

Risk factors for hospital mortality in valve replacement with porcine bioprosthesis at an university institution

Fatores de risco hospitalar para pacientes submetidos à substituição valvar com a bioprótese porcina em instituição universitária

Ana Carolina Tieppo Fornari¹, Luís Henrique Tieppo Fornari¹, Juan Victor Piccoli Soto Paiva¹, Pauline Elias Josende¹, João Ricardo Michelin Sant'Anna², Paulo Roberto Prates³, Renato A. K. Kalil³, Ivo A. Nesralla⁴

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Abstract

Objective: Study designed to identify characteristics of patients related to increased hospital mortality after valve replacement, assumed as risk factors.

Methods: Retrospective study including 808 patients submitted to the implant of St. Jude Biocor porcine bioprosthesis between 1994 and 2009 at Instituto de Cardiologia do Rio Grande do Sul. Primary outcome was hospital death and hospital mortality was related to demographic and surgical characteristics. Statistics include t-test, qui-square test and logistical regression analysis.

Results: There were 80 (9.9%) hospital deaths. Risk factors identified with univariable logistical analysis (and

respective odds-ratio) were: tricuspid surgery (OR 6.11); mitral valve replacement (OR 3.98); left ventricular ejection fraction < 30% (OR 3.82); diabetes mellitus (OR 2.55); atrial fibrillation (OR 2.32); pulmonary arterial hypertension (OR 2.30); serum creatinine $\geq 1,4$ mg/dL (OR 2.28); previous cardiac surgery (OR 2.17); systemic arterial hypertension (OR 1.93); functional class III e IV (OR 1.92); coronary bypass (OR 1.81); age ≥ 70 years-old (OR 1.80); congestive heart failure (OR 1.73); e female gender (OR 1.68). Multivariable logistic regression for independent factors identified preponderant risk factors mitral valve replacement (OR 5.29); tricuspid surgery (OR 3.07); diabetes mellitus (OR 2.72); age ≥ 70 years-old (OR 2.62); coronary

1 - Medical Student with Scholarship at the Support Research Fund of the Institute of Cardiology of Rio Grande do Sul / University Cardiology Foundation (IC / FUC), Porto Alegre, RS, Brazil.

2 - PhD at IC / FUC, Advisor, Porto Alegre, RS, Brazil.

3 - Cardiovascular Surgeon at Cardiovascular Surgery Team of IC / FUC, Porto Alegre, RS, Brazil.

4 - Leader of the Cardiovascular Surgery Team at IC / FUC and CEO of University Cardiology Foundation, Porto Alegre, RS, Brazil.

Work performed at the Institute of Cardiology of Rio Grande do Sul / University Cardiology Foundation. Porto Alegre, Rio Grande do Sul, Brazil.

Correspondence address:

João Ricardo Michelin Sant'Anna

Av. Princesa Isabel Avenue, 395 - Porto Alegre, RS, Brazil – Zipcode: 90620-000

E-mail: santana.pesquisa@cardiologia.org.br

Abbreviations, acronyms and symbols

CABG	Coronary artery by-pass grafting
DM	Diabetes mellitus
AF	Atrial fibrillation
LVEF	Left ventricular ejection fraction
SAH	Systemic arterial hypertension
CI	Confidence interval
CHF	Congestive heart failure
NYHA	New York Heart Association
OR	Odds ratio

bypass (OR 2.43); previous cardiac surgery (OR 1.82); e systemic arterial hypertension (OR 1.79).

Conclusions: Mortality rate is within values found in literature. Identification of risk factors could contribute to changes in surgical indication and medical management in order to reduce hospital mortality.

Descriptors: Risk factors. Prosthesis implantation. Heart valve prosthesis implantation. Prostheses and implants. Cardiac surgical procedures.

Resumo

Objetivo: Identificar fatores de risco hospitalar em pacientes submetidos ao implante de bioprótese porcina no Instituto de Cardiologia do Rio Grande do Sul.

Métodos: Estudo retrospectivo, com informações de prontuário, de 808 pacientes submetidos ao implante de pelo menos uma bioprótese porcina St. Jude Medical

Biocor, no período entre 1994 e 2009. Foi analisada a relação entre mortalidade hospitalar e características clínicas e demográficas definidas em estudos reconhecidos, visando identificar fatores de risco. Foram utilizados testes qui-quadrado, t de Student e regressão logística uni e multivariável ($P \leq 0,05$).

