



Medication non-adherence in heart transplant patients

Não adesão medicamentosa nos pacientes transplantados cardíacos

No adherencia a la medicación en pacientes con trasplante de corazón

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ABSTRACT

Objective: To measure medication non-adherence in patients after heart transplantation using the Basel Assessment of Adherence to Immunosuppressive Medications Scale (BAASIS) and the Visual Analogue Scale (VAS); to compare the results of biopsies performed with the prevalent comorbidities and survival. **Method:** Quantitative historical cohort. The population consisted of patients undergoing transplantation between 2009 and 2016. **Results:** Participation of 60 patients. The measurement using the BAASIS was 46.7% of non-adherence and 53.3% of patient adherence. The group with greater difficulty in non-adherence reported up to 2 hours delay of medication intake in relation to the prescribed time (25%), although there was no interruption in medications. The initial diagnosis was Chagas disease (33.3%). The studied comorbidities were systemic arterial hypertension (SAH), diabetes mellitus (DM), dyslipidemia (DLP) and chronic renal failure (CRF). **Conclusion:** Assessment using the BAASIS showed medication non-adherence in 46.7% of heart transplant patients. The VAS according to patients' self-report and nurse's assessment showed high values (93.3% vs 83.3%). The BAASIS tends to address the difficulties reported by patients, when there is a change in doses, delays or anticipations of time and dose.

DESCRIPTORS

Medication Adherence; Heart Transplantation; Immunosuppressive Agents; Cardiovascular Nursing.

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INTRODUCTION

Heart transplantation has grown since 2006, despite the decrease in the number of heart transplants (6.7%) in Brazil between January and September 2018, and the disproportion in relation to the donor rate (0.6%) data which revealed less utilization of this organ. Only in Distrito Federal-DF (11.8 pmp), the rate of heart transplants was higher than 5 pmp, and in the state of Pernambuco (4.9 pmp) it was very close. Of the 27 Brazilian states, only 11 (none in the North) and the DF performed heart transplantation. It is interesting that in the three states of the South region with high organ donation rates, less than two transplants (pmp) were performed. In a total of 256 heart transplants in the country in 2018, the state of São Paulo (SP) registered 78⁽¹⁾.

Despite the diagnostic and therapeutic evolution of heart failure (HF), since 1980, heart transplantation remains the indicated therapy for stage D heart failure refractory to clinical treatment⁽²⁾.

The analysis of numbers shows the scarcity of procedures performed and the need to pay attention to the survival of individuals who undergo heart transplantation. As immunosuppressive therapy is essential to avoid graft rejection, patients' medication adherence as prescribed is crucial for graft and patient survival.

The World Health Organization (WHO) conceptualizes adherence to treatment "as the extent to which a person's behavior – taking their medication, following their diet and/or changing their lifestyle – corresponds to the recommendations of a health professional"⁽³⁾.

Currently, non-adherence is recognized as a determining factor for higher morbidity and mortality, reduction of quality of life, higher medical costs and excessive use of health services for transplanted patients⁽⁴⁾.

In order to increase the survival of transplanted patients and the graft, immunosuppressive medication must be used properly, because the success of the graft quality depends on the control of rejection⁽⁴⁾.

The graft loss due to rejection is a constant concern of transplant teams. It happens in the presence of tissue antigens encoded by genes of the main histocompatibility complex (HPC) and human leukocyte antigens (HLA), proteins that are present in all cells of the human organism⁽⁵⁾.

There are two types of acute rejection, namely the hyperacute humoral rejection (HAR) and acute cellular rejection (ACR). Hyperacute humoral rejection occurs immediately after transplantation, that is, within the first 24 hours, in the presence of anti-donor antibodies and causes graft failure. It is characterized by the formation of thrombi and granulocyte infiltrates⁽⁵⁾. In ACR, the main immunological component is involved in the rejection of allograft mediated by T lymphocyte and occurs in the first six months of the transplant, but it can occur over time, when the therapeutic regimen changes or mainly if there are failures in patients' medication adherence and/or interaction with other drugs⁽⁶⁾. From the rejection event,

T cells are involved and lead to a cascade of reactions and antibodies that cause the destruction of grafts if this is not controlled immediately by the immunosuppressive therapeutic regimen⁽⁴⁾.

Humoral rejection (HR) is mediated by pre-existing antibodies or after transplantation⁽⁷⁾. Its diagnosis is usually confirmed in the presence of graft dysfunction through echocardiography and the patient's clinic. This complication reduces survival in the late stage of transplantation⁽⁸⁾.

