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Research Article

Outcomes of Enhanced Recovery After Sutureless Aortic Valve Replacement in Older Patients

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Abstract

Background/Aim

In surgery, enhanced recovery protocols including minimally invasive surgery and the use of sutureless valves can play an important role to decrease invasiveness and improve outcomes, certainly in older patients. The objective of this study was to analyze outcomes of enhanced recovery after cardiac surgery (ERACS) to older patients after sutureless AVR (SU AVR).

Materials and Methods

We analyzed all patients between 2007 and 2022 who underwent SU-AVR and were included in the ERACS program. The primary outcome was 30-day mortality. Secondary outcome were 5-year survival, postoperative complications and hemodynamic performance.

Results

We identified 237 ERACS patients with a median age of 78 years and the median EuroSCORE II was 2.2%. Isolated AVR accounted for 80.2% of cases, and a minimally invasive approach was used in 70.5% of patients. Thirty-day mortality was 0.4% with a stroke rate of 0.8%. Valves performed well at discharge with a peak and mean gradient of 22.5 mmHg (IQR, 19-29 mmHg) and 12 mmHg (IQR, 10-16 mmHg), respectively. Paravalvular leakage > 1/4 occurred in 0.8% and new pacemaker implantation was needed in 5.1%. Five-year survival was 90.1%.

Conclusions

In a cohort with most patients older than 75 years old, we observed very low rates of both 30-day mortality and stroke, good hemodynamic performance of the sutureless valve and low rates of paravalvular leak or pacemaker need. Sutureless AVR facilitates minimal access surgery and allows for application of a ERACS regime in a wide variety of patients, even in older patient cohort.

Keywords: sutureless AVR; Perceval; fast-track recovery; ERACS; older patients

Introduction

According to the most recent guidelines for the management of patients with valvular heart disease, aortic valve replacement is recommended for patients with aortic stenosis [1, 2]. The number of patients diagnosed with aortic stenosis is increasing, due to population aging and improvements in diagnostic imaging [3].

Given the advancing age of many patients, often in combination with increased comorbidity, surgical aortic valve replacement (SAVR) remains to be associated with significant risks, thus driving the need for less invasive options. Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI), was first performed in 2002 [4], rapidly becoming the first-line treatment for high surgical risk in older patients [1, 2].

Current guidelines suggest to perform TAVI in patients older than 75 or 80 years old, however, there is still an important fraction of patients for whom this procedure is not recommended, including those with contraindications for TAVR or non-severe aortic stenosis [1, 2]. In addition, indications for TAVI procedures differs across Europe, with reimbursement being limited in some countries [5, 6], highlighting the importance of improving SAVR outcomes. Consequently, SAVR is still

an important procedure, but requires further optimization to reduce associated perioperative surgical risks.

In recent years, the adoption of enhanced recovery after surgery (ERAS) protocols has led to shorter patient recovery periods and improvement of postoperative outcomes in many surgical specialties [7-9]. Implementation of ERAS protocols, which focus on maintaining adequate organ function in the perioperative period in a holistic way and reducing the body's stress response following surgery [10, 11], are steadily gaining momentum, also for heart valve procedures [12, 13]. Specifically for cardiac surgery, the implementation of ERAS (enhanced recovery after cardiac surgery—ERACS) protocols focuses on several aspects of treatment and hospitalization, including early extubation, early drain removal, early ambulation, and a multi-modal pain strategy [14]. While becoming increasingly popular in cardiac surgery, ERACS protocols are quite extensive, so implementation can be gradual. It is also important to note that many patients are not eligible for a full ERACS protocol, due to the complexity of certain procedures and postoperative care, as well as their age [13, 15, 16], but they may still benefit from the implementation of ERACS elements that result in better patient outcomes.

One way to reduce invasiveness of cardiac surgery is to use minimally invasive surgical approaches, such as a mini-sternotomy [17]. Another way is to use sutureless technology for aortic valves, which eliminates the need for sutures after annular decalcification, therefore reducing both aortic cross-clamp (AXC) time and cardiopulmonary bypass (CPB) time [18]. The Perceval aortic valve (Corcym S.r.l, Saluggia, Italy) is a bioprosthetic valve designed with a nitinol alloy frame allowing it to be collapsed for implantation and self-expands in the annulus.

The objective of this study was to analyze outcomes of ERACS to older patients after sutureless AVR (SU-AVR) at our institution.

