Original Article

Prognostic Evaluation of Chagasic and Non-Chagasic Patients Undergoing Pacemaker Implantation and Cardiac Resynchronization in a Tertiary Center

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Abstract

Background: **Chagas cardiomyopathy (ChCC) is one of the causes of the implantation of pacemakers (PM) in many patients and has been associated with an adverse prognosis.**

Objectives: **To compare the prognosis of the chagasic and non-chagasic populations undergoing PM and cardiac resynchronizer implantation.**

Methods: **Observational, retrospective study, which analyzed a cohort of patients who underwent implantation of these devices, in a tertiary center, from October 2007 to December 2017, comparing the chagasic group with non-chagasic patients. The non-parametric Kaplan-Meier method was used to calculate patient survival. The significance level adopted in the statistical analysis was 5%. The primary outcome was mortality from any cause, while the secondary outcomes were the occurrence of hospitalization and the combination of hospitalization and death.**

Results: **A total of 911 patients were included, of which 23.4% had ChCC. In a Cox analysis adjusted for sex and age, Chagas disease (ChD) was not associated with an increased risk of death (HR: 1.14, CI:95%, 0.86-1.51, p=0.365), hospitalization (HR: 0.79, CI:95%, 0.61-1.04, p=0.09) or combined outcome of death and hospitalization (HR: 0.90, CI:95%, 0.72-1 .12, p=0.49).**

Conclusions: **ChD was not associated with an increased risk of death, hospitalization, or combined outcome of death and hospitalization, even after adjustment for sex and age. These results contrast with those of previous studies and suggest changes in the quality of care of patients with cardiomyopathy.**

Keywords: **Artificial Pacemaker; Artificial Cardiac Pacing; Chagas Cardiomyopathy.**

Introduction

Cardiac electrical stimulation stands out as one of the greatest achievements in the field of cardiology in the 20th century.[1] Over the past decades, there has been an increase in the number of implants, which can be attributed to population aging, technological advancements in these devices, and an increase in clinical indications.[2,3]

Among these implants, ChCC still accounts for a significant portion of permanent artificial cardiac stimulation indications in our country.[4] However, there has been a gradual decline in PM implants due to this etiology, reflecting improved epidemiological control of ChD in the national territory.[5,6]

Despite the reduction in its prevalence, especially in Latin America, ChD evolving with ChCC still presents high morbidity and mortality rates in Brazil, with a worse prognosis than non-inflammatory cardiomyopathies.[7] However, few studies have evaluated epidemiological characteristics associated with mortality predictors in patients with PM and ChCC.[4,5,8,9]

The present study aimed to compare the outcomes of Chagas and non-Chagas patients undergoing PM and cardiac resynchronization therapy (CRT) implantation at a Brazilian tertiary center.

Methods

This is an observational, retrospective, and longitudinal study. All patients who underwent PM and CRT implantation at the specified tertiary center from October 2007 to December 2017 were included. The research project was approved by the Research Ethics Committee of the institution, following the terms of Resolution No. 466/12 of

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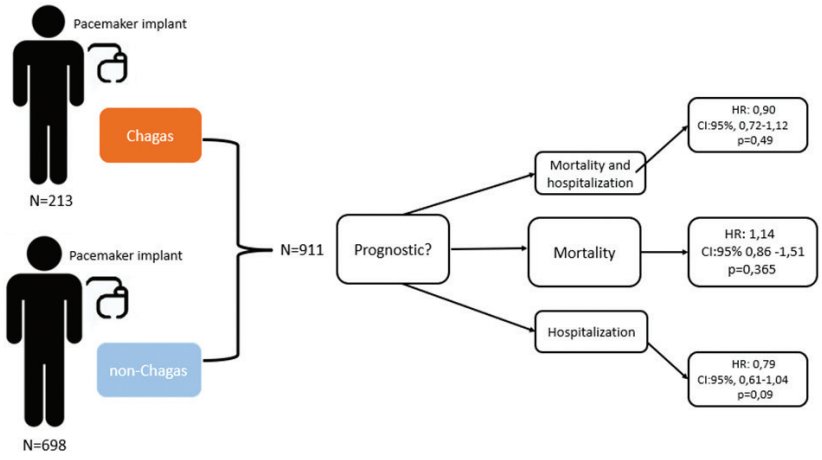
Central Illustration: Prognostic Evaluation of Chagasic and Non-Chagasic Patients Undergoing Pacemaker Implantation and Cardiac Resynchronization in a Tertiary Center