Resultados: Ocorreram 80 (9,9%) óbitos hospitalares. Fatores de risco identificados na regressão logística univariável foram: plastia tricúspide (odds ratio 6,11); lesão mitral (OR 3,98); fração de ejeção de ventrículo esquerdo < 30% (OR 3,82); diabete melito (OR 2,55); fibrilação atrial (OR 2,32); hipertensão pulmonar (OR 2,30); creatinina $\geq 1,4$ mg/dL (OR 2,28); cirurgia cardíaca prévia (OR 2,17); hipertensão arterial sistêmica (OR 1,93); classe funcional III e IV (OR 1,92); revascularização miocárdica (OR 1,81); idade ≥ 70 anos (OR 1,80); insuficiência cardíaca congestiva (OR 1,73); e sexo feminino (OR 1,68). Pela regressão logística multivariável, para fatores independentes, identificados: lesão mitral (OR 5,29); plastia tricúspide (OR 3,07); diabete melito (OR 2,72); idade ≥ 70 anos (OR 2,62); revascularização miocárdica (OR 2,43); cirurgia cardíaca prévia (OR 1,82); e hipertensão arterial sistêmica (OR 1,79).

Conclusões: A mortalidade observada nesta casuística é compatível com literatura. Fatores de risco preponderantes são reconhecidos e devem motivar programas específicos de neutralização.

Descritores: Fatores de risco. Implante de prótese. Implante de prótese de valva cardíaca. Próteses e implantes. Procedimentos cirúrgicos cardíacos.

INTRODUCTION

The valve replacement surgery is the accepted treatment in structural heart valve disease, representing approximately 20% of all cardiac surgeries performed and accounts for 30% of the total surgery mortality rate [1]. The mortality rate recorded in the literature for this type of surgery ranges from 1% to 15%, regardless of the type of the implanted prosthesis [2-9]. This variation is justified by differences in demographic and clinical characteristics of patients considered for surgery, the surgical techniques, the

position of the valve implantation, the associated surgical procedures [9,10] and in the postoperative care. Retrospective studies with large numbers of patients were performed to identify characteristics that may affect the surgery outcome and create models of individual risk stratification for different institutions [2-5,11]. The importance of these studies lies in the prospect of identifying patients at increased surgical risk by assessing their demographic, clinical and operative characteristics, neutralizing or minimizing the risk factors in order to reduce surgical mortality and morbidity, as well as the cost of care [12].

About 500 valve surgeries are performed annually at the Institute of Cardiology of Rio Grande do Sul. The porcine bioprostheses are used in approximately 40% of patients who underwent implantation of biological valve replacements, however, the results of these procedures have not been evaluated, unlike what happened with the surgical valve replacement with a bovine pericardial prostheses [13,14] and mechanical prostheses[15], whose analysis has allowed to stratify the implant surgical risk and decrease the operative mortality.

This study objective is to characterize the population of patients undergoing implantation of a porcine biological valve prosthesis model at the Institute of Cardiology of Rio Grande do Sul, and also evaluate deaths and identify risk factors for hospital mortality.

METHODS

Study Design

A retrospective cohort study

Population

We included all patients undergoing implantation of at least one St. Jude Medical Biocor porcine bioprosthesis, from January 1994 to December 2009 at the Institute of Cardiology of Rio Grande do Sul - University Cardiology Foundation, totaling 808 patients. Among them, 351 (43.4%) were female and 457 (56.6%) were male. Their ages ranged between 16 and 90 years, with a mean of 66.5 years and a standard deviation of ± 11.3 years. The functional class according to the standards of the New York Heart Association (NYHA) was I in 75 (10.3%) patients, II in 247 (34%), III in 279 (38.4%) and IV in 125 (17.2%). The left ventricular ejection fraction (LVEF) was over 50% in 620 (81.4%) patients, between 30 and 50% in 124 (16.3%) and less than 30% in 18 (2.4%). Congestive heart failure (CHF) was present in 137 (17%) patients, atrial fibrillation (AF) in 179 (22.2%), systemic arterial hypertension (SAH) in 442 (54.8%), pulmonary hypertension in 212 (26.5%), and diabetes mellitus (DM) in 116 (14.4%). The value of serum creatinine was <1.4 mg / dL in 702 (87.4%) patients and ≥ 1.4 mg / dL in 101 (12.6%).

