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Clinical Research

Thrombocytopenia after Aortic Valve Replacement Using Sutureless Valves

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Background: Sutureless valves are widely used in aortic valve replacement surgery, with Perceval valves and Intuity valves being particularly prominent. However, concerns have been raised about postoperative thrombocytopenia with Perceval valves (Corcym, UK). We conducted a comparative analysis with the Intuity valve (Edwards Lifesciences, USA), and assessed how thrombocytopenia affected patient and transfusion outcomes.
Methods: Among 595 patients who underwent aortic valve replacement from June 2016 to March 2023, sutureless valves were used in 53 (Perceval: n=23; Intuity: n=30). Platelet counts were monitored during hospitalization and outpatient visits. Daily platelet count changes were compared between groups, and the results from patients who underwent procedures using Carpentier Edwards Perimount Magna valves were used as a reference group.
Results: Compared to the Intuity group, the Perceval group showed a significantly higher amount of platelet transfusion (5.48±1.64 packs vs. 0.60±0.44 packs, p=0.008). During the postoperative period, severe thrombocytopenia (<50,000/μL) was significantly more prevalent in the Perceval group (56.5%, n=13) than in the Intuity group (6.7%, n=2). After initial postoperative depletion, daily platelet counts increased, with significant differences observed in the extent of improvement between the Perceval and Intuity groups (p<0.001). However, there was no significant difference in early mortality or the incidence of neurological complications between the 2 groups.
Conclusion: The severity of postoperative thrombocytopenia differed significantly between the Perceval and Intuity valves. The Perceval group showed a significantly higher prevalence of severe thrombocytopenia and higher platelet transfusion volumes. However, thrombocytopenia gradually recovered during the postoperative period in both groups, and the early outcomes were similar in both groups.

Keywords: Thrombocytopenia, Perceval valve, Intuity valve, Sutureless valve, Aortic valve replacement

Introduction

The valves used in aortic valve replacement surgery have undergone various advancements over recent decades. Among the different areas of innovation, some valves are designed to reduce surgical time. Noteworthy examples include the Perceval valves (Corcym, London, UK) and the Edwards Intuity Elite valves (Edwards Lifesciences, Irvine, CA, USA). Unlike traditional aortic valves, these models decrease the time required for suturing, thereby shortening the total duration of surgery. Although these valves provide benefits such as reduced surgical time and increased convenience, they have also been associated with unintended adverse effects when compared to conventional valves.

The Perceval valve, for instance, has been linked to an increased incidence of postoperative thrombocytopenia [1]. Research indicates that this may be due to the technique

used to preserve the valve's leaflets during its manufacture. While the propensity for thrombocytopenia is evident, further investigation is required to assess its clinical significance for patients. Like the Perceval valve, the Intuity valve is also well-known as a rapid deployment valve. This valve has a structure similar to the conventional stented aortic valve bioprosthesis. However, since stented aortic valves are also known to be associated with thrombocytopenia, it is essential to determine whether the Intuity valve also has this association. Therefore, our research also aims to compare the incidence of thrombocytopenia with the Perceval valve to that of the Intuity valve. The Intuity valve utilizes a suturing method similar to that of traditional valves but with notable differences. Through our analysis, we seek to determine if the trend towards thrombocytopenia is a general feature of sutureless valves or if it is specific to the Perceval valve.

Methods

Ethics statement and blinded review information

The study received approval from the Institutional Review Board of Seoul National University Bundang Hospital (B-2307-841-101), and informed consent was obtained from all participants. To ensure a blinded review, any information that may indicate author identity, such as the name of the institution, has been intentionally concealed in the main text during the review process.

Study population

Between June 2016 and March 2023, a total of 595 patients underwent isolated aortic valve replacement at our institution. Of these, 53 patients received sutureless aortic valve implants, which were divided into 2 categories: Perceval (n=23) and Intuity (n=30) valves. We monitored platelet counts in these patients throughout their hospitalization, ensuring follow-up until at least postoperative day 7, and continued tracking this parameter in the outpatient setting.

