

Early Outcome after Aortic Valve Replacement with a Sutureless Bioprosthesis

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Abstract

Background: Aortic stenosis is one of the most prevalent valvular disorders. In people experiencing symptoms, the life expectancy decreases if the condition is not addressed. The only effective treatment for significant aortic lesions is valve replacement. This study aimed at reporting the early clinical outcomes of aortic valve replacement with Perceval sutureless bioprosthesis.

Methods: The study involved 50 patients aged 21 to 82 years, comprising both genders, who were indicated for aortic valve replacement with or without additional cardiac procedures and consented to participate. Patients were included based on their desire for or indication of receiving a tissue valve.

Results: Dedicated Aortic cross clamp time was 43.90 ± 7.53 minutes, and Effective orifice Area at discharge was 1.51 ± 0.12 . Hemodynamics assessment at discharge showed good function of all implanted valves with low trans-valvular pressure gradients (mean, 11.14 ± 4.19 mmHg and peak, 20.72 ± 7.31 mmHg) and low incidence of paravalvular leakage. We had one In-hospital mortality (2%). Up to six months after surgery, survivors demonstrated a positive clinical outcome, and the valve prosthesis maintained stable hemodynamic functionality. One patient (2%) had a Paravalvular leak progressing over time and required reoperation. Permanent pacemaker incidence was 6%.

Conclusions: Prosthetic hemodynamic performance was satisfactory, early results showed a high rate of successful implantation, and times for aortic cross-clamp and cardiopulmonary bypass were shorter than those for traditional aortic valve replacement, according to published data. Mortality and morbidity rates were also low.

Keywords: Early Outcome; Aortic Valve Replacement; Sutureless Bioprosthesis; Aortic Stenosis, Perceval

1. Introduction

Aortic stenosis (AS) ranks high among the several valvular diseases. Individuals experiencing symptoms have a reduced life expectancy if the condition is not addressed.¹

Removal of mechanical obstruction is the only effective treatment for AS. The goal of lowering mortality has only been demonstrated to be achieved by aortic valve replacement (AVR).²

Traditional AVR is still the gold standard for treating severe AS symptoms because of its proven effectiveness in both the short and long term.³

Age and demographics of patients referred for

AVR are changing. Surgical AVR was not offered to over one third of patients in Europe who were 75 years old or older because to the greater risks associated with old age and comorbidities. In addition, the database of the Society of Thoracic Surgeons (STS) revealed that, in the last 20 years, the number of patients who need both the procedure and a coronary artery bypass graft (CABG) has increased from 5% to 25%.^{4, 5}

As a result, minimally invasive procedures like percutaneous transcatheter aortic valve implantation (TAVI) and the creation of "sutureless" aortic valves have been developed to address the increased risk profiles of modern patients. These innovations eliminate the need for sutures during surgical AVR.^{6, 7}

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Sutures are usually threaded through the prosthetic valve's sewing cuff and into the annulus during surgical AVR. Sutureless valves eliminate the need for sutures, thus expediting the procedure and reducing both ACC and CPB times—factors that independently predict thirty-day postoperative mortality in cardiac surgeries.⁸⁻¹⁰ Patients at high risk or undergoing lengthy concurrent or redo procedures are the ones who ultimately benefit from a shorter implantation time.¹¹

The calcified AV cannot be removed with a TAVI, and there is a high risk of paravalvular leak (PVL), permanent pacemaker installation (PPI), neurological abnormalities, and dramatically increased costs. TAVIs were created to help patients who could not have standard AVR with CPB.¹¹ More importantly, TAVIs are limited to patients with isolated AV pathology.¹²

The notion of a “sutureless” valve dates back to the 1960s when Magovern and Cromie introduced a ball-in-cage sutureless valve. Though the use of this valve persisted into the 1980s, potential complications such as PVL and embolization hindered its further advancement.^{13,14} Recently, interest in sutureless aortic valves has surged due to rapid advancements in valve technologies. Among sutureless bioprostheses, the Perceval aortic valve (Livanova PLC, London, UK) stands out; multiple studies have shown promising outcomes in terms of mortality, morbidity, and hemodynamic performance.¹⁵

