

Temporal trends of transcatheter aortic valve implantation practice in South Africa

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
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ABSTRACT

Background: The temporal trends in transcatheter aortic valve implantation (TAVI) practice and procedural benefits are well documented in high-income countries; however, data for upper-middle-income countries (UMIC) are sparse.

Objectives: This study aimed to describe the evolution of TAVI practice in South Africa, including patient and procedural characteristic profiles and outcomes, from 1 September 2014 to 31 December 2023.

Methods: The South African Heart Association (SHARE)-TAVI registry is a web-based, all-comers prospective registry. The 18 centres that were involved from the outset of the registry in September 2014 were included in our analysis.

Results: A total of 2 532 TAVIs were performed across the 18 centres. There was a steady increase in TAVI procedures, with most performed in private hospitals ($n = 2\ 251$). Waiting times were shorter in the private hospitals, with a median of 52 days (interquartile range [IQR] 29–82), compared with public hospitals, with a median of 70 days (IQR 61–85). Over time, the median age remained stable at 81 years (IQR 75–85). The European System for Cardiac Operative Risk Evaluation (EuroSCORE) II showed a continuous and significant decline from 4.9% (IQR 4.4, 8.6) in 2014/15 to 3.5% (1.9, 6) in 2023 ($p < 0.001$). Transfemoral access was the most prevalent access route utilised throughout the study period, and there was a trend of increased use of percutaneous closure devices with lower vascular complications (11% in 2014/15 to 5% in 2023; $p < 0.001$). There was also a notable reduction in peri-procedural strokes (10% in 2014/15 to 2% in 2023; $p < 0.0001$). Kaplan–Meier survival curves showed a gradual decrease in mortality risk ($p = 0.0344$). Accordingly, the 1-year mortality fell from 17% in 2014/15 to 6% in 2022 ($p < 0.001$).

Conclusion: This data showed a steady increase in the number of TAVI procedures during the study period, with a reduction in risk profiles despite the mean age remaining stable, consistent with international recommendations. Technical aspects of the procedures evolved and were associated with reduced complications.

Keywords: transcatheter aortic valve implantation practice, temporal trends, procedural benefits.

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INTRODUCTION

The advent of TAVI marked a paradigm shift in managing symptomatic, severe aortic stenosis, particularly in patients deemed high-risk for surgical aortic valve replacement. Pioneered by Cribier in 2002, this minimally invasive approach improved clinical outcomes, with 1-year mortality rates declining from

approximately 50% in inoperable patients to below 20% in contemporary studies.^(1,2) The remarkable progress can be attributed to refinements in patient selection, procedural expertise, evidence-based practice, and advancements in transcatheter device technology.⁽³⁻⁵⁾ To our knowledge, South Africa is the only African country performing TAVI in both the

public and private sectors. It is therefore a valuable source of TAVI data in the developing world.⁽⁶⁾ In South Africa, the first TAVI was performed in 2009, with subsequent expansion to 30 centres nationwide; the procedure is mostly performed in the private sector.^(4,5)

TAVI registries in high-income countries use patient and procedural characteristics to describe temporal trends in TAVI practice. Procedural characteristics include the anaesthesia type, the transcatheter device, and the vascular access used for the procedure. Modifications in these components are associated with reduced peri-procedural vascular complications and shorter hospital stays.⁽⁷⁾ Multiple previous TAVI registries demonstrated the importance of these modifications for immediate and long-term outcomes.⁽⁸⁻¹⁰⁾ The transfemoral route is preferred, with up to 90% of procedures now performed via this route.^(11,12) The current TAVI approach favours conscious sedation (CS) over general anaesthesia, and femoral arterial access via percutaneous femoral puncture and closure over surgical cut down.⁽¹³⁻¹⁶⁾

International guidelines for TAVI are based on data from high-income countries, whereas implementation in a UMIC has not been well characterised.^(8,17) Despite the promising data from first-world registries, funding for TAVI is severely limited in South Africa. There is an urgent need for more robust, local data on TAVI to inform patient selection and guide policy and funding for TAVI. To systematically evaluate TAVI outcomes within a local setting, the SHARE-TAVI registry was established in September 2014. This multicentre registry encompasses all TAVI referrals and procedures nationwide and represents the most comprehensive and robust database of TAVI in South Africa. This study seeks to analyse temporal trends in TAVI practice in South Africa based on data from the SHARE-TAVI registry, thereby contributing to the optimisation of patient care and procedural standards in the region.

METHODS

Study rationale

This study aims to characterise the demographic and procedural characteristics of patients receiving TAVI in South Africa. Analyses include temporal trends in waiting times, funding sources, hospital stay duration, and short- and long-term clinical outcomes.

Study population

The SHARE-TAVI registry is a prospectively collected, multicentre registry of all patients referred for TAVI in the South African public and private sectors. From September 2014 to December 2023, this registry enrolled 3 931 patients across 30 participating centres. The analysis was restricted to 18 centres ($n = 2\,532$ patients) that contributed to the registry since its inception to detect temporal trends. Twelve centres were excluded from the analysis because they did not enrol patients from the inception of the registry; therefore, data from these centres do not inform the temporal trends of the registry (Figure 1).

