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Original Article

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Surgical aortic valve replacement by St. Jude/Abbott -Trifecta® bioprostheses: Durability and long-term outcomes

Abstract

Aim: The STJ/Abbott-Trifecta® bioprosthesis, known for its low post-implantation gradients in small aortic annuli, was withdrawn from the market in July 2023 due to early structural valve deterioration (SVD). This study evaluates its mid- to long-term outcomes and durability (up to 10 years) in patients treated at our institution.
Material and Methods: From 2010 to 2018, 164 adult patients (≥18 years) underwent aortic valve replacement with STJ/Abbott-Trifecta® bioprostheses at the University Hospitals of Geneva (HUG). We retrospectively analyzed 72 patients with complete follow-up data from hospital records and referring cardiologists.
Results: The study cohort had a mean age of 77±10.6 years (62.5% male). At follow-up, only 34 patients (47.2%) were alive. Isolated AVR was performed in 30 patients (41.7%), while 42 (58.3%) underwent concomitant procedures. The most common valve sizes were 21 mm (31.9%) and 23 mm (31.9%). Despite a high proportion of small valves (≤21 mm, 37.5%), only 2 patients (2.4%) had severe patient-prosthesis mismatch. Hospital mortality was 13% (11/83 patients). Significant hemodynamic deterioration due to SVD was observed 6-8 years post-implantation, requiring reoperation in 12 patients (16%) within 6.3±2.9 years. Kaplan-Meier estimates for 5-year survival varied by valve size: 19 mm (20%), 21 mm (56%), 23 mm (90%), 25 mm (77.9%), and 27 mm (75%).
Conclusion: While STJ/Abbott-Trifecta® bioprostheses provided low gradients in small annuli, they showed high early degeneration rates, necessitating frequent reoperations. Given the 2023 market withdrawal, patients with these valves require close echocardiographic monitoring.

Keywords: Aortic valve diseases, bioprosthesis, heart valve prosthesis

INTRODUCTION

Symptomatic aortic valve pathologies are treated by aortic valve replacement (AVR) or repair using surgical (SAVR or SAVRep) or percutaneous technics (TAVI) depending on the pathology, operability, and age of the patient. Biological or mechanical prostheses are the two main types of SAVR devices. Bioprosthesis are preferred for patients older than 65 years as they do not require anticoagulation. However, bioprosthesis have a limited lifespan because of progressive degeneration related to the biological tissues, which is why they are implanted at older ages. Conversely, mechanical prostheses are preferred for patients under the age of 60-65 because the valve is more durable but requires lifelong anticoagulation (1).

Regularly, newer designs and anti-calcification treatments challenge the standard bioprostheses on the market. STJ/Abbott-Trifecta® aortic valve bioprosthesis is one of these new prostheses designed by St. Jude Medical in 2007. This

new bioprosthetic valve was promoted for its excellent low trans-valvular gradient following implantation in small sized prostheses. The unique feature of the valve is the attachment of the leaflets on the outside of the stents which improves the mean effective orifice area (EOA) (2). Perfect early postoperative hemodynamic performances with lower gradients and good short term follow-up results have been described in many clinical studies (3,4). Eventually, STJ/Abbott-Trifecta® aortic valve bioprostheses became very attractive for implantation in patients with small aortic annuli to avoid prosthesis-patient mismatch (PPM) (5). However, at the beginning of 2014, some case reports have been published to warn the medical community about possible early valve deteriorations (6,7). This was later confirmed by other studies that described leaflet tears with dehiscence along the stent as the main mode of early failure (8-10).

Despite it's well known characteristic of generating a low-gradient following the implantation of smaller size prostheses, it is withdrawn from the market in July 2023 following observations of early SVD which required earlier reoperations (11). The aim of this outcome quality-based study is to evaluate the long-term outcomes and durability (10 years postoperatively) of STJ/Abbott-Trifecta® bioprostheses implanted in our institution.

MATERIAL AND METHODS

Study Plan and Data Collection

The quality control was established between November 2022 and January 2023. Data collection was performed between February 2023 and December 2023.

