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Perspectives of Patients With Cardiovascular Implantable Electronic Devices Who Received Advisory Warnings

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Abstract

Objective—To learn the perspectives of patients with cardiovascular implantable electronic devices (CIEDs) who received device-related advisories.

Background—CIEDs are placed under advisory because of potential malfunctions.

Methods—Qualitative methods were used. Focus groups were conducted of 10 patients who had CIEDs under advisory. Audio recordings of the focus group discussions were transcribed and analyzed for content in accordance with qualitative analysis methods, specifically thematic analysis.

Results—Major themes were identified: patients' attitudes toward their devices under advisory, education about advisories, emotional responses to advisories, impact on loved ones, and what affected patients would say to the chief executive officers of CIED manufacturers. Although the patients felt "fortunate and blessed" to have their devices, they reported a range of emotional responses to the advisories (from no concern to "outrage"). Patients preferred to learn about advisories from their physicians, not from news media. Loved ones had as many, if not more, advisory-related concerns than the patients. Patients had recommendations for chief executive officers of CIED manufacturers regarding advisories, including providing timely and comprehensible information and emotional support, taking responsibility, and collaborating with health care providers. Patients wanted to know what prompted the advisory and what will be done to fix the problem.

Conclusions—The experiences and perspectives of patients with CIEDs under advisory not only encompass their emotional responses to advisories, but also their views on how the advisory notification process can be improved. These findings should be informative to CIED manufacturers and clinicians.

Keywords

cardiac resynchronization therapy devices; ethics; implantable cardioverter-defibrillator

Introduction

Pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy defibrillators (CRT-Ds), also known as *cardiovascular implantable electronic devices* (CIEDs), prolong life in patients with cardiac conduction abnormalities,

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arrhythmias, and heart failure. Patients with clinical indications for a CIED favor intervention and proceed with treatment based on the advice of health care professionals.

Indeed, millions of patients worldwide have undergone implantation of these devices (1). Nevertheless, despite a strong safety record, malfunctions of CIED system components (eg, pulse generator and lead) occur. One study found that advisories relating to ICDs or leads occur in 25% of patients with implants, for an average malfunction rate of 5.6%. If a malfunction trend is observed, the CIED manufacturer is required to notify the US Food and Drug Administration (FDA), which in turn may issue an *advisory* (also known as *recall* and *safety alert*) (2–4). In recent decades, hundreds of thousands of patients have been affected by CIED-associated advisories, resulting in tens of thousands of device explantations and replacements costing hundreds of millions of dollars (2,5,6).

Unsurprisingly, CIED advisory notifications differ in the likelihood and severity of device malfunction (7), resulting in complex decision making for clinicians and patients. The Heart Rhythm Society (HRS) recommends that the risks and benefits of responses to advisories, such as device monitoring vs replacement, be carefully weighed (8). Overtreatment is ill advised; in many cases, device removal and replacement are riskier than leaving intact the CIED under advisory and closely monitoring it (3,6). Patients should be informed of their options, including the option of device monitoring, and reassured of their decisions (7).

A number of studies have assessed the psychological impact of CIED advisories on patients (9–17). These studies used validated survey instruments that assessed various psychological end points, including device acceptance, anxiety, distress, quality of life, depression, uncertainty, and confidence in the device. Nearly all of these studies compared patients who had CIEDs under advisory with patients who had CIEDs unaffected by advisories (9–11,13–17). One study assessed anxiety before and after CIED advisory (12). Several studies showed that patients with CIEDs affected by advisories experienced higher levels of anxiety, ICD concerns, and distress than patients with CIEDs unaffected by advisories (10,12,14,15). In the other studies, device advisories had no adverse psychological impact on affected patients (9,11,13,16,17).

A limitation of studies that use generic or even disease-specific survey instruments is that they may miss unanticipated themes. For example, it is unlikely that a study that assesses anxiety levels in patients affected by advisories through a survey tool will uncover all of the concerns these patients have. Qualitative studies, by comparison, can discern these themes. The results of qualitative studies are valid because they represent the actual experiences of individual patients and only small numbers of participants are needed to generate the most important themes (18–21). Hence, in this study, we used a qualitative approach to determine the experiences and perspectives of patients with CIEDs under advisory.

