Psychological Distress in Patients with ICD Recall

FLORIM CUCULI, M.D., WERNER HERZIG, M.D., RICHARD KOBZA, M.D., and PAUL ERNE, M.D.

From the Department of Cardiology, Kantonsspital Luzern, Switzerland

Background: Multiple clinical trials have shown that a properly functioning implantable cardioverter-defibrillator (ICD) is capable of interrupting sudden death caused by ventricular tachyarrhythmias. However, ICDs are complex medical devices, and they do not always perform as expected or they may fail completely. Exposure of ICD recipients to professional or media reports that their specific device type is potentially malfunctioning could negatively influence their psychological status.

Methods: This study aimed to evaluate and quantify psychological distress in patients implanted with an ICD-recall device. Thirty patients implanted with ICD-recall devices (ICD-recall group) and 25 patients with unaffected ICD devices (ICD-control group) were interviewed using the Brief Symptom Inventory (a psychological self-report symptom scale).

Results: Mean values of all primary psychiatric distress symptom dimensions and global indices were within the normal range for both the ICD-recall and the ICD-control group. New York Heart Association (NYHA) class was a predictor of higher distress symptoms in all categories, independently of the ICD group. NYHA II group patients tended toward higher stress levels than the NYHA I group, but only somatization was significantly different. An upward, but not significant, trend in 7 of the 12 scales was associated with symptomatic shock experience.

Conclusion: This study demonstrates that psychological distress was not significantly increased in patients recently informed about a potential malfunction of their device. (PACE 2006; 29:1261–1265)

quality of life, ICD, recall

Introduction

Permanent pacemakers and implantable cardiac defibrillators (ICD) are two of the most important medical advances of the 20th century. Multiple trials have shown that a properly functioning ICD is capable of interrupting sudden death due to ventricular tachyarrhythmias.

Given the complexity of ICD, which have undergone technical changes since their introduction, it is not surprising that they can also malfunction. A recent study showed that ICD replacements due to malfunction increased in number and rate between 1996 and 2002. In this study, the replacement rate for ICD was more than five times that for pacemakers. When a trend in device malfunctions is noted, the United States Food and Drug Administration (FDA) may analyze the data and issue a “recall.” Recall is a technical term, defined by the FDA. It does not mean that all recalled devices need to be removed and sent back to manufacturer.

The unexpected failure of an ICD can be catastrophic. During the first 6 months of 2005, several ICD from the three largest manufacturers were subject of safety alert notifications initiated by the manufacturer and the FDA. On July 1, 2005, the FDA classified the recall of certain Guidant defibrillator models as a Class 1 recall, the most serious level of product recall. Class 1 recall indicates that a reasonable probability exists that the use of these devices will cause serious adverse health consequences or death.

The alert and recall notifications, and particularly the spotlight articles in the news media, could possibly create much anxiety in ICD recipients. Depressive and anxiety states in ICD recipients may be frequent, clinically significant, and resistant to spontaneous resolution. Because ICD implantation often occurs against a complex medical background with inevitable psychological stress (frequently including anxiety due to having survived sudden cardiac death [SCD]), all implanted patients should be considered at high risk for developing psychopathology. In patients bearing a potentially malfunctioning ICD, extensive media coverage on specific ICD-recall devices might further increase psychological distress.

Despite the fact that ICD recall has been a major topic in the news media, controlled data on the psychological impact of recall are sparse. The subject of our study was the evaluation and quantification of psychological distress in patients implanted with an ICD-recall device.

Methods

Study Population

From July to August 2005 30 patients with a recalled, potentially flawed ICD were invited for
extraordinary system control in the Department of Cardiology. ICD-recall patients were informed in writing about the recall notification and possible consequences. To evaluate their current psychological status patients were asked to participate in an interview on the same day that their system control was conducted. Patients from the ICD-recall group were questioned as to whether they had received any information regarding potentially malfunctioning ICD recalls prior to being contacted and informed by the Department of Cardiology.