Materials and Methods

Study Design and Patient Selection

This study is a retrospective analysis of all patients who were treated at our institution with the Perceval sutureless valve between 2007 and June 2022 and who were included in our ERACS-program. Patients were not admitted to the intensive care unit after surgery but stayed overnight in the post-anesthesia care unit (PACU), with the additional goals of extubation within six hours, early mobilization, drain removal, peroral intake and removal of deep venous lines [19]. Patients received a routine postoperative follow-up schedule involving blood controls, chest X-ray control and transthoracic echocardiography just before discharge home. After discharge, the patient returns on a cardiology outpatient clinic at 4 weeks after the hospital discharge. Thereafter, next visit will be at 6 months followed by yearly cardiological outpatient visits (including echocardiography).

Inclusion criteria were SU-AVR using the Perceval valve, with or without additional procedures such as coronary artery bypass grafting (CABG) or multiple valve repair/replacement that were part of our PACU-centric ERACS program. Until 2017, guidelines for ERACS inclusion in our institution were age between 18-80 years, being scheduled for single procedures, body mass index (BMI) less than 40 kg/m², left ventricular ejection fraction above 30% and serum creatinine below 2 mg/dl. After January 2018, inclusion criteria were simplified to EuroSCORE II below 3%, age above 16 years, and a BMI below 40 kg/m² [19-22]. Deviation from these inclusion criteria was permitted following an uneventful procedure and assessment of the surgeon and anesthesiologist.

Data on patient's characteristics, operative information, and follow-up details were retrospectively extracted from patient's records, in accordance with regulations on data protection. Permission to perform this analysis was granted by the ethics committee UZ/KU Leuven in 7/12/2020, with approval number S64845.

Outcome Measures

The primary outcome measure in this study was 30-day mortality. Secondary outcome was 5-year survival, postoperative complications and hemodynamic performance using transthoracic echocardiography at discharge. Severe structural valve deterioration (SVD) was defined as presence of central valve insufficiency of >2/4, an increase in mean gradient >20 mm Hg or a mean gradient >40 mm Hg, in accordance with the standardized definitions by ESC/EACTS/EAPCI [23].

Statistical Analysis

Statistical analysis was performed using SPSS version 27 (IBM Corp) and GraphPad Prism version 9.4.0 (GraphPad). The Shapiro-Wilk test was used to check normality. Continuous data are presented as median and interquartile range (IQR). Categorical data are presented as frequency and percentage. Incidence rates were calculated by the number of events divided by the total patient-years. Long-term survival was estimated and presented using the Kaplan-Meier method.

Results

Between 2007 and June 2022, 237 patients underwent SU-AVR with the Perceval valve at our institution and followed an ERACS regime. These patients had a median age of 78 years (IQR, 74-82 years), with 95 (40.1%) patients being octogenarians (Table 1). The median EuroSCORE II was 2.2% (IQR, 1.5-3.1%) and 70 (29.5%) patients had a EuroSCORE II > 3%. The decision for fast-tracking in certain patients deviated from the specified criteria, according with the procedure type (full sternotomy versus minimally invasive approach) or favorable perioperative characteristics. The majority (96.2%) of patients underwent elective surgery, with only 9 (3.8%) needing urgent surgery.

Age (years)	78 (74 - 82)
Octogenarians	95 (40.1)
Gender (male)	115 (48.5%)
BSA (m²)	1.8 (1.7 - 2.0)
Previous cardiac surgery	4 (1.7%)
IDDM	10 (4.2%)
Recent MI	3 (1.3%)
Receiving dialysis	1 (0.4%)
Chronic lung disease	29 (12.2%)
Peripheral arterial disease	33 (13.9%)
Active endocarditis	0 (0%)
NYHA Class	
I	21 (8.9%)
II	119 (50.2%)
III	92 (38.8%)
IV	5 (2.1%)
LV ejection fraction (%)	

> 50%	219 (92.4%)
31-50%	15 (6.3%)
21-30%	3 (1.3%)
< 21%	0 (0%)
Pulmonary hypertension	
< 31 mmHg	150 (92.4%)
31-55 mmHg	15 (6.3%)
> 55 mmHg	3 (1.3%)
Urgency	
Elective	228 (96.2%)
Urgent	9 (3.8%)
Emergency	0 (0%)
Salvage	0 (0%)
EuroSCORE II (%)	2.2 (1.5 - 3.1%)
Data are presented as median (interquartile range), or n (%). BSA: body surface area; IDDM: insulin-dependent diabetes mellitus; MI: myocardial infarction; NYHA: New York Heart Association; LV: left ventricle; EuroSCORE: European System for Cardiac Operative Risk Evaluation.	

