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Impact of Implantable Cardioverter Defibrillator Recalls on Patients' Anxiety, Depression, and Quality of Life

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Abstract

Background—In the past 2 years, multiple implantable cardioverter defibrillator (ICD) manufacturers have issued recalls on ICD models due to the potential for serious malfunction and even patient death. Previous studies examining the relationship between these recalls and patients' psychological well-being have been limited by small sample size and conflicting results. The purpose of this study is to examine the association between ICD recalls and patients' anxiety, depression, and quality of life.

Methods—Patients were drawn from an outpatient electrophysiology clinic at a tertiary care hospital in New York City. Patients who had devices subject to a recall (cases) were identified from lists provided by device manufacturer and controls (patients with ICDs not subjected to a recall) were drawn from a convenience sample of outpatients. The survey instrument consisted of two validated questionnaires—Hospital Anxiety and Depression Score (HADS) and MacNew Heart Disease Health related Quality of Life (QOL) instrument. In addition, a series of Likert type scales were designed to elucidate patients' concerns related to the following domains: anger, trust, hope, concerns regarding ICD shock, fear of death (FOD) and physicians' ability to reduce their concern about the ICD recall. Data were analyzed using simple descriptive statistics and bivariate analyses (chi-square and t-test) as appropriate.

Result—61 cases and 43 control patients were enrolled. Thirty two patients (52%) with devices subject to a recall opted for a generator replacement. There were no significant differences in the mean scores on the HADS scale, or the MacNew QOL scale between these two groups of patients (cases and control). Subgroup analysis within the group of patients whose ICDs were recalled (cases) revealed a reduced QOL amongst patients with a Class I recall (reasonable probability that the product will cause serious adverse health consequences or death) as compared to those with a Class II recall (product may cause temporary or medically reversible adverse health consequences) ($p=0.01$). Both cases and control patients reported having reduced trust in the health care system. On the whole, however, patients were satisfied with the way their physicians dealt with the recall. There was no significant change in the overall concern of ICD shocks or FOD between the two groups.

Conclusion—In this study of ICD recall, we found no difference in the levels of anxiety, depression or QOL expressed by patients with an ICD subject to a recall as compared to those without. These

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findings may be a reflection of good physician-patient communication, which might have reduced any anxiety associated with recalls.

Keywords

ICD Recalls; Anxiety; Depression; Quality of Life; Case Control Study

Introduction

Cardiac pacemakers and implantable defibrillators (ICDs) have been one of the most innovative medical advances of the twentieth century. The preceding decade has seen a marked increase in the number of ICDs implanted related to improved survival associated with these devices¹⁻³. While often life saving and associated with improved quality of life (QOL) amongst patients with advanced heart disease⁴, these devices occasionally malfunction with an incidence of 27.4 % per 1000 devices⁵. Since 1990 there have been several reports of device malfunctions affecting ICDs in the form of electrical or circuitry malfunction, battery or capacitor malfunction, inadequate hermetic seal, defective crystals and device header abnormalities⁶. This increased incidence is in part related to improved surveillance of these devices by manufacturers as well as an increase in the reporting of potential malfunctions^{7, 8}.

A significant body of literature suggests that ICD implantation is associated with psychological distress⁴. Approximately 13 % to 38 % patients implanted with ICDs experience symptoms of anxiety and depression⁹⁻¹¹. It could be hypothesized that knowing that a life saving device is at risk for malfunction leads to increased anxiety and perhaps worsening of depression. Some ICD recalls require the need for device replacement¹², which may also adversely affect the overall emotional status. ICD recalls have been a focus of significant media attention¹³ and the increased public awareness of recalls may further add to the anxiety already associated with the device itself. There is conflicting data regarding the impact of ICD recalls on the psychosocial status of patients with and without recalled ICDs^{14,15}. The purpose of this study was two-fold:

1. To determine the overall perception patients (both those with and without ICD recalls) have towards their defibrillators, as well as the impact of a recall on the trust towards the health care system and industry.
2. To determine the relationship between ICD recalls and patients' reports of anxiety, depression and QOL.

