

Thrombocytopenia and perioperative complications after stentless Freedom Solo valve implantation

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Abstract

Background: Freedom Solo (FS) stentless bioprostheses have superior haemodynamic performance compared to stented valves; however, the data of thrombocytopenia after FS implantations is disturbing.

Aim: To compare platelet count and perioperative complications between stentless and stented biological valves in patients undergoing aortic valve replacement.

Methods: In 29 patients, FS bovine valves (Sorin Group, Saluggia, Italy) were implanted. Platelet counts were analysed before surgery, on the day of operation, on four consecutive postoperative days (POD) as well as at discharge, and compared to 29 control patients with biological stented porcine valves (Labcor Laboratorios TLBP-A Supra). The analysis of the perioperative variables extra-corporeal circulation (ECC), aortic cross clamping (XC) and mechanical ventilation times, as well as blood supply, was performed.

Results: Initial platelet counts were comparable in both groups. In the FS group, platelet levels on the four consecutive POD were significantly lower. The lowest platelet value ($13 \times 10^3/\mu\text{L}$), related to fatal thrombotic thrombocytopenic purpura, was found in one patient from the FS group. ECC as well as XC and mechanical ventilation times, were significantly longer in the FS group, and more blood transfusions in these patients were required. In multiple regression analysis, ECC and XC times did not correlate with platelet count.

Conclusions: Implantations of FS stentless bioprostheses are related to significantly lower platelet counts. Severe perioperative complications and their relation to thrombocytopenia need further evaluation.

Key words: aortic valve, bioprosthesis, stentless valve, stented valve, thrombocytopenia

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INTRODUCTION

Stentless bioprosthesis in the aortic position has superior haemodynamic performance compared to stented valves, which allows better outcome regarding survival and left ventricular mass reduction [1–3].

In 2006, we started to implant Freedom Solo prosthesis. After the implantation of 29 prostheses, we became aware of significant reduction of platelet count. After the death of one of the operated patients in the course of thrombocytopenia, we ceased further implantations.

The aim of this study was to compare platelet count and perioperative complications between stentless and stented biological valves in patients requiring aortic valve replacement (AVR).

METHODS

Patient population

Between March 2006 and June 2008 in the Department of Cardiac Surgery, Medical University of Białystok, Poland, 29 patients received a stentless bovine pericardial prosthesis

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(Freedom Solo Valves, Sorin Group, Saluggia, Italy) in the aortic position (FS group, Group 1). Mean age was 73 ± 4.8 , and there were ten (34.5%) men and 19 (65.5%) women. Eight of these patients additionally underwent coronary artery bypass grafting (CABG), two patients mitral valvuloplasty and one patient underwent both of these procedures.

With the purpose of gaining comparative results and excluding the possibility of influence of cardio-pulmonary bypass as well as therapeutic agents on platelet count, an age- and sex-matched control group was created. This group consisted of 29 consecutive patients operated in the same period of time, in whom biological stented porcine valves (Labcor Laboratorios TLBP-A Supra, Labcor group, Group 2) were implanted. There were 15 (51.7%) men and 14 (48.3%) women with a mean age of 72 ± 4.7 years. Eight of these patients underwent CABG, two CABG and mitral valve replacement, and one supracoronary replacement of ascending aorta. The two analysed groups were comparable in terms of clinical and demographic data.

The procedures for the study group (Group 1), as well as the control group (Group 2), were performed by the same operating team with the same equipment for extracorporeal circulation (ECC, Oxygenator Compactflo Evo Sorin Dideco). There were no significant differences regarding demographics and clinical parameters between the groups. Patients' characteristics in both groups are presented in Table 1.

Biochemical assessments

Only selected parameters of haemostasis fibrinogen concentration and international normalised ratio (INR) measurements and platelet count have been analysed. The concentrations of fibrinogen and INR values were assessed using Roche/STAGO STA Compact.

The platelet count was assessed automatically by Siemens equipment (ADVIA 2120i) before operation, on the day of operation, on four consecutive postoperative days (POD), and on the day of discharge (6–8 POD).