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Prognostic evaluation of Chagas and non-Chagas patients undergoing pacemaker implantation. HR: Hazard Ratio; CI: Confidence Interval.

the National Health Council, under the protocol number CAAE: 56119122.0.0000.5149.

Patient information was obtained from a database of electronic health record data from the Laboratory of Implantable Cardiac Devices (LICD) at a Unified Health System reference tertiary hospital in Minas Gerais, with follow-up until December 2018. The database was created using Natural Language Processing (NLP), an artificial intelligence tool that extracted relevant information from free-text electronic health records.[10] Subsequently, records of all hospital admission authorizations from the Unified Health System Hospital Information System for cardiovascular procedures in the city of Belo Horizonte were obtained, along with death records from the Mortality Information System of the Department of Informatics of the Unified Health System (DATASUS) in Minas Gerais. The final patient dataset was generated by matching common patients from these information sources.

Patients who were followed but did not have the device implanted during the study period, those who had the device definitively explanted for any reason, patients without follow-up records in the LICD of the hospital, minors under 18 years of age, and patients with isolated implantable cardioverter-defibrillators (ICDs) were excluded.

The analyzed variables included the presence or absence of Chd (exposure), sex, and age. The implanted devices were categorized as pacemakers (single-chamber or dual-chamber) or resynchronization devices (multisite) alone or combined with ICDs. The hospitalization variable was obtained from hospital admission authorization data and was considered positive when the patient had at least one cardiovascular-related hospitalization after the device implantation date.

The primary outcome analyzed was all-cause mortality, comparing Chagas and non-Chagas patients. Secondary outcomes included hospitalization occurrence, combined hospitalization and all-cause mortality, mortality comparison between Chagas and non-Chagas patients in each of the three eras, and mortality comparison by device type.

Patients were further divided into three eras based on the device implantation date. The total study inclusion time was divided into three 41-month periods: October 2007 to February 2011 (era 1), March 2011 to July 2014 (era 2), and August 2014 to December 2017 (era 3), aiming to assess differences in mortality between Chagas and non-Chagas patients in each of these different eras.

Statistical analysis

For data analysis, we used the R program (version 4.3, Vienna, Austria). Continuous variables were presented as mean and standard deviation if they followed a normal distribution, or as median and interquartile range (percentiles 25 and 75) if they did not. The Shapiro-Wilk test was used to assess data normality. Categorical variables were expressed as absolute numbers and proportions. To evaluate the age variable, the Student's T-test was performed to compare means. To compare variables between groups of chagas and non-chagas patients, the Student's T test was also used. The chi-square test (X^2) and Kruskal-Wallis test were used to evaluate continuous variables to assess other baseline characteristics of patients and studied devices over the study periods. The non-parametric Kaplan-Meier method was used to calculate patient survival. The statistical significance level was set at p-values less than 0.05. A multivariate Cox proportional hazards regression model, with a hazard ratio (HR), estimates, and 95% confidence intervals, was used to analyze the effect of covariates on the studied

outcomes. The proportional hazards assumption was verified using log-log survival curves.

We also conducted a sensitivity analysis by evaluating all-cause mortality according to device type in the Chagas and non-Chagas populations after excluding resynchronization devices and resynchronization devices combined with ICDs. These exclusions were made due to the complexity and unequal distribution of these devices in the two populations, aiming to assess whether the results remained consistent.

