Aortic valve replacement with different types of prosthesis. Are there differences in the outcomes during hospital phase?

Troca valvar aórtica com diferentes próteses. Existem diferenças nos resultados da fase hospitalar?

Gibran Roder FEGURI¹, Hugo MACRUZ², Domingos BULHÕES³, Antônio NEVES³, Rodrigo Moreira CASTRO³, Luciana da FONSECA¹, José Francisco BAUNGRATZ¹, José Pedro da SILVA⁴

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Abstract

Objective: To analyze intraoperative data and possible differences in clinical evolution during postoperative hospital phase for aortic valve replacement surgery using different types of prosthesis.

Methods: Analysis of 60 patients divided into three groups. Valve replacement with bioprosthesis (20), mechanical prosthesis (20) and homologous valve (20). The mean age was 51.1, 60% were male and 40% female patients; 86.7% were in NYHA II or III; 63.3% presented arterial hypertension and 18.3% had diabetes. Aetiology of valve disease was degenerative for 39%, rheumatic for 36% and endocardits for 15%.

Results: The hospital mortality was 5%; there were no differences in the incidence of septical or cardiogenic shock, acute renal failure, rhythms disorders during surgery or intensive care, neither for total time in intensive care and mechanical ventilation. However, there was statistical differences as regards the cardiopulmonary bypass total time (P=0.02) and the aortic clamping time (P<0.0001) unfavorable to homograft valve group. The ward admission time was greater for mechanical valve group (P=0.05) as well as for total admission time, but without statistical significance. It was observed that patients with preoperative hematocrit smaller than 38.1% used 2.73 units of blood components,

and with postoperative hematocrit smaller than 32% used 1,79 units of blood components. Echocardiography control showed minimal evolutional differences.

Conclusion: The use of different types of prosthesis for this study does not cause differences in the results of postoperative hospital phase. The use of homograft valve is a feasible option with good clinical applicability.

Descriptors: Heart valve diseases. Aortic valve/surgery. Transplantation, homologous. Cardiac surgical procedures.

Resumo

Objetivos: Analisar dados intra-operatórios e possíveis diferenças na evolução clínica da fase hospitalar de pósoperatório da troca valvar aórtica com diferentes próteses.

Métodos: Análise de 60 pacientes, divididos em três grupos: os submetidos a troca valvar por prótese biológica (20); por prótese mecânica (20); e finalmente, por valva homóloga (20). A média da idade foi de 51,1 anos; 60% eram do sexo masculino e 40% do feminino; 86,7% estavam em NYHA II ou III; 63,3% eram hipertensos, 18,3% diabéticos; a etiologia valvar foi degenerativa em 39%, reumática em 36% e endocardite em 15%.

Resultados: A mortalidade hospitalar foi de 5%; não houve diferenças entre os grupos na incidência de choque séptico

This study was carried out at the São Joaquim Hospital da Real e

Benemérita Associação Portuguesa de Beneficência of São Paulo — Team of the PhD José Pedro da Silva. (JP da Silva Clinics). Rua Maestro Cardim, 769, Paraíso. São Paulo - SP

Correspondence address: Gibran Roder Feguri. Rua Mal. Floriano Peixoto, 1520/503, Duque de Caxias II. Cuiabá - MT. CEP: 78043-395. Phone. Cel. (65) 81186488 - Phone (65) 36217000. Fax (65) 33211969. E-mail: gibranrf@sbccv.org.br

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Specialist Member of the BSCVS (Cardiovascular Surgery Assistant Physician).

MD in Surgery by UNICAMP. Specialist Member of the BSCVS (Cardiovascular Surgery Assistant Physician).

Resident in Cardiovascular Surgery (Cardiovascular Surgery Assistant Physician).