Methods

The research protocol including review of the registry of recall patients was approved by the institutional review board of the Mount Sinai School of Medicine.

Subject Selection (Cases)

Patients were drawn from the outpatient ICD clinic at Mount Sinai Hospital (MSH), a large clinic serving an ethnically and socio-demographically diverse population. Patients were eligible if they were fluent in English and not cognitively impaired, as defined by a score of 8 or more on the Short Portable Mental Status Questionnaire¹⁶.

Cases were identified from the registry maintained by the device manufacturers and included patients followed in the ICD clinic at MSH. All cases were previously aware of the nature of their recall and the clinical implications of the recall, as part of a standard post ICD recall management protocol established at MSH. The post recall management (which was not a part

of any study protocol), included emotional and psychological counseling as needed with the option to participate in various ICD support groups to alleviate concerns regarding the recalls. The data from the recall registry included the patient's name, the date of implant, and the type of recall-class I or class II. Recalls are defined as class I when there is reasonable probability that as a result of the defect, the product will cause serious adverse health consequences or death and class II when the use of the product may cause temporary or medically reversible adverse health consequences or if the probability of a serious adverse health consequence is remote¹⁷. Once identified, all cases were mailed a letter asking them to participate in a research survey "evaluating how the recalls had affected their lives". Patients were given the option to call a number if they wished to decline participation. If a patient did not call the "decline to participate number," it was assumed that they consented to be called by the research team. Three investigators (PC, KS and DB) contacted cases to administer the survey instrument over the phone, and at the start of this call, informed consent to participate in the study was obtained. Control patients were approached during routine ICD follow-up and interviewed by two investigators (MS and TM) at the time of their routine ICD follow-up. Informed consent was obtained at the time of the interview. The enrollment of the control patients was done concurrent with enrollment of cases.

Survey Design

Because no validated instrument assessing the impact of ICD recall on patients' psychological states exists, the investigators created a novel survey instrument consisting of both previously validated scales as well as a series of Likert type scales examining patients' overall perception towards the news of the ICD recall. The Hospital Anxiety and Depression Scale (HADS) is a 14-item instrument consisting of a series of four-point Likert scales and includes questions relating to patients' overall level of anxiety and depression. The HADS has been validated in a variety of clinical arenas including patients in the general population, those with somatic, psychiatric and cardiac disease, and has been shown to be a valid and reliable instrument with Cronbach's alpha ranging from 0.67 to 0.93 for the two subscales¹⁸⁻²¹. Based on a recent review, a score of ≥ 8 was considered abnormal on either the anxiety or depression subscales¹⁸. QOL was assessed using MacNew Heart Disease Health Related QOL survey (MacNew HRQL)²². This 27-item questionnaire assesses the relationship between heart disease and daily physical activities as well as emotional and social functioning. Based on the scores from the physical, emotional and social domains, a global HRQL score is calculated where higher scores suggest a better HRQL (maximum score of 7). This questionnaire has been validated in patients with myocardial infarction, angina and cardiac pacemakers²³. To determine the relationship between device recalls and patients' overall perception of the health care system, the investigators created a novel, non-validated series of questions assessing nine domains of care, based on the clinical and research expertise of the clinicians who care for these patients. Likert type scales (0-10; 0 was "much less", 5 was "no change", and 10 was "much more") were used to assess the relationship between an ICD recall and changes in these domains. (Table1) Both cases and controls received identical survey instruments.

Demographic information was obtained from all patients at the time of interview. The clinical history, relevant cardiac conditions, medications, prior history of anxiety/or depression and patients' telephone numbers were obtained by medical record review.

Statistical Analysis

Descriptive statistics were used to compare the two groups of patients. To compare categorical variables, a Chi-square test was used, while the differences in the mean scores of anxiety, depression and QOL were calculated using the student t test. Subgroup analyses were performed to evaluate differences based on the type of recall (class I versus class II) and the

indication of the initial implant (secondary versus primary prevention). Since a number of *a priori* hypotheses about associations between characteristics of device recalls and patients' psychological states were made, correction for multiple comparisons was not performed. In addition, the small sample size makes it unlikely that any association found would occur by chance alone. Therefore, to reduce the probability of a type II error, adjustment of the significance levels for individual tests was not performed. All calculations were performed using the SAS® 9.0 statistical software (Cary, NC, USA).