Results

Out of the 2819 patients registered in the LICD at the hospital where the research was conducted, 911 patients who underwent PM and CRT implantation during the study period were included (Figure 1). The mean age of the included patients was 68 years (ranging from 20 to 97 years), with 48.5% being male. Among all patients, 23.4% had ChCC. The mean age at PM implantation in the Chagas population was 65 years, while in the non-Chagas population, it was 69 years. Regarding implantable cardiac devices, in the Chagas population, 77.5% received dual-chamber PMs, 16.4% received single-chamber PMs, 3.3% received CRT devices, and 2.8% received CRT devices combined with ICDs (Table 1).

The mean follow-up duration was 64.2 months for mortality, 60.6 months for hospitalization, and 57.4 months for the combined outcome of mortality and hospitalization.

A total of 306 deaths (33,6%) occurred, with 80 (37.6%) in the Chagas population and 226 (32.4%) in the non-Chagas population (p=0.187). Cardiovascular-related hospitalizations occurred in 275 (30.2%) patients, with 76 (35.7%) having a diagnosis of Chd and 199 (38.5%) without this diagnosis (p=0.056). The combined outcome of mortality and hospitalization occurred in 419 (46%) patients, with 109 (51.2%) being Chagas patients and 310 (44.4%) non-Chagas patients (p=0.098).

Kaplan-Meier survival curves, using the log-rank test with p=0.99, did not demonstrate a difference in mortality between the Chagas and non-Chagas groups (Figure 2), nor did they show differences between the two groups in any of the different eras (Figure 4 – see appendix).

Moreover, no difference was observed in the analysis of combined mortality and hospitalization curves between the two groups (Figure 3).

The Kaplan-Meier curves for mortality evaluation in patients with dual-chamber PMs showed no difference between Chagas and non-Chagas patients, as well as for patients with single-chamber PMs (Figure 5 – see appendix). Unfortunately, we could not perform this analysis for patients with isolated CRT devices and CRT devices combined with ICDs due to the small number of Chagas patients with these devices. We conducted a sensitivity analysis by excluding patients with CRT devices (isolated or combined with ICDs) and analyzing only patients with single-chamber and dual-chamber PMs together. The Kaplan-Meier curves from this analysis also did not show a difference in mortality between Chagas and non-Chagas patients (Figure 6 – see appendix).

In the Cox univariate analysis, the presence of Chd was not associated with all-cause mortality, even when considering all devices and analyzing each device type separately. However, male sex and age were related to an increased risk of death (Table 3 -see appendix).

In the multivariate Cox model, adjusted for sex and age, the results remained consistent and Chd was not associated with an increased risk of death, hospitalization, or the combined outcome of mortality and hospitalization (Central Figure), even when analyzed across different eras (Table 2).

Discussion

The primary finding of this study highlights the absence of a difference in mortality between Chagas patients with PM and CRT devices compared to non-Chagas patients.

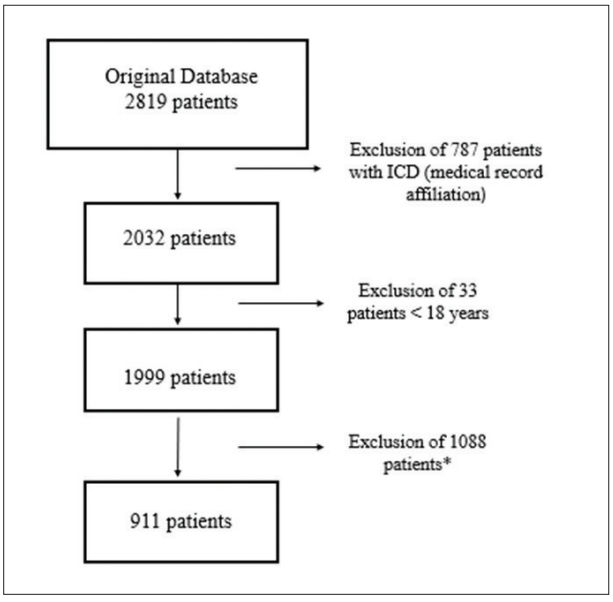

Figure 1 – *Patient Selection Flowchart. *Patients undergoing follow-up at the tertiaty center's cardiac device laboratory, but the initial implantation of the device was performed in another hospital or at a different time period to the present study.*

