

# Quality of life in patients before and after implantation of an implantable cardioverter-defibrillator: a longitudinal study

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## ABSTRACT

**Objective:** To assess the quality of life of patients before and after implantable cardioverter defibrillator implantation. **Methods:** An analytical, longitudinal, observational study conducted at a university hospital in the interior of São Paulo. A consecutive, non-probabilistic sample consisted of 18 patients of both sexes, aged over 18 years, with indication for surgery for implantable cardioverter defibrillator implantation. Data collection was performed through individual interviews and consultation of participants' medical records. The SF-36 Medical Outcomes Study 36 - Item Short-Form Health Survey instrument was used to assess the health-related quality of life of patients, considering the eight domains. The Friedman test, with  $\alpha = 5\%$ , was used to compare the measures of the construct in the three investigated periods. **Results:** Most patients were male and lived with a partner. The age range was from 29 to 77 years, with a mean of 57.7 years. A significant difference was obtained in the median value when comparing the three times only in the "Pain" Domain ( $p=0.029$ ), namely: median of 35.0 in the preoperative period versus 15.0 three months after surgery. **Conclusion:** The effect of time was observed in the evaluation of the "Pain" Domain, that is, patients presented more pain symptoms at the three-month return when compared to the preoperative period.

**Descriptors:** Quality of Life; Implantable defibrillators; Perioperative Nursing.

## RESUMO

**Objetivo:** Avaliar a qualidade de vida de pacientes antes e após o implante de cardioversor desfibrilador implantável. **Método:** Estudo observacional analítico e; longitudinal, realizado em um hospital universitário do interior de São Paulo. Uma amostra consecutiva; e não probabilística; foi constituída por 18 pacientes de ambos os sexos, com idade acima de 18 anos, com indicação de cirurgia para implante do cardioversor desfibrilador implantável. A coleta de dados foi realizada por meio de entrevistas individuais e consulta aos prontuários dos participantes. Para a avaliação da qualidade de vida relacionada à saúde dos pacientes, foi utilizado o instrumento SF-36 Medical Outcomes Study 36 - Item Short-Form Health Survey, considerando os oito domínios. Para a comparação das medidas do constructo nos três tempos investigados, foi utilizado o teste de Friedman, com  $\alpha = 5\%$ . **Resultados:** A maioria dos pacientes era do sexo masculino e vivia com companheiro. A faixa etária variou de 29 a 77 anos, com média de 57,7 anos. Obteve-se diferença significativa no valor das medianas, quando comparados os três tempos somente no domínio "dor" ( $p=0,029$ ), a saber: mediana de 35,0 no pré-operatório versus 15,0 três meses após a cirurgia. **Conclusão:** Observamos o efeito do tempo na avaliação do domínio "dor", ou seja, os pacientes apresentaram mais sintomas de dor no retorno de três meses, quando comparados com o pré-operatório.

**Descritores:** Qualidade de Vida; Desfibriladores implantáveis; Enfermagem Perioperatória.

## RESUMEM

**Objetivo:** Evaluar la calidad de vida de los pacientes antes y después del implante de un cardiodesfibrilador implantable. **Método:** Estudio observacional analítico, longitudinal, realizado en un hospital universitario del interior de São Paulo. Se conformó una muestra consecutiva y no probabilística de 18 pacientes de ambos sexos, mayores de 18 años, con indicación quirúrgica para el implante del cardiodesfibrilador implantable. La recolección de datos se llevó a cabo mediante entrevistas individuales y consulta a los expedientes clínicos de los participantes. Para la evaluación de la calidad de vida relacionada con la salud de los pacientes, se utilizó el instrumento SF-36 Medical Outcomes Study 36-Item Short-Form Health Survey, considerando sus ocho dominios. Para la comparación de las medidas del constructo en los tres momentos investigados, se aplicó la prueba de Friedman, con  $\alpha = 5\%$ . **Resultados:** La mayoría de los pacientes eran hombres y vivían con pareja. La franja etaria osciló entre 29 y 77 años, con una media de 57,7 años. Se observó una diferencia significativa en el valor de las medianas al comparar los tres momentos solo en el dominio "Dolor" ( $p=0.029$ ), con una mediana de 35.0 en el período preoperatorio frente a 15.0 tres meses después de la cirugía. **Conclusión:** Se evidenció el efecto del tiempo en la evaluación del dominio "Dolor", es decir, los pacientes presentaron más síntomas de dolor en el seguimiento a tres meses en comparación con el período preoperatorio.

