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## Quality of life of patients with implanted cardiac devices: a transversal study

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### ABSTRACT

**Objective:** Evaluate the quality of life (QL) of patients with implanted cardiac devices and describe the recognition of electromagnetic sources, and symptoms, in the event of failure of the device. **Method:** This is a transversal study that used the SF-36 questionnaire and an instrument developed to observe other variables. **Results:** The research included 100 patients, 58±13 years of age, predominantly male. In relation to QL, scores were: functional capacity = 58±26; pain = 65±32; vitality = 58±26; social aspects = 72±31; mental health = 69±26; physical aspects = 12.5(0-50); emotional aspects = 33(0-100); general health status = 49±25. The majority of the patients (91%) know that the device could suffer from interference. **Conclusion:** The sample of this study showed low QL scores in physical and emotional aspects, and in general health status. Besides that, patients were aware that their devices could suffer from magnetic interference, but they could not name the main source of that interference.

**Keywords:** Quality of Life; Implantable Defibrillators; Artificial Cardiac Pacing; Nursing

## INTRODUCTION

Implanted defibrillator cardioversors (IDC) are used for the treatment of ventricular arrhythmia and the prevention of sudden death. IDC controls the cardiac rhythm in a similar way to the traditional bypass, with stimulus during bradycardia, or its inhibition in the case of an adequate rhythm on the part of the patient. In patients with heart failure (HF) and with an ejection fraction (EF) lower than 35%, independently of the etiology, IDC has an important role to play in primary prophylaxis of sudden death, as described in the studies *Multicenter Automated Defibrillator Implantation (MADIT1)* and *Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)*<sup>(1)</sup>. Besides the benefits resulting from the implantation of IDC, it is acknowledged that 50% of the patients present a significant increase in levels of anxiety, depression, anger, fear of returning to normal physical activities, fear of death, fear of failure in the equipment, and fear of having an electrical discharge from the IDC<sup>(2)</sup>.

Cardiac resynchronization (CR) been developed recently as a alternative treatment for patients with advanced HF; EF  $\leq$  35%, wide QRS ( $>$  120ms) and with optimized clinical therapy. This device works by resynchronizing the contractions of the ventricle through electrodes implanted in each ventricle, thus improving the ejection volume by assisting the systolic movement. The combination of IDC and CR increases the survival rate of patients, as was described in *Comparison of Medical Therapy Pacing And Defibrillation in Heart Failure Trial (COMPANION)*<sup>(1)</sup>.

Considering that the implantation of such devices usually generate doubts, fear and anxiety among patients and caregivers, some studies have evaluated the quality of life (QL) in this group of patients using *The Medical Outcomes Study 36-Item Short-Form Healthy Survey (SF-36)*. The quality of life related to health is related to the way people perceive their own general health status, their social life, their physical and psychological situation, and how they perform their daily activities<sup>(2,3)</sup>.

Using the SF-36, one study evaluated the QL of 50 patients who were fitted with IDC, with ages averaging 58 years, and presented scores below 50 in physical and emotional aspects.

The authors concluded that patients felt safer and were relieved to have been fitted with the

IDC in that it protected them from sudden death<sup>(4)</sup>. Other factors that compromised the QL in this group of patients were anxiety and uneasiness due to a lack of information<sup>(5)</sup>. Because of the short period of hospitalization necessary for installing IDC and CR, there is not enough time to minimize a patient's anxiety and to assimilate the important information regarding the maintenance of the device. To recognize the sources of electromagnetic interference and the necessary healthcare related to the use of such devices is fundamental with regard to minimizing the stressful situations in the everyday lives of the patients, which reflect directly on the QL. This specific study was developed to evaluate the QL of patients with implanted cardiac devices, to describe the sources of electromagnetic interference, and to identify the symptoms in the event of device failure.

