Patient Perceptions, Physician Communication, and the Implantable Cardioverter-Defibrillator

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Importance: Implantable cardioverter-defibrillators (ICDs) have changed the way in which patients with chronic ventricular dysfunction are evaluated and treated.

Objective: To examine patient-physician communication at the time the decision is made to implant an ICD.

Design, Setting, and Participants: Forty-one patients with ICDs and 11 cardiologists were recruited by a national marketing research company for a study comprising patient focus groups and standardized patient interviews in 3 different metropolitan areas.

Interventions: Eight patient focus groups and (separately) 22 standardized patient interviews with cardiologists.

Main Outcome Measures: Patient focus group findings and the results of standardized patient interviews (each cardiologist interviewed 2 patients).

Results: The mean (SD) patient age was 61.4 (14.7) years; 21 were female. Thirty-three patients could not recall a discussion about periprocedural or long-term complications. On a scale of 1 to 10, the mean (SD) rating of the degree to which patients felt informed before the implant procedure was 5.7 (3.2) (1 indicates “not at all informed,” and 10 indicates “I had all the information I needed or wanted”). The mean (SD) estimated number of patients out of 100 who would be saved by the ICD was 87.9 (20.1). A negative perception on body image and lifestyle was prevalent. Across 22 standardized patient interviews, cardiologists frequently (in >17 of 22 of interviews) did not address or minimized or denied quality-of-life issues and long-term consequences of ICD placement, including the risk for depression, anxiety, and inappropriate delivery of shock or device advisory. In 15 of 22 of the standardized patient interviews, cardiologists used unexplained medical terms or jargon.

Conclusions and Relevance: Patient-physician communication about ICDs is characterized by unclear representation and omission of information to patients, with notable lack of attention to psychological and long-term risks. Training of cardiologists on information exchange with patients may promote informed decision making and preempt threats to patient quality of life.


I learned a long time ago that minor surgery is when they do the operation on someone else, not you.

Bill Walton (http://www.quotegarden.com/medical.html)

The introduction of transvenous cardioverter-defibrillators (ICDs) has changed the way in which patients with chronic ventricular dysfunction are evaluated and treated.1-3 Historically, sudden death risk assessment strategies failed to accurately stratify patients. As a consequence, asymptomatic patients often receive ICDs as part of a primary prevention strategy,4 despite the potential for postimplantation complications,5-7 including anxiety and other psychosocial sequelae.8,9 Furthermore, significant numbers of recipients have advanced age or comorbidities that serve as competing risks for mortality.10,11 However, few studies12,13 have addressed information exchange between physicians and patients on pertinent issues such as risk vs benefit and potential consequence for quality of life.

See Invited Commentary at end of article

Consequently, we conducted focus groups composed of patients with ICDs to address the nature of preimplantation discussions. Separately, we observed communication content and style of cardiologists using standardized patient (SP) interviews designed to further evaluate communication about the ICD decision process.
METHODS

PATIENT FOCUS GROUPS

Patient focus groups were designed to explore (1) the effect of ICD placement and downstream events on patient acceptance of the device, (2) the patient’s evaluation of communication about risks and benefits during preimplantation discussions, and (3) patient expectations. Eight patient focus groups convened at midwestern and northeastern suburban and urban locations. Patients were recruited by a national health care marketing research company. Screening questions were designed to identify patients who had not experienced a sudden death event before ICD placement and to ensure that not more than 1 patient was drawn from the same cardiology practice. Patients gave verbal consent to participate and received an honorarium for participation.

A topic guide was used to structure discussions, which were scheduled to last approximately 120 minutes. Patients were asked to rate the degree to which they felt informed before the implant procedure and to estimate the number of patients of 100 who would be saved by the ICD. Patients were queried about a range of ICD-related experiences. Patient focus groups were audio recorded, and the tapes were searched for commonalities and differences in descriptions of those experiences. Focus group composition was adequate to identify frequent and infrequent experiences among patients.14-19

One member of the research team (E.S.A.) facilitated all patient focus groups. Two other researchers (P.J.H. and J.T.C.) reviewed the patient focus group discussions for a priori themes derived from clinical experience and a literature review and extracted primary themes based on recurrent content, amount of group discussion time, consistency across group participants, and participant-perceived degree of importance. The resulting index of themes was independently reviewed and verified by the moderator (E.S.A.); themes identified by only one observer were discussed until group consensus was reached about their relative importance.

