

# Impact of Updated Guidelines on TAVI Outcomes in a Health Maintenance Organization in Brazil: A Decade-Long Retrospective Study

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## Abstract

**Background:** Aortic stenosis is a progressive condition that leads to significant morbidity and mortality if untreated. Transcatheter aortic valve implantation (TAVI) provides a less invasive alternative to surgical aortic valve replacement (SAVR), particularly for high-risk patients.

**Objectives:** This study evaluates the outcomes of TAVI procedures performed in a Health Maintenance Organization (HMO) in Brazil from 2013 to 2023, focusing on the impact of clinical guidelines updated in 2018.

**Methods:** A retrospective cohort study included 325 patients diagnosed with severe symptomatic aortic stenosis who underwent TAVI. Patients were divided into two groups: those treated before January 2019 (n=56) and those treated from January 2019 onwards (n=269). The primary outcomes included all-cause mortality and major complications, while the secondary outcomes encompassed procedural success rates and specific complication rates. Continuous variables were analyzed using the Mann-Whitney test, and categorical variables were analyzed using the chi-square test or Fisher's exact test. Statistical significance was defined as  $p < 0.05$ .

**Results:** After January 2019, the shift to self-expanding valves was associated with a statistically significant reduction in pacemaker implantation rates (from 28.6% to 18.2%,  $p=0.03$ ), whereas other outcomes did not reach statistical significance.

**Conclusions:** The implementation of updated protocols was associated with improved TAVI outcomes, especially a reduced need for pacemaker implantation, supporting its expanded use in intermediate-risk patients.

**Keywords:** Aortic Valve Stenosis; Transcatheter Aortic Valve Replacement; Practice Guideline; Cardiovascular Surgical Procedures.

## Introduction

Aortic stenosis is one of the most common and serious valve diseases, particularly affecting the elderly population. This progressive condition, characterized by the narrowing of the aortic valve, leads to obstructed blood flow from the heart, resulting in significant morbidity and mortality if left untreated. Traditionally, the gold standard for treating severe symptomatic aortic stenosis has been surgical aortic valve replacement (SAVR), which has proven to be highly effective. However,

SAVR is associated with substantial surgical risks, particularly in elderly patients and those with multiple comorbidities.<sup>1-3</sup>

In response to these challenges, transcatheter aortic valve implantation (TAVI) emerged in 2002 as a less invasive alternative to SAVR. Initially, TAVI was indicated for patients with prohibitive surgical risks who were unsuitable for SAVR. Over time, robust clinical data and advancements in technology have expanded TAVI's indications to include patients with intermediate and even low surgical risks. Studies have demonstrated that TAVI offers comparable, if not superior, outcomes to SAVR across various risk profiles. Additionally, TAVI procedures are associated with shorter hospital stays, quicker recovery times, and lower rates of complications such as severe bleeding and atrial fibrillation, making it an increasingly preferred option.<sup>2,4</sup>

Despite its benefits, TAVI is not a risk-free procedure. Complications such as paravalvular leaks, the need for permanent pacemaker implantation, and stroke have been areas of concern. However, continuous improvements in valve technology and

