Thrombocytopenia after sutureless aortic valve implantation: Comparison between Intuity and Perceval bioprostheses

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Video clip is available online.

Aortic valve replacement continues to be the “gold standard” for the treatment of severe symptomatic aortic stenosis. The development of alternative techniques for the treatment of aortic stenosis (transcatheter aortic valve implantation) has encouraged research of new prostheses and less-invasive and quicker techniques for sutureless valves. The Sorin Perceval S sutureless valve (Sorin Group, Saluggia, Italy) and the Edwards Intuity rapid deployment valve system (Edwards Lifesciences LLC, Irvine, Calif) belong to the “sutureless family.” The aim of this study was to analyze whether the use of a specific sutureless bioprosthesis is linked to postoperative thrombocytopenia.

PATIENTS AND METHODS

Isolated aortic valve replacement with the Edwards Intuity and Sorin Perceval S bioprostheses was performed in 43 patients divided into 2 groups: 27 in the Edwards Intuity group and 16 in the Sorin Perceval S group (Video 1). Patients' data are shown in Table 1. The study was approved by the institution's Ethical Committee/Institutional Review Board, and informed consent was obtained from each patient.

All patients received low-molecular-weight heparin postoperatively. Warfarin was commenced on postoperative day 1 and administered for 3 months, and then all patients were administered antiplatelet therapy. Variations in platelet count (PLT), mean platelet volume (MPV), and platelet distribution width (PDW) were observed preoperatively; at postoperative days 1, 3, and 5; at discharge; and at 1-year follow-up. Postoperative thrombocytopenia was defined as a PLT less than $50 \times 10^9/L$ within the first 5 postoperative days. The study end point was the lowest PLT within the first 5 postoperative days.

Statistical analysis was performed with the SPSS program for Macintosh, version 21.0 (IBM SPSS Statistics for Macintosh, Armonk, NY) checking data for normality with the Shapiro–Wilk test. Unpaired *t* test and Mann–Whitney *U* test were used for normally distributed variables and not normally distributed variables, respectively. A multivariate analysis was performed. A *P* value $\leq .05$ was considered statistically significant.

Federica Jiritano, MD

Central Message

A significant decrease in PLT postoperatively is associated with the Sorin Perceval S valve (Sorin Group, Saluggia, Italy).

See Editorial Commentary page 1633.

RESULTS

No reexplorations for bleeding were performed. No operative mortality and major cardiovascular events were observed. From day 3 onward, a different PLT behavior was observed between groups (Table 2). In the Edwards Intuity group, a steady increase continued until discharge, but without reaching preoperative values. In the Sorin Perceval S sutureless valve group, a marked decrease of the PLT was observed on day 3, followed by a slight increase on day 5; mild improvement was observed at discharge, although never reaching the preoperative value. The mean PLT was significantly higher in the Edwards Intuity group than in the Sorin Perceval S sutureless valve group from day 3 to discharge ($P < .01$). MPV significantly increased in the Sorin Perceval S group from day 1 to 5. PDW was significantly higher in the Sorin Perceval S group compared with the Edwards Intuity group on days 3 and 5 (Table 2). On multivariate analysis, the following independent risk factors for postoperative thrombocytopenia were revealed: age, body surface area, preoperative PLT, cardiopulmonary bypass time, and units of red blood cells. When the type of bioprosthesis was included in the multivariate analysis with the other risk factors, there was a statistically significant difference in PLT based on the type of prosthesis

VIDEO 1. Hypothermic cardiopulmonary bypass was performed, and cold crystalloid cardioplegia was infused antegrade into the aortic root and retrograde into the coronary sinus. A transverse aortotomy was performed, and cold crystalloid cardioplegia was selectively administered into both coronary ostia. Excision of the aortic valve and annulus decalcification are shown. Sizing, lowering, and delivering of the prosthesis size M (Sorin Perceval S; Sorin Group, Saluggia, Italy) are shown. Postdilatation modeling, closure of the aortotomy, and weaning from cardiopulmonary bypass are shown. Video available at: [http://www.jtcvsonline.org/article/S0022-5223\(16\)30874-1/addons](http://www.jtcvsonline.org/article/S0022-5223(16)30874-1/addons).

implanted: $F(4,38) = 10.89$, $P < .0005$; Wilk's $\Lambda = 0.466$, partial $\eta^2 = 0.53$. The use of the Sorin Perceval S bioprosthesis was an independent predictor of postoperative thrombocytopenia. At 1-year follow-up, the PLT in the

TABLE 1. Preoperative, operative, and postoperative data (April 2013 to May 2015)

Parameter	Prosthesis		P value
	Edwards Intuity Elite prosthesis (Edwards Lifesciences LLC, Irvine, Calif) (n = 27)	Sorin Perceval S prosthesis (Sorin Group, Saluggia, Italy) (n = 16)	
Age (y)	73.37 ± 6.79	75.94 ± 7.07	.621
Female gender	9	6	.606
BSA (m ²)	1.88 ± 0.24	1.77 ± 0.19	.482
COPD	4	2	.678
Diabetes	8	6	.337
Smoking	8	5	.830
Hypertension	12	9	.931
Dyslipidemia	6	4	.690
LVEF (%)	51.04 ± 7.82	56.13 ± 4.33	.096
MG (mm Hg)	47.80 ± 20.96	54.67 ± 20.02	.744
PG (mm Hg)	70.33 ± 22.48	88.07 ± 26.93	.340
Logistic euroSCORE II (%)	11.63 ± 4.15	9.26 ± 4.49	.921
Aortic crossclamp time (min)	40.77 ± 2.42	40.62 ± 3.18	.156
CPB time (min)	57.77 ± 4.25	61.75 ± 5.62	.109
RBCs (units)	7	10	.012
Platelets (units)	0	4	<.01
ICU stay (h)	32.89 ± 6.40	33.19 ± 4.92	.117
In-hospital stay (d)	7.26 ± 1.87	6.81 ± 1.05	.367

Preoperative data. BSA, Body surface area; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; MG, mean transvalvular gradient; PG, peak transvalvular gradient; euroSCORE, European System for Cardiac Operative Risk Evaluation; CPB, cardiopulmonary bypass; RBC, red blood cell; ICU, intensive care unit.