PhD in Cardiovascular Surgery by INCOR/SP. Titular Member of BSCVS (Cardiovascular Surgery Physician – Team's chief).

ou cardiogênico, insuficiência renal aguda, arritmias no centro cirúrgico e na unidade de terapia intensiva (UTI), assim como para o tempo de internação na UTI e tempo de ventilação mecânica. Houve diferença estatística nos tempos de circulação extracorpórea (P=0,02) e pinçamento aórtico (P<0,0001) desfavorável aos pacientes com valva homóloga. O tempo de internação na enfermaria foi maior para os pacientes com valva mecânica (P=0,05), assim como o tempo total de internação hospitalar tende a ser maior neste grupo, porém sem significância estatística. Pacientes com hematócrito pré-operatório abaixo de 38,1% utilizaram 2,73

unidades de hemoderivados; e com hematócrito no pósoperatório abaixo de 32% utilizaram 1,79 unidades. Controle ecocardiográfico mostrou mínimas diferenças evolutivas.

Conclusão: A utilização de diferentes próteses, nesta amostra, não gerou diferenças nos resultados da fase hospitalar de pós-operatório; O homoenxerto é uma opção viável e com boa aplicabilidade clínica.

Descritores: Doenças das valvas cardíacas. Valva aórtica/ cirurgia. Transplante homólogo. Procedimentos cirúrgicos cardíacos.

INTRODUCTION

In Brazil, the biological prosthesis has been the most used replacement valve. We see this preference for countless reasons, such as patient's socioeconomic condition, and cases when there is no need for life-long anticoagulation. These prostheses have evolved in our country, beginning with the biological tissues of dura mater, as published by Puig et al. [1,2], and shifting to bovine pericardium and porcine valves made into rings [3,4]. Undoubtedly, since the first replacement valves were produced by Hufnagel in the 1950s, there has been great technological change provided by several researchers and many marketable prostheses [3,4].

Bioprostheses in general present low thrombogenicity, good hemodynamics, and no noise in the postoperative and, due to their central flow, low turbulence. However, the limitation for their use is directly related to their durability and calcification issues, as well as a need for reoperation with increased surgical risk [4,5]. But they are often recommended, especially in the elderly and those unable to undergo an anticoagulation regime.

Various types of mechanical prostheses are widely used when they meet the criteria, albeit ever-changing criteria. They are an option for valve replacement in young adults and children who have the disadvantage of rapid structural degeneration with bioprostheses coupled with somatic growth. Double-leaflet mechanical prostheses are widely used, have good hemodynamics, a low profile, good durability, and reduced incidents of thrombosis and thromboembolic phenomena, especially if the anticoagulation protocol is used under strict control [5]. Usually, limitations result from the use of anticoagulants, and a small volume of bleeding can occur, as well as severe cases of stroke, thrombosis on the prosthesis, hemolysis, fracture, and occluder wear and tear.

The homologous or homograft valve, which seems to be less vulnerable to infection, has good hemodynamic and recovery to the normal flow in the aortic root and coronary sinus. It is also presents acceptable gradients in the postoperative period [6]. Due to the lack of donors and the difficulty of sterilization and storage, some limitations to the use of such prostheses may occur, leading researchers to test tissue from animals such as pigs, sheep and calves [3]. There are also reports of early changes in the valve because of poor commissural alignment and distortion, causing early aortic insufficiency caused by the surgical technique [6]. Nationally, there are still few centers with experience or routine use of homografts.

Despite different characteristics, such as flow, area, gradients and durability, the type of prosthesis must be chosen carefully, and is generally influenced by the team's experience. This choice is always made after an assessment of the patient's clinical status, socioeconomic and psychological aspects, age, disease history and the possibility for frequent medical follow-up in the postoperative period.

The aim of this study was to establish whether there are variables in the hospital phase that could influence the choice of prosthesis (apart from those that are clearly established and discussed in the literature regarding decision-making in advanced stages of diseases [7-10]). We also analyzed some hemodynamic variables during surgery and echocardiographic variables during the preand postoperative period.

