

Mortality after partial left ventriculectomy in relation to contraindications for heart transplantation

Mortalidade da ventriculectomia parcial esquerda relacionada às contra-indicações para transplante cardíaco

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Abstract

Objective: To analyze the impact of the contraindications for heart transplantation in mortality and survival time after partial left ventriculectomy. **Method:** A prospective clinical study of a cohort of 43 patients submitted to partial left ventriculectomy, in whom there were contraindications for heart transplantation was performed. The following contraindications were analyzed: psychological, sociocultural, age of 65 years of age and older, elevated pulmonary arteriolar resistance and pulmonary arterial hypertension and the refusal or not for transplantation. These variables were tested for association with postoperative mortality and survival time after partial left ventriculectomy. Statistical analysis included the Chi-square test, Kaplan-Meier survival analysis, non-parametric log-rank test, Cox regression model, 95% confidence intervals and p values (significant if less than 0.05).

Results: higher postoperative mortality rates for partial left ventriculectomy were found when the following contraindications of heart transplantation were present preoperatively: poor sociocultural conditions ($p = 0.037$), psychological disturbances ($p = 0.037$) and in patients who accepted heart transplantation even when counseled against this procedure ($p = 0.017$). Survival time was significantly

shortened in the presence of psychological disturbances ($p = 0.0466$), in patients older than 65 years ($p = 0.0397$) and in those who did not accept heart transplantation ($p = 0.0306$). Elevated pulmonary arteriolar resistance and pulmonary arterial hypertension were not associated with higher mortality rates or shortened survival time.

Conclusion: Some of the contraindications for heart transplantation adversely affected the mortality and survival time after partial left ventriculectomy, thus revealing the ineffectiveness of this alternative procedure in this subset of patients.

Descriptors: Cardiomyopathy, congestive. Heart failure, congestive. Heart ventricle, surgery. Cardiac surgical procedures, mortality.

Resumo

Objetivo: Analisar o impacto das contra-indicações para transplante cardíaco na mortalidade e no tempo de sobrevivência dos pacientes submetidos a ventriculectomia parcial esquerda. **Método:** Ensaio clínico não controlado, prospectivo, de uma coorte de 43 pacientes com contra-indicação para transplante,

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submetidos a ventriculectomia. Foram analisadas as seguintes contra-indicações: psicológicas, socioculturais, idade superior a 65 anos, hiperresistência arteriolar pulmonar e hipertensão arterial pulmonar e recusa do paciente ao transplante. A análise estatística incluiu testes do Qui-quadrado, o método atuarial de Kaplan-Meier, o teste do "log-rank", a regressão de Cox, os intervalos de confiança de 95% e a probabilidade p, considerada significativa quando inferior a 0,05.

Resultados: As contra-indicações para transplante que resultaram em maior mortalidade após a ventriculectomia foram as socioculturais (p = 0,037), psicológicas (p = 0,037) e a aceitação do transplante (p = 0,017). Tiveram impacto negativo no tempo de sobrevida pós-operatório as contra-indicações psicológicas (p = 0,0466), a idade superior a 65

anos (p = 0,0397) e a aceitação do transplante (p = 0,0306). A presença de hiperresistência arteriolar pulmonar e/ou de hipertensão arterial pulmonar não interferiu na mortalidade e no tempo de sobrevida após a ventriculectomia.

Conclusão: Algumas contra-indicações para transplante tiveram impacto prognóstico desfavorável na mortalidade e no tempo de sobrevida após a ventriculectomia parcial esquerda, a qual não se revelou tratamento alternativo efetivo para este grupo de pacientes.

Descritores: Miocardiopatia congestiva. Insuficiência cardíaca congestiva. Ventrículo cardíaco, cirurgia. Procedimentos cirúrgicos cardíacos, mortalidade.

