ORIGINAL ARTICLE

AORTIC VALVE SURGERY IN PATIENTS WITH INFECTIVE ENDOCARDITIS: MID-TERM FOLLOW-UP OF PATIENTS TREATED WITH THE ST. JUDE MEDICAL TRIFECTA™ VALVE

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Abstract

Background: *It is particularly difficult to choose the appropriate prosthesis to treat infective endocarditis.*

Objectives: *To investigate the outcomes after aortic valve replacement with a stented bioprosthesis (Trifecta) in patients with active or previous infective endocarditis.*

Methods: *We performed a single-centre, retrospective study including consecutive patients with infective endocarditis who underwent aortic valve replacement between July 2011 and June 2019. Survival and reintervention were assessed as of December 2021. Hospital mortality was defined as death in-hospital or within 30-days of surgery. Kaplan-Meier method was used for time-to-event outcome assessment (all-cause mortality and reoperation). Data are median (minimum and maximum) or absolute (relative) frequencies.*

Results: *We included 51 patients, median age of 69 (40 to 87) years, 78% male. The median follow-up time was 5.4 years and the maximum was 10 years. Most patients (71%) had native valve infective endocarditis and 16% had previous endocarditis. Surgery was urgent in 82%. Hospital mortality occurred in 10 patients (20%). After excluding these patients, 1-, 3-, 6-, and 9-years cumulative survival rates were 93%, 78%, 72%, and 72%, respectively. There were five bioprosthesis-related reoperations: 4 due to endocarditis at 1-year, 3-years, and 5-years on follow-up (n=1, 1 and 2, respectively) and 1 due to non-structural deterioration, 6-years after surgery.*

Conclusions: *Despite the small sample size, this report supports a satisfactory performance profile of the Trifecta bioprosthesis in the treatment of infective endocarditis.*

Keywords: *Infective endocarditis; Aortic Valve Surgery; Bioprosthesis; St. Jude Medical Trifecta valve*

INTRODUCTION

Infective endocarditis (IE) afflicts 3.6—5.4/100,000 individuals per year with a male: female ratio of 2:1.[1], but incidence rises to 15/100,000 per year in those aged over 65 years old. IE's causes and epidemiology have evolved in recent decades with a doubling of mean patient age and increasing prevalence in patients with indwelling cardiac devices. The microbiology of the disease has also shifted, and staphylococci, previously associated with health-care contact and invasive procedures, have overtaken streptococci as the most common agent. In the meantime, prosthetic valves have also evolved to achieve better hemodynamic stability and long-term survival throughout the years. [2]

The presence of heart failure due to acute and severe valvular regurgitation is the principal indication for urgent surgery in most patients with IE, but intervention is also warranted without clinical HF if severe acute aortic or mitral

Table 1 **Baseline sample characteristics**

Variable	n= 51
Age y, median (min – max)	69 (40 – 87)
Male sex, n (%)	40 (78.4)
NYHA III-IV, n (%)	31 (62.0)
Missing (n=1)	
Angina, n (%)	16 (32.0)
Missing (n=1)	
Hypertension, n (%)	39 (76.5)
Diabetes, n (%)	17 (33.3)
Dyslipidemia, n (%)	30 (58.8)
History of smoking, n (%)	19 (37.3)
Body mass index kg/m2, median (min – max)	26.1 (18.0 – 38.4)
Obesity (BMI ≥ 30.00 kg/m2), n (%)	8 (15.7)
EuroSCORE II (%), median (min – max)	
Overall sample	12.3 (0.9 to 91.0)
Isolated Procedures (n= 17)	6.3 (0.9 to 24.5)
Multiple Procedures (n=34)	19.4 (2.7 to 91.0)
Active IE (n=43)	13.8 (1.7 to 91.0)
Previous IE (n=8)	6.9 (0.9 to 20.0)
Coronary artery disease, n (%)	13 (25.5)
Cerebrovascular disease*, n (%)	10 (19.6)
Chronic kidney disease, n (%)	
Severe (clearance creatinine <50mL/min)	15 (29.4)
Dialysis	6 (11.7)
Critical preoperative status**, n (%)	13 (26.0)
Missing (n=1)	
Priority	
Elective, n (%)	5 (9.8)
Urgent, n (%)	42 (82.4)
Emergent, n (%)	4 (7.8)
Moderate-severe LV systolic dysfunction, n (%)	9 (18.0)
Missing (n=1)	