Between 2010 and 2018, 164 adult patients (≥18 years old) underwent an aortic valve replacement with the STJ/Abbott-Trifecta® bioprostheses at the University Hospitals of Geneva. We retrospectively analyzed the perioperative data from the digitalized intrahospital information system (DPI) concerning the patients who had a long-term follow-up of up to 10 years. Pre-operative, intra-operative, and early post-operative data were collected by reviewing electronic records, surgical reports, and referral letters to HUG. Post-operative follow-up data were supplemented by contacting patients' treating cardiologists to obtain transthoracic echocardiography (TTE) reports. The electronic health system allowed us to determine if the patient was alive or had died when the patient was lost to follow-up.

Out of the 164 patients initially identified, medical follow-up information was obtained for 83, as shown in Figure 1. Some patients could not be located as they had left Switzerland or undergone surgery as part of a humanitarian exchange program, making it impossible to obtain their follow-up information.

We obtained written or verbal consent from all patients or their families for data use, either directly or through their treating cardiologist. This quality control project was deemed to be outside the scope of Swiss legislation on research involving human subjects, and therefore, the need for local ethics committee approval was waived.

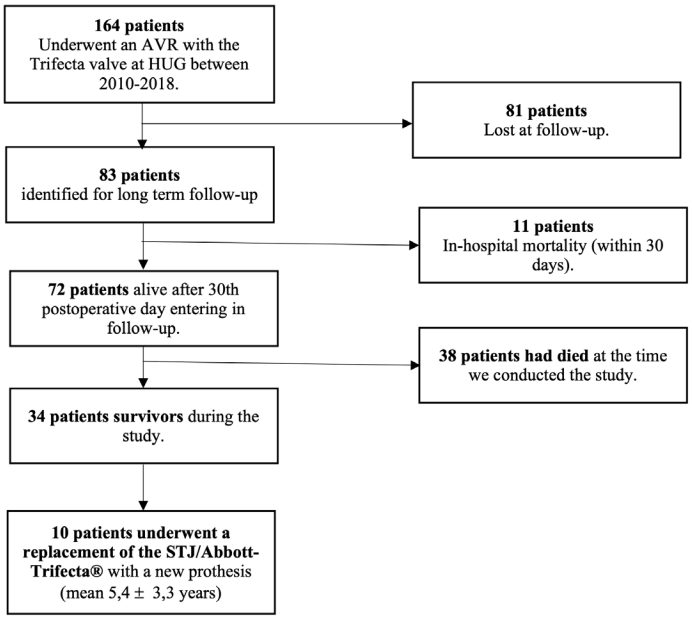

Figure 1. Study workflow of follow-up and quality control of aortic Trifecta bioprosthesis implanted in Geneva between 2010-2018

Patient Background and Characteristics

For this retrospective study, we collected demographic, clinical, and operative data retrieved from the informatized medical reports of the hospital. Patient height and weight, which were used to calculate body mass index (BMI) and body surface area (BSA), were obtained from the anesthetist's intraoperative reports. Diagnoses of hypertension, dyslipidemia, diabetes mellitus, and ischemic heart disease were assessed by the HUG cardiology department. All patients were assessed for physical capacity and symptoms according to the New York Heart Association (NYHA) classification system (12).

Patients with in-hospital death (defined as up to 30 days after surgery) were excluded. This approach provides data that best reflects the durability of the valve.

Echocardiographic Findings

Follow-up TTE were performed by experienced cardiologists and reports were obtained by direct contact. When patients were followed at HUG, reports were obtained from the informatized medical record. All patients underwent a standard examination, including 2-dimensional and Doppler echocardiography.

TTE reports were collected for each patient at 2 and at 6 months and annually during the long-term follow-up period. Standard follow-up variables, including mean and maximum gradient, maximum transvalvular velocity, and aortic valve opening area (EOA), were assessed. To determine PPM during

the earlier post-operative period, the indexed effective orifice area (EOAi) was calculated and divided by the BSA.

