Transcatheter aortic valve replacement in a Tunisian reference center: About 32 cases

Implantation transcathéter valvulaire aortique dans un centre de référence Tunisien : A propos de 32 cas

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Summary

Introduction: Transcatheter aortic valve replacement (TAVR) adoption in developing countries is challenged by procedure high costs. This study aimed to evaluate immediate and 12-month outcomes in patients undergoing TAVR in a reference Tunisian center.

Methods: Between July 2016 and December 2023, all patients who underwent TAVR were included. A minimum 12-month follow-up was required. Study endpoints were efficacy and safety of the technique, according to criteria established by the Valve Academic Research Consortium 3 (VARC-3).

Results: 32 patients. Mean age 79±5 years, 56% were women. 22%, 50% and 28% were at high, Intermediate and low surgical risk respectively. Balloon-expandable and self-expanding valves were implanted in 9 (28%) and 23 (72%) patients respectively. VARC 3 procedural technical success was 84%, with one intra-procedural death related to cardiac perforation. Besides, were noted one valve embolization, one annular rupture, one coronary obstruction, and one major vascular access bleeding. During hospital phase, four deaths occurred relevant to stroke (2 patients), cardiogenic and septic shock (1 patient) and hemorrhagic shock (1 patient). Permanent pacemaker was implanted in 5 patients of whom 4 had self-expandable valves. At 12 months, only one non cardiovascular death was recorded. No valve dysfunction was noted. Echocardiographic evaluations demonstrated excellent hemodynamic performance, with a mean transvalvular gradient of 11.5±9.1 mmHg and no instances of moderate or severe paravalvular leak.

Conclusion: Despite small sample size, this initial TAVR cohort results proved high technical success rate albeit complications. Patients' screening and procedural planification are crucial for complications prevention.

Keywords

Transcatheter valve replacement; Aortic stenosis; Tunisia; Outcomes

Résumé

Introduction: L'adoption de l'implantation valvulaire aortique par voie transcathéter (TAVI) dans les pays en développement est entravée par le coût élevé de la procédure. Cette étude visait à évaluer les résultats immédiats et à 12 mois chez les patients bénéficiant de TAVI dans un centre tunisien de référence.

Méthodes : Entre juillet 2016 et décembre 2023, tous les patients ayant bénéficié de TAVI ont été inclus. Un suivi minimum de 12 mois était requis. Les critères d'évaluation de l'étude étaient l'efficacité et la sécurité de la technique, selon les critères établis par le Valve Academic Research Consortium 3 (VARC-3).

Résultats : 32 patients. Âge moyen 79±5 ans, 56% de femmes. 22%, 50% et 28% présentaient respectivement un risque chirurgical élevé, intermédiaire et faible. Des valves à ballonnet et auto-expandables ont été implantées chez 9 patients (28%) et 23 patients (72%) respectivement. Le succès technique selon VARC-3 était de 84%, avec un décès intra-procédural lié à une perforation cardiaque. Par ailleurs, une embolisation valvulaire, une rupture annulaire, une obstruction coronaire et une hémorragie majeure liée à l'accès vasculaire ont été constatées. Durant la phase hospitalière, quatre décès sont survenus, liés à un accident vasculaire cérébral (2 patients), un choc cardiogénique et septique (1 patient) et un choc hémorragique (1 patient). Un stimulateur cardiaque permanent a été implanté chez 5 patients, dont 4 faisant suite à une valve auto-expandable. À 12 mois, un seul décès non cardiovasculaire a été enregistré. Aucun dysfonctionnement valvulaire n'a été constaté. L'évaluation échocardiographique a démontré d'excellentes performances hémodynamiques, avec un gradient transvalvulaire moyen de 11,5±9,1 mmHg et aucun cas de fuite paravalvulaire modérée ou sévère.

Conclusion : Malgré un effectif réduit, cette étude a démontré que la TAVI était associée à un succès technique élevé, malgré des complications. La sélection des patients et la planification de la procédure sont essentielles à la prévention de ces complications.

Mots-clés

Implantation transcathéter valvulaire aortique; Sténose aortique ; Résultats ; Tunisia

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INTRODUCTION

Aortic stenosis is the most common primary valve lesion requiring surgery or transcatheter intervention (1). Surgical treatment was for years the gold standard treatment, but not all patients are suitable for open heart surgery due to advanced age and severe comorbidities. Since 2002, transcatheter aortic valve replacement (TAVR) has emerged as an option for high risk patients who were recused for surgery (2). Partner 1A and US CoreValve were the pivotal trials that proved the safety and efficacy of this alternative technique among patients with high surgical risk (3,4). More recently, indications has been extended to intermediate and even to low risk patients (5,6).