The results related to adherence to treatment guidelines are important for its success, for example, taking the medication correctly; following the prescribed diet; seeking changes in lifestyle, such as physical activity practice; and not smoking⁽⁷⁾. Since it is difficult to measure adherence, predictors have been studied to help monitor the failures arising in the treatment process⁽⁹⁾.

Among the predictors to detect rejection, such as acute worsening of the graft and its accurate diagnosis, endomyocardial biopsy (EMB) and control by immunosuppressive drugs are used with the function of modulating such episodes⁽⁵⁾. In the study in question, the institutional protocol adopts the recommendations of the International Society for Heart Transplantation (ISHLT) for proposing follow-up procedures in the first year after heart transplantation⁽⁶⁾.

The assessment of medication adherence in transplanted patients has been performed especially by means of biopsies and biochemical measurements, but the assessment in the light of patient information is poorly studied. In addition to the clinical procedures already adopted, the objective was to measure medication non-adherence in patients after heart transplantation using the Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS)⁽¹⁰⁾ and the Visual Analogue Scale (VAS)⁽¹¹⁾ by comparing with the results of biopsies performed and identifying the survival of these patients and their prevalent comorbidities.

METHOD

TYPE OF STUDY

This is a quantitative, historical cohort study.

SCENARIO

The research was performed to measure non-adherence to immunosuppressive therapy in heart transplant patients treated at the Instituto Dante Pazzanese de Cardiologia (Portuguese acronym: IDPC), located in the city of São Paulo, Brazil.

POPULATION

The study population were all heart transplant patients seen at the outpatient clinic of the IDPC from August 2014 to May 2016, totaling 60 patients.

Patients with at least one year after transplant and five years of follow-up were selected, and those with less than one year of treatment were excluded.

DATA COLLECTION

Data collection was performed by the nurse responsible for the study, from an invitation during visits to the heart transplant clinic of the IDPC. Patients with heart transplantation (Cardiac TX) with advanced heart failure and refractory to treatment are treated daily by a specialized team in the IDPC.

Multidisciplinary care is offered in nursing consultations focused on providing guidance and teaching self-care in the search for better quality of life for patients and their families.

The study outcome was medication non-adherence assessed with use of instruments validated in Brazil, namely the BAASIS⁽¹⁰⁾ and the VAS⁽¹¹⁾ through patients' self-report and nurses' reports of adherence.

The VAS was applied by patients themselves with the self-report of their perception of medication adherence and simultaneously by the nurse professional involved in the study, who followed the patients in nursing consultations throughout the pre- and post-transplant process⁽¹²⁾.

An instrument to collect information and trace the sociodemographic profile was also developed, including age, sex, marital status, employment status and education, in addition to clinical variables such as post-transplant time, immunosuppressive therapy, comorbidities and rejection episodes⁽¹²⁾.

The result of endomyocardial biopsies to assess the degree of graft rejection was the third variable of choice for the analysis of non-adherence measured through the instruments. These were performed according to the Biopsy Protocol of the IDPC, totaling 11 biopsies in a one-year period. In the first month, one biopsy is performed per week, totaling four. In the second and third months, biopsies are performed every two weeks, and monthly until the sixth month, ending with one year after the transplant⁽⁵⁾. Biopsies are classified as: 0R, absence of infiltrates; 1R, focal and/or diffuse infiltrate without necrosis; 2R infiltrated with cellular aggression or myocyte damage; 3R diffuse inflammatory infiltrate with necrosis, vasculitis, hemorrhage and edema⁽⁹⁾.

During outpatient visits, patients filled out the assessment instruments and biopsy-related data were taken from medical records.

ANALYSIS AND TREATMENT OF DATA

Descriptive and analytical statistics were used for data treatment. The association between two categorical variables was verified through the chi-square test, or alternatively, in cases of small samples, with the Fisher's exact test. Student's t test was used to compare means between two groups.

One of the assumptions of the Student's t test is the normality in data distribution, which was verified using the Kolmogorov-Smirnov test. In case of data normality violation, the means were compared using the non-parametric Mann-Whitney test.

The linear association between the perception of self-reported adherence and that of nurses was assessed through Spearman's correlation (r_s) given the small variation in the amplitude of the score.

