

# Quality of life of patients with implantable cardioverter-defibrillator: the usage of SF-36 Questionnaire

*Qualidade de vida em pacientes com cardioversor desfibrilador implantável: utilização do questionário SF-36*

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## Abstract

**Objective:** To observe the quality of life of patients with implantable cardioverter-defibrillator (ICD).

**Methods:** This is a descriptive research with a quantitative approach. Data collection was done through an interview. The Questionnaire SF-36 was used to analyze data, which has been collected in a cardiovascular outpatient service. Fifty patients with this device took part in the study during their medical follow-up from January to December.

**Results:** Of the 50 patients, 19 (38%) were female and 31 (62%) male. The mean age of the patients was 58.4 years, with ages ranging from 21 to 75 years. It was observed two domains regarding limitations by physical and emotional profiles below score 50. The domain social profiles presented the higher score 80.5. Most of the patients reported that their health was a little better compared with a year ago.

**Conclusion:** The results showed a loss in the patients' quality of life, with lower scores in the physical and emotional profiles. There was no correlation between quality of life with the variables age, sex, marital status and education

level. However, patients feel relieved and secure with the benefits provided by ICD in maintaining their lives by protecting them from sudden death.

**Descriptors:** Defibrillators, Implantable. Quality of Life. Death, Sudden. Arrhythmia, Sinus.

## Resumo

**Objetivo:** Verificar a qualidade de vida em pacientes portadores de cardioversor desfibrilador implantável (CDI) por meio do Questionário SF-36.

**Métodos:** Pesquisa descritiva com abordagem quantitativa realizada em um ambulatório de Cardiologia, por meio de entrevista e do Questionário SF-36 a 50 portadores de CDI durante a consulta médica de acompanhamento, no período de janeiro a dezembro de 2009.

**Resultados:** Dentre os indivíduos incluídos no estudo, 19 (38%) eram do gênero feminino e 31 (62%), do masculino. A idade média foi de 58,4 anos, variando de 21 a 75 anos.

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Verificaram-se apenas dois domínios abaixo do escore 50, relacionados às limitações por aspectos físicos e emocionais. O domínio aspectos sociais apresentou o maior escore, 80,5. A maioria dos pacientes relatou que sua saúde estava um pouco melhor em comparação ao ano anterior.

**Conclusão:** Os resultados evidenciaram prejuízo na qualidade de vida, demonstrando menores escores nos aspectos

físicos e emocionais. Não houve correlação da qualidade de vida com as variáveis idade, gênero, estado civil e nível de escolaridade. Entretanto, os pacientes se sentem aliviados e seguros com os benefícios proporcionados pelo CDI na manutenção de suas vidas, protegendo-os da morte súbita.

**Descritores:** Desfibriladores Implantáveis. Qualidade de Vida. Morte Súbita. Arritmia Sinusal.

## INTRODUCTION

Sudden death from arrhythmia is one of the problems encountered in the field of Cardiology [1]. In 80% to 85% of cases, occurs an interaction between an event that promotes electrical instability, which leads to ventricular tachycardia that triggers ventricular fibrillation [2]. The therapy used in the treatment include antiarrhythmic drugs, surgical resection, endocardial catheter ablation, and implantation of an electric device: the implantable cardioverter-defibrillator (ICD) [1,3]. Since 1984, it has been used for primary prevention of sudden death [4].

In selected cases, several clinical series and prospective randomized trials completed such as AVID (Antiarrhythmics Versus Implantable Defibrillators) and MADIT (Multicenter Automatic Defibrillator Implantation Trial) showed the superiority of ICD over the antiarrhythmic drugs in reducing sudden cardiac death and improving survival [5]. Thus, it has been shown to be a more efficient alternative to interrupt sustained ventricular tachycardia and ventricular fibrillation. It has been holding for a significant reduction in sudden death, which also turned to be evident in the MADIT and AVID [1]. Treatment of heart failure underwent a major breakthrough with the use of ICD [6].