Statistical Analysis

Descriptive statistics are reported as mean±standard deviation (SD) for continuous variables and as frequencies and percentages for categorical variables. Follow-up echocardiographic results are graphically presented with curves of means over time for the whole cohort. A comparison between means in categories was performed with an unpaired t-test. Statistical analyses were performed with R by using "survival", "survminer", "dplyr" and "ggsurvplot" packages (R version 4.3.2, R Foundation for Statistical Computing, Vienna, Austria) (13), and Excel software. The normality of data distribution was evaluated using the Kolmogorov-Smirnov test (14). A comparison between the groups was performed with an unpaired Student t test for continuous variables to determine if there is a significant difference between means of two independent group. After testing the normality, to check if the continuous data follow a normal distribution, to ensure that the assumptions of the t-test are met and that the results are valid. P-values less than .05 were considered statistically significant. To calculate it we used the online software calculators Social Science Statistics (15). For PPM, the data are presented with whisker plots for the whole cohort and each size valve in the post-operative period Figure 2. Means of post-operative echocardiographic follow-ups over ten years are graphically presented for the entire cohort in Figure 3 with a coefficient of correlation (R^2). Analysis of mortality was performed using the Kaplan-Meier method with 95% confidence intervals. The results are graphically presented as curves of mortality risk Figure 4.

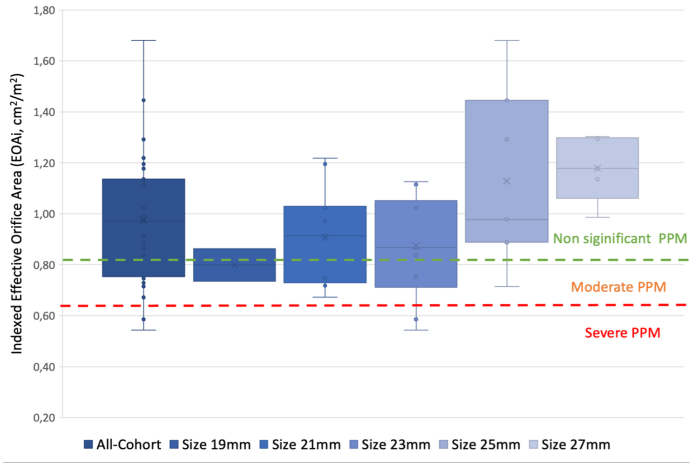

Figure 2. Indexed effective aera for the whole cohort and each size of valve in post-operative; The data are shown as single values (circles) and box and whiskers plot where the upper and lower borders of the box represent the 25% and 75% percentile, the middle horizontal line represents the median, and the upper dans lower wishers represent the maximum and minimum value; Number of each group: all cohort, n=36; Trifecta 19 mm, n=2; 21 mm, n=11; 23 mm, n=10; 25 mm, n=7; 27 mm, n=5

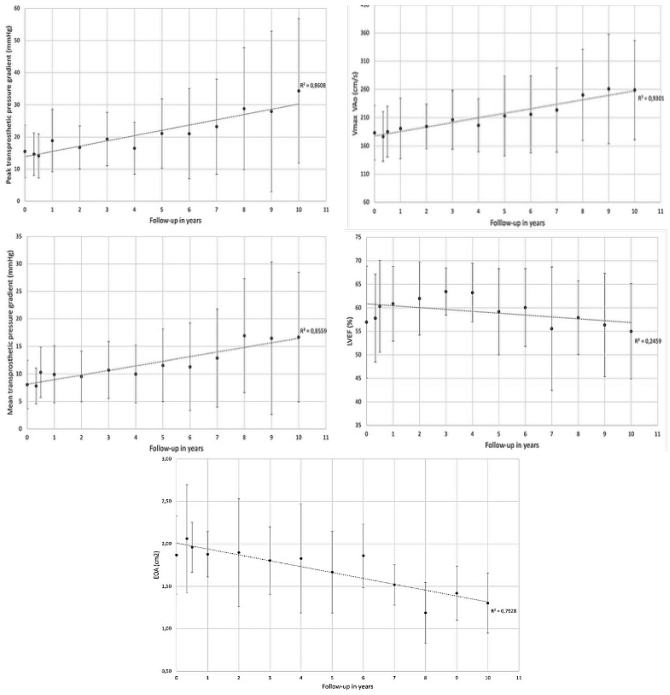

Figure 3. Scatters plots of follow-up result over 10 years for the whole cohort for each mean echocardiographic parameter (Peak and mean transprosthetic pressure gradient, LVEF, EOA and maximal velocity); For each graphic, there is a tendance curve with the R square corresponding