## **METHOD**

This is a transversal study performed between January and July 2009, in a specialized arrhythmia clinic in a public College hospital in the municipality of Porto Alegre, Brazil. The patients studied were of both genders, of 18 years old or above, fitted with an IDC combined or not with CR, irrespective of when the device had been placed. Excluded patients had a certain level of cognitive impairment which prevented them being able to answer the research instruments, or who had been hospitalized in the last month due to HF. An instrument containing demographic questions was used, as well as questions related to their cardiac arrest history, the number of discharges received, comorbidities and awareness of electromagnetic interference sources.

To evaluate the QL, the SF-36 form was used. This is a multidimensional questionnaire, self-applicable, composed by 36 items distributed in eight domains: functional capacity, physical aspects, pain, general health status, mental health, vitality, social aspects and emotional aspects. The scores of each domain can vary from zero to 100, the higher the score, the better the QL<sup>(6)</sup>. The application of the SF-36 form, and the interviews, were standardized and performed in an ambulatory visit by a nurse who is a participant of this study.

This study was approved by the Ethics in Research Committee of the *Hospital de Clínicas* of Porto Alegre (HCPA/UFRGS), under registration number 08-629. All participants read and signed the Free and Clear Consent Term, according to Resolution 196/96.

### Statistical Analysis

The data were submitted to statistical analysis using the software *Statistical Package for the Social Sciences* version 17.0. The continuous variables were described with  $\pm$  average, standard deviation or median and interquartile range. The categorical variables were expressed in absolute and relative frequencies. To calculate the sample, we considered the SF-36 emotional aspects domain, which presented the highest flexibility, with an estimated average of  $66.7 \pm 38.5^{(7)}$ . With a margin of error of 15% on average, with a safety factor of 95%, it was decided to include 56 patients.

## RESULTS

### Socio-demographic and clinical characteristics of the sample

A total of 56 patients fitted with electronic cardiac devices were included in this study. Of these, 54 (or 96.4%) had an IDC, and two (3.6%) had an IDC combined with a CR. The average age was  $58 \pm 13$  years. There was a large number of male patients, and 50% of the sample was composed of people with up to five years of schooling. Cardiorespiratory arrest (CRA) was reported in 55.4% of the cases, and 27 patients (or 48.2%) felt the electrical discharge from the IDC. The general characteristics of the studied patients are as shown in Table 1.

**Table 1** – Socio-demographic and clinical characteristics of patients with implanted electronic cardiac devices. Porto Alegre, Brazil: 2009.

Characteristics	n = 56
Age (years)	$58 \pm 13$
Gender (male)	41 (73.2%)

Years in school*	5 (0-18)
Living with relatives	48 (86%)
Cardiorespiratory arrest †	31 (55.4%)
Implanted cardio-defibrillator	54 (96.4%)
Implanted cardio-defibrillator + cardiac resynchronizer	2 (3.6%)
Felt electrical charge from the implanted cardio-defibrillator	27 (48.2%)
Number of medications in use *	5 (1-11)
Heart failure diagnosed	41 (73.2%)
Acute myocardial infarction	15 (26.7%)
Chagas disease	3 (5.3%)
Chronic renal failure	11 (19.6%)
Stroke	7 (12.5%)
Depression	8 (14.2%)
Systemic arterial hypertension	29 (51.7%)
Ventricular tachycardia	18 (32.4%)
Ejection fraction (%)	35 ± 12.8

†History of cardiorespiratory arrest before the insertion of implanted cardio-defibrillator.

\*Numbers expressed with median and interquartile range. Other measures are presented with average ± standard deviation and n (%).

### Quality of life

Table 2 demonstrates the average results of SF-36. Three aspects were highlighted: physical limitations, general health status and emotional aspects.

**Table 2** – Quality of life of patients with implanted electronic cardiac device, SF-36 domains (n=56). Porto Alegre, Brazil: 2009.

Domains	Average ± Standard deviation
Functional Capability	57.7 ± 25.6
Physical Aspects	12.5 (0-50)*
Pain	65.3 ± 31.6

General Health Status	49.4 ± 24.7
Vitality	58 ± 26.4
Social Aspects	71.6 ± 30.8
Emotional Aspects	33 (0-100)*
Mental Health	68.9 ± 25.9

\*Numbers expressed with median and interquartile range.