Methods

In October 2009, a computerized search was conducted to identify all patients with CIEDs cared for at our institution and who were residents of our county. Of these patients, those who were affected by CIED-related advisories issued since 2005 were identified. We selected 3 CIED-related advisories for analysis because of adequacy of numbers of affected patients: the Sprint Fidelis lead, Marquis ICD and CRT-D, and Kappa or Sigma pacemaker advisories (all of Medtronic, Inc, Minneapolis, Minnesota). Overall, 38 patients meeting these criteria were identified and were invited by phone to participate in the study; 10 patients consented to participate.

The reasons for and potential severity of the 3 advisories differed. The Sprint Fidelis advisory was issued in 2007 after fractured leads were shown to be a “likely” or “contributing” factor in 5 deaths. As of October 15, 2007, 268,000 Sprint Fidelis leads had been implanted and 665 long-term fractures were confirmed. The Marquis advisory was issued in 2005 because of potential battery shortage in ICD and CRT-D devices with batteries manufactured before December 2003. The Marquis advisory affected 87,000 patients and carried a failure rate of 0.2% to 1.5% over the second half of device life. The Kappa and Sigma pacemaker advisory was issued in 2009 when it was discovered that bonded wires could become separated from the electronic circuit. The failure rate for Kappa and Sigma pacemakers was estimated at 3.9%.

Study participants were randomly assigned to 2 focus groups with at least 1 patient from each of the advisories. The focus group sessions took place during October 2009. The discussions were directed with a semistructured interview guide composed of original questions based on a review of the literature (Figure). Two trained focus group facilitators facilitated each discussion. The sessions lasted 1.5 hours and were audio recorded. Transcripts of the recordings were completed by a contract transcriptionist and verified for accuracy by the assistant facilitator who took field notes during the session. Each transcript was deidentified before performing transcript analyses.

Transcripts of the focus group discussions were analyzed by hand for content according to qualitative analysis methods, specifically thematic analysis (18,19,21,22). Each transcript was independently reviewed by 3 experienced analysts. Open coding was performed where the analysts read each transcript line by line. The analysts were instructed to highlight sections of the text and assign initial codes on the basis of phenomena in the data. The analysts met to share initial codes, to categorize the codes, develop a codebook, and establish themes. Each transcript was then reviewed page by page to determine the fitness of the themes, code additional data, and recode portions of the text. Instances of coding disagreement were discussed and resolved by consensus. Five themes formed the basis for our results.

Our sample size was sufficient to achieve data saturation (20). Selection of the sample size was based on qualitative methods, including a desire to capture the patient perspective, the benefits of focus group methodology, and what could be accomplished with the resources available (21). The study was conducted independent of support or influence by any CIED manufacturer. The study was approved by the institutional review board in accordance with federal regulations.

Results

The sample for this study contained 10 patients (2 women and 8 men) at our institution who reportedly were notified of an advisory on a Sprint Fidelis lead, Marquis ICD and CRT-D, and Kappa or Sigma pacemaker (Table 1). Only residents of our county were invited to participate. Patients who had received one of these devices were evenly dispersed among the 2 focus groups. All patients were white and 9 were married. The median (range) age at focus group participation was 70 (50–86) years, and occupations included administrator, business owner, pharmacist, software engineer, clergy person, and physician. Analysis of focus group transcripts revealed major themes associated with patients’ experiences with device advisory notifications (Table 2).

Attitudes Toward Devices

Patients spoke about their attitudes toward their devices before learning of the device advisory and after. All patients felt “fortunate and blessed” to have their devices. A common

perception was that the device had become part of the patient's body, with 1 patient referring to herself as a "bionic woman." Another patient viewed the device as an "insurance policy."

"If I would have said, 'I don't want it, in December,' and 'I'll wait a couple months,' and never had another event, I . . . I may have said 'no.' But again, the echo doesn't lie. [My] heart's not normal, so I probably . . . yeah, I would. Just, again, for the insurance part of it." (P9)

Some patients called the device their "friend" and a "lifesaver."