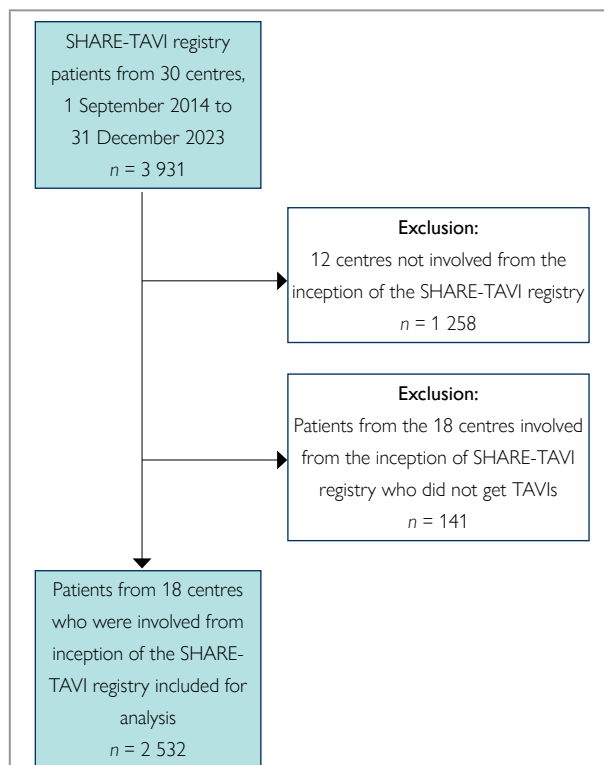


FIGURE 1: Recruitment of study participants. SHARE-TAVI: South African Heart Association transcatheter aortic valve implantation registry.

Statistical analysis

All analyses were performed using descriptive statistical methods. Continuous variables were assessed for normality using the Shapiro–Wilk test and represented as mean ± standard deviation for normally distributed data, or median with IQR for non-normally distributed data. Categorical variables were summarised using frequencies and percentages. For temporal trend analysis, we employed non-parametric Wilcoxon rank-sum tests to

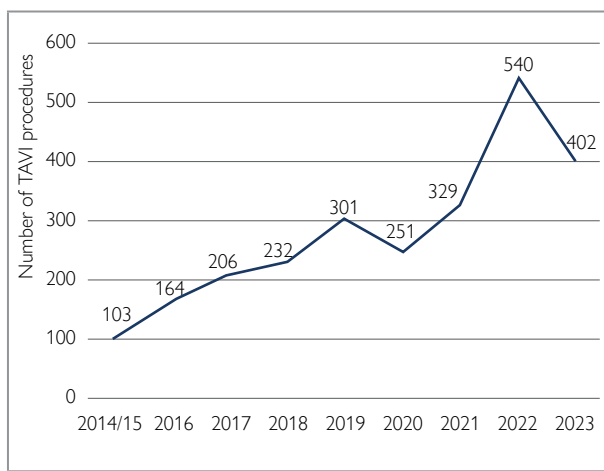


FIGURE 2: Trends in the number of TAVI (transcatheter aortic valve implantation) procedures from 2014 to 2023.

evaluate median differences in continuous variables across the study years. Proportional differences in categorical variables between years were assessed using chi-squared tests of association. The log-rank test was used to compare survival differences between groups. For normally distributed, cumulative mortality proportions, we performed one-way ANOVA (analysis of variance) to examine mean differences between study years. All tests were two-tailed, with $p < 0.05$ considered statistically significant.

Ethical considerations

Ethical approval was obtained from the Health Research Ethics Committee of Stellenbosch University (reference: N14/06/073). All data were anonymised to ensure the privacy and confidentiality of participants' personal information, and each participant was assigned a unique identifier.

RESULTS

From 1 September 2014 to 31 December 2023, 2 532 patients were prospectively included in the SHARE-TAVI registry at centres participating since its inception (Figure 1). Annual procedural rates increased from 103 in 2014/15 to 402 in 2023 (Figure 2). Most TAVI procedures were performed in the private sector, with the number increasing from 83 in 2014/15 to a peak of 490 in 2022. The number of cases performed in public hospitals annually remained ≤ 50 throughout the study period (Figure 3). Medical insurance companies covered most cases performed in private hospitals, either with full payment or co-payment, with the patient contributing out of pocket for the procedure. There was a decline in the full payment coverage provided by medical insurance companies from 55% in 2014/15 to 24% in 2023 (Figure 4). The waiting times to TAVI were significantly shorter in private hospitals, with a median of 52 days

