No long-term psychological morbidity living with an implantable cardioverter defibrillator under advisory: the Medtronic Marquis experience

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Received 29 August 2008; accepted after revision 27 October 2008; online publish-ahead-of-print 13 November 2008

Aims

It is unclear whether there is important psychological morbidity associated with living with an implantable cardioverter defibrillator (ICD) under advisory and whether this should be factored into decision-making.

Methods and results

Our study focused on patients living with advisory Medtronic Marquis ICDs. Patient adjustment to the ICD was evaluated using a validated device-specific metric of patient acceptance, the Florida Patient Acceptance Survey (FPAS). A comparison group of patients with other models of ICDs that were not under an advisory also completed the study measure. The questionnaire return rate was 86/122 (70.5%) in the advisory group and 94/134 (70.1%) in the non-advisory group. Only one patient in our clinic elected for generator change due to severe anxiety. There were no differences in demographic or clinical variables between the groups. There were no differences in the mean total FPAS score between the two patient groups (advisory patients 85.97 ± 14.95 and 86.23 ± 15.76 for non-advisory, P=0.340). Also there were no differences in any of the subscores. Correlates of poor device acceptance were younger age and a history of electrical storm.

Conclusion

We found no evidence of increased long-term psychological morbidity in patients living with an ICD under advisory compared with patients with an ICD not under advisory. Our data suggest that patients and physicians should avoid hasty decisions about ICD replacement for psychological reasons.

Keywords

Psychological morbidity • ICD • Advisory • Recall • Anxiety

Introduction

Implantable cardioverter defibrillators (ICDs) advisory notices are issued to patients and physicians when an ICD component is found to have the potential to malfunction. These advisories present treatment dilemmas for physicians and patients. On the one hand, the risk of device malfunction and the likely severity of clinical sequelae have to be estimated. This estimate has to be weighed against the risks of surgery to replace the advisory component. It is currently unclear whether there is important psychological morbidity associated with living with an ICD under advisory and whether this should be factored into decision-making.1 One study suggested that there was an acute increase in anxiety,2 whereas patients from two other studies did not confirm this finding.3,4 None of these studies used a device-specific measure of psychological morbidity.

The current study focused on patients living with Medtronic Marquis ICDs. Theses devices were subject to an advisory in February 2005, which indicated a life-time risk of perhaps 1% of rapid battery depletion, resulting in abrupt loss of pacing and shock capability.5 Identified advisory patients were advised to at least weekly self-test their battery status with a hand-held magnet. This self-testing likely serves as a regular reminder that there is a potential problem with the device. The objective of our study was to examine whether there is decreased patient acceptance of ICD devices when an ICD is under advisory...
compared with a control group of ICD patients without advisory
devices, using a device-specific measure of psychological wellbeing.

**Methods**

**Advisory details and patients**

In February 2005, Medtronic announced a world-wide advisory on
Marquis ICDs manufactured between April 2001 and December 2003. Nine patients out of 87 000 had experienced rapid battery
depletion due to an internal battery short. The projected life-time
risk of this occurring was estimated to be 0.2–1.5%. Rapid battery
depletion would lead to an abrupt loss of pacing output and shock
capability.5

Patients affected by the advisory at our institution were immediately
contacted. They were invited to special information sessions which
consisted initially of a 1 h lecture for them and their relatives, with
the opportunity to ask questions after the lecture. The patients
were then seen individually by an electrophysiologist to discuss the
most appropriate plan of action for them. Two options were discussed
with all patients. The first was to have their device changed and the
risks of this were reviewed with the patient. All patients were
offered the option of device change, although this was only rec-
commended in the pacemaker-dependent group. The second option
was regular testing with a self-applied magnet. All patients in our prac-
tice who still had an implanted advisory Marquis device in December
2007 (i.e. 32 months after the advisory) were eligible for this study.
Patients who had had their device changed to an alternative device
were excluded from the study.

**Non-advisory patients**

All contemporaneous patients in our practice with models of ICDs
that were not under any advisory formed the control group. No
ICD leads in either group were under advisory.