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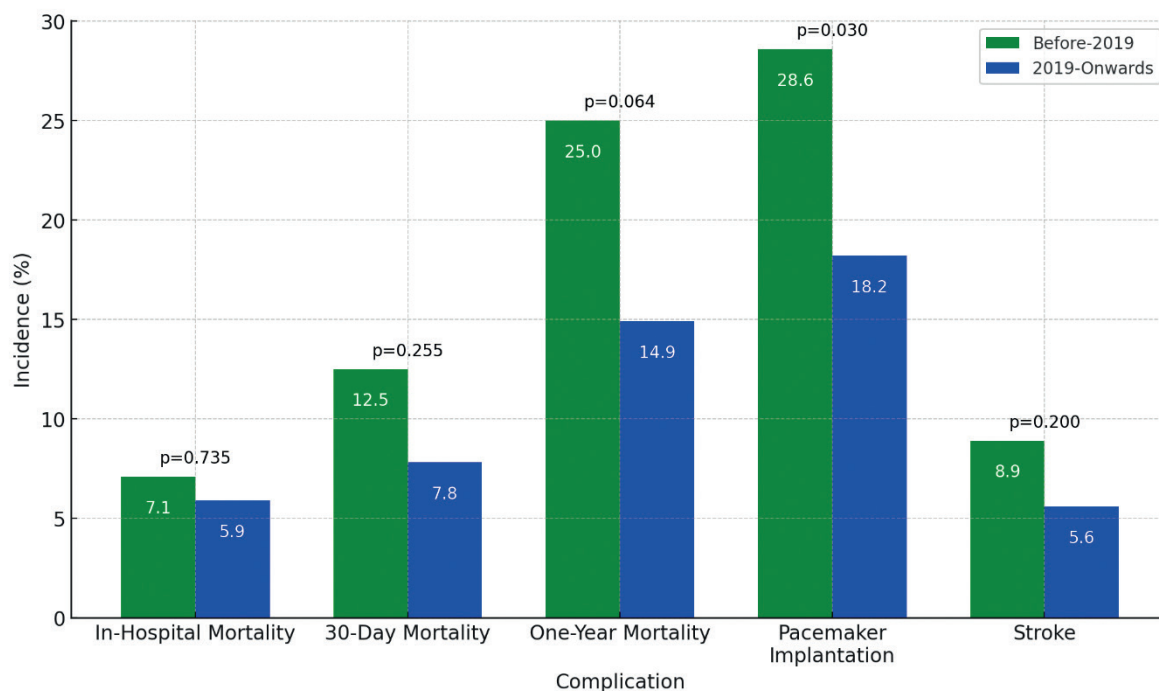
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procedural techniques have significantly mitigated these risks. For instance, the introduction of next-generation balloon-expandable and self-expanding valves has led to improved procedural outcomes and reduced complication rates.<sup>5-7</sup>

The durability of TAVI valves, especially as their use extends to younger patients with longer life expectancies, remains a critical consideration. Long-term data from studies like the FRANCE-2 Registry and the NOTION trial indicate that TAVI valves demonstrate favorable durability, with lower rates of structural valve deterioration (SVD) compared to SAVR over follow-up periods extending beyond five years.<sup>8-10</sup>

This study aims to evaluate the outcomes of TAVI procedures performed within a Health Maintenance Organization (HMO) in Belo Horizonte, Brazil, over a decade (2013-2023). Specifically, it seeks to assess the impact of the updated clinical guidelines and procedural protocols introduced in 2018 on patient outcomes. Understanding these dynamics will help clarify TAVI's role in modern cardiovascular care and its potential to improve the quality of life for patients with severe aortic stenosis.

## Methods

### Study Design

This is a retrospective cohort study with a secondary data analysis design that evaluated the outcomes of patients undergoing TAVI from July 2013 to December 2023. Data

were collected and analyzed to assess the impact of updated clinical guidelines and procedural protocols introduced in 2018 on patient outcomes.

### Study Setting

The study was conducted within a private health insurance provider with approximately 1.54 million beneficiaries in Belo Horizonte and its metropolitan region.

### Patient Population

The study included all patients diagnosed with severe symptomatic aortic stenosis who underwent TAVI. Patients were divided into two groups according to the timing of their procedures: those treated before January 2019 and those treated from January 2019 onward. This division enabled the evaluation of outcomes within the context of new clinical guidelines and protocols implemented at our institutions. Severe aortic stenosis was defined as an aortic valve area  $\leq 1.0$  cm<sup>2</sup>, mean gradient  $\geq 40$  mmHg, or peak velocity  $\geq 4$  m/s, in addition to the presence of compatible symptoms.

**Before 2019:** The TAVI procedure was primarily indicated for patients with severe symptomatic aortic stenosis who were considered at high or prohibitive surgical risk. These patients typically had multiple comorbidities or were deemed unsuitable candidates for traditional SAVR based on clinical assessments and multidisciplinary team discussions. The

selection criteria were more conservative, with the procedure being reserved for cases where surgery posed a significantly higher risk of mortality and morbidity.

**2019 onwards:** Following the introduction of updated clinical guidelines and protocols, the eligibility criteria for TAVI were expanded. The new protocols incorporated recent evidence from major clinical trials and expert consensus, which demonstrated the safety and efficacy of TAVI in patients with intermediate — and in some cases, even low — surgical risk. As a result, TAVI became more broadly accessible to a wider population of patients, including those with moderate comorbidities and lower surgical risk profiles. Furthermore, the updated protocols emphasized the use of newer-generation transcatheter valves, which have been associated with improved outcomes, including lower rates of paravalvular leak and a reduced need for permanent pacemaker implantation. As of 2018, the healthcare provider also began authorizing TAVI for patients aged  $\geq 70$  years with intermediate surgical risk, in accordance with evidence from the PARTNER trials.