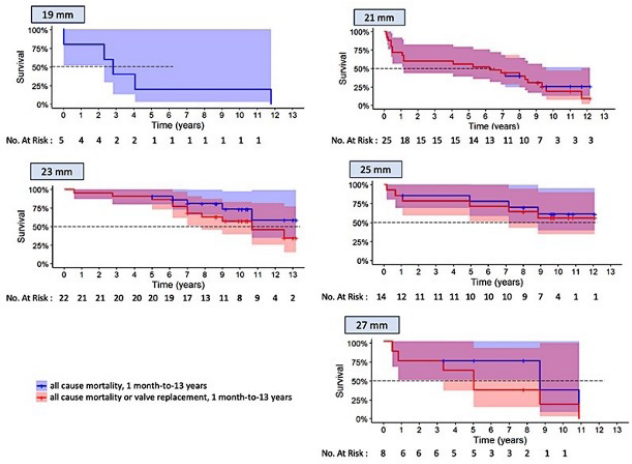

Figure 4. Kaplan-Meier estimates for each size of valve; All-cause mortality with the blue line, and all-cause mortality or valve replacement with the red line both over the study period; The number at risk correspond for all cause death or valve replacement

RESULTS

Baseline Characteristics and Procedural Data

As shown in Figure 1, 164 patients underwent an AVR with the STJ/Abbott-Trifecta® valve at HUG between 2010 and 2018. Among them, 83 patients were accessible for long term follow-up and only 72 survived after the 30th postoperative day. During the study, 34 patients were still alive, and 12 patients underwent a replacement of the STJ/Abbott-Trifecta® with a new prothesis.

The baseline characteristics data are summarized in Table 1. The mean age was 77±10.6 years. Only 6 patients were under 60 years of age. In these patients, 2 were women in childbearing age (mean age 36 years (range 32-38 years)) and 4 were men. We observed a marked gender distribution concerning valve size, with the largest valve sizes more frequent in males. Only the 21-mm size had an almost equal gender distribution. In terms of percentage, 86.7% of size 25-mm valve patients were males with only 2 females (13.3%). In the 23-mm and 19-mm size the gender distribution was almost equal, respectively 58.3%/57.14% male and 41.7%/42.8% female. In the 27-mm size, 100% were male.

Perioperative characteristics are reported in Table 2. Trifecta valve 21-mm was most frequently used (34.9%) followed by 23-mm (28.9%).

Table 1. Pre-operative patient characteristics (n=72)

Characteristic	Value
Gender, M/F, n (%)	45/27 (62.5/37.5)
Age, (years), mean±SD	77±10.6
Group of age, n (%)	
>75	44 (61.1)
60-75	22 (30.6)
<60	6 (8.3)
Non-cardiac comorbidity, n (%)	
Hypertension	51 (70.8)
Active smocking	19 (26.4)
Dyslipidemia	37 (51.4)
Diabetes mellitus	21 (29.2)
Autoimmune disease (ankylosing spondylitis, rheumatoid arthritis, dysthyroidism…)	8 (11.0)
Cardiac comorbidity, n (%)	
Atrial fibrillation	12 (16.7)
Previous cardiac surgery (ascending aortic replacement, CABG, mitral valve replacement, SAVR…)	23 (31.9)
Native valve dysfunction, n (%)	
Aortic stenosis	62 (86.1)
Aortic regurgitation	10 (13.9)
BSA, (m^2), mean (range)	1.9 (1.5-2.5)
BMI, (Kg/m^2), mean (range)	28.6 (17.4-43.9)
NYHA class, n (%)	
IV	36 (50)
III	36 (50)
Preoperative echocardiography	
LVEF, (%), mean (range)	54.1 (20-70)
HFmrEF, n (%)	1 (1.4)
HFrEF, n (%)	12 (16.7)
Patient with an aortic stenosis	
Valve gradient, (mmHg), mean (range)	
Mean	39.8 (11.8-82.6)
Peak	65.5 (32-69.7)
EOA (cm^2), mean (range)	0.80 (0.39-2)
EOAi (cm^2/m^2), mean (range)	0.40 (0.24-0.97)
Vmax VAo (cm/s), mean (range)	388.8 (221.7-596.3)
Patient with an aortic regurgitation	
Valve gradient, (mmHg), mean (range)	
Mean	21.1 (4.0-39.5)
Peak	29.5 (6.1-62.5)
EOA (cm^2), mean (range)	1.13 (0.37-1.7)
EOAi (cm^2/m^2), mean (range)	0.40 (0.19-0.77)
Vmax VAo (cm/s), mean (range)	241.19 (123.5-395.3)