If this technique has defined a new therapeutic era for aortic stenosis, with a proven reduction in mortality compared with surgical treatment, it inevitably entails the risk of complications. In response, the Valve Academic Research Consortium 3 (VARC-3) recently updated its standardized definitions of clinical endpoints for aortic valve clinical research allowing more consistent comparisons between different trials (7).

In Tunisia, the first TAVR was performed in November 2013 at the Military hospital in Tunis, and the first implantation in La Rabta Hospital was in July 2016. Since, TAVRs procedures are clearly on the rise, particularly since 2021, with the introduction of the national TAVR program piloted by the ministry of health. Few data have been published on the results of these early experiments.

The Aim of this work is to evaluate immediate and 12-month results of TAVR in patients with symptomatic severe AS, performed at La Rabta hospital between 2016 and 2023 according to the VARC-3 definitions.

METHODS

Study Design

This was a retrospective descriptive study that included all patients with severe symptomatic AS treated with TAVR in La Rabta hospital of Tunis between December 2016 and December 2023.

Study population

All consecutive patients who underwent TAVR in La Rabta hospital between 2016 and 2023 were included. TAVR was performed after Heart Team discussion according to the 2012 ESC recommendations updated in 2021 (5). Only patients who did not consent to participate in this registry were excluded.

Study definitions

According to VARC-3 (7), following end-points were analyzed : all-cause and cardiovascular mortality, central nervous system injury, bleeding events, vascular access site and access-related complications, cardiac structural complications, other acute procedural and technical valve related complications including need for conversion to open surgery, use of unplanned hemodynamic support, valve malposition, and PVR, conduction disorders and arrhythmia, and acute kidney injury.

Composite endpoints (7) of this study are listed in table 1:

Table 1. Composite study endpoints according to the third Valve Academic Research Consortium (VARC-3) definitions (7).

Technical success (at exit from procedure room):
- Freedom from mortality
- Successful access, delivery of the device, and retrieval of the delivery system
- Correct positioning of a single prosthetic heart valve into the proper anatomical location
- Freedom from surgery or intervention related to the device* or to a major vascular or access-related, or cardiac structural complication

Device success (at 30 days):
- Technical success
- Freedom from mortality
- Freedom from surgery or intervention related to the device or to a major vascular or access-related or cardiac structural complication
- Intended performance of the valve‡ (mean gradient <20 mmHg, peak velocity <3 m/s, Doppler velocity index ≥0.25, and less than moderate aortic regurgitation)

Early safety (at 30 days):
- Freedom from all-cause mortality
- Freedom from all stroke
- Freedom from VARC type 2–4 bleeding (in trials where control group is surgery, it is appropriate to include only Type 3 and 4 bleeding)
- Freedom from major vascular, access-related, or cardiac structural complication
- Freedom from acute kidney injury stage 3 or 4
- Freedom from moderate or severe aortic regurgitation
- Freedom from new permanent pacemaker due to procedure-related conduction abnormalities
- Freedom from surgery or intervention related to the device

Clinical efficacy (at 1 year and thereafter):
- Freedom from all-cause mortality
- Freedom from all stroke
- Freedom from hospitalization for procedure- or valve-related causes
- Freedom from KCCQ Overall Summary Score <45 or decline from baseline of >10 point (i.e. Unfavourable Outcome)

Follow up

A minimal 12-month follow-up was required. Clinical and echocardiographic evaluation were performed at 1, 6 and 12 months.

Statistical methods

Data were recorded and analyzed using SPSS software version 26. Numbers and frequencies (percentages) were calculated for categorical variables and means ± standard deviation, or median (interquartile range) for quantitative variables.

Ethical considerations

There were no conflicts of interest or ethical considerations during the development of this work.

RESULTS

Baseline characteristics

32 patients had TAVR during the study period. Mean age was 79 ± 5 years, 88% of whom were aged over 75. Sex ratio was 0,8.

Dyspnea was the most revealing symptom, being noted in 94% of patients.

26 patients were in sinus rhythm and 6 in AF representing 19% of study population.

All patients had severe high-flow high-gradient native valve AS. It is of note that one patient had severe associated aortic regurgitation.

Pre-TAVR CT was consistent with 2 patients with bicuspid valve (6%).