### Understanding of electromagnetic interference sources

Out of the 56 patients, 51 (91%) believed that their device could suffer from some sort of electromagnetic interference, especially from the use of cellular phones and revolving doors in banks. In the event of device failure due to battery failure, for example, 62.5% of the patients answered that they could faint and 60.7% believed that their hearts would cease to beat. See Table 3.

**Table 3** – Recognition of electromagnetic interference sources and symptoms of device failure by the patients (n=56). Porto Alegre, Brazil: 2009.

Questions	n(%)
Electromagnetic interference	
Yes	51 (91)
Devices that cause interference	
Cellular Phone	41 (73.2)
Bank Revolving Doors	38 (67.9)
Household Appliances	32 (57.1)
Metal Detectors	20 (35.7)
Radiotherapy	8 (14.3)
Transcutaneous Nervous Electric Stimulation	4 (7.1)
Possible symptoms in device failure*	
Fainting	35 (62.5)
Asystole	34 (60.7)
Tachycardia	24 (42.9)
Bradycardia	18 (32.1)
Weakness	17 (30.4)

Nausea	8 (14.1)
Others	11 (19.6)

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\*Multiple choice answers.

## DISCUSSION

In this study, it was demonstrated that the quality of life of patients who were fitted with IDC achieved relatively low scores in domains related to physical and emotional aspects and general health status. When comparing patients who were fitted with RC without IDC, the research data shows the associated quality of life with higher scores in all domains<sup>(2)</sup>.

These findings are in agreement with other similar studies performed with adult holders of IDC and bypasses. These have presented lower scores of QL in terms of emotional state and social relationships, which develop to a stressful situation, loss of control, anxiety and depression<sup>(4,5)</sup>.

In another study which used a sample of 29 patients, with ages averaging 15 years and using the SF-36 form, the authors found a reduction in the scores relating to physical aspects, emotional aspects, vitality and mental health. Fear and preoccupation with the IDC were reported by all patients, and the incidence of electrical discharges was related to the difficulty in adapting to the device and feelings with regard to the quality of life<sup>(7)</sup>. A bibliographical review, which included publications from 2003 to 2007 and which focused on QL after the implantation of the IDC and the limitations in lifestyle, concluded that adult who were fitted with IDC had a decrease in QL, especially related to the occurrence of electrical discharges, changes in their emotional state and social relationships, and reportedly more frequently, feelings of fear and rejection<sup>(5)</sup>.

A recent study with an adult population aged over 50 years, predominantly males and fitted with IDC, stated that there were no correlation in QL domains with regard to age, gender and schooling. Even though these patients reported they were feeling better than previously, they were also afraid of electrical discharges from the device<sup>(4)</sup>. In collaboration

with these findings, our study presents a sample mostly male, fitted with IDC, lower EF and reduced scores in terms of the psychological aspects.

According to the Brazilian Directives for Implanted Electronic Cardiac Devices (DCEI, in Portuguese), all phenomena that can generate functional modifications in the devices are considered to be a source of interference. These can be of an electromagnetic or mechanical nature. In relation to the level of risk to the patient, the directives classify them as being acceptable, acceptable but risky or unacceptable. Acceptable – safe and harmless – are appliances in general, escalators and automatic doors, automobiles, busses and motorcycles. Acceptable but risky – they can generate a certain amount of damage and there is no consensus about the risks – include magnetic mattresses, cellular phones, wireless phones, Bluetooth equipment, walkie-talkies, cellular phone antennas, MP3 players in general, electro cautery, therapeutic radiation, devices that produce mechanical vibrations, metal detection and anti-theft systems, transcutaneous and electro-acupuncture stimulation. Sports and physical activities in general (as far as the pectoral muscles are not being used) and physical contact sports are, therefore, not suggested. Unacceptable – considered harmful to those fitted with IDC – are nuclear magnetic resonance equipment and body fat counters that use an electrical discharge throughout the body.