Table 1 – Baseline characteristics of the population

Characteristics	Chagas (N=213)	Non-Chagas (N=698)	Total (N=911)	p-Value
Age – years	65 (23-93)	69 (20-97)	68 (20-97)	<0.001
Male sex- n (%)	96 (21.7%)	346(78.3%)	442 (48.5%)	0.284
Devices- n (%)				<0.001
Single-chamber PM	35 (16.4%)	114 (16.3%)	149 (16.4%)	
Dual chamber PM	165 (77.5%)	409 (58.6%)	574 (63%)	
CRT	7 (3.3%)	126 (18.1%)	133 (14.6%)	
CRT with ICD	6 (2.8%)	49 (7.0%)	55 (6.04%)	

PM: pacemaker; ICD: implantable cardioverter-defibrillators; CRT: cardiac resynchronization therapy.

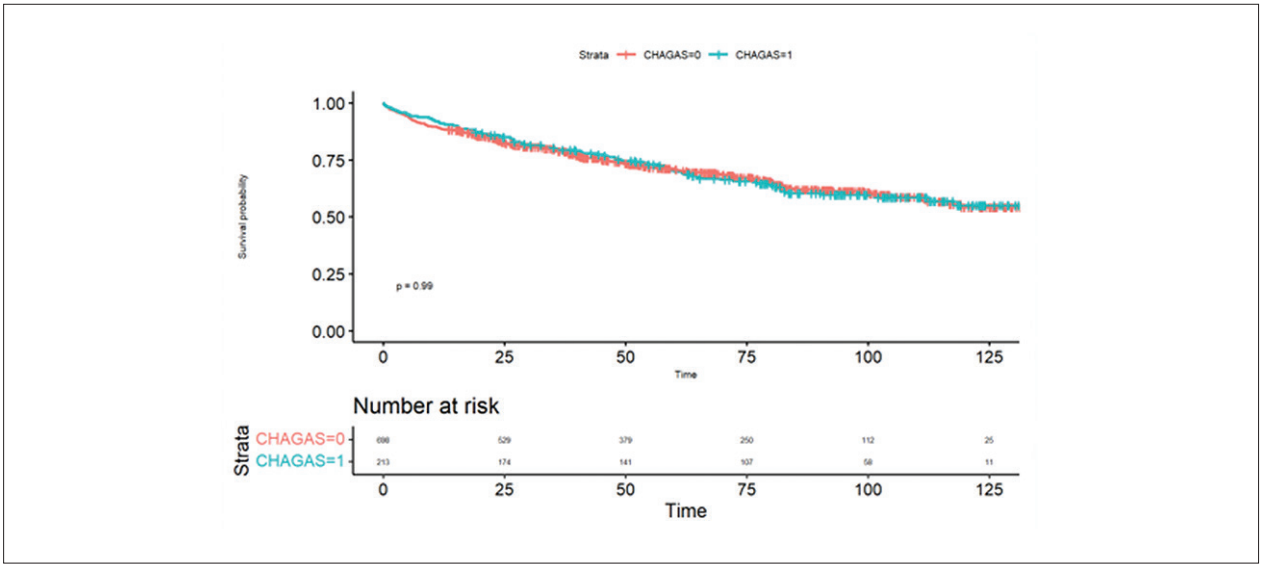

Figure 2 – *Kaplan-Meier Survival Curve for All-Cause Mortality by Etiology. Chagas=0: Absence of Chagas Disease; Chagas=1: Presence of Chagas Disease. Survival curves were compared using the long rank test, p=0.99.*

This result contrasts with previous studies that have shown worse prognoses for Chagas patients when compared to other dilated cardiopathies.[8,11,12] Typically, this worse prognosis is associated with a high incidence of sudden cardiac death (responsible for 55% to 65% of deaths in these patients), as well as non-cardiac deaths and various arrhythmias.[4,11,13,14] In a comparison between Chagas and non-Chagas patients with PM, Rincon et al. also found worse clinical outcomes in Chagas patients, with a higher incidence of ventricular arrhythmias.[8]