During the same time period an ICD-control group comprising 25 randomly selected patients with an ICD implant not subject to recall was also interviewed. It was specifically emphasized to these control patients that they were absolutely not affected by the ICD recall. All subjects signed an informed consent and the project was evaluated and approved by the local ethical committee.

Affected ICD Devices

In our study population all ICD devices subject to recall were produced by Guidant Corporation (St. Paul, MN, USA) and included the following: Contak Renewal Model H135, H155 CRT-D, Renewal 3, -4, AVT, Ventak Prizm 2DR, Prizm ABT, Vitality AVT, Renewal 3AVT, Renewal 4ABT, and Renewal RF.

Type of Interview

The Brief Symptom Inventory (BSI) is a recognized and widely used self-report symptom inventory designed to serve as a screen for psychological distress. The BSI is a short alternative to its parent instrument, the SCL-90-R, and provides an overview of individual’s symptoms and their intensity at a specific point in time. It contains 53 items which reflect psychological status according to the following primary symptom dimensions.

Somatization

Psychological burden arising from the perception of bodily dysfunction is questioned. The items range from simple somatic troubles through to functional disorders (cardiovascular, gastrointestinal, respiratory, etc.).

Obsessive-Compulsive Behavior

The perception of ideas, impulses, and actions as being incessant, overwhelming, strange, and unwanted is questioned.

Interpersonal Sensitivity

Feelings ranging from small interpersonal sensitivity through to a feeling of personal insufficiency are questioned.

Depression

Indicative symptoms ranging from sadness to clinically manifest depression are considered.

Anxiety

Indicative sentiments ranging from somatically sensed nervousness through to deeply felt anxiety are considered, with focus on anxiety, nervousness, tension and trembling, sheer panic, and fright.

Hostility

Feelings ranging from irritability and unevenness of temper up to strong aggressiveness with hostile aspects are questioned.

Phobic Anxiety

Indicative sentiments ranging from a slight feeling of threat until to massive phobic anxiety are questioned.

Paranoid Ideation

Syndromal behavior ranging from mistrust and feeling of inferiority to strong paranoid thinking are questioned.

Psychoticism

Indicative symptoms ranging from a mild feeling of isolation and estrangement to dramatic evidence of psychotic episodes are questioned.

Each item within the BSI is rated on a five-point scale of distress (0–4), ranging from “not at all” (0) to “extremely” (4).

In addition, three global indices of stress that can be calculated from the raw scores of the BSI: The General Severity Index (GSI), a weighted frequency score based on the sum of the ratings the subject has assigned to each symptom. It combines measures on the number of symptoms and the intensity of perceived distress. It is considered as the single best indicator of current distress level. The positive symptom total, a frequency count of the number of symptoms the subject reported. The positive symptom distress index, a score reflecting the intensity of distress, corrected for the number of symptoms endorsed. It is a pure intensity measure that does not include the number of symptoms. It is a measure of response style that indicates if the patient is “faking good” or “faking bad.”

The BSI analysis was performed using a commercial computerized test system by Hogrefe TestSystem 3.8.4 (Hogrefe Verlag, Goettingen, Germany). BSI score ranges from a normal adult population from Germany (n = 600; 300 males and 300 females) served as the “normal” reference for our study population.
Table I.
Baseline Characteristics of the Subjects in Both ICD Groups