The clinical consequence of a source of interference to the proper functioning of IDC, with or without CR, will depend especially of the level of dependency the patient has on the implanted device<sup>(8)</sup>. Facing the possibility of an unnecessary electrical discharge or interference from electromagnetic sources, it is fundamental that the patients are properly informed so that they can adapt themselves to their own home appliances and the external environment.

Some authors mention the importance of information with regard to possible sources of interference and the safety measures that patients must adopt. For example, the use of cellular phones on the opposite side to the implant is mentioned, as well as maintaining a safe distance from sources of interference. They also emphasize the procedures needed to protect the device, as well as to aid the holder in what to do with regard to a certain treatment that may cause some damage to clothing; and the constant use of an



identification card. It is also reported the new devices will suffer from increasingly less interference due to the development of technology<sup>(5,8)</sup>.

The majority of the patients in this study mentioned that their devices could suffer some interference, but they did not know that the main sources of interference were in the hospital. The implantation of such cardiac devices requires a very short period of hospitalization and, in many cases, the nurse, because of a lack of information and time, does not provide the patient with the necessary knowledge. This situation reminds us of the important role of the nurse during the hospitalization of such patients, for both the patient and his family who should also be included in the process of information, and who are also insecure, fearful and full of questions about the new condition of their family member. Time and some work is necessary to adapt the patient to his new lifestyle, which inevitably involves an adaptation on the part of his family<sup>(5)</sup>.

Besides the lack of information regarding the device and the main sources of electromagnetic interference, the patients of this study also demonstrated little or no knowledge regarding the implications of device failure or electrical discharges from the IDC. The majority of the patients did not know how to control their heart frequency (and also they were not informed on how to proceed) and many were not capable of recognizing when they were in an arrhythmia state. In a study published in 2007, of patients fitted with IDC, it was observed that there was a significant relationship between uncertainties and QL. However, the acknowledgement of IDC had no important correlation to QL<sup>(9)</sup>.

Questions about sexual activity also arose in the results and must be discussed in the period prior to hospital discharge. Authors have mentioned that an IDC electrical discharge can be frightening for the patient and his companion, and can also be avoided by some adjustments to the device<sup>(10)</sup>.

The electrical discharge is sometimes surprising and discomforting. However, it must be seen as an indication that the device is working properly, protecting the patient from arrhythmias and life-threatening situations<sup>(7,9)</sup>. This concept can help the patient to control his reaction during such discharges, and realize that it also works as a life-saving process.

This can ease the patient's uncertainty and anxiety, and especially can give the patient the chance to be fully conscious during situations in which he must look for medical assistance.

These results indicate that nursing staff must be in a position to provide information to the patients, and be in a position to provide aid to improve the conditions to self-care. The nurse must inform the patients about the frequency of electrical discharge, the risk of interference, the restart of sexual activity and other essential information. The publication of guides or the setting up of support groups that provide the patients and caregivers with information about the functioning of cardiac devices, will aid understanding, and should be considered as important elements in terms of promoting a better quality of life.

### **Implications for clinical practice**

Facing the possibility of sudden death as a result of any pathology, we believe it is necessary for family members to have a certain basic training in cardiorespiratory resuscitation. They must also be involved in the process of caregiving, as they are proactive elements in terms of improvement in the patient's quality of life.

### **Limitations**

The majority of the studies into the quality of life of patients with implanted cardiac devices present the application of the SF-36 form prior to the implant, and with a second interview three to twelve months after the procedure. In this study, the data collection was performed only once, in an interview at the clinic with patients who were fitted with these devices, rather than when the procedure happened, which does not permit an analytical statistical comparison.

### **CONCLUSION**

Based on the presented information, we can conclude that patients who were fitted with implanted electronic cardiac devices present reduced scores in terms of the quality of life, especially in the domains related to the physical and emotional aspects and the general

health state. In addition, the data analysis indicates a limited amount of understanding on the part of the patients regarding the sources of electromagnetic interference and possible symptoms in the event of device failure.

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