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Perceval S, sutureless aortic valve: cost-consequence analysis

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Abstract

Introduction: Sutureless aortic valve prostheses have the potential of shortening ischemic time.
Aim: We conducted the present study to assess the clinical and economic impact of the biological, sutureless, self-expanding Perceval S valve since the effect of shortened operative times on hospital costs remains unclear.
Material and methods: This is a retrospective analysis. From January 2018 to January 2019, 29 patients underwent isolated aortic valve replacement with the Crown PRT bioprosthetic Aortic Valve, whereas 35 patients underwent aortic valve replacement with Perceval S (auto-expanded, sutureless, bioprosthesis). Preoperative data, hospital outcome, and health care resource consumption were compared, using χ^2 and *t*-test.
Results: Aortic cross-clamp, cardiopulmonary bypass, and operation times were significantly shorter in the Perceval S group ($p < 0.001$). Patients in the sutureless group required blood transfusion less frequently ($p = 0.03$) and had a shorter intensive care unit (ICU) stay ($p = 0.01$). Hospital stay ($p = 0.57$) and pacemaker implantation were similar between groups. The reduction of aortic cross-clamp, extracorporeal circulation times, and ICU stay resulted in reduced resource consumption in the sutureless group.
Conclusions: The use of the Perceval S valve is clinically safe and effective. A shorter procedural time in the sutureless group is associated with better clinical outcomes and reduced hospital costs.

Key words: Perceval S, sutureless aortic valve, cost effectiveness, aortic valve replacement.

Introduction

The prevalence of heart valve disease within European countries is estimated at about 13.3 million patients [1]. Despite the fact that rheumatic fever prevalence (once a prominent cause of heart valve disease) is being reduced, in certain countries – mostly the developing ones – valvular heart disease is still a major issue [2]. The magnitude of the problem is not to be ignored either; today, it is estimated that 10–20% of all cardiac surgery is performed to treat some form of valvular disease [3]. On the other hand, and as the life expectancy of the population increases [4], the recommendations on the management of cardiac surgery patients are modified accordingly. As a result, today's cases are harder to manage, and include many high-risk patients. Therefore, the cardiac surgeon must be ever ready to adapt and include surgical techniques that are better tolerated by the at-risk population. One such important advance in cardiac surgery is the application of self-expandable bioprosthetic valves, utilized in surgical aortic valve replacement, indicated for severe aortic stenosis or insufficiency. Literature on self-expanding valve use is expanding rapidly, and the indications for their utilization are broadened accordingly.

Aim

Our retrospective study aims to depict our experience with the Perceval S (LivaNova PLC, UK) self-expanding bioprosthetic aortic valve, in a single cardiac surgery center as well as to evaluate its safety profile, effectiveness and economic efficiency.

Material and methods

Our team retrospectively studied all patients in the two-year period of 2018–2019 who underwent aortic valve replacement with the use of a bioprosthetic valve in our cen-

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ter. Inclusion criteria of the study were eligibility for aortic valve replacement surgery in accordance with international guidelines and ability to provide informed consent. Patients excluded from the study included those whose valve replacement was part of a reoperation, patients undergoing combinatory surgery and patients who underwent replacement of the aortic valve with any bioprosthetic valve other than the two types included in the study. After analysis of the enrolled patients, 3 patients were further excluded from the study (2 from the control group and 1 from the study group), due to extraordinary and rare complications that would alter the study's results (intraoperative arrest and intensive care unit (ICU) hospitalization with open chest, intraoperative aortic dissection and multiple intraoperative efforts of valve installment). The two final patient populations were: the control population of 29 patients, in which the classic bioprosthetic Crown PRT (LivaNova PLC, UK) valve was used, and the test population of 35 patients, in which the self-expanding bioprosthetic Perceval S (LivaNova PLC, UK) was used.

In order to evaluate the economic impact of sutureless valve implementation, we utilized literature data to measure the cost of several aspects of cardiothoracic surgery. In that aspect, the average cost of a packed red blood cell (pRBC) unit was set at €500 [5, 6], use of the operating room at €20/minute of operation [5–7], and admission to the ICU at €700 for the first 3 days and €500/day afterwards.

Statistical analysis

Our results included usage of the *t*-test and the χ^2 test to compare measures of means and proportions. Results were viewed as significant for p levels < 0.05.