STANDARDIZED PATIENT INTERVIEWS

Four primary methods have been used to study patient-physician communication, including SPs, surveys of physicians and patients, written and video vignettes, and direct observation of actual visits. Standardized patients were used in this study because they can portray complex clinical conditions, while controlling for patient characteristics and behavior, thereby reducing unwanted variability in the patient presentation.20-25

Twelve cardiologists were recruited from 2 urban areas (the Midwest and the South) who were primary decision makers for ICD placement in at least 10 patients per year. Each cardiologist interviewed 2 SPs.

One SP portrayed a 61-year-old white man with ischemic heart disease and symptoms of moderate heart failure; the other SP portrayed a 31-year-old African American woman with postpartum cardiomyopathy, persistent ventricular dysfunction, and recurrent hospitalization for heart failure (eAppendix 1; http://www.jamainternalmed.com). Both were taking medications congruent with published guidelines26 and were candidates for ICD placement based on criteria from randomized controlled trials that formed the basis for regulatory approval. The SPs were extensively trained from a standardized script about symptoms, presentation, and prognosis for their respective conditions and were educated about ICD indications and function. Mock SP interviews with feedback and retraining were performed before the cardiologist encounters. Standardized patients were instructed to allow reasonable time for cardiologists to initiate discussion of quality-of-life and risk issues; if a cardiologist did not initiate such discussions, the SP could initiate them.

Using scripted instructions, a researcher (P.J.H. or E.S.A.) informed the cardiologists about the objective of the session, namely, to evaluate patient-physician decision-making processes. Cardiologists were encouraged to interact as though the SPs were typical patients. The interview order was kept constant, with the male SP first and the female SP second. No research personnel were present during the SP interviews, but cardiologists were aware that interviews were being videotaped and observed through a mirrored window.

To analyze the SP interviews, a data abstraction tool (eAppendix 2) was developed and used independently by each research team rater to code the following: (1) occurrences of interview events (eg, medical history, description of the implant procedure, use of unexplained medical terms, statements of implantation benefits, and expressions of empathy), (2) ratings of strength of psychosocial inquiry and empathy (1 indicates low, 2 indicates moderate, and 3 indicates high), (3) initiator (cardiologist or SP) of a discussion, (4) quotations that exemplified an issue, (5) interview duration, and (6) time to first mention of a quality-of-life issue, in an effort to understand its hierarchical importance. The use of analogy by the cardiologist to describe the ICD (eg, safety net) was also coded. The study was approved by the Saint Louis University Institutional Review Board.

RESULTS

PATIENT FOCUS GROUPS

The 41 patient focus group participants (21 women and 20 men) had a mean (SD) age of 61.4 (14.7) years. Almost 40% (n = 16) of the patients were 70 years or older; 22% (n = 9) were younger than 50 years. Dates of initial ICD placement were as follows: before 2000 (n = 3), 2000 to 2002 (n = 5), 2003 to 2005 (n = 8), 2006 to 2008 (n = 10), and 2009 to 2011 (n = 15).

Precise indications for implantation were difficult to assess. Among 14 patients who knew their precise history, 12 underwent implantation for primary prevention. Most patients seemed to have ischemic cardiomyopathy, but 5 patients had uncommon underlying conditions, including congenital heart disease, long QT syndrome, familial, hypertrophic, or Takotsubo cardiomyopathy. Twenty patients (49%) had experienced 2 or more device procedures (upgrade, revision, or generator replacement), 8 on the basis of a device recall or an advisory.

Thirty-three patients (80%) did not report discussing periprocedural risks or potential long-term complications (Table 1); the concept of device malfunction was new to some patients. Generally, patients recalled that physicians presented the ICD option in absolute terms.

<p>| Table 1. Patient Focus Group: Recall of Preimplantation Discussion About Select Long-term Complications of Implantable Cardioverter-Defibrillator (ICD) Use |
|--------------------------|----------------|----------------|----------------|</p>
<table>
<thead>
<tr>
<th>Topic Discussed</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD recall</td>
<td>2</td>
<td>33</td>
<td>6</td>
</tr>
<tr>
<td>Inappropriate shock</td>
<td>5</td>
<td>30</td>
<td>6</td>
</tr>
<tr>
<td>Depression</td>
<td>2</td>
<td>33</td>
<td>6</td>
</tr>
</tbody>
</table>
Patients estimated the degree to which they felt informed before the implant procedure on a scale of 1 to 10 (1 indicates “not at all informed,” and 10 indicates “I had all the information I needed or wanted”). The mean (SD) rating for 39 patients was 5.7 (3.2); at the time of the implant procedure and during the patient focus group meeting, 2 patients indicated little interest in detailed knowledge of risks. The mean (SD) estimated number of patients out of 100 who would be saved by the ICD was 87.9 (20.1).