**Questionnaire**

The Florida Patient Acceptance Survey (FPAS) measures device patient
acceptance using 18 items rated on a 5-point Likert scale from 0
(strongly disagree) to 5 (strongly agree), with a high score indicating
more acceptance.6,7 Four subscale scores can be derived from the
patient responses, including: (i) return to function (four items; e.g. ‘I
am confident about my ability to work if I want to’); (ii) device-related
distress (five items; e.g. ‘When I think about the device, I avoid doing
things that I enjoy’); (iii) positive appraisal (four items; e.g. ‘I would
receive this device again’); and (iv) body image concerns (two items;
e.g. ‘I feel less attractive because of my device’). The remaining three
items are filler items. A composite score referring to total patient
acceptance is also possible. Total FPAS score and return-to-function
and positive appraisal scores are positively correlated with device
acceptance, i.e. a lower score reflects poorer device acceptance; in
contrast, device-related distress and body image concern subscores
are negatively correlated with device acceptance, i.e. a higher score
means lesser device acceptance.

This tool is considered to be a more sensitive instrument than general
quality-of-life or anxiety measurement tools because it is a disease-
specific instrument specifically assessing symptoms relevant to ICD
patients.6,7 The questionnaire was mailed to all patients. If the patient
did not reply within 3 weeks, they were contacted by telephone and
the questionnaire was completed verbally by a trained nurse.

**Clinical and demographic characteristics**

Clinical variables were recorded from our device clinic charts and
database (PACEART, Medtronic, Minneapolis, MN, USA). Device
type, age, gender, New York Heart Association (NYHA) class at
implant, left ventricular ejection fraction (LVEF), primary or secondary
indication, and shock history including history of electrical storm
defined as at least three shocks in 24 h) were collected.

**Statistics**

Quantitative variables (age, length of follow-up, LVEF) were analysed
using the Wilcoxon two-sample test or the Kruskall–Wallis test
where appropriate. Categorical variables (gender, primary/secondary
indication, aetiology, NYHA class, history of any shock, and history
of electrical storm) were analysed using Fisher’s exact test. A priori
on the basis of the literature, we decided to include the following vari-
ables in multiple linear regression models, as they have been associated
with patient-centred outcomes in ICD patients: age, gender, length of
follow-up, advisory status, history of any shock, and history of electrical storm.7,9,10 These variables were entered into multiple linear
regression models using FPAS scores as the dependent variables. For
the models, using a Bonferonni correction, a P-value <0.01 was
used to indicate statistical significance. It can be estimated that with
a sample size of 86 in the advisory group and 94 in the non-advisory
group, there is 99.25% power, with alpha=0.05, to detect a 10% reduction in the total FPAS score (based on data from11). The statistics
were calculated using SAS version 9.1.

**Ethics**

The protocol received ethics approval from the University of Ottawa
Heart Institute ethics board, and all patients signed informed consent.

**Results**

**Patients**

A total of 241 patients in our clinic were implanted with an advi-
sory Marquis. Nine patients were recommended to have a genera-
tor change, because of pacemaker dependency, and all agreed to
this. One other patient elected for generator change due to severe anxiety. Fifty-eight patients have subsequently died and
three patients have undergone cardiac transplantation. Thirty-six
patients have reached elective replacement interval and undergone
pulse generator change and 11 patients had declined to be
approached for research. This study consisted of the residual
122 patients who are still living with a device under advisory. It
should be noted that no patient in the Marquis group had suffered
sudden battery depletion. The control group consisted of all con-
temporaneous patients in our practice with models of ICDs that
were not under any advisory (n=134). The questionnaire
return rate was 86/122 (70.5%) in the advisory group and 94/134
(70.1%) in the non-advisory group.

**Comparison between advisory and non-advisory patients on baseline
characteristics and device acceptance**

There were no statistically significant differences in baseline demo-
graphic and clinical variables [age, gender, NYHA class at implant,
LVEF, aetiology, primary or secondary ICD indication, and shock
history including history of electrical storm (Table 1)]. There
were no differences in the total FPAS score (advisory patients 85.97 ± 14.95 and 86.23 ± 15.76 for non-advisory, P = 0.340). There was no difference in any of the FPAS subscores between the two patient groups (Table 2).

**Effect of other clinical variables on Florida Patient Acceptance Survey scores**

Shock history and history of electrical storm were univariate correlates of adverse FPAS return-to-function scores. The mean score in 93 patients who had never experienced a shock was 67.69 ± 24.96. In comparison, the score in 46 patients who had had shocks but not electrical storm was 63.70 ± 26.46 and in 16 patients who had had storm was 48.79 ± 22.45 (P = 0.020).

