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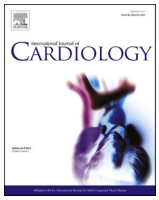

In-hospital outcomes of valve-in-valve vs. native valve transcatheter aortic valve implantation in Brazil: A propensity-matched analysis

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ABSTRACT

Introduction: Transcatheter aortic valve implantation (TAVI) has become the standard of care for elderly patients with severe aortic stenosis. While valve-in-valve TAVI (ViV-TAVI) offers a less invasive alternative to redo surgery in patients with degenerated surgical heart valves (SHV), evidence remains limited.
Methods: This is a retrospective study based on a Brazilian clinical registry of TAVI patients between January 2009 and December 2021. We compared ViV-TAVI patients with native aortic valve (NV-TAVI) patients. Temporal trends, procedural, and in-hospital outcomes were evaluated. We performed propensity score matching (PSM) and multivariable regression to adjust comparisons.
Results: Among 3194 patients from 25 centers, 135 underwent ViV-TAVI. The ViV volume increased slightly over time in proportion to NV-TAVI. After PSM, there were 127 ViV and 248 NV-TAVI patients. ViV patients had lower device success (71.7% vs. 87.9%; OR 0.35; 95% CI 0.20–0.60; $p < 0.01$) and permanent pacemaker implantation (4.7% vs. 12.9%; OR 0.35; 95% CI 0.13–0.79; $p < 0.01$) compared with NV-TAVI. Valve embolization was more frequent in ViV-TAVI (3.9% vs. 0.8%; OR 4.44; 95% CI 1.03–25.59; $p = 0.04$). Among ViV patients, no difference in embolization risk was detected (OR 1.11; 95% CI 0.18–11.80; $p = 0.91$) between radiopaque vs. radiolucent SHV. Major vascular complication, major or life-threatening bleeding, stroke, and in-hospital mortality did not differ significantly between groups.
Conclusion: During the study period, a modest but significant increase was observed in the number of ViV-TAVI procedures. Device success and PPI were lower, and valve embolization was more frequent in ViV-TAVI compared with NV-TAVI. In-hospital safety outcomes did not differ between groups.

1. Introduction

Transcatheter aortic valve implantation (TAVI) has become an established therapeutic option for elderly patients with severe aortic stenosis across the surgical risk spectrum. [1–4] In developed nations, TAVI has become the standard of care for this population over the last decade, overtaking surgical aortic valve replacement (SAVR) [5].

Originally developed for use in native valve aortic stenosis (NV-TAVI), the technique has evolved to include valve-in-valve (ViV) procedures for treating degenerated surgical heart valves (SHV), offering an alternative to redo SAVR in high-risk elderly patients [6]. Although ViV-TAVI can improve valve function and symptoms, some concerns remain regarding its safety and effectiveness in routine clinical practice, due to greater procedural complexity and potential differences in outcomes when compared with NV-TAVI [7].

Despite its clinical relevance, as few trials have been conducted and registries have enrolled only a limited number of patients, there is a lack of evidence in the literature on ViV-TAVI. Furthermore, most published evidence on ViV-TAVI and NV-TAVI patients derives from observational studies conducted in advanced economies, which may not reflect reality in underserved populations, as there are several inherent disparities, such as differences in patient characteristics, available equipment, and centers' expertise. Importantly, comparisons between ViV-TAVI and NV-TAVI are intended to contextualize procedural and safety outcomes rather than to establish therapeutic equivalence, as both procedures address fundamentally diverse disease states and patient populations.

Therefore, the objectives of this study were: I) to evaluate temporal trends in ViV-TAVI procedures in Brazil, and II) to compare procedural and in-hospital outcomes between ViV and NV-TAVI groups.

2. Methods

2.1. Study sample and protocol

This is a retrospective observational study based on a Brazilian multicenter clinical registry, evaluating clinical and imaging variables before and after ViV and NV-TAVI from January 2009 to December 2021. All centers in Brazil that routinely perform TAVI were contacted and invited to participate in the Brazilian Registry for Evaluation of the Results of Aortic Bioprosthesis Catheter Implantation (RIBAC-NT), coordinated by the Brazilian Society of Hemodynamics and Interventional Cardiology (SBHCI). The only exclusion criterion for this analysis was TAVI in previously implanted transcatheter heart valves (THV; TAV-in-TAV procedures).