M/F: male/female, BMI: body mass index, BSA: body surface area, NYHA: New York Heart Association, LVEF: left ventricular ejection fraction, HF: heart failure, EF: ejection fraction, HFmrEF: HF with midly reduced EF (LVEF 41-49%), HFrEF: HF with reduced EF (LVEF≤40%), Vmax VAo: maximum velocity through the aortic valve

Table 2. Peri-operative patient characteristics (n=72)

Characteristic	Value
Bioprosthesis valve size, n (%)	
19 mm	4 (5.6)
21 mm	23 (31.9)
23 mm	23 (31.9)
25 mm	14 (19.4)
27 mm	8 (11.1)
Concomitant procedures, n (%)	
Coronary bypass	23 (31.9)
Other valve surgery	10 (13.9)
Ascending aortic surgery	6 (8.3)
Ascending aortic surgery and coronary bypass	2 (2.8)
Other valve surgery and coronary bypass	1 (1.4)
Cardiopulmonary bypass time (min), mean (range)	
Overall population	103 (37-333)
Isolated AVR	76 (37-148)
Concomitant procedure	138 (42-333)
Cross-clamp time, (min) mean (range)	
Overall population	77 (29-230)
Isolated AVR	60 (29-112)
Concomitant procedure	101 (32-230)

Prothesis-Patient Mismatch

The prothesis used for AVR can be too small in relation to body size, thus causing valve PPM and abnormally high transvalvular pressure gradient (16). For the PPM after AVR, we have complete data for 36 patients (the EOA was not always measured post-operatively by cardiologists) Figure 2. Severe PPM (EOAi<0.65 cm^2/m^2) was found in 2 out of 36 patients (5.6%) only with a 23mm size. Moderate PPM (EOAi <0.85 cm^2/m^2) was found in 9 of the patients (25%) including 5 with a 21mm size, 2 with a 23mm size, 1 with a 25mm size and 1 with a 19mm size. The other patients had a non-significant PPM.

Echocardiographic Follow-up

Echocardiographic follow-ups are presented for the entire cohort in Figure 3. There was a steady decrease in EOA (R^2=0.79) with a strong coefficient of correlation and a steady increase with the maximal velocity (R^2=0.93) mean (R^2=0.85) and peak pressure (R^2=0.86) over the study period. There is a strong correlation between these parameters and the time passed with the bioprosthesis except for the LVEF, which has a low coefficient of correlation (R^2=0.25).

We compared means of hemodynamic parameters for the entire cohort, regardless of valve size, by performing an unpaired T-test after verifying the normality of the data. We found significant differences in hemodynamic parameters during the follow-up. At two months of follow-up, the EOA was measured for 10 patients (mean 2.1±0.6 mmHg) and compared with that measured for 6 patients at eight years of follow-up (mean 1.2±0.4 mmHg). The results demonstrated a significant decreased in the EOA (t=3.06; p<0.01). At three years of follow-up, the mean aortic pressure gradient measured in 36 patients (mean 10.7±5.2 mmHg) and compared to that measured in 34 patients at two months of follow-up (mean 7.8±3.3 mmHg). The results demonstrated a significant increase in the mean aortic pressure gradient (t=2.6; p<0.05). At six years of follow-up, the maximum velocity of the aortic transvalvular jet was measured in 26 patients (mean 215.9±68.0 mmHg) and compared to that measured in 73 patients over the post-operative period (mean 183.2±48.8 mmHg). The results demonstrated a significant increase in the maximum velocity of the aortic transvalvular jet (t=2.6; p<0.05). At seven years of follow-up, the maximum aortic pressure gradient measured in 25 patients (mean 23.2±14.8 mmHg) and compared to that measured for 26 patients at two months of follow-up (mean 14.65±6.6 mmHg). The results demonstrated a significant increase in the maximum aortic pressure gradient (t=2.7; p<0.05). At seven years of follow-up, the LVEF measured in 33 patients (mean 55.6±13.1 mmHg) and compared to that measured for 45 patients at two years of follow-up (mean 62.0±7.7 mmHg). The results demonstrated a significant decrease in the LVEF (t=2.7; p<0.05).