#### Data Collection and Patient Outcomes

Administrative and clinical data were retrieved from the healthcare provider's internal database, which contains detailed records of all TAVI procedures performed within the system. Data collection encompassed a broad range of information, including patient demographics, clinical characteristics, procedural details, and follow-up outcomes. Specifically, demographic and clinical characteristics included age, sex, New York Heart Association (NYHA) functional class, comorbidities, and surgical risk scores. Procedural details included the type of valve used (balloon-expandable or self-expanding), the access route (transfemoral or transapical), and procedural success. Follow-up data were obtained through a review of electronic medical records, administrative databases, and, when necessary, telephone contact with the patients or their families.

Primary clinical outcomes focused on overall mortality rates and the incidence of major complications such as stroke, the need for pacemaker implantation, and paravalvular leak. Secondary outcomes encompassed procedural success rates, hospital readmission, and acute kidney injury. These outcomes were assessed at multiple time points: during the hospital stay, at 30 days post-procedure, and one year post-procedure.

#### Statistical Analysis

Descriptive statistics were used to summarize patient characteristics and outcomes. Continuous variables were expressed as medians with interquartile ranges, and categorical variables as frequencies and percentages. Comparisons between groups (before and after 2019) were performed using chi-square or Fisher's exact tests for categorical variables, and the Mann-Whitney test for continuous variables. Statistical significance was defined as  $p < 0.05$ . All analyses were performed using R software, version 4.3.1.

#### Data Source and Handling

The study's database was retrieved from secondary databases maintained by the HMO in its own data repositories. Data are stored at the individual level in a pseudonymized

form, but are handled anonymously thereafter. All these data represent administrative claim data or beneficiary registration information routinely collected by the HMO, which comprises comprehensive and mature databases that undergo strict security, governance, and validation procedures.

#### Ethical Considerations

The study protocol was reviewed and approved by the Institutional Review Board of the healthcare system. Additionally, ethical oversight was provided by an external Ethics Committee, which approved the study under protocol number 65934522.0.0000.5138. To safeguard patient confidentiality, all data were anonymized in accordance with ethical standards.

#### Results

From July 2013 to December 2023, a total of 325 patients underwent TAVI within the HMO. Of these, 56 procedures were performed before January 2019, and 269 from January 2019 onwards.

Patient age was presented as a median and interquartile range because the data did not follow a normal distribution, as indicated by the Shapiro-Wilk test. The median age was 83.4 years (66.5–97.9) before 2019 and 84.2 years (66.8–100.0) from 2019 onwards, with no statistically significant difference between the groups ( $p=0.21$ , Mann-Whitney test).

A higher proportion of females was observed in both groups, accounting for 51.8% before 2019 and 58.0% from 2019 onwards, without significant difference ( $p=0.37$ , chi-square test). The distribution of NYHA functional classes was predominantly in classes III and IV, with a similar pattern across the two periods. The demographic and clinical characteristics are summarized in Table 1.

**Table 1 – Demographic and Clinical Characteristics of Patients**

Characteristics		Before-2019 (n=56)	2019-Onwards (n=269)
Number (%) of procedures		56 (17.2)	269 (82.8)
Age, years (median, interquartile range)		83.4 (66.5–97.9)	84.2 (66.8–100.0)
Sex, n (%)	Female	29 (51.8)	156 (58.0)
	Male	27 (48.2)	113 (42.0)
NYHA classification Number (%)	NYHA Class III	28 (50.0)	135 (50.0)
	NYHA Class IV	16 (29.0)	78 (29.0)
Device Model. Number (%)	CoreValve	5 (8.9)	0 (0.0)
	Sapien 3	4 (7.1)	1 (0.4)
	CoreValve/ Evolute R	37 (66.1)	29 (10.8)
	Other	10 (17.9%)	239 (88.8%)

NYHA: New York Heart Association.