Results

The survey was conducted from November 2005 to January 2006. The mean time from the issuance of the recall and the interview was 7.6 ± 1.6 months. Of the 115 patients approached, 104 were enrolled (response rate=90 %). These included 61 cases (study group) and 43 controls. Four patients refused (by calling the “decline to participate” number), and 7 patients did not meet eligibility criteria (5 patients due to inability to understand English and 2 patients for failing the short portable mental status questionnaire). Table 2 lists the patient demographics, cardiac risk factors, indications for ICD implant and prior history of anxiety and depression. There were no significant differences between the groups in terms of: age, gender, race, income, ethnicity, marital status, religion, or educational status. There was no significant difference in the left ventricular function between the two groups.

Among cases, 43 patients (72 %) had a device subject to a class I recall, and 32 (52%) of these patients underwent a generator change. The mean interval between the generator change and the interview period was 2 ± 2.5 months. The ICD was implanted in the majority of patients (in both groups) for secondary prevention. There was no statistically significant difference in the history of depression and anxiety or in the history of prior ICD discharges between the two groups of patients.

HADS data are shown in table 3. There was no significant difference between the anxiety and depression scores between the two groups of patients. Fifteen (25 %) of the cases were found to have clinically relevant levels of anxiety compared with 14 (32 %) of the controls (P=0.6). Similarly, 10 (17 %) cases and 5 (11 %) controls met the diagnostic score suggestive of depression (P=0.5).

Table 4 reports the results of the QOL scores in cases and controls as well as in the prespecified subgroups. There was no significant difference in the physical, social, emotional or global QOL score between cases and controls.

No differences were noted between the two groups in terms of the responses to the questions designed to assess patients' satisfaction with care relating to the ICD recall. There was a slightly reduced degree of trust towards the health care industry in cases (mean Likert score for case of 3 vs. control of 7) but this was not statistically significant. Overall, patients from both groups were satisfied with the way their physicians handled the issue of recalls (mean Likert score of 7 in both groups).

Sub-group Analyses of Cases and Controls

There was no significant difference in the mean anxiety and depression scores for patients with devices implanted for primary prevention versus those implanted for secondary prevention. Additionally, there was no significant difference in patients with devices subject to a class I versus a class II recall. Table 3

Sub-group analysis with respect to the QOL indicators demonstrated that patients with a device subject to a class I recall had a slightly worse overall QOL as compared to patients with a

device subject to a class II recall. The difference in the QOL between patients with class I and class II recall devices was small but statistically significant and consistent across all the three domains.

There was no difference in the QOL between patients with devices implanted for primary prevention versus secondary prevention or those patients who underwent a generator replacement versus those who did not. Table 4

Discussion

In this study designed to evaluate the impact of ICD recalls on patients' anxiety, depression and QOL, we found no significant differences in patients with ICDs subject to recall vs. those patients whose ICDs were not subjected to a recall. Sub-group analyses based on the type of recall revealed a lower QOL in patients with a device recall associated with a greater likelihood of potentially life-threatening malfunction (class I recall). This difference may be related to the fact that patients with class I recall were more emphatically recommended to undergo a generator change, and in fact, in our patients, over 50 % underwent generator replacement. Although an outpatient procedure, generator replacement is associated with an increased morbidity as a result of possible procedural related complications as well as the increased in the number of office visits. We therefore hypothesize that this may have negatively affected the perceived QOL for these patients. Recently, Gould and colleagues¹² evaluated the risk of ICD generator replacement in a population of patients with device subject to ICD recalls. Their study involving 17 centers in Canada and over 2900 patients found that ICD replacement was associated with an overall complication rate of 8.1 % and major complication rate of 5.8 %, including 2 deaths. Similarly, Goldstein et al reported a single center experience and found the complication rate from generator replacement approached 12 % with no fatal events²⁴. The results of these two studies suggest that reduced QOL and psychosocial functioning may not only result from the knowledge of a potentially defective and malfunctioning device but also from substantial peri-operative morbidity. These findings were not confirmed in our study as no significant difference in the QOL domains were found between patients who underwent generator change and those who did not. Whether this is a reflection of the small sample size in our study or the lower complication rate we noted in our cohort of patients cannot be said with certainty.