NYHA: New York Heart Association Functional Classification; BMI: Body Mass Index, IE: Infective Endocarditis; min: minimum; max: maximum; LV: left ventricle.
**Cerebrovascular disease was defined as previous stroke, transient stroke, carotid surgery, carotid occlusion or >50% stenosis*
***Critical preoperative status was defined as need for inotropic support, invasive mechanical ventilation or cardiogenic or septic shock before surgery.*

regurgitation presents elevated left ventricular end-diastolic pressure (e.g., premature mitral valve closure) and high left atrial pressure or moderate to severe pulmonary hypertension on echocardiography.[3] Moreover, the presence of an abscess, recurrent embolic events with residual vegetations, multi-drug-resistant organisms, persistent bacteraemia or locally uncontrolled infection are usually not effectively treated with antibiotic therapy alone and commonly constitute surgical indication.[4] Surgical intervention is performed during hospitalisation in about 50% of left-sided infections (infection of a native or prosthetic mitral or aortic valve).

Low thrombogenic risk, enhanced haemodynamic performance, and extended durability have made recent pericardial bioprosthesis models appealing solutions promising good clinical outcomes even for younger patients. The Trifecta prosthesis (St. Jude Medical, Inc., St. Paul, MN, USA) is an aortic pericardial bioprosthesis with a titanium stent that was designed to have minimal haemodynamic impact enabling lower transprosthetic gradients and increased effective orifice area (EOA). Leaflets are mounted as a single pericardial patch in the outer aspect of the struts which allows for almost circular cross-section during systole[5,6]. Trifecta bioprosthesis received European CE-mark approval in 2010 and Food and Drug Administration (FDA) approval in 2011[6]. Some reports have shown a favourable haemodynamic profile with positive impact on ventricular remodelling and ventricular mass regression[7-10].

Previous studies showed controversial results regarding the choice of prosthesis to treat IE [11,12]. Most studies compared biological with mechanical valves, without specifying differences between distinct bioprosthetic or mechanical prosthesis types. As we previously reported, the hemodynamic profile of the TF valve seems highly favourable [10].

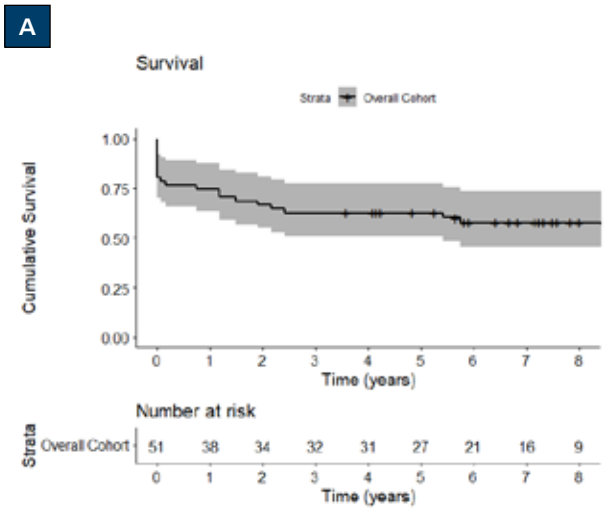
The aim of the current study was to evaluate the clinical performance of the Trifecta bioprosthesis in IE patients. The primary outcomes were mid-term survival and reoperation rates. Secondary outcomes were early results, such as hospital mortality and early postoperative complications (stroke, de novo atrial fibrillation, permanent pacemaker implantation, need for re-intervention due to bleeding) as well as an assessment of haemodynamic performance by echocardiography.

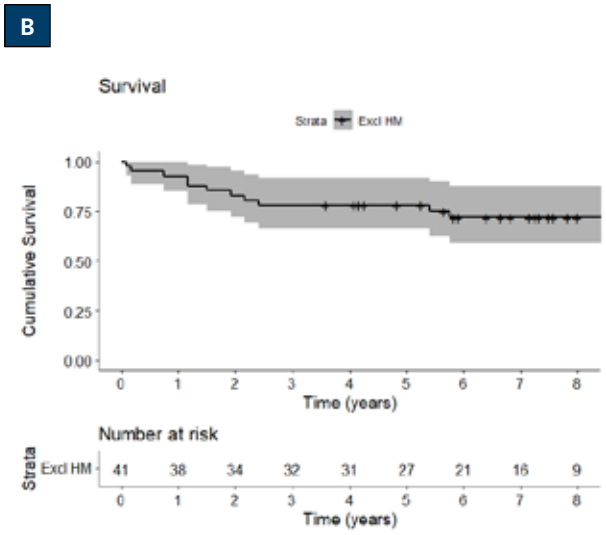
PATIENTS AND METHODS

Study design, setting and patients

We performed a single-centre, retrospective observational study. Consecutive adult patients with a definite diagnosis of active or previous (healed) IE, according to Modified Duke criteria[13], who underwent aortic valve replacement (AVR) with the Trifecta bioprosthesis from July 2011 to June 2019 were included. No exclusion criteria were applied.