In the survival analysis, the probability of a patient survival after a certain period was estimated by the adherence with use of the Kaplan-Meier model. The Log Rank test (Mantel-Cox) was used for comparisons.

For all statistical tests, a significance level of 5% was adopted. Statistical analyzes were performed using the statistical software SPSS 20.0.

ETHICAL ASPECTS

The study complied with assumptions of Resolution number 466/12 of the National Health Council and was submitted to the Research Ethics Committee of the Instituto Dante Pazzanese de Cardiologia and the Plataforma Brasil (CEP number 647.508), (Date of the Rapporteur: 05/14/2014). The Informed Consent form was applied and signed by study participants.

RESULTS

According to Table 1, the predominant sociodemographic profile of patients was the following: men (71.7%); married (66.1%); does not live alone (88.3%); retired (43.3%); white color (63.3%); and 11.7% had a college degree (incomplete or complete). Data of 60 patients were analyzed, and their mean age was 47.2 years (SD=15.6 years), minimum age of 14 years and maximum of 75 years. The median of age was 47.5 years.

The McNemar's test was used to assess prevalence before and after transplantation; for systemic arterial hypertension (SAH), the results remained similar, 48.3% and 30.0% ($p=1,000$), respectively. However, occurrences ($p=0.008$) of diabetes mellitus (DM) increased from 11.7% to 25%. The percentage ($p=0.012$) of patients with chronic renal failure (CRF) also increased from 15.0% to 30.0%. Regarding comorbidities before transplantation, 38.3% had SAH and 30.0% had dyslipidemia (DLP), and after transplantation these percentages remained similar (48.3% and 30.0%, respectively). On the other hand, the occurrences of DM increased ($p=0.008$) (11.7% to 25.0%), as well as those of CRF ($p=0.012$) (15.0% to 30.0%). Additionally, 35.0% were hospitalized, although from a cause other than rejection. The prevalent diagnosis of the transplanted group was Chagas heart disease with 33.3%, followed by dilated heart disease with 26.7% and ischemic heart disease with 23.3%. The higher incidence of chagasic etiology can be related to the care of the population coming from endemic areas such as the North and Northeast of Brazil.

Table 1 – Distribution of heart transplant patients, according to sociodemographic and clinical profile – São Paulo, SP, Brazil, 2017.

	N	%
Sex		
Male	43	71.7
Female	17	28.3
Marital status*		
Single	18	30.5
Married	39	66.1
Divorced/separated	2	3.4
No information	1	
Living alone		
No	53	88.3
Yes	7	11.7
Schooling		
Illiterate	4	6.7
Incomplete primary education	17	28.3
Complete primary education	6	10.0
Incomplete high school	11	18.3
Complete high school	15	25.0
Incomplete higher education	3	5.0
Complete higher education	4	6.7
Occupation		
Unemployed	3	5.0
Student	6	10.0
Retired	26	43.3
Sickness benefit/pensioner	14	23.3
Housewife	2	3.3
Volunteer	9	15.0
Ethnicity		
White	38	63.3
Non-white	62	36.7
Initial diagnosis		
Chagas	20	33.3
Congenital	3	5.0
Dilated	16	26.7
Hypertrophic	2	3.3
Ischemic	14	23.3
Peripartum	2	3.3
Valvar	3	5.0
Comorbidities – pre-transplant		
Systemic arterial hypertension		
No	37	61.7
Yes	23	38.3
Diabetes mellitus		
No	53	88.3
Yes	7	11.7

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	N	%
Dyslipidemia		
No	42	70.0
Yes	18	30.0
Chronic renal failure		
No	51	85.0
Yes	9	15.0
Comorbidities – post-transplant		
Systemic arterial hypertension		
No	31	51.7
Yes	29	48.3
Diabetes mellitus		
No	45	75.0
Yes	15	25.0
Dyslipidemia		
No	42	70.0
Yes	18	30.0
Chronic renal failure		
No	42	70.0
Yes	18	30.0
Other occurrences post-transplant		
Neoplasias		
No	54	90.0
Yes	6	10.0
Chagas reactivation		
No	51	85.0
Yes	9	15.0
Cytomegalovirus reinfection		
No	45	75.0
Yes	15	25.0
Hospitalization		
No	39	65.0
Yes	21	35.0

Note: *Only for the marital status variable, 59 patients had the information recorded.

Table 2 shows that 15% stopped taking their immunosuppressive medications once or twice in the four weeks prior, and five patients skipped one or two doses, while 25% of patients acknowledged having changed the prescribed schedule, which could compromise their graft quality and evidence of rejection.