Discussion

We found no evidence of reduced patient acceptance of devices in patients living with an ICD under advisory compared with patients with an ICD not under advisory. These data extend the current literature related to the impact of recalls on ICD patients because a device-specific metric (i.e. the FPAS) with likely greater sensitivity was employed. Previous work examining this question used generic measures of anxiety and produced conflicting results in small numbers of patients. Van Den Broek et al.² studied 33 patients with devices subject to the same advisory as in our study using the State-Trait Anxiety Inventory. These patients were already recruited to an ongoing study of ICD patient anxiety prior to the recall event and then were re-assessed immediately after being informed of the recall. They found that a high level of anxiety was experienced by two patients at baseline and eight patients immediately post-recall (P = 0.031).² In contrast, Cuculi et al.³ reported on 30 patients implanted with an ICD recall device and compared this group with 25 patients with unaffected ICD devices. They had no data on these patients prior to their recall. Again the psychological assessment was conducted on the same day as the recall information was first reviewed with the patient by their cardiologist. The study used a generic measure of distress, the Brief Symptom Inventory, and failed to show differences between study groups. Similarly, Gibson et al.⁴ compared 31 patients with advisory ICDs with 50 unaffected controls and found no difference using standard psychological (Patient Health Questionnaire) and quality-of-life (SF-36) questionnaires.

We chose to use a device-specific measure of psychological well-being because it has been shown that the FPAS is able to detect differences between patients that were not detected by general quality-of-life scores, for example the SF-36.⁶ The SF-36 may not have the specificity needed to detect subtle differences in changes of health statutes in patients after they have been treated.⁶ Also previous work has shown that general quality-of-life tools are not sensitive enough to detect differences in psychological well-being between pacemaker and ICD patients.¹²,¹³ In contrast, Burns et al.⁶ found that the total FPAS score and the four subscores were all significantly different between ICD and pacemaker patients, with ICD patients showing lower device acceptance in all domains.

The current study confirmed that the FPAS had utility in detecting differences in important subgroups of ICD patients, including sex differences, shock differences, and age differences. These important differences are consistent with previous work that outlined ‘at risk’ groups for psychosocial difficulties in ICD patients such as the young and shocked patients.⁹ Recently, Pedersen

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**Table 1** Demographic and clinical characteristics, stratified by advisory and non-advisory patients

<table>
<thead>
<tr>
<th></th>
<th>Advisory (n=86)</th>
<th>Non-advisory (n=94)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>67.72 ± 9.75</td>
<td>64.96 ± 11.79</td>
<td>0.10</td>
</tr>
<tr>
<td>Length of follow-up (months), mean (SD)</td>
<td>52.40 ± 9.00</td>
<td>50.58 ± 13.30</td>
<td>0.29</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>72 (83.6)</td>
<td>72 (76.6)</td>
<td>0.23</td>
</tr>
<tr>
<td>Primary indication, n (%)</td>
<td>34 (39.5)</td>
<td>41 (43.6)</td>
<td>0.50</td>
</tr>
<tr>
<td>Ischaemic aetiology, n (%)</td>
<td>72 (83.6)</td>
<td>71 (75.5)</td>
<td>0.27</td>
</tr>
<tr>
<td>NYHA (I/II), n (%)⁴</td>
<td>46 (80.7)</td>
<td>41 (75.9)</td>
<td>0.54</td>
</tr>
<tr>
<td>LVEF (%), mean (SD)⁴</td>
<td>29.60 ± 14.00</td>
<td>29.80 ± 12.33</td>
<td>0.92</td>
</tr>
<tr>
<td>Any shock, n (%)</td>
<td>32 (43.2)</td>
<td>30 (37.0)</td>
<td>0.43</td>
</tr>
<tr>
<td>Any electrical storm, n (%)</td>
<td>7 (9.4)</td>
<td>9 (11.1)</td>
<td>0.74</td>
</tr>
</tbody>
</table>

LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.⁴ Data available on 111 patients (57/54).⁵ Data available on 67 patients (80/87).