METHODS

In the Dr. José Pedro da Silva Cardio-Surgical Clinic of São Joaquim da Real and the Benemérita Associação Portuguesa de Beneficência of São Paulo, a cross-sectional study was performed, with an analysis of the records of 60 patients who underwent aortic valve replacement.

We selected 20 patients from a total of 35 who received homologous valve operations from our team between the years 1995 and 2003, because the medical records of these patients contained all of the variables that the researchers intended to study. From the 200 consecutive patients receiving a valve replacement using bovine pericardial biological prostheses, which were included in the team's database, 20 patients were randomly selected. For this, we used the function Random () within the Microsoft Excel 2003 software. Similarly, another 20 patients who had received a valve replacement using a double-leaflet mechanical prosthesis were randomly selected. Thus, we obtained the same number of patients per group.

The homologous valve was removed from the donor's heart (the hearts would not be used for transplant because of standards set and met by the regulatory center for the donation of organs and tissues, obeying the current legislation). These valves were stored in a solution containing an antibiotic with spectrum against Gramnegative and Gram-positive, and cooled in an appropriate place for the maximum time determined by the team 48 hours after the removal.

24 patients were female (40%) and 36 (60%) were male, with ages ranging from 12 to 90 years old with mean of 51.1 years for all groups involved (biological, 59.2 years old; mechanic, 43.8 years old; and homologous, 50.3 years old). The distribution of weight ranged from 42 to 98 kg, with a mean of 68.8 kg. The patients' heights ranged from 1.45 to 1.86 meters with a mean of 1.67 meters.

Among the patients analyzed, 63.3% presented with hypertension, and 18.3% had diabetes. 32.7% presented with some type of dyslipidemia, and 41.7% were smokers. The etiology of valve disease was the predominantly degenerative in 39% of the cases. It was rheumatic in 36%, and 15% were determined to be infective endocarditis. The etiology was not found in 10% of the records. The primary valve lesion was pure aortic stenosis with some cases of such lesion in patients with biological and mechanical valve and pure aortic insufficiency and primary in the homologous group. Among the patients studied, 90% presented sinus rhythm. The mean of hematocrit count in the preoperative was 40.1%.

At the time of surgery, functional class according criteria of the New York Heart Association (NYHA) was II in 55% of cases and III in 31.7% of cases, and the ejection fraction in the preoperative (using the cube method) ranged from 37% to 84%, with a mean of 67.2% for all patients.

Neither re-operated patients nor those who underwent associated surgical procedures were excluded from the study. A total of 12 patients (20%) had previously undergone valve replacement. The most frequent procedures associated were CABG, aortic annulus enlargement and mitral repair. There were seven patients in the biological group and seven patients in the homologous group underwent associated procedures, as well as four patients in the mechanical group.

All patients underwent cardiopulmonary bypass (CPB) using a membrane oxygenator, moderate hypothermia (32 to 28°C) and myocardial protection with hypothermic antegrade/retrograde blood cardioplegia, according to type of valve lesions and the surgical team's preference.

For statistical evidence, analysis of variance (ANOVA) was used to test effects and compare mean values of various parameters in the three groups when there was a parametric distribution; non-parametric ANOVA was used for groups of data with non-Gaussian distribution; the Student t-test was also used for comparisons of means between groups; the simple linear regression model was used to identify relationships between variables and chisquare test for testing of equality between proportions when it is considered more than two groups simultaneously. Statistical significance was set at $P \le 0.05$.

RESULTS

The mortality of the sample in the period studied was 5% (three patients). There was one patient who had undergone valve replacement using homologous valve due to late endocarditis of biological prosthesis and underwent reoperation. This patient died due to cardiogenic and septic shock in the intensive care unit (ICU). The other two patients underwent valve replacement using biological prosthesis, and also underwent reoperation due to endocarditis of late biological prosthesis. They died of septic shock.