Although 46.7% of patients had difficulties with medication, that is, they presented non-adherence, no patient stopped taking immunosuppressive medications completely without medical advice. At the same time, 53.3% presented medication adherence in 100% of the instrument questions with a positive response.

Most patients used prednisone - PRD (95%), mycophenolate mofetil - MMF and cyclosporin (58.0%). A small portion used two or four medications (5.0%).

Table 2 – Distribution of patients by (BAASIS)⁽¹⁰⁾ items – São Paulo, SP, Brazil, 2017.

Distribution	N	%
Do you recall of forgetting to take your immunosuppressive medications in the past four weeks?		
No	51	85.0
Yes	9	15.0
Frequency of forgetting to take immunosuppressive medications at any time in the past four weeks		
Never	51	85.0
Once	7	11.7
Twice	2	3.3
Do you remember skipping two or more doses of immunosuppressive medications in the past four weeks?		
No	55	91.7
Yes	5	8.3
Frequency of having skipped two or more doses of immunosuppressive medications in the past four weeks		
Never	55	91.7
Once	2	3.3
Twice	1	1.7
Three times	1	1.7
Four times	1	1.7
In the past four weeks, do you remember taking immunosuppressive medications 2 hours in advance or two hours behind the prescribed time?		
No	45	75.0
Yes	15	25.0
Frequency with which you remember taking immunosuppressive medications with more than 2 hours' difference compared to the prescribed time, in the last four weeks		
Never	45	75.0
Once	6	10.0
Two or three times	8	13.3
Four or five times	1	1.7
In the past four weeks, have you changed the amount of immunosuppressive medications without medical advice?		
No	53	88.3
Yes	7	11.7
In the past year, have you completely stopped taking immunosuppressive medications without medical advice?		
No	60	100.0
Adherence		
Non-adherence	28	46.7
Adherence	32	53.3

As shown in Table 3, there were no associations between adherence and rejection. However, rejection in the 1st month was marginally significant ($p=0.088$), indicating lower rejection in patients with adherence (75.0%), compared to non-adherent patients (92.9%). At other times, these percentages were very similar. The results of biopsies were distributed in the 1st, 3rd and 6th months, and those above 1R were considered as rejection. As results were similar in the other biopsies, it is not possible to infer that the improvement was the result of better patient adherence. This fact may be related to changes in the dosage of immunosuppressants during treatment.

Table 3 – Distribution of heart transplant patients by adherence, according to rejection by means of endocardial biopsy – São Paulo, SP, Brazil, 2017.

Endocardial biopsy	Adherence						p
	No		Yes		Total		
	N	%	N	%	N	%	
1st month	28	100.0%	32	100.0%	60	100.0%	0.088 ^a
No rejection	2	7.1%	8	25.0%	10	16.7%	
Rejection	26	92.9%	24	75.0%	50	83.3%	
3rd month	28	100.0%	32	100.0%	60	100.0%	0.775
No rejection	7	25.0%	7	21.9%	14	23.3%	
Rejection	21	75.0%	25	78.1%	46	76.7%	
6th month	28	100.0%	32	100.0%	60	100.0%	0.796
No rejection	6	21.4%	6	18.8%	12	20.0%	
Rejection	22	78.6%	26	81.3%	48	80.0%	

Note: p – descriptive level of Fisher's exact test.

In the VAS self-reported perception⁽¹¹⁾, nurses' assessment (93.3% X 82.5%, $p<0.001$) was superior. Additionally, there was no significant correlation between the two adherence values ($rS=0.008$, $p=0.950$). Patients with adherence were those who indicated no or never in all items. According to the BAASIS⁽¹⁰⁾, 53.3% had medication adherence, while patients' self-report (VAS) reached 93.3% and the lowest value in nurses' assessment using the VAS was 82.5%.⁽¹¹⁾ Survival of transplant patients was analyzed at 1, 2, 6 and 7 years after transplantation. There were no differences in patient survival in comparisons by adherence. There were six deaths (10.0%), half of which in each adherence group. According to the Kaplan Meier model, the mean survival time was 85.1 months (95%CI=[78.6 ; 91.6]) (Table 4).

Table 4 – Summary measures of self-reported adherence and the nurse's perception - São Paulo, SP, Brazil, 2017.