**Table 2** FPAS scores in patients with advisory and non-advisory ICDS

<table>
<thead>
<tr>
<th></th>
<th>Advisory (n=86)</th>
<th>Non-advisory (n=94)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPAS return to function</td>
<td>62.08 ± 25.73</td>
<td>65.77 ± 25.95</td>
<td>0.34</td>
</tr>
<tr>
<td>FPAS device-related distress</td>
<td>17.61 ± 19.17</td>
<td>19.55 ± 19.13</td>
<td>0.50</td>
</tr>
<tr>
<td>FPAS positive appraisal</td>
<td>85.63 ± 21.75</td>
<td>89.21 ± 15.97</td>
<td>0.21</td>
</tr>
<tr>
<td>FPAS body image concerns</td>
<td>13.11 ± 23.68</td>
<td>17.95 ± 26.60</td>
<td>0.20</td>
</tr>
<tr>
<td>Total FPAS score</td>
<td>85.97 ± 14.95</td>
<td>86.23 ± 15.76</td>
<td>0.91</td>
</tr>
</tbody>
</table>

FPAS, Florida Patient Acceptance Survey. Note that total FPAS score and return-to-function and positive appraisal scores are positively correlated with device acceptance, i.e. a lower score means lesser device acceptance; in contrast, device-related distress and body image concern subscores are negatively correlated with device acceptance, i.e. a higher score means lesser device acceptance.
et al. \(^7\) performed the most detailed assessment to the FPAS in 566 ICD patients. They found that correlates of poor device acceptance included older age, symptomatic heart failure, Type D personality, anxiety, and depression.\(^7\) Despite these capabilities of the FPAS to detect important differences in psychological well-being, the FPAS did not detect differences between advisory vs. non-advisory patients in our study. Hence, although patients often feel acutely anxious after notification of device advisories, our data suggest that patients and physicians should avoid hasty decisions about ICD replacement for psychological reasons.

We also believe our data will help patients contemplating ICD implantation (and their physicians). Since the recent ICD advisories, we and many electrophysiologists have had high-risk patients refusing ICDs because of concerns about reliability. The falling ICD sales have been ascribed to these concerns. As part of the discussion, patients need to be informed that they are quite likely to have an ICD component under advisory at some point, they are likely to adjust well to living with an advisory ICD (based on our data), the risk of death from an ICD malfunction is very small, and it is far more likely that they will benefit from an ICD than come to harm from ICD malfunction.\(^14\)

The influence of shocks on ICD patients’ psychological state is subject to debate with some\(^10,15,16\) but not all studies,\(^11,12,17,18\) confirming a relationship between shocks and adverse outcomes. The inconsistency in findings is likely multi-factorial, including whether potential confounders were controlled for; the way that

### Table 3 Multivariate analysis of correlates of FPAS scores (denotes significant at \(P < 0.01\)) (Bonferonni correction)