<table>
<thead>
<tr>
<th></th>
<th>ICD-Recall Group (n = 30)</th>
<th>ICD-Control Group (n = 25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61.6 (30–81)</td>
<td>60.0 (44–78)</td>
</tr>
<tr>
<td>Males</td>
<td>N = 26 (86.7%)</td>
<td>N = 22 (88%)</td>
</tr>
<tr>
<td>SCD survivor</td>
<td>N = 5 (16.7%)</td>
<td>N = 6 (24%)</td>
</tr>
<tr>
<td>History of myocardial infarction</td>
<td>N = 18 (60%)</td>
<td>N = 13 (52%)</td>
</tr>
<tr>
<td>Cardiac surgery</td>
<td>N = 6 (20%)</td>
<td>N = 5 (20%)</td>
</tr>
<tr>
<td>Positive family history</td>
<td>N = 14 (46.7%)</td>
<td>N = 15 (60%)</td>
</tr>
<tr>
<td>NYHA class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>N = 18 (60%)</td>
<td>N = 15 (60%)</td>
</tr>
<tr>
<td>II</td>
<td>N = 11 (36.7%)</td>
<td>N = 8 (32%)</td>
</tr>
<tr>
<td>III</td>
<td>N = 1 (3.3%)</td>
<td>N = 2 (8%)</td>
</tr>
</tbody>
</table>

Statistical Analysis
Baseline age is expressed as mean (minimal/maximal). The means of the different categories of the BSI test are expressed as means (standard deviation [SD]) and compared with each other by the use of the Mann-Whitney U Test. Differences were considered significant at the P < 0.05 level. All statistical analyses were performed using STATVIEW from the SAS Institute (Cary, NC, USA).

Results
We included 30 patients in the ICD-recall group and 25 patients in the ICD-control group. All patients with an ICD recall from our hospital participated in the study. Table I presents the baseline characteristics of the ICD-recall and ICD-control groups. Age, sex, and history of cardiac surgery were comparable between the two groups. More patients in the ICD-control group were survivors of SCD (24% vs 16.7%) and more patients of the ICD-control group had a positive family history of cardiac deaths (60% vs 46.7%), but these differences were not statistically significant. At the time of interview most patients were in good cardiac status (60% dyspnea New York Heart Association [NYHA] I in both groups). About 30% of the patients in both groups were slightly symptomatic (dyspnea NYHA II). Only one patient in the recall group and two subjects in the control group had dyspnea NYHA III and none had dyspnea NYHA IV.

Six subjects (20%) from the ICD-recall group were aware of ICD-recalls prior to being contacted by the Department of Cardiology. Three subjects did not recall how they received this information, two were informed by relatives, and one subject read about the ICD recall on the Internet.

The scores of the three global indices and nine different primary psychiatric distress symptom dimensions from the BSI test are summarized in Table II. The mean values were all within the normal range (40–60) for the ICD-recall and the ICD-control group. Three distress symptoms (obsessive-compulsive behavior, hostility, paranoid ideation) were significantly higher in the control group.

An overall comparison of the different scores according to the grade of dyspnea (NYHA I vs NYHA II) showed a general trend toward higher values in subjects with NYHA II (Fig. 1). This trend was independent of the ICD group (Recall vs Control). Differences between NYHA I and NYHA II were not significant, with the exception of somatization (P < 0.01).

An overall comparison of the scores with respect to the symptomatic shock experience (Fig. 2) showed a trend toward higher values (excepting paranoid and obsessive-compulsive behavior) in the shock-experienced group; no significant differences emerged.

Patients with lower left ventricular ejection (<30%) fraction had higher scores than patients with higher ejection fraction (>30%) in following categories (somatization, anxiousness) but the differences were not significant.

Discussion
Our study was designed to evaluate psychological distress in subjects who had been recently informed that their life-saving device could potentially malfunction. Using the BSI test we found that the distress profiles of both ICD-recall affected and nonaffected patient groups were more or less normal; the mean values were within the normal range for all primary and global stress categories measured.
NYHA class was a strong predictor of higher values in all categories, independently of the ICD group (control vs recall). All values of the NYHA II group patients tended toward higher levels than those of the NYHA I group, but somatization was the only category where patients of the NYHA II group reached pathological values (>60). While it might be assumed that symptomatic shocks should result in psychological distress, we found no such cause-effect relationship. Our results reveal only an upward, but not significant, trend in 7 of the 12 scales.