"Well, it saved my life. A couple dozen times. It's a lifesaver, it's a friend. I give it a hug every day [chuckles]." (P4)

When asked whether they would still choose to get their device knowing what they know now, all patients said "yes." Clinical evidence and family history indications were weighed against the "cost" of the advisory experience.

"Knowing the history in my loved ones and how my dad died...and I have a sister with the same thing, I think [getting the device] would [still] be the intelligent thing to do. Yes." (P7)

Overall, the advisory did not appear to sway overtly the patients' confidence in their devices.

"I still regard [my device] as a great comfort, knowing it's there, and I can go and live my life with the reasonable expectation that if a disaster happens, at least I have a fighting chance of surviving, because it's here, in me." (P5)

Indeed, patients' opinions of their devices after the advisory appeared to remain positive.

Patient Education About the Advisory

Patients learned about their advisory notification in different ways, including mail, phone call, and the news media. There did not appear to be a standardized system for notification. A letter by mail was the most frequent type of notification of advisory, although many patients described being notified of the advisory multiple times and in more than 1 way. Learning about the advisory from the news media before hearing from the device manufacturer or a health care professional was common.

"I was listening to the radio early in the morning and then I called [my electrophysiologist], asking, 'Is mine on the list?' . . . they said, 'Your [device] is on the list. There will be something going on and we will keep you informed.'" (P4)

Whereas the means of contact varied among the study participants, they were in agreement that they did not want to learn of advisories from the news media.

"Publicity on the advisory does nothing except create worry." (P10)

Instead, the patients preferred that they be notified about advisories involving their CIEDs by their physicians or health care teams.

"It's sort of like if the car is broken, do you take it to the dealer or to Detroit?" (P4)

The study participants looked to health care professionals (ie, physicians and nurses) for information about the advisory and answers to their questions. Comments were made that affirmed trust in health care professionals' opinions and skepticism toward device companies.

“Do you think I should [get a different device]? And the nurse said, ‘They are both good and they both make mistakes.’ I thought that was a very good answer.” (P6)

Patients viewed the advisory as an indication that their device was flawed but not necessarily dysfunctional. Nevertheless, the notion of how a flawed device made it to the consumer market was difficult for most to understand.

“Why would we want to put this [device] in if it’s not a good product to start with?” (P2)

Of note, not all patients reported undergoing generator or lead explantation after being notified of the advisory; health care professionals influenced these decisions.

“I felt very comfortable with not getting it replaced and so did [my wife]. The [health care professionals] explained the risks . . . and I felt perfectly fine.” (P9)

Most patients were comfortable in following the advice of health care professionals, including keeping the “flawed” device implanted and closely monitoring its function. One patient, however, reported requesting that the device be removed despite the recommendations of health care professionals.

“My wife said, ‘Why don’t you just make them replace that [lead]?’ And I said, ‘Well, I guess that is an option if I want to push the issue.’ According to the letter that I received, that if I absolutely wanted that thing out of there, that they would do that. There were some downsides to [removal], too, and my wife and I have talked about them with my daughters. What it boils down to is we still think it needs to come out of there even with the risk.” (P8)

In general, health care professionals were viewed as a primary source for comprehensible information, follow-up care, and emotional support.

“I can’t even think of anything [my health care professionals] could have done that they didn’t already do. And I thought the attention they gave me, the service, it just went like clockwork...they took me in right away and that gave me very much a peace of mind.” (P7)

Emotional Response to Advisory Notification

The emotional response exhibited by patients in response to the advisory notification varied from mild concern to anger. Strong emotions were exhibited by some of the patients, including frustration directed toward the company that produced the faulty device.

“I’m outraged! I say, ‘This is a lead, this is a wire, and I know it’s in a hostile environment, but for God’s sake, you can’t make a lead that can maintain integrity? You should be able to do that.’ This is totally unacceptable.” (P5)

Fear on learning about the advisory was commonly cited in conjunction with a sense of not knowing what would happen next.

“The news terrified me!” (P7)

A number of patients expressed only mild concern about the advisory. These patients expressed confidence in their health care professionals and the device manufacturer that calmed their emotions.