2.2. Data collection

The following information was collected for each patient: I) baseline clinical characteristics and complementary tests; II) TAVI planning information; III) techniques and materials used in the procedure; IV) procedural success and complications; V) in-hospital TAVI care-related data. Clinical outcomes were evaluated according to VARC-2 criteria [8]. Predicted effective orifice areas were obtained for all sizes of the following THVs implanted in native valves: Sapien XT, Sapien 3/Ultra (Edwards Lifesciences, Irvine, CA), CoreValve, Evolut R/PRO (Medtronic, Minneapolis, MN), Acurate neo and neo2 (Boston Scientific, Boston, MA) [9,10]. Subsequently, these values were indexed by the patients' body surface area.

2.3. Study outcomes

The outcomes of interest were: I) the number of ViV-TAVI procedures per year; II) procedural outcomes, including rates of device success, coronary artery occlusion, valve embolization, conversion to open surgery; III) in-hospital outcomes for ViV vs. NV-TAVI patients, specifically major vascular complication, major or life-threatening bleeding, stroke, permanent pacemaker implantation (PPI) and in-hospital mortality; IV) in an exploratory analysis, compare predicted prosthesis-patient mismatch (PPM) between ViV-TAVI and NV-TAVI and; V) also as an exploratory analysis, compare valve embolization rates in ViV-TAVI procedures with radiopaque vs. radiolucent SHV.

2.4. Statistical analysis

Categorical variables are reported as n (%). Continuous variables are expressed as mean ± SD or median (interquartile range), as appropriate. Normality was assessed by the Anderson-Darling test. Baseline variable comparisons between groups were made using Welch's *t*-test or the Mann-Whitney *U* test for continuous variables, as appropriate, and the chi-square test for categorical variables. The annual ViV-to-NV TAVI ratio was calculated and a local polynomial regression curve was fitted to model and visualize the trend over time. A traditional logistic regression model was fitted to test the interaction between procedure group and time. Propensity score matching, using a one-to-two matching process and a 0.2 caliper, was carried out to adjust for intergroup (ViV vs. NV-TAVI) differences, using the greedy nearest neighbor matching algorithm by the R package "MatchIt". The variables used for propensity score matching included age, gender, body mass index, hypertension, diabetes, New York Heart Association class, previous coronary artery

disease, previous percutaneous coronary intervention, previous coronary artery bypass graft (CABG), chronic obstructive pulmonary disease, creatinine, hemoglobin, left ventricular ejection fraction (LVEF), mean aortic valve pressure gradient, pulmonary artery systolic pressure (PASP), EuroSCORE II, THV generation, approach, procedure year and state where TAVI was performed. Standardized mean differences (SMD) were used to assess balance across all variables, while variance ratios (VR) were calculated only for continuous variables. Cutoffs for adequately balanced variables were < 0.1 SMD and VR between 0.5 and 2 [11,12]. To account for covariate imbalances, Firth's bias-reduced penalized-likelihood logistic regression models were fitted and adjusted for imbalanced covariates. In the study of valve embolization in ViV-TAVI, a Firth's model with only the intercept and SHV radiopacity was fitted due to the low number of events. All *p*-values were 2-sided, and p-values <0.05 were considered significant. For data analysis, R Statistical Software 4.5.2 (Foundation for Statistical Computing, Vienna, Austria) was used.

3. Results

3.1. Temporal trends

Fig. 1 outlines the flow diagram of the study sample for the ViV vs. NV-TAVI comparison. There were 3194 patients from 25 Brazilian centers in the RIBAC-NT registry, of whom 2 underwent TAV-in-TAV and were excluded. A total of 135 patients underwent ViV-TAVI, accounting for 4.2% of the total sample. The number of ViV-TAVI procedures performed in Brazil per year is shown in Fig. 2. During the study period, there was a significant increase in the number of ViV-TAVI and NV-TAVI procedures performed annually. Regression analysis showed that has remained stable since 2017.

3.2. Sample characteristics

Baseline clinical and echocardiographic characteristics of the study population before and after matching are shown in Table 1. The majority of procedures for both groups were performed in the Southeast (70%) and South (18%) regions. Before matching, ViV-TAVI patients were younger than NV-TAVI (77 [71, 81.5] vs. 82 [77, 86], respectively), presented higher rates of previous CABG (25.2% vs. 14.1%), worse LVEF (60 [48, 66] % vs. 63 [53, 68] %), higher PASP (50.4 ± 16.8 mmHg vs. 41.9 ± 13.2 mmHg) and a markedly greater EuroSCORE II (8.2 [4.2, 13.5] vs. 4.5 [2.5, 8.2]), all $p < 0.05$. Among ViV-TAVI patients, information on SHV radiopacity was available for 54 patients: 14 were radiolucent and 40 were radiopaque. Characteristics of these patients are provided in Supplemental Table 1. After one-to-two matching, a total of 127 ViV-TAVI and 248 NV-TAVI were selected. EuroSCORE II, gender, and hypertension were the only remaining imbalanced covariates after matching, with EuroSCORE II presenting VR < 0.5 and the other two SMD > 0.1. The complete matching balance assessment is presented in Supplemental Table 2.