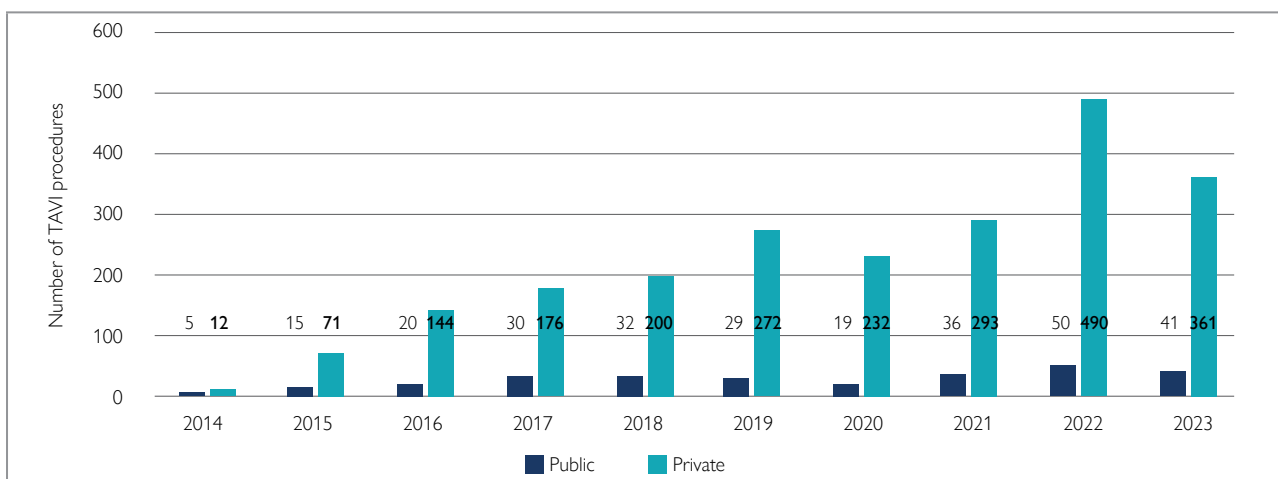


FIGURE 3: Trends in the number of TAVI (transcatheter aortic valve implantation) procedures in public and private hospitals.

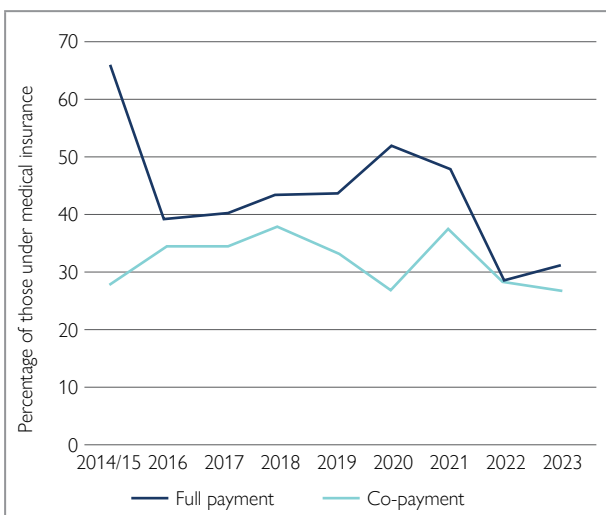


FIGURE 4: Payment method trends for transcatheter aortic valve implantation procedures performed in private hospitals.

Note: Co-payment indicates patients who were required to make an additional payment to supplement their medical insurance coverage.

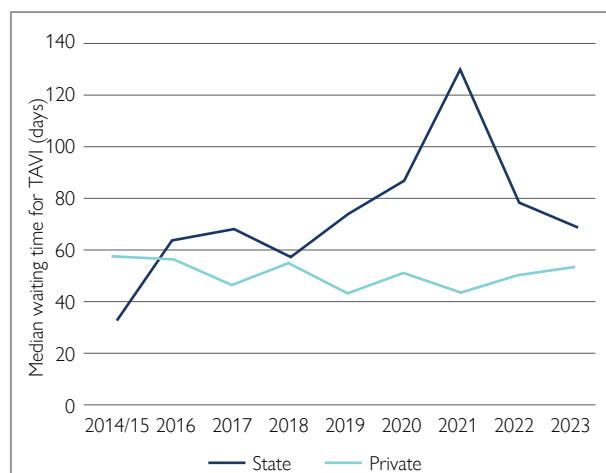


FIGURE 5: Trends in median waiting times to TAVI (transcatheter aortic valve implantation).

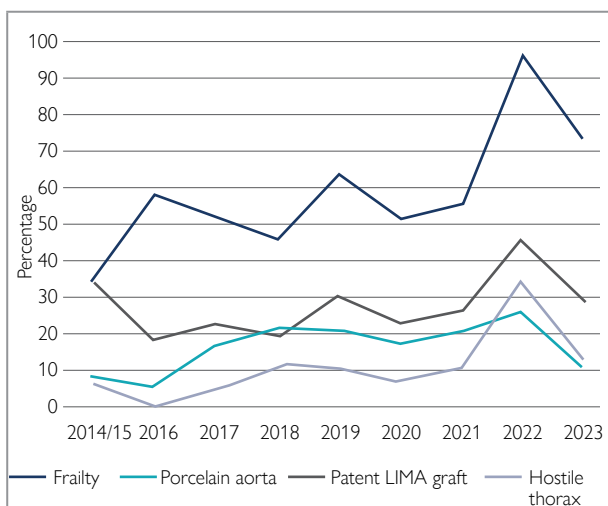


FIGURE 6: Contraindications to surgical aortic valve replacements leading to transcatheter aortic valve implantation.