INTRODUCTION

Partial left ventriculectomy (PLV) is an alternative surgical technique for a group of heart disease patients defined as with dilated cardiomyopathies (DCM) [1]. The intention is to benefit patients who suffer from advanced heart failure (HF), in which the diagnosis is reserved and there is a contraindication or impossibility of immediate heart transplantation [2]. In some published series, this constitutes the main selection criteria for PLV [3,4]. Obviously, contraindications for any intervention aim at selecting a sample in which the effectiveness or efficiency of treatment can be tested and achieved, or at least, in which the proposed procedure is not prejudicial. There are no published reports analyzing the impact of the contraindications for transplantation as criteria in the selection of candidates for PLV in respect to the results of this procedure. Do such contraindications and risk factors, which knowingly disfavor the prognosis of transplanted patients, play the same prognostic role in patients who undergo ventriculectomy? This work aims at answering this question, by the analysis of an association or correlation which may exist between the contraindications and transplantation, mortality and the survival of patients submitted to PLV. We were concerned with testing the effectiveness of this alternative surgery, in the presence of the reported contraindications of transplantation, as this is one of its main indications.

METHOD

Design – A prospective, non-controlled clinical trial with a cohort of 43 patients submitted to PLV in the Hospital São Francisco da Irmandade Santa Casa de Misericórdia of Porto

Alegre, Brazil between December 1994 and December 1999 was performed. The main characteristics of this cohort are listed in Table 1.

Table 1. Pre-operative characteristics of the 43 patients submitted to partial left ventriculectomy.

Variables	Number (%)	Mean or Median	Variation
Demographic			
Age		55.1±10.4	32-77
Male gender	31 (72.1)		
Clinical			
NYHA functional class		4	3-4
NYHA III	4 (7.7)		
NYHA IV	39 (90.7)		
Right heart failure	22 (51.2)		
Echocardiographs			
Left ventricle Ejection Fraction (%)		21.3 ± 6.3	9-35
Final left ventricle diastolic diameter (mm)		78.6 ± 9.1	70-118
Final left ventricle systolic diameter (mm)		70 ± 9.7	57-108
Left ventricle shortening Fraction (%)		10.8 ± 3.6	3-18
Ergonomics			
Maximum consumption O ₂ (ml/Kg/min)		11.6 ± 5.9	1.8-24.7
Heart catheterism			
Left ventricle Ejection Fraction (%)		20.5 ± 6.3	9-33
Pulmonary vascular resistance (U. Wood)		3.9 ± 2.2	0.6-8.5
Heart index (l/min/m ² of body surface)		2.1 ± 0.7	1-5.4

U: unit; min: minutes; m: meters:

Inclusion criteria – All the patients fulfilled the following criteria: 1) diagnosis of dilated cardiomyopathy; 2) contraindication for heart transplantation; 3) Permanently function class IV of the NYHA or frequently alternating between classes III and IV, despite optimized clinical treatment; 4) left ventricle ejection fraction (LVEF) equal to

or less than 30%; 5) left ventricle final diastolic diameter (LVFDD) greater than 70 mm. The patients were operated on after simple informed consent according to the terms on the formulary designed in the Cardiovascular Surgery Department of the institution in 1994.

Exclusion criteria – Patients with valvular lesion heart disease, ischemic heart disease, acute myocarditis, cardiomyopathies caused by congenital heart disease, coexistent chronic degenerative systemic diseases, ages greater than 75 years old, neurological disease and chronic renal or pulmonary disease and also children and adolescents.

Initial assessment tests for the PLV protocol – All the patients were considered as potential transplantation candidates and submitted to evaluations established in the institutional transplantation program, which included: 1) transthoracic or transoesophageal echocardiogram (Hewlett-Packard, model 21369A, Sonos 5500, with harmonic image, USA); 2) Stress test on a treadmill with calculation of the maximum oxygen consumption utilizing the Naughton protocol, when the clinical conditions permitted; 3) right and left heart catheterism with coronary cineangiography (Siemens, Coroskope model, Germany); 4) Clinical examination with evaluation of NYHA functional class; 5) evaluation of the patient and close relations using a questionnaire designed in the institution based on the “Minnesota Multiphase Personality Inventory Test” (MMPIT) [5].