Relationship between Recall and Anxiety/Depression

Despite the changes in perceived QOL, we found no difference in reported levels of depression and anxiety between those patients with an ICD subject to a recall as compared to those who were not. Similar to our study population, the majority of published data evaluating the psychological impact of ICDs on patients has been in patients whose ICDs have been implanted for secondary prevention. Recent estimates suggest that anxiety after ICD implantation especially for secondary prevention is very common with 24-87 % of patients reporting increased symptoms of anxiety after implantation. Clinically significant anxiety is seen in 13-38 % of patients, whereas depressive symptoms are seen in 24-33 % patients who receive ICD for secondary prevention^{4,11}. Additionally, approximately 10-39 % patients with an ICD implanted for secondary prevention experience a shock within the first year after implant²⁵⁻²⁷. The adverse psychosocial effects of ICDs, however, are not limited to patients who receive a shock. The fear of death, fear of receiving shocks, and dependency on a device may contribute to the increased incidence of anxiety and depression seen in patients with ICDs¹¹. The psychosocial impact of ICD recalls has been an area of significant controversy. Van den Broek et al¹⁵ studied the psychosocial impact of ICD recalls in 33 patients who enrolled as a part of an ongoing longitudinal study and found a significant increase in the mean levels of anxiety, as well as the number of patients with increased levels of anxiety as compared to

baseline (6 % vs. 24%). While differences in the overall anxiety levels were significant, that study did not factor in the potential bias that could be introduced as a result of ICD shocks over time. Similar results were not found in a study by Cuculi et al¹⁴ who compared the psychosocial impact of recalls between patients with a potentially flawed ICD (recalled ICD) vs. those without a recalled ICD. In this study of 55 patients (30 study, 25 controls), the mean value of all primary psychiatric distress symptom dimensions and global indices were within the normal range for both the ICD recall and the control group. Sears and Conti, in an editorial, speculated that although a profound psychological impact of device recalls was unlikely, a more specific approach for every patient to detect change in “faith” towards their device was warranted²⁸.

Clinician's Role in Management of ICD Recalls

One plausible explanation for the similarity in outcome between the two groups of patients in our study may relate to the way the physicians managed the issue of the recalls. As part of a standardized protocol established at our institution, patients with a recalled ICD were asked to come for an unscheduled office visit and attempts were made by the following physician to answer and alleviate all patient concerns related to the recall. Furthermore, patients were encouraged to participate in special support groups formed to address recall related concerns. Consistent with these actions, one of the key findings in our survey was a high degree of satisfaction by both cases and controls in the way their physicians addressed the issues associated with the recall. It is plausible, that physician-patient communication along with a level of trust and an established rapport may have played an important role in alleviating concerns and anxiety in those patients subject to ICD recall. Physician-patient communication has long been considered integral and invaluable in patient care. It is well established that a positive outlook towards a clinical condition can significantly impact patients' perceptions of their disease^{29,30}. The impact of “the power of suggestion” on a patient's health is often under appreciated. In a systematic review of the literature, Di Blasi et al examined the possible therapeutic effects of patient-physician relationship. The investigators found that out of 19 trials examining the effects of influencing patients' expectations about treatment, half demonstrated a significant impact on patients' health outcomes³¹. It appeared that suggestions were more effective when treatment expectations were positively, rather than negatively enhanced. Positive outcomes as a result of an effective patient-physician relationship is well established in cancer patients. Zachariae et al found that a higher score on the patient-physician relationship inventory (a survey instrument assessing physician's communicative skills) was associated with a greater degree of patient satisfaction, increased self-efficacy and reduced emotional distress³². Similarly, Roberts et al found that psychological adjustment in cancer patients was significantly improved by expressing empathy, allowing sufficient time for patients to absorb the cancer diagnosis, providing adequate information, and engaging the patient in treatment decision-making process³³.

