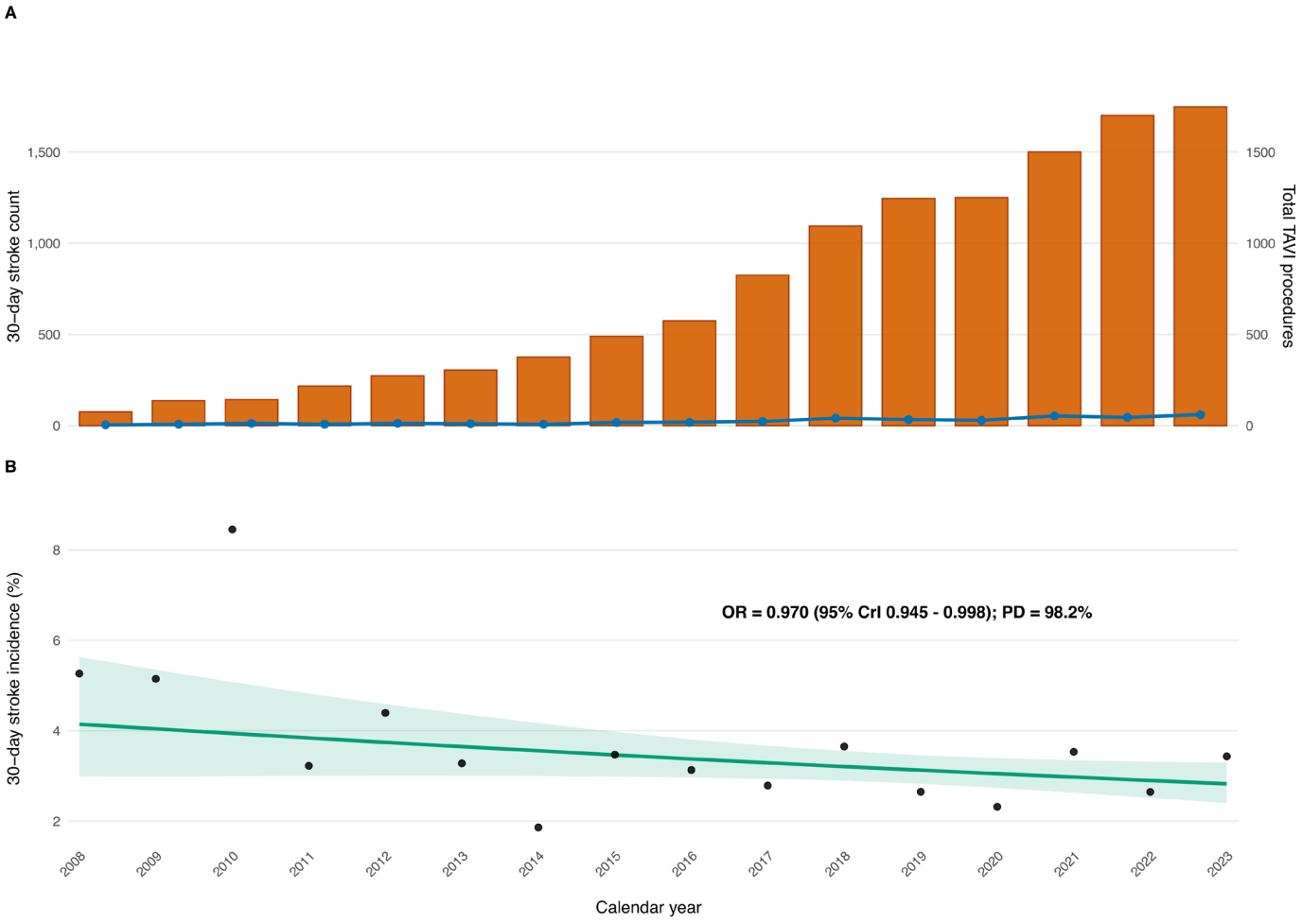

Figure 2 (A) The annual number of TAVI procedures (bars) and absolute 30-day stroke counts (blue line) from 2008 to 2023. (B) The observed 30-day stroke incidence (black dots) and the Bayesian posterior median estimates (solid green line) with 95% credible intervals (shaded green area). CrI, credible interval; PD, probability of direction; TAVI, transcatheter aortic valve implantation.