Analyzed variables – The contraindications for transplantation (Table 2) were analyzed and correlated with the survival time and with the mortality after PLV. In patients who died and those who were transplanted, the data collected at the last routine evaluation of the protocol, before the event, were considered for analysis and comparison.

Table 2. Contraindications for heart transplantation.

Criteria	N	%
Socio-cultural	26	60.5
Psychological	19	44.2
RVP > 5 U Wood*	13	30.2
Use of alcoholic beverages	8	18.6
Age (> 65 years)	7	16.3
Patient refusal	5	11.6

* U = unit; RVP = Pulmonary arteriolar vascular Resistance

Intra-operative aspects – With the aim of reducing the diameter and improving the LV mass-volume, the basic surgical technique utilized was that described by Batista et al. [1], with some modifications introduced by the cardiovascular department of our institution [2,6]. Thirty-five patients were operated on using aortic clamping and eight without clamping. The mean time of CPB was 101.3 ± 43.5 minutes (range 20 to 204), and the mean aortic clamping time was 56.5 ± 23.2 minutes (range 17 to 131). Procedures associated with PLV were performed in 36 (83.7%) of the cases with an average of 1.44 per patient with a total of 62 procedures as has already been published [7].

Statistical analysis – The program “Software Package for Social Sciences” - SPSS, version 10.0 (SPSS Inc., Chicago, IL, USA) was used for analysis. The nominal categorical variables were expressed in percentages and measurements, discreet and continuous, by the mean and standard deviation. The median was cited when important asymmetry was observed in the distribution of the variables. Associations among the categorical variables and the correlations among continuous variables were expressed by the Pearson chi-square test or by the Fisher exact test. Hazard ratios included confidence intervals of 95%. All the tests were 2-tailed. The Kaplan-Meier actuarial method was used to estimate the probability of survival, as death was the event of interest. The non-parametric log-rank or the Cox-Mantel tests were employed to compare the survival curves. For the survival group, the last clinical and laboratorial evaluations of the protocol, the transplantation date or the 31st December 2000, were considered as the time limits in the comparison of the curves. Associations among the individual explanatory variables and the survival curves were assessed by the Cox regression model. The probability, p, of the statistical tests was considered statistically significant if it was less than 0.05.

RESULTS

The duration of the study was six years from December 1994 to December 2000 and included 43 patients operated over five years, with a mean follow-up period of 11.8 ± 15.8 months (range 0.30 to 68.7 months; median = 6.2 months). Table 3 demonstrates the frequency of the contraindications for transplantation and the deaths which occurred in the immediate and long-term post-operative periods.

Mortality and survival time when socio-cultural factors were contraindications for heart transplantation.

The difference in the total mortality rate among those who presented with this contraindication for transplantation (22 patients – 84.6%) and those who did not (9 patients – 52.9%) was statistically significant for the general mortality (p-value = 0.037, Fisher exact test).

Table 3. Contraindications for transplantation and the immediate and late mortality rates after ventriculectomy.

	Patients N (%)	Immediate deaths		Late deaths	
		Nº	%	Nº	%
Socio-cultural contraindication *					
No	17 (39.5)	2	11.8	7	41.1
Yes	26 (60.5)	9	34.6	13	50
Psychological contraindication					
No	23 (53.4)	3	13	10	43.4
Yes	19 (44.1)	7	36.8	10	52.6
Refusal of transplantation					
No	38 (88.3)	10	26.3	20	52.6
Yes	5 (11.6)	1	20	0	0
contraindication due to age (> 65 years) **					
No	36 (83.7)	10	27.8	15	41.6
Yes	7 (16.2)	1	14.2	5	71.4