Another serious manifestation resulting in fatal outcomes due to cardiac involvement in Chagas disease is advanced heart failure (HF), accounting for 25% to 30% of deaths in this population.[7,11,15] As Chagas patients progress with ventricular dysfunction and worsening functional class, their severity increases, leading to a poorer quality of life, higher mortality rates, and hospitalizations.[7] Consequently, they require specialized clinical and pharmacological treatment with regular multidisciplinary follow-up,[7,16] becoming more sensitive to economic and social circumstances that disproportionately impact the health-disease continuum.[4,17,18]

On the other hand, establishing reference services for managing and monitoring individuals with chronic diseases

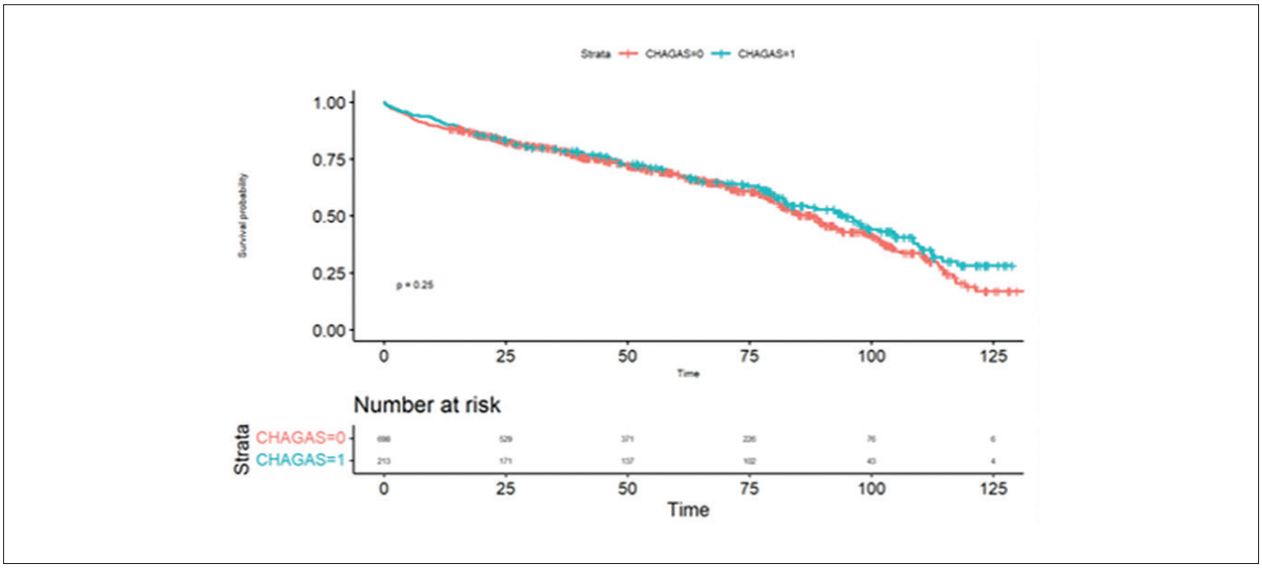

Figure 3 – *Kaplan-Meier Survival Curve for Combined Mortality and Hospitalization by Etiology. Absence of Chagas Disease; Chagas=1: Presence of Chagas Disease. Survival curves were compared using the long rank test, p=0.25.*

Table 2 – Cox Regression Model for the Chagas Population – Multivariate Analysis (adjusted for sex and age)

Chagas Disease	HR (CI- 95%)	p- Value
Total Mortality	1.14 (0.86-1.51)	0.365
Mortality by Eras		
Era 1	1.17 (0.83-1.66)	0.38
Era 2	0.87 (0.53-1.41)	0.56
Era 3	1.29 (0.57-2.90)	0.55
Hospitalization	0.79 (0.61-1.04)	0.09
Mortality and Hospitalization	0.90 (0.72-1.12)	0.49

HR: hazard ratio; CI: confidence interval.