ICD monitors the heart rhythm in the same way as a conventional pacemaker does. ICD is self-stimulated in case of bradycardia risk or it self-inhibits if there is an appropriate own pace. If a ventricular tachycardia is detected, the cardioverter can be used to try to reverse it by programmed ventricular stimulation and/or synchronized cardioversion shock according to pre-established schedule. If a case of arrhythmia is detected, ICD applies a high-energy shock for defibrillation. The high-energy is very uncomfortable, but most patients tolerate the electric discharges, mostly because they understand that it represents the security for their lives [7].

Although the use of ICD has advantages, improvement in physical health does not mean similar improvement in the psychological well-being of patients [8]. Changes in

the routine of these people have requested a better understanding of this device, both for the multidisciplinary team, in which the nurse fits into as an educator and caregiver during the process of implementation and follow-up, as well as, for the patients and their families. People with ICD correlated their anxiety with the fear of death, device malfunction, and increased physical symptoms [9].

In recent decades, health interventions have targeted not only to extend life but how to achieve the improvement of its quality. Instruments to measure the quality of life have been developed to assess whether such interventions are enabling a better and more comfortable life [1,5].

According to the definition of the World Health Organization (WHO), quality of life is the individual's perception of his/her place within the conditions in which he/she lives, which is set in his/her cultural context and system of values, expectations, life-style standards, expectations, and concerns [5-7].

The perception that the patient has of his/her disease will affect his/her quality of life, interfering with his/her health conditions and other general aspects of life [7]. Clinical trials and behavioral changes of individuals in the face of specific treatments provided the establishment of measures in the accurate assessment of the answers of the health profile of the patients [10]. Several instruments and scales have been developed to assess the quality of life and one of them is the SF-36 (Medical Outcomes Study 36-Item Short-Form Health Survey). It is a generic form widely used around the world demonstrating properties of reproducibility, validity, and sustainability to the changes [11].

In Brazil, the SF-36 was translated and validated, and it is used in different areas of health to review the understanding of the individual about his/her health in order to help him/her to take decisions about his/her treatment [11-14]. We have started from the corroboration that it is possible to achieve a state of physical and mental well-being resulting in recovery of the autonomy in his/her daily work and leisure, and the preservation of hope and sense of usefulness of these individuals [15,16].

Patients with ICD patients require some changes in their daily activities, which, consequently, can affect their quality of life. In view of the facts, this study aimed at verifying the quality of life in patients with CDI using the SF-36 Questionnaire.

METHODS

This is a descriptive research with a quantitative approach carried out at the Outpatient Cardiology Clinic of a teaching hospital (Hospital de Base) that attends patients from the Unified Health System, which is Brazil’s publicly-funded health care system, known as ‘Sistema Único de Saúde’ or SUS, in Sao Jose do Rio Preto, São Paulo State, and region. Fifty patients with ICD who were treated at this facility in 2009 took part in this study.

The inclusion criteria were: ICD patients of both sexes with age > 18 years, with no cognitive impairment, who attended the returning visit to the Cardiology Service, on Fridays in 2009, and most importantly they might have signed an informed consent to participate in the study. The project was approved by the Research and Ethics Committee of FAMERP, Protocol No. 3230/2006.

The quality of life SF-36 questionnaire was used as an instrument of data collection. It consists of 36 items covering eight domains: physical functioning (performance of daily activities, such as limitations in self-care, dressing, bathing and climbing flights of stair), physical (physical health impact on the performance of daily activities and/or professional), pain (pain level and the impact on performance of daily activities and/or professional), general health (subjective perception of general health), social (reflecting the condition of physical health on social activities), emotional (emotional reflection of the conditions in the performance of daily activities and/or professional), and mental health (mood scale and well-being). Each domain is examined individually and receives a score from 0 to 100 (from worst to best health status), mean 50 and standard deviation of 10 [14].