Content of Preimplantation Discussion

Patients recalled that discussions of quality-of-life issues were limited in scope and were often characterized by physician statements that the ICD would have no lifestyle effect. No participants reported administration of a quality-of-life instrument before or after implantation. Preimplantation mention of the possibility of depression, anxiety, or other emotional impact was infrequent.

Quality of Preimplantation Discussion

Participants reported that most interactions were brief. Those who were hospitalized at the time of initial discussion noted that decisions were made quickly, with little time provided to understand the implications; few participants recalled that they were offered time to think about it at home. Older participants frequently mentioned that they deferred the decision to family members.

Effect of ICD on Quality of Life

The effect of the ICD on daily activities such as routine physical labor was a major issue for multiple participants. Passing through security checkpoints at airports was a frequent topic; several patients stated that they no longer fly because they disliked the extra screening. For some, the ICD created a perceived social stigma, negatively influencing return to work. The implications for medical care were also noted, including interference with mammograms, inability to undergo magnetic resonance imaging, and changes in ICD programming that are required during surgical procedures.

Several participants cited early adjustment difficulties and sought counseling for anxiety and mood disturbance. Several were not convinced of the ongoing need for the ICD (“they could have done something [else]”). Concerns were raised about the influence on family members and the effect of the ICD on mode of death.

Multiple participants mentioned the effect on body image, reflecting the cosmetic change and physical discomforts associated with the ICD. Body discomfort included “pulling sensations,” discomfort lying on the side where the ICD was situated, and the interrogation process during routine follow-up visits. Patients also discussed the mechanical and electrical aspects of the ICD, indicating that these made them feel robotic. Nevertheless, participants frequently agreed that the ICD provided security. Many participants recalled that physicians stated the ICD was implanted “just in case,” and there was wide acceptance of this concept. Representative patient responses are given in Table 2.

Table 2. Patient Focus Groups: Representative Responses About the Effect of Implantable Cardioverter-Defibrillator (ICD) Use on Quality of Life

<table>
<thead>
<tr>
<th>Representative Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statements on ICD Discharge</td>
</tr>
<tr>
<td>What if this will go off...so you think, don’t do this, don’t do that.</td>
</tr>
<tr>
<td>What if the kids find me on the floor?</td>
</tr>
<tr>
<td>[I had] all sorts of crazy thoughts...is it going to shake me if I die?</td>
</tr>
<tr>
<td>Will you suffer if something else [another illness] takes you away?</td>
</tr>
<tr>
<td>Will this shock me so that I end up living to 150 years old?</td>
</tr>
<tr>
<td>Description of ICD in Positive Anthropomorphic Terms</td>
</tr>
<tr>
<td>Security...like an insurance policy.</td>
</tr>
<tr>
<td>Guardian angel.</td>
</tr>
<tr>
<td>Safety net.</td>
</tr>
<tr>
<td>It’s like having a cardiologist in me.</td>
</tr>
</tbody>
</table>

Expectations

Some patients initially thought of the ICD as a cure but realized shortly after implantation that this was not the case. There was near unanimity that they learned more about ICD risks and benefits after implantation than before implantation. The use of ancillary educational material before the implant procedure was limited.

Uncertainties

Several areas of uncertainty in the postimplantation period were identified. These included (1) generator life, the procedure required to change the generator, and the frequency of generator changes; (2) the sensation of a shock, response to a shock, and concerns about occurrence during “bad times” such as when driving; (3) the effect on life extension; and (4) remote radio or telecommunication interference with ICD operation.

STANDARDIZED PATIENT INTERVIEWS

Before interviewing the SPs, one cardiologist expressed suspicion that the interview had ulterior motives and voiced concern that the project was designed by federal regulatory officials to entrap physicians about ICD prescribing practice. Despite assurances, this cardiologist would not directly address the ICD decision issue; these data were excluded from the final analyses.