**Descritores:** Calidad de Vida; Desfibriladores Implantables; Enfermería perioperatoria.

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## Introduction

In recent decades, Non-Communicable Chronic Diseases (NCDs) have claimed the lives of approximately 57 million individuals each year, accounting for 82% of all deaths worldwide. In Brazil, NCDs are a health priority due to their significant contribution to the mortality rate of the Brazilian population <sup>(1)</sup>. Cardiovascular diseases (CVDs) make up nearly half of these NCDs, potentially affecting over 23.6 million individuals by around 2030 <sup>(2)</sup>. In Brazil, CVDs have remained the leading cause of death, responsible for 17.9 million deaths per year, which represents 44% of all deaths due to NCDs <sup>(3)</sup>.

Among cardiovascular diseases, arrhythmias are particularly noteworthy. Cardiac arrhythmias accounted for more than 150.000 hospitalizations in the last five years in Brazil, with the Southeast region alone recording 82.295 hospitalizations during the same period <sup>(2)</sup>. Currently, it is estimated that over 20 million people suffer from some type of cardiac arrhythmia, which is responsible for more than 300.000 sudden deaths annually in the country, predominantly affecting the elderly <sup>(4)</sup>.

Regarding arrhythmia treatment, available resources include antiarrhythmic drugs, surgical resection, endocardial catheter ablation, and the implantation of devices such as the Implantable Cardioverter-Defibrillator (ICD) <sup>(5)</sup>.

The primary indication for ICD implantation is the prevention of sudden cardiac death (SCD) resulting from ventricular tachycardia (VT) and/or ventricular fibrillation (VF). The ICD is indicated for primary prevention in individuals at high risk for SCD, even if they have not experienced a cardiac arrest, and for secondary prevention in individuals who have already experienced a potentially fatal arrhythmic episode or have been resuscitated from cardiac arrest due to VF or pulseless VT <sup>(6)</sup>.

Thus, when an individual suffers from severe arrhythmias, the ICD becomes the best option for survival; however, these patients experience ambivalent feelings regarding both the underlying disease and the necessity of the device. They live with a constant worry about potential device failure, anxiety concerning the battery's lifespan, fear of performing routine household activities, concerns about job loss, changes in sexual activity, and loss of social, family, and professional status. Additionally, they report perceptions of alterations in self-image and a sense of premature bodily deterioration <sup>(7)</sup>.

The individual undergoing ICD implantation is typically exposed to various experiences that can adversely affect mood, such as a recovered cardiac arrest, prolonged hospitalizations, the diagnosis of a heart condition that necessitates the ICD as a treatment modality, the prospect of recurrent potentially fatal arrhythmias, the reality of mortality, uncertainty about the future, and the device's shock therapies <sup>(8)</sup>. It is considered that the period immediately following implantation is the most aversive and psychologically challenging due to the numerous adjustments required <sup>(9)</sup>.

Despite the numerous proven clinical benefits, there is evidence that the ICD can cause psychological adverse effects to varying degrees, potentially impacting patients' lifestyle and quality of life (QoL). Although most patients with an ICD adapt well, some may

experience difficulties in psychological adjustment<sup>(7-8)</sup>.

Some studies in the literature have cross-sectionally evaluated the Health-Related Quality of Life (HRQoL) in patients with ICDs. However, there is a scarce number of longitudinal investigations of this construct in this population<sup>(10-13)</sup>. Moreover, available longitudinal studies were published more than five years ago and are international studies<sup>(8-9)</sup>.

Given the above, the following question is posed: Will patients undergoing ICD implantation show differences in the assessment of health-related quality of life (HRQoL), as measured by the SF-36, as well as in symptoms of anxiety, depression, and cardiac anxiety, as evaluated by the HADS and QAC, in the preoperative period, and three and nine months after implantation? To answer this question, the objective was set to evaluate the quality of life of patients before and after the implantation of an implantable cardioverter-defibrillator.