“Never worried real bad ’cause I knew they were gonna do something about it . . .” (P1)

One patient referred to the advisory notification process as an “adventure” and was fascinated with the process despite his concerns.

“If my pacemaker doesn’t work, I die. I was somewhere between concerned and interested . . . the whole process has been kind of an adventure and interesting.” (P4)

Another patient viewed his device as an experimental therapy, which appeared to influence his response to the advisory.

“So, I think it was very much experimental and I’m just happy that maybe I played a part in that.” (P7)

The wide range of emotional response—from mild concern to anger—tended to reflect the patient’s relationship with his or her health care professional and confidence in the device.

Negative emotional responses were directed toward the device company solely; none of the patients in our study expressed anger toward health care professionals.

Impact on Loved Ones

All patients reported that their family was supportive when they decided to get the device.

“[My loved ones] thought, ‘If he needs it, then it’s a good thing.’” (P3)

Some loved ones took a more assertive role in the decision-making process.

“[My physician] told me, ‘I want you to go home and think about this for 5 days. Talk it over with your loved ones, think it over, and you call me and tell me your decision.’ He didn’t tell me I had to have one, but when my wife heard the story, she said, ‘Well, there’s no decision to make.’ . . . So they put in the first device.” (P8)

On learning of the advisory, the loved ones of affected patients tended to be more worried than the patients.

“Well, my wife wanted to make sure I followed up. She was probably more concerned, more nervous than I was.” (P4)

The patients in our study reported that loved ones were part of the decision-making process on how to proceed in responding to the advisory notification. Advance care planning was also discussed. Eight of the patients indicated they had an advance directive (eg, living will), but none reported that they had specifically addressed device management in their directive.

Speaking to the Chief Executive Officer

We asked patients to imagine what they would say if they were invited to speak to the chief executive officers of the companies that manufactured the devices on advisory. Overall, patients stated they would want to know why their device was placed on advisory, how the company planned to “make the situation right” with patients, and what the companies planned to do to make devices safer.

“[Device companies] don’t intentionally make a product and install it with an idea that it would possibly fail. You know, as long as they are willing to back up their product, I guess that is all you can [ask]. You’ve really got to appreciate [if] they stand behind it.” (P8)

Patients perceived the level of culpability of the device companies differently. Some patients were angry at the device manufacturer:

“How many active elements does a stinking cable have? It is inexcusable from an engineering point of view. I am angry at those clowns.” (P5)

More typically, patients were at once disappointed about the error and grateful it was caught.

“I guess I would say, ‘You’ve got a little more testing to do, don’t you? There’s something not quite right here, but thanks for catching it.’” (P10)

Patients recognized that human error could not be avoided and innovation was not fail proof.

“I think I’m willing to take the risk because I’d rather the device was available when I needed it than being in testing somewhere to make sure it never kills anybody.” (P4)

An established threshold for safety before putting a device on the market for patient use was discussed without a strong consensus. All of the patients understood that they assumed a certain amount of risk when choosing to live with a device, balanced with the clinical need for the device, but they wanted to know how device companies arrived at what constitutes acceptable consumer risk.

Regarding notification of patients affected by CIED advisories, the study participants recommended that device manufacturers take a standardized approach, be expedient and transparent, and ensure that the advisory be comprehensible along with instructions for follow-up. Doing so would demonstrate CIED manufacturers’ conscientiousness and restore patients’ confidence in their devices.

“Everybody makes mistakes, nobody is perfect. But when you don’t own it and you slink away and you try to avoid taking responsibility publicly, that is when the problems come. It is important for [patients] to have confidence in these devices since their lives are riding on it.” (P5)

From the patients’ perspective, CIED manufacturers should partner with health care professionals to ensure that patient needs are being met.

Discussion

Although prior quantitative studies have assessed the psychological impact of CIED advisory notifications on affected patients, the present study is, to our knowledge, the first qualitative approach to capturing patients’ experiences and perspectives relating to CIED advisory notifications. Five themes emerged from the analysis of the transcripts of our focus group sessions. Patients’ attitudes toward their devices under advisory comprised 1 theme. Despite the advisory notifications, all of the patients felt “fortunate and blessed” to have their devices and would undergo device implantation again if given the choice. This finding suggests that patients contextualize advisories within the broader clinical indications for having CIEDs. For example, a patient who experienced sudden death, was resuscitated, and underwent ICD implantation and whose ICD was later placed under advisory may understandably still appreciate having the ICD, given its potential life-prolonging properties.