Operative techniques

All aortic valve replacement procedures were performed through a full median sternotomy using standard cardiopulmonary bypass (CPB). Following sternotomy and pericardiotomy, heparin was administered to initiate CPB. Cardioplegia was delivered in both antegrade and retrograde fashion, adhering to the standard sequence of procedures during aortic cross-clamping. The selection of the prosthetic valve was at the surgeon's discretion, with options including the Perceval and Intuity valves, as well as traditional tissue valves such as the Carpentier-Edwards (C-E) Perimount Magna.

Neither sutureless valve was surgically sutured to the annulus 360° around. Instead, the stent-mounted valve, in its compressed state, was placed within a valve delivery system and subsequently deployed. Intuity valves were implanted with the aid of 3 positioning sutures for guidance. In contrast, conventional tissue valves were implanted using the standard method of 360° suturing, typically involving 12 to 18 horizontal mattress sutures reinforced with pledgets.

Anticoagulation therapy was typically initiated on postoperative day 1 for patients who received either sutureless valve, with a daily aspirin dose of 100 mg. For those who received a C-E valve, warfarin maintenance was generally prescribed for approximately 4 months, starting from postoperative day 1 or 2.

Statistical analysis

The data are presented as means with standard deviations for variables that are normally distributed, and categorical data are presented as counts and percentages. Numerical values were compared using the independent t-test. Platelet counts according to valve types were compared using the chi-square test. Changes in the platelet count were analyzed using a linear mixed model. All p-values were derived from 2-sided tests, and p-values <0.05 were considered statistically significant.

For each valve group, we graphically visualized and compared changes in postoperative platelet count using a linear mixed model. All statistical analyses were performed with R software ver. 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

In this study, the primary focus was to compare the Perceval and Intuity valves, using the conventional tissue valve (C-E Perimount Magna) as a reference. We analyzed patients who had received C-E valve implants in the aortic position by randomly selecting a sample of 50 individuals from the same time frame for research purposes (C-E group).

Table 1 compares the perioperative characteristics of 2

Table 1. Perioperative characteristics

Characteristic	Perceval valve (n=23)	Intuity valve (n=30)	p-value	C-E valve (n=50)
Male	14 (60.9)	16 (53.3)	0.592	33 (66.0)
Age (yr)	78.4±5.69	79.3±4.67	0.495	72.5±8.25
Body mass index (kg/m^2)	22.9±3.68	23.5±3.32	0.533	24.5±3.18
Smoking	11 (47.8)	14 (46.7)	0.935	24 (48.0)
Alcohol consumption	7 (30.4)	6 (20.0)	0.473	12 (24.0)
Hypertension	20 (87.0)	25 (83.3)	0.721	35 (70.0)
Diabetes mellitus	12 (52.2)	17 (56.7)	0.750	12 (24.0)
Dyslipidemia	17 (73.9)	18 (60.0)	0.298	26 (52.0)
History of cerebrovascular disease	7 (30.4)	9 (30.0)	0.973	5 (10.0)
Chronic kidney disease	2 (8.7)	6 (20.0)	0.020	6 (12.0)
Peripheral arterial vessel disease	4 (17.4)	7 (23.3)	0.605	1 (2.0)
Liver cirrhosis	1 (4.3)	0	0.283	3 (6.0)
Heart failure	1 (4.3)	4 (13.3)	0.704	4 (8.0)
Atrial fibrillation	9 (39.1)	3 (10.0)	<0.001	14 (28.0)
Left ventricular ejection fraction (%)	55.0±13.8	56.1±15.9	0.792	58.8±11.0
Creatinine (mg/dL)	1.40 (0.57–7.60)	1.35 (0.36–6.57)	0.896	1.03 (0.42–2.02)
EuroScore	6.34±2.18	5.45±1.12	0.701	3.37±0.50
Concomitant cardiac procedure	13 (56.5)	14 (46.7)	0.813	38 (76.0)

Values are presented as number (%), mean±standard deviation or median (range).
C-E valve, Carpentier-Edwards valve.