## Methods

This is an analytical observational longitudinal study conducted in the Medical Clinic Inpatient Units, the Surgical Block reception area, and the Arrhythmia Outpatient Clinic of a university hospital in the interior of São Paulo.

This article was prepared according to the guidelines for observational studies Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), recommended by The EQUATOR Network. Data were collected from October 2018 to March 2020.

A consecutive, non-probabilistic sample was comprised of patients of both sexes, aged over 18 years, who were indicated for ICD implantation surgery.

Patients who did not demonstrate orientation to time, place, and person to answer the questionnaires in the preoperative period, those who exhibited clinical decompensation of their heart condition on the day of preoperative data collection (i.e., the presence of dyspnea, arrhythmia, syncope, or orotracheal intubation), and those indicated for concomitant implantation of a cardiac resynchronization device with the ICD were excluded.

To identify patients with adequate orientation, six questions were administered (14): "What is today's date?", "What is your age?", "What day of the week is it?", "What is the name of the place where we are right now?", "What is your full name?", and "What is the name of the city where you were born?" Participants were excluded from the study if they answered three or more of these questions incorrectly or were unable to answer them.

Data were collected through individual interviews and by reviewing the participants' medical records at three different time points.

At the first time point, "T<sub>0</sub>," data were collected on the day of the ICD implantation

surgery, during the preoperative period, either in the Medical Clinic Inpatient Units or in the waiting area of the Surgical Block. Sociodemographic and clinical characterization data were obtained through patient interviews and review of medical records, in addition to the assessment of health-related quality of life (HRQoL). Patients could be either outpatients or inpatients. Outpatients arrived at the hospital on the day of the implantation in the morning, while inpatients remained in the wards until the anesthetic-surgical procedure. Since the surgeries took place in the afternoon, data collection for both groups occurred in the morning.

At the second time point, "T<sub>1</sub>," data were collected three months after the ICD implantation during a routine visit to the arrhythmia outpatient clinic. Information regarding the patients' postoperative progress was gathered through interviews and review of their medical records, in addition to an assessment of health-related quality of life (HRQoL).

At the third and final time point, "T<sub>2</sub>," data were collected nine months after the ICD implantation during a routine consultation at the arrhythmia outpatient clinic. Postoperative progress information was gathered through interviews and review of medical records, along with an assessment of health-related quality of life (HRQoL).

For the characterization of the participants, an instrument was developed based on a review of the literature and previous studies, containing the data necessary for their description<sup>(9-12)</sup>:

*T<sub>0</sub> – Preoperative:*

- Sociodemographic Data: Birth date, date of hospitalization, date of the anesthetic-surgical procedure, and date of the interview; sex (female or male), presence of a partner (yes or no), education (in complete years), employment status (active or inactive), and monthly family income (in Brazilian reais). Age, in complete years, was calculated by subtracting the birth date from the interview date.
- Clinical data,: we recorded the ICD implantation rhythm indication (VT or VF), the underlying disease (including ischemic cardiomyopathy, Chagas cardiomyopathy, hypertrophic cardiomyopathy, idiopathic dilated cardiomyopathy, arrhythmogenic right ventricular dysplasia, or Brugada syndrome), associated conditions (such as dyslipidemia, hypothyroidism, diabetes mellitus, chronic obstructive pulmonary disease, neurological diseases, acute renal failure, chronic renal failure, systemic arterial hypertension, heart failure, Chagas disease, and atrial fibrillation), lifestyle habits (current and past smoking), a family history of coronary artery disease and sudden death, the indication for ICD implantation (primary or secondary), and the use of psychotropic medications.

*T<sub>1</sub> – Three months after implantation:*

- Postoperative evolution data: were collected, including the date of the three-month follow-up visit, attendance at the 15-day return, the need for additional visits outside of the scheduled period, and the presence of postoperative complications (such as surgical site infection, ICD extrusion, lead displacement, shocks, syncope, arrhythmias, and dyspnea).