3.3. Procedural characteristics and outcomes

Procedural characteristics and outcomes for the unmatched and matched cohorts are provided in Table 2 and Fig. 3. Among matched patients, THV platform (self-expanding vs. balloon-expandable) and generation were well balanced between groups: self-expanding valves were used in 55.9% of ViV-TAVI and 54.0% of NV-TAVI cases, and new-generation devices in 74.8% and 74.6%, respectively. Temporal trends in THV device selection are shown in Supplemental Fig. 1, which shows a clear shift toward newer-generation devices over time in both groups. Among ViV-TAVI patients, the most implanted balloon-expandable valve (BEV) and self-expanding valve (SEV) sizes were both 23 mm; in NV-TAVI, the most frequent sizes were 26 mm for BEV and 29 mm for SEV. As expected, THVs were, on average, smaller (24.6 mm vs. 27.0 mm) in the ViV-TAVI group. A comprehensive description of THV size stratified by THV type (balloon-expandable vs. self-expanding) may be found in Supplemental Table 3. Postprocedural aortic valve mean gradient was higher in ViV patients (16.5 vs. 9.4 mmHg; $p < 0.01$). Device success rate was significantly lower in ViV-TAVI compared with NV-TAVI (71.7% vs. 87.9%; OR 0.35, 95% CI 0.20–0.60; $p < 0.01$), mostly due to elevated post-implant gradients. A detailed breakdown of device failure causes in the ViV-TAVI group is shown in Supplemental Fig. 2. The rate of predicted severe PPM in the ViV group was 14.1% compared with 1.2% for the NV group ($p < 0.01$), as shown in

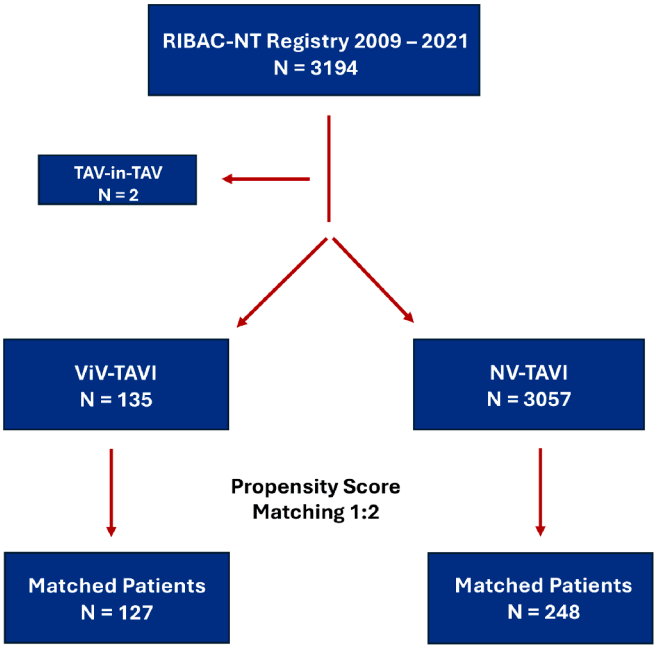

Fig. 1. Patient flow. From a pool of 3194 patients, propensity score matching was used to match valve-in-valve (ViV-TAVI) and native valve transcatheter aortic valve implantation (NV-TAVI) at a 1:2 ratio.