Table 2. Postoperative blood transfusion amounts according to valve type

Variable	Perceval valve (n=23)	Intuity valve (n=30)	p-value	C-E valve (n=50)
Red blood cell (packs)	0.52±0.20	0.97±0.60	0.530	2.74±1.33
Fresh frozen plasma (packs)	0.74±0.74	0.10±0.07	0.399	1.92±1.04
Platelets (packs)	5.48±1.64	0.60±0.44	0.008	4.80±2.90

Values are presented as mean±standard deviation.
C-E valve, Carpentier-Edwards valve.

valve groups. Among these characteristics, the Perceval group exhibited a higher percentage of patients with chronic kidney disease (20% versus 8.7%, p=0.020) and a significantly greater proportion of patients with atrial fibrillation (39.1% versus 10.0%, p<0.001) than the Intuity group. Patients' chronic kidney disease history was identified through previous diagnostic assessments, relying on the past medical history obtained from previous blood tests and imaging examinations.

Table 2 presents a comparison of postoperative blood transfusion volumes for different valve types during the index hospitalization. The Perceval group required a significantly higher volume of platelet transfusions compared to the Intuity group (5.48±1.64 units versus 0.60±0.44 units, p=0.008). However, there were no significant differences in the volume of red blood cell (RBC) transfusions (0.52±0.20 units versus 0.97±0.60 units, p=0.530) or fresh frozen plasma (FFP) transfusions (0.74±0.74 units versus 0.10±0.07 units, p=0.399) between the 2 groups. When comparing the Perceval group with the C-E group, the volume of platelet transfusions was slightly higher in the Perceval group (5.48±1.64 units versus 4.80±2.90 units), but this difference was not statistically significant, and there were no significant differences in the volumes of RBC or FFP transfusions.

Table 3 displays the lowest postoperative platelet counts stratified by valve type. The lowest platelet counts were classified using a threshold of 50,000/μL. The data revealed significant differences in the incidence of severe thrombocytopenia: 56.5% of patients (n=13) in the Perceval group and 6.7% (n=2) in the Intuity group had counts below 50,000/μL (p<0.001). For moderate thrombocytopenia, defined as platelet counts between 50,000/μL and 100,000/μL, there were notable differences, with 39.1% (n=9) in the Perceval group and 70% (n=21) in the Intuity group, and a similar pattern was observed in the C-E group. In instances where counts exceeded 100,000/μL, the Intuity group exhibited higher platelet counts.

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Table 3. Lowest platelet count during the postoperative course according to valve type

	Perceval valve (n=23)	Intuity valve (n=30)	p-value	C-E valve (n=50)
Platelet count			<0.001	
<50,000/μL	13 (56.5)	2 (6.7)		10 (20.0)
≤50,000/μL and <100,000/μL	9 (39.1)	21 (70.0)		28 (56.0)
≥100,000/μL	1 (4.3)	7 (23.3)		12 (24.0)

Values are presented as number (%).
C-E valve, Carpentier-Edwards valve.

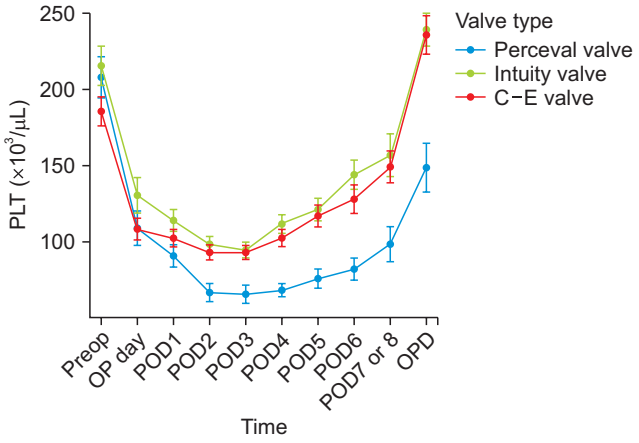

Fig. 1. Changes in mean platelet (PLT) count over time according to valve type. The changes in mean platelet count over time were significant regardless of valve type (p<0.001). However, there was no significant difference between the Perceval valve and Intuity valve in terms of changes in platelet count over time (p=0.658). Preop, preoperative; OP day, operation day; POD, postoperative day; OPD, outpatient department; C-E valve, Carpentier-Edwards valve.