Table 1: Preoperative characteristics (N=237)

A minimally invasive approach was used in 70.5% of patients and 80.2% were treated with single AVR (Table 2). In 19.8% of patients, surgery was combined, being mainly single CABG. The rate of minimal access surgery within the single AVR group was 90.5%. The median CPB time was 60 minutes (IQR, 50-74 minutes) and the median AXC time was 37 minutes (IQR, 34-47 minutes). The implanted valve type was a Perceval S in 150 (63.3%) patients and a Perceval PLUS in the remaining 87 (36.7%) patients.

AVR + CABG	28 (11.8%)
Multiple procedures	19 (8.0%)
Access	
Full sternotomy*	63 (26.5%)
Mini-sternotomy	167 (70.5%)
Anterior right thoracotomy	7 (3.0%)
Valve Type	
Perceval S	150 (63.3%)
Perceval PLUS	87 (36.7%)
Cardiopulmonary bypass time (min)	60 (50 - 74)
Cross-clamp time (min)	37 (31 - 47)
Data are presented as median (interquartile range) or n (%). AVR: Aortic valve replacement; CABG: coronary artery bypass grafting. * 2 patients underwent conversion from MICS to sternotomy.	

Table 2. Intraoperative characteristics (N=237)

Early Outcomes

All patients stayed overnight in the PACU and the hospitalization period was 7 days (IQR, 6-9 days; Table 3). The 30-day mortality was 0.4% (1 patient) and the rate of major complications was also low, with a stroke rate of 0.8%, reoperation for bleeding in 0.4% and no new need for dialysis. A new pacemaker was needed for 12 (5.1%) patients at 30 days.

Reoperation for bleeding	1 (0.4%)
Stroke	2 (0.8%)
New dialysis	0 (0%)
Pacemaker rate at 30 days	12 (5.1%)
In hospital mortality	1 (0.4%)
Hospital lenght of stay (days)	7 (6 - 9)
Data are presented as median (interquartile range) or n (%).	

Table 3. Postoperative events (N=237)

At discharge, the hemodynamic performance of the Perceval valve showed a peak and mean gradient of 22.5 mmHg (IQR, 19-29 mmHg) and 12 mmHg (IQR, 10-16 mmHg), respectively. Only 2 (0.8%) patients had a mild paravalvular leak (Table 4). Median iEOA was 0.9 cm^2/m^2 (IQR, 0.8-1.1 cm^2/m^2).

Peak gradient (mmHg)	22.5 (18 - 29)
Mean gradient (mmHg)	12 (10 - 16)
EOA (cm^2)	1.7 (1.4 - 2.1)
iEOA (cm^2/m^2)	0.9 (0.8 - 1.1)
PVL > 1/4	2 (0.8%)
CVL > 1/4	2 (0.8%)
Data are presented as median (interquartile range) or n (%). EOA: effective orifice area; iEOA: indexed effective orifice area.	

Table 4. Discharge echocardiography (N=237)

Late Outcomes

The cumulative follow-up was 612.8 patient-years. During follow-up, there where 3 (1.3%) cases of endocarditis, corresponding to an incidence rate of 0.21% per patient-year. All 3 patients underwent reoperation. There were no cases of severe structural valve deterioration. The 5-year survival was 90.1%, and the Kaplan-Meier mean survival estimate was 6.98 ± 0.26 years (Figure 1).

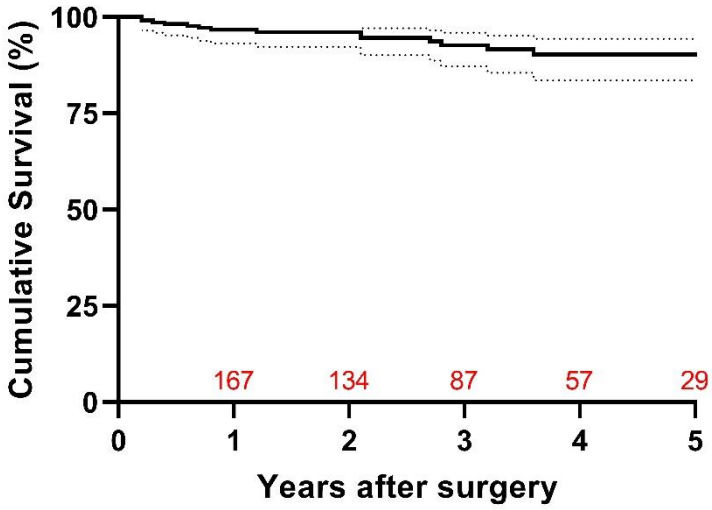

Figure 1. Kaplan-Meier estimate of the cumulative survival of the study population. Dotted lines represent 95% confidence interval and the number at risk are shown in red.