*T<sub>2</sub> – Nine months after implantation:*

- Postoperative evolution data: postoperative evolution data were collected, including the

date of the nine-month follow-up visit, attendance at the three-month follow-up visit, the need for additional visits outside of the scheduled period, the presence of postoperative complications (such as surgical site infection, ICD extrusion, lead displacement, shocks, syncope, arrhythmias, and dyspnea), and the outcome after nine months of ICD implantation (alive, deceased, or lost to follow-up at the hospital).

For the evaluation of health-related quality of life, the SF-36 Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)<sup>(15)</sup> was used, in its version validated in Brazil by Ciconelli and colleagues<sup>(16)</sup>.

The SF-36 is a generic, multidimensional instrument composed of 36 items distributed across eight domains: "Functional Capacity" (10 items), "General Health Perceptions" (5 items), "Mental Health" (5 items), "Physical Aspects" (4 items), "Vitality" (4 items), "Emotional Aspects" (3 items), "Pain" (2 items), and "Social Aspects" (2 items). The scores for each domain are standardized on a scale from zero to 100, where lower numerical values indicate a poorer evaluation of health-related quality of life in that domain. There is no single overall score for the assessment; rather, the evaluation is based on the performance in each domain. This approach is intended to prevent the averaging out of values, which could obscure the true health-related problems experienced by the patient or even lead to their underestimation<sup>(15)</sup>.

In addition to the eight domains, the instrument includes a comparative evaluation question regarding the current health status versus that of one year ago (this item does not belong to any domain). The response options are: (1) "Much better now than one year ago"; (2) "A little better now than one year ago"; (3) "Almost the same as one year ago"; (4) "A little worse now than one year ago"; and (5) "Much worse now than one year ago." Thus, the possible response range for this item is from one to five, with lower scores indicating a better evaluation of the current health condition. In the present study, to analyze the response to this item, we compared the median score in the preoperative period with that obtained nine months after implantation.

To answer the items, patients considered the last four weeks of their lives. The data were entered into IBM SPSS, version 22.0 for Windows (SPSS, Inc., Chicago, IL, USA).

For the sociodemographic and clinical characterization, simple frequency analyses were conducted for nominal or categorical variables, while measures of central tendency (mean and median) and dispersion (standard deviation) were used for numerical variables.

To compare the HRQoL measures in the preoperative period, as well as three and nine months after ICD implantation, the Friedman test was employed. In this analysis, all eight domains of the SF-36 were utilized.

For the analysis of the comparative evaluation question regarding current health status versus that of one year ago, the Mann-Whitney test was used, comparing the median obtained in the preoperative period with the median obtained at the nine-month follow-up after implantation. The significance level adopted was 0.05.

The research project was developed in accordance with the ethical guidelines outlined in the National Health Council Resolution No. 466 of December 12, 2012, and was

approved by the Human Research Ethics Committee of the proposing institution (Approval No. 2.768.856). Patients were invited to participate in the study, and after agreeing, they received a thorough explanation of the study before signing the Informed Consent Form (ICF). Two copies of the ICF were provided one for the patient and one to be filed by the researcher.

## Results

During the data collection period, 18 patients participated in the study.

The sociodemographic and clinical characteristics of the patients who underwent ICD implantation are presented in Tables 1 and 2.

**Table 1 – Sociodemographic characterization of patients who underwent implantable cardioverter-defibrillator (ICD) implantation according to sex, age, marital status, education, monthly income, number of dependents, and employment status. São Paulo, Brazil, 2018-2020**

Variable	n (%)	Média (DP)*	Mediana
<b>Gender</b>			
Male	13 (72,2)		
Female	05 (27,8)		
<b>Age (years)</b>		57,7 (13,2)	57,0
<b>Presence of a Partner</b>			
Yes	13 (72,2)		
<b>Education (complete years)</b>		8,1 (3,8)	8,0
<b>Family Monthly Income (in reais)</b>		2.276,3 (1.291,0)	
<b>Dependents on the Income</b>		2,4 (1,04)	2,0
<b>Employment Status</b>			
Inactive	16 (88,9)		

Média (DP)\* = Média (Desvio-Padrão).