A semi-structured interview was used to the effect of characterizing the subjects as to the variables: age, gender, marital status, educational level, time of ICD implantation, previous heart disease, as well as the fear of using ICD. The interview was also used to see the perception of patients about their health compared with a year ago. Regarding the procedure, the patients were interviewed in the waiting room of the cardiology outpatient clinic at this point preceding the medical visit. The patients were informed about the study by the researchers and, then the SF-36 questionnaire was applied. Data collection occurred from January to December 2009.

The data obtained were gathered, transferred to a database (Excel®) and then processed. We used descriptive

statistics to characterize the subjects; the averages were compared by Student’s *t* test for analysis of variables related to the SF-36 (mean and standard deviation). The test was carried out at 5% level of significance and the data are presented as cross tabulations (cross-tables).

RESULTS

From the sample of 50 patients with CDI, the mean age was 58.4 years (interquartile range from 21 to 75 years), 62% (31) were male, 76% (38 patients) were married, and 46% (23 patients) had incomplete elementary education (Table 1).

In relation to the basal heart disease reported by the patients, we identified 26 (52%) cases of Chagas’ disease, 10 (20%) of systemic arterial hypertension, five (10%) Chagas disease and arterial hypertension, and nine (18%) reported no previous heart disease. The time of ICD implantation ranged from 3 to 5 years in 20 (40%) patients, 1 to 3 years in 19 (38%), above 5 years in 6 (12%), and less than one year in 5 (10%) cases.

Regarding the analysis of variables related to the SF-36 questionnaire, the averages for each domain are presented in Table 2. It was observed that the domains’ physical and emotional aspects presented lower averages, being the most affected in the opinion of patients, with averages of 40.5 and 47.3, respectively.

Concerning the data obtained from the SF-36 domains according to the variables age, gender, marital status, and schooling, there was no statistically significant difference (*P* < 0.05). Most patients (28-56%) reported fear of the shock

Table 1. Distribution of Patients according to sociodemographic variables.

Gender	N	%
Female	19	38
Male	31	62
Total	50	100
Marital Status		
Married	38	76
Single	5	10
Divorced	3	6
Widow/Widower	4	8
Total	50	100
Schooling		
Semiliterate	9	18
Incomplete Elementary Education	23	46
Elementary Education	7	14
Secondary Education	8	16
Higher Education	1	2
Not Reported	2	4
Total	50	100

from the ICD and 22 (44%) reported they had no fear at all. Of the patients who reported fear, 56% explained that had fear of the shock caused by the discharges. On the question regarding the patient's perception about their health compared with a year ago, the majority (18-36%) reported that it was somewhat better (Table 3).

Table 2. Values obtained for each domain related to the quality of life questionnaire SF-36 in patients with ICD.

SF-36 Domains	N	Mean	SD
Physical functioning	50	54.1	23.8
Physical role functioning	50	40.5	40.9
Bodily pain	50	66.6	29.1
General Health Perceptions	50	67.3	24.6
Vitality	50	64.2	26
Social role functioning	50	80.5	26.9
Emotional role functioning	50	47.3	38.7
Mental Health	50	64.1	27.4

SD - Standard Deviation; ICD - implantable cardioverter-defibrillator

Table 3. Opinion of patients regarding their health status compared to the previous year.

	N	%
Much better	15	30
Somewhat better	18	36
About same	5	10
Somewhat worse	10	20
Much worse	2	4
Total	50	100

## DISCUSSION

According to the results of the eight domains of the SF-36 questionnaire, two had a score below average with values below 50 only: the physical (40.5) and emotional (47.3) aspects. The social domain had the highest average (80.5), and it was the least affected factor in the lives of these patients. The number of ICD patients has increased. However, the benefits of the treatment are being attenuated by the symptoms of anxiety, stress, and depression [17].