This study was approved by the local Ethics Committee. Patient informed consent was waived due to the retrospective and observational nature of the study. Confidentiality and anonymity were ensured during data handling.





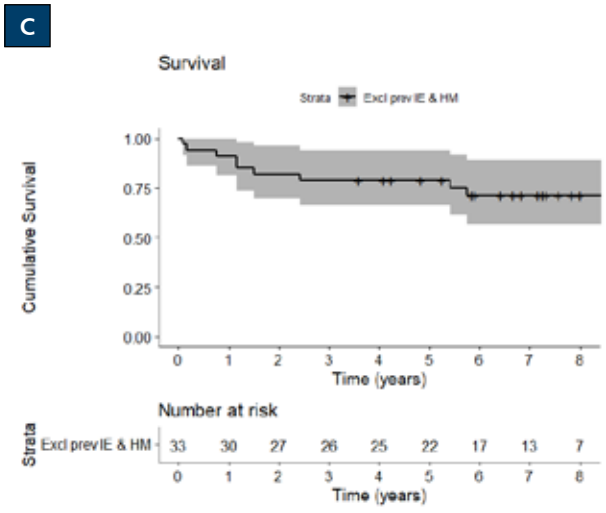


Figure 1 *Cumulative survival curves including the overall cohort a); excluding hospital mortality (HM) b); and excluding both hospital mortality and previous infective endocarditis (IE) cases c).*

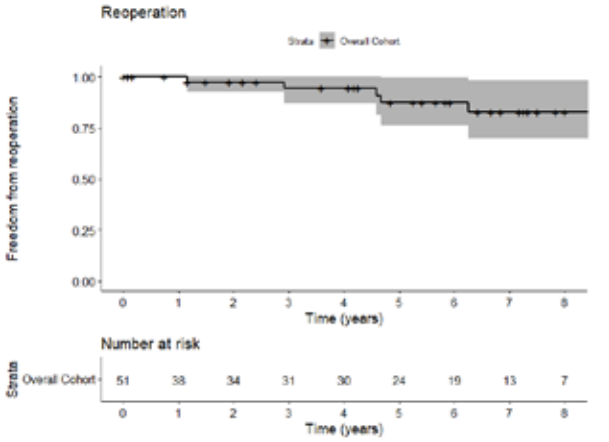


Figure 2 *Freedom from prosthesis-related reoperation*

Surgical technique

Selection of prosthesis was left at the patients' and surgeons' discretion. As previously described, TF was implanted in a supra-annular position under mild hypothermic or normothermic cardiopulmonary bypass (CPB) and cardioplegic arrest. According to surgeons' preference, the valves were sutured using interrupted U-shaped pledgeted 2-0 polyester stitches, interrupted simple 4-0 polyester sutures or continuous polypropylene suture. [10]

Surgery for IE is demanding. If the infection is restricted to native valve leaflets (cusps), removal of the infected material suffices, but if it evolves into the annulus or surrounding myocardium further debridement is warranted.[14]

Variables

Clinical and surgical information regarding preoperative and postoperative periods were retrospectively collected through clinical files and national registries. With respect to IE data, the number of affected valves, the microorganisms involved, and the presence of vegetations or abscesses were systematically recorded. Echocardiographic evaluation data were also obtained from the local database.

According to centre protocol, patients were evaluated for postoperative clinical observation and transthoracic echocardiography (TTE). From this evaluation, we obtained mean gradients and Effective Orifice Area (EOA).

The priority of the surgery was classified as elective (patients who were electively admitted for surgery), urgent (patients not admitted for surgery who required AVR before discharge) and emergent (patients requiring intervention before the next working day). EuroSCORE II was estimated for all patients.