Twenty-two SP interviews were analyzed. The mean (SD) duration was 23.5 (6.1) minutes. The cardiologists were predominantly male (n = 10) and in private practice (n = 10); their mean (SD) age was 51.0 (9.8) years. Professional categorizations were electrophysiologist (n = 1), invasive noninterventional cardiologist (n = 2), noninvasive cardiologist (n = 3), and interventional cardiologist (n = 5). Four of the cardiologists regularly implanted ICDs.

The interviews focused on issues of the SP’s medical history and procedure-related processes in the context of stating the medical benefit of ICD placement (Table 3). Psychosocial history was obtained in 11 of 22 SP interviews; when present, the strength of the inquiry about
psychosocial history was low, with a mean (SD) rating of 1.1 (0.3) on a scale of 1 to 3 (1 indicates low, and 3 indicates high). Unexplained medical terminology or jargon was frequently used by cardiologists (in more than two-thirds of SP interviews) (Table 4 and Table 5).

Discussion of Benefit

Cardiologist statements about the major benefit of ICD placement were simple and were generally reiterated during the SP interviews. The primary emphasis was the prevention of sudden death. No cardiologist discussed the epidemiological or clinical data on the prevalence of actual lifesaving ICD shocks, the prevalence of patients who ever require a shock, or the risk for death, despite ICD shock. Rather, positively valenced analogies were used to describe the purpose and operation of the ICD (Table 4).

Discussion of Effect on Quality of Life and Related Topics

The mean (SD) time to first mention of a quality-of-life issue was 12.2 (7.3) minutes, or about halfway through the SP interview. The mean (SD) time to first quality-of-life mention was longer when the discussion was initiated by the SP (14.5 [5.3] minutes) than when it was initiated by the cardiologist (8.4 [8.2] minutes) (P = .06). The most common quality-of-life issues referred to social functioning (Table 3) and usually were about limitations imposed by the ICD on airport security check-ins and magnetic resonance imaging. Other related issues were acknowledged in only 1 to 5 of the SP interviews, often pertaining to potential limitations on vigorous exercise, choice of profession, and feeling or seeing the ICD under the skin. Quality-of-life implications were minimized in 14 SP interviews.
The risk for anxiety was mentioned in one-third of the SP interviews (n = 7; minimized in 3, denied in 1, and initiated by a cardiologist in 3); depression was not mentioned by a cardiologist as a risk. Possible deactivation of the ICD at the end of life was addressed in 1 of 22 SP interviews.

Bleeding (11 of 22 [50%]) and infection (10 of 22 [45%]) were the most common periprocedural risks acknowledged by the cardiologists. Other risks, including ICD lead dislodgment (6 of 22 [27%] and pneumothorax (discussed without minimizing in 7 of 22 [32%]), were mentioned in less than one-third of the SP interviews. Risk statements tended to be responsive to SP queries and typically were minimized (eg, “there is always the possibility of complications with surgery”). In 2 SP interviews, the possibility of surgical risks was denied. Only one cardiologist in one interview mentioned the possibility of death with the implant procedure.

Long-term issues were acknowledged in 9 of 22 SP interviews (41%). These typically involved statements about the need for continual monitoring and possible damage to the ICD in the event of trauma. The risk for inappropriate shock was discussed in 15 of 22 SP interviews (68%) and was initiated by the cardiologist in 7 of 15 cases (47%); however, when noted, the risk was minimized in 11 of 15 interviews (73%). Several statements of minimization and denial are listed in Table 5.

The need for ICD generator replacement was mentioned in 10 of 22 SP interviews (45%) (initiated by the cardiologist in 6 of 10 cases). The possibility of ICD recall was mentioned in 6 interviews and was typically initiated by the SP (in 5 of 6 cases).

**Expressions of Empathy**

Some expression of empathy occurred in more than half (12 of 22) of the SP interviews but tended to be cursory. On a scale of 1 to 3, the mean (SD) empathy rating was 1.5 (0.8). Expressions of empathy included the following: “I want you to have hope,” “I want you to be around for a long time,” “We want to make the decision that is right for you,” and “I know this sounds scary, but. . .”