Clinical Events

As presented in Table 3. during follow-up, 12 replacements of the STJ/Abbott-Trifecta® valve occurred, at a mean of 6 years and 3 months (range 14-152 months) after the AVR. Of those who received a bioprosthesis, 4 were men and 1 was a woman (mean age 71.8 SD±5.4 years). For TAVI, 4 men and 1 woman benefited from this procedure at a mean age of 72.8 SD±11.6 years. Finally, only 1 man and 1 woman received a mechanical prosthesis at a mean age of 46.5 years SD±0.7 years.

Table 3. Replacement of Trifecta valve (n=12)

Characteristic	Value
Time spent with Trifecta valve, (months), mean (range)	76 (14-152)
Procedures of replacement, n (%)	
TAVI	5 (41.7%)
Others bioprosthesis, n (%)	
Perimount magna ease	4 (33.3)
Freestyle	1 (8.3)
Mechanic valve	2 (16.7)

Following statistical analysis, the numerical findings reveal the 5-year survival rates for each valve size, as illustrated in Figure 4. These rates are as follows: 19mm, 20% (95% confidence interval [CI] 3.46-100); 21mm, 56% (95% CI 39.6-79.3); 23mm, 90.0% (95% CI 79.7-100); 25mm, 77.9% (95% CI 58.7-100); and 27mm, 75% (95% CI 50.3-100).

DISCUSSION

Our previous concerns have been validated by the study findings, which reveal an earlier degeneration of the STJ/Abbott-Trifecta® valve compared to the other aortic valvular bioprosthesis. In fact, 12 patients underwent STJ/Abbott-Trifecta® valve replacement

at a mean of 6 years and 3 months (range 14-152 months) after initial AVR. However, for this type of bioprosthesis, we would expect a lifespan of at least 15 years. In the following section, we will demonstrate the good hemodynamic performance of the bioprosthesis during a short follow-up period, which made it a promising option at its launch. Then, we will examine the high replacement rate of STJ/Abbott-Trifecta® valve observed and the reasons for this early degeneration.

Prosthesis-Patient Mismatch (PPM)

In this study, severe PPM was present in only two patients (5.6%). Previous studies have reported a favorable PPM outcome for the STJ/Abbott-Trifecta® valve compared to other aortic bioprosthesis since its introduction. For example, in 2014, a study compared the STJ/Abbott-Trifecta® valve, implanted in 33 patients, with the Perimount-Magna® valve, implanted in 41 patients with aortic valve disease in Japan. The incidence of PPM was significantly lower in the STJ/Abbott-Trifecta® group than in the Perimount-Magna® group. The STJ/Abbott-Trifecta® valve has been identify as particularly useful in preventing PPM, especially in patients with a small aortic annulus relative to body size, a common scenario in Japanese patients, whose body size is generally smaller than that in Western populations (17).

In another prospective randomized study from 2019, significantly lower transvalvular gradients were observed in the STJ/Abbott-Trifecta® group compared to the Medtronic-Mosaic Ultra® group for the same annulus size. Severe PPM was present in 28% of patients in the Medtronic-Mosaic® group compared to just 3% of patients in the STJ/Abbott-Trifecta® group (18). These characteristics made the STJ/Abbott-Trifecta® valve very attractive. However, each of these observations pertained to a very short post-operative period, and the initial benefits were later overshadowed by a high rate of STJ/Abbott-Trifecta® valve replacements.

Replacement of Trifecta

The study reports 12 instances of Trifecta valve replacements (16.7%) with an average duration of 75 months (range 14-152 months) between the initial implantation and the replacement. However, due to the limited number of patients, no statistically significant difference could be established. Notably, the timing of these reinterventions aligns with the 5-6 year deterioration period reported by Paul Werner and colleagues (19).