Outcomes

All-cause mortality and prosthesis-related reoperation

Table 2 **Characteristics of Infective Endocarditis.**

Variable	n= 51		
Aortic valve endocarditis			
Native, n (%)	36 (70.6)		
Prosthetic, n (%)	15 (29.4)		
Active Endocarditis, n (%)	43 (84.3)		
Microorganisms	Total (n=50)	Native valve (n=35)	Prosthetic valve (n=15)
Staphylococci (St.), n (%)	10 (20.0)	6 (17.1)	4 (26.7)
St. aureus, n (%)	7 (14.0)	5 (14.3)	2 (13.3)
Streptococci, n (%)	14 (28.0)	11 (31.4)	3 (20.0)
Viridians streptococci, n (%)	5 (10.0)	5 (14.3)	0 (0.0)
Enterococcus species, n (%)	10 (20.0)	6 (17.1)	4 (26.7)
Enterococcus faecalis, n (%)	9 (18.0)	5 (14.3)	4 (26.7)
Others, n (%)	5 (10.0)	4 (11.4)	1 (6.7)
Culture negative, n (%)	12 (24.0)	9 (25.7)	3 (20.0)
Missing (n=1)			
Presence of abscesses and vegetations			
Abscess only, n (%)	7 (14.9)		
Vegetations only, n (%)	32 (68.0)		
Both abscess and vegetation, n (%)	7 (13.7)		
Without abscess or vegetation, n (%)	1 (2.1)		
Missing (n=4)			

were queried by accessing the National Registry and local clinical files as of December 2021, respectively.

Immediate postoperative adverse events recorded were: de novo atrial fibrillation (AF), need for permanent pacemaker implantation, prolonged invasive ventilation (>24 h), stroke, hospital mortality (within 30 days of intervention or before discharge), and need for re-intervention due to bleeding or mediastinitis.

Structural valve deterioration (SVD) was considered if any intrinsic changes in the valve occurred, non-structural valve dysfunction (NSVD) was defined as any abnormality not intrinsic to the implanted valve that did not directly involve valve components, including new onset of coronary ischemia from ostial coronary obstruction[15] according to standardised definitions of structural deterioration and valve failure for long-term durability of transcatheter and surgical aortic bioprosthetic valve assessment.

Statistical analysis

Data processing and statistical analysis were carried out in Statistical Package for Social Sciences, IBM Corporation, Armonk, NY, USA, for Windows and R version 4.0.4 (survival package) [16]. Normality distribution was assessed by visual inspection histograms. Continuous variables are presented as mean ± standard deviation or median (minimum and maximum), as adequate. Categorical variables are given by absolute values and relative frequencies (valid percentage, excluding missing values). Kaplan-Meier curves were used to evaluate time-to-event data, specifically cumulative survival, and freedom from prosthesis related reoperation.

RESULTS

Sample characteristics

We included 51 patients aged 69 (40-87) years. The median European System for Cardiac Operative Risk Evaluation (EuroSCORE) II was 12.3% (0.9% to 91.0%), 78% were male, 77% had arterial hypertension, 59% dyslipidemia, 37% had a history of smoking, 33% diabetes mellitus, and 16% were obese. The majority (82%) of surgical interventions were

urgent (n=42), 10% were elective (n=5), and 8% were emergent (n=4). Detailed patient characteristics are presented in Table 1.

Table 2 presents IE features. Most patients (71%) had native aortic valve IE, and 15 (29%) prosthetic IE. The most frequently isolated microorganisms were Enterococcus Faecalis (n=8) and Staphylococcus aureus (n=6), and in 1 patient, both Staphylococcus aureus and Enterococcus Faecalis. Moreover, Streptococci spp were the most prevalent microorganisms in patients with native valve IE (31.4%). Enterococcus species were mostly isolated in the subgroup of previous prosthetic valve (26.7% vs 17.1%). Vegetations without abscess were present in 32 patients, whereas 7 and 7 patients presented only abscesses or both vegetations and abscess, respectively. Forty-three patients presented active IE (clinically uncontrolled infection).

Data related to the intervention is presented in Table 3. IE involved the aortic valve alone in 59% of patients, aortic and mitral in 20%, aortic and tricuspid valves in 8%, and 14% had aortic, tricuspid, and mitral valve involvement. The majority of patients underwent concomitant cardiac procedures (67%) and only 17 patients underwent isolated AVR. Fourteen patients had abscesses closure/drainage and 10 patients had intervention on the aortic root.