* P = 0.037; P = 0.037; P = 0.017; ** P = NS

The actuarial survival rate for the patients with and without social-cultural contraindications for transplantation were 42.3% and 58% respectively over 6 post-operative months, 21.1% versus 45.7% over one year and 12.6% versus 45.7% in three years. The mean survival time was 3.2 months (CI 95% = 0 to 7.4) for the patients with this contraindication and of eight months for patients who did not present with this contraindication. The accumulated survival probability for those with contraindications was 9.7 ± 2.5 months (CI = 17.6 to 49.1). This difference was not significant (log rank = 0.0858). Cox regression also did not give a significant difference for the general medium and long-term mortalities (p-value = 0.0956; hazard ratio = 1.9; CI 95% = 0.8 to 4.2).

Mortality and survival when psychological conditions contraindicated heart transplantation.

The difference in the total number of deaths among patients who presented with contraindications (17 patients – 89.5%) due to psychological conditions and those who did not (13 patients – 56.5%) was statistically significant to

the general mortality rate (p-value = 0.037, Fisher exact test). Figure 1 illustrates the actuarial survival rates for the patients with and without contraindications at six post-operative months (42.1% versus 56.5%), at one year (15.7% versus 46.0%) and at three years (10.5% versus 38.3%). For the patients with contraindications, the mean survival time was 3.2 months (CI 95% = 0 to 8). For those who did not present with contraindications, the mean survival time was 10.3 months (CI 95% = 0 to 35.2). The accumulated survival probability for the patients with contraindications was 8.3 ± 2.6 months (CI 95% = 3.2 to 13.4), whilst for those without contraindications this probability was 30.3 ± 6.9 months (CI 95% = 16.8 to 43.9). This difference was statistically significant (log-rank = 0.0466) (Figure 1). Cox regression did not reveal significant differences for the general short-term and long-term mortality (p-value = 0.0535; Hazard ratio = CI 95% = 0.9 to 4.2). An analysis of two groups of patients did not present a significant difference between those who reported abusive use of alcoholic beverages compared to those who did not.

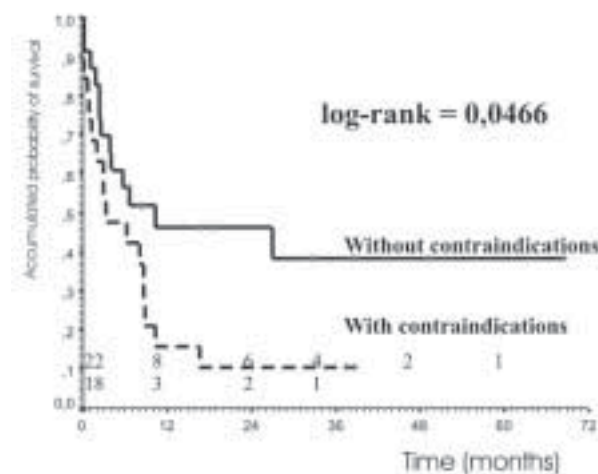


Fig. 1 - Kaplan-Meier survival curves for patients with and without contraindications for transplantation for psychological reasons after ventriculectomy.

Mortality and survival time when the patient refused transplant.

Five (11.6%) of the patients refused transplantation for personal reasons, even though they were considered candidates and only one (20%) died after PLV. Thirty-eight (88.3%) of the patients, although they were aware of having established contraindications, opted for transplantation if there was a possibility. Of these, 30 (78.9%) died. The difference for general mortality was significant (p-value 0.017, Fisher exact test), this was also verified with relation to the long-term mortality (71.4% versus 0; p-value = 0.014; Fisher exact test).

Figure 2 illustrates the actuarial survival rates for the patients who refused transplantation or opted for transplantation at six post-operative months (80.0% versus 47.3% respectively), at one year (80.0% versus 46.0%) at two years (80.0% versus 19.5%) and at three years (80.0% versus 16.3%). The survival probability for those who refused transplantation was 39.6 ± 8.6 months (CI 95% = 22.7 to 56.6) and for those who opted for transplantation was 15.6 ± 4.1 months (CI 95% = 7.5 to 23.8). This difference was statistically significant (log-rank = 0.0306) (Figure 2).