Table II.
Means (SD) of the Different Psychiatric Distress Symptoms

<table>
<thead>
<tr>
<th></th>
<th>ICD Recall (n = 30)</th>
<th>ICD Control Group (n = 25)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSI</td>
<td>47.6 (13.6)</td>
<td>54.8 (14.1)</td>
<td>ns</td>
</tr>
<tr>
<td>PSDI</td>
<td>51.7 (12.4)</td>
<td>52.9 (13.4)</td>
<td>ns</td>
</tr>
<tr>
<td>PST</td>
<td>46.5 (13.6)</td>
<td>53.9 (14.0)</td>
<td>ns</td>
</tr>
<tr>
<td>Somatization</td>
<td>53.1 (10.9)</td>
<td>57.6 (11.3)</td>
<td>ns</td>
</tr>
<tr>
<td>Obsessive-compulsive behavior</td>
<td>45.8 (11.3)</td>
<td>52.6 (9.8)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Interpersonal sensitivity</td>
<td>46.1 (9.8)</td>
<td>51.2 (9.9)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Depression</td>
<td>48.3 (10.6)</td>
<td>53.3 (11.0)</td>
<td>Ns</td>
</tr>
<tr>
<td>Anxiety</td>
<td>51.1 (12.7)</td>
<td>52.4 (11.2)</td>
<td>ns</td>
</tr>
<tr>
<td>Hostility</td>
<td>48.2 (11.0)</td>
<td>54.8 (10.3)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Phobic anxiety</td>
<td>53.8 (10.2)</td>
<td>52.9 (9.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Paranoid ideation</td>
<td>48.6 (10.0)</td>
<td>54.9 (11.5)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Psychoticism</td>
<td>49.4 (8.0)</td>
<td>53.6 (10.4)</td>
<td>ns</td>
</tr>
</tbody>
</table>

GSI = global severity index; PSDI = positive symptom distress index; PST = positive symptom total.

Figure 1. BSI scores according to NYHA class. Somatization was the only category which reached statistical significance (p < 0.05).

Figure 2. BSI scores in patients with or without symptomatic shock events. No statistical significance reached.
Previous investigations during the early era of extended ICD therapy have reported a high proportion of anxiety and depression in patients with ICD.\textsuperscript{10,11} Our study shows that psychological distress was not significantly increased in patients recently informed about a potential malfunction of their device. Furthermore, the psychological status of all analyzed patients (ICD-recall and ICD-control) was within the normal range.

Considering that ICD patients frequently have a complex medical background, the normal psychological status of our implanted patients may appear surprising. Possibly the patient of today is better informed regarding the firm establishment of ICD therapy. The current era of providing comprehensive information to the patient is another possible explanation for the moderate reaction shown by patients upon learning about the potential malfunction of their ICD. As mentioned in the results, only six patients (20\%) knew about the ICD recall before being contacted by the Department of Cardiology. It is indeed possible that patients who first hear about their potentially malfunctioning device through the media might be more anxious than those who are first informed by their own physicians. However, regular monitoring of ICD patients and a close contact with their cardiologist can positively influence their psychological status and limit the impact of media-transmitted anxiety-evoking information. Regular clinical surveillance might increase trust in both the device itself and the management of possible malfunction.

Our study can be viewed to concord with a recently published study\textsuperscript{14} comparing the quality of life and psychological status of ICD implanted patients with that of pacemaker implanted patients. This study found that ICD patients were not more likely to suffer from anxiety, depression, or general psychological distress.

Our study has some limitations. Our sample size is relatively small and may have limited the ability to detect differences where they perhaps do exist (i.e., trends noted but not reaching statistical significance). Additionally it should be noted that comparisons of various scores between NYHA classes and frequencies of shocks represent a post hoc analysis and not the primary question of this study. Our study should be viewed as a pilot project; further studies with a much larger sample are required to make exact statements about the psychological status in patients with potentially malfunctioning medical devices.

References