Table 3 **Operative data.**

Variable	n= 51
Cross-clamp time, minutes, median (min – max)	
Overall sample	110 (28 to 279)
Isolated procedure	52 (28 to 150)
Multiple procedures	142 (48 to 279)
Missing (n=10)	
Bypass time, min, median (min – max)	
Overall sample	175 (45 to 400)
Isolated procedure	70 (45 to 216)
Multiple procedures	190 (77 to 400)
Missing (n=10)	
Isolated AVR, n (%)	17 (33.3)
Double valve replacement	
Aortic + Mitral, n (%)	10 (19.6)
Aortic + Tricuspid, n (%)	4 (7.8)
Triple Valve replacement	
Aortic + Mitral + Tricuspid, n (%)	7 (13.7)
CABG, n (%)	9 (17.6)
Abscesses closure/drainage	14 (27.5)
Aortic root	10 (19.6)
Trifecta Prosthesis size	
19, n (%)	3 (5.9)
21, n (%)	10 (19.6)
23, n (%)	18 (35.3)
25, n (%)	18 (35.3)
27, n (%)	2 (3.9)

AVR: aortic valve replacement; CABG: coronary artery bypass grafting.

Early Outcomes

Hospital mortality was 20%. From the 10 cases of hospital death (median EuroSCORE 44.3%), 5 were redo cases and 7 required concomitant procedures. From 3 cases of isolated AVR, 2 were emergent. None of the patients with previous endocarditis died in hospital whereas 5 out 15 patients with prosthetic IE did.

As for early post-operative adverse outcomes, 30% of patients required prolonged invasive ventilation, 27% developed postoperative AF, and 7% required definitive pacemaker implantation. Three patients underwent chest re-exploration due to bleeding/tamponade, one of them also required myocardial revascularization (Table 4).

Follow-up Outcomes

Mortality and reoperation data were available for all patients. Median and maximum follow-up time was 5.6 years and 10 years, respectively. Overall cumulative survival rates at 1-, 3-, 6-, and 8-years were 75, 63, 58, and 58%, respectively (Figure 1a). Upon exclusion of hospital deaths, the 1-, 3-, 6-, and 8-years cumulative survival rates were 93, 78, 72, and 72%, respectively (Figure 1b). An analysis restricted to patients with active IE excluding early deaths showed cumulative survival rates of 91, 79, 71, and 71% at 1-, 3-, 6-, and 8-years, respectively (Figure 1c). Amongst 8 patients with clinically controlled infection there were only 2 deaths, at 2 years of follow-up.

There were 5 reoperations related to the bioprosthesis on follow-up: 4 due to IE (1, 1 and 2 cases at 1-year, 3-years, and 5-years, respectively) and 1 due to nonstructural valve deterioration (intra-prosthetic regurgitation) 6-years after the procedure. Freedom-from valve-related reoperation, at 1-, 3-, 6-, and 8-years was 100, 94, 87, and 83%, respectively (Figure 2).

Regarding follow-up echocardiography, it was performed in 36 of 41 discharged patients at a median of 5 months after AVR. The mean transprosthetic gradient (MTG) was 11±4 mmHg and the mean effective orifice area was 2.3±0.6 cm2. Seven patients had intraprosthetic regurgitation (minimum to mild). Five patients had paravalvular leaks, 2 being moderate and 3 being mild, but none of them were reoperated. Furthermore, 4 patients presented with pseudoaneurysms or shunts or subaortic persistent cavity. Of these, one patient with a subaortic shunt was reoperated due to

new infective endocarditis ~5 years after the index procedure; and another patient persisted with an abscess linked to right ventricle being reoperated 8 months after Trifecta implantation. However, this patient does not need to replace the Trifecta valve.

DISCUSSION

This retrospective study described 51 patients with IE who underwent AVR with the St. Jude Medical Trifecta (TF) bioprosthesis. Most patients presented with active IE in native valves and underwent urgent or emergent procedures, resulting in a median EuroSCORE II of 12.3% (0.9% to 91% and mean of 20.2%). In-hospital mortality and 9-year cumulative survival was 20% and 58%, respectively. Five patients required reintervention due to prosthesis IE or dysfunction.

After an exhaustive search we couldn't find any studies that investigated the outcomes of IE treatment with TF valve. Nevertheless, there are studies with other valves, most of them comparing biosprothesis valves with mechanical valves. Regarding the bioprosthesis valve, we compared our data versus theirs.

Some authors found no significant differences in mortality between biological and mechanical prothesis, having observed, as expected, a higher rate of reoperation in younger patients who received biological prosthesis. [11,17,18] However, further studies should be performed to determine the factors related to the type of aortic prosthesis implanted in the context of active IE and the prosthesis-related outcomes. [19]

The study by Toyoda et al. (2018)[11] including 1844 aortic valve replacement for active IE did not find differences in 12-year survival after AVR between mechanical and biological prostheses (cumulative survival of ~62% vs ~52%, respectively) when adjusted for patient characteristics. Regarding the Kaplan-Meier related to the bioprosthetic aortic valve at 1-, 3-, and 6-years cumulative survival rates were 84.0%, 77.3%, and 73.3%, respectively. However, these authors excluded patients who had multiple valve surgery, history of previous valve surgery, heart transplant or ventricular assist device placement or a history of drug abuse, which could explain their better survival results when compared with our cohort that includes all-comers that received a TF valve.