Source: Author

**Table 2 – Clinical characterization of patients undergoing implantable cardioverter defibrillator implantation, according to the indication for the implantation, the underlying disease, presence of associated diseases, lifestyle habits, previous family history of coronary artery disease and/or sudden death, and the use of psychotropic drugs at home. São Paulo, Brazil, 2018-2020**

Variable	n (%)
<b>ICD Implantation Indication</b>	
Ventricular Tachycardia (VT)	11 (61,1)
Ventricular Tachycardia (VT)	5 (27,8)
Not described in the medical record	2 (11,1)

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**Continuation**

Variable	n (%)
<b>Underlying Disease</b>	
Chagas cardiomyopathy	7 (38,9)
Ischemic cardiomyopathy	6 (33,4)
Hypertrophic cardiomyopathy	4 (22,2)
Idiopathic dilated cardiomyopathy	1 (5,6)
<b>Associated Diseases</b>	
Systemic Arterial Hypertension	10 (55,6)
Chagas Disease	7 (38,9)
Diabetes Mellitus	4 (22,2)
Hypothyroidism	1 (5,6)
Chronic Obstructive Pulmonary Disease (COPD)	1 (5,6)
<b>Smoking</b>	
Past	7 (38,9)
Current	1 (5,6)
Family History of Coronary Artery Disease (Yes)	12 (66,7)
Family History of Sudden Death (Yes)	8 (44,4)
Use of Psychotropic Medications at Home (Yes)	3 (16,7)

**Source: Authors**

In addition to the results presented, four patients (22.2%) underwent ICD implantation as primary prevention, while 14 patients (77.8%) received it as secondary prevention.

Table 3 presents the postoperative evolution at three and nine months following ICD implantation.

**Table 3 – Postoperative Evolution of Patients at T1 and T2, Based on attendance at follow-up visits, the need for additional visits outside the scheduled period, and the occurrence of postoperative complications- São Paulo, Brazil, 2018-2020.**

Variable	3 Months After Implantatio (%)	9 Mouths After Implantation (%)
Attendance at the 15-day and 3-month follow-up visits	18 (100)	18 (100)
Need for additional visits outside the scheduled period	2 (11,1)	4 (22,2)
Postoperative Complications	4 (22,2)	2 (11,1)
Arrhythmias		

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Continuation		
Presence of shocks	3 (16,7)	2 (11,1)
Presence of syncope	2 (11,1)	2 (11,1)
Dyspnea	1 (5,6)	4 (22,2)
Surgical site infection	zero	zero
ICD extrusion	zero	zero
Lead displacement	zero	zero

Source: Authors

Table 4 presents the medians for the eight SF-36 domains and their comparison across the three time points in this study: preoperative, three months, and nine months after ICD implantation.

**Table 4 – Comparison of the medians for the eight SF-36 domains among patients undergoing ICD implantation at T0, T1, and T2, along with the p-values associated with the Friedman test. São Paulo, Brazil, 2018-2020.**

Variable	Median (Mín-Máx)*	Median (Mín-Máx)*	Median (Mín-Máx)*
SF-36 Domains†			
Functional Capacity	27,5 (10-75)	35,0 (10-75)	35,0 (5-75)
P-value		0,059	
Physical Aspects	zero (0-100)	zero (0-100)	zero (0-100)
P-value		0,779	
Pain	35,0 (0-70)	15,0 (0-60)	20,0 (0-70)
P-value		0,005 ‡	
General Health	54,5 (25-77)	49,5 (27-92)	49,5 (27-82)
P-value		0,500	
Vitality	45,0 (15-90)	50,0 (15-90)	55,0 (20-100)
P-value		0,109	
Social Aspects	56,2 (13-100)	75,0 (25-100)	56,2 (25-100)
P-value		0,247	
Emotional Aspects	33,3 (0-100)	33,3 (0-100)	33,3 (0-100)
P-value		0,687	
Mental Health	58,0 (28-100)	64,0 (24-96)	66,0 (24-92)
P-value		0,252	

\* Mín-Máx: Mínimo-Máximo; SF-36†: Medical Outcomes Study 36 - Item Short-Form Health Survey; p<0.05‡: significância estatística.