Results

The preoperative, intraoperative and postoperative data of the patients are presented in Tables I–III respectively. The patients within the two groups differed in several preoperative factors, mainly in their disease severity, measured by the EuroSCORE II scale. This finding is in line with another characteristic of the study group, which was the older age, a major factor in valvular disease severity and heart failure. Despite the observed differences, the study group can be seen to have comparable outcomes with the control group in most of the expected complications of the operation (Table I).

Another difference between the two groups is that the study group began the operation with significantly lower Hb levels than the control group (11.2 ±1.1 versus 12.3 ±1.3, $p < 0.001$); however, postoperative hemoglobin (Hb) levels did not differ significantly between the two groups. The average number of pRBC units also differed significantly between the two groups, with the Perceval S population requiring 0.9 ±0.9 pRBC units on average, as opposed to 1.5 ±1.3 units of the Crown group ($p = 0.03$). As a result, average transfusion costs were also significantly reduced, measuring at 485.7 ±461.5 euros per patient for the Per-

Table I. Preoperative characteristics of our patients

Parameter	Crown (%)	Perceval S (%)	*P*-value
Men	20 (69)	11 (31.4)	< 0.01
Women	9 (31)	24 (68.6)	< 0.01
BSA	1.89 ±0.24	1.76 ±0.19	0.015
Age	70.3 ±6.07	80.34 ±4.22	< 0.001
PVD	3 (10.3)	5 (14.2)	NS
Presence of diabetes mellitus	7 (24.1)	15 (42.85)	< 0.001
Presence of COPD	4 (13.8)	7 (20)	0.05
Presence of chronic renal disease	2 (6.9)	7 (20)	0.05
Presence of arterial hypertension	19 (65.5)	25 (71.4)	NS
Presence of dyslipidemia	16 (55.1)	20 (57.1)	NS
Presence of pulmonary hypertension	2 (6.9)	6 (17.1)	0.001
Ejection fraction:			< 0.05
Good	15 (51.7)	10 (28.5)	
Moderate	10 (34.5)	18 (51.5)	
Bad	4 (13.8)	7 (20)	
EuroSCORE	2.90 ±0.91	4.37 ±0.51	< 0.001

Table II. Intraoperative data

Parameter	Crown	Perceval S	*P*-value
Hb prior to surgery	12.3 ±1.3	11.2 ±1.1	< 0.001
Hb after surgery	7.6 ±1.03	7.9 ±5.8	0.79
No of pRBC transfusions	1.5 ±1.3	0.9 ±0.9	0.03
Transfusion cost	793.1 ±661.6	485.7 ±461.5	0.03
ECC time	89.7 ±30.2	54.1 ±9.8	< 0.001
ACC time	68.2 ±17.8	37.6 ±7.2	< 0.001
Length of surgery	181.8 ±45.2	132.1 ±18.1	< 0.001
Prosthetic valve size	21.8 ±1.5	22.5 ±2.0	0.1
Total surgery cost	3640 ±919.8	2664.2 ±350.2	< 0.001

Table III. Postoperative data

Parameter	Crown	Perceval S	*P*-value
Length of ICU stay [days]	1.8 ±0.9	1.2 ±0.6	0.01
Total length of hospital stay [days]	5.7 ±1.0	5.8 ±0.9	0.57
ICU cost	1417.2 ±679.1	998.5 ±495.9	0.007
Atrial fibrillation	3 (10.3%)	3 (8.1%)	NS
Pleural effusion	5 (17.2%)	7 (20%)	NS
Permanent pacemaker placement	1 (3.4%)	1 (2.8%)	NS
Reoperation	2 (6.9%)	2 (5.7%)	NS
Wound infection	0	0	NS
Respiratory infection	2 (6.9%)	2 (5.7%)	NS

ceval S group, and 793.1 ±661.6 euros for the Crown group (p = 0.03) (Table II).

Surgical times of great interest in cardiac surgery, such as the aortic cross-clamp (ACC) time and the extracorporeal circulation (ECC) time, also differed significantly between the two groups. The ECC time was found to be 89.7 ±30.2 min for the study population on average for the Crown group, and 54.1 ±9.8 min for the Perceval group (p < 0.001). Likewise, mean ACC time was 68.2 ±17.8 min and 37.6 ±7.2 min respectively (p < 0.001). In addition, the average valve size was comparable between the two groups, measuring 21.8 ±1.5 mm for the Crown group versus 22.5 ±2.0 for the Perceval group (p = 0.1) (Table II).