In 2022, a large single-center retrospective analysis was conducted on 5,053 patients. Of these patients, 2,630 received a Perimount-Magna® prosthesis with internally mounted leaflets, while 2,423 received an STJ/Abbott-Trifecta® prosthesis with externally mounted leaflets. The study revealed that the Trifecta group had a significantly higher cumulative reoperation rate at 8 years when compared to the Perimount-Magna® group (16.9±1.9% vs. 3.8±0.4%; $p<0.01$) (20). This data indicates that the rate of re-intervention is higher with the STJ/Abbott-Trifecta® valve than with other bioprosthesis, supporting the notion of early valve deterioration.

Additionally, the design of the STJ/Abbott-Trifecta® valve is TAVI-unfriendly (Transcatheter Aortic Valve Implantation). In a standard bioprosthesis, the leaflets are placed inside the suture ring, ensuring that they do not extend beyond the ring's circumference when a TAVI is performed. However, in the STJ/Abbott-Trifecta® valve, leaflets are positioned outside the suture ring, so there is nothing to hold them back when the TAVI is placed. The leaflets can therefore go well beyond the ring and potentially obstruct the coronary ostia, which poses a risk to coronary perfusion and increases the risk of myocardial ischemia (21).

Structural Valve Deterioration (SVD)

In 2020, Paul Werner and colleagues (19) analyzed data on 347 consecutive patients (mean age 71.6±9.5 years, 63.4% male) who underwent AVR with the STJ/Abbott-Trifecta® between 2011 and 2017. They found that the durability of the prothesis decreased at 5-6 years post-surgery, leading to high rates of SVD-associated complications. In our study, hemodynamic parameters showed a significant increase in maximal velocity of the transvalvular jet and peak transprosthetic pressure gradient from 6-7 years of follow-up. Similarly, there was a significant decrease in the EOA and LVEF 7-8 years of follow-up. Thus, there was a deterioration in hemodynamics parameters between 6 and 8 years of follow-up, consistent with previous observations. In a larger cohort of patients studied in 2022, it was revealed that leaflet degeneration is the main mechanism leading to early reintervention, occurring as early as 4-5 years after implantation (9).

Study Limitations

The study has limitations due to its retrospective design, which may affect data collection and analysis. Additionally, variations in post-operative follow-up periods among patients could introduce analytical bias. The results are primarily based on all-cause mortality because data regarding SVD is unavailable, limiting our ability to determine its relevance to STJ/Abbott-Trifecta® failure. Moreover, differences in echocardiographic follow-up among patients, with the majority being monitored in outpatient settings, may result in inconsistent recording of measurements by cardiologists, thus reducing data consistency. The study is further limited by the small number of patients for certain valve sizes, particularly for the 19mm and 27mm. There is also a potential bias since the STJ/Abbott-Trifecta® valve is often implanted in smaller annuli due to its expected better performance despite the smaller size. Out of 164 patients, 81 were not found, largely because they were part of humanitarian missions or were abroad, which is explained by Geneva's international location. However, this is unlikely to represent selection bias as the missing cases were random, but this could lead to a substantial alteration of the results.

CONCLUSION

STJ/Abbott-Trifecta® aortic valve bioprostheses implanted in our institution have shown low gradients for small sizes but have required high number of reoperations secondary to early degenerations. Based on our results and withdrawn-decision by the company, the patients still alive with their STJ/Abbott-Trifecta® bioprostheses should be followed closely by regular echocardiographic controls.

Conflict of Interests: The authors declare that there are no conflict of interests.

Financial Disclosure: The authors declare that there is no financial support.

Ethics Committee Approval: This quality control project was deemed to be outside the scope of Swiss legislation on research involving human subjects, and therefore, the need for local ethics committee approval was waived.

Patient Informed Consent: We obtained written or verbal consent from all patients or their families for data use, either directly or through their treating cardiologist.