<table>
<thead>
<tr>
<th>Score</th>
<th>Parameter</th>
<th>Parameter estimate</th>
<th>SE</th>
<th>(P)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPAS return to function</td>
<td>Age (10-year increments)</td>
<td>4.386</td>
<td>2.435</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>Male gender</td>
<td>14.557</td>
<td>6.243</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Advisory status</td>
<td>4.669</td>
<td>4.970</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>Any shock</td>
<td>0.049</td>
<td>5.428</td>
<td>0.99</td>
</tr>
<tr>
<td></td>
<td>Any electrical storm</td>
<td>-29.053</td>
<td>10.086</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td></td>
<td>Length of FU (months)</td>
<td>0.613</td>
<td>0.261</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>NYHA class</td>
<td>-2.013</td>
<td>3.341</td>
<td>0.55</td>
</tr>
<tr>
<td>FPAS device-related distress</td>
<td>Age (10-year increments)</td>
<td>-4.506</td>
<td>1.690</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td></td>
<td>Male gender</td>
<td>-2.803</td>
<td>4.331</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>Advisory status</td>
<td>-0.487</td>
<td>3.448</td>
<td>0.89</td>
</tr>
<tr>
<td></td>
<td>Any shock</td>
<td>2.826</td>
<td>3.765</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Any electrical storm</td>
<td>1.077</td>
<td>6.997</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>Length of FU (months)</td>
<td>-0.373</td>
<td>0.180</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>NYHA class</td>
<td>-0.337</td>
<td>2.318</td>
<td>0.89</td>
</tr>
<tr>
<td>FPAS positive appraisal</td>
<td>Age (10-year increments)</td>
<td>-1.600</td>
<td>0.137</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>Male gender</td>
<td>3.651</td>
<td>3.500</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>Advisory status</td>
<td>-2.411</td>
<td>2.790</td>
<td>0.39</td>
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<tr>
<td></td>
<td>Any shock</td>
<td>1.795</td>
<td>3.043</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>Any electrical storm</td>
<td>-3.763</td>
<td>5.655</td>
<td>0.51</td>
</tr>
<tr>
<td></td>
<td>Length of FU (months)</td>
<td>0.036</td>
<td>0.146</td>
<td>0.80</td>
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<tr>
<td></td>
<td>NYHA class</td>
<td>1.254</td>
<td>1.873</td>
<td>0.50</td>
</tr>
<tr>
<td>FPAS body image concerns</td>
<td>Age (10-year increments)</td>
<td>3.480</td>
<td>2.341</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Male gender</td>
<td>-4.309</td>
<td>6.005</td>
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<td></td>
<td>Advisory status</td>
<td>2.557</td>
<td>4.780</td>
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<tr>
<td></td>
<td>Any shock</td>
<td>7.115</td>
<td>5.220</td>
<td>0.60</td>
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<tr>
<td></td>
<td>Any electrical storm</td>
<td>-8.392</td>
<td>9.700</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>Length of FU (months)</td>
<td>0.086</td>
<td>0.251</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>NYHA class</td>
<td>-4.636</td>
<td>3.213</td>
<td>0.15</td>
</tr>
<tr>
<td>Total FPAS score</td>
<td>Age (10-year increments)</td>
<td>2.932</td>
<td>1.310</td>
<td>0.03</td>
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<tr>
<td></td>
<td>Male gender</td>
<td>6.705</td>
<td>3.359</td>
<td>0.05</td>
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<tr>
<td></td>
<td>Advisory status</td>
<td>0.325</td>
<td>2.674</td>
<td>0.90</td>
</tr>
<tr>
<td></td>
<td>Any shock</td>
<td>-1.946</td>
<td>2.921</td>
<td>0.51</td>
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<td></td>
<td>Any electrical storm</td>
<td>-7.970</td>
<td>5.427</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>Length of FU (months)</td>
<td>0.281</td>
<td>0.140</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>NYHA class</td>
<td>0.942</td>
<td>1.798</td>
<td>0.60</td>
</tr>
</tbody>
</table>

FPAS, Florida Patient Acceptance Survey; NYHA, New York Heart Association; FU, follow-up. Note that total FPAS score and return-to-function and positive appraisal scores are positively correlated with device acceptance, i.e. a lower score means lesser device acceptance; in contrast, device-related distress and body image concern subscores are negatively correlated with device acceptance, i.e. a higher score means lesser device acceptance.
shocks were assessed; and the questionnaire used (all previous studies used generic anxiety and/or quality-of-life tools). In our study, using an ICD patient-specific tool and controlling for likely confounding, we found that history of electrical storm was an independent correlate of adverse patient device acceptance.

Our study has a number of limitations. First, we did not have detailed information on patient co-morbidity, which has previously been shown to influence ICD patient’s quality of life. However, our two groups were well matched on all other variables and hence we do not expect that this is an important factor. Second, the findings of this study are related to one specific advisory and may not be generalizable to other advisories. For example, in the Marquis advisory, patients were at risk of sudden battery failure with abrupt loss of pacing output and shock capability but with no risk of inappropriate shocks. Hence it is possible that, for example, the Fidelis advisory with the risk of inappropriate shocks may affect patients differently. Thirdly, all patients were from the same clinic and all received a rapid information and counselling programme. Thus, the results might not generalize to situations where an advisory is handled differently. Fourth, the study was performed 2 years after the advisory notification, and hence there may have been a period of lower quality of life that resolved by the time of the testing. Finally, it is possible that anxious patients may be over-represented in the 30% of patients that did not respond to the questionnaires. However, it is reassuring in this regard that the non-response rate was the same in both advisory and non-advisory groups.

In conclusion, our study focused on patients living with Medtronic Marquis ICDs. These devices were subject to an advisory (February 2005), indicating a risk of rapid battery depletion. Only one patient in our clinic elected for generator change due to severe anxiety. We found no evidence of increased long-term psychological morbidity in patients living with an ICD under advisory compared with patients with an ICD not under advisory. Patients often feel acutely anxious after notification of device advisories, but our data suggest that patients and physicians should avoid hasty decisions about ICD replacement for psychological reasons.

Conflict of interest: none declared.

References