LIMA: left internal mammary artery.

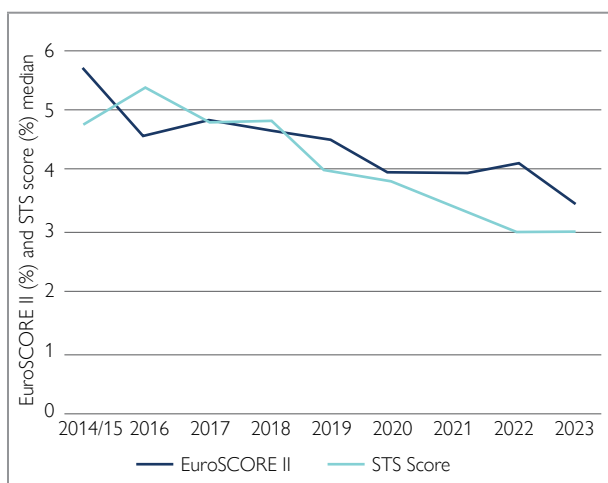


FIGURE 7: Trends in predicted risk of mortality according to EuroSCORE II and STS score.

Note: $p < 0.001$ comparing the initial scores to the last scores in 2023.

EuroSCORE II: European System for Cardiac Operative Risk Evaluation, STS: Society of Thoracic Surgeons.

TABLE I: Baseline characteristics of the study population.

n	2 532
	n (%)
Demographics	
Age, years median (IQR)	81 (75–84)
Male	1 491 (59)
Female	1 041 (41)
STS score, median (IQR)	4 (2.6–6.5)
Log EuroSCORE II, median (IQR)	16.3 (8–27)
Comorbidities	
Hypertension	1 858 (73)
Diabetes mellitus	601 (24)
Chronic lung disease	392 (15)
Peripheral vascular disease	386 (15)
Clinical findings	
Syncope	518 (20)
CCS	892 (35)
Atrial fibrillation	331 (13)
Previous CVA	218 (9)
Previous CABG	522 (20)
Previous aortic valve procedure	199 (8)
Previous PPM	250 (10)
Lab values	
Haemoglobin, median (IQR)	13 (11.8–14)
Contraindications to SAVR	
Frailty	536 (21)
Porcelain aorta	147 (6)
Patent LIMA graft	228 (9)
Hostile thorax	149 (6)
NYHA class, n (%)	
II	853 (39)
III	1160 (53)
IV	192 (9)
Not recorded	323

CABG: coronary artery bypass graft, CCS: chronic coronary syndrome, CVA: cerebrovascular accident, EuroSCORE II: European System for Cardiac Operative Risk Evaluation, IQR: interquartile range, LIMA: left internal mammary artery, NYHA: New York Heart Association, PPM: permanent pacemaker, SAVR: surgical aortic valve replacement, STS: Society of Thoracic Surgeons.

(IQR 29–82), compared with public hospitals, with a median of 70 days (IQR 61–85). There was an upward trend in TAVI waiting times in public hospitals, peaking in 2021, which coincided with the COVID-19 pandemic; however, waiting times remained unchanged in private hospitals (Figure 5).

Baseline characteristics

The study population’s median age was 81 years (IQR 75–84). The gender distribution revealed 59% males ($n = 1\,491$) and 41% females ($n = 1\,041$). Tables I and II show patients’ baseline characteristics. There were no significant differences in age, sex,

and left ventricular ejection fraction (LVEF) throughout the study period. A large proportion of the study population was hypertensive (73%, $n = 1\,858$). Diabetes mellitus (24%, $n = 601$) and atrial fibrillation (13%, $n = 331$) were common comorbidities. The median transvalvular aortic gradient was 44 mmHg (IQR 40–66.2), and the median LVEF was 58% (IQR 49–65). The 4 common contraindications to surgical aortic valve replacement (SAVR) were frailty, porcelain aorta, previous coronary artery bypass graft with a patent left internal mammary artery, and hostile thorax (Figure 6). As illustrated in Figure 7, the

TABLE II: Baseline characteristics per year of transcatheter aortic valve implantation procedure.