Baseline characteristics were summarized in table 2.

Table 2. Baseline characteristics.

Variable	N=32
Age	78.8 ± 4.8
Sex (Male)	14 (44%)
• <4%	9 (28%)
• 4-8%	16 (50%)
• ≥8%	7 (22%)
BMI	28.4 ± 5.4
• BMI 25-29.9 kg/m²	10 (31%)
BMI ≥30 kg/m²	11 (34%)
Hypertension	21 (66%)
Diabetes	12 (38%)
Dyslipidemia	17 (53%)
Percutaneous coronary intervention history	10 (31%)
Coronary artery bypass graft history	3 (9%)
Chronic obstructive pulmonary disease	4 (13%)
Chronic kidney disease	9 (28%)
Chronic hemodialysis	1 (3%)
Cancer history	4 (13%)
Dyspnea	28 (94%)
• NYHA II	3 (9%)
• NYHA III	23 (71%)
• NYHA IV	2 (6%)
Congestive heart failure	1 (3%)
Angina	15 (47%)
Lipothymia	7 (22%)
Syncope	3 (9%)
ECG findings	
• Sinus rhythm	26 (81%)
• Atrial fibrillation	6 (19%)
• Paced rhythm	2 (6%)
Echocardiographic data	
• Aortic-valve area (cm²)	0.68 ± 0.18
• LVEF (%)	54.69 ± 11.69
• Peak velocity (m/s)	4.68 ± 0.69
• Mean gradient (mmHg)	55.22 ± 19.20
• Mean pulmonary systolic pressure (mmHg)	38.77 ± 12.51
ECG findings	3 (6%)

Mean STS-PROM score was 5.51 ± 2.72 with a minimum of 2 and a maximum of 11.3. Mean Euroscore II was 4.38 ± 2.22. Patient's risk profile has evolved during the investigation period according to the 2021 ESC guidelines for the management of valvular heart disease extending TAVI indications to intermediate surgical risk patients (Figure 1).

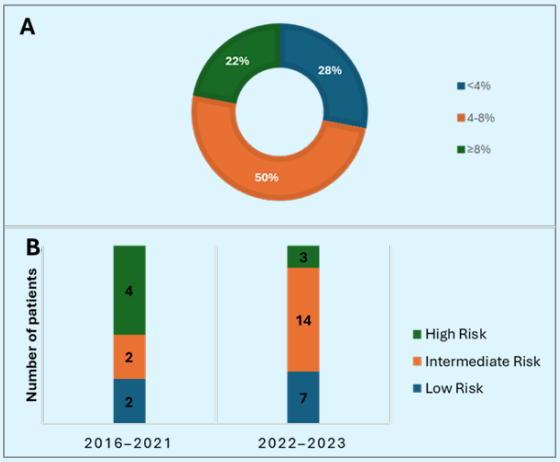

Figure 1. Patient's surgical risk profile according to STS-PROM scoring in overall study population (Panel A) and before and after 2021 ESC guidelines for the management of valvular heart disease (Panel B).

Procedural data

General anesthesia was the rule in this beginning TAVI experience. Transfemoral access was used in all cases. Echo-guidance was adopted for femoral puncture since 2022. Ballon predilation was performed in 20 patients, mandated by the instructions for use (i.e. Accurate Neo II valve, Boston Scientific), severe valve calcifications, severe valve stenosis and/or bicuspid anatomy. In some situations, predilation aimed to assess the coronary occlusion risk before valve implantation in the setting of low coronary artery height. Coronary protection was applied in 5 patients with high risk of coronary artery obstruction. Postdilation was performed in 4 patients, motivated by significant residual paravalvular aortic regurgitation. Percutaneous closure with 2 proglides was attempted in all cases and was successful in 97%. Only one surgical cut-down was needed in the setting of proglides failure in a chronic hemodialysis obese patient (BMI=36 Kg/m^2). Procedural data are summarized in table 3.

0Table 2. Baseline characteristics.

Variable	N=32
Anesthesia	
• General	31
• Conscious sedation	1
Vascular access	
• TransfemoralBMI ≥30 kg/m²	32
• Echo-guidance	24
• Alternative access	0
Valve predilation	20
Coronary protection	5
Implantation's view	
• 3-cusp coplanar view	10
• Cusp-overlap view	22
Implanted valve	
• Self-Expanding Valve	25
• Corevalve (Medtronic)	3
• Evolut R	4
• Evolut Pro	0
• Evolut Pro+	14
• Acurate Neo II	4
• Balloon-Expanding Valve	7
• Sapien	0
• Sapien XT	0
• Sapien 3	7
Prosthesis postdilation	4
Vascular access closure	
• 2 proglides	31
• Surgical cut-down	1

Study endpoints

Cardiovascular mortality

At 12 months, 5 cardiovascular deaths were recorded.