TABLE 2. Platelet count, mean platelet volume, and platelet distribution width variation

Time	Prosthesis		P value
	Edwards Intuity Elite prosthesis (n = 27)	Sorin Perceval S prosthesis (n = 16)	
PLT - preoperative ($\times 10^9/L$)	243.59 ± 74.07	268.69 ± 84.68	.470
PLT - d 1 ($\times 10^9/L$)	143.93 ± 54.68	124.75 ± 41.99	.517
PLT - d 3 ($\times 10^9/L$)	140.67 ± 49.63	71.88 ± 21.20	.004
PLT - d 5 ($\times 10^9/L$)	177.77 ± 76.68	73.25 ± 19.71	<.001
PLT - discharge ($\times 10^9/L$)	213.11 ± 74.04	102.18 ± 29.34	.001
PLT - 1-y follow-up	266.92 ± 46.83	265.56 ± 53.36	.460
MPV - preoperative (μm^3)	7.79 ± 0.68	7.81 ± 0.67	.996
MPV - d 1 (μm^3)	8.31 ± 0.43	9.13 ± 0.64	.040
MPV - d 3 (μm^3)	8.73 ± 0.49	10.97 ± 1.51	.001
MPV - d 5 (μm^3)	8.65 ± 0.78	10.11 ± 1.44	.015
MPV - discharge (μm^3)	8.28 ± 0.62	8.97 ± 0.82	.313
MPV - 1-y follow-up (μm^3)	8.14 ± 0.78	8.01 ± 0.62	.102
PDW - preoperative (%)	14.26 ± 1.24	14.91 ± 1.52	.301
PDW - d 1 (%)	14.71 ± 0.94	15.27 ± 1.33	.134
PDW - d 3 (%)	14.34 ± 1.12	16.54 ± 1.72	.018
PDW - d 5 (%)	14.47 ± 0.91	16.21 ± 1.60	.026
PDW - discharge (%)	13.99 ± 0.93	15.85 ± 1.57	.288
PDW - 1-y follow-up (%)	14.58 ± 1.24	14.40 ± 1.02	.298

Values in bold are statistically significant ($P \leq .05$). PLT, Platelet count; MPV, mean platelet volume; PDW, platelet distribution width.

Sorin Perceval S group was not significantly different than the preoperative count, as well as in the Edwards Intuity group ($P = .063$).

DISCUSSION

There are few studies on thrombocytopenia and sutureless valves.^{1,2} Albacker¹ reported a comparison among sutureless prostheses and traditional sutured valves, and he concluded that thrombocytopenia is a transient phenomenon linked to sutureless valves with a significantly higher transfusion of red blood cells. Flameng and colleagues² confirmed a decrease in PLT after Sorin Perceval S sutureless valve implantation up to 1-year follow-up.² Thrombocytopenia after Sorin Perceval S implantation could be a transitory direct toxic effect of these valves on platelets caused by the storage solution³ or the microhemodynamic effects of the prosthetic structure.⁴ Miceli and colleagues⁵ analyzed MPV and PDW, indices of platelet activation, reporting that the Sorin Freedom Solo bioprosthesis might induce thrombocytopenia.⁵ Likewise, in our study, MPV and PDW were higher in the Sorin Perceval S group. The stainless-steel frame of the Edwards Intuity valve is hidden by a sealing cloth, whereas the alloy stent of the Sorin Perceval S valve is “naked.” According to this observation, we might conclude that the type of stent may play a pivot role in platelet activation, resulting in thrombocytopenia.

Study Limitations

The limitations of this study were linked to the limited number of cases and the retrospective analysis.

CONCLUSIONS

The results showed that the reduction in PLT depends on the type of sutureless bioprosthesis used. A significant but transient reduction in PLT is associated with the Sorin Perceval S valve without adverse outcomes, although larger prospective, randomized studies are mandatory.

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EDITORIAL COMMENTARY

Tissue valve, nitinol stent, or storage solution? The mystery still goes on

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Thrombocytopenia is a frequent and transient event after cardiac surgery. It usually occurs between the second and third postoperative days and results in a reduction of platelet counts by 30% to 60% from baseline values.¹ In this setting, cardiopulmonary bypass plays an important role in inducing qualitative and quantitative platelet defects, resulting in platelet activation (structural and biochemical changes), formation of platelet conjugates, altered platelet force generation, and thrombocytopenia.¹ Furthermore, factors such as hemodilution, hypothermia, and the use of exogenous drugs, as well as the perioperative blood loss, may amplify these platelet changes. Finally, some studies have reported that some biologic valves might increase the risk of thrombocytopenia.²⁻⁴

In this issue of the *Journal*, Jiritano and colleagues⁵ have investigated whether the use of a specific sutureless bioprosthesis is linked to postoperative thrombocytopenia.

Antonio Miceli, MD, PhD

Central Message

Thrombocytopenia is a frequent and multifactorial complication after cardiac surgery. A well-designed study is required to investigate on the role of sutureless valves in this complex phenomenon.

See Article page 1631.

Of 43 patients undergoing aortic valve replacement, 27 received the Intuity Edwards rapid-deployment valve