The following parameters were compared in both groups: ECC time, aortic cross clamping time (XC-time), ventilation time, Intensive Care Unit stay, drainage loss and blood supply (i.e. the need for transfusion of fresh frozen plasma, red blood cells concentrate as well as platelet concentrate).

The study was approved by the institutional ethics committee on human research in Medical University of Białystok. The procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983.

Operating technique

Operations were performed under general anaesthesia. The chest was opened by median sternotomy. Unfractionated heparin was administered in initial doses of 300 U/kg to maintain activated clotting time above 450 s.

Table 1. Baseline characteristics of the study patients (Freedom Solo, Group 1) and control group (Labcor, Group 2)

| | Group 1 (n = 29) | Group 2 (n = 29) | P |
|-------------------------|---------------------|---------------------|----|
| Age [years] | 73.03 ± 4.8 | 72 ± 4.7 | NS |
| Gender: | | | |
| Female | 19 (65.5%) | 14 (48.3%) | NS |
| Male | 10 (34.5%) | 15 (51.7%) | NS |
| Body mass index | 28.0 ± 5.2 | 26.3 ± 3.0 | NS |
| Euro-score [points] | 5.97 ± 1.94 | 6.24 ± 1.77 | NS |
| Diabetes | 7 (24%) | 10 (34%) | NS |
| Coronary artery disease | 9 (31%) | 10 (34%) | NS |
| Mitral valve disease | 3 (10%) | 2 (7%) | NS |
| Atrial fibrillation | 8 (27%) | 9 (31%) | NS |
| Arterial hypertension | 21 (72%) | 21 (72%) | NS |

The cannulas for ECC were inserted into the distal ascending aorta and the right atrium secured with tourniquets. ECC was conducted in normothermia. The aorta was opened by transverse incision 1.5 cm above the sinotubular junction. Cardiac arrest was obtained by cold blood cardioplegia administered through the coronary ostia and repeated every 20–30 minutes throughout the surgery.

In Group 1, implanting of the stentless valves was carried out with the sewing technique suggested by the Sorin Company, with continuous monofilament Prolene sutures 4/0. In Group 2, porcine stented valves were implanted with interrupted sutures 2/0 on Teflon felts. After performing necessary concomitant procedures (CABG, mitral valve repair), the heart was deaired, and aortic cross clamp released. After reperfusion, cardiopulmonary bypass was discontinued in both groups without complications. In both groups, the initial postoperative course was also uneventful.

Postoperative management

All patients received low molecular weight heparin (LMWH, enoxaparin) in a dose related to the body mass, not earlier than six hours after surgery. In Group 1, LMWH was discontinued after removal of drainage and mobilisation of the patient. In patients with concomitant CABG, 150 mg of acetylsalicylic acid (ASA) was administered additionally. In Group 2, in addition to LMWH during the first 48 hours, vitamin K antagonist was initiated and used to reach and maintain the appropriate levels of INR 2.0–3.0 for three months. If concomitant CABG was done, additional 75 mg of ASA daily was given within 24 hours of the operation. Clopidogrel was not administered to any of the patients.

Statistical analysis

The results were analysed statistically, in which continuous variables were calculated for mean and standard devia-

Table 2. Extracorporeal circulation and aortic cross clamping times in both groups

| | Group 1 | Group 2 | P |
|---------------------------------------|-----------------|-----------------|-------|
| Extracorporeal circulation time [min] | 174.79 ± 48.884 | 134.79 ± 45.317 | 0.002 |
| Aortic cross clamping-time [min] | 123.55 ± 32.083 | 97.55 ± 34.414 | 0.003 |