REFERENCES

1. Punjabi P, Nawaz MA, Chan KMJ. How a prosthesis in aortic valve replacement is chosen. E Journal of Cardiology Practice. 2011;9.
2. The trifecta valve: in vitro hydrodynamic and durability comparisons of aortic bioprostheses. Available at: https://ptabdata.blob.core.windows.net/files/2013/IPR2013-00041/Exhibit-2007.pdf Accessed Feb 3, 2024.
3. Ruggieri VG, Anselmi A, Chabanne C, Lelong B, Flecher E, Verhoye JP, et al. Three-year haemodynamic performance of the St Jude Trifecta bioprosthesis. Eur J Cardiothorac Surg. 2016;49:972-7.
4. Permanyer E, Estigarribia AJ, Ysasi A, Herrero E, Semper O, Llorens R. St. Jude Medical Trifecta aortic valve perioperative performance in 200 patients. Interact Cardiovasc Thorac Surg. 2013;17:669-72.
5. Levy F, Donal E, Bière L, Szymanski C, Remadi JP, Flécher E, et al. Hemodynamic performance during exercise of the New St. Jude Trifecta aortic bioprosthesis: results from a french multicenter study. J Am Soc Echocardiogr. 2014;27:590-7.
6. Saxena P, Greason KL, Schaff HV. Early structural valve deterioration of the Trifecta aortic valve biological prosthesis: a word of caution. J Thorac Cardiovasc Surg. 2014;147:e10-1.
7. Piñón M, Durán D, Pazos P, Pradas G. Leaflet tear in a Trifecta aortic bioprosthesis 34 months after implantation. Interact Cardiovasc Thorac Surg. 2015;20:281-2.
8. Kaneyuki D, Nakajima H, Asakura T, Yoshitake A, Tokunaga C, Tochii M, et al. Early first-Generation Trifecta valve failure: a case series and a review of the literature. Ann Thorac Surg. 2020;109:86-92.
9. Malvindi PG, Kattach H, Luthra S, Ohri S. Modes of failure of Trifecta aortic valve prosthesis. Interact Cardiovasc Thorac Surg. 2022;35:ivac086.
10. Schaeffer T, Berdajs D, Reuthebuch O. Early surgical aortic bioprosthesis failure caused by cusp tear: a word of caution. Clin Case Rep. 2021;9:286-90.
11. MedTech Dive. Abbott pulls Trifecta heart valves from US market over deterioration rate. Available at: https://www.medtechdive.com/news/abbott-pulls-trifecta-heart-valves-deterioration/689515/ Accessed Feb 3, 2024.
12. Grashkoska Civkaroska S, Grossen C, Meyer P, Perone N, Jackson Y. Management of chronic heart failure: updates and implications for the primary care physician. Rev Med Suisse. 2022;18:1798-801.
13. R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. https://www.R-project.org. 2023.
14. Social Science Statistics. Kolmogorov-Smirnov Calculator (Test of Normality). Available at: https://www.socscistatistics.com/tests/kolmogorov/default.aspx Accessed Mar 8, 2024.
15. Social Science Statistics. T-Test Calculator for 2 independent means. Available at: https://www.socscistatistics.com/tests/studentttest/default2.aspx Accessed Mar 12, 2024.
16. Uğur M, Demir İ, Demirsoy E. Management of prosthesis-patient mismatch after aortic valve replacement. E J Cardiovasc Med. 2019;7:60-5.
17. Maruyama M, Daimon M, Kawata T, Kasai T, Ichikawa R, Miyazaki S, et al. Early hemodynamic performance of the trifecta bioprosthetic valve in patients with aortic valve disease. Circ J Off J Jpn Circ Soc. 2014;78:1372-8.
18. Braathen B, Husebye T, Lunde IG, Tønnessen T. Trifecta has lower gradient and less prosthesis-patient mismatch than Mosaic Ultra in the aortic position: a prospective randomized study. J Thorac Cardiovasc Surg. 2019;158:1032-9.
19. Werner P, Gritsch J, Scherzer S, Gross C, Russo M, Coti I, et al. Structural valve deterioration after aortic valve replacement with the Trifecta valve. Interact Cardiovasc Thorac Surg. 2021;32:39-46.
20. Lange R, Alalawi Z, Voss S, Boehm J, Krane M, Vitanova K. Different rates of bioprosthetic aortic valve failure with PerimountTM and TrifectaTM bioprostheses. Front Cardiovasc Med. 2021;8:822893.
21. Dvir D, Leipsic J, Blanke P, Ribeiro HB, Kornowski R, Pichard A, et al. Coronary obstruction in transcatheter aortic valve-in-valve implantation. Circ Cardiovasc Interv. 2015;8:e002079.