Table 2 and the Central Figure show the distribution of valve device models and access routes used over the study period. A significant shift was observed after 2019, with a decrease in the use of balloon-expandable valves and an increase in the adoption of self-expanding valves ( $p < 0.01$ , chi-square test). The transfemoral route remained the preferred access in both cohorts, with no significant difference.

Regarding clinical outcomes, the in-hospital mortality rate decreased from 7.1% before 2019 to 5.9% after 2019 ( $p = 0.735$ , chi-square test). Similarly, the 30-day mortality rate declined from 12.5% to 7.8% ( $p = 0.255$ ), and the one-year mortality rate decreased from 25% to 14.9%, showing a trend toward statistical significance ( $p = 0.064$ ).

The need for permanent pacemaker implantation, an important complication associated with TAVI, was significantly reduced from 28.6% to 18.2% ( $p = 0.030$ , chi-square test) in the 2019-onwards group. The incidence of stroke also declined from 8.9% to 5.6%, although without reaching statistical significance ( $p = 0.200$ ). These outcomes are summarized in Table 3.

## Discussion

The results of this study highlight significant improvements in clinical outcomes for patients undergoing TAVI within a private healthcare system, particularly following the implementation of updated guidelines and procedural protocols in 2018. The data reveal enhanced procedural success rates and reduced mortality and complication rates, consistent with broader trends observed in contemporary TAVI research.<sup>2,11</sup>

The procedural success rates in our study were notably high, with 98% in the pre-2019 cohort and 99% in the post-2019 cohort. These results are consistent with other studies indicating that TAVI is a reliable procedure with high success rates across various patient populations. For example, the PARTNER 3 trial reported a procedural success rate exceeding 98%, reinforcing the robustness of TAVI procedures.<sup>4,12</sup>

The observed reduction in mortality rates is particularly encouraging. The one-year mortality rate decreased from 25% in the pre-2019 cohort to 14.9% in the post-2019 cohort. This improvement aligns with findings from recent studies documenting enhanced survival rates with the advent of next-generation TAVI devices and refined procedural techniques. Additionally, studies have reported significant reductions in all-cause mortality and stroke rates in TAVI patients compared to those undergoing SAVR, highlighting the effectiveness of TAVI in improving patient outcomes.<sup>7,13</sup>

The incidence of major complications, such as the need for pacemaker implantation and stroke, also showed a notable decline in the post-2019 cohort. The rate of pacemaker implantation decreased from 28.6% to 18.2%, and the stroke incidence fell from 8.9% to 5.6%. These reductions reflect global trends where newer TAVI technologies and improved procedural protocols have led to better safety profiles. The meta-analysis by Lerman et al. supports these findings, showing that the risk of complications such as stroke and pacemaker implantation has decreased with the use of newer TAVI devices.<sup>11,14,15</sup>

One of the critical considerations for TAVI, especially as it is increasingly used in younger, lower-risk patients, is valve durability. Our study aligns with recent data suggesting that the hemodynamic performance and durability of TAVI valves are comparable to those of surgical valves over mid- to long-term follow-ups. For instance, the PARTNER 3 trial and other long-term studies have reported similar rates of bioprosthetic valve failure and the need for reintervention between TAVI and SAVR, suggesting that TAVI is a viable long-term solution for aortic stenosis.<sup>12,15,16</sup>

The integration of TAVI into the Brazilian healthcare landscape, particularly with its recent inclusion in the Brazilian Unified Public Health System (SUS) in 2022, represents a significant milestone in the treatment of aortic stenosis. Data from the RIBAC-NT and TAVIDOR registries illustrate the evolving nature of TAVI procedures in Brazil, demonstrating a trend towards improved outcomes and reduced complications over time. The TAVIDOR registry highlights a shift towards minimalistic implantation techniques and a reduction in the clinical complexity of patients undergoing TAVI, which has contributed to lower in-hospital mortality and complication rates in recent years. This trend is further supported by findings from the RIBAC-NT registry, which emphasizes the critical impact of procedural complications, such as major vascular complications

**Table 2 – Valve Type and Access Route**

Valve Type	Before-2019 (n=56)	2019-Onwards (n=269)	p-value
Balloon-Expandable, n (%)	36 (64)	105 (39)	<0.01
Self-Expanding, n (%)	20 (36)	165 (61)	<0.01
Transfemoral, n (%)	50 (89)	248 (92)	0.52
Transapical, n (%)	6 (11)	22 (8)	0.52