Source: Authors



We can observe the effect of time on the HRQoL evaluation of patients undergoing ICD implantation in the “Pain” domain. The multiple comparisons test revealed that the rank values for the “Pain” domain in the preoperative period and at the three-month follow-up were significantly different ( $p=0.029$ ). Patients exhibited more pain symptoms at the three-month follow-up compared to the preoperative period.

Regarding the result of the comparative evaluation question between the current health condition and that of one year ago, the median obtained in the preoperative period was 4.0, whereas the median obtained nine months after implantation was 2.0. The difference was statistically significant ( $p=0.004$ ). Patients evaluated their current health condition as better compared to one year ago.

## Discussion

Currently, the benefits of the ICD in reducing sudden cardiac death (SCD) are indisputable. However, there is a need to understand the emotional consequences and impact on health-related quality of life (HRQoL) following implantation.

Issues related to HRQoL have been drawing interest in the field of surgical specialties due to their individual, social, and economic implications<sup>(17)</sup>.

Our data showed that the majority of the median scores for HRQoL domains did not exceed 50 points both before and after ICD implantation. However, some reflections are warranted.

Regarding the longitudinal assessment of HRQoL, it was observed that patients exhibited higher median scores over time in the “Functional Capacity,” “Vitality,” and “Mental Health” domains, although the differences were not statistically significant.

The “Functional Capacity” domain indicates the extent to which a patient’s health conditions interfere with daily physical activities, such as the ability to walk, climb stairs, or perform strenuous tasks. The “Vitality” domain assesses the energy and enthusiasm displayed by the patient. Finally, the “Mental Health” domain aims to investigate aspects such as nervousness, feelings of discouragement, or experiences of happiness and tranquility, among others<sup>(18)</sup>.

Therefore, it is believed that the three SF-36 domains described above are related to the patient's adaptation to the device implantation. Over time, the patient recovers from the implantation procedure, adapts to the device, and demonstrates increased willingness to perform daily activities as well as improvements in emotional symptoms<sup>(10)</sup>. Moreover, an improvement in the symptoms caused by the underlying disease is expected, as the device has begun to contribute to the treatment.

On the other hand, we found that the patients exhibited lower median scores over time in the “Pain,” “General Health Perceptions,” and “Social Aspects” domains, with the difference being statistically significant only in the “Pain” domain.

Patients exhibited more pain symptoms at the three-month follow-up compared to the preoperative period.

This finding may be directly related to the recent surgical procedure. In light of this result, it becomes important to evaluate the prescribed analgesia for these patients during the intermediate and late postoperative periods.

It is known that pain can influence an individual's functional capacity, as it may have a negative impact on the performance of daily and/or work-related activities. Observations indicate that the more pain an individual experiences, the more likely their health-related quality of life is compromised <sup>(19)</sup>.

It is noteworthy that, even without significant differences, patients exhibited a worsening in the evaluation of the “General Health Perceptions” and “Social Aspects” domains.

The “General Health Perceptions” domain assesses how patients perceive their overall health—whether they feel healthy, believe they fall ill easily, compare their health to that of others, among other factors. It is important to note that the nature of the items in this domain differs from those in the “Functional Capacity” domain, which are more focused on assessing the ability to perform physical activities. In light of this, patients may have shown improvement in performing physical activities, possibly due to the alleviation of symptoms associated with the underlying disease, yet they might still harbor concerns about their overall health even after ICD implantation.

The “Social Aspects” domain assesses the extent to which physical or emotional health interferes with the patient's normal social activities, particularly in relation to family and other social relationships. This finding can be linked to evidence in the literature indicating that the first year after implantation is the most challenging for the patient <sup>(9)</sup>, as well as to issues regarding self-image perception due to the presence of the ICD <sup>(7)</sup>.

Patients exhibited the same median values across the three time points in the “Physical Aspects” and “Emotional Aspects” domains. The “Physical Aspects” domain evaluates issues related to the patient's work, such as whether they needed to reduce their working hours, performed less work than desired, or experienced difficulties due to their physical health. Similarly, the “Emotional Aspects” domain assesses factors related to work performance, like reduced working hours or lack of concentration, but as a consequence of emotional health. This finding may be related to the fact that the majority of the study's patients were already inactive before the implantation.