	All years	2014/15	2016	2017	2018	2019	2020	2021	2022	2023	p-value
n	2 532	103	164	206	232	301	251	329	540	402	
Age, years (range)	81 (33–91)	81 (50–91)	81 (59–97)	81 (59–97)	80 (33–96)	80 (50–94)	80 (42–96)	80 (41–97)	80 (38–95)	80 (54–95)	0.4463
	n (%)										
Men	1 491 (59)	54 (52)	85 (52)	120 (58)	128 (55)	160 (53)	153 (61)	211 (64)	323 (60)	257 (64)	0.023
HPT	1 858 (73)	71 (68)	108 (66)	139 (67)	174 (75)	206 (68)	175 (70)	210 (64)	370 (69)	285 (71)	0.001
DM	601 (24)	25 (24)	38 (23)	59 (29)	51 (22)	63 (21)	70 (28)	79 (24)	133 (25)	83 (21)	< 0.001
CVA/embolism	187 (7)	8 (9)	10 (6)	17 (8)	16 (7)	25 (8)	17 (7)	39 (12)	55 (10)	31 (7)	< 0.001
Previous CABG	522 (21)	28 (27)	41 (25)	50 (24)	53 (23)	61 (20)	53 (21)	63 (19)	104 (19)	69 (17)	< 0.001
Previous PPM	250 (10)	10 (9)	15 (9)	23 (11)	26 (11)	22 (7)	23 (9)	39 (12)	55 (10)	31 (7)	< 0.001
AF	331 (13)	7 (7)	27 (16)	27 (13)	36 (16)	27 (8)	32 (13)	38 (15)	89 (16)	48 (12)	0.002
NYHA											
II	853 (39)	27 (26)	44 (30)	59 (32)	64 (29)	108 (39)	109 (49)	138 (47)	175 (40)	129 (38)	< 0.001
III	1160 (53)	47 (45)	89 (61)	108 (59)	133 (60)	144 (52)	96 (42)	134 (46)	219 (50)	190 (56)	< 0.001
IV	192 (9)	14 (18)	12 (9)	15 (9)	23 (11)	24 (9)	19 (9)	19 (7)	44 (10)	22 (6)	< 0.001
Median											
Hb (g/dl)	13 (11.8, 14)	12.2 (11.3, 13.8)	12.4 (11.3, 13.5)	13 (11.9, 14)	13 (12, 14.2)	12.8 (11.3, 13.9)	13 (11.8, 14.1)	13.2 (12, 14.3)	13 (11.8, 14)	13 (11.9, 14.1)	< 0.001
Mean PG (mmHg)	44 (40, 66.2)	47 (40, 60)	47 (40, 58)	44 (38, 57)	45 (38.9, 54)	45 (40, 35)	44 (38, 55)	44 (39, 55)	44 (39, 55)	45 (38, 55)	0.0633
LVEF (%)	58 (49, 65)	53 (40, 63)	57 (45, 65)	58 (45, 65)	58 (45, 65)	56 (45, 65)	60 (50, 65)	58 (50, 65)	59 (50, 65)	60 (50, 65)	0.0853
EuroSCORE II	4.2 (2.3, 7.8)	5.7 (4.1, 8.7)	4.6 (3, 8.8)	4.8 (2.9, 8.9)	4.7 (2.5, 8)	4.5 (2.4, 8)	4 (1.9, 8)	4.2 (2.1, 8.9)	4.1 (2.2, 8)	3.5 (1.9, 6)	< 0.001
STS score	4 (2.6, 6.5)	4.8 (3.2, 7.25)	5.3 (3.3, 9)	4.8 (3.2, 7)	4.8 (2.5, 7.5)	4 (2.5, 6.2)	3.8 (2.3, 6.9)	3.4 (2.2, 5.9)	3 (2.3, 6)	3 (2.3, 6)	< 0.001

AF: atrial fibrillation, CABG: coronary artery bypass graft, CVA: cerebrovascular accident, DM: diabetes mellitus, EuroSCORE II: European System for Cardiac Operative Risk Evaluation, Hb: haemoglobin, HPT: hypertension, LVEF: left ventricular ejection fraction, NYHA: New York Heart Association, PG: pressure gradient, PPM: permanent pacemaker, STS: Society of Thoracic Surgeons.



FIGURE 8: Trends of balloon-expandable and self-expanding valves in TAVIs (transcatheter aortic valve implantations).

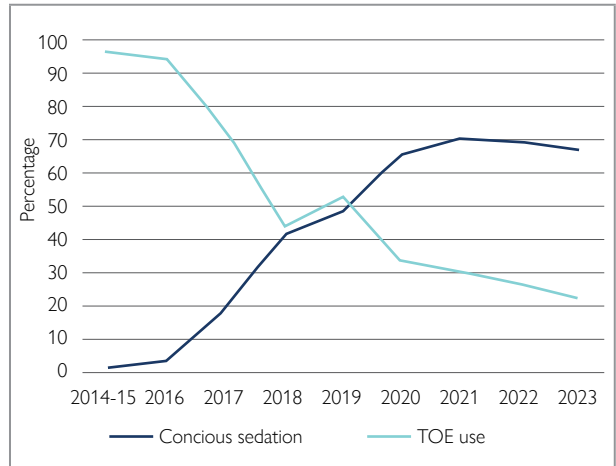


Figure 11: Trends in TOE (transoesophageal echocardiography) use and conscious sedation.