The group with the lowest mean age was the mechanical valve group. However, the mean age of this group was only statistically significant when compared to the group with biological prosthesis replacements (*P*=0.03), and didn't interfere with the overall analysis of the sample.

Regarding the occurrence of shock in the ICU, it is noted that there was no difference in the occurrence of cardiogenic shock (P=0.76) and septic shock (P=0.34) when measured in terms of type of prosthesis used. Cardiogenic shock occurred in two patients from the biological prosthesis group, one patient from the mechanical prosthesis group, and one from the homologous prosthesis group. Septic shock affected two patients undergoing replacement valve using biological prosthesis and two patients undergoing replacement using homologous valve.

The cardiac rhythm in the preoperative in 54 patients (90%) was sinus. There were four (6.7%) with atrial fibrillation (AF), one (1.6%) with a permanent pacemaker and another (1.6%) in atrial rhythm. The postoperative cardiac rhythm changed after surgery, with 45 (75.5%) patients in sinus rhythm, four (6.7%) in AF, one (1.7%) with a pacemaker, one (1.7%) in the infra-Hissian scape rhythm, seven (11.7%) in atrial rhythm and two (3.3%) in junctional escape. These changes had equivalent distribution for the three groups.

Researchers also studied the occurrence of supraventricular and ventricular arrhythmias in the surgical center based on type of prostheses. They defined as significant those arrhythmias that cause hemodynamic instability, a need for the use of antiarrhythmic agents and cardioversion and/or defibrillation procedures after removal of CPB cannulas. There was equality in the proportion of patients who suffered arrhythmias for the three types of prostheses (P=0.13). Similarly, there was equality between the three groups in the proportion of patients who suffered arrhythmias in the ICU (P=0.21) with some kind of intervention (chemical or electrical).

We analyzed the use of catecholamines and vasoactive drugs by the type of prosthesis in the operating room and ICU. According to the data, there was a predominance of dobutamine and sodium nitroprusside used in the three groups, with no statistical differences in the use of such drugs by groups in the sample studied.

The total time of surgery was equal for both genders (P=0.48) and for the three types of prosthesis implanted (P=0.07).

Figure 1 presents the descriptive measures of time of CPB (minutes) by group. There was a statistically significant difference between the types of prostheses used, with more CPB time for patients who had undergone homologous valve implants (P=0.02); there were no significant differences between genders (P=0.32). The time of aortic clamping (minutes) by gender was not different (P=0.71), but there are again clear and important statistical differences between the types of prostheses used (P<0.0001), caused largely by the longer length of CPBs in the homologous group, as shown in Figure 2.

During analysis, it was found that mediastinal stroke assessed by echocardiography in the postoperative period (ranging from moderate to severe) occurred at the same rate among the three groups (P=0.64). The rates were also the same for pleural effusion (P=0.88). There were four patients with mediastinal effusion in the biological and mechanical prosthesis groups and three patients in the homologous valve group (not everyone needed intervention).

Was also analyzed the percentage of patients who returned to the operating room in each group; there was, again, equality among the three types of prostheses (P=0.36). The cause of the return to operating room was hemostasis review for one patient from the mechanical prosthesis group, two patients from the biological prosthesis group, and one from the homologous prosthesis group. Two patients from the biological prosthesis group and one patient from the homologous group also returned to the operating room so that surgeons could drain the mediastinum after severe effusion.