Valve surgery

Surgical procedures and postoperative care were performed as previously described routines. All patients underwent surgery with cardiopulmonary bypass, membrane oxygenation, variable levels of hemodilution and hypothermia and myocardial preservation by

hypothermic crystalloid cardioplegia with St. Thomas II solution. After surgery, the patients were taken to the recovery room, where they received intensive care for at least 24 hours; the patients were discharged on the fifth postoperative day [16]. After discharge, patients were referred to the clinical assistant or were followed-up at the institution outpatient clinic.

The number of operated patients was 808605 (74.9%) underwent first heart surgery, 178 (22%) had previously undergone heart surgery and 25 (3.1%) two or more heart surgeries earlier. We performed 193 (23.9%) isolated bioprosthetic mitral implants, 552 (68.3%) isolated bioprosthetic aortic implants and 63 (7.8%) implants associated with mitral and aortic bioprostheses. The valve replacement surgeries were combined with coronary artery bypass grafting (CABG) in 156 (19.3%) patients and with tricuspid valvuloplasty in 21 (2.6%). During hospitalization for surgical interventions, 52 (6.4%) patients were reoperated.

Outcomes and definition of risk factors

Deaths during hospitalization for surgical valve replacement with porcine bioprosthesis were considered as primary outcomes.

Deaths were classified according to the preponderant factors in: a surgical cause (such as bleeding), due to cardiac causes (such as acute myocardial infarction and heart failure) or non-cardiac causes (such as infection and nervous, renal and pulmonary complications).

The demographic, clinical and operative characteristics analyzed were: gender, age, functional class (according to the model proposed by NYHA), LVEF, CHF, atrial fibrillation, SAH, pulmonary arterial hypertension (systolic blood pressure greater than 100 mmHg), DM, serum creatinine, previous cardiac surgery, valvular lesion (mitral, aortic or mitral-aortic), associated CABG, associated tricuspid valve replacement and reoperation during hospitalization. The characteristics associated with the increased hospital mortality were considered as predictors of risk.

Ethical Considerations

This research project was submitted to the Research Institute of Cardiology of Rio Grande do Sul, which was approved by the Institute Research Ethics Committee, being registered under No. 3734/05. Norms related to patient privacy and confidentiality in the handling of medical information was respected. The data used in this study were obtained from records of the Department of Cardiovascular Surgery and hospital records.

Collecting and analyzing data

This research was based on four phases: selection of patients, chart review with data logging, tabulation of data and statistical analysis. The latter included the distribution of demographic, clinical and operative characteristics in the study population, determining the percentage of deaths, the mortality ratio with the selected features and the identification of risk factors for hospital mortality.

We used univariate and multivariate statistical analysis using SPSS for Windows, version 14.0 to determine predictors of prevailing and independent hospital mortality risk. In order to obtain this information, Chi-square test, Student's t test and logistic regression were used. In multivariate analysis, the variables were used in the form that had greater discriminatory power. All significant characteristics ($P \leq 0.05$) in univariate analysis were considered for multivariate analysis.

We considered risk characteristics those with significant association with hospital mortality, for an alpha level of 0.05. The odds ratio (OR) with a 95% confidence interval was obtained by logistic regression analysis to estimate the relative risk of each analyzed characteristic.

RESULTS

Characterization of the valve disease

Among the 808 patients included in this study, 65 (8%) patients had rheumatic valvular disease and 14 (1.7%) with congenital valve alteration, in which the bicuspid aortic valves were the most common one, 31 (3.8%) patients had valve lesion determined by infective endocarditis and 14 (1.7%) ischemic disease, 684 (84.6%) patients did not have the etiology of valve lesions identified in their medical record.

The most common signs and symptoms reported by patients at the time of hospital admission were, in decreasing order of frequency: dyspnea (57.9%), angina / chest pain (31.3%), syncope (10.3%), fatigue (8.7%), dizziness (6.8%), palpitations (3%), lower limb edema (1.4%) and fever (1.3%). About 4% of all patients undergoing valve replacement surgery were asymptomatic.

Hospital mortality

There were 80 (9.9%) deaths. As for the causes of death, 10% were due to surgery, 46% of cardiac causes and 44% of non-cardiac causes.

Risk Factors

Table 1 shows the demographic, clinical, surgical

characteristics analyzed, also their distribution in the study population and the association with hospital mortality. These variables were significantly associated ($P < 0.05$) with increased hospital mortality, except for reoperation during hospital admission ($P = 0.064$, ns). Characteristics associated with greater absolute mortality were associated procedure of tricuspid valve repair (38.1%), LVEF less than 30% (27.8%) and the presence of mitral valve disease (21.2%), as can be noted in Table 1.