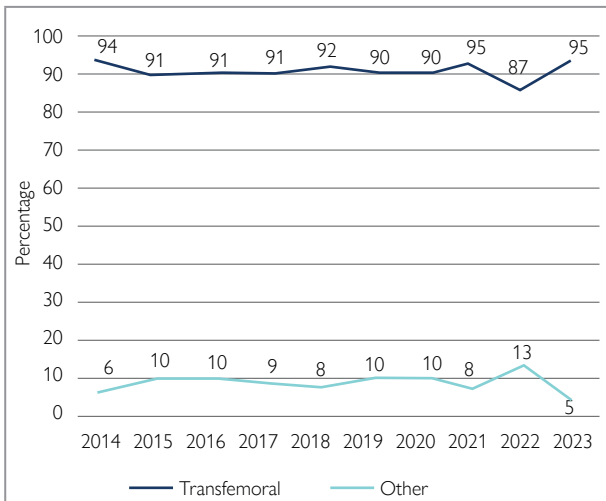


FIGURE 9: Trends in access sites for transcatheter aortic valve implantation.
Note: Other includes transaortic, transapical, subclavian, and carotid.

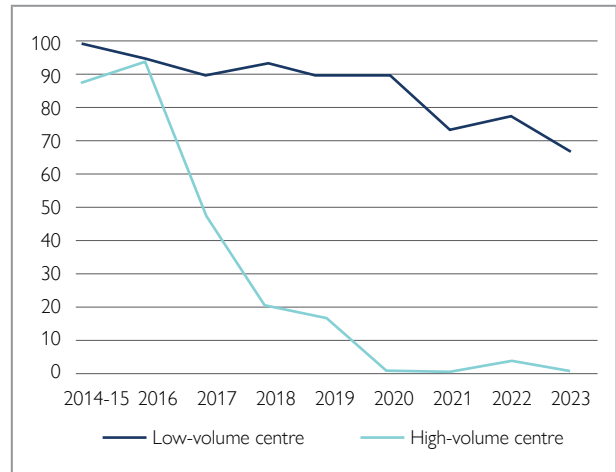


FIGURE 12: Trends in transoesophageal echocardiography use according to total transcatheter aortic valve implantation rates for the centres.
Note: Low-volume means < 200 transcatheter aortic valve implantations performed over the study period; high-volume means > 200 transcatheter aortic valve implantations performed over the study period.

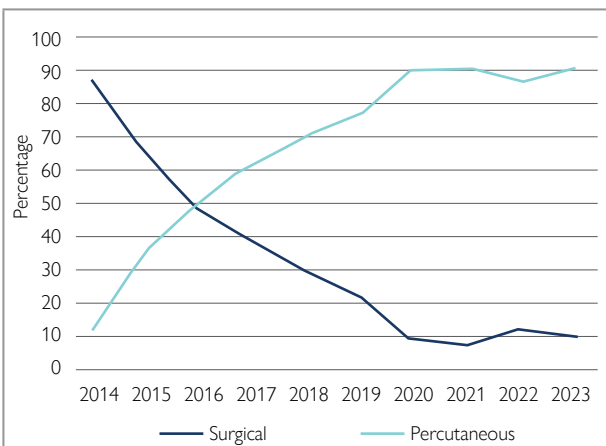


FIGURE 10: Trends in use of surgical versus percutaneous closure of transfemoral access sites.

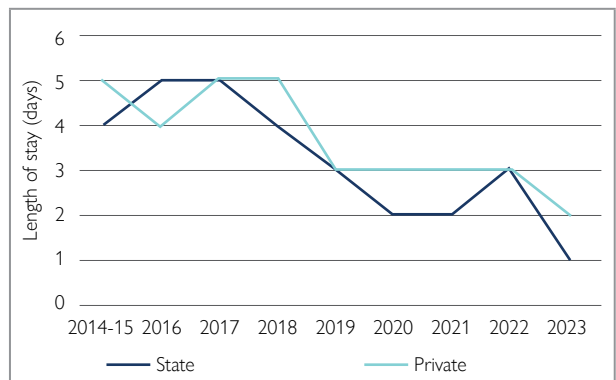


FIGURE 13: Trends of median length of hospital stay for transcatheter aortic valve implantation patients in public and private hospitals.

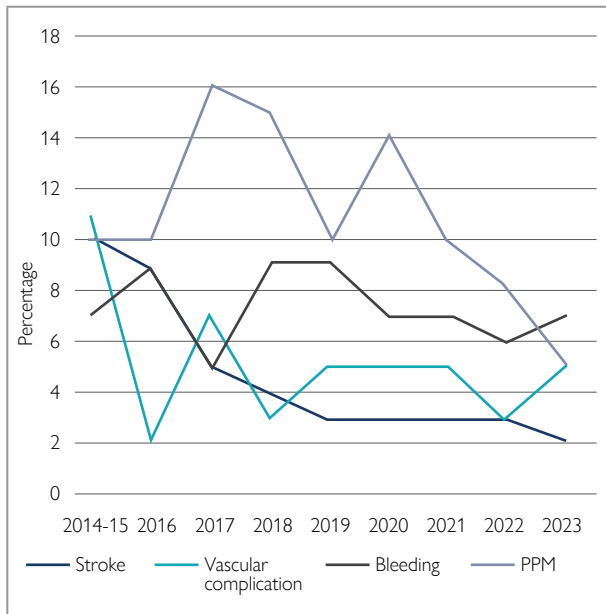


FIGURE 14: Trends of major adverse outcomes.
 Note: Bleeding as per VARC-2 (Valve Academic Research Consortium-2) definition. PPM: permanent pacemaker.