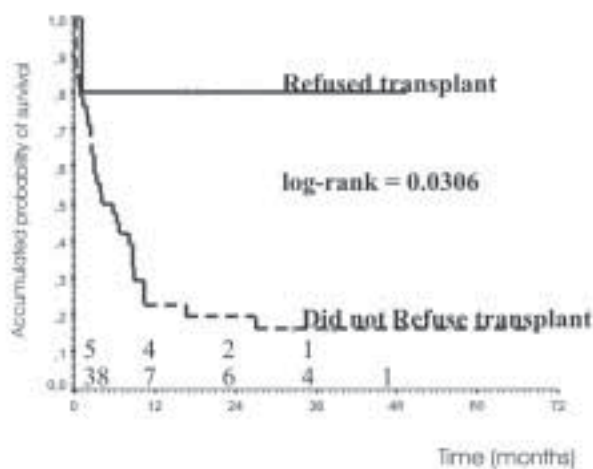


Fig. 2 - Kaplan-Meier survival curves for patients who refused or not transplantation after ventriculectomy.

Analysis of the long-term mortality, excluding immediate death, revealed that all the patients who refused transplantation survived during the study period, whilst those who opted for the surgery survived for 21.1 ± 5.2 months (CI 95% = 10.0 to 31.4; log-rank = 0.0306) (Figure 3). Cox regression did not demonstrate statistical significance for short and long-term general mortality (p-value = 0.0631; hazard ratio = 0.1; CI 95% = 0 to 1.10).

Mortality and survival time when an age of greater than 65 years contraindicated transplantation.

In the total study time, six patients out of seven (85.7%) who presented with contraindications of transplantation due to ages greater than 65 years passed away versus 25 of 36 patients (69.4%) without this contraindication. This difference was not statistically significant for the short and long-term general mortality.

The post-operative actuarial survival rates for patients with and without contraindication for transplantation were 42.8% versus 52.7% at six months and 0% versus 34.6% at one year. For the patients with this contraindication, the mean survival time was 3.8 months (CI 95% = 1.3 to 6.4). For those who did not have contraindications, their mean

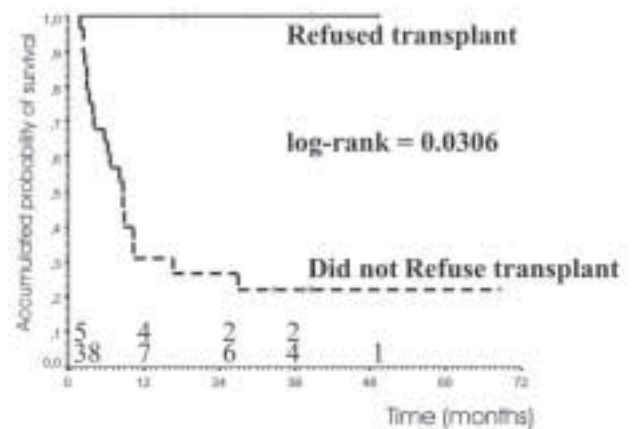


Fig. 3 - Kaplan-Meier late survival curves for patients who refused or not transplantation after ventriculectomy.

survival time was 6.2 months (CI 95% = 0 to 12.6). The accumulated survival probability was 4.7 ± 1.1 months (CI 95% = 13.0 to 32.6) for under 65-year-old individuals. The difference was not considered to be statistically significant (log-rank = 0.2952). In relation to the late mortality excluding the early mortality, the difference between the survival curves was statistically significant (log-rank = 0.0397). The accumulated survival probability for the group with ages less than 65 years old was 31.4 ± 6.1 months (CI 95% = 19.4 to 43.4) (Figure 4). Additional analysis by the Cox regression model did not present with statistical significance for immediate and late general mortality (p-value = 0.0501; hazard ratio = 2.9; CI 95% = 0.9 to 8.6 for general mortality).