The importance of physician communication has also been substantiated in patients with defibrillators by Stutts et al³⁴ who used hypothetical vignettes in 66 ICD patients (20% of whom had actual ICD recalls) to evaluate how different ways of communicating a recall affected patients' responses. The two main findings in this study were that patients had more confidence and preferred learning about the recalls from their physicians over media and device manufacturers and contrary to the results of our study, regardless of whether the recall directly involved them, the news of a recall generated a significant degree of anxiety in all patients.

Our study has several limitations. As a single center study these results may not be applicable to a larger population. Furthermore, because of the novel study design and the descriptive nature of the study, a formal power calculation was not performed prior to the study initiation and as such the study may not have been adequately powered to detect significant differences between the two groups. The ICD specific questionnaire used in our survey was based on the

clinical experience of the investigators and has not been previously validated. Additionally, the mode of administration may introduce a potential bias in the results. While the HADS survey has been previously administered over telephone³⁵, this mode of administration has not been previously validated for the MacNew HRQL. Because of this, the results from this new questionnaire cannot be compared between patients with and without a device recall, and are meant for illustrative purposes only. The differences in the techniques of interviewing the two groups of patients (face to face versus over the telephone) may potentially confound the results of the survey. This methodology was used to limit the number of office visits required by the study population to a minimum in order to reduce any additional anxiety resulting from a formalized visit and a face-to-face interview. To reduce this possible confounder, both groups received identical surveys. Finally, unlike most patients who currently undergo ICD implantation, the majority of the patients in our study had ICD implantation for secondary prevention. While this is unlikely to contribute any bias in our data analysis (since both groups were similar in this regards), these results should be interpreted with caution in patients with device implanted for primary prevention indication.

Conclusion

With increasing reports of advisories in the medical device industry, the issue of psychosocial well being in patients with defibrillators is of substantial significance. Our study attempts to address these important issues and evaluate the impact of ICD recalls on the overall psychological well-being in patients with ICDs subject to recall. Although no differences in the overall anxiety, depression and QOL were found between the two groups, the reduction in the QOL amongst patients with ICDs subject to class I recall is noteworthy and perhaps suggests an area for further research. This sub-group of patients may represent a “high-risk” group for psychological maladjustment and may benefit from a more intense psychosocial intervention. With the expanding indications for ICD implantation, it is likely that advisories and recalls will continue to occur in the future. Future studies aimed at prospectively addressing the psychosocial status and QOL in these patients on a larger scale is therefore warranted.

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Table 1

Novel questions designed to determine satisfaction with quality of care and concerns relating to ICD recall

Questions 2-9 were answered on a 10-point scale where 0 was “much less”, 5 was “no change”, and 10 was “much more”.	
1) Has the news of the cardiac defibrillator recall affected your trust in the healthcare system?	Yes/No
2) If yes, on a scale of 0-10, where 0 is much less trustworthy, 5 is no change and 10 is much more, how would you rate how the defibrillator recall has changed your trust in the healthcare system?	
3) On a scale of 0-10, where 0 is much less, 5 is no change and 10 is much more since the defibrillator recall, how would you rate your feelings of anger towards the defibrillator company?	
4) On a scale of 0-10, where 0 is much less, 5 is no change and 10 is much more, since the news of the defibrillator recall, how hopeful are you about your future?	
5) On a scale of 0-10, where 0 is much less, 5 is no change and 10 is much more, since the news regarding the defibrillator recall, how much have you been preoccupied with thoughts about your defibrillator?	
6) On a scale of 0-10, where 0 is much less, 5 is no change and 10 is much more, since the news regarding the defibrillator recall, how concerned are you regarding the possibility of getting defibrillators shocks?	
7) On a scale of 0-10, where 0 is much less, 5 is no change and 10 is much more, since the news of the defibrillator recall, how concerned are you that your defibrillator shock may not be successful in treating a potentially fatal heart rhythm?	
8) On a scale of 0-10, where 0 is made it worse, 5 is no change, and 10 is very effective, how effective have your physicians and health care workers been in lessening your fears or concerns regarding the defibrillator recall?	
9) On a scale of 0-10, where 0 is much less, 5 is no change and 10 is much more, how has the news of defibrillator recall affected your fear of death?	