EuroSCORE II declined significantly from 4.8% (IQR 3.2–8.6) in 2014 to 3.5% (IQR 2.3–6.9) in 2023 ($p < 0.001$).

Procedural characteristics

There was a higher overall utilisation of BEVs, which remained unchanged (Figure 8). The ratio between BEVs and self-expanding valves remained constant at 0.87 to 1. There was no change in the rate of transfemoral access (92%, IQR 87–95) (Figure 9). Alternate access sites for those with poor femoral access included transaortic, transapical, subclavian, and carotid. In cases utilising transfemoral access, there was a temporal increase in the use of percutaneous vascular closure devices (12% in 2014 vs. 90% in 2023; $p < 0.001$), accompanied by a concurrent reduction in surgical closure (Figure 10). There was a statistically significant increase in the use of CS for TAVI (0% in 2014/15 vs. 70% in 2023; $p < 0.001$). There was a notable reduction in the utilisation of intra-procedural transoesophageal echocardiography (TOE) (Figure 11). Another notable reduction was TOE utilisation in centres with higher TAVI rates; centres that performed > 200 cases over the study period had a significant decline in TOE use (100% in 2014 vs. to 1% in 2023; $p < 0.001$), while centres that performed < 200 cases had consistent TOE use > 60% (Figure 12).

Clinical outcomes

The hospital stay length in both the public and private sectors shortened throughout the study period (4 days in 2014/15 vs. 1 day in 2023) (Figure 13). During the study period, there was a significant decline in peri-procedural complications. The rate of peri-procedural strokes reduced from 10% in 2014/15 to 2% in 2023 ($p < 0.0001$) (Figure 14). The need for permanent pacing declined, possibly reflecting improvements in the implantation

technique of self-expanding valves (Figure 14). Kaplan–Meier survival curves showed a gradual decrease in mortality risk over the years ($p = 0.0344$) (Figure 15).

DISCUSSION

The global adoption of TAVI has demonstrated exponential growth, particularly in high-income countries, whereas UMICs have seen a more gradual uptake. Registry data reveal striking disparities: Germany’s procedural volume increased from 637 cases in 2008 to 13 264 in 2014, while the United Kingdom (UK) TAVI registry reported growth from 366 procedures in 2008 to 1 271 in 2012.^(14,15) Conversely, UMICs such as Brazil documented only 661 cases over a decade (95 in 2012–2017 vs. 566 in 2018–2019), while the SHARE-TAVI registry recorded 3 931 procedures from 2014 to 2023, demonstrating steady, though comparatively slower, expansion.^(19,20) This differential adoption pattern reflects the complex interplay of economic, infrastructural, and healthcare system factors that characterise procedural differences in resource-variable settings.

Consistent with global trends, the SHARE-TAVI registry reflects a transition from treating only high-risk patients to treating those with intermediate and low risk.^(18,21) This paradigm shift, particularly evident after 2015, aligns with expanding indications supported by international guidelines and registry data.⁽²²⁾ The median patient age of 81 years corresponds closely with European registries, suggesting comparable patient demographics despite differing healthcare landscapes.^(9,10,17) The observed improvement in baseline risk may be multifactorial, potentially reflecting broader patient selection criteria, as recommended by guidelines based on large, randomised trials; however, further research is needed to elucidate these relationships in an African context.⁽²⁶⁾

In South Africa, TAVI utilisation remains constrained by financial and systemic barriers. Procedural costs pose a significant burden, particularly in the public sector, where 86% of the population seeks healthcare.⁽²³⁾ Private sector adoption, while more robust, remains hampered by insurance coverage limitations, particularly regarding valve prosthesis reimbursement. This has created a growing disparity in access, with public hospital procedures declining from one-third of total cases to just 10% by 2023 in our study. The resulting inequities lead to prolonged waiting times in the public sector, potentially compromising clinical outcomes and underscoring the need for healthcare system interventions to ensure equitable access to TAVI in the future.

Notable procedural refinements were observed in the SHARE-TAVI registry, paralleling global trends. High-volume centres demonstrated particularly notable progress, reducing TOE utilisation from > 80% to < 5% while increasing CS adoption from 0% to 70%. Transfemoral access was predominant in our registry (> 90% of cases), with percutaneous closure replacing surgical methods (67% in 2014/15 vs. 10% by 2020), which correlated with reduced bleeding complications according to VARC-2 (Valve Academic Research Consortium-2) criteria. Alternative access routes remained uncommon, likely due to low