It is evident that the period immediately following ICD implantation is the most complex and challenging due to the various adaptations required after the procedure. Moreover, during the first year post-implantation, some patients experience difficulties adapting to their new way of life, such as fear of shocks, sleep disturbances, reduced physical activity, pain, and decreased self-esteem. In addition, they are more prone to developing anxiety and depression, which can negatively impact their health-related quality of life <sup>(9,20)</sup>.

Even in light of these findings, in the present study, patients demonstrated an overall better evaluation of their health condition nine months after ICD implantation, which is consistent with two other studies <sup>(5, 21)</sup>. As previously reported, although the first year after implantation tends to be the most challenging period in terms of adapting to the new health

condition due to dependence on the device, it is expected that over time and with increased familiarity with the device the treatment provided by the ICD will improve the symptoms of the underlying cardiac disease, thereby enhancing the overall health condition.

The authors conducted a longitudinal study to describe the changes in the life situation of patients with an ICD. As a result, they found an improvement in the patients' lives during the 12 months following ICD implantation. Furthermore, they noted that the physical, emotional, intellectual, sociocultural, and spiritual dimensions were affected to some extent after the implantation <sup>(12)</sup>.

When comparing the HRQoL of patients before and at two, six, and 12 months after ICD implantation, the authors found that HRQoL was significantly reduced before and two months after the implant; however, it improved over time. According to the authors, this improvement may be related to the adaptation to the device <sup>(11)</sup>.

In general, during the first year after ICD implantation, patients tend to progress and achieve better physical and emotional functioning in their lives, especially during the first six months. Moreover, this improvement in physical functioning may influence enhancements in both vitality and functional capacity <sup>(21)</sup>.

The study demonstrated that the transition toward better health significantly improved over the course of the year, supporting the claim that patients' health perception was enhanced one year after ICD implantation <sup>(13)</sup>.

Regarding the study's limitations, it is important to note that, as a longitudinal study, the sample size was considerably small despite efforts to recruit participants. Due to the COVID-19 pandemic, caused by the spread of the novel coronavirus, the population of the State of São Paulo was advised by global health authorities and local leaders to remain at home and cease attending their workplaces during the period of social isolation. Consequently, data collection had to be interrupted.

Nonetheless, despite its limitations, this study provides important insights regarding the impact of ICD implantation on patients' health-related quality of life (HRQoL) both before and after the procedure. The generation of national data is essential to properly design interventions addressing the psychological aspects of these patients. Furthermore, these findings allow us to understand the variance of the HRQoL construct longitudinally, which can be used in future sample size calculations for intervention studies aimed at improving HRQoL in this population.

Finally, it is important to emphasize that when a patient undergoes ICD implantation, their life is transformed, and it is essential for professionals to recognize these changes and facilitate the patient's understanding and adaptation after the procedure keeping in mind the patient's own perceptions and concerns, and looking beyond the electronic device. It is crucial to identify strategies that can assist patients in adapting to living with an ICD, as well as to contribute to improvements in their health-related quality of life.

## Conclusions

Regarding the longitudinal assessment of patients' HRQoL before and after ICD implantation, we found that patients exhibited worse evaluations in the "Pain" domain at the three-month follow-up compared to the preoperative period. We did not observe any

any differences in the other SF-36 domains when comparing the preoperative, three-month, and nine-month assessments following ICD implantation.

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## Author Contribution

Fernandes PA. I participated in: Conception and development of research, obtaining of data, analysis and interpretation of data, obtaining of financing, drafting of the manuscript, critical review of the manuscript regarding intellectual content. Maier SRO. I participated in: Conception and development of research, obtaining of data, analysis and interpretation of data, statistical analysis, obtaining of financing, drafting of the manuscript, critical review of the manuscript regarding intellectual content. Dessotte CAM. I participated in: Conception and development of research, obtaining of data, analysis and interpretation of data, statistical analysis, obtaining of financing, drafting of the manuscript, critical review of the manuscript regarding intellectual content.

## Conflict of Interest

The authors certify that no commercial or associative interest presents a conflict of interest regarding the manuscript.

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