Fig. 1 depicts the daily fluctuations in mean platelet counts for each group. Both groups experienced a decline in platelet counts immediately following surgery, with a subsequent increase around the third postoperative day. This indicates that platelet counts varied over time within each group. A significant difference was observed in the patterns of platelet count changes between the 2 groups when comparing them (p<0.001). Unlike the Perceval group, the C-E and Intuity groups demonstrated a return of platelet counts to preoperative levels during outpatient follow-up. In contrast, the Perceval group did not show such a recovery in comparison to their preoperative counts.

Figs. 2 and 3 graphically represent the changes in platelet counts for individual patients. We observed a decline in platelet counts until postoperative days 3 or 4, followed by a gradual recovery. A comparison of the 2 figures reveals that a higher proportion of patients in the Perceval group had platelet counts fall below 100,000/μL. In contrast, the majority of patients in the Intuity group maintained platelet counts above this threshold. Furthermore, during outpatient follow-up, there were fewer instances of platelet counts rebounding to above 200,000/μL in the Perceval group than in the Intuity group. The outpatient follow-up visits took place 2 weeks after discharge for further assessment. Thus, in this study, we analyzed cases involving extracorporeal membrane oxygenation (ECMO) insertion before and after surgery. In such cases, it was natural for there to be a higher volume of transfusions, including platelets, which could potentially introduce significant bias into our analysis. However, the general pattern of recovery was comparable between the 2 groups.

Table 4 presents a comparison of postoperative morbidity and early mortality. Although there was a significant between-group difference in changes in the platelet count, this did not translate into significant differences in early outcomes, as previously mentioned. The incidence of complications related to cerebrovascular events was similar between the groups (4.3% versus 3.3%, p=0.386), and the rates of re-exploration for postoperative bleeding were also comparable (0% versus 3.3%, p=0.851). Early mortality within 30 days post-surgery was observed in 2 cases, with one occurring in the Perceval group and the other in the Intuity group. The number of deaths was not sufficient to draw a conclusion regarding statistical significance. The mortality in the Perceval group involved a patient who underwent surgery for infective endocarditis. This patient exhibited elevated inflammatory markers starting on postoperative day 2. Effective infection control was not achieved, and the patient developed progressive multi-organ failure, leading to septic shock and death by postoperative day 4. In the Intuity group, the patient experienced unstable vital signs after weaning from CPB, necessitating the insertion of ECMO. Although initially weaned off ECMO, the patient required reinsertion due to recurrent instability of vital signs and ultimately died from septic shock with disseminated intravascular coagulation on postoperative day 7.

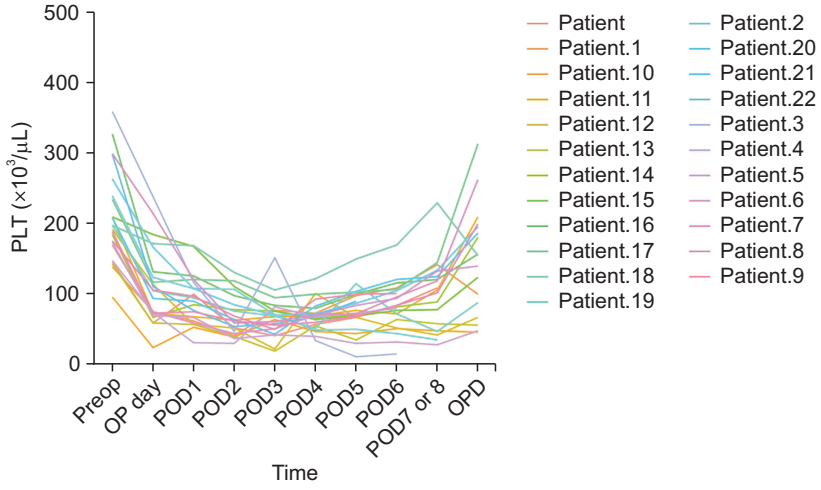

Fig. 2. Individual changes in platelet (PLT) count over time for each patient who received a Perceval valve. The timing of transfusions was within 7 days postoperatively, with the majority occurring within 3 days. In some cases, multiple transfusions were administered if deemed necessary, although typically not exceeding once per day. Preop, preoperative; OP day, operation day; POD, postoperative day; OPD, outpatient department.

