Evaluation of Thrombocytopaenia-Related Complications After Bioprosthetic Aortic Valve Implantation*

Sabit Sarıkaya, Eray Aksoy, Mehmet Dedemoğlu, Davut Çekmecelioğlu, Özge Altaş, Yücel Özen, Kaan Kırali

University of Health Sciences, Kartal Koşuyolu High Specialization Health Application and Research Center, Clinic of Cardiovascular Surgery, İstanbul, Turkey

ABSTRACT

Introduction: We aimed to determine whether thrombocytopaenia (TCP) is associated with postoperative complications in patients undergoing bioprosthetic aortic valve replacement.

Patients and Methods: Clinical records of 39 consecutive patients undergoing bioprosthetic aortic valve replacement for aortic stenosis were reviewed. Patients were divided into 2 groups based on whether they had TCP or not within 7 days after the operation [TCP (+), 9 patients and TCP (-), 30 patients]. TCP was defined as a platelet count less than 50×10^9/L.

Results: Both the groups were similar with regard to baseline clinical characteristics and operative variables. Stentless bioprosthesis was used in 16 patients (41.02%). The use of Sorin Pericarbon Freedom was significantly more common in the TCP (+) group. Postoperative complications such as the removal time of the drainage tube, intensive care unit (ICU) stay and acute renal failure were significantly higher in the TCP (+) group. Overall, 30-day mortality occurred in 3 (7.7%) patients, and the difference between the groups was not statistically significant.

Conclusion: Postoperative TCP may be associated with a substantial threat for the postoperative status of patients undergoing bioprosthetic valve replacement. The issue is still subject to further research until the exact mechanism underlying its occurrence is elucidated.

Key Words: Bioprosthesis; aortic valve; thrombocytopaenia; postoperative complication

Biyoprotez Aort Kapak Replasmanı Sonrası Görülebilen Trombositopeni ve İlişkili Komplikasyonların Değerlendirilmesi

ÖZET

Giriş: Biyoprotez aort kapak replasmanı yapılan hastalarda görülebilen trombositopeninin (TCP) postoperatif komplikasyonlar ile ilişkili olup olmadığını belirlemeyi amaçladık.

Hastalar ve Yöntem: Aort darlığı nedeniyle biyoprotez aort kapak replasmanı yapılan 39 ardışık hastanın klinik kayıtları incelendi. Hastalar operasyondan sonraki 7 güne kadar trombositopeni görülen ve görülmeyenler olarak iki gruba ayrıldı. (TCP+; 9 hasta ve TCP-; 30 hasta) Trombositopeni, 50 x 10^9/L'den az trombosit sayısı olarak tanımlandı.

Bulgular: İki grup bazal klinik özellikleri ve operasyonel değişkenler açısından benzerdi. Stentsiz biyoprotez kapak 16 hastada kullanıldı (41.02%). Sorin Pericarbon Freedom kullanımı TCP (+) grubunda anlamlı olarak daha yaygındı. Drenaj tüplerinin çekilme süresi, yoğun bakım ünitesi (YBÜ)'nde kalış süresi ve akut böbrek yetmezliği gibi postoperatif komplikasyonlar, TCP (+) grupta anlamlı olarak yüksek bulundu. Otuz günlük mortalite 3 (%7.7) idi ve mortalite açısından iki grup arasındaki fark istatistiksel olarak anlamlı değildi.

Sonuç: Biyoprotez aort kapak replasmanı sonrası görülebilen trombositopeni tablosu, hastalar için önemli bir tehdit ile ilişkili olabilmektedir. Bu fenomenin oluş mekanizması tam olarak aydınlatılamamış olmakla beraber yüksek sayılı araştırmalara tabi tutulması gerekmektedir.

Anahtar Kelimeler: Biyoprotez; aort kapağı; trombositopeni; postoperatif komplikasyon

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Correspondence

Sabit Sarıkaya

E-mail: sabitsarikaya@yahoo.com
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INTRODUCTION

Porcine aortic valves and pericardial tissue-mounted valves have widespread use in the surgical treatment of aortic stenosis. These stented tissue valves have replaced homografts because of their easy implantation technique. Further, they are superior to mechanical valves because they offer from life-long anticoagulation. However, the increased stress at the stent-tissue attachment site and haemodynamic consequences of a relatively small orifice became major concerns for earlier development of valve failure[1]. In contrast, stentless aortic valves achieve optimised haemodynamics by means of patient-prosthesis harmony and offer durability comparable to that offered by mechanic valves[2,3]. Stentless are also associated with better regression of left ventricular mass in the long term[4,5]. However, long-term survival has not been shown to be significantly different in randomised studies[6, 7].

