Observational study on the quality of life for people with implantable cardioverter-defibrillator for the prevention of sudden cardiac death

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Abstract

Introduction: the Implantable Cardioverter Defibrillator (ICD) prolongs significantly the lifespan of patients at risk for sudden cardiac death, but its effects on the psycho-social aspects besides the quality of life related to health are not yet clear. The aim of this study is to test the hypothesis that an ICD determines a deterioration in the quality of life in relation to health status.

Methods: data were collected through interviews with a non-probabilistic sample of convenience. The instrument used was the SF-36, which investigates the quality of life in relation to health status. The collected data were entered into a database (Excel®) and processed with the software Matlab® to perform a multivariate analysis.

Results: the analysis shows a significant worsening of quality of life in patients with defibrillator in 3 domains, which refer to physical health, while those in reference to mental health have not shown significant changes. Nevertheless, the majority of patients perceive their health basically unchanged (37%) compared to a year ago. This is probably due to the fact that all subjects enrolled in the study have not experienced arrhythmic events treated with shock.

Discussion: the initial hypothesis that the ICD determines a deterioration in the quality of life is partly confirmed. On one hand the physical health suffers the effects of the defibrillator, as shown by the worsening of score of the 3 domains regarding physical aspects. On the other hand mental health, which is composed of both the psychological and social aspects, is not affected.

KEY WORDS: implantable defibrillators, quality of life, sudden cardiac death.

Introduction

Sudden cardiac death is a natural event due to cardiac causes, preceded by a sudden loss of consciousness that occurs within one hour from the beginning of the acute symptoms, in a patient with or without known pre-existing heart disease but when the time and the mode of death are unexpected (1). It is the major cause of death in all industrialized countries, with a survival rate of less than 5%, in Western Europe (2). About 80% of episodes of sudden cardiac death are caused by malignant ventricular tachyarrhythmias, such as ventricular tachycardia and ventricular fibrillation, induced by acute ischemic events. For this type of arrhythmias, the only possible intervention to restore the normal sinus rhythm of the heart is early defibrillation.

Defibrillation is an emergency cardiac care that is carried out on a person in a state of cardio-respiratory arrest, with unconsciousness, no pulse and breathing, in order to stop potentially malignant cardiac arrhythmia and restore normal sinus rhythm (3). Several studies have shown the benefits of implantable defibrillator, particularly in the secondary prevention of sudden cardiac death among patients who survived an arrhythmic event, with a reduction in mortality of 7%. It was also established its effectiveness in primary prevention in patients with coronary heart disease and non-ischemic cardiomyopathies. Other studies support the use of implantable defibrillators in hereditary or infiltrative diseases. When used as resynchronization therapy it has been shown to improve survival and quality of life in patients with congestive heart failure (4).

From these data it is easy to understand the wide use of these devices in clinical practice; for example in Italy in 2011 were implanted 17,574 defibrillators (5). In the present study the attention is focused on the hypothesis that an ICD determines a deterioration in the quality of life in relation to health status.

Although the person feels safe in case of malignant cardiac arrhythmia, however must live with a device that can adversely affect the social, professional, family, etc. aspects of life (6); in fact, beyond the fear of recurrence of malignant arrhythmias, the main concerns are the scar of the wound resulting from the implant, the development of infections in the insertion site, inappropriate shocks, battery depletion. This leads the person to live with anxiety, panic attacks, emotional instability, ineffective coping, post...
traumatic stress disorder and depression (7). Also the dependence on other people increases (6). So, although it is established that the implantation of these devices has extended the length of life (8, 9), it is unclear whether this longevity is accompanied by a deterioration in quality of life.

**Methods**

The non-probabilistic sample of convenience consists of patients with an ICD; exclusion criteria were patients under 18 years old and those with cognitive impairment. The instrument used for data collection was the questionnaire validated Short Form-36 items Health Survey (SF-36) (10). It was also dispensed a brief semi-structured questionnaire that has allowed us to collect data regarding the variables age, sex, years of implantation, underlying illness, employment status, housing situation, level of education and number of shocks delivered by the defibrillator. The data were then entered into a database (Excel®) and processed with the software Matlab® in order to perform a multivariate analysis with the variables mentioned above. The mean values of the variables on the SF-36 were compared with the Student t test, placing 95% as level of significance of the test.