- 1 was intra-procedural (cardiac perforation),
- 3 occurred during the in-hospital phase (vascular access bleeding, coronary occlusion and stroke)
- and 1 after hospital discharge on the 28th day (stroke).

Neurologic events

Two patients presented neurological complications: 1 multiple ischemic strokes and 1 ischemic stroke with hemorrhagic transformation occruing 25 days after disacharge in a patient under DAPT, both with a fatal outcome.

Vascular complications

Vascular complications were noted in 8 patients. One of them had a fatal outcome and was related to hemorrhagic shock after failure of closure devices despite surgical successful cat-down on the groin.

Bleeding events

Six patients presented bleeding complications with two of them being major with a fatal outcome (1 intracranial and 1 related to vascular access site).

Cardiac structural complications

Three patients presented cardiac structural complications consisting of:

- 1 cardiac perforation due to the pacing lead revealed by an electromechanical dissociation when retrieving the lead with a fatal outcome despite pericardiocentesis and surgical cut-down.
- 1 partial annular rupture following valve predilation with a non-compliant in relation to an excentric annulus calcification, complicated by cardiac tamponade, sealed by a valve implantation with a fatal subsequent outcome due to severe ischemic stroke.
- 1 delayed coronary obstruction after a SEV implantation in a patient with low coronary artery height (7 mm) and borderline sinuses of Valsalva despite per-procedural coronary protection and commissural alignment managed by a chimney stenting but with a fatal outcome.

Others acute complications

Other acute procedural and technical valve related complications included 1 Prothesis embolization: following a spontaneous pop-up in the ascending aorta due to severe septal hypertrophy and small LVOT. Embolized valve was snared to the aortic arch with a successful implantation of second valve. No severe residual paravalvular leak was noted.

Conduction disturbances and arrythmias

Twelve patients developed conductive disturbances, consisting of 7 new bundle branch blocks and 5 complete atrioventricular blocks mandating a permanent pacemaker implantation (16%). These patients and potential precipitating factors were detailed in table 4. Only one patient presented a new onset of AF.

Table 2. Characteristics of patients with a permanent pacemaker implantation

	Baseline QRS	PR interval	CT scan data	Prothesis	Implantation depth	Pre-dilation	Post-dilation
Pt 1	**RBBB/LAFB (130)**	**190**	**Large excentric annular calcification extending from NCC into LVOT**	**EVOLUT PRO 26**	**3 mm**	**1**	**0**
Pt 2	LBBB (120)	216	No	EVOLUT PRO 26	5 mm	1	0
Pt 3	LBBB (130)	AF	Excentric annular calcification extending from NCC into LVOT	SAPIEN 3 26	2 mm	0	0
Pt 4	RBBB (130)	140	_No	EVOLUT PRO 26	5 mm	0	0
Pt 5	RBBB (160)	AF	Bicuspid Sievers 1 LR	EVOLUT PRO 13	5 mm	1	0

CT scan: Computed Tomography scan; LBBB: left bundle branch block, RBBB: right bundle branch block, AF atrial fibrillation.

Acute kidney injury

Six patients presented acute kidney injury. All of them were reversible.

Echocardiographic endpoints

Immediate post-procedural echocardiographic findings

Noting that only one intra-procedural death occurred, prothesis hemodynamics were evaluated in 31 patients. A clear improvement was noted in the ultrasound parameters with a mean gradient decreasing from 55 ± 19 mmHg before TAVR to 13 ± 8 mm Hg at 48h control (p<0.001).

One-month echocardiographic follow-up

Twenty-seven patients were alive at one month control. An improvement in Prothesis hemodynamics was noted, between 48h and one month control, with mean gradient estimated 9.41 ± 3.61 mmHg, but this improvement was not statistically significant.

One-year echocardiographic follow-up

Twenty-six patients were alive at one year control. Hemodynamic parameters remained stable during follow-up. LVEF was noted in 2 patients among 4 who had baseline LVEF<40%, coronary artery disease was present in the 2 patients who didn't have an improvement of LVEF.