Discussion

In this study, we observed low rates of 30-day mortality, stroke and reoperation for bleeding in combination with a good hemodynamic performance and low pacemaker rates after sutureless AVR in an ERACS regime.

The current available evidence supports the use of TAVI in high-risk, older patients, although there are some uncertainties regarding long-term outcomes [24]. This is mostly related to the surgical risk of these patients and the subsequent poorer outcomes following a major surgery. However, the determination of surgical risk is not always straightforward, involving a multidisciplinary preoperative assessment of each patient which accounts for age, comorbidities and frailty [25]. Older patients who are not at a high surgical risk can still benefit from surgical AVR, which has excellent long-term outcomes in terms of event-free survival and quality of life, especially when the procedure is minimally invasive [26].

The implementation of ERACS elements in minimally invasive cardiac surgery has shown to be beneficial, even if a full ERACS protocol is not implemented [19, 27]. In our study, the use of a PACU-centric ERACS program and a minimally invasive procedure in the majority of cases resulted in a very low 30-day mortality, as well as a short hospital stay.

The use of SU-AVR with the Perceval valve enables a wider adoption of minimally invasive cardiac surgery as a treatment option for older patients, due to the simple and quick implantation process, with minimal manipulation of the aortic root [28]. In our study, the median CPB and AXC times were 60 and 37 minutes, compared to a median CPB and AXC times in conventional surgical AVR of 87 and 63 minutes, respectively [29]. This reduction in CPB and AXC times is relevant for all patients, but especially for older patients or those undergoing a repeat intervention [30].

Recently, the DEDICATE trial (Blankenberg et al.) investigated TAVI and SAVR in a low-risk population (mean age 74y, mean STS score 1.8) [31]. In the surgical arm of this German multi-centre study, the 30-day mortality was 1.5% with a stroke rate of 1.7%. Sutureless valves were only used in 12% of cases (explaining longer cross-clamp and CPB times up to 61 and 88min. respectively) and minimal access surgery was used in only 48% of cases. The median hospital stay was 9 days. Our study population shows lower mortality and 30-day complication rates. Of the 237 ERACS patients, 2 (0.8%) had a stroke and none had a transient ischemic attack. There were also no patients with new onset kidney injury requiring dialysis. There were 12 (5.1%) patients requiring a new permanent pacemaker at 30-days post-SU-AVR. This pacemaker rate is lower than previously reported for Perceval in combination with mini-sternotomy but slightly higher than the rate reported with the use of a stented prosthesis and a mini-sternotomy approach [32]. New pacemaker implantation remains a serious complication after surgical and mainly after transcatheter AVR. In a recent study comparing outcomes in a matched cohort of patients undergoing SU-AVR or TAVI, TAVI had much higher rates of permanent pacemaker implantation after the procedure [33].

Regarding valvular function, our results showed a favorable profile after Perceval implantation. As demonstrated before, correct sizing of the valve is very important to ensure optimal transvalvular gradients and limiting pacemaker implantation, while not influencing the incidence of (para)valvular regurgitation [34].

In regard to late complications, reintervention was only due to endocarditis in 3 cases (1.3%), while no cases of severe structural valve deterioration up to 5-year follow-up occurred. We recently published the 13-year follow-up data from our overall Perceval population and valve durability looks promising, with a limited number of structural valve deterioration cases [36]. Although it has been limited, if deterioration occurs, the Perceval valve lends itself well to TAVR valve in valve [36, 37].

Overall, our results show that the addition of an enhanced recovery program to the use of a sutureless valve for AVR (with a majority of minimal access procedures, up to 91% in single AVR) contributes to better patient outcomes, even in older patients.

Limitations

Despite the favorable results in this population of older patients, it is important to note some limitations of the study. The retrospective nature of the analysis, together with the lack of control group and the single-center setting, restrict the generalization of results.

Conclusion

In a cohort with most patients older than 75 years old, we observed very low rates of both 30-day mortality and stroke, good hemodynamic performance of the sutureless valve and low rates of paravalvular leak or pacemaker need. The shortness and simplicity of sutureless AVR allows for application of a ERACS regime in a wide variety of patients, even in an older patient cohort. The combination of ERACS, sutureless valves and minimally invasive surgery is certainly still competitive to transcatheter treatments.

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