Table 3. Platelet count* changes in both groups

| Time period | Bovine valves (stentless, FS) | | | | Porcine valves (stented, Labcor) | | | | p |
|----------------|-------------------------------|------|------|------|----------------------------------|------|------|------|---------|
| | Mean | ± SD | Min. | Max. | Mean | ± SD | Min. | Max. | |
| Before surgery | 214.7 | 74.9 | 109 | 487 | 213.8 | 65.6 | 83 | 375 | 0.8 |
| Day 0 | 105.6 | 37.7 | 51 | 221 | 118.5 | 37.8 | 69 | 205 | 0.2 |
| POD 1 | 100.2 | 51.9 | 36 | 278 | 122.6 | 41.5 | 73 | 211 | 0.01 |
| POD 2 | 77.6 | 33.7 | 13 | 168 | 109.1 | 40.0 | 49 | 196 | 0.003 |
| POD 3 | 76.4 | 42.6 | 34 | 198 | 118.9 | 51.5 | 46 | 259 | < 0.001 |
| POD 4 | 79.4 | 41.0 | 29 | 153 | 158.6 | 64.6 | 59 | 307 | < 0.001 |
| Discharge | 150.9 | 75.9 | 53 | 391 | 247.0 | 85.1 | 105 | 488 | < 0.001 |

*All platelets count results are shown $\times 10^3/\mu\text{L}$; POD — postoperative day; SD — standard deviation

tion, and the categorical factors as frequencies and relative frequencies. Variables consistent with a normal distribution were assessed by the Shapiro-Wilk test, comparisons between two groups used t-Student test, and for the characteristics inconsistent with the distribution Mann-Whitney U test was used. To compare between the categorical factors of the selected groups, χ^2 test of independence was used. The level of significance for all statistical tests was 0.05. Multiple regression analysis was performed. All statistical calculations were performed using the statistical package SPSS.

RESULTS

ECC and aortic XC-time were prolonged in both groups, but statistically longer in the study group (Table 2).

Initial platelet count measured before surgery was within normal laboratory limits (i.e. $150\text{--}400 \times 10^3/\mu\text{L}$) for both groups, and did not differ significantly between the groups (Table 3). After the surgery (Day 0), platelet count fell in both groups, with no significant differences between the groups. For the next two days, platelet counts in both groups remained below the lower normal limit, but in the study group the level was significantly lower compared to the control group (Fig. 1). Following the 3rd POD, the platelet count in the control group showed a marked increase, reaching in the 4th day normal values exceeding the initial measurements, but only in the stented valve group. In the study group, the platelet count reached normal values on the day of discharge, but did not reach the initial measurement (Table 3, Fig. 1). In the study group, platelet count showed significantly lower values compared to the control group throughout the whole observation period.

The lowest value of platelet count was found on the 2nd POD in one case from the study group: $13 \times 10^3/\mu\text{L}$. In this

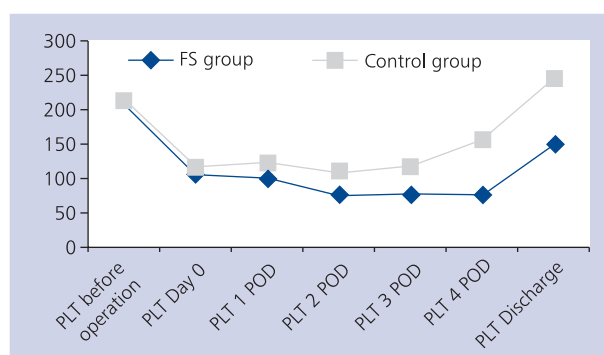


Figure 1. Changes in platelets levels during study period; PLT — platelet count (shown as $\times 10^3/\mu\text{L}$); POD — postoperative day; FS group — Freedom Solo group

patient, a severe thrombocytopenia occurred as a result of thrombotic thrombocytopenic purpura. Therapy, including daily plasmapheresis together with fresh frozen plasma as well as steroids, initially improved the patient's condition. However, on the 18th POD the patient died.

The analysis of duration of mechanical ventilation as well as blood supply revealed significant differences between the groups, with Group 1 performing worse (Table 4). However, there were no significant differences between the groups in terms of the amount of drainage on the 1st POD or the total amount of drainage. There were neither biochemical nor physical symptoms suggestive of thrombo-embolic disorders in either group.