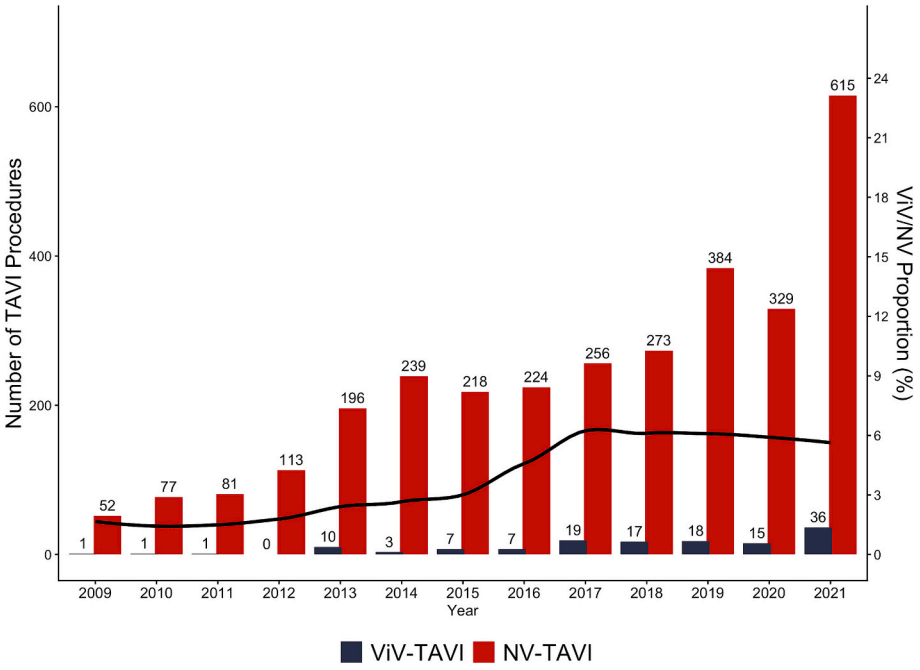

Fig. 2. Temporal trends of valve-in-valve (ViV-TAVI) and native valve transcatheter aortic valve implantation (NV-TAVI) patients undergoing TAVI in Brazil from 2009 to 2021. The black line shows the local polynomial regression for the ViV/NV proportion.

Supplemental Fig. 3. Conversion to open surgery was not statistically different between groups (2.4% vs. 1.2%; OR 1.55, 95% CI 0.32–7.39; $p = 0.57$). Two cases of coronary artery occlusion were reported in the matched NV-TAVI group. Valve embolization was more frequent in ViV-TAVI (3.9% vs. 0.8%; OR 4.44, 95% CI 1.03–25.59; $p = 0.04$). Among the five valve embolizations in ViV patients, four occurred with new-generation THVs (three with Evolut R/Pro and one with a Portico) and one with an early-generation (Sapien XT). The two embolizations in the NV-TAVI group involved a CoreValve (early-generation THV) and an Evolut R/Pro. In an exploratory analysis comparing embolization rates