A previous study by Malvindi et al. (2021)[20] that evaluated the outcomes of patients with acute prosthetic aortic valve endocarditis, reported hospital mortality of 17%. Survival rate at 1-year was 78%. This study reports better outcomes than our study with TF even if all patients already had a previous AVR surgery. However, the majority of surgeries performed were isolated Aortic valve replacement (38%) and composite valve graft aortic root replacement (24%), concomitant procedures being less frequent. These findings are similar to ours and small differences may be due to different patients' characteristics (mean age 65 years vs. our cohort median age 69 years) and disease severity.

A study by Michelle Musci et al. (2008)[1] reported, in 255 patients with active IE receiving the Shelhigh Stentless bioprothesis, a 30-day, 1-, 3- and 5-year survival of 77, 60, 53 and 47%, respectively. In the same study, a total of 22 out of 255 patients (8.6%) developed reinfection. Of these, 17 (6.6%) had to be re-operated. Our findings reported higher cumulative survival and lower reoperation rate due to reinfection (7.8%, n=4/51). Differences between the Shelhigh Stentless and the Trifecta Stented bioprosthesis could be due to the small sample size of our cohort and our inclusion of patients with previous IE whose prognosis is more favourable. Corroborating this, Schaefer and colleagues[21] reported impaired survival results with the stentless bioprosthesis in their subgroup analysis of patients with native valve IE (Sorin Freedom Solo vs. Carpentier Edwards Perimount).

Delahaye et al. (2015)[19] conducted a study among 5591 patients included in the International Collaboration on Endocarditis Prospective Cohort Study, where 1467 patients with definite IE were operated on during the active phase and had a biological (37%) or mechanical (63%) valve replacement. The in-hospital and 1-year death rates in the bioprosthesis group were 20.6% and 25.3%, respectively. These results are identical with our findings (20% and 25% respectively).

Postoperative echocardiograms of our patients were similar to the postoperative echocardiograms of an overall study of AVR with Trifecta valve by Raimundo et al, where the mean transprosthetic gradient was 10.9±4.1 mmHg and the effective orifice area was 2.0±0.5 cm2 (10). This translates into a satisfactory overall haemodynamic performance of the TF bioprosthesis in IE patients.

The main limitations of our study are those inherent to single-centre studies and the small sample size. The un-

Table 4 **Post-operative immediate outcomes.**

Variable	n= 51
Invasive Ventilation (>24h), n (%)	15 (30.0)
Missing (n=1)	
De novo AF*, n (%)	14 (27.4)
Definitive Pacemaker Implantation**, n (%)	3 (6.5)
Stroke, n (%)	1 (2)
Chest re-exploration due to bleeding/mediastinitis, n (%)	2 (3.9)
Chest re-exploration and CABG, n (%)	1 (2)
Hospital mortality, n (%)	10 (19.6)

AF: atrial fibrillation, CABG: Coronary Artery Bypass Graft.
**Excluding patients with pre-operative AF or pacemaker rhythm*
***Excluding patients with pre-operative pacemaker or peri-operative pacemaker probes implantation*

availability of information during follow-up about total re-infection rate and serial hemodynamic evaluations is also an important limitation. Similarly, we do not have access to causes of death and the analysis corresponds to all-causes-mortality. Even though, we believe this data is of value and adds to the existing limited evidence for assisting decision on the type of prothesis and intervention in IE patients.

CONCLUSION

Our descriptive analysis reinforced the severity of IE disease and the high surgical risk of this population (median and mean EuroSCORE II of 12.3% and 20.4%, respectively) which translated into high early mortality rates (20%).

After excluding early mortality patients, the 1-, 3-, 6-, and 8-years cumulative survival rates were 93, 78, 72, and 72%, respectively. Freedom-from valve-related reoperation at 8-years was 83%. Despite the small sample size, the findings of this report indicate that the TF valve seems to have a satisfactory overall mid-term safety profile in the treatment of IE. Further studies are needed to establish the better prosthesis choice for a long-term perspective according to patient characteristics and specific clinical conditions.

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