Rapid and sutureless deployment of aortic valves is a biological, pericardial prosthesis that can be anchored within the aortic annulus with a maximum of three sutures. Among the prostheses that were available were the now-defunct 3F Enable (Medtronic in Minneapolis, USA; Perceval from Livanova PLC in London, UK) and Intuity Elite (Edwards Lifesciences in Irvine, USA). Notably, Perceval is the only true sutureless valve (SU-AV) since it does not require any permanent sutures, while the Intuity valve is classified as a rapid deployment valve (RD-AV).¹⁶

The Perceval bioprosthesis is an adaptation of the Sorin Pericarbon valve (Sorin Biomedica Cardio Srl). It consists of a Nitinol stent attached to bovine pericardium. To place the bioprosthesis in the right place, it is compressed, placed on a valve delivery system, and maneuvered over three sutures at the annulus level. The stent is expanded using a balloon for 30 seconds at a pressure of 3 atm after the delivery system is in situ. Once the valve position and coronary ostia have been visually examined, the sutures are removed and

the aorta is reopened.¹⁷

This study detailed the results of early follow-up on the clinical outcome, hemodynamic performance of the Perceval bioprosthesis, and the influence of sutureless implantation on aortic cross-clamp and bypass times.

2. Patients and methods

Our prospective cohort study included 50 patients aged 21-82 years old, 56% males, requiring AVR with or without concomitant cardiac procedure, as decided by the local Joint Cardiac Committee, who agreed to participate in the clinical evaluation. We included all patients who were either candidates for or already had a tissue valve and for whom the Perceval valve was not a contraindication. Of the 50 patients, 35 (70%) underwent isolated AVR and 15 (30%) had a concomitant procedure.

The study was conducted from January 2019 to January 2023 after approval from the Ethical Committee. It was ensured that all patients provided written informed consent.

Exclusion criteria were acute infective endocarditis, ascending aortic dilatation/dissection, and an aortic valve annulus measurement of 19 mm or larger than 27 mm.

A comprehensive history, physical, and cardiac examination, as well as the standard laboratory testing, chest x-ray, echocardiography, and coronary angiography for patients above 40 years of age, and multi-slice CT were performed on each patient.

The patients' operational risk was assessed using the EuroSCORE II and STS scores.

A local database was updated with the registered data, which included the following when the data collection forms were filled out:

Pre-operative:

Demographic data (age, sex), New York Heart Association (NYHA) class, comorbidities, baseline echocardiographic data, and baseline rhythm.

Operative data:

Cardio-pulmonary bypass time, cumulative Aortic cross-clamp time, cross-clamp time for aortic valve replacement only, and inotropic support if used.

Intraoperative Trans Esophageal Echo (TEE) was used for all patients to assess successful Perceval implantation but intraoperative TEE measurements were not used in the registered data. We elected to use pre discharge Trans Thoracic Echo (TTE) as it compares better with preoperative and post discharge TTE.

Postoperative data:

Time spent on mechanical ventilation, length of

stay in the intensive care unit (ICU), mortality rate, and length of hospital stay are all factors to consider.

Recordings of Pre-discharge echocardiography data and data after one month and after six months, collected on the follow up visits, were compared with the recorded preoperative echocardiographic measurements namely: LV end diastolic diameter, LV end systolic diameter, fractional shortening and LV ejection fraction, aortic valve area and trans-aortic gradients.

All patients were prescribed aspirin for a duration of three months following surgery. Anticoagulation was administered to those with persistent atrial fibrillation or other relevant conditions.

Sample Size Calculation:

The statistical software Epi-Info 2002 was employed to calculate the sample size. In determining the sample size, the following factors were taken into account: 95% confidence level and the prevalence of In-hospital/30-d mortality was 3.2% according to a previous study¹⁸ $\pm$ 5% confidence limit. In order to prevent dropout, two more cases were added. Hence, fifty cases were recruited.