**Results**

Statistical analysis shows a significant worsening of quality of life in the group of people with ICD respect to general population (Tab. 1). This data coincides in part with many studies, although in different domains of the SF-36 (7, 11-15). In this study there is a reduction of the scores in physical functioning, role limitations due to physical health and general health (Tab. 2). The scores of multivariate analysis do not show significant changes, regardless of the variable taken into consideration. These data do not agree with those studies that affirm that there is a gender disparity in quality of life in the population with defibrillator, with a reduction of scores in every domains and symptoms of anxiety and depression in women (12, 14). This difference could be due to the small population selected and to the heterogeneous distribution of sex (n. 12 females vs n. 23 males).

Some Authors have observed that there is a correlation between the number of shocks and a reduction in quality of life, in particular with regard to the psychological aspect (7). In this study it was not possible to make this analysis, because none of the people enrolled in the study had previously experienced an arrhythmic event treated with shock. Despite the negative impact that the implantable defibrillator seems to have on the quality of life, most of the people interviewed perceives their health tendentially unchanged, as shown by the answers to the question “How would you rate your health compared to one year ago?” (Tab. 3).

![Image](https://example.com/image.png)

**Table 1 - Domains SF-36 averages and standard deviation. §: p<0.05.**

<table>
<thead>
<tr>
<th>SF-36 domains</th>
<th>Average</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>56,00 §</td>
<td>36,50</td>
</tr>
<tr>
<td>Role-physical</td>
<td>52,86 §</td>
<td>45,69</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>68,86</td>
<td>33,41</td>
</tr>
<tr>
<td>General health</td>
<td>52,29 §</td>
<td>19,28</td>
</tr>
<tr>
<td>Vitality</td>
<td>62,00</td>
<td>12,96</td>
</tr>
<tr>
<td>Social functioning</td>
<td>80,57</td>
<td>19,04</td>
</tr>
<tr>
<td>Role-emotional</td>
<td>73,26</td>
<td>38,68</td>
</tr>
<tr>
<td>Mental health</td>
<td>64,34</td>
<td>16,90</td>
</tr>
</tbody>
</table>

**Table 2 - Averages of domains of ICD patients compared to general population.**

**Table 3 - ICD patients opinion on their general health compared to one year ago.**

<table>
<thead>
<tr>
<th></th>
<th>N(tot)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much better</td>
<td>4(35)</td>
<td>11</td>
</tr>
<tr>
<td>Somewhat better</td>
<td>4(35)</td>
<td>11</td>
</tr>
<tr>
<td>About the same</td>
<td>13(35)</td>
<td>37</td>
</tr>
<tr>
<td>Somewhat worse</td>
<td>8(35)</td>
<td>23</td>
</tr>
<tr>
<td>Much worse</td>
<td>6(35)</td>
<td>17</td>
</tr>
</tbody>
</table>

Although this is only one of the questions of the SF-36, and the only one not involved in the composition of the scores, it is interesting to note that only 8 people feel their health somehow worse than a year ago and the majority of these patients is affected by heart failure, that is the functionality of their heart is irreversibly compromised. This data coincides with the study of Johansen, which affirms that heart failure is the most important factor related to a deteriorating quality of life (15).
Discussion

From what emerges from the present study, the initial hypothesis is partially confirmed. In fact, while it is true that physical health suffers the effects of implantable defibrillator, on the other side mental health is not affected in any domains.

In support of the results obtained it can be assumed that the positive effects of defibrillator, such as feeling safer from malignant arrhythmic events, are balanced by the negative ones, like fear of receiving shocks at any time and as consequence there is a reduction of the scores of physical health, in the domains of physical activity and role limitations. But the fact that the person feels better protected from potentially life-threatening arrhythmic events is reflected in the scores of mental health that are not affected in any way.

The study also found out that there is no correlation between the scores of the SF-36 and the variables gender, age, years from the plant and underlying disease, although many studies affirm the contrary (7, 11, 14, 15).

References