**Table 3 – Procedural Outcomes and Complications**

Outcomes	Before-2019 (n=56)	2019-Onwards (n=270)	p-value
In-Hospital Mortality, n (%)	4 (7.1)	16 (5.9)	0.735
30-Day Mortality, n (%)	7 (12.5)	21 (7.8)	0.255
One-Year Mortality, n (%)	14 (25.0)	40 (14.9)	0.064
Pacemaker Implantation, n (%)	16 (28.6)	49 (18.2)	0.030
Stroke, n (%)	5 (8.9)	15 (5.6)	0.200



and acute kidney injury, on patient outcomes. These results underscore the importance of continued refinement in procedural techniques and operator experience, especially as TAVI is adopted across a diverse range of healthcare facilities with varying levels of expertise. As Brazil continues to integrate TAVI more broadly, adherence to best practices and the development of high-volume centers will be crucial in ensuring optimal outcomes for patients nationwide.<sup>17,18</sup>

The findings from this study have several clinical implications. Firstly, the high procedural success and reduced complication rates underscore the viability of TAVI as a first-line treatment for aortic stenosis, even in lower-risk patients. Secondly, the data support the continued use and development of TAVI technologies, emphasizing the need for ongoing refinement of procedural techniques and post-procedural care protocols to further enhance patient outcomes.<sup>16,19,20</sup>

Furthermore, the improvements observed from 2019 onwards underscore the importance of adhering to updated clinical guidelines and adopting new technologies in clinical practice. This is consistent with the broader trend in cardiovascular interventions, where continuous innovation and evidence-based practice are essential for optimizing patient care.<sup>1,2,21</sup>

While the results are promising, this study has certain limitations. The retrospective design and single healthcare system setting may limit the generalization of the findings. Additionally, longer follow-up periods are needed to fully assess the durability and long-term performance of TAVI valves, particularly in younger patient populations.

## Conclusion

This study demonstrates that the implementation of updated clinical guidelines and the refinement of institutional TAVI protocols have contributed to significant improvements in clinical outcomes, particularly a reduction in the need for permanent pacemaker implantation. The expansion of eligibility criteria and the adoption of newer-generation transcatheter valves have facilitated broader access to the procedure for patients across a spectrum of surgical risk profiles, while maintaining standards of safety and efficacy. These findings reinforce the role of TAVI as a well-established therapeutic option for the treatment of severe aortic stenosis, even in real-world clinical settings beyond randomized controlled trials.

## Author Contributions

Conception and design of the research: Horta MGC, Kelles SMB; acquisition of data: Horta MGC, Scherrer LR, Souza

MG, del-Valle M, Martin FB; analysis and interpretation of the data: Horta MGC, Borin MC, Scherrer LR, Souza MG, del-Valle M, Martin FB, Kelles SMB; statistical analysis: Borin MC, Scherrer LR, Souza MG, del-Valle M, Martin FB; writing of the manuscript: Horta MGC, Borin MC, Kelles SMB; critical revision of the manuscript for intellectual content: Horta MGC, Borin MC, Tupinambas JT, Martins CR, Reis DP, Ribeiro GJC, Zocrato KC, Carvalho LMA, Freitas MP, Barbosa MM, Talim MCT, Kelles SMB.

## Potential Conflict of Interest

All authors are employees of Unimed-BH, the health maintenance organization where the study was conducted. This institutional affiliation may represent a potential conflict of interest, as Unimed-BH was both the setting of the study and the source of data. However, Unimed-BH did not influence the study design, data analysis, interpretation of results, or the decision to submit the manuscript for publication. The authors declare no other conflicts of interest related to this work.

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This study was funded by Unimed-BH.

## Study Association

This study is not associated with any thesis or dissertation work.

## Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee on Animal Experiments of the Francisco das Chagas Lima e Silva da Santa Casa de Misericórdia de Belo Horizonte under the protocol number 65934522.0.0000.5138.

## Use of Artificial Intelligence

During the preparation of this work, the author(s) used Microsoft Copilot for to enhance translation to english. After using this tool/service, the author(s) reviewed and edited the content as needed and take full responsibility for the content of the published article.

## Availability of Research Data

The data cannot be made publicly available due to the data are confidential patient records from Unimed-BH and cannot be shared due to legal and ethical restrictions.

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