Statistical analysis

The statistical application for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA), was employed to analyze the recorded data. When quantitative data followed a normal distribution, it was shown as the mean $\pm$ standard deviation and range. On the other hand, variables that did not follow a normal distribution were shown as the median with inter-quartile range (IQR). Qualitative variables were expressed as percentages and frequencies. The Kolmogorov-Smirnov and Shapiro-Wilk tests were employed to examine the data for normality. To compare related samples, we employed a paired sample t-test for significance. A 95% confidence interval and a 5% margin of error were both accepted. Since the p-value was less than 0.05, it was deemed significant.

3. Results

Results are summarized in the following tables and graphs:

Table 1. Demographic data, NYHA class and comorbidities among study group

DEMOGRAPHIC DATA		TOTAL (N=50)
AGE (YEARS)		63.44 $\pm$ 10.66
SEX	Male	28 (56.0%)
	Female	22 (44.0%)
NYHA CLASS		
CLASS 1		1 (2.0%)
CLASS 2		25 (50.0%)
CLASS 3		19 (38.0%)
CLASS 4		5 (10.0%)
CO-MORBIDITIES		
	DM: Diabetes mellitus	25 (50.0%)

SMOKING	HTN:	31 (62.0%)
	Hypertension	
	Ex-smoker	1 (2.0%)
	Heavy smoker	2 (4.0%)
IHD: ISCHEMIC HEART DISEASE	Current smoker	6 (12.0%)
	IHD (non-significant lesions)	7 (14.0%)
	IHD with previous PCI	6 (12.0%)
HEART FAILURE		4 (8.0%)
RENAL IMPAIRMENT		5 (10.0%)
BRONCHIAL ASTHMA		2 (4.0%)
ARRHYTHMIA	Permanent AF	3 (6.0%)
	Paroxysmal AF	3 (6.0%)
	PPI	1 (2.0%)
HYPOTHYROIDISM		2 (4.0%)
COPD		3 (6.0%)
OLD STROKE		2 (4.0%)
PREVIOUS CARDIAC INTERVENTION	Previous AVR (tissue) for previous Infective Endocarditis with root abscess	
	Previous Mitral balloon Valvuloplasty	1 (2.0%)
	Previous AVR (tissue) & subaortic membrane resection	1 (2.0%)
	Sub aortic membrane resection	1 (2.0%)
	Percutaneous Coronary Intervention	6 (12.0%)
MORBID OBESITY		1 (2.0%)

Data are presented as number (%). PCI: Percutaneous Coronary Intervention. AF: Atrial Fibrillation. PPI: Permanent Pacemaker Implant. COPD: Chronic obstructive pulmonary disease.

Table 2. Euro SCORE, STS score mortality, STS score morbidity descriptive and baseline rhythm distribution among study group

EURO SCORE		1.94 ± 1.89
STS SCORE		1.96 ± 1.85
MORTALITY		
STS SCORE		12.07 ± 8.38
MORBIDITY		
BASELINE RHYTHM	Normal sinus Rhythm	43 (86.0%)
	Permanent AF	3 (6.0%)
	Sinus with paroxysmal AF	3 (6.0%)
	Permanent Pacemaker Implant	1 (2.0%)

Table 3. Perceval size distribution and type of operation among study group

PERCEVAL SIZE	
LARGE	18 (36.0%)
MEDIUM	18 (36.0%)
SMALL	9 (18.0%)
X LARGE	5 (10.0%)
TYPE OF OPERATION	
ISOLATED AVR	35 (70.0%)
COMBINED PROCEDURE	15 (30.0%)
VALVULAR	10 (20.0%)
VALVULAR PLUS CABG	2 (4.0%)
CABG	2 (4.0%)
AUGMENTATION OF AORTOTOMY WITH A PATCH (FRIABLE AORTIC WALL)	1 (2.0%)

CABG: Coronary artery bypass graft surgery.