Table 5 and figure 2 resume the echocardiographic findings during follow-up.

Table 5. Evolution of echocardiographic parameters during the 12-month follow-up

	Before TAVR (n=26)	48h after TAVR (n=26)	1 month after TAVR (n=26)	1 year after TAVR (n-26) p value
Vmax(m/s)	4.68 ± 0.69	2.26 ± 0.56	2±0.45	1.98 ± 0.48
Mean gradient (mmHg)	55.22 ± 19.20	12.52 ± 8.48	11.8±9	11.5 ± 9.1
Mean Aortic surface (cm²)	0.66 ± 0.17	1.82 ± 0.46	1.93±0.5	1.98 ± 0.41
LVEF	54.69 ± 11.69	54.48 ± 11.50	55±10	55.3 ± 10.9
Aortic regurgitation	15	12	10	10
• Grade 1-2	14	11	10	10
• Grade 3-4	1	0	0	0

LVEF: Left Ventricle Ejection Fraction; TAVR: Transcatheter Aortic Valve Replacement.

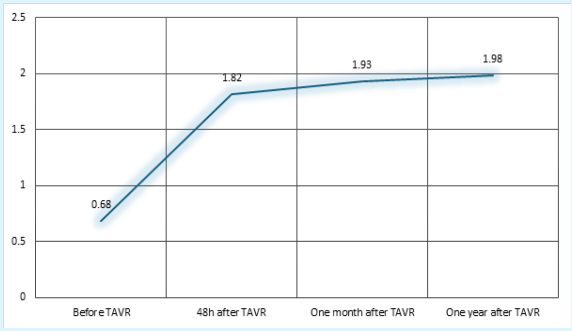

Figure 2. Evolution of aortic surface (cm²) in pre-, post-TAVR, at one month and at one year.

Composite endpoints

Technical success (at exit of procedure room)

Technical success was achieved in 27 patients out of 32 (84% of cases) according to VARC-3 definition. Technical failure was due to 3 cardiac structural complications (1 cardiac perforation, 1 annular rupture, 1 coronary occlusion), 1 valve embolization and 1 major vascular access complication. Intra-procedural death occurred in 1 patient (3%).

Device success (at 30 days)

No further surgery or intervention were indicated after exit from the procedure room. Gradient continued to improve reaching 9.41 ± 3.61. Rate of aortic regurgitation was 38%, all of them were mild.

Early safety (at 30 days)

Besides the intra-procedural death, 3 deaths occurred during the hospital phase and one 28 days after discharge. Median length of hospital stay was 5.2 ± 3.0 days with longer length stay noted during first procedures. Early safety details are listed in table 6.

Table 6. Early safety

	N=32
Mortality	5
Major cardiac structural complication	3
Stroke	2
Pacemaker Implantation	5
Major vascular complications	1
Major bleeding	2
AKI stage 3	2
Hemodialysis	1
Moderate or severe aortic regurgitation	0
Surgery or intervention related to the device	0

AKI: Acute kidney injury

Clinical efficacy (between one month and one year)

All survivors remained clinically stable; with 28% of patients suffering from dyspnea, 80% of whom were stage II. One death occurred at 8-month follow-up due to pancreatic cancer (diagnosed 6 months after TAVR procedure). Table 7 summarizes outcomes at one-year follow-up.

Table 7. Clinical efficacy between one month and one year.

	N=26
Mortality	1
Cardiovascular mortality	0
MI	0
Stroke	1
CHF	0
MACE	1

MI: Myocardial infraction; CHF: Congestive heart failure; MACE: Major adverse cardiac events

Figure 3 shows dyspnea evolution according to the NYHA classes.

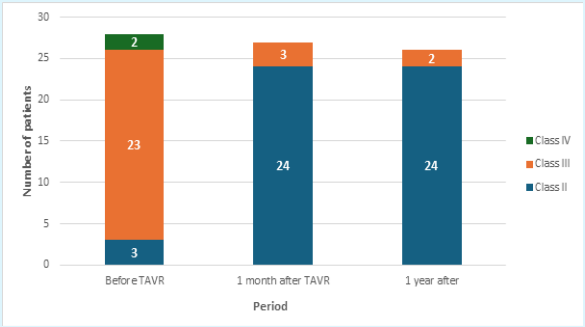

Figure 2. Evolution of number of patients according to NYHA classification.