	Mean	Standard Deviation	Min.	Max.	1st quartile	Median	3rd quartile	N
Adherence – self-reported (VAS)	93.3%	11.6%	50.0%	100.0%	90.0%	100.0%	100.0%	60
Adherence – nurse	82.5%	19.1%	50.0%	100.0%	70.0%	80.0%	100.0%	60

Note: Student's t test for paired samples - $p<0.001$.

DISCUSSION

In recent years, heart transplantation has proven to be an effective therapy for patients with advanced heart failure and refractory to all available therapies⁽²⁾. This remains a great choice for patients who have undergone several clinical and surgical treatments that have shown limited activities and clinical worsening over time. Thus, transplantation improves quality of life and prolongs survival⁽⁵⁾.

Regarding sociodemographic variables of heart transplant patients, their profile does not differ from other Brazilian centers, where the median age of 47.5 years characterizes them as young adults. The multicenter study with

participation of Brazilian transplant centers obtained similar variables, such as an mean age of 53.7 years, predominance of men (72.7%), married (68.9%), employed (29.7%), university education (34.1%) and white (85.9%)⁽¹³⁾.

A recent American study assessed the impact of racial and economic disparities with data from the United Network for Organ Sharing (UNOS), including 33,893 adult patients transplanted between 1994 and 2014. Although transplant disparities have narrowed over time, especially the socio-economic level (health insurance, education, black race and neighborhood), they are still not explained by differences in the clinic or characteristics of grafts, which can be an important differential for survival. There are few studies on this relationship between survival of the recipient and organ, especially in associations with borderline donors⁽¹⁴⁾.

The First Brazilian Registry of Heart Failure, considering clinical aspects, quality of care and hospital outcomes, included a total of 1,263 patients (64 ± 16 years old, 60% women) and data from 51 centers in different regions of Brazil. The most common comorbidities were arterial hypertension (70.8%), dyslipidemia (36.7%) and diabetes (34%)⁽¹⁵⁾.

Regarding comorbidities before transplantation, 38.3% and 30.0% had SAH and DLP, respectively. The study showed that 33.3% of initial diagnoses were due to Chagas disease.

There was also 15% of Chagas reactivation after transplantation⁽¹⁶⁾. Even receiving preventive treatment with recommended medication (benznidazole) to inhibit parasitic reactivation, the disease can occur as a result of the use of immunosuppression⁽¹⁷⁾.

Thus, Chagas disease is a negative predictor for the quality of life of patients and graft survival, because of the disease reactivation that increases the mortality of transplanted patients⁽¹⁸⁾.

Despite the implementation of policies to control the disease transmission in Brazil, difficulties still exist. In addition to modern drugs for its control, the disease involves sanitary, educational and economic measures. Studies have shown high mortality in chagasic patients without the prospect of heart transplantation, and a survival of only 1.5 months⁽¹³⁾.

With the expansion of Chagas disease to the United States of America and Europe, it ceased to be a disease of poor countries. Although small, this may be another cause for the development of heart disease, which brings the need for heart transplantation in these other countries and the same consequences, such as disease reactivation⁽¹⁸⁾.

In this study, there was an increase ($p=0.008$) in occurrences of DM that went from 11.7% to 25.0% in the post-transplant period, as well as an increase ($p=0.012$) in occurrences of chronic renal failure from 15.0% to 30.0%. Additionally, 35.0% were hospitalized, although from causes other than rejection.

The onset of other clinical conditions is another worrying reality that may compromise the graft. The reason for this result is that post-transplant diabetes mellitus (DMPT) is a possible complication due to the use of immunosuppressants, mainly corticosteroids and calcineurin inhibitors (cyclosporin and tacrolimus)⁽¹⁹⁻²⁰⁾.

Thus, in addition to the need for regular intake of medications for graft preservation, other medications can be added for controlling the comorbidities, thereby leading to an adherence process that involves several factors.

According to BAASIS a four-item questionnaire, conducted through patient interviews assessing self-reported adherence, only if 100% of responses, all positive, is considered adherence. Regarding the questions, one can assess medication adherence or non-adherence of transplant patients⁽¹⁰⁾.

In this sense, the study showed that 46.7% of heart transplant patients treated in a Cardiology Center in the city of São Paulo had time-related medication non-adherence; 2 hours before or after the prescribed time and dose change. The highest percentage of medication non-adherence was by intake with more or less 2 hours' difference in relation to the prescribed time (25.0%). No patient stopped taking medications completely without medical advice and 53.3% had medication adherence.