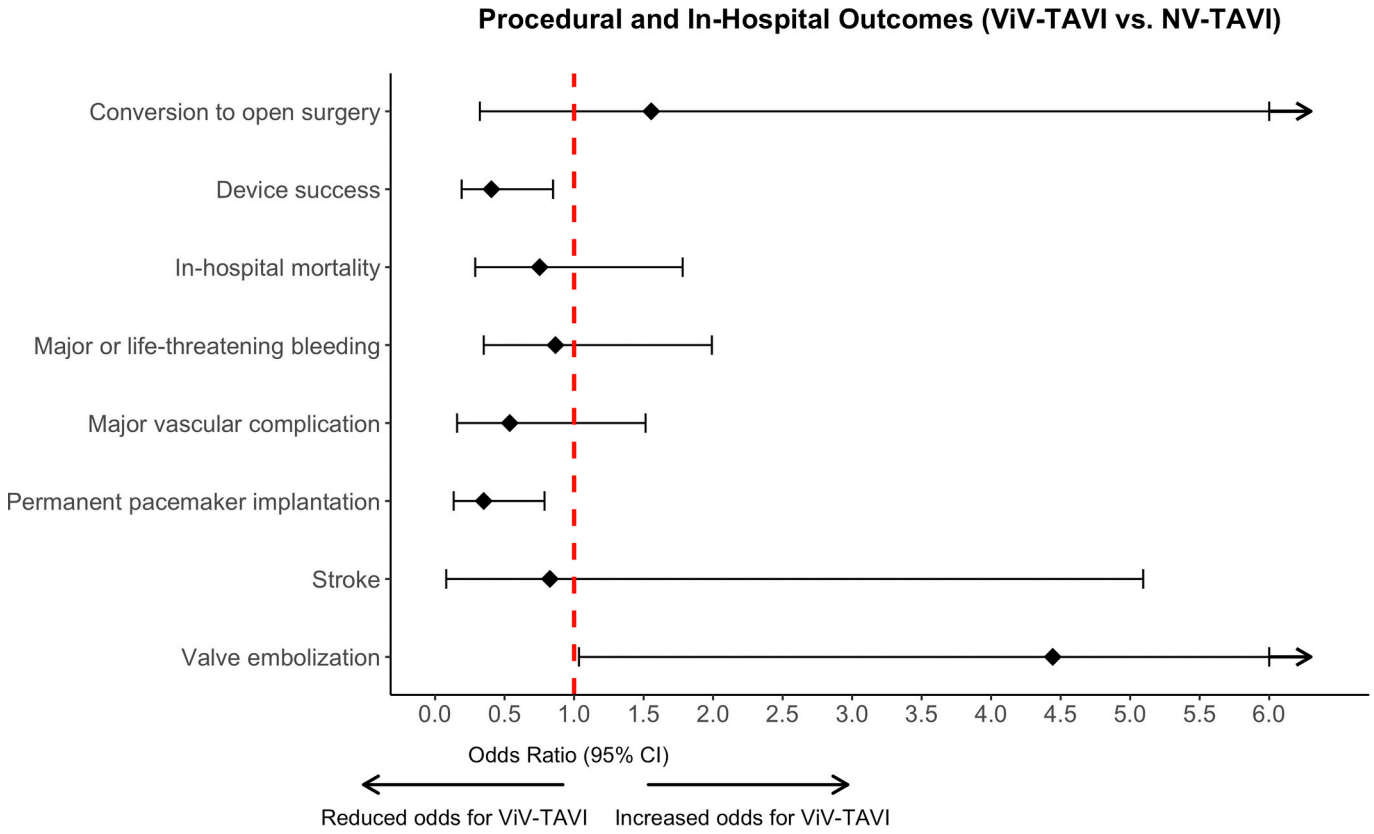

Fig. 3. Forest plot illustrating results of Firth's logistic regression models adjusted for gender, EuroSCORE II, and hypertension comparing valve-in-valve (ViV-TAVI) and native valve transcatheter aortic valve implantation (NV-TAVI) patients from the matched cohort.

Table 1
Baseline and echocardiographic characteristics for the unmatched and matched patient cohorts.

	Non-matched			Matched		
	ViV-TAVI (*n* = 135)	NV-TAVI (*n* = 3057)	P-value	ViV-TAVI (*n* = 127)	NV-TAVI (*n* = 248)	P-value
Age, y	77.0 [71.0, 81.5]	82.0 [77.0, 86.0]	<0.01	77.0 [72.1, 82.0]	78.0 [72.0, 83.0]	0.81
Male gender	89 (65.9)	1553 (50.8)	<0.01	83 (65.4)	173 (69.8)	0.45
BMI, kg/m^2	26.4 ± 4.8	26.6 ± 4.7	0.63	26.6 ± 4.8	26.8 ± 4.6	0.61
Hypertension	93 (68.9)	2065 (67.5)	0.82	88 (69.3)	160 (64.5)	0.42
Diabetes mellitus	49 (36.3)	1015 (33.2)	0.58	48 (37.8)	85 (34.3)	0.58
NYHA III/IV	101 (74.8)	1972 (64.5)	0.02	93 (73.2)	183 (73.8)	1.00
CAD	59 (43.7)	1451 (47.5)	0.44	55 (43.3)	116 (46.8)	0.60
Previous MI	11 (8.1)	370 (12.1)	0.21	11 (8.7)	24 (9.7)	0.89
Previous PCI	25 (18.5)	785 (25.7)	0.08	22 (17.3)	45 (18.1)	0.96
Previous CABG	34 (25.2)	430 (14.1)	<0.01	31 (24.4)	64 (25.8)	0.87
COPD	26 (19.3)	478 (15.6)	0.31	24 (18.9)	45 (18.1)	0.97
Creatinine, mg/dl	1.3 ± 0.5	1.3 ± 0.9	0.74	1.3 ± 0.5	1.3 ± 0.7	0.79
Hemoglobin, g/dl	11.3 ± 2.1	10.9 ± 2.1	0.05	11.3 ± 2.1	11.2 ± 2.2	0.90
EuroSCORE II, %	8.2 [4.2, 13.5]	4.5 [2.5, 8.2]	<0.01	8.0 [4.0, 13.2]	4.9 [2.3, 10.3]	<0.01
Region	–	–	<0.01	–	–	0.98
Central-West	10 (7.4)	79 (2.6)	–	8 (6.3)	16 (6.5)	–
Northeast	6 (4.4)	197 (6.4)	–	6 (4.7)	10 (4.0)	–
South	24 (17.8)	806 (26.4)	–	24 (18.9)	50 (20.2)	–
Southeast	95 (70.4)	1975 (64.6)	–	89 (70.1)	172 (69.4)	–
LVEF, %	60.0 [48, 66.0]	63.0 [53.0, 68.0]	<0.01	61.0 [48.0, 66.0]	60.0 [45.0, 65.0]	0.91
Mean aortic gradient, mmHg	36.0 ± 18.0	46.1 ± 17.4	<0.01	38.8 ± 18.2	38.7 ± 15.4	0.96
PASP, mmHg	50.4 ± 16.8	41.9 ± 13.2	<0.01	47.2 ± 15.0	46.1 ± 15.4	0.50