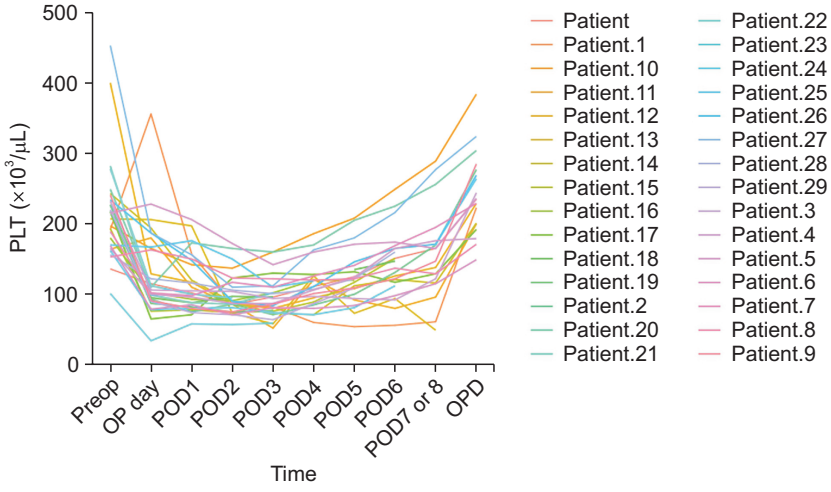

Fig. 3. Individual changes in platelet (PLT) count over time for each patient who received an Intuity valve. The timing of transfusions was within 7 days postoperatively, with the majority occurring within 3 days. In some cases, multiple transfusions were administered if deemed necessary, although typically not exceeding once per day. Preop, preoperative; OP day, operation day; POD, postoperative day; OPD, outpatient department.

Table 4. Postoperative morbidity and early mortality according to valve type

	Perceval valve (n=23)	Intuity valve (n=30)	p-value	C-E valve (n=50)
Stroke or TIA	1 (4.3)	1 (3.3)	0.386	1 (2.0)
Re-exploration for bleeding	0	1 (3.3)	0.851	4 (8.0)
Early mortality	1 (4.3)	1 (3.3)	0.846	2 (4.0)

Values are presented as number (%).
C-E valve, Carpentier-Edwards valve; TIA, transient ischemic attack.

Discussion

Surgery for heart valve diseases is known to cause temporary thrombocytopenia for various reasons. These include the characteristics of the valve, hemodilution from CPB, hypothermia, and exposure to heparin or protamine [2,3]. However, if thrombocytopenia occurs to a degree beyond the acceptable range with a particular type of valve, this could be considered a significant drawback of that valve. With recent advancements in valve technology, sutureless valves that facilitate quicker surgery are becoming more popular. They can shorten surgical time and enhance the feasibility of concomitant or minimally invasive surgeries [4]. Among these sutureless valves, the Perceval valve is one of the most commonly used. There is also a rapid deployment valve, known as the Intuity valve, which offers the advantage of reduced surgical time. Several studies have confirmed the stability of the Intuity valve not

only immediately post-surgery but also over the long term, contributing to its widespread use in accelerating surgical procedures [5]. While some studies indicate that the Perceval valve's ability to decrease surgical time without significantly increasing other complications may render it a viable alternative [6], other research highlights concerns regarding the severity of thrombocytopenia observed after its use [1]. Nonetheless, it is not clear-cut whether this level of thrombocytopenia should be universally considered as indicating a disadvantage for patients. Therefore, this study aimed to determine whether thrombocytopenia following the use of the Perceval valve is indeed significant and to assess its relationship with critical complications or mortality.

In this study, both the Perceval and Intuity groups exhibited a trend for decreasing platelet counts immediately following surgery. This was succeeded by a rise beginning around the third postoperative day, suggesting a time-dependent fluctuation in platelet counts. However, there was a significant difference in the patterns of platelet count changes between the 2 groups (p<0.001). Severe thrombocytopenia, defined as a platelet count below 50,000/μL, was significantly more common in the Perceval group, affecting 56.5% of patients (n=13), compared to just 6.7% in the Intuity group (n=2). According to our internal policy, platelet transfusion was typically performed when the platelet count fell below 50,000/μL, and consequently, patients who received the Perceval valve required significantly more platelet transfusions than those with the Intuity valve. Based on the results of this study, it can be concluded that the Perceval valve temporarily induces thrombocytopenia, but this does not pose a significant issue in terms of bleeding events throughout the patient's postoperative course. Therefore, our institution does not consider low platelet counts in preoperative patients as a factor in valve selection.