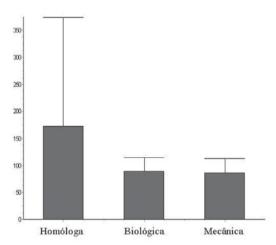


Fig. 1 - Mean time of cardiopulmonary bypass (CPB) in minutes with standard deviation for different types of prostheses. Through analysis, we note that there is a difference with statistical significance that disfavors the homologous valve group. We used the non-parametric ANOVA test

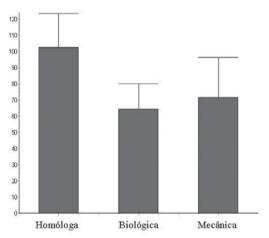


Fig. 2 - Mean time of aortic clamping in minutes with standard deviation for different types of prostheses. Through analysis, we note that there is difference with statistical significance that disfavors the homologous valve group. We used the non-parametric ANOVA test

The use of blood derivatives (concentrated red blood cells, platelets, crioprecipitate and fresh human plasma) was tested, and was affected by hematocrit counts in pre-and postoperative period. It was noted that the relationship between a preoperative hematocrit count below 38.1% and the use of a blood derivative is significant (P = 0.03), and these patients used at least 2.73 units of blood derivatives compared to patients on which hematocrit counts above 38.1% (95% CI: 1.70; 3.76). The same fact occurs for

hematocrit counts below 32.0% in the postoperative period (p=0.01) - these patients used at least 1.79 units of blood derivatives (95% CI: 1.14; 2.44). There were no differences in the sample among the three groups in the general use of blood derivatives in the operating room and ICU, nor in the absolute values of bleeding by the mediastinal drain postoperatively. The red blood cell concentration was the most commonly used blood derivative in all groups.

Assessing other factors related to the ICU, there is equality in the time of mechanical ventilation with respect to gender (P=0.56) and type of prosthesis (P=0.32), showing that there were no significant statistical differences between the three studied groups. In relation to the total time in ICU (Table 1), there were no significant differences with respect to gender (P=0.73) or the type of prosthesis (P=0.27).

Regarding the incidence of acute renal failure in the ICU, it was found that there were no differences in incidents of acute renal failure (P=0.77), or the need for dialysis (P=0.86) between the groups. From the homologous valve group, three patients presented acute renal failure, and one underwent dialysis and died; from the biological prosthesis group, three patients presented acute renal failure and two went on dialysis. Finally, from the mechanical prosthesis group, two patients presented acute renal failure and one needed dialysis.

The time of hospital stay in the recovery ward did not favor the patients who underwent mechanical valve replacement (P=0.05). Analyzing Table 2, we find that the patients in this group presented a higher average hospital stay than the other groups. This data also increased the total time of hospital stay for the mechanical valve group in relation to the two other studied groups (P=0.57), but without statistical significance.

The effect of a patient who returned to the ICU on the total time of hospital stay was also assessed. Note that there is a difference in the total time of hospital admission with regard to the need for readmission to the ICU (P<0.0001); thus, the total time of hospital stay of those who returned to the ICU is, on average, 8.7 days longer than the time of stay for those who did not return. However,

the occurrence of returning to ICU by type of implanted prosthesis was not different, and was not significant among the three groups (P=0.77). The most common reason for returning to the ICU was acute AF, followed by failure or respiratory distress.

We also assessed some pre- and postoperative echocardiographic variables. Regarding ventricular diameters, it is noted that there were evolutive differences expected in this phase of admission, though they were not statistically different between the types of prostheses used (P=0.73). The mean preoperative left ventricle end-diastolic diameter was 54.8 mm for the biological replacement group, 64.6 mm for the mechanical prosthesis group, and 64.4 mm in the homologous prosthesis group. There was improvement in the postoperative period, with the mean falling to 49.2 mm for the biological prosthesis group, 55.2 mm for the mechanical prosthesis group, and 58 mm in the homologous prosthesis group. The left ventricle enddiastolic volume (LVEDV) and left ventricular end systolic volume (LVESV) were tested, and we found no statistical differences by group in the postoperative when compared to values in the preoperative (P=0.35 P=0.59), but with a tendency toward an evolutive improvement, especially in cases of aortic valve insufficiency.