A similar study was conducted in Israel using the BAASIS⁽¹⁰⁾ to assess medication adherence. It was found that in the past four weeks, 64% of patients had problems with the implementation of medication. For example, they missed a dose or skipped two or more doses, took medication 2 hours before or after the recommended time, or changed the prescribed amount. The highest score was for the item "non-adherence over time", 56.9% of patients. Three patients (3%) had discontinued the medication⁽²¹⁾.

A study that analyzed secondary data of 36 transplant centers in 11 countries, in which Brazil participated, on four continents, called the Research Initiatives Group: Chronic Disease Management and Adherence to Transplant Study (BRIGHT)⁽¹³⁾ totaled a sample of 1,397 and 83.3% patients responded to the study. It demonstrated that non-adherence to the implementation of immunosuppressants was observed in 37.4% of participants. More specifically, the prevalence of immunosuppressive non-adherence was 17.3% by non-adherence, 1.9% by medication not taken on a holiday, 28.7% by the time of taking medication, and 1.6% by dose change. For discontinuation of medication, a prevalence of 0.5% was found⁽¹⁵⁾.

In a Brazilian study with kidney transplant patients, general BAASIS scores⁽¹⁰⁾ were used, calculated from the arithmetic sum of the score attributed to questions related to time, dose change, holiday dose and time change; 58.6% of recipients reported total adherence to the immunosuppressive medication, 41.4% did not adhere and 18.8% did not adhere to at least one or more of the four situations assessed (related to time, dose change, holiday dose, and time change) in the previous four weeks⁽²²⁾.

The concept of adherence to drug therapy has been increasingly studied to assess the effectiveness of treatment⁽¹⁰⁻¹²⁾.

Thus, it is emphasized the need to reflect on the process of measuring adherence, scales used, and factors related to individuals evaluated. The appropriateness of the measurement of adherence must be discussed, as well as all perspectives of factors leading to non-adherence, such as forgetting to take the medication, the lack of perception of the disease/health status, and social characteristics. It is also important

to review the educational process of preparing the individual before receiving the organ and the discharge guidance provided after the transplant to achieve the proposed goals. Several strategies to assist patients in maintaining drug adherence must be implemented, such as active search by telephone and mobile digital technologies⁽²³⁻²⁴⁾.

According to Table 3, there were no associations between adherence and rejection. The rejection in the 1st month was marginally significant ($p=0.088$), indicating lower rejection in patients with adherence (75.0%), compared to patients without adherence (92.9%). At other times, these percentages were very similar. The results of biopsies were distributed in the 1st, 3rd and 6th months, and results of rejection evaluation above 1R were considered as rejection. Results were similar in the other biopsies.

It is estimated that 15% to 60% of late rejections and 5% to 36% of graft losses are related to non-adherence to the correct treatment of solid organs⁽²³⁻²⁴⁾.

The self-report assessment depends on the respondent's sincerity, despite its low cost and the possibility in the clinical follow-up. In the study, the self-reported perception (VAS)⁽¹¹⁾ was superior to the nurse's assessment (93.3% X 82.5%, $p<0.001$). Additionally, no significant correlation was found between the two forms of assessing adherence ($rS=0.008$, $p=0.950$).

In survival analyzes of transplanted patients at 1, 2, 6 and 7 years after transplantation using the Kaplan Meier model, the mean survival time was of 85.1 months (95%CI=[78.6;91.6]). There was no difference in patient survival in comparisons by adherence, although six deaths (10.0%) occurred, of which half in each adherence group.

In a study conducted eight years ago in the same service, survival after orthotopic transplantation was of one year in 72.7%, five years in 61.5% and seven years in 56.4%. Survival after transplantation was correlated with the variables age, cause of death and donor sex, and if the transplant was the patient's first heart surgery or not⁽²⁵⁾.

One can consider as a limitation the instruments used to assess adherence. For example, the BAASIS⁽¹⁰⁾ assesses patient adherence to drug therapy only with 100% of positive responses for non-adherence. Visual analog scales involve a subjectivity of assessment, in which the professional's perception can be influenced by other characteristics of patients and their history, the same way that patients' self-report can also be influenced by personal concepts and values inherent to treatment.

CONCLUSION

This study allowed the conclusion that 46.7% of patients had difficulties with medication, i.e., presented non-adherence.