Comparing the two patient groups as regards their length of hospital stay revealed no overall difference (5.7 ±1.0 vs. 5.8 ±0.9, p = 0.57), but the length of cICU stay between two groups differed significantly. Patients in the Crown group of patients stayed a mean of 1.8 ±0.9 days in the cICU, in contrast to 1.2 ±0.6 days in the Perceval group of patients (p = 0.01). Naturally, their average cICU costs also differed, being 1417.2 ±679.1 euros in the Crown group of patients and 998.5 ±495.9 euros in the Perceval group of patients (p = 0.007) (Table III).

Discussion

Aortic valve stenosis is the most common acquired form of valvular disease, and its prevalence is expected to rise, mostly due to the predicted increase in the average lifespan. In fact, it has been documented that while the prevalence of aortic valve disease is estimated at 2.5% at 75 years of age, it increases to 8.1% at 85 years of age [8]. As a consequence, aortic valve replacement, due to the magnitude of symptom resolution it offers, is now the most commonly performed type of cardiac surgery, pertaining to 60–70% of elderly cardiac surgery [9, 10]. This operation is also indicated for asymptomatic patients in the presence of additional factors such as concurrent cardiac surgery for any reason and co-existing moderate or severe, yet asymptomatic aortic valve disease. This operation is associated with mortality rates of 3–4% that rise to 5–7% if the operation is done as part of a combined surgical procedure, and can be further increased to 10% if there are comorbidities present, the major one of which is older age [10–12]. Due to this increased mortality risk, there are a number of patients who despite having adequate indications for surgical intervention will not eventually undergo surgery [13]. As presented in a recent meta-analysis of 92 centers, it seems that up to 38.2% of the patients suffering from severe and symptomatic aortic stenosis did not undergo surgery due to the severity of their comorbidities [14]. Therefore, it can be hypothesized that advances in the surgical method that have favorable effects on certain morbidity-associated factors may be utilized to make aortic valve replacement more inclusive towards older and more difficult to manage patients [15–17]. Authors investigating the performance of sutureless valve replacement in severe aortic valve stenosis in high and very high surgical risk patients report enhanced surgical outcomes and favorable safety profiles with comparable mortality rates to those of traditional bioprosthetic valves [18–20]. Factors that influence mortality rates include both the ACC and ECC times studied here. ACC time in cardiac surgery is an independent risk factor for serious postoperative morbidity, with a 1.4% increase in postoperative morbidity risk for every minute of ACC time [15, 21, 22]. Our results demonstrated added value for sutureless valve replacement, in the form of both ACC and ECC times being driven down when compared to the Crown valve replacement. These findings are in line with those of previous studies evaluating the use of Perceval bioprosthetic valves [16, 17, 23–27]. Most prominently, results from the SURD-IR registry, with an analysis of more than 4,500 patients, also demonstrated reduced cross-clamp times and ECC times, that were in fact associated with improved hemodynamic status of the patients, when compared to traditional bioprosthetic valve options [28].

In addition, sutureless valve utilization will allow for minimally invasive surgical procedures, a practice that until now has been excessively demanding, when conventional bioprosthetic valves were used. These procedures also result in minimal trauma and reduced recovery times and therefore can also be employed to make valve replacement surgery accessible to patients with a heavy comorbidity burden [17, 20]. The additional costs of implementing newer bioprosthetic materials seem to be counterbalanced by the clinical benefits, and the hastened patient discharge that as our study suggests can be effective in lowering the overall cost of the patient admitted for cardiac surgery. In fact, data suggest that elderly patients have higher overall costs for a heart valve implantation than younger patients [14, 29]. Therefore, novel bioprosthetic valves such as the one we studied are not only able to be implemented in elderly and comorbidity-ridden patients, but by doing so they might reduce the admission costs of the costliest age group of patients.

The major areas of focus for the economic cost of a patient undergoing cardiac surgery are thought to be the operating room, days spent either on ICU admission or normal ward admission, and the cost of complications. In our study cohort, there were no significant complications recorded, so the focus of the analysis was on the length of the operation and hospital stay. Especially concerning the length of cICU admission, it is widely known that this can be the costliest aspect of admitting a patient for cardiac surgery [29]. In our study, length of both ICU and non-ICU stay was significantly decreased within the study group, and led to significant per-patient cost reduction. This is in line with previous findings of research on sutureless valves, and is additionally associated with lower complication rates among patients, apart from the reduced cost of the operation [24, 30, 31].