We also assessed the descriptive measures in ejection fraction (EF) according the pre- and postoperative cube method measurements by types of prostheses, with no differences between groups (P=0.66). However, in relation to the postoperative EF, there was a significant difference between different types of prostheses. There was an increase in postoperative EF - it was higher for patients in biological prosthesis group and lower for patients in the mechanical prosthesis group (P=0.01). Possible reasons will be discussed later. Table 3 presents the descriptive EF measures for the pre-and postoperative periods using the cube method. The measurement of the aorta diameter in the pre- and postoperative periods was also analyzed by group, and we noted the absence of evolutive differences according to the type of prosthesis (P=0.59), as well as for left atrial dimension and the aorta/left atrial relationship (P=0.53 and P=0.58).

Table 1. Descriptive measurements of hospital stay in the ICU (in days) by gender and type of prosthesis.

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Female					Male		Sample			
Type of valve	Minimum	Mean	Maximum	Minimum	Mean	Maximum	Minimum	Mean	Maximum	
Homologous	2.0	3.0	5.0	1.0	2.5	6.0	1.0	2.6	6.0	
Biological	1.0	2.2	6.0	1.0	2.6	7.0	1.0	2.5	7.0	
Mechanical	1.0	1.9	5.0	1.0	2.0	4.0	1.0	1.9	5.0	
General	1.0	2.2	6.0	1.0	2.4	7.0	1.0	2.3	7.0	

Table 2. Descriptive measurements of postoperative hospital stay in ward (in days) by gender and type of prosthesis.

		Female			Male			Sample	
Type of valve	Minimum	Mean	Maximum	Minimum	Mean	Maximum	Minimum	Mean	Maximum
Homologous	4.0	6.0	12.0	3.0	7.0	18.0	3.0	6.7	18.0
Biological	4.0	7.4	20.0	4.0	5.5	10.0	4.0	6.2	20.0
Mechanical	5.0	8.9	16.0	6.0	9.4	15.0	5.0	9.1	16.0
General	4.0	7.8	20.0	3.0	7.1	18.0	3.0	7.4	20.0

Table 3. Descriptive measurements of the pre- and postoperative ejection fraction by Cube method, by type of prosthesis.

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Type of	Pro	eopera	tive	Postoperative			
valve	Minimum	Mean	Maximum	Minimum	Mean	Maximum	
Homologou	ıs 0.56	0.68	0.75	0.58	0.67	0.79	
Biological	0.37	0.64	0.84	0.43	0.69	0.79	
Mechanical	0.59	0.69	0.82	0.39	0.66	0.80	
General	0.37	0.67	0.84	0.39	0.67	0.80	

DISCUSSION

Earlier this decade, in a multicenter study involving the use of the Carpantier-Edwards bovine pericardial prostheses (Perimount), Marchand et al. [11] showed 37.1% of actuarial survival, with 68.8% free of structural dysfunction in 14 years in the atrioventricular position. Regarding this frequent late complication that occurs primarily in young, MyKen et al. [12] published a good sample with porcine bioprosthesis and satisfactory evolution over 15 years, and a survival rate of 41% in the aortic position, especially in the adult population. Studies also performed by Braile et al. [4] at Incor, Clinic Hospital of the Faculty of Medicine of the University of São Paulo (HC-FMUSP) with bovine pericardial bioprostheses (even in patients over 70 years) [2,14] showed results similar to the international literature; with excellent results after 12 years of follow-up.

According to Lund et al. [15] and Jamieson et al. [16], under late postoperative period analysis, double-leaflet mechanical prostheses also have low mortality rates related to the valve, low thrombogenicity, hemolysis rate and absence of mechanical failure over 18 years of follow-up, especially when associated with rigorous anticoagulation protocol.

Regarding the aortic homograft, there is the study of O'Brien et al. [17], with a sample of 1,022 patients over 29 years of follow-up and survivals free of reoperation in 50% of the patients over 20 years. Similar results were seen in the study by Sadowski et al. [18], who reported on 655

patients over 23 years and 49.5% of survivals free of reoperation over 20 years.