In this study, we observed a loss in quality of life of ICD patients with respect to the physical and emotional aspects, regardless of age ( $P < 0.05$ ). These findings corroborate a study, which assessed the quality of life through the SF-36 questionnaire in young patients with ICD, who were under 21 years of age, by comparing them with healthy subjects, which showed a reduction in the quality of life and difficulty in adapting to the device. In this study, we observed a loss in quality of life of ICD patients with respect to physical and emotional aspects, regardless of age ( $P < 0.05$ ), and these

findings corroborate a study that assessed the quality of life by SF-36 in young patients with CDI who were younger than 21 years and compared with healthy subjects and showed a reduction in quality of life and difficulty in adapting to the device. It was also verified that fear and concerns related to the ICD were reported by all patients [18].

Despite the negative impact on quality of life of the patients with ICD, we found that most of these people consider their health somewhat better compared to a year ago. This was followed by the opinion that their health is much better. However, 24% considered their health somewhat or much worse. A study conducted with ICD patients under the age of 40 years revealed that all reported improved quality of life ranging from good to excellent after implantation. Nonetheless, it was also found that young people have concerns about their body image and with the fact that the device limits their activities. However, it was shown that they are active participants in the society [19].

In a meta-analysis of quality of life in patients with ICD, 30 articles met our selection criteria. The most used instrument to collect data was the Quality of Life SF-36 questionnaire. Most randomized trials found that the quality of life of the patients with an implanted defibrillator was equal to or better than before. However, those who received shock reported that their quality of life was impaired [20].

The ICD, despite representing a major breakthrough in reducing sudden cardiac death, presents a negative impact on the quality of life as far as it refers to the influence of the shocks in these people [21]. The high-energy is uncomfortable, but most patients tolerate the discharges, mainly because they perceive that it represents the security for their lives [7].

In this study, we found that most patients had as basal heart disease, the Chagas' disease and systemic arterial hypertension, with an ICD implantation time of 3 to 5 years. A retrospective study in 80 clinical patients with ICD at the University of Pittsburgh Medical Center showed a mean age of  $64.4 \pm 12.5$  years and survival rates of 93.8%, 65% and 50% at 1.5, and 10 years, respectively. The presence of more than one risk factor in the same patient was associated with higher mortality rates, including advanced age, myocardial ischemia, and renal insufficiency [22].

The quality of life in relation to the variables age, gender, marital status, and schooling showed no statistically significant differences in this study. However, in the research about perception of quality of life in patients with ICD before and after the device implantation revealed no significant difference in the overall health status, but it showed a correlation with age. The young people showed a higher deficit in the quality of life [23].

The physical (physical health impact on the performance of daily activities and/or professional) and pain (pain level and the impact on performance of daily

activities and/or professional) domains showed a negative correlation with the quality of life in ICD patients, as well as a tendency to the somatization of non-specific symptoms, such as sweating, decreased muscle strength in lower limbs, and nausea [24]. In another study, the quality of life of patients with arrhythmia was also affected mainly in the emotional aspect regardless of the treatment the patient might have received [25], which corroborates the findings of this research.

Thus, this study, besides supplying motivation for further research, provides subsidies to implement new strategies to improve the quality of life. Attempts should be made to support these people, offering guidelines for activities of daily life, discussing an appropriate lifestyle through multidisciplinary support group in order to minimize the negative effects of ICD.

## CONCLUSION

This study showed that the quality of life of patients with ICD, according to the SF-36, presented lower scores for physical and emotional profiles. The domains of quality of life in relation to the variables: age, gender, marital status, and schooling showed no statistically significant difference.

Concerning the perception of patients relative to their health status compared to the previous year, they reported it was somewhat better in relation to the benefits provided by the device in the maintenance of their lives, by preventing sudden death, although they also reported fear from the electric shock received from the discharges. So it is necessary to make a better follow-up of the treatment course and the physical and mental health of patients with ICD.

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