Sorin Freedom Solo and Sorin Pericarbon Freedom are the latest generation of stentless aortic tissue valves, which have structural flexibility, an easy single-suture implantation technique and excellent haemodynamics[8,9]. However, postoperative thrombocytopaenia (TCP) is a potentially serious problem following implantation, and recent reports have suggested a strong relationship[10-18]. Nevertheless, previous studies have not shown any significant mortality or morbidity effect or association with adverse outcomes in patients with TCP. We retrospectively investigated the clinical data of patients in whom we used bioprosthesic valves for the treatment of aortic stenosis and found that there is an important correlation between TCP as a complication following aortic valve replacement and morbidity, particularly in patients with perioperative risk factors.

PATIENTS and METHODS

Patients

This was a cross-sectional study in which clinical records of 39 consecutive patients who underwent bioprosthetic aortic valve replacement for aortic stenosis between March 2001 and January 2013 were analysed. The study was performed in a tertiary hospital. Patients were divided into 2 groups based on whether they had TCP or not within 7 days after the operation [TCP (+), 9 patients and TCP (–), 30 patients]. TCP was defined as a platelet count less than 50×10^9/L. Patient charts, routine laboratory tests and echocardiographic data were retrospectively reviewed and recorded.

Operation

All the patients were operated under general anaesthesia and via median sternotomy incision. All the operations were performed using cardiopulmonary bypass. The route of cardioplaegia was continuous retrograde in 21 patients (53%), intermittent antegrade in 5 (12.8%) patients and combined antegrade–retrograde in 13 (33.3%). Diseased valvular leaflets were resected and calcified plates were scraped before the placement of annular sutures. Mitral valve replacement and radiofrequency ablation, distal anastomoses of coronary artery bypass grafts and, if needed, aortic root enlargement were performed, in that order. Seven different types of tissue valves were used, and each type of valve was implanted according to its specific technique of implantation. As a general rule, the use of single interrupted pledgeted sutures was preferred for all types of valves. As an exception, Sorin Freedom Solo valve implantation was performed using a continuous suture technique, as described previously[9]. Following the discontinuation of cardiopulmonary bypass, heparin was reversed with protamine sulphate.

Statistical Analysis

All statistical analyses were performed using MedCalc statistical software. Continuous variables were expressed as mean ± standard deviation. Categorical variables were compared using chi-square test and Fisher's exact test where appropriate. Continuous variables were compared using independent samples t-test or Mann-Whitney U test. A p value of < 0.05 was considered to be statistically significant.

RESULTS

Both the groups were similar with regard to baseline clinical characteristics and echocardiographic findings (Table 1). There were 19 males (48.71%), and the mean age was 66.62 ± 14.72 years (range, 19-86 years). Overall, combined procedures were performed in 21 patients (53.8%), coronary artery bypass grafting (CABG) in 16 (41%), mitral valve replacement in 2 (5.0%), posterior annular enlargement in 2 (5.0%) and radiofrequency ablation of the left atrium in 2 (5.0%). Reoperation was performed in 2 patients (the previous operation was CABG in both the patients). Operative variables were similar between the groups. Extensive calcification of the aortic valve and use of stentless valves tended to be more frequent in the TCP (+) group, but these differences were not statistically significant.

The degree of aortic stenosis was severe (considered as valve area less than 1.0 cm^2, mean gradient greater than 40 mmHg or jet velocity greater than 4.0 m/s) in 27 patients (69%) and moderate (considered as valve area of 1.0 to 1.5 cm^2, mean gradient of 25 to 40 mmHg or jet velocity of 3.0 to 4.0 m/s) in the remaining 12 patients (31%) who underwent concomitant procedures. Two patients who presented with signs of systemic infection and heart failure symptoms had been diagnosed with annular abscess and treated with appropriate antibiotics before and after the operation. Severe mitral regurgitation was present in 2 patients (5%).