In order to increase the discriminatory power of the statistical analysis, the variables with multiple categories (age, functional class, LVEF, heart valve lesion and previous cardiac surgery) were transformed into dichotomous variables, and its distribution and association with hospital mortality are shown in Table 2.

Estimating the relative risk

By logistic regression analysis OR values were obtained in order to estimate the relative risk of the characteristics considered. Table 3 shows the OR values and their respective 95% confidence intervals (95% CI). Risk factors for hospital mortality with higher OR ($OR > 3$) were age groups above 60 years (variable OR, but greater than 3), associated tricuspid valve repair (OR 6.111, 95% CI 2.451 to 15.235), mitral valve lesion (OR 3.984, 95% CI 2.481 to 6.396) and LVEF less than 30% (OR 3.824, 95% CI 1.323 to 11.048), although other characteristics have demonstrated $OR > 1$, a value considered significant.

Independent risk factors

The characteristics that were significantly associated with increased hospital mortality in univariate analysis were considered for multivariate analysis, and also sought to show independent risk factors. The variables were used in the dichotomous form, which showed greater discriminatory power in the statistical analysis.

Multiple logistic regression was used by the method Backward Stepwise with 0.05 P value input and a 0.10 Q output, leaving the last step of the method the following characteristics expressed in decreasing OR: mitral valve disease (OR 5.291, 95% CI 2.898 to 9.615), associated tricuspid valve repair (OR 3.074, 95% CI 1.013 to 9.327), diabetes (OR 2.722, 95% CI 1.437 to 5.157), age greater than or equal to 70 years (OR 2.620, CI 95% from 1.478 to 4.646), associated CABG (OR 2.435, 95% CI 1.290 to 4.596), previous cardiac surgery (OR 1.816, 95% CI 1.005 to 3.281) and hypertension (OR 1.791, 95% CI 0.991 to 3.237) (Figure 1).

Table 1. Hospital mortality according to demographic, clinical and operative characteristics

Characteristics	Frequence	%	Deaths	%	P
Gender					
Female	351	43.4	44	12.5	0.028
Male	457	56.6	36	7.9	
Age group					
< 50 years	57	7.1	1	1.8	0.012
50 - 59 years	133	16.5	7	5.3	
60 - 69 years	280	34.7	28	10	
70 - 79 years	268	33.2	32	11.9	
≥ 80 years	70	8.7	12	17.1	
Functional Class (NYHA)					
I	75	10.3	5	6.7	0.032
II	247	34	17	6.9	
III	279	38.4	30	10.8	
IV	125	17.2	20	16	
LVEF					
> 50%	620	81.4	52	8.4	0.009
30 - 50%	124	16.3	16	12.9	
< 30%	18	2.4	5	27.8	
Congestive heart failure					
Absent	668	83	60	9	0.045
Present	137	17	20	14.6	
Atrial Fibrillation					
Absent	626	77.8	50	8	0.001
Present	179	22.2	30	16.8	
Systemic arterial hypertension					
Absent	364	45.2	25	6.9	0.008
Present	442	54.8	55	12.4	
Pulmonary arterial hypertension					
Absent	587	73.5	45	7.7	< 0.001
Present	212	26.5	34	16	
Diabetes mellitus					
Absent	691	85.6	58	8.4	< 0.001
Present	116	14.4	22	19	
Serum Creatinine					
< 1,4 mg/dL	702	87.4	61	8.7	0.004
≥ 1,4 mg/dL	101	12.6	18	17.8	
Valvular Lesion					
Mitral	193	23.9	41	21.2	< 0.001
Aortic	552	68.3	35	6.3	
Mitro-aortic	63	7.8	4	6.3	
Previous heart surgery					
No	605	74.9	48	7.9	0.005
1 surgery	178	22	28	15.7	
2 surgeries or more	25	3.1	4	16	
Myocardial Revascularization Associated					
No	652	80.7	57	8.7	0.024
Yes	156	19.3	23	14.7	
Tricuspid valve repair associated					
No	787	97.4	72	9.1	< 0.001
Yes	21	2.6	8	38.1	
Reoperation in hospital stay					
No	756	93.6	71	9.4	0.064 n.s.
Yes	52	6.4	9	17.3	

NYHA: New York Heart Association, LVEF: left ventricular ejection fraction

Table 2. Hospital mortality as modified variables.