Categorical variables are reported as n (%). Continuous variables are expressed as mean ± SD or median [interquartile range], as appropriate.
BMI: body mass index; CABG: coronary artery bypass grafting; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association functional classification; PASP: pulmonary artery systolic pressure; PCI: percutaneous coronary intervention.

Table 2
Procedural characteristics and in-hospital outcomes for the unmatched and matched patient cohorts.

	Non-matched			Matched		
	ViV-TAVI (n = 135)	NV-TAVI (n = 3057)	P-value	ViV-TAVI (n = 127)	NV-TAVI (n = 248)	P-value
Femoral approach	124 (91.9)	2814 (92.1)	0.31	122 (96.1)	235 (94.8)	0.76
THV type (SEV)	73 (54.1)	1507 (49.3)	0.35	71 (55.9)	134 (54.0)	0.38
New-generation THV	99 (73.3)	1859 (60.8)	0.01	95 (74.8)	185 (74.6)	0.77
THV			<0.01			<0.01
Acurate neo/neo2	3 (2.2)	217 (7.1)	–	3 (2.4)	20 (8.1)	
CoreValve	9 (6.7)	642 (21.0)	–	8 (6.3)	36 (14.5)	
Evolut R/Pro	59 (43.7)	631 (20.6)	–	58 (45.7)	76 (30.6)	
Inovare	2 (1.5)	35 (1.1)	–	2 (1.6)	8 (3.2)	
Lotus	1 (0.7)	61 (2.0)	–	1 (0.8)	0 (0.0)	
Myval	1 (0.7)	30 (1.0)	–	1 (0.8)	9 (3.6)	
Portico	2 (1.5)	17 (0.6)	–	2 (1.6)	2 (0.8)	
Sapien XT	24 (17.8)	434 (14.2)	–	21 (16.5)	18 (7.3)	
Sapien 3/Ultra	34 (25.2)	957 (31.3)	–	31 (24.4)	77 (31.0)	
Mean THV size, mm	24.3 ± 2.0	26.4 ± 2.7	<0.01	24.6± 2.2	27.0± 2.9	<0.01
Balloon predilation	20 (14.8)	1195 (39.1)	<0.01	20 (15.7)	79 (31.9)	<0.01
Balloon postdilation	38 (28.1)	849 (27.8)	0.85	36 (28.3)	73 (29.4)	0.92
Postprocedural mean aortic gradient, mmHg	16.5 ± 10.0	9.9 ± 5.8	<0.01	16.5 ± 10.1	9.4 ± 4.7	<0.01
Device success	97 (71.9)	2696 (88.2)	<0.01	91 (71.7)	218 (87.9)	<0.01
Coronary artery occlusion	0 (0.0)	15 (0.5)	0.86	0 (0.0)	2 (0.8)	0.79
Valve embolization	5 (3.7)	51 (1.7)	0.11	5 (3.9)	2 (0.8)	0.04
Conversion to open surgery	3 (2.2)	64 (2.1)	0.99	3 (2.4)	3 (1.2)	0.57
PPI	6 (4.4)	315 (10.3)	0.17	6 (4.7)	32 (12.9)	<0.01
Stroke	1 (0.7)	67 (2.2)	0.40	1 (0.8)	3 (1.2)	0.84
Major vascular complication	4 (3.0)	192 (6.3)	0.17	4 (3.1)	13 (5.2)	0.25
Major or life-threatening bleeding	8 (5.9)	261 (8.5)	0.36	8 (6.3)	17 (6.9)	0.74
In-hospital death	7 (5.2)	187 (6.1)	0.80	7 (5.5)	17 (6.9)	0.53

PPI: permanent pacemaker implantation; SEV: self-expanding valve; THV: transcatheter heart valve.

in ViV-TAVI procedures with radiopaque vs. radiolucent SHV, there were four embolizations in radiopaque SHV and one embolization in radiolucent SHV; nevertheless, no statistically significant difference was observed (OR 1.11, 95% CI 0.18–11.80; $p = 0.91$).