Stentless bioprosthesis was used in 23 patients (59.0%). The use of Sorin Pericarbon Freedom was significantly more common in the TCP (+) group (Table 2). The postoperative course is summarised in Table 2. The duration of postoperative chest tubes were significantly higher in the TCP (+) group (2.92 ± 2.11 days, p= 0.04). However, the TCP (+) group had a significantly longer duration of intensive care unit (ICU) stay (2.92 ± 2.11days, p= 0.03). Total mortality was observed in 3

Table 1. Baseline characteristics

Characteristic	All patients (n= 39)	Thrombocytopaenia (+) (n= 9)	Thrombocytopaenia (–) (n = 30)	p value
Age (years)	66.62 ± 14.72	72.00 ± 6.10	65.00 ± 16.18	0.31
Male	19 (49.7)	3 (33.3)	16 (53.3)	0.45
Body mass index (kg/m²)	27.76 ± 5.49	28.23 ± 3.56	27.62 ± 5.99	0.38
Body surface area (m²)	1.71 ± 0.16	1.66 ± 0.11	1.72 ± 0.17	0.29
NYHA Class > II	16 (41.0)	5 (55.6)	11 (36.7)	0.44
Diabetes (type II)	7 (17.9)	0 (0)	7 (23.3)	0.16
Hypertension	24 (61.5)	4 (44.4)	20 (66.7)	0.26
Chronic pulmonary disease	6 (15.4)	1 (11.1)	5 (16.7)	1.00
Coronary artery disease	18 (46.2)	4 (44.4)	14 (46.7)	1
Dyslipidaemia	11 (28.2)	1 (11.1)	10 (33.3)	0.39
Renal failure	2 (5.1)	1 (11.1)	1 (3.3)	0.41
Cerebrovascular disease	4 (10.3)	0 (0)	4 (13.3)	0.55
Echocardiography				
Ejection fraction* (%)	55.4 ± 13.3	58.55 ± 12.65	54.48 ± 13.65	0.41
Aortic valve area (cm²)	0.98 ± 0.17	0.94 ± 0.17	0.99 ± 0.17	0.61
Transaortic velocity	3.98 ± 0.80	3.65 ± 1.10	4.09 ± 0.68	0.28
Peak transaortic gradient	80.97 ± 22.30	83.11 ± 17.5	80.33 ± 23.78	0.74
Mean transaortic gradient	50.00 ± 17.02	51.44 ± 11.87	49.56 ± 18.43	0.77
LVESD	3.56 ± 0.89	3.10 ± 0.64	3.66 ± 0.91	0.09
LVEDD	5.08 ± 0.81	4.77 ± 0.80	5.10 ± 0.80	0.42
IVS thickness	1.41 ± 0.19	1.40 ± 0.18	1.41 ± 0.19	0.90
PW thickness	1.36 ± 0.15	1.38 ± 0.14	1.36 ± 0.15	0.73
Severe mitral regurgitation	2 (5.1)	0 (0)	2 (6.7)	1
Severe aortic regurgitation	0 (0)	0 (0)	0 (0)	1

Continuous variables are represented as mean ± standard deviation and intervals, and categorical variables are represented as number (%). Denotations: NYHA, New York Heart Association; LVESD: Left ventricular end-systolic diameter, LVESS: Left ventricular end-diastolic diameter, IVS: Interventricular septum, PW: Posterior wall.

patients (7.7%). Two (22.2%) of these patients were in the TCP (+) group and 1 (3.3%) was in the TCP (–) group. There was no statistically significant difference between the groups (p= 0.51). Although we do not assume that low platelet count is a major risk factor for mortality in these 2 patients in the TCP (+) group, TCP was a remarkable attributor of the obstinate terminal medical status. In the remaining patient in the TCP (–) group, TCP was intractable despite the transfusion of platelets, and the clinical progress was similar to that in case of severe disseminated intravascular coagulation (DIC): abundant gastrointestinal bleeding, acute renal failure, cardiovascular collapse and death.

DISCUSSION

The main finding of our study was that TCP after bioprosthetic valve implantation may be serious because of its morbidity and it may be intractable even though optimal management is undertaken. Patients with TCP had similar baseline characteristics before the operation, and Sorin Pericarbon Freedom-type bioprosthetic valves were more common in the TCP (+) group. Endothelial injury due to renal failure and heavy smoking was associated with DIC in these patients. Although all patients with low platelet counts receive platelet transfusion, non-survivors did not have benefit in terms of an increase in platelet counts and clinical improvement. This is assumed to be a crucial point for discussion on the subject. Based on our observations, we emphasise that TCP after bioprosthetic aortic valve implantation should not only be considered as the sole feature to target therapy, but it should be considered as the prominent manifestation of a complex pathogenetic process that may involve many organ and systems with fatal consequences. TCP, as an established complication after bioprosthetic aortic valve implantation, should be assumed to be a remarkable attributor of the obstinate terminal medical status in patients with a high preoperative risk.