Numerous studies have been conducted to compare the Perceval valve with various other valves in terms of thrombocytopenia incidence. Mujtaba et al. [1] compared patients who underwent aortic valve replacement using the Perceval valve or Perimount Magna Ease bioprostheses. Their research included 173 patients and revealed a marked decrease in platelet counts within the Perceval group—a 58% reduction by postoperative day 2.3. In contrast, the Perimount Magna group experienced a 44% decrease by postoperative day 1.7 (p=0.0001). Furthermore, the Perceval group consistently had lower platelet counts from postoperative days 1–6 (p<0.05). At the time of discharge, platelet counts had normalized in only 26% of the Perceval group compared to 44% in the Perimount Magna group (p=0.018). Severe thrombocytopenia, defined as a platelet count below 50,000/μL, occurred in 6% of patients with the Perceval valve but was not observed in the Perimount Magna group (p=0.007). Additionally, the Perceval group required significantly more RBC transfusions (p=0.009).

Sánchez et al. [7] investigated the immediate postoperative changes in platelet count after aortic valve replacement using the Perceval valve, comparing these changes to those observed with other tissue valves. The study included 27 patients who underwent replacement with the Perceval valve and 50 patients who received other tissue valves between July 2011 and July 2014. The results showed a higher incidence of severe thrombocytopenia—defined as platelet counts below 50,000/μL—in the Perceval group (33.3%) than in the Mitroflow group (14%) (p=0.046). Multivariate logistic regression analysis revealed that Perceval valve replacement was a significant predictor of severe thrombocytopenia (odds ratio, 0.06; 95% confidence interval, 0.008–0.5; p=0.009). Notably, this severe thrombocytopenia resolved without leading to any specific clinical complications.

Stegmeier et al. [8] compared the Perceval valve, Labcor TLPB-A valve, and Hancock II valve. While preoperative platelet counts were similar across the 3 groups, the Perceval group exhibited significantly lower postoperative platelet counts (median, 47/nL; interquartile range [IQR], 38–66/nL) when compared to the Labcor (median, 76/nL; IQR, 61–110/nL) and Hancock (median, 78; IQR, 61–111/nL) groups (p=0.001). This difference remained even after adjustments and persisted until discharge, with the Perceval group consistently showing lower platelet counts. However, despite the lower postoperative platelet count in the Perceval group, there were no significant differences in blood loss, transfusion requirements, or major complications such as stroke or reoperation due to bleeding. Therefore, the reduced postoperative platelet counts in the Perceval group did not seem to lead to significant clinical issues during the postoperative period.

The study by Lorusso et al. [9] made a significant contribution to the growing knowledge base in the field of aortic valve replacement by comparing the Perceval valve with a sutured stented bioprosthetic aortic valve. Conducted from March 2016 to November 2018, the research aimed to evaluate the reduction in platelet count and the clinical significance of platelet count changes in patients undergoing aortic valve replacement. The results indicated that patients in the Perceval group experienced a more substantial decrease in platelet count (46%) than those in the control group

(32%). This reduction, however, was transient, with platelet counts returning to baseline levels by the time patients were discharged. Notably, there were no significant differences between the groups regarding the need for blood transfusions, the volume of bleeding, or the occurrence of major complications, such as stroke or reoperation due to bleeding.

Multiple studies have shown that the use of the Perceval valve in aortic valve replacement often results in postoperative thrombocytopenia, which is more pronounced than with other conventional valve types. This issue is not exclusive to surgical aortic valve replacement but has also been noted in transcatheter aortic valve implantation (TAVI) [10]. Jiritano et al. [11] carried out a systematic review and meta-analysis comparing the incidence of thrombocytopenia across various valve types, including isolated bio-aortic valve replacement, rapid deployment aortic valve replacement, stentless aortic valve replacement, stented aortic valve replacement, and TAVI. They reported varying degrees of platelet reduction, with stented aortic valve replacement showing a 35%–55% decrease, stentless aortic valve replacement a 60%–77% decrease, rapid deployment aortic valve replacement a 53%–60% decrease, and TAVI a 21%–72% decrease. These results indicate that transient thrombocytopenia is a common occurrence in TAVI.