Characteristics	Frequency	%	Deaths	%	P
Age					
< 70 years	470	58.2	36	7.7	0.012
≥ 70 years	338	41.8	44	13	
Functional Class(NYHA)					
I / II	322	44.4	22	6.8	0.013
III / IV	404	55.6	50	12.4	
LVEF					
≥ 30%	744	97.6	68	9.1	0.008
< 30%	18	2.4	5	27.8	
Valvular lesion					
Mitral	193	23.9	41	21.2	< 0.001
Aortic / Mitro-aortic	615	76.1	39	6.3	
Previous heart surgery					
No	605	74.9	48	7.9	0.001
Yes	203	25.1	32	15.8	

NYHA: New York Heart Association, LVEF: left ventricular ejection fraction

Table 3. Odds ratios and 95% confidence intervals (95% + OR) for risk factors.

Characteristics	Odds ratio	95% CI
Female	1.676	1.053 - 2.667
50 - 59 years	3.111	0.374 - 25.888
60 - 69 years	6.222	0.829 - 46.697
70 - 79 years	7.593	1.016 - 56.759
≥ 80 years	11.586	1.458 - 92.074
Functional Class II	1.035	0.369 - 2.905
Functional Class III	1.687	0.631 - 4.509
Functional Class IV	2.667	0.956 - 7.437
LVEF 30 – 50%	1.618	0.891 - 2.94
LVEF < 30%	4.201	1.441 - 12.245
Congestive heart failure	1.732	1.006 - 2.982
Atrial Fibrillation	2.319	1.425 - 3.775
Systemic arterial hypertension	1.927	1.175 - 3.161
Pulmonary hypertension	2.301	1.429 - 3.705
Diabetes mellitus	2.554	1.494 - 4.368
Serum Creatinine ≥ 1,4 mg/dL	2.279	1.285 - 4.043
Mitral valve lesion	3.984	2.451 - 6.478
Mitro-aortic valve lesion	1.001	0.344 - 2.917
1 previous heart surgery	2.166	1.314 - 3.57
Previous surgeries > 2	2.21	0.729 - 6.701
Myocardial Revascularization	1.805	1.074 - 3.034
Associated tricuspid valve repair	6.111	2.451 - 15.235
Reoperation in hospital stay	2.019	0.945 - 4.313

LVEF: left ventricular ejection fraction

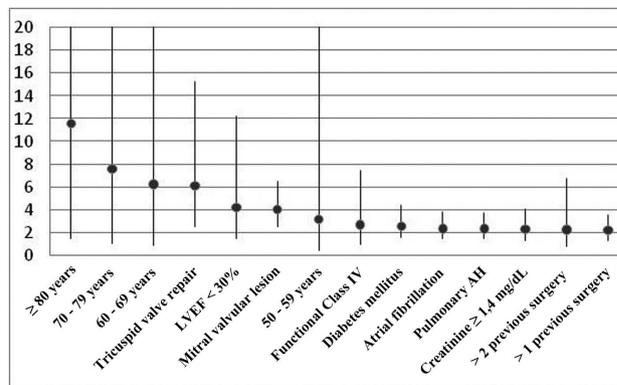


Fig. 1- Risk factors for hospital mortality, with expression value in the odds ratios and 95% confidence limit

DISCUSSION

The identification of risk factors for patients undergoing valve replacement surgery has been studied for over 20 years [17]. The quantification of the factors identified and its neutralization by clinical and operative measures have decreased the risk of surgery [18]. Patients with severe valvular disease and minor systemic repercussions

are being considered for surgery, due to their tendency to intervene earlier in the disease state, reflecting lower prevalence / intensity of recognized risk factors and, thus, resulting in lower hospital mortality [19]. But if some of the demographic or operative characteristics, which in the past increased surgical mortality and morbidity, can now have its influence minimized, and surgical indication progressively increased of older patients (and with more comorbidities) in different surgical series, can also induce changes in the profile of patients considered for valve surgery [20]. Thus, it is justified the periodic study of risk factors and keep this subject up-to-date.

The study of risk factors begins with the selection of demographic and surgical characteristics that characterize the population evaluated and the procedures performed. Overall, we can state that the surgical experience confirms the influence of characteristics such as advanced age, low body mass index, renal insufficiency, low LVEF, indication for emergency surgery, heart surgery and others in the increased in-hospital mortality of patients with valvular heart diseases, and these must receive greater attention from physicians involved in their clinical and surgical management [21-23].