In our study, 4 of 9 patients with TCP received the Sorin Freedom Solo valve and 3 patients received the Sorin Pericarbon Freedom valve. Van Straten et al. reported in a large series of patients that postoperative TCP was not directly associated

Table 2. Operational values

Variable	All patients (n= 39)	TCP (+) (n= 9)	TCP (–) (n= 30)	p
Operation data				
Extensive calcification	21 (53.8%)	7 (77.8)	14 (46.7)	0.13
Bicuspid valve	2 (5.1%)	0 (0)	2 (6.7)	1
Annular abscess	2 (5.1%)	0 (0)	2 (6.7)	1
Time of ACC (min)	110.66 ± 41.85	113.66 ± 42.64	109.76 ± 42.30	0.88
Time of CPB (min)	140.97 ± 47.82	146.66 ± 56.67	139.26 ± 45.80	0.75
Hypothermia (°C)	29.48 ± 2.43	29.18 ± 1.92	29.57 ± 2.59	0.68
Stentless valve	23 (59.0%)	7 (77.8)	16 (53.3)	0.26
Valve type				
Sorin Freedom Solo	13 (33.3%)	4 (44.4)	9 (30.0)	0.44
Sorin Pericarbon Freedom	4 (10.3%)	3 (33.3)	1 (3.3)	**0.03**
Cryolife O'Brien	1 (2.6%)	0 (0)	1 (3.3)	1
Medtronic Freestyle	5 (12.8%)	0 (0)	5 (16.7)	0.31
Sorin Soprano	2 (5.1%)	1 (11.1)	1 (3.3)	0.41
Medtronic Hancock II	4 (10.2%)	0 (0)	4 (13.3)	0.55
St Jude Epic	10 (25.6%)	1 (11.1)	9 (30.0)	0.40
Combined operation	21 (53.8%)	5 (55.6)	16 (53.3)	1
Postoperative data				
Time to extubation (h)*	15.29 ± 8.95	10.25 ± 3.50	15.96 ± 9.27	0.21
ICU stay (days)*	3.97 ± 3.45	4.25 ± 2.21	2.93 ± 2.61	**0.03**
Hospital stay (days)*	11.05 ± 7.29	14.37 ± 13.89	9.93 ± 4.28	0.66
Chest tube removal date (days)	1.97 ± 1.24	2.92 ± 2.11	1.23 ± 1.04	**0.04**
Inotropes	10 (25.6%)	5 (55.6)	6 (20.0)	0.08
Respiratory distress	4 (10.3%)	5 (55.6)	3 (10.0)	**0.01**
Atrial fibrillation	2 (5.1%)	0 (0)	2 (6.7)	1
Conduction block	2 (5.1%)	0 (0)	2 (6.7)	1
Acute renal failure	4 (10.3%)	3 (33.3)	1 (3.3)	**0.03**
Infection	1 (2.6%)	0 (0)	1 (3.3%)	1
Overall hospital mortality	3 (7.7%)	2 (22.2%)	1 (3.3%)	0.51

Continuous variables are represented as mean ± standard deviation, and categorical variables are represented as number (%). Denotations; TCP: Thrombocytopenia, ACC: Aortic cross-clamping, CPB: Cardiopulmonary bypass, ICU: Intensive care unit.
* Values among survivors. * OR 14.50 (range 1.27-164.35, 95% CI)

with the implantation of the Freedom Solo valve; however, in controversy, a lower platelet count within the first 5 postoperative days was more common in patients receiving a Carpentier–Edwards Perimount bioprosthesis or Medtronic Freestyle bioprosthesis[19]. Interestingly, several studies in recent years have focused on the relationship between TCP and the Freedom Solo valve[10-18]. In our study, because the patients for whom the Freedom Solo and Pericarbon Freedom valves were used had similar baseline features to those for whom other types of valves were used, our results support the presence of an ambiguous relationship that has been repeatedly announced. TCP-related morbidity was the core point of this study.

Yerebakan et al. were the first to report their experiences in an institutional report regarding the remarkable decrease in platelet counts observed after using the Sorin Freedom valve since 2005[10]. In this study, the authors presented the average platelet counts that they obtained daily after the operation and they made statistical adjustment for clopidogrel use, which was more common among patients receiving the Freedom Solo valve. They found that platelet loss was significantly more severe in the Freedom Solo group and in contrast to the control group, the platelet counts did not recover during follow-up. Although we did not find any direct correlation between TCP and mortality, they reported no morbidity or bleeding complications in patients with postoperative TCP.