The structural similarities between the Perceval and TAVI valves suggest that the observed reduction in platelet count may be due to shared design elements. Although the precise mechanisms underlying thrombocytopenia associated with TAVI remain to be fully understood, current research indicates that factors such as platelet activation, blood coagulation, and compromised baseline platelet production are likely involved [12,13]. The use of contrast agents during TAVI procedures has been linked to both platelet activation and reduction. However, the presence of metal stents in the valves should also be considered as a contributing factor. Both Perceval and TAVI valves incorporate these distinctive structural features, including the anchoring metal stent that is placed into the aortic root. This design could lead to turbulent blood flow and mechanical stress, which in turn may promote platelet consumption [14,15].

Given these mechanisms, it is reasonable to hypothesize that the Intuity valve, which lacks a metal stent and is balloon-expandable, may reduce the likelihood of platelet activation and, consequently, mitigate thrombocytopenia. However, further research is needed to validate this hypothesis and determine its extent. The observed correlation between valve design and thrombocytopenia underscores the importance of ongoing research into these structural distinctions to enhance patient outcomes and guide clinical decision-making.

An alternative theory posits that changes in the processing of valve leaflets could be associated with the emergence of thrombocytopenia. The Intuity valve, similar to tissue valves crafted from traditional bovine pericardium leaflets, is subjected to a leaflet processing method known as ThermaFix treatment. In contrast, the Perceval valve employs a different technique called FREE treatment, which is designed to significantly reduce tissue calcification. The FREE treatment process includes the extraction of phospholipids using an alcohol mixture, a post-sterilization amino acid treatment to neutralize unbound aldehydes, and final storage in an aldehyde-free solution. A key aspect of the FREE treatment is its effectiveness in eliminating and neutralizing unbound glutaraldehyde. Moreover, these valves are coated with a thin layer of turbostratic carbon (CarboFilm), which improves biocompatibility and encourages endothelialization. Although these leaflet processing methods are theoretically proposed to avert bioprosthetic dysfunction, their long-term effects are still largely unexplored [16,17]. Despite the scarcity of research in this area, it is hypothesized that these leaflet preservation techniques might, for various reasons, play a role in the onset of thrombocytopenia. Further investigation is required to explore these potential links.

Limitations

This study has several limitations that warrant consideration. First, the relatively small sample size may limit the generalizability of our findings to a broader patient population. As sutureless valves and rapid deployment valves themselves represent relatively new technological advancements, our institution had a limited number of surgical cases relevant for this study due to their recent introduction. While the sample size is relatively small, it is important to note that as the safety and effectiveness of these valves continue to be established and the volume of operations increases, it will be necessary to assess whether this trend persists over time. Another limitation is that the selection of the Perceval valve, Intuity valve, or C-E valve appeared to be influenced by individual surgeon preferences rather than being guided by specific criteria, which could introduce variability in the study results. Nonetheless, it should be taken into consideration that we included cases involving ECMO insertion before and after surgery. In such cases, it was natural for there to be a higher volume of

transfusions, including platelets, which could potentially introduce significant bias into our analysis. Finally, there may have been a time-related bias present. Changes in clinical practices or patient management strategies during the study period could have affected the outcomes.

Conclusion

The severity of postoperative thrombocytopenia differed significantly between patients undergoing aortic valve replacement with Perceval and Intuity valves. The Perceval group exhibited a significantly lower nadir platelet count and required significantly higher platelet transfusion volumes. However, thrombocytopenia in both groups gradually resolved to within the normal range during the postoperative period. Additionally, early outcomes revealed no significant differences between the 2 groups. Further research is necessary to identify the underlying cause of the more pronounced thrombocytopenia associated with the Perceval valve.

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Conflict of interest

No potential conflict of interest relevant to this article was reported.

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