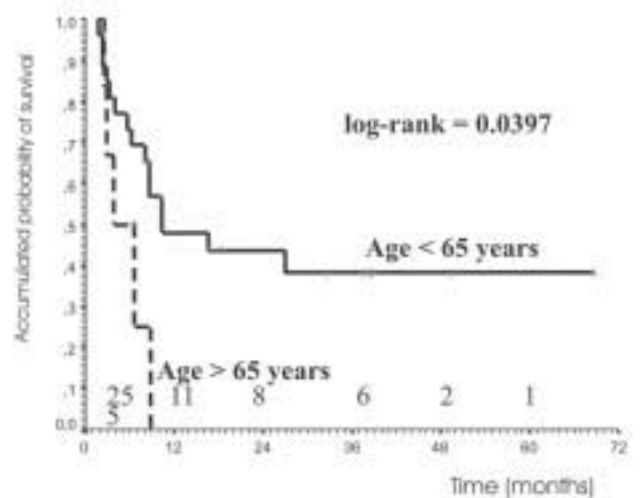


Fig. 4 - Kaplan-Meier survival curves excluding immediate death for patients with and without contraindications for transplantation due to age after ventriculectomy.

Mortality and survival time when high pulmonary arteriolar vascular resistance (PVR) was a contraindication for transplantation.

Of 13 (30.2%) patients with PVR greater than 5 U Wood, 10 (76.9%) patients died. Of 30 (69.8%) of patients with PVR lower than 5 U Wood, 21 (70.0%) died. There was no significant difference for the immediate or late general mortality when comparing the two groups. Also there was no difference in the probability of survival (Kaplan-Meier) between the two groups (log-rank = 0.4803).

Mortality and survival time when high pulmonary arterial hypertension (PAH) was a contraindication for transplantation.

Nineteen patients (44.1%) presented with PAH and 16 (84.2%) died. Twenty-four patients (55.8%) did not present with PAH and 15 (62.5%) died. There was no statistical difference for the immediate and late mortality (p-value 0.174, Fisher exact test, p-value = 0.0849, Cox regression). Also there was no difference in the accumulated survival probability between the two groups (log-rank = 0.076).

Comments

One of the main proposals for PLV has been as an alternative procedure in patients with contraindications for heart transplantation. The patients consist of a population with dilated cardiomyopathy in an advanced critical phase but commonly with associated unfavorable psychological and socio-cultural conditions or even advanced ages all factors which are intrinsically linked to greater mortality. The results of this study revealed that some conditions which are considered contraindications for transplantation have a negative impact on the mortality and the survival time of patients submitted to PLV.

Additionally, there were differences in the evaluation processes and the selection criteria in the transplantation programs, about when a patient should be excluded due to socio-cultural or psychological criteria. In our study the MMPIT protocol [8] served as a basis for interviews of patients and their relatives. These interviews evidenced socio-cultural contraindications for transplant in 60.5% of the cases and psychological in 44.2%. We confirmed that the greatest mortality (p-value = 0.037) and the shortest survival time (log-rank = 0.0466) of the patients with these contraindications was mainly due to non-compliance with the essential post-operative treatment, as PLV was not proposed as a definitive treatment that implicated abandoning the medication for the treatment of heart failure [4,9]. There were several reasons for this which included a low family budget for the purchase of the necessary medicines, late negation of the seriousness of the disease, lack of support from the family, and, in some cases, the

placebo effect of the PLV. In the literature, the social and cultural conditions of heart transplant patients, when they are adverse, as well as the psychological instability, exert a significant negative prognostic influence, principally on non-compliance to post-operative treatment, one of the main causes for late deaths [8]. It is important to emphasize that patients suffering from irreversible heart disease, but with possibilities for heart transplantation or other alternative procedures, should be evaluated and counseled, from the socio-cultural and psychological point of views, before they are too critically ill. This is so that they can absorb the essential information about the characteristics of the disease and, especially, of their personalities, in the aspects that can interfere with the outcome of the treatment. In this phase, the wide ranging factors linked to the prognosis can be resolved at an early time. Family involvement at each stage of the treatment plays a critically important role as compliance to the complex post-operative medications also depends on the set of family actions [11-13]. The people who are responsible of looking after critical or chronic patients are at risk of developing psychiatric disorders which can discourage the treatment of the patient [14].