Because in Group 1 the cardiopulmonary bypass time was significantly longer compared to the control group, other coagulation determinants were investigated apart from platelet

Table 4. Characteristics of perioperative period

| Parameter | Groups | Mean | ± SD | P |
|--|--------|---------|--------|-------|
| Mechanical ventilation time [h] | 1 | 36.8 | 80.5 | 0.022 |
| | 2 | 13.8 | 5.05 | |
| Intensive Care Unit hospitalisation time [h] | 1 | 49.5 | 80.4 | 0.6 |
| | 2 | 28.8 | 14.8 | |
| Hospitalisation time [days] | 1 | 14.3 | 6.4 | 0.2 |
| | 2 | 12.5 | 4.2 | |
| First postoperative day drainage [mL] | 1 | 664.9 | 324.0 | 0.4 |
| | 2 | 595.7 | 304.6 | |
| Whole drainage [mL] | 1 | 1,034.4 | 661.7 | 0.6 |
| | 2 | 871.3 | 432.8 | |
| International normalised ratio | 1 | 1.4 | 0.17 | 0.1 |
| | 2 | 1.34 | 0.2 | |
| Fibrinogen [mg/dL] | 1 | 279.3 | 109.43 | 0.7 |
| | 2 | 271.1 | 69.25 | |
| Fresh frozen plasma [U] | 1 | 4.32 | 8.28 | 0.04 |
| | 2 | 1.35 | 2.58 | |
| Red blood cells concentrate [U] | 1 | 3.24 | 2.68 | 0.01 |
| | 2 | 1.56 | 1.58 | |
| Platelet concentrate [U] | 1 | 2.24 | 3.49 | 0.001 |
| | 2 | 0.00 | 0.00 | |

count. The fibrinogen concentrations and the INR values were analysed in both groups and compared, showing no significant differences (Table 4).

In multiple regression analysis, the following parameters significantly correlated with platelet count: fibrinogen concentration, the value of INR, and the usage of dobutamine after operation (Table 5). In the control group, the factors associated with the lowest platelet count were: postoperative haemorrhage and total drainage loss, concentrations of fibrinogen and creatinine, as well as patients' age (Table 5).

DISCUSSION

The present study demonstrates still unexplained differences in postoperative platelet count changes, which is related to the type of aortic valve prosthesis used. Patients with stentless Freedom Solo prostheses had significantly lower platelet count compared to biological stented porcine Labcor valves. ECC time, as well as aortic XC times, were unfavourable in the stentless FS study group. However, multiple regression analysis did not reveal the impact of ECC and XC times on platelet count in either group. Longer mechanical ventilation time and not significantly longer Intensive Care Unit hospitalisation time found in the study group might be influenced by the one fatal case observed in that group of patients. The need for blood transfusions (including platelet concentrate) was higher in the

Table 5. Multiple regression analysis for platelet count

| Variable | Standardised coefficients Beta |
|---|-----------------------------------|
| Freedom Solo group (R = 0.729, R² = 0.531) | |
| Fibrinogen | 0.526 |
| Dobutamine | -0.475 |
| International normalised ratio | -0.322 |
| Control group: stented valves (R = 0.718, R² = 0.515) | |
| Postoperative haemorrhage and total drainage loss | -0.230 |
| Fibrinogen | 0.501 |
| Creatinine | -0.397 |
| Age | -0.306 |

study group, which may be related to thrombocytopenia. In spite of significantly lower platelet count in the FS group, no significant increase of drainage was found.

Current data suggests that Freedom Solo implantations are related to good early- and intermediate-term results [4]. Compared to other stentless valves, the relatively short implantation time, as well as good haemodynamic parameters, allow these valves to be implanted into older patients with other co-morbidities [4]. Recently, Horst et al. [5] performed a study on 143 patients who underwent primary AVR using the FS valve, implanted using the supra-annular subcoronary technique. Long term follow up, lasting five years, disclosed very good clinical performance of the valve [5]. In another large registry of over 220 patients, implantation of FS valves was related to an excellent haemodynamic performance both at rest and during exercise, and was associated with rapid regression of the left ventricle [6].

The frequency of thrombocytopenia due to Freedom Solo implants is increasing as a subject of debate, and occasionally occurs in the literature [7]. Recently, this problem has been discussed by Tarzia et al. [8]. It has been emphasised that thrombocytopenia is transient and not related to adverse clinical events [9, 10]. None of the papers have described a fatal consequence of thrombocytopenia after FS implantation. In our material, the death of one particular patient most probably can only be explained by severe thrombocytopenia. This incident has led us to stop FS valve implantations.