DISCUSSION

This is a pilot single-center study publishing the first results of a monocentric experience in a developing country. Main results were: 1- Technical success, as defined by VARC-3, was 84%, with one intra-procedural death related to cardiac perforation. 2- Other procedural complications included one valve embolization, one annular rupture following predilation, one coronary obstruction, and one major vascular access bleeding. 3- During the hospital phase, four deaths occurred relevant to stroke (2 patients), cardiogenic and septic shock (1 patient) and hemorrhagic shock (1 patient). 4- Permanent pacemaker was implanted in 5 patients (16%) of whom 4 had self-expandable valves. 5- At 12-month follow-up, only one major adverse event was recorded consisting in one non cardiovascular death. 6- No valve dysfunction was noted. Echocardiographic evaluations demonstrated excellent hemodynamic performance, with a mean transvalvular gradient of 11.5 ± 9.1 mmHg and no instances of moderate or severe paravalvular leak.

To evaluate these results of this study, two of the largest registries, i.e. ACC/STS TVT (8) and FRANCE TAVI (9) were selected. At the national level, results of the military Hospital of Tunis between November 2013 and September 2021 as reported by Talhaoui et al. (10), as well as those of Siala et al. (11) coming from the same center and dedicated to the Accurate Neo2 valve between January 2021 and December 2023 were considered.

Population of this study appears to be younger than the cohorts of FRANCE TAVI and the STS-ACC TVT registry. Females were more prevalent in this series.

Mean STS score was lower in this cohort than in the Military hospital of Tunis and FRANCE TAVI population but comparable to the STS-ACC TVT registry. For instance, only 16% were considered at high risk according to the risk scores but all patients were recused for surgery STS-ACC TVT registry. This constatations highlights the limits of risk scores and the need of a heart team to make the appropriate decision for each patient according to clinical judgment, patient preferences, and individual circumstances. Actually, risk scores do not contain all relevant factors associated with increased risk in the elderly population, in particular, frailty and disability (12).

Table 8 highlights the key demographic data in comparison to the selected studies for discussion.

Table 2. Characteristics of patients with a permanent pacemaker implantation

	La Rabta (n=32)	Talhaoui et al 2022 (n=63)	Siala et al 2024 (n=41)	France TAVI (n=9982)	STS-ACC TVT (n=276316)
Mean age	78.8±4.8	79,1±7,3	80,1±8,6	83.4±7.2	81
Mean age	56%	47.6%	70.7%	50%	45.8%
Female (%)	28.4±6.6	_	25,9± 8.3	26.5±4.7	_
BMI	5.51±2.72	11,15±6.12	11,15± 6.12	17.9±12.3	5.22
STS score	23/2	22/31	23/2	8269/12241(67.6)	166232/37141
NYHA III/IV	23/2	22/31	23/2	8269/12241(67.6)	166232/37141

Excepting the VARC-3 procedural success, which was met in 84% in this beginning experience, being lower than literature, other major complications' rates were almost comparable to the military hospital reported series, FRANCE-TAVI and STS-ACC TVT registries (Table 10). Interpretation of these initial results is challenged by the small sample size of the study population and the low incidence of these complications.

Table 2. Characteristics of patients with a permanent pacemaker implantation

	La Rabta (n=32)	Talhaoui et al 2022 (n=63)	Siala et al 2024 (n=41)	France TAVI (n=9982)	STS-ACC TVT (n=276316)
Technical success	84%	87.3%	83%	96.8%	92.7%
Discharge alive	28 (88%)	57 (90%)	41 (100%)	12242 (95.6%)	270743 (97.98%)
Stroke	2 (6%)	6 (9.5%)	0	249 (2%)	15940 (6.24%)
Coronary obstruction	1 (3%)	-	0	-	-
Cardiac tamponade	1 (3%)	7 (11%)	1 (2.4%)	256 (2.0%)	-
Annular rupture	1 (3%)	0	1 (2.4%)	52 (0.4%)	-
Device embolization	1 (3%)	1 (1.6%)	1 (2.4%)	139 (1.1%)	-
VARC-3 major bleeding	2 (6%)	5 (7.9%)	0	-	-
Permanent pacemaker implantation	5 (16%)	8 (12.6%)	1 (2.4%)	1870 (17.5%)	24333 (11.5%)

CONCLUSION

TAVR was feasible and effective, despite the small sample size of this cohort study. With the increase in number of implantations and optimal patients' selection, we can look forward to a reduction in the complications rate, which remains relatively high. At 12-month follow-up, TAVR has demonstrated excellent functional and hemodynamic results.

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