3.4. In-hospital outcomes

In-hospital outcomes for the matched cohort are provided in Table 2 and Fig. 3. Major vascular complication (3.1% vs. 5.2%; OR 0.54, 95% CI 0.16–1.51; $p = 0.25$), major or life-threatening bleeding (6.3% vs. 6.9%; OR 0.87, 95% CI 0.35–1.99; $p = 0.43$), stroke (0.8% vs. 2%; OR 0.83, 95% CI 0.08–5.09; $p = 0.84$) and in-hospital mortality (5.5% vs. 6.9%; OR 0.75, 95% CI 0.29–1.78; $p = 0.53$) did not differ significantly between ViV-TAVI and NV-TAVI groups. PPI was considerably lower in ViV-TAVI (4.7% vs. 12.9%; OR 0.35, 95% CI 0.13–0.79; $p < 0.01$). Moreover, as shown in Supplemental Fig. 4, in-hospital outcome rates have declined significantly for both ViV and NV-TAVI patients, and no statistically significant interaction between time and procedure type was observed for any outcome.

4. Discussion

The main findings of this nationwide analysis of the RIBAC-NT registry comparing ViV-TAVI and NV-TAVI, which should be interpreted within the descriptive and hypothesis-generating scope of this study, were as follows: I) during the study period, there was a significant rise in the number of TAVI procedures per year in both ViV and NV-TAVI patients. ViV/NV case proportion has remained stable since 2017; II) device success was lower for ViV-TAVI patients; III) valve embolization was more frequent in ViV procedures and among these patients, SHV type (radiopaque vs. radiolucent) did not differ significantly; IV) no coronary obstruction events were reported in ViV-TAVI; V) PPI was more frequent in NV-TAVI; VI) major vascular complication, the composite outcome of major or life-threatening bleeding, stroke and in-hospital mortality did not differ significantly between groups and have declined over time for ViV and NV-TAVI.

First, it should be noted that these findings are intended to provide a descriptive benchmark for ViV-TAVI outcomes within contemporary TAVI practice in Brazil, not to establish therapeutic equivalence or comparative effectiveness between two procedures that address fundamentally different disease states and patient populations. Importantly, the marked rise in ViV-TAVI numbers observed during the study period reflects increasing adoption of this technique as familiarity with its indications and procedural particularities grows. Interestingly, when compared with US data, despite the massive procedural volume difference for both procedures, the ViV/NV proportion per year remained broadly comparable [5]. These findings suggest that ViV-TAVI is increasingly adopted as an alternative to redo SAVR for degenerated SHV in both developing and developed countries.

Implanting a THV within the rigid annular frame of a SHV is inherently associated with procedural and hemodynamic challenges. Elevated post-implant gradients mainly drove the lower device success rate in ViV-TAVI patients and are in line with previous reports, regardless of the VARC-2 or VARC-3 definitions [13–15]. Importantly, post-dilatation with high-pressure non-compliant balloons and bioprosthetic valve fracture, strategies that have been shown to significantly reduce residual gradients and improve device success in ViV-TAVI, were not systematically employed in this registry [16]. This represents a relevant procedural limitation that may have contributed to the elevated post-implant gradients observed in our cohort, and whose broader adoption could potentially improve hemodynamic outcomes in future ViV-TAVI practice in the region.

Another significant component of device failure was valve embolization. The risk of valve embolization in ViV procedures was higher than previously reported rates for large US cohorts (0.1–0.5%) in both the unmatched (3.7%) and matched (3.9%) cohorts [17,18]. For NV-TAVI procedures, embolization occurred in 1.7% of cases in the unmatched cohort - also higher than prior data (0.4%) - while in the matched cohort, the rate was comparable to historical reports (0.8%) [17].

These findings are consistent with a learning-curve effect observed in lower-volume real-world settings, where embolization rates tend to exceed those reported from high-volume experienced centers - a pattern that reflects the heterogeneity of procedural expertise across participating institutions in this registry. Furthermore, while prior studies have suggested a higher incidence of THV embolization in ViV procedures involving radiolucent SHV, our exploratory analysis does not support this association. However, it is insufficiently powered for definitive inference [19].