Hilker et al. [11] compared platelet count in patients receiving AVR: stentless Freedom Solo and stented biological Edward Perimount prostheses. During the postoperative period, significantly lower platelet counts have been noticed in the Solo group compared to the Perimount group. In one of the most recent studies, thrombocytopenia occurred after Freedom Solo stentless aortic bioprosthesis implantation with additional decrease between the 1st and 3rd POD, but without any adverse clinical outcome [7]. In our study group with bovine stentless

pericardial Freedom Solo valves, platelets count dropped below $100 \times 10^3/\mu\text{L}$ and during the postoperative period did not attempt to reach initial values compared to stented porcine Labcor valves. The longer ECC and aortic XC-time in the FS group could also affect the degree of thrombocytopenia. However, in multivariate analysis, prolonged ECC time and XC-time were not associated with lowering of platelet count.

The mechanisms of platelet activation leading to severe thrombocytopenia have not been yet determined. In previous reports, the markers of platelet activation have been found in patients after aortic and mitral valve replacements as well as in patients with either bioprosthesis or mechanical valves implantations [12]. Leguyader et al. [12] observed platelet activation after AVR with the use of either bioprosthesis or bileaflet mechanical valves, but not with tilting disc mechanical valves. Using flow cytometry, they proved platelet activation (increased platelet-neutrophil conjugates, platelet-monocyte conjugates and platelet microparticles) as well as increased platelet P-selectin expression [12], but only in bioprostheses or bileaflet mechanical valves. Interestingly, this platelet activation two months after surgery returned to the basic level in bileaflet mechanical valves, but remained increased in the bioprosthesis group. It is speculated that slower recovery of platelet level could be the sign of their higher activation.

On the other hand, platelet activation is correlated with thromboembolic complications [13]. Aortic valve thrombosis has been detected in Solo prosthesis [14] and also in another Sorin stentless aortic valve prosthesis (Pericarbon Freedom) [15]. Although it has not been noticed in our study, this problem is serious and cannot be ignored.

The case in whom thrombotic thrombocytopenic purpura was diagnosed after Freedom Solo valve implantation has brought about a good deal of consideration and deeper investigation. The most important was to establish the degree of importance of thrombocytopenia as to the cause of death, and if any other factors, such as medication or surgical procedures during the valve replacements, had any influence on the outcome. No other cases had severe and life-threatening postoperative complications. Thrombocytopenia was investigated to determine its cause and origin. However, fibrinogen concentrations as well as INR values compared between groups showed no significant differences. Interestingly, the decrease of platelet count during the operations (Day 0) was the same in both groups, which could be due to the influence of ECC *per se*. However, during the following days, there was a significant difference between groups in platelet count. The group with stented porcine Labcor valves had a platelet count that never dropped below $100 \times 10^3/\mu\text{L}$, and almost through the entire postoperative period (five consecutive measurements) showed a steady recovery to normal values.

Besides proven platelet activation found after AVR, heparin-induced-thrombocytopenia (HIT) is considered to be the main cause of postoperative thrombocytopenia [16].

The observed reduction of platelet count $\geq 50\%$ suggests this phenomenon. HIT is observed in 1–5% of patients receiving unfractionated heparin for 1–2 weeks after orthopaedic, cardiac or vascular surgery [17]. Among the symptoms associated with a reduction of platelet count, additional elements, which constitute the criteria of being diagnosed with HIT, should be considered: heparin resistance which is manifested in the need to increase the dose of heparin, and the occurrence of thromboembolic complications in the arterial and venous system causing acute limb ischaemia [18]. These symptoms did not occur in any of our patients from either group. Laboratory diagnosis of HIT is limited. The available enzyme-linked immunoassays deliver positive results in only 50% after CABG operations, but possess a high negative predictive value [16]. Yerebakan et al. [19] found similar to ours thrombocytopenia after implantation of stentless Freedom Solo aortic valve bioprosthesis. HIT was suspected in half of the patients with implanted FS valves, but in none of them HIT antibodies were detected by enzyme immunoassay. Unfortunately, we had no opportunities to perform antibody test for the presence of HIT. However, other parameters (fibrinogen concentration, INR value) did not show the presence of this syndrome. The use of clopidogrel in the Yerebakan et al. study [19] had no effect on the degree of thrombocytopenia, because reduction of platelet levels was noted before its administration. They stated that the aetiologic agent could be related to the direct toxic platelet damage originating from the implanted pericardial stentless valves.