DISCUSSION

In this analysis of nearly 12 000 consecutive TAVI procedures performed between 2008 and 2023 and recorded in nationwide Swedish registries, the main findings can be summarised as follows:

- The cumulative incidence rate of stroke at 30 days post-TAVI was 3.1%, with only 63 cases (16.8%) occurring after discharge.
- The crude incidence of 30-day stroke post-TAVI declined over time, corresponding to an average relative reduction of approximately 3% per year.
- Temporal changes in patient case-mix explained part, but not all, of this decline, while centre-level procedural volume did not significantly modify the temporal trend.
- Stroke within 30 days remained strongly associated with excess mortality at 1 year, underscoring its continued clinical relevance despite declining incidence.

Periprocedural stroke within 30 days of TAVI has been consistently reported across randomised controlled trials (RCTs), with rates typically clustering between 2% and 5%.[3 19] The comparable incidence between our nationwide registry and RCTs strengthens the validity of our cohort and confirms the generalisability of our findings to real-world practice.

In contrast to several prior observational studies reporting stable stroke rates over time,[10 20 21] we observed a consistent decline in 30-day stroke incidence despite a marked increase in procedural volume. Patient-level analyses demonstrated that temporal reductions in baseline risk, particularly declining EuroSCORE II, attenuated the association between calendar year and stroke by approximately 15%. These findings indicate that evolving patient selection towards lower-risk profiles has played an important role in reducing early stroke risk. However, the persistence of a calendar-year effect after full adjustment suggests that additional factors beyond case-mix, such as advances in device technology, procedural techniques and peri-procedural management, are also likely to have contributed.

The observed decline in baseline mean transvalvular gradient over time likely reflects expanding TAVI indications and an increasing proportion of low-flow, low-gradient cases.

Centre-level analyses did not demonstrate a clear modifying effect of procedural volume on the temporal association between calendar year and stroke. This finding suggests that the observed decline in stroke risk reflects broad, system-wide improvements in TAVI practice rather than volume-dependent effects confined to individual centres. Progressive dissemination of best practices, standardisation of procedural workflows and nationwide adoption of newer-generation devices may therefore represent important contributors to improved outcomes over time.[6 22]

Periprocedural stroke after TAVI is thought to arise primarily from embolisation of calcific and tissue debris during mechanical manipulation, particularly valve crossing, balloon valvuloplasty and valve deployment. This mechanism is supported by