Embolization may also occur as a consequence of using an excessively small THV or placing the valve too low or too high [20]. Accurate valve positioning is particularly challenging in ViV procedures due to the absence of annular calcification as a natural fluoroscopic landmark and the need to balance implantation depth against the risk of coronary obstruction. Regarding sizing, while THV oversizing may help, it should be approached with caution due to the increased risk of coronary obstruction [21]. Suboptimal oversizing may contribute to anchoring instability in some cases and might be particularly relevant for self-expanding valves, which accounted for four of the five embolization events in our series. Using periprocedural 3D echocardiography to determine THV height and balloon sizing further may assist in proper THV placement in such cases. Another possible explanation for the observed embolization rates is operator inexperience with ViV procedures and the relatively low national procedural volumes during the study period.

Coronary obstruction is the most feared procedural complication. The most extensive report to date, encompassing procedures from 2007 to 2016, estimated an incidence of 2.3% [22]. In contrast, another large series, covering procedures from 2011 to 2016, reported an incidence of only 0.6% [17]. In our registry, in which most procedures occurred after 2016, no coronary obstruction events were reported with ViV-TAVI. This likely reflects improved preprocedural planning, particularly the systematic use of CT-based assessment and virtual transcatheter-to-coronary distance calculation, as well as appropriate patient selection, which may have led to deferral of cases deemed at prohibitive coronary risk [22,23].

It is well documented that PPI is less frequently required after ViV-TAVI than after NV-TAVI, a finding corroborated by our analysis [24,25]. The presence of a rigid surgical valve ring is likely to reduce mechanical trauma to the conduction system [26]. A report from the VIVID Registry, covering procedures from 2007 to 2020, estimated a PPI rate of 6.4%, which is slightly higher but consistent with our 4.4% estimate [27].

In-hospital safety outcomes for ViV-TAVI were comparable to those of NV-TAVI, with no significant differences in major vascular complication, bleeding, stroke, or in-hospital mortality. This corroborates the findings from a 2020 meta-analysis of observational studies wherein ViV-TAVI had similar (stroke, major vascular complication) or better outcomes (major or life-threatening bleeding, short-term mortality) [28]. Furthermore, mortality rates observed in both groups (5.5% and 6.9% for ViV-TAVI and NV-TAVI, respectively) should be interpreted in the context of the elevated baseline surgical risk of the study population: in the matched cohort, the median EuroSCORE II was 8.0% for ViV-TAVI and 4.9% for NV-TAVI. Additionally, the study period spans from 2009 to 2021, encompassing early-era procedures performed before current standards of patient selection and procedural technique were fully established. Additionally, while one must acknowledge relatively high rates of adverse outcomes, a clear temporal trend toward a reduction in complications was observed. Therefore, despite the inherent limitations of observational studies, particularly the presence of unmeasured and unadjusted confounders, as well as selection bias, these results reinforce the safety of ViV-TAVI despite its increased technical complexity compared with NV-TAVI.

5. Limitations

This study has limitations. First, despite propensity score matching, selection bias and residual confounding from unmeasured variables cannot be excluded; furthermore, outcomes were restricted to the in-hospital period, with no 30-day or mid-term follow-up available. Second, incomplete characterization of the index surgical bioprosthesis – including model, manufacturer, and radiopacity - and the absence of systematic post-procedural echocardiographic data limit the interpretation of certain procedural outcomes; additionally, PPM was assessed using predicted values derived from NV-TAVI reference data, which likely underestimate the true burden of PPM in the ViV setting, as they do not account for the constraining effect of the surgical valve ring on full THV expansion. Third, the heterogeneity of center-level experience and the concentration of data in high-volume institutions in the Southeast region may limit the generalizability of these findings to lower-volume centers in Brazil and elsewhere.

6. Conclusions

During the study period, the absolute number of ViV-TAVI procedures increased modestly but significantly, while their proportion relative to NV-TAVI remained stable. In comparison with NV-TAVI, ViV-TAVI was associated with lower device success, a reduced need for PPI, and higher rates of THV embolization. Rates of major vascular complication, the composite endpoint of major or life-threatening bleeding, stroke, and in-hospital mortality, did not differ significantly between the groups.

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Declaration of competing interest

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Data availability statement

The data are held by SBHCI, but restrictions apply to their availability, as they were used under license for the present study. However, data may be obtained upon reasonable request and with permission from SBHCI.

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