A second theme was patient education about advisories. Although our study participants learned about advisories differently, none of them reported that they liked receiving information about advisories through the news media, especially when the information preceded contact from health care professionals or device manufacturers. This finding is consistent with the results of a prior study (23). The patients in our study also recommended that CIED advisory notifications be standardized, expedient, transparent, and comprehensible—recommendations that are remarkably similar to those in a recent HRS position paper (3). These findings are not surprising. Patients do not want to be blind-sided by adverse health information. They want to receive this information, which should be comprehensible, from their clinicians. We also recommend that clinicians inform patients—before CIED implantation—of the possibility that their devices may be placed under advisory (3), while at the same time assuring patients that they will be available should an advisory occur.

A third theme that emerged was the emotional response to advisories. The patients in our study reported a range of emotional responses to the advisories that affected them—from no concern to feeling “outraged” and “terrified.” Concern, however, was the most common sentiment. The perspectives of patients in our study reflect, in part, the results of prior quantitative studies, which showed varied psychological effects of CIED advisories on affected patients (10,12,14,15). These results suggest that clinicians who care for patients with CIEDs be prepared for patients’ emotional responses to advisories. Indeed, the patients in our study not only viewed health care professionals as a source for information, but also as a source for emotional support. If a patient perceives an advisory experience is being well managed, the patient is less likely to have a strong emotional reaction. In fact, a prior study showed that patients affected by CIED advisories who are counseled and informed about the risks associated with their advisories and the most appropriate clinical approaches to them (which often is observation only) experience improved psychological outcomes (24).

Impact on loved ones was a fourth theme that emerged from our analysis. Caregivers had large roles in the lives of the patients in this study, including decision-making related to CIEDs. Notably, loved ones were more concerned than patients about the consequences of the advisory. Prior research has shown that caregivers of patients with CIEDs can be adversely affected by advisories (15). Furthermore, caregivers of patients with heart disease in general experience significant burdens and distress while caring for their sick loved ones (25). These findings suggest that clinicians who care for patients with CIEDs under advisory should be attentive to the needs and concerns of loved ones.

The final theme that emerged from our analysis was what our study participants would say to the chief executive officers of companies that manufactured their devices. Providing comprehensible information about and emotional support during advisories, demonstrating willingness to take responsibility for the advisories, and collaborating with health care providers were perceived as measures CIED manufacturers could take to soften the blow of the advisory notification and quickly emerged as the best reply companies could give to disappointed patients. Again, these findings are remarkably consistent with a recent HRS position paper (3). The CIED manufacturers should partner with clinicians in providing timely information to and support of patients affected by advisories.

Our study had a number of limitations, which may impact the transferability of our findings. First, there was a small number of female participants (2 of 10 participants). Although the ratio of women to men in our study was representative of the full study sample (10 to 38), women’s concerns may not be adequately represented. Second, the patients in our study were cared for at a large, tertiary medical center and, therefore, our results may have limited applicability to other medical settings. Third, we included patients affected by only 3 advisories: Sprint Fidelis lead, Marquis ICD and CRT-D, and Kappa or Sigma pacemaker. Other recalls may have different implications. Fourth, our study did not include patients younger than 50 years or patients of diverse racial backgrounds.

Overall, our findings add to current knowledge on how patients—in their own words—respond to device advisories. Our qualitative approach allowed for discernment of themes not identified by prior studies. Future qualitative research should include patients who live in other geographical regions, are affected by other advisories, and are of diverse age, gender, and racial backgrounds. Themes identified by qualitative research should be assessed further in quantitative studies. Areas of future research include quality improvement studies evaluating the delivery and transmission of information related to advisory notifications (eg, methods of transmission, readability of notification letters). Other research should determine best practices on how to provide emotional support to affected patients and their loved ones (eg, support groups, social media).