Table 4. Intraoperative data, Postoperative, mortality and morbidity distribution among study group

INTRAOPERATIVE DATA	
BYPASS TIME (MIN)	98.56 ± 55.08
CROSS CLAMP TIME (MIN)	67.32 ± 42.38
DEDICATED CROSS CLAMP	43.90 ± 7.53
POSTOPERATIVE DATA	
VENTILATION TIME (HOUR)	13.99 ± 19.98
INOTROPES	27 (54.0%)
ICU STAY (DAYS)	5.02 ± 5.20
HOSPITAL STAYS (DAYS)	11.48 ± 7.23
MORTALITY	
MORTALITY	1 (2.0%)
MORBIDITY	
REOPERATION FOR BLEEDING	1 (2.0%)
REOPERATION FOR PERICARDIAL EFFUSION OR TAMPONADE	1 (2.0%)
REOPERATION FOR VALVULAR PROBLEMS (PARAVALVULAR LEAK)	1 (2.0%)
STERNOTOMY WOUND INFECTION	2 (4.0%)
POSTOPERATIVE NEUROLOGICAL DYSFUNCTION	3 (6.0%)
HEMOFILTRATION POSTOPERATIVELY	3 (6.0%)
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME	1 (2.0%)
NEW ARRHYTHMIA	
LEFT BUNDLE BRANCH BLOCK	3 (6.0%)
PERMANENT PACEMAKER	3 (6.0%)
ATRIAL FIBRILLATION	2 (4.0%)

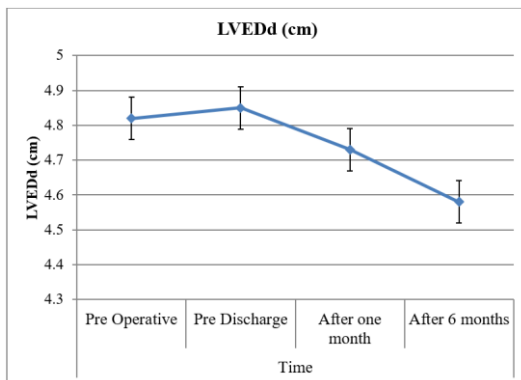


Figure 1. Comparison between preoperative LVEDd and postoperative measurements “pre discharge, after one month and after 6months” among study group.

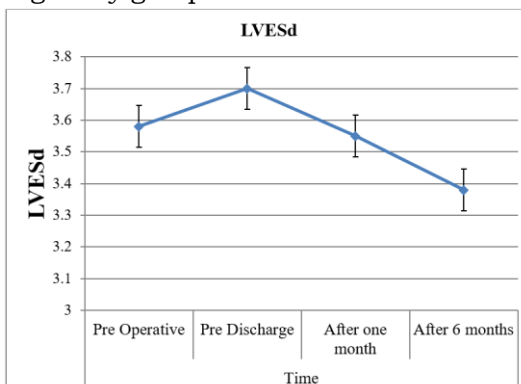


Figure 2. Comparison between preoperative LVESd and postoperative measurements “pre discharge, after one month and after 6months” among study group.

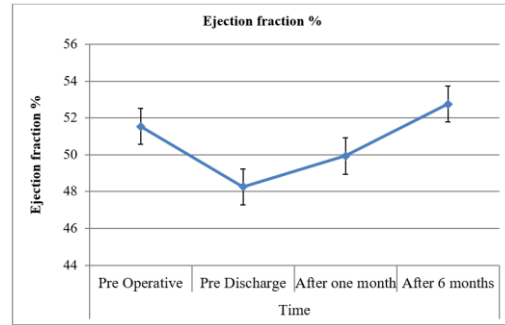


Figure 3. Comparison between preoperative ejection fraction and postoperative measurements “pre discharge, after one month and after 6months” among study group.

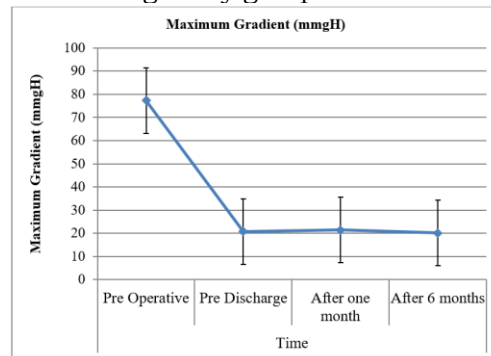


Figure 4. Comparison between preoperative maximum gradient and postoperative measurements “pre discharge, after one month and after 6months” among study group