Table 3 – Cox Proportional Hazards Model for Mortality Outcome Assessment – Univariate Analysis

Variables	HR (CI- 95%)	p- Value
Age	1.02 (1.01-1.03)	p<0.001
Male Sex	1.49 (1.16-1.92)	p=0.002
Chagas		
Overall Mortality	0.99 (0.75-1.30)	p=0.91
Device-related Mortality		
Biventricular Pacemaker	1.1 (0.79-1.53)	p=0.59
Univentricular Pacemaker	0.84 (0.51-1.37)	p= 0.49

HR: hazard ratio; CI: confidence interval.

promotes better adherence to pharmacological and non-pharmacological treatments, improves quality of life, and reduces mortality and hospitalization rates.[4] The center where this study was conducted underwent continuous structural improvements to provide care for such patients over the past two decades. Therefore, the present results could also be attributed to the organization, effective follow-up, and treatment of cardiopathies in general, including specialized teams managing arrhythmias and heart failure.[16,19] The evaluation of mortality across three different eras reinforces the quality of care over time, demonstrating no difference in mortality between Chagas and non-Chagas populations, regardless of the analyzed period.

Regarding the general characteristics of the study population, advanced age and male sex were predictors of higher mortality in the univariate Cox analysis. These results align with other studies that evaluated the clinical profile of pacemaker recipients, showing that Chagas patients were younger than the non-Chagas population at the time of implantation.[8,9] Additionally, female patients tend to have better survival after pacemaker implantation.[20] Considering these factors, all results were adjusted for age and sex, maintaining no difference in mortality, hospitalization, or the combined outcome of mortality and hospitalization between the Chagas and non-Chagas populations.

In summary, this study demonstrated relevant findings regarding the prognosis of patients with implantable electronic cardiac devices, both for those with Chagas disease and those without. The creation of a large database using natural language processing allowed for the evaluation of a significant cohort of individuals with PM and CRT, with a substantial representation of Chagas patients.

However, there are some limitations to consider. First, the use of NLP does not achieve 100% sensitivity,[10] which may result in some loss of outcomes. Nevertheless, the random sampling of NLP results with manual review and adjustments demonstrated good accuracy and sensitivity. Second, the exclusion of patients with isolated ICDs, who are supposed to have more severe cardiomyopathy and prone to present with serious arrhythmias,[13,21] could have selected a less severe group. Still, this would apply equally to chagasic and non-chagasic patients with the device in question. Additionally, a complementary study using the same database, focusing solely on the ICD population (Chagas and non-Chagas), found no difference in all-cause mortality between the two groups.[14]

Unequal distribution of more complex devices, such as isolated CRT and CRT combined with ICDs, could also be considered a limitation. It is well-established that Chagas disease imposes restrictions that predict a poorer response to cardiac resynchronization therapy.[4,22-27] However, the potential influence of these devices on patient mortality was evaluated through sensitivity analysis, excluding patients with CRT devices, and the results remained consistent, showing no difference in mortality between the Chagas and non-Chagas populations.

Finally, it is essential to note that this retrospective and observational analysis relies on the quality of information in medical records, which lacked detailed clinical and laboratory conditions of patients and did not include data on medication therapy. Therefore, further studies, preferably prospective ones, are necessary to confirm these findings.

Conclusion

The presence of Chagas disease was not associated with an increased risk of death, hospitalization, or the combined outcome of mortality and hospitalization in this cohort of patients with pacemakers and cardiac resynchronization devices. These results remained consistent even when analyzed across different follow-up periods and adjusted for sex and age.

Author Contributions

Conception and design of the research, Analysis and interpretation of the data and Critical revision of the manuscript for content: Vasconcelos LT, Castilho FM, Ribeiro ALP; Acquisition of data: Vasconcelos LT, França AT; Statistical analysis: Martins LNA; Writing of the manuscript: Vasconcelos LT.

Potential conflict of interest

No potential conflict of interest relevant to this article was reported.

Sources of funding

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Study association

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Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Universidade Federal de Minas Gerais under the protocol number CAAE 56119122.0.0000.5149. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013.

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*Supplemental Materials

For additional information, please click here.