The mechanism underlying the relationship between TCP and the Freedom Solo valve remains unknown. Some authors have attributed this relationship to the commercial release and preparation of the valve before the operation[10,11]. The Freedom Solo valve does not necessitate rinsing before implantation because it is provided by the manufacturer and the valve is detoxified with homocysteic acid during its preparation before implantation. It was proposed by Yerebakan et al., without evidence, that the possible toxic effect of homocysteic acid on platelets may not be eliminated without rinsing[10]. Supporting this, without evidence, Piccardo et al. mentioned that there may be a toxic effect associated with the aldehyde-free solution in which the valve is stored[11]. However, a consultant from Sorin justified that the final homocysteic acid concentration in the storage solution is far from the toxic levels and is comparable with the physiological ranges of homocysteine and its derivatives in healthy humans[20]. This is still a matter of debate because no study has been performed to elucidate the underlying mechanism; this is possibly because low platelet counts have not been found to be associated with poor outcomes in most previous studies, similar the findings of our study.

Which patients are not suitable for Sorin Freedom Solo valve implantation and how postoperative loss of platelets may be prevented remain debatable. Repossini et al. reported that patients with low platelet counts before the operation had 8.69-fold increased risk of having a postoperative platelet count below 150 $\times 10^3/mm^3$[16]. Because platelet transfusion is known to increase vasoplegia and may lead to transfusion-related acute lung injury, patients with low platelet counts before the operation do not seem to be suitable to receive this type of bioprosthesis[21,22]. In our study, patients in the TCP (+) group had normal platelet counts before the operation and both survivors and non-survivors received platelet transfusion to prevent further complications. Non-survivors had no signs of acute lung injury; we did not observe any deterioration in partial oxygen and carbon dioxide pressures and saturations under optimal fractioned inhaled oxygen concentrations, and there were also no positive radiographic signs of parenchymal lung infiltration. Therefore, based on our results, we cannot reach any conclusion regarding the possible effect of preoperative platelet count on postoperative TCP. However, one should keep in mind the side effects of transfusions on endothelial injury, which may cause further complications such as severe DIC, particularly in patients with high preoperative morbidity similar to those our study.

The haemodynamic performance of the Freedom Solo valve and other types of stentless valves has been well established, both in early and mid-term phases[23,24]. Although stentless valves initially had a similar technique of implantation as many other stentless or stented valves, the Sorin Pericarbon Freedom valve and Freedom Solo valve had an easier implantation technique involving 3 sutures or a single suture throughout the aortic annulus[8,9]. The Sorin Freedom Solo valve has been increasingly used in operations in which the expected time for cross-clamping is somewhat long. In our study, all the patients receiving the Sorin Pericarbon Freedom valve and 7 of 13 patients receiving the Sorin Freedom Solo valve had also undergone a concomitant CABG procedure. The 2 groups were similar with regard to combined procedures, and 3 of the non-survivors underwent a combined procedure, whereas aortic valve replacement was isolated in 2 of them. Despite the occurrence of 2 deaths with the Sorin Pericarbon Freedom valve and 1 death with the Sorin Freedom Solo value, surgeons in our institution still tend to use the Sorin Freedom Solo valve, particularly in patients requiring multiple procedures, owing to its technical and haemodynamic properties.

CONCLUSION

In contrast to previous reports, we observed that postoperative TCP may be associated with a substantial risk of death as a remarkable attributor of the obstinate terminal medical status in patients undergoing bioprosthetic valve replacement with a high perioperative risk. Although we found that the Sorin Pericarbon Freedom valve was significantly more common in patients with low platelet counts, the number of patients included in this report was lower than expected to reach a conclusion about this observation. We would like to conclude that TCP after bioprosthetic valve operations may be associated with worse outcomes because of related complications, and the issue is still subject to further research until the exact mechanism underlying its occurrence is elucidated.

LIMITATIONS

The low patient number, retrospective design and lack of randomisation were among the main limitations of our study. This institutional report is also subject to criticism because we did not prospectively collect thrombocyte values based on a daily scale.

CONFLICT of INTEREST

The authors reported no conflict of interest related to this article.

AUTHORSHIP CONTRIBUTIONS

Concept/Design: SS, EA
Analysis/Interpretation: SS, DÇ
Data Acquisition: DÇ, ÖA
Writting: EA, MD
Critical Revision: KK, MD, YÖ
Final Approval: All of authors

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