We draw a conclusion from the above observations i.e. the fact that significant reduction in platelet count after FS valves implantation might have essential postoperative consequences. However, no cause of this phenomenon has yet been found.

Our findings are similar to those published by other authors. However, so far there has not been any description of a dramatic fatal haematologic complication after Freedom Solo implantation. The possible reaction of the body to biological tissue valves manufactured by Sorin requires further studies. Moreover, the clinical significance of worse perioperative course observed in our study after FS implantations also needs further examination.

Limitations of the study

The main limitations of this study were the lack of randomisation and the relatively small number of patients enrolled. However, a matching process allowed us to create comparable groups, so we consider the results obtained to be representative. Moreover, it should be pointed out that this is not the first study on this topic. There is data reflecting the drop of platelet count in the postoperative course in patients who received the stentless Freedom Solo, but without any clinical consequences. We have presented one fatal case related to thrombocytopenia. However, this did not add any further information towards a better understanding of this phenomenon.

CONCLUSIONS

Implantations of FS stentless bioprostheses are related to significantly lower, transient platelet counts. Severe perioperative complications, and their relation to thrombocytopenia, need further evaluation.

Conflict of interest: none declared

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Trombocytopenia i powikłania okołoperacyjne po implantacji biologicznej protezy bezstentowej Freedom Solo

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Streszczenie

Wstęp: Biologiczne protezy bezstentowe Freedom Solo (FS) implantowane w miejsce zastawki aortalnej mają lepszą wydajność hemodynamiczną w porównaniu z protezami stentowymi. Jednak dane dotyczące trombocytopenii obserwowanej po implantacji FS są bardzo niepokojące.

Cel: Celem pracy była ocena liczby płytek krwi i powikłań okołoperacyjnych u pacjentów po implantacji bezstentowych protez FS w porównaniu z chorymi, u których wszczepiano protezy stentowe.

Metody: Dwudziestu dziewięciu kolejnym pacjentom implantowano protezy bezstentowe FS (Sorin Group, Saluggia, Włochy). Liczbę płytek krwi oceniano przed operacją, w dniu operacji, w kolejnych 4 dniach przebiegu pooperacyjnego i w dniu wypisu. Wartości te były porównywane z grupą kontrolną, którą stanowiło 29 pacjentów z implantowanymi biologicznymi protezami stentowymi (Labcor Laboratorios TLBP-A Supra). W okresie okołoperacyjnym analizowano następujące parametry: czas krążenia pozaustrojowego (ECC), czas zaklemania aorty (XC), a także czas wentylacji mechanicznej oraz konieczność transfuzji krwi i preparatów krwiopochodnych.

Wyniki: Wyjściowe liczby płytek krwi były porównywalne w obu grupach. W grupie FS w kolejnych 4 dniach obserwacji liczba płytek krwi była istotnie statystycznie niższa niż w grupie kontrolnej. Najniższą wartość trombocytów ($13 \times 10^3/\mu\text{l}$) zaobserwowano w grupie FS u 1 pacjenta ze śmiertelnym przebiegiem zakrzepowej plamicy małopłytkowej. Czasy ECC, XC i wentylacji mechanicznej były istotnie dłuższe w grupie FS. W analizie regresji wielokrotnej czasy ECC i XC nie korelowały z liczbą płytek krwi. Ponadto pacjenci z grupy badanej wymagali większej liczby transfuzji.

Wnioski: Implantacja bezstentowych protez FS wiąże się z istotnym spadkiem liczby płytek krwi. Potencjalny związek trombocytopenii i gorszego przebiegu okołoperacyjnego wymaga przeprowadzenia dalszych badań.

Słowa kluczowe: zastawka aortalna, proteza biologiczna, proteza bezstentowa, trombocytopenia

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