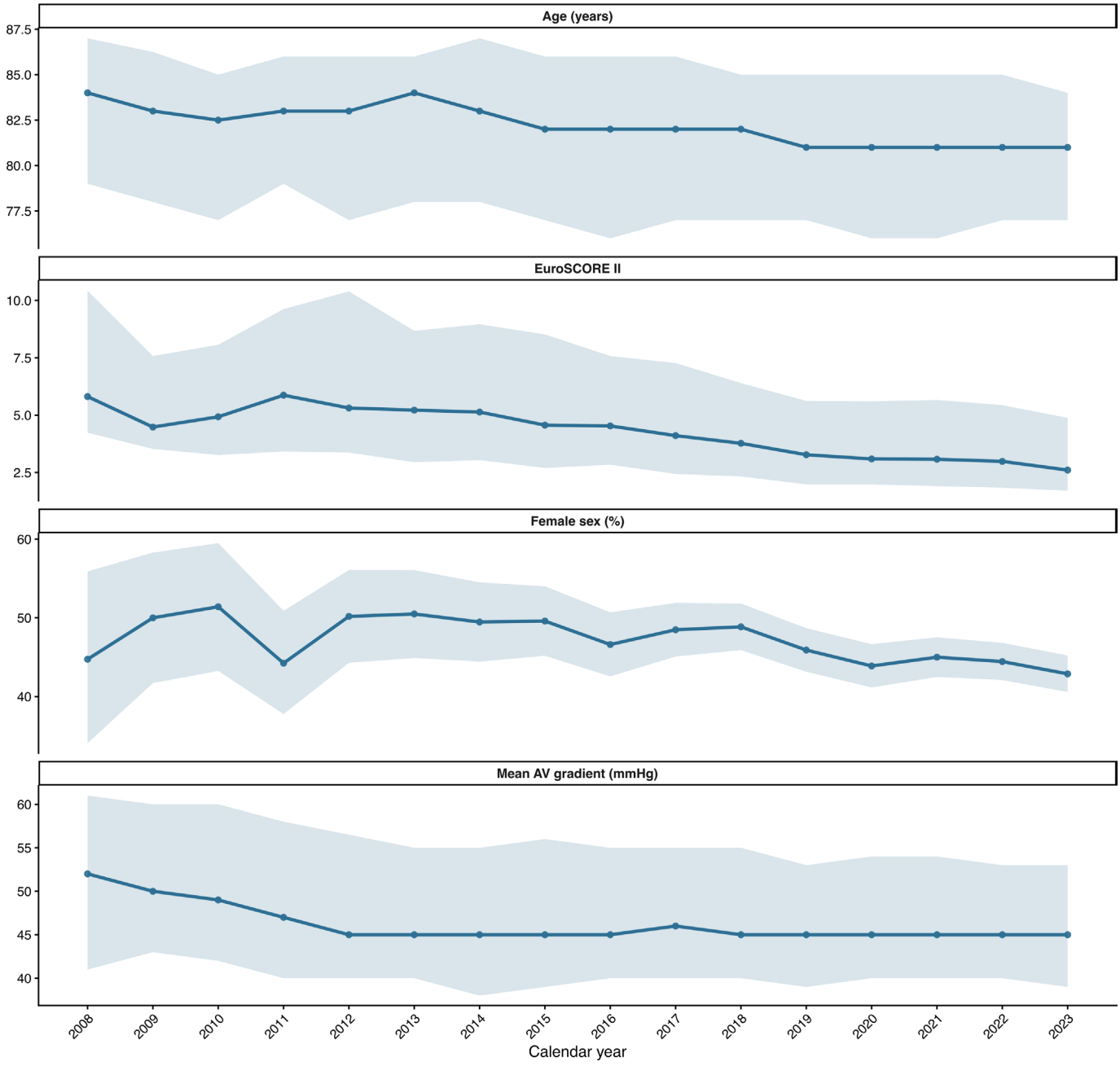

Figure 3 Temporal trends in baseline risk characteristics among patients undergoing transcatheter aortic valve implantation (TAVI). Lines represent annual medians with shaded areas indicating IQRs. EuroSCORE, European System for Cardiac Operative Risk Evaluation.

cerebral protection studies demonstrating retrieval of valvular and vascular debris,[21] as well as by transcranial Doppler studies showing surges in microembolic signals during key procedural steps.[23] In this context, the association between porcelain aorta and higher stroke risk is biologically plausible, as it likely reflects a greater burden of friable calcific material. Similarly, a history of stroke likely reflects an underlying burden of cerebrovascular and systemic atherosclerosis, including carotid and aortic arch pathology, which predisposes to recurrent embolic events. Patients with prior stroke may also be more susceptible to clinically manifest ischaemic injury owing to reduced cerebrovascular reserve.[24]

Previous studies have also confirmed that women have an increased risk of stroke.[25 26] Anatomical and physiological differences, including smaller aortic arch dimensions and vessel size, are well documented and may predispose women to embolic events during or after the procedure.[27] In addition, hormonal factors, particularly the loss of oestrogen's cerebroprotective effects after menopause, may further contribute to worse neurological outcomes.[28]

An apparent lower risk of early stroke was observed among patients undergoing TAVI-in-SAVR compared with those treated for native aortic valve disease. This finding contrasts with a recent meta-analysis,[29] which did not detect a significant difference in stroke risk between TAVI-in-SAVR and native TAVI. Importantly, the present observation should be interpreted strictly as exploratory. Patients undergoing TAVI-in-SAVR differed substantially from those with native valve disease, including younger age, lower transvalvular gradients, less frequent predilatation and a higher prevalence of aortic regurgitation, indicating pronounced

Table 3 Independent baseline and procedural predictors of 30-day stroke within 30 days after TAVI (multivariable model)