The highest percentage of non-adherence was when taking immunosuppressive medications with more than 2 hours' difference from the prescribed time (25.0%). No patient completely stopped taking immunosuppressive medications without medical advice, while 53.3% had medication adherence measured by 100% of items of the instrument with a positive response.

The initial prevalent diagnosis of the transplanted group was Chagas heart disease with 33.3%, followed by dilated heart disease with 26.7% and ischemic heart disease with 23.3%. Most patients used a triple regimen (prednisone, mycophenolate mofetil and cyclosporin). In addition, the self-reported perception - VAS was higher than the nurse's assessment (93.3% X 82.5%, $p<0.001$). This scale is criticized for its low sensitivity in assessing the real situation of patients' non-adherence, and after this study, it is no longer indicated to compose this type of assessment. There was no significant association between adherence and rejection using biopsy values ($p=0.088$). Systemic Arterial Hypertension and DLP had similar results; 38.3% and 30% in the pre-transplant and 48.3% and 30% in the post-transplant period. The mean 7-year survival was 85.1 months post-transplant, regardless of the adherence and non-adherence group.

RESUMO

Objetivo: Mensurar a não adesão medicamentosa nos pacientes pós-transplante cardíaco mediante o uso da Escala Basel para Avaliação de Aderência a Medicamentos Imunossupressores e Escala Analógica Visual; comparar os resultados das biópsias realizadas, com comorbidades prevalentes e sobrevida. **Método:** Coorte histórica de abordagem quantitativa. A população foi composta de pacientes transplantados no período de 2009 a 2016. **Resultados:** Participação de 60 pacientes. A mensuração da não adesão por meio do instrumento Escala Basel para Avaliação de Aderência a Medicamentos Imunossupressores foi de 46,7% e adesão de 53,3% dos pacientes. O grupo com maior dificuldade de não adesão foi aquele com relato de atraso de até 2 horas do prescrito (25%), porém, sem interrupção nas medicações. O diagnóstico inicial foi Doença de Chagas (33,3%). As comorbidades estudadas foram hipertensão arterial sistêmica, diabetes mellitus (DM), dislipidemias e insuficiência renal crônica. **Conclusão:** A avaliação por meio da Escala Basel para Avaliação de Aderência a Medicamentos Imunossupressores verificou não adesão medicamentosa de 46,7% dos pacientes transplantados cardíacos. A Escala Analógica Visual pelo autorrelato do paciente e avaliação do enfermeiro apresentaram valores elevados (93,3% vs 83,3%). A Escala Basel para Avaliação de Aderência a Medicamentos Imunossupressores tende a se aproximar das dificuldades informadas pelos pacientes, quanto há alteração de doses, atrasos ou antecipações de horário e dose.

DESCRITORES

Adesão à Medicamento; Transplante de Coração; Imunossupressores; Enfermagem Cardiovascular.

RESUMEN

Objetivo: Medir la falta de adherencia a la medicación en pacientes después de un trasplante de corazón utilizando la *Basel Assessment of Adherence to Immunosuppressive Medications Scale* (BAASIS) y la Escala Visual Analógica (EVA); comparar los resultados de las biopsias realizadas con las comorbilidades prevalentes y la supervivencia. **Método:** Cohorte histórica con un enfoque cuantitativo. La población consistió en pacientes trasplantados de 2009 a 2016. **Resultados:** Participación de 60 pacientes. La medición utilizando la BAASIS fue del 46,7% para no adherencia y del 53,3% para la adherencia de los pacientes. El grupo con la mayor dificultad en la no adherencia fue

de aquellos con un retraso de hasta 2 horas en la ingesta de medicamentos desde el tiempo prescrito (25%), aunque sin interrupción en los medicamentos. El diagnóstico inicial fue enfermedad de Chagas (33,3%). Las comorbilidades estudiadas fueron hipertensión arterial sistémica, diabetes mellitus, dislipidemia e insuficiencia renal crónica. **Conclusión:** La evaluación con BAASIS mostró la no adherencia a la medicación en el 46,7% de los pacientes con trasplante de corazón. La EVA según el autoinforme de los pacientes y la evaluación de los enfermeros mostró valores altos (93,3% frente a 83,3%). La BAASIS tiende a abordar las dificultades reportadas por los pacientes, cuando hay un cambio en las dosis, retrasos o anticipaciones de tiempo y dosis.

DESCRIPTORES

Complimiento de la Medicación; Trasplante de Corazón; Inmunosupresores; Enfermería Cardiovascular.

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