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Psychological Reaction to Potential Malfunctioning of Implantable Defibrillators

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Background: Psychological problems following implantable cardioverter defibrillators (ICD) implantation are diverse and include increased levels of anxiety. Anxiety may even rise further when possible malfunctioning of an ICD is announced, with a higher risk of serious ventricular arrhythmias and death as a consequence. Following the public statement of Medtronic, all patients in the Netherlands with the specific Medtronic ICD were contacted for extra device evaluation. The aim of this exploratory study was to determine whether the proportion of ICD patients with high levels of anxiety would increase after this extra device evaluation.

Methods: Patients were recruited from an ongoing prospective study on psychological effects of ICD implantation. Thirty-three patients completed the State subscale of the State-Trait Anxiety Inventory (STAI) before and after extra device evaluation. The STAI can identify patients with high levels of anxiety.

Results: A high level of anxiety was experienced by two patients (6.1%) at baseline and eight patients (24.2%) at follow-up ($P = 0.031$). Hence, ICD patients were significantly more likely to experience high levels of anxiety following the public statement of potential malfunctioning of their device.

Conclusion: A public statement regarding device safety may increase levels of anxiety among ICD patients. Given the potential triggering effect of high levels of anxiety on arrhythmias, psychological support may be considered for some of the ICD patients after such public statement. (PACE 2006; 29:953–956)

implantable cardioverter defibrillator, anxiety

Introduction

Implantation of implantable cardioverter defibrillators (ICDs) is increasingly common in patients who have experienced serious ventricular arrhythmias or in those patients who are at risk for such arrhythmias.¹ Psychological problems following ICD implantation are diverse and include increased levels of anxiety.^{2–4} However, symptoms of anxiety may even rise further when possible malfunction of an ICD is announced. Recently, the safety of ICDs has been questioned;⁵ e.g., Medtronic (Minneapolis, MN, USA) sent out a news report regarding the possibility of rapid battery depletion in some models of the Marquis and Maximo series.⁶ Patients may have different psychological reactions to these public statements about the safety of devices and to the options or advice regarding replacement. Some patients may experience acute stress and anxiety, with a higher risk of ventricular arrhythmias as a consequence.⁷

In the Netherlands all patients with an ICD of the Marquis or Maximo series were contacted for extra device evaluation. The aim of this exploratory study was to determine whether the number of ICD patients with high levels of anxiety would increase after this extra device evaluation.

Method

Patients

In the Catharina Hospital in Eindhoven, the Netherlands, ICD patients were approached who (1) had been called for the extra device evaluation of their Medtronic Marquis series ICD, and (2) who were enrolled in a larger ongoing 18-month prospective study on psychological effects of ICD implantation, which started in May 2003 ($N = 39$). Of these patients, 35 (90%; 28 men and 7 women) returned their questionnaire; two patients were excluded from analysis because of missing data. This procedure resulted in a final sample of 33 patients. After the extra device evaluation, 5 (15%) had their ICD replaced and the remaining patients were recommended to perform regular self-checks of their device by a handheld magnet. Criteria for ICD replacement were: (1) having experienced an ICD shock in the year prior to the extra device evaluation and/or (2) pacemaker dependency. The study was approved by the medical ethics committees of the participating hospital. The study was

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conducted in accordance with the Helsinki Declaration, and all patients provided written informed consent.

Self-Report Measures and Procedure

At baseline, i.e., following ICD implantation, patients completed the State subscale of the State-Trait Anxiety Inventory (STAI)⁸ as part of the ongoing study. After the extra device evaluation, patients completed the STAI scale once again. This self-report scale measures the current presence of symptoms of anxiety. The scale consists of 20 statements that ask people to describe how they feel at a particular moment of time (e.g., “I feel upset,” “I feel calm”), which can be rated on a four-point intensity scale ranging from (1) *not at all* to (4) *very much so*. Ten items are positively worded and 10 items are negatively worded. Scores can range from 20, i.e., low level of state anxiety to 80, i.e., high level of state anxiety. The Dutch version of the STAI has good reliability (α ranges from 0.87 to 0.92) and validity.⁸ The STAI was also used in recent studies on (1) the influence of psychological distress on ICD patients’ report of atrial fibrillation symptoms,⁹ and (2) the effect of behavioral intervention on psychological adjustment post-ICD implantation.¹⁰

Statistical Analysis

Given the relatively small sample and wide ranges of anxiety scores, we used a nonparametric test (i.e., McNemar’s χ^2 test) to compare the proportion of patients with high levels of anxiety at baseline and after extra device evaluation. The upper quartile score on the STAI (≥ 56) was used to identify patients with markedly increased anxiety scores following extra device evaluation. In previous research,¹¹ we found that a score of 56 on the state scale of the STAI corresponds to the 90% percentile in patients who were recovering from an acute coronary event. Moreover, this score is at least half a standard deviation above the mean STAI-state scores obtained among panic disorder patients,¹² once again indicating clinically relevant levels of anxiety.

Results

The mean time between assessment of anxiety at baseline and after device evaluation was 14 ± 4 months with a range from 5 to 20 months. Sociodemographic and clinical baseline characteristics of the patients are shown in Table I. The mean age in this patient group was 60 ± 11 years. Of these 33 patients, 29 (88%) had a partner, 15 (46%) had received higher education, and 25 (76%) had a history of ischemic heart disease.