Predictor	30-day stroke		
	OR	95% CrI	PD
Age (years)	1.06	0.93–1.21	0.82
Sex			
Male		Reference	
Female	1.33	1.01–1.76	0.98
Body mass index	0.99	0.97–1.00	0.92
Estimated glomerular filtration rate	0.97	0.85–1.10	0.66
Hypertension	1.29	0.88–1.90	0.90
Diabetes mellitus	1.09	0.86–1.39	0.76
Chronic pulmonary disease	1.19	0.94–1.50	0.93
Peripheral vascular disease	1.22	0.94–1.58	0.93
Atrial fibrillation	1.04	0.84–1.29	0.62
History of myocardial infarction	1.12	0.86–1.46	0.80
History of PCI	0.86	0.66–1.12	0.86
History of cardiac surgery	0.79	0.55–1.10	0.92
History of stroke	2.42	1.88–3.09	1.00
Left ventricular ejection fraction			
≥50%		Reference	
31–49%	1.24	0.94–1.61	0.94
21–30%	1.02	0.61–1.67	0.54
<20%	1.33	0.58–2.82	0.77
Average aortic valve gradient	1.09	0.97–1.23	0.93
Annulus diameter	1.04	0.90–1.20	0.71
Aortic valve area	0.99	0.87–1.12	0.57
Moderate/severe aortic valve insufficiency	0.90	0.61–1.29	0.70
Moderate/severe mitral valve insufficiency	0.94	0.68 – 1.29	0.64
Valve morphology			
Tricuspid		Reference	
Bicuspid	1.03	0.70–1.49	0.57
Indication for TAVI			
Aortic stenosis		Reference	
Aortic insufficiency	0.32	0.07–1.17	0.96
Porcelain aorta	1.92	1.32–2.75	0.99
Predilatation	0.88	0.67–1.16	0.82
Postdilatation	0.84	0.64–1.09	0.90
Oversizing	1.17	0.90–1.52	0.87
Rapid pacing	1.21	0.89–1.65	0.89
Valve-in-valve			
Native		Reference	
TAVI-in-SAVR	0.38	0.16–0.84	0.99
Expanding mechanism			
BEV		Reference	
SEV	1.44	1.01–2.07	0.98
Access site			
Transfemoral		Reference	
Transapical	0.66	0.36–1.17	0.92
Direct aortic access	0.71	0.27–1.64	0.77
Via subclavian	1.47	0.83–2.51	0.91

PD is the probability of direction, p (OR>1).
BEV, balloon-expandable valve; CrI, credible interval; PCI, percutaneous coronary intervention; PD, probability of direction; SAVR, surgical aortic valve replacement; SEV, self-expanding valves; TAVI, transcatheter aortic valve implantation.

selection and indication bias. Given these marked baseline and procedural differences, no causal inference can be drawn, and this finding should not be interpreted as evidence favouring one treatment strategy over another.

Similarly, the higher stroke incidence observed among patients treated with SEVs should be viewed with caution. Prior head-to-head randomised trials, including SOLVE-TAVI[30] and SCOPE I,[31] have not demonstrated consistent differences in early stroke risk between self-expanding valve (SEV) and balloon-expandable valve (BEV). Some analyses[32] restricted to newer-generation devices have suggested modest differences; however, these findings remain inconsistent. Although several mechanistic hypotheses have been proposed, such as increased procedural manipulation related to repositionable SEV,[33] as well as potential interactions between supra-annular leaflet position or taller stent frames and the ascending aorta, the present analysis lacks device-generation detail and procedural granularity to evaluate these mechanisms. Consequently, the observed association between valve type and stroke in this study should be regarded as descriptive and hypothesis-generating, rather than evidence of a causal device-specific effect.

Although relatively infrequent, stroke after TAVI carries a disproportionate impact, being strongly associated with increased mortality, long-term disability, reduced quality of life and substantial healthcare costs. Preventing stroke, therefore, remains a major clinical priority. The two large RCTs of routine cerebral embolic protection during TAVI (PROTECTED-TAVR[8] and BHF PROTECT-TAVI)[9] did not demonstrate an overall reduction in stroke, underscoring the continued challenges in preventing neurological complications. However, exploratory analyses have suggested potential benefit in some geographic regions,[34] leaving open the possibility that certain high-risk patients may derive meaningful protection. A better understanding of patient-related and procedure-related risk factors, as highlighted in the present study, may facilitate improved clinical judgement to identify patients at the highest risk and guide the adoption of procedural strategies or future RCTs of neuroprotective devices in those most likely to benefit.

Limitations

Several limitations need to be acknowledged. Stroke events were identified through registry coding rather than central adjudication, which may have introduced misclassification, particularly of milder events. Although multiple imputation was applied to address missing covariates, measurement error may still have influenced the estimates.

Residual confounding due to unmeasured or incompletely measured variables cannot be excluded. Important predictors such as detailed procedural complexity, carotid or aortic arch atherosclerosis and imaging-derived measures of calcification were not available in the registries and may therefore have influenced the observed associations.