Conclusion

Despite a strong safety record and federal oversight, CIED malfunctions and associated advisories occur. Although affected patients have favorable views of their devices, they may experience a wide range of emotional responses to the advisories. Affected patients prefer to learn about advisories from their health care professionals. Comprehensible information, support, and transparency from device manufacturers are essential. These results should be informative to clinicians who care for patients with CIEDs under advisory, for device manufacturers, and for investigators regarding responsible advisory notification practices. New research areas should focus on improving the quality of the advisory notification process and on establishing best practices for care and support of affected patients.

Abbreviations

CIED	cardiovascular implantable electronic device
CRT-D	cardiac resynchronization therapy defibrillator
FDA	US Food and Drug Administration
HRS	Heart Rhythm Society
ICD	implantable cardioverter-defibrillator

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1. [Opening] Please tell me a little bit about you. Where are you from? Tell me about your loved ones and other relationships. What is your loved ones' structure? How would you describe your faith? (Probe: Are you a member of a particular faith community? What role has faith played in your daily living?) How far in school did you get? What is your work background?
2. How would you describe your current health (eg, very poor, poor, average, good, or very good)? Besides the cardiac issues that have been identified, are you living with any other life-altering diseases or conditions? What are they?
3. In your own words, what were the reasons you first underwent device implantation? Did someone tell you that you needed a device (eg, primary physician, cardiologist, nurse)? If so, how were you told? What devices, if any, were offered to you? Was "not implanting" an option?
4. How did your loved ones respond to your decision to proceed with getting a device? How did they react after the procedure? What were some of their concerns?
5. How did you first learn about the advisory? How did you respond? Did news of the advisory surprise you? How did your loved ones respond?
6. Did you speak with your physician, nurse, or another clinician about the advisory? What did they say? Did you follow their recommendations?
7. How do you regard your device now (eg, lifesaver, nuisance, friend, part of you)? Has this changed since you first learned about the advisory? If you had to do it all over again, knowing what you know now, would you still have chosen to get your device?
8. What would you say if you could talk to the company who manufactures and sells your product that was placed on the advisory or advisories?
9. How could the advisory notification process be improved?
10. What have you done in terms of advance care planning? Have you completed an advance directive? If so, did you include comments about your device? What are they? Are your loved ones aware of your wishes?
11. Please talk about your own aging process. How has your illness and living with your device affected how you think about aging? Your sense of self and your self-image? Your life expectancy? Your relationship with your loved ones? How has your device affected your thoughts on these topics?
12. What advice would you give to patients and families who have experienced a lead advisory or device advisory? What advice would you give to clinicians or others?
13. [Closing] Is there anything I forgot to ask that you would like to add?

Figure.
Interview Guide for Advisory Focus Group.

Table 1

Characteristics of Study Participants

Patient	Age at Time of Advisory, y	Sex	Device	Indication	Advisory Type
P1	73	M	Pacemaker, 2002	A-fib with slow ventricular response	Kappa or Sigma Pacemaker
P2	58	M	ICD, 2005	Ischemic cardiomyopathy	Sprint Fidelis Lead
P3	84	M	ICD, 2006	Nonischemic dilated cardiomyopathy	Sprint Fidelis Lead
P4	61	M	ICD, 2007	Ischemic cardiomyopathy	Sprint Fidelis Lead
P5	64	M	ICD, 2006	Ischemic cardiomyopathy	Sprint Fidelis Lead
P6	80	F	ICD, 2005	Nonischemic cardiomyopathy	Sprint Fidelis Lead
P7	73	F	ICD, 2003	Atrial arrhythmia	Marquis ICD
P8	62	M	ICD, 1999	Hypertrophic cardiomyopathy	Sprint Fidelis Lead
P9	48	M	ICD, 2007	Arrhythmogenic right ventricular dysplasia	Sprint Fidelis Lead
P10	78	M	ICD, 2004	Ischemic cardiomyopathy	Marquis ICD

Abbreviations: A-fib, atrial fibrillation; F, female; ICD, implantable cardioverter-defibrillator; M, male.

Table 2

Major Themes of the Focus Group Responses to Advisory Notification

Attitude toward the device
Patient education
Emotional response
Impact on loved ones
Speaking to the device manufacturer's chief executive officer