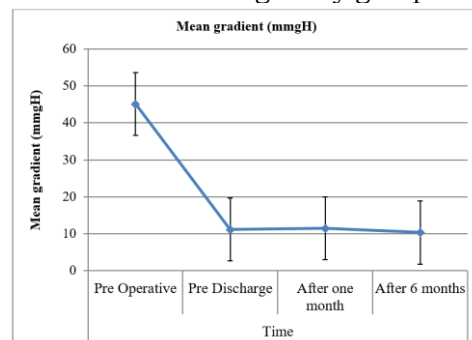


Figure 5. Comparison between preoperative mean gradient and postoperative measurements “pre discharge, after one month and after 6months” among study group.

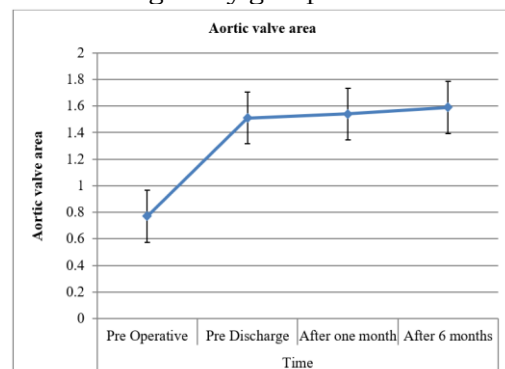


Figure 6. Comparison between preoperative aortic valve area and postoperative measurements “pre discharge, after one month and after 6months” among study group.

6months" among study group.

No conversion to conventional AVR surgery was needed; however, 2 patients required intraoperative repositioning of the valve due to PVL on intraoperative TEE.

4. Discussion

The creation of sutureless bioprosthetic valves was prompted by the higher surgical risks associated with traditional sutured AVR.¹⁹ Although TAVI has been created for this high-risk group, it is only appropriate for patients who have isolated aortic valve disease at the moment.

Aortic bioprostheses like the Perceval valve don't require permanent sutures for a quick and painless installation.²⁰

A decrease in ACC and CPB timings is the primary benefit of employing such valves.²¹ This helps lower the risk of death and illness, which is especially helpful for those at higher risk.²²

Operative times

In present study bypass time was 98.56(±55.08) min. Cross-clamp time was 67.32 (±42.38) min. The dedicated cross clamp was 43.90(±7.53).

Sian et al.²³ revealed that the weighted mean ACC time was 39.7 minutes (range, 17-59.3 minutes) and the CPB time was 64.2 minutes (range, 35-92.3 minutes) for an isolated AVR.

Fischlein et al.²⁴ performed the first randomized controlled experiment (PERSIST-AVR) to show that the Perceval sutureless implant was better than the standard aortic valve replacement method. Time savings in individual or combination procedures are part of this advantage.

The learning curve, patient characteristics, surgical expertise, and other factors make it hard to compare ACC and CPB timings between studies.²⁵ However, our present analysis shows that ACC and CPB times are substantially lower than the standard AVR times described in the literature.

Hemodynamic Performance:

The current study revealed that mean PG across Perceval was significantly lower at discharge (11.14±4.19), after one month (11.46±3.12), and after 6 months (10.35±4.03) compared to pre-operative (45.09±16.74) (P value <0.001).

In line with that, the EOA of the aortic valve significantly improved from (0.77±0.25) preoperatively to (1.51±0.12) at discharge and continued to improve after one month (1.54±0.13) and after 6 months (1.59±0.14) (P value <0.001).

Harmonious to our results, Kosasih et al.¹⁹ showed that the mean gradient was significantly lower at discharge and over 12 months following

SU-AVR compared to pre-operative.

In accordance with our results, Meuris et al.²⁶ noted that Perceval demonstrated satisfactory hemodynamic performance throughout a five-year period, with mean gradients ranging from 7.6±3.6 to 9.9±4.6 mmHg, all in the single-digit range..