The study period spanned more than a decade, during which valve technologies, implantation techniques and adjunctive therapies evolved considerably; some associations may therefore reflect temporal changes in practice rather than true patient-level risk. Although centre-level heterogeneity was modelled using random intercepts, practice-level differences in operator experience, procedural volume and peri-procedural management may not have been fully captured. In addition, stroke severity and functional outcomes could not be assessed, as standardised neurological or disability scales were not available in the registries. Detailed information on in-hospital antithrombotic and

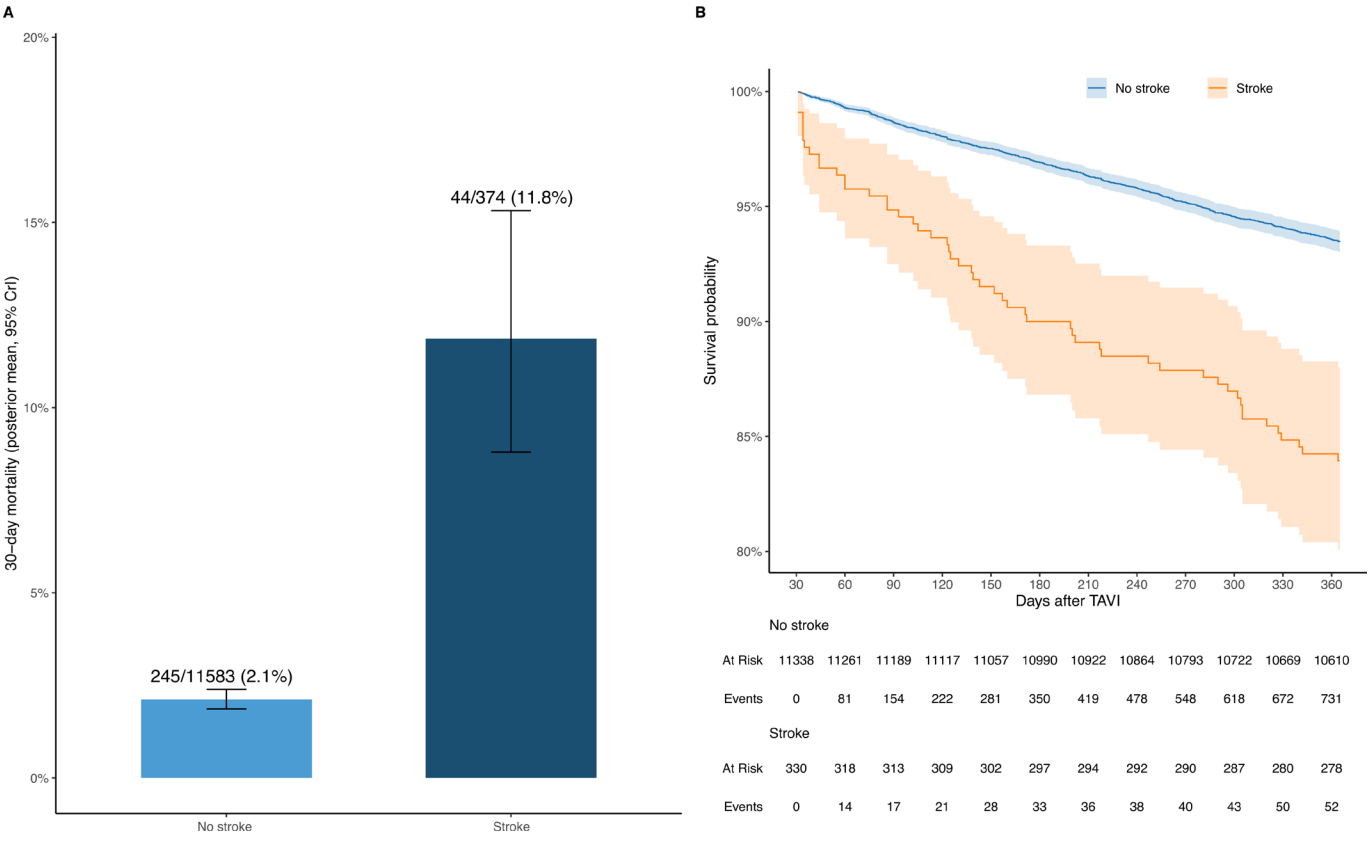

Figure 4 (A) The absolute numbers and percentages of all-cause mortality at 30 days in patients with and without stroke within 30 days after transcatheter aortic valve implantation (TAVI). (B) The Kaplan-Meier survival curves from a landmark analysis starting at 30 days and extending to 1-year post-TAVI.

anticoagulation therapy was not consistently available, which limited our ability to evaluate treatment-related effects on early stroke risk or to distinguish mechanisms underlying ischaemic vs haemorrhagic events. Finally, the HRs from the landmark survival analyses should be interpreted cautiously, as they represent conditional relative hazards among patients surviving to the landmark and are best viewed as measures of association rather than causal effects. Finally, as this analysis reflects Swedish practice within a universal healthcare system, generalisability to different healthcare settings may be limited.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

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