The mean level of anxiety rose from 39.1 (± 10.73) at baseline to 42.0 (± 15.34) after extra

Table I.

Sociodemographic and Clinical Characteristics

Age, Mean (SD)	60 (± 11)
Female	6 (18%)
Partner	29 (88%)
High education	15 (46%)
Employment	7 (21%)
Current smoking	5 (15%)
History of ischemic heart disease*	25 (76%)
Indication for ICD	
Primary indication	8 (24%)
Secondary indication	25 (76%)
Months since implant and Medtronic’s news report, mean (SD)	14 (± 4)

*Previous AMI, PCI, or CABG.

device evaluation. The mean anxiety level after device evaluation corresponds to the upper quintile of the Dutch general population,⁸ and indicates clinically relevant symptoms of anxiety. High levels of anxiety were experienced by two patients (6.1%) at baseline and by eight patients (24.2%) at follow-up ($P = 0.031$) (Fig. 1). Hence, ICD patients were significantly more likely to experience high levels of anxiety following the public statement of possible malfunctioning of their device.

Discussion

Significant differences were found in ICD patients regarding levels of anxiety before and after the extra device evaluation following a public statement from Medtronic about the possibility of a short circuit in the battery; i.e., a larger proportion of ICD patients was found to have high

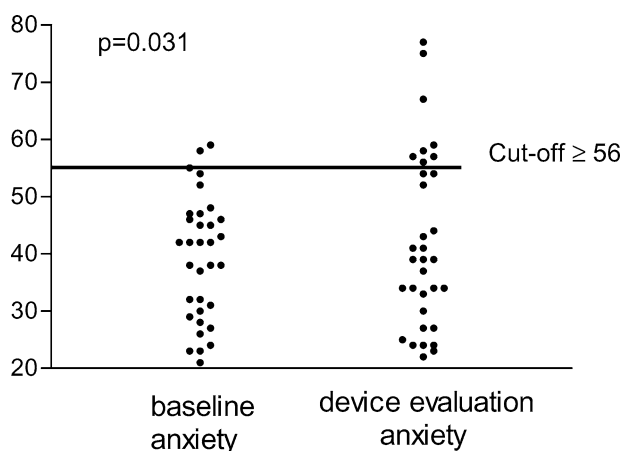


Figure 1. Symptoms of anxiety in ICD patients before and after extra device evaluation.

levels of anxiety after extra device evaluation as compared to their baseline anxiety level. Psychological distress, including anxiety, has been shown to predict ventricular arrhythmias requiring shocks in ICD patients.^{7,13,14} In addition, preliminary evidence suggests that behavioral¹⁵ or psychopharmacological¹⁶ intervention may decrease the risk of ventricular arrhythmias in these patients. Psychological distress and anxiety are at least as strong as ICD shocks in reducing quality of life post-ICD implantation.¹⁷ Anxiety may also increase atrial fibrillation symptoms, causing a further decline in quality of life.⁹ Given the detrimental effects of anxiety on ventricular arrhythmias and quality of life, ICD patients should be monitored more frequently after an anxiety-evoking event such as a news report about the safety of an ICD.

Although cardiologists or nurses may not feel very comfortable in managing anxiety problems in ICD patients,¹⁸ our findings indicate that managing these problems may be important in patients who are being called for extra device evaluation because of potential malfunctioning. There is evidence that specific behavioral intervention may be indicated for ICD patients with high levels of anxiety. For example, a structured nursing intervention resulted in a significant and stable reduction in anxiety post-ICD implantation.¹⁰ Cognitive behavioral therapy may also be an effective way of reducing anxiety¹⁹ and ventricular arrhythmias¹⁵ among ICD patients.

The present findings should be interpreted with some caution because of the small number of patients. The strength of this explorative study is the fact that patients are participating in an ongoing study, so that baseline data were available.

To the best of our knowledge, no other studies including such data have been published.

Currently, a number of steps are being taken to provide clear guidelines for the notification of medical device malfunctioning. These steps should result in the reassurance of patients that ICD therapy is reliable and effectively regulated.²⁰ In his commentary, Maisel has proposed a number of changes to this notification process, e.g., "manufacturers should annually publish detailed data on device reliability."²¹ In addition, the Heart Rhythm Society (HRS) has formed a task force on device performance and in September 2005 a conference was organized about the current policy and possible improvements. In April 2006, a document regarding recommendations on performance policies for pacemakers and ICDs was released by the HRS.²² In a report issued on March 20, 2006, a Guidant-commissioned panel made recommendations to "strengthen postmarket surveillance of the products, to actively pursue any potential device-related problems and be completely open with clinicians and the public about safety issues."²³ The present data suggest that this policy also needs to account for possible psychological consequences for patients making news regarding safety of devices public.

Conclusion

ICD patients were significantly more likely to experience high levels of anxiety after a public statement about possible malfunctioning of ICDs as compared to their baseline anxiety level. Given the potential triggering effect of anxiety on arrhythmias and its detrimental effect on quality of life, psychological support may be considered for some of the ICD patients after such a public statement.

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