Table 2
Clinical Characteristics of the Two Groups

Clinical Variable	Case (n= 61)	Control (n=43)
Mean Age	67.39±14.5	64.67±14.9
Male n(%)	43 (70)	28(65)
Non-White n(%)	18 (29)	20 (46)
Mean LVEF	31.8±12.7	34.2±14.3
Cardiac Risk Factors n(%)		
HTN	31(50)	20 (47)
DM	12 (20)	5 (12)
CAD	42 (69)	21(49)
CHF	47 (77)	29 (67)
Chol	39 (64)	22 (51)
Type of ICD n(%)		
ICD (single or dual)	45 (74)	37 (86)
BiV -ICD	16 (26)	6 (14)
Duration of Device (months)	24.5±10.7	19.1±25.6
Duration from Recall notification and interview (days)	230±55	N/A
Class I Recall n(%)	43 (70)	N/A
ICD Indication n(%)		
PP	20 (33)	17 (40)
SP	41 (67)	26 (60)
H/o Psychiatric Illness (Anxiety or Depression) n(%)	13 (21)	12 (28)
Prior h/o Shocks n(%)	23 (38)	18 (42)

None of the variables were significant between the two groups. ICD-implantable cardioverter defibrillator, PP-primary prevention, SP-secondary prevention.

Table 3
Measures of Anxiety and Depression between the cases and controls

Variable	Case (n=61)	Control (n=43)	P value
Clinically relevant Anxiety * n (%)	15 (25)	14 (32)	0.6
Clinically relevant Depression * n (%)	10 (17)	5 (11)	0.5
Mean Anxiety Score	4.8± 3.9	6.0 ± 3.3	0.1
Mean Depression Score	4.4± 3.4	4.2± 3.6	0.73
Mean anxiety scores (subgroups, cases only):			0.81
Primary prevention (n=20)	5.0 ± 4.2	N/A	
Secondary prevention (n=41)	4.7±3.9	N/A	0.3
Class I recall (n=43)	4.5±4.0	N/A	
Class II recall (n=18)	5.7± 3.8	N/A	
Mean depression scores (subgroups, cases only):			
Primary prevention	4.3± 2.6	N/A	0.90
Secondary prevention	4.5±3.7	N/A	
Class I recall	4.3±3.50	N/A	0.45
Class II recall	5.1±3.3	N/A	

* Based on the HADS scoring system

Table 4

Differences in the QOL scores between cases and controls and subgroups within the recall group-Class I and II recall and primary and secondary prevention

Population Type	Physical (M±SD)	Emotional (M±SD)	Social (M±SD)	Global (M±SD)
Case	5.2 ±1.2	5.3±1.1	5.3±1.2	5.2±1.0
Control	4.8±1.3	4.9±1.2	5.1±1.1	5.0±1.1
<i>P value</i>	0.4	0.5	0.2	0.2
Class I recall	4.6±1.3	4.8± 1.2	4.7±1.4	4.8±1.1
Class II recall	5.4±1.1	5.4±1.0	5.6±1.0	5.5±1.0
<i>P value</i>	0.01	0.04	0.009	0.01
Primary prevention	5.2±1.2	5.2±1.2	5.3±1.2	5.2±1.1
Secondary prevention	4.8±1.3	5.2±1.1	5.0±1.2	5.0±1.1
<i>P value</i>	0.2	0.7	0.2	0.3
Generator Changed	5.0±1.2	5.1±1.1	4.9±1.1	5.2±1
Generator Not Changed	4.9±1.1	5.0±1.2	5±1.1	5.3±1
<i>P value</i>	0.3	0.8	0.6	0.6