In this research, we used recognized characteristics from the literature [3,4,9,17,18], focusing on those presented by Ambler et al. [2]. This attitude is justified by the ready availability of medical information considered as part of the hospital record, and also because they had been previously used by the authors [13-15]. We opted to include pulmonary arterial hypertension as an additional factor, but other recognized factors were excluded, such as chronic obstructive pulmonary disease and peripheral vascular disease [3], which were not always correctly referred or quantified in hospital records.

The risk factors identified were female gender, age greater than or equal to 70 years, NYHA functional class III and IV, LVEF less than 30%, congestive heart failure, atrial fibrillation, hypertension, pulmonary hypertension, diabetes, serum creatinine greater than or equal to 1.4 mg / dL, mitral valve disease, previous cardiac surgery and CABG or associated tricuspid valve. It is interesting to note that these factors participate with their own score in the risk stratification model for heart valve surgery proposed by Ambler et al. [2]. These authors highlight the performance of previous cardiac surgery (regardless of type), emergency surgery; age over 79 years and renal failure with dialysis as strong predictors of increased mortality.

For Nowicki et al. [24] in a study on independent risk

factors for surgical aortic valve replacement, previous heart surgery represent a risk factor associated with age over 70 years, small body surface, elevated creatinine, NYHA class IV, previous cardiac arrest, CHF, AF, emergency and associated MR. For the mitral valve surgery, the statistically significant characteristics were: female patients, advanced age, DM, CABG, previous cerebrovascular accident, elevated creatinine, NYHA class IV, emergency situations and CHF.

Roques et al. [25], in the EuroSCORE study, which configures program with score predictor of hospital mortality, found that previous heart surgery and concomitant CABG were associated with increased surgical risk. Other variables significantly associated with high mortality were: advanced age, creatinine, low LVEF, heart failure, pulmonary hypertension, emergency situations, multiple valve replacement or tricuspid procedure.

Edwards et al. [26] identified as independent risk factors for isolated valve replacement surgery, emergency situations, renal failure and cardiac arrest, and also the need for reoperation. This was also identified by Jamieson et al. [3] as well as emergency surgery, renal failure (whether or not on dialysis), low LVEF, and NYHA functional class IV (NYHA). The need for reoperation during hospitalization was not identified in this study as a risk factor.

The use of odds ratio or OR as a resource for statistical analysis made it possible to estimate the surgical risk determined by each of the evaluated characteristics [27]. The predictors of increased risk in this study, in descending order, as the clinical characteristics were LVEF below 30%, DM, AF and pulmonary hypertension and as surgical characteristics were concomitant tricuspid valve surgery, mitral valve lesion and previous heart surgery.

Interestingly, age greater than or equal to 70 years, while contributing to increased mortality, it is quantified in reduced values in the OR, when compared to other factors. Although elderly patients with valvular heart diseases may show more severe cardiac or systemic involvement (and comorbidities may contribute individually as risk factors), it is difficult to deny surgical treatment, so that specific perioperative care should be developed. This factor has been providing reduction in mortality, as stated in surgical experiments with groups of patients over the age of 70 [28] or 80 [29]. It is possible that the diffusion of percutaneous valve interventions may modify the surgical indication for older patients and may help to reduce surgical mortality.

However, consideration of age as a risk factor to be noted is illustrated when comparing current results with those of a study conducted by the authors regarding the

definition of hospital risk for mechanical valve prosthesis implantation [15], in which hospital mortality observed was 3.9%, in favor of the present series, 9.9%. It is possible that several demographic characteristics determine the difference in mortality, taking into account the mean age of patients referred for mechanical prostheses implantation and bioprostheses implantation, higher in the latter group (46.8 years and 66.5 years, respectively). Studies comparing results with implantation of a bioprosthesis or mechanical prosthesis in populations with overlapping patients as clinical characteristics, similar to that performed by Feguri et al. [30] can determine whether the observed differences in relation to mortality and risk factors are due to the type of valve replacement or to several characteristics of populations with indications for different cardiac valves.

CONCLUSIONS

Hospital mortality observed in this study (9.9%) is consistent with the literature results. Risk factors for hospital mortality identified (associated tricuspid valve repair, mitral valve disease, LVEF less than 30% DM, AF, pulmonary hypertension, serum creatinine greater than or equal to 1.4 mg / dL, previous heart surgery, SAH functional class III and IV, associated CABG, aged greater than or equal to 70 years, CHF and female sex) had already been reported by other authors.

The possible neutralization of risk factors through changes in criteria for surgical indications, better clinical preoperative compensation and postoperative routine changes, may contribute to the reduction of surgical morbidity and mortality, as well as the costs of care.

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