Patients who refuse transplantations and accept PLV as a definite surgical treatment, even though it is palliative, generally survive (78.9% versus 20.0%; p-value = 0.014) and for a longer time (log-rank = 0.0306). These patients, as they fill criteria for transplantation, are obviously in better clinical conditions than the others. Consequently, there could be a selection bias which confuses the conclusions. Anyway, we consider valid to argue that individuals who reject transplantation and accept PLV as a definitive operation, refuse to have their bodies modified by the organ of another person, objectivity creating greater determination in their decision of preserving the integrity of the body. This is an attitude that stimulates them to comply with alternative treatment, in the case of PLV, and the post-operative follow-up, positively influencing the outcome. This hypothesis is corroborated by the argument of Escotto [15] who emphasized that, apart from the indignation that all patients have when faced with disease and death the probability that a transplantation modifies the organism, internally or externally that can produce a greater emotional impact. The reaction of the patient oscillates between the fear (reaction when faced with a real threat) and anxiety (reaction when faced with a subjective threat), leading them to utilize defense mechanisms. To fight against the disease directly without permitting profound internal modifications of the organism itself (for example a transplant) is one of the most frequent attitudes taken [15].

The comparison between the death rate observed in patients with and without contraindications due to age was not different to the expected, in agreement with previously

published reports [16,17]. However, the probability of late survival was greater for the under 65-year-old patients (p-value 0.0397), without having detected an aggravating factor, in relation to the patients older than 65 years, which leads to the greater incidence of late deaths. The over 65-year-old patients died due to progressive and refractory heart failure or they suffer sudden death, similar to others. An exception was in relation to stroke and renal failure associated with heart failure. There is no consensus in relation to the upper age limit that contraindicates transplantation. Some centers consider 60 years as the limit and these patients lose priority on waiting lists for the lower expectations when compared to younger patients [18], in spite of the actuarial survival being similar in follow-ups over four years [19,20]. The difference in the survival rate between transplantation and PLV, in these cases, probably is intrinsic to the procedures, remembering that with PLV, the heart remains with the underlying disease, which will evolve to death due to heart failure or sudden death.

PAH and PVR, when elevated, are not correlated to a higher death rate or a lower survival rate after PLV, on the contrary to what has been reported in the literature [16,21]. Our patients greatly benefited from PLV, with a reduction in the PAH and PVR in the post-operative period, without these factors being categorized as predictive risk factors for post-operative mortality, as was previously reported [9,22].

The greatest challenge, both logically and obviously, in the selection of patients for heart transplantation or alternative treatment [23], is to identify those who will most benefit in terms of survival and quality of life. The effectiveness of the procedure also depends on the variables related to the disease, on the patient and on the patient's socio-cultural situation, among other aspects. Returning to the initial question, do the contraindications for transplantation, which are known to disfavor the prognosis of transplanted patients, exert the same prognostic role in patients after ventriculectomy? Could it be that PLV is an effective alternative in this scenario? When there are contraindications for transplantation, the indication of an alternative procedure such as PLV, implicates the obligation to consider some of these factors as predictors of a worse prognosis. With the exception of high PAH and PVR, the other contraindications for transplantation limit the effectiveness of PLV as an alternative.

In summary, we observed greater mortality after PLV when there were socio-cultural or psychological contraindications for and in the patients who did not refuse transplantation. The post-operative survival was lower for patients with psychological contraindications for transplantations, when the patients did not refuse the procedure and at a later stage in over 65-year-old patients.

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