By making the assumption that all other variables within the operating room remained approximately the same (personnel use, methods of disinfection, anesthesia methods, etc.), we attributed the observed difference in surgical

times, and in turn costs, to the different methods utilized. Our results showed that on average there were cost savings of approximately 1000 euros per surgical patient when the Perceval S was utilized.

Results on transfusion outcomes also differed between the two groups. Despite the fact that our study population presented with significantly lower Hb levels preoperatively, it also required significantly fewer pRBC transfusions than the control population. Transfusions during aortic valve replacement have also been studied by several teams, demonstrating less reliance on intraoperative blood transfusion in all studies, which was also related to better outcomes and less time spent in the ICU [18, 23, 32, 33]. Therefore, another positive outcome of sutureless valve implementation was the requirement of fewer transfusion procedures, which further reduces surgical costs for the patient.

When evaluating a novel surgical method, one must not forget to look into the reported shortcomings of the technique. In the literature it is reported that utilization of sutureless aortic valve replacement may be associated with high incidence of postoperative rhythm disturbances, most frequently heart blocks, that can affect up to 7.9% of the patients, as opposed to 3.1% when conventional stented bioprostheses were used [34–37]. However, follow-up of the patients still revealed better hemodynamic status of the patients who underwent sutureless aortic valve replacement, despite the conduction abnormalities [37]. Predictors of permanent pacemaker implantation including age, the presence of preoperative right bundle branch block (RBBB) as well as left bundle branch block (LBBB) and pre-existing first-degree block are all factors that predict postoperative pacemaker placement [32]. There are also concerns raised by several authors regarding the postoperative ocurrence of thrombocytopenia with sutureless valve usage, but none of the authors described further complications stemming from thrombocytopenia [38–40]. Thrombocytopenia after sutureless valve implantation has been a cause for debate among cardiac surgeons for a while. Current literature seems to indicate that there is no real need for concern stemming from the transient decrease in platelet counts in patients with sutureless valve replacement, compared to other valve replacement methods. In one recently published randomized controlled trial (RCT), the researchers found that while platelet reduction on the third postoperative day was indeed higher in the Perceval group of patients, platelet counts quickly normalized without further intervention, and there were no differences in the occurrence of bleeding or stroke events, or transfusion needs [41]. Centers have also reported that postoperative platelet counts were more favorable in sutureless valve patients, compared to standard stented valve patients [42]. At any rate, the observed tendency towards thrombocytopenia has not been associated with worse patient outcomes or major bleeding events in several studies [42–45]. Thrombocytopenia was not assessed within our patient cohort, largely due to previous experience that showed only a minimal to moderate decrease in platelet counts, which recovered to normal values without requiring platelet transfusions. A 2016 international consensus of cardiac surgery experts, however, stated that complications including prolonged ventilation, atrial fibrillation, pleural effusion, paravalvular leakage and aortic regurgitation are reduced with the use of sutureless valves [46]. In our study, there were not sufficient numbers of the aforementioned complications in order to compare them.

There are a few limitations of our study design. Due to a lack of specific data on our country's operating room cost, the estimate employed here was based on observations from other countries within the EU. However, in any case, the observed percentile difference remains the same. Also, a more accurate estimate of the economic effects of the Perceval S implementation would require a detailed micro-costing model to be employed, but this was not the focus of our study. Finally, it would be appropriate to include data on the long-term follow-up of our patients in order to truly evaluate the impact of different material used, and it is within our future goals to evaluate this mid- to long-term impact, once sufficient data are available from our patient cohort.

Conclusions

It seems that the studied method of sutureless aortic valve implantation is effective in the treatment of high-risk patients with aortic valve disease, while at the same time it provides satisfactory clinical results; patients achieved a lower average length of stay, including length of stay in the cICU, and no major postoperative complications were recorded. Additionally, patients required fewer blood transfusions on average, and a reduction in surgical times that specifically impact mortality was noted. These results can be attributed to the unique technical characteristics of the utilized material that allows for high-risk surgical interventions to be achieved in a less burdensome manner towards the patient. Adding to the observed advantages, the Perceval S valve use was also associated with a reduction in resources employed and total expenses, mainly through improvement of the overall hospital stay of the patients.

Disclosure

The authors report no conflict of interest.

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