According to three prospective, multi-center trials that included 731 patients who had Perceval valves implanted, the average gradient dropped from 42.9±16.4 mmHg before surgery to 10.3±4.4 mmHg at discharge, and these numbers stayed relatively constant for another five years after surgery.²⁷

Our findings are supported by Phan et al.²⁸, who found a pooled weighted mean gradient of 11.13 mmHg at discharge, 9.0 mmHg at 6 months, and 9.6 mmHg at 12-month follow-up. The area of the effective orifice at discharge (1.77 cm²; P<0.001), 6-month (1.75 cm²; P<0.001), and 12-month (1.73 cm², P<0.001) follow-up tests were substantially different.

Because complete annular decalcification is critical for enabling the prosthesis to extend to its maximum potential while minimizing paravalvular leaks, it is probable that it is responsible for these great hemodynamic outcomes. Improving the EOA of the valve is another benefit. Proper fixation of the prosthesis without dislodgement over time is ensured by "the balloon deployable frame, lack of annular suture material, and the prosthesis's ability to adapt to the anatomy of the aortic root".²⁶

Although Perceval demonstrated outstanding hemodynamics in short-term investigations, there is a lack of data from long-term follow-ups.

Valve Safety:

We had one mortality (2%) among our cohort in a 67-year-old male. He underwent a combined procedure replacing his Aortic and Mitral valves and repairing his Tricuspid valve. The patient needed postoperative ECMO support for cardiac impairment, which was complicated by massive brain haemorrhage.

According to previous studies, the mortality rate was estimated between 1.5% and 3.7% as²⁹⁻³⁵.

In their meta-analysis, Phan et al.²⁸ found a 30-day mortality rate of 2.1%, but Williams et al.³⁶ found a rate of 1.4%. Sian et al.²³ revealed a comparable rate of 2.34% in their recent meta-analysis on Perceval.

In the CAVALIER trial by Laborde et al. [33], stroke rate was 3.0%, and 1.9% for valve-related reoperation.

Our findings are in line with those of the Sutureless and Rapid deployment valve International Registry (SURD-IR), which found that "the main postoperative complications included bleeding requiring revision (97 of 2198, 4.4%), acute kidney injury (>Stage 1) (78 of 2169,

3.6%), respiratory failure (111 of 3343, 3.3%) and neurological dysfunction (99 of 2636, 3.8%) involving stroke (75 of 2636, 2.8%) and transient ischaemic attack (24 of 2133, 1.1%)".³⁷

In contrast to our study, Sian et al. [23] reported a rate of 1.37% for cerebrovascular events in a sample with an average age of 78.5 years, which contradicts our findings. Set against this backdrop of a concurrent procedure rate that is 42.5% lower than our younger cohort.

Valve-related complications:

Permanent pacemaker implantation and Paravalvular leak are well-known complications of AVR. In our study, three patients (6%) developed new-onset third-degree heart block postoperatively, requiring PPI.

In agreement with our results, Phan et al.²⁸ Pooled estimates of PPI were (5.6%), and in Williams et al.³⁶ was (6.0%) at early and (8.2%) at late follow-up. Also, Sian et al.²³ reported similar rate of 6.76%.

The incidence of PVL among our study cohort is 2% diagnosed after discharge as regurge increased from grade 1 to grade 3 in one patient necessitating reoperation. Phan et al.²⁸ revealed that 3.0% of patients experienced postoperative paravalvular leaking across 10 investigations.

The prevalence of aortic regurgitation was greatly affected by the so-called "learning curve effect." According to SURD-IR data, postoperative aortic insufficiency rates and severity decreased dramatically over time.³⁷

Limitations:

Without a control group or randomization in design, we examined a small number of instances within a single institution's experience. More research into long-term performance is required, since this study only revealed preliminary results.

4. Conclusion

Our early outcome study showed a high rate of successful implantation, low mortality and morbidity rates, satisfactory hemodynamic performance of the prosthesis, and reduced ACC and CPB times compared to documented times in literature and databases for conventional aortic valve replacement. Cardiac improvements were observed over postoperative intervals, underscored by significant reductions in key echocardiographic parameters such as V max, maximum gradient, mean gradient, V mean, and the increase in aortic valve areas.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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