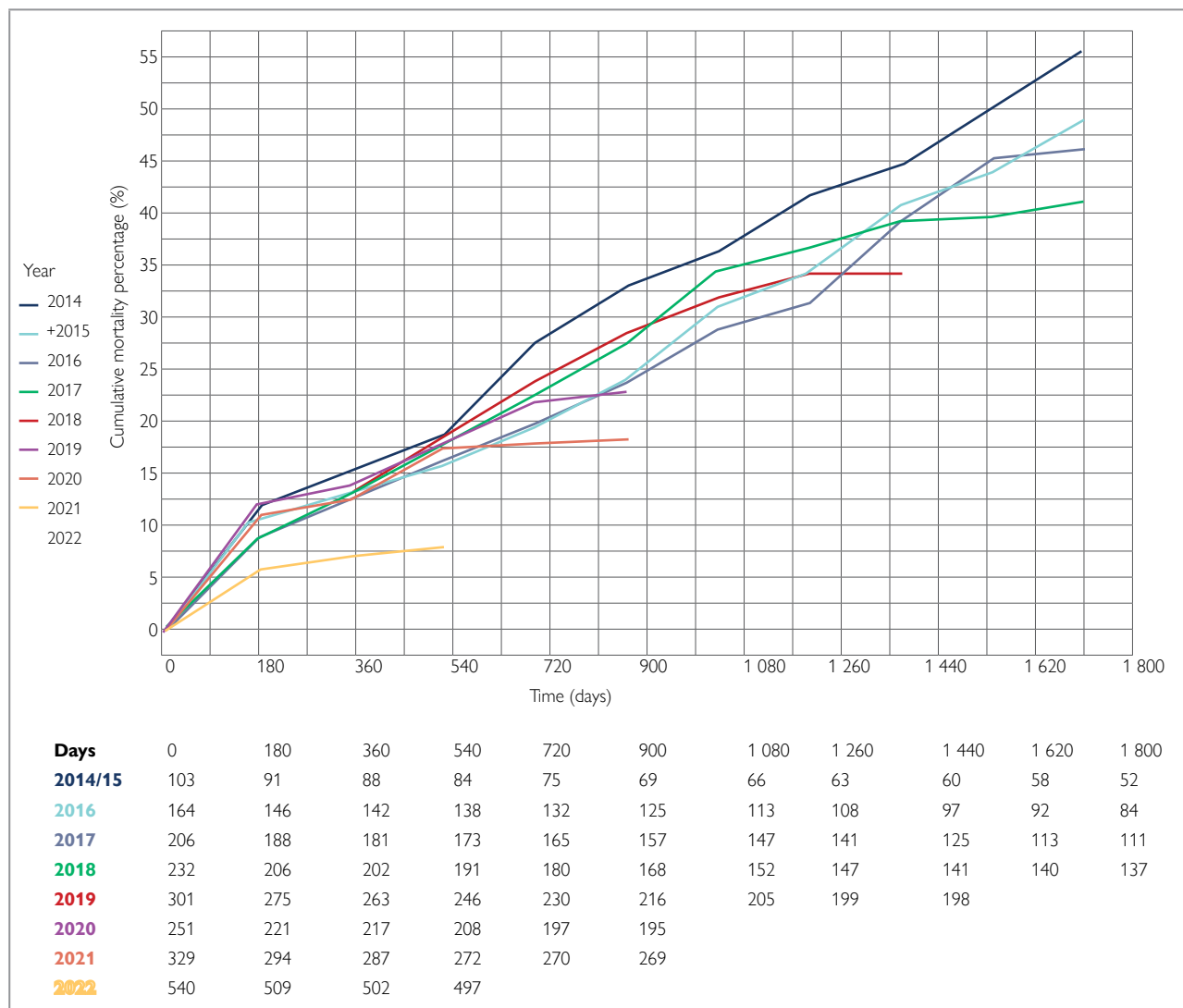


FIGURE 15: Mortality at 5 years; Kaplan–Meier curves for all-cause mortality between 2014 and 2022.

procedural volumes and technical complexity.⁽²⁴⁾ Transapical access has been phased out due to poorer outcomes. The need for pacemaker implantation was 10% in 2014/15 compared with 11.8% in the United States TAVI registry and 12.4% in the UK registry in a similar time frame.^(8,10) The pacemaker implantation rate then fluctuated and stands at 5% (2023), which is comparable to other registries.⁽¹⁸⁾

The length of hospital stay declined for both private and public sector patients: 5 days in the early study period versus 1 day in recent years in public hospitals, and 6 days versus 2 days in private hospitals. The overall length of stay was similar to the findings in the UK TAVI, FRANCE 2, FRANCE TAVI, and Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) registries.^(8,25) Longer hospital stays in the private sector were likely due to multidisciplinary discharge protocols, including physiotherapy, which is not freely available in the public sector. This decline in length of stay will positively affect procedure costs.

There was a significant temporal trend in survival, showing improved long-term survival with each consecutive calendar year. The mortality reduction likely reflects multiple synergistic factors, including improved patient selection, with more low-to-intermediate risk patients with fewer comorbidities, and it highlights the safety of the procedure in this population. The data reported here help inform our local heart teams' decision-making and patient counselling.

CONCLUSION

The findings of the SHARE-TAVI registry provide compelling evidence of a successful TAVI implementation in a UMIC, despite continued challenges of healthcare inequity. Temporal trends mirrored those in first-world countries, and refinements in the procedure over time have led to shorter hospital stays, reduced peri-procedural strokes, and lower overall mortality risk.

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Conflict of interests : none declared

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