The results presented in this study relate to the patients' postoperative time in the hospital - the time of hospital admission until the patient's discharge - and, as previously mentioned, we did not find any other similar comparisons of the three types of prostheses for that specific period in the literature.

The results presented herein in relation to overall mortality of the groups showed no statistically significant differences due to the extent of the sample. We emphasize the high morbidity and mortality, with survival that may be less than 50% in aortic valve replacements in the presence of infected endocarditis associated with acute aortic insufficiency, acute renal failure and congestive heart failure [19]. This combination can be seen in severe cases of aortic ring abscesses, which are generally difficult to treat, which led researchers [20] to search for new techniques to enhance and improve surgical outcomes.

There were cardiac rhythm changes in all groups during the postoperative period. These changes were related to surgical manipulation of the heart and sutures that are in close relationship with the path of the conduction system, in addition to the aortic ring's impairment. However, these findings are described in the postoperative of aortic valve replacements, especially in the presence of endocarditis [21], and, in most cases spontaneous reversion to the preoperative rate can occur. This usually occurs after improvement of the local inflammatory process and reduction of edema.

The times of aortic clamping and CPB were higher for the homologous valve group, and these findings were expected because the surgical technique of the implant procedure of this valve is more delicate and laborious than the bioprosthesis or the mechanical valve, with possible occurrence of early aortic insufficiency during postoperative, as shown by Staab et al. [6]. This fact was not noted in echocardiographic control of the studied group. The total time of surgery did not negatively affect the results and statistical significance to the homologous valve, because the other groups were related to greater number of associated procedures.

The time of stay in the recovery ward was higher for the mechanical replacement group, with statistical significance. This finding is important because, through analysis of medical records, it was noted that such time was needed for the proper adjustment of anticoagulation before hospital discharge. All patients in the sample received oral anticoagulants and did not suffer bleeding or stroke.

In relation to postoperative echocardiographic findings and their correlation with the values in preoperative, we found no major evolutive differences, and the improvement of EF and ventricular diameters occurred at similar rates for the three groups, although two patients from the mechanical prosthesis group (who had associated CABG), presented a decrease in EF due to ventricular dysfunction in the postoperative period.

Overall, when we analyzed the other studied and tested variables, we found that they differ little within the three groups of our study, showing equality in both the operating room and the ICU, particularly in terms of mechanical ventilation time in ICU, use of catecholamines or vasoactive drugs, incidence of arrhythmias and acute renal failure; involvement in cardiogenic or septic shock, use of blood derivatives, and postoperative bleeding.

Nevertheless, we note that it is possible to perform valve replacement in our country by using the homograft, which is an excellent option in the therapeutic arsenal of valve replacements. Our options are improving, especially with the possibility of using crioprecipitate valves, with better storage, and sterilization, and quality control, and also with the establishment of human heart valve banks, as demonstrated by Costa et al. [22].

Recently, in a review article, Saadi [23] discussed the development and application of new experimental techniques for the treatment of aortic stenosis in selected groups of patients (techniques such as percutaneous aortic valve implants and transapical implants through beating heart minithoracotomy). This new information is relevant, because in the future, we may discuss the differences within the evolutive phases of the postoperative period of the replacement valves cited in this study (among others), but implanted through new techniques.

LIMITATIONS

A sampling of 60 patients, 20 per group, was a limiting factor for this study.

CONCLUSION

The results of the clinical patient's evolution in the hospital phase of postoperative was not affected by different types of prostheses used in the study despite some variables which have statistical significance, such as increased surgical time (CPB and clamping) in those patients who used homologous valve. The time of hospital stay in patients who had undergone mechanical valve replacement tends to be longer to achieve appropriate anticoagulation control.

The use of the aortic homograft is a viable option, with good clinical applicability in various cases, especially in infections of the aortic valve or prosthesis.

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