**COMMENT**

Clinical trials of ICDs in the primary prevention cohort demonstrate a 5% to 7% absolute mortality reduction among patients with implanted devices over a period of 2 to 4 years.27 Several clinical variables such as advanced heart failure symptoms and renal failure have been shown to moderate survival benefit.3,38-42 In addition, potential complications have been described, including product advisories33 and infection and inappropriate ICD discharges.34 As reported in clinical trials,35-37 the experience of a shock is a distinguishing feature for patients and has been associated with diminished psychological functioning and quality of life. According to Sears et al,38,39 health care providers report that 15% of ICD recipients experience diminished quality of life after implantation, and 10% to 20% note diminished emotional functioning and strained family relationships. Previous investigations have identified problems with patient anxiety,40 sexual func-

**Table 4. Standardized Patient Interviews: Cardiologist Terminology on Implantable Cardioverter-Defibrillator (ICD) Use**

<table>
<thead>
<tr>
<th>Cardiologist Terminology</th>
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<tbody>
<tr>
<td><strong>Examples of Unexplained Medical Terminology</strong></td>
</tr>
<tr>
<td>Ejection fraction, lethal arrhythmia, VT/VF, fluoroscopy, 2-D echo, sinus pauses, supraventricular, ventricular tachycardia, LAD artery, cardiomyopathy, couplet, electrophysiologist, class II indication, internal leads, catheterization, nuclear test, cell death, fibrillation, aspiration, malignant event, randomized, interventional cardiologist, angiotensin, titration, pacing wire, device interrogation, dissection pocket, rales, Holter monitor, radial artery, hypothyroidism, Steri-Strips.</td>
</tr>
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**Examples of Benefit Statements**

- The ICD is a safety mechanism for preventing you from being taken away.
- The ICD will save your life and prevent sudden death.
- The ICD will prolong your life; without it, there is a very high chance of sudden death.
- The ICD is a lifesaver.
- This will decrease your risk of dying suddenly by greater than 50%.
- The ICD will control any developing tachycardia.
- The ICD is there as a lifesaving measure in instances of dangerous heart rhythms.
- The ICD will improve your long-term survival.
- The main benefit is prevention of lethal arrhythmia.
- Analogies to Describe the ICD
  - Watcher . . . standing in the background watching over you.
  - Insurance policy.
  - Seat belt.
  - Safety net.
  - An ambulance that follows you around.

**Table 5. Standardized Patient Interviews: Cardiologist Statements About Implantable Cardioverter-Defibrillator (ICD) Inappropriate Shock and Device Advisories**

<table>
<thead>
<tr>
<th>Cardiologist Statements</th>
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</thead>
<tbody>
<tr>
<td><strong>Statements on Inappropriate Shock</strong></td>
</tr>
<tr>
<td>Inadvertent shock is not detrimental.</td>
</tr>
<tr>
<td>Inappropriate shock . . . does not happen very often; happens very rarely; almost never happens; happens with very few people.</td>
</tr>
<tr>
<td>The chances for an accidental shock are low because we can monitor it [the device] and adjust it in order to decrease your risk of accidental shock.</td>
</tr>
<tr>
<td>No, the ICD will only go off if you are in VT/VF.</td>
</tr>
<tr>
<td>Inappropriate shocks are definitely not the norm.</td>
</tr>
</tbody>
</table>

**Statements on Device Advisories**

- We haven’t had any issues with recalls lately. These devices are well tested and rarely have problems, so don’t worry about it.
- The device can malfunction, but because of placement or programming problems.
- All companies have experienced issues with the device, but when problems are discovered, they fix them.

**Abbreviations:** VF, ventricular fibrillation; VT, ventricular tachycardia.
cate that patients are uninformed and overly optimistic about expectations for the future.

Our data provide further insight into the patient experience. We obtained data from a diverse group of patients who gave a consistent message about the inadequacy of information shared before the implant procedure and inattention to psychosocial issues following the implantation. Many patients described ICD-related effects on body image and lifestyle. In cases where the ICD need was deemed urgent, most patients reported feeling overwhelmed by the pace of decision making. Many patients struggled with competing views of the ICD, seeing it as a safety net and as a source of physical and emotional discomfort.

Our findings are consonant with other studies\(^\text{50,51}\) that have focused on patient perceptions of physician communication about ICD management at the end of life. For example, Kirkpatrick et al\(^\text{51}\) found that 96% of 278 patients surveyed had never discussed with a medical practitioner what to do with their ICD if faced with an end-of-life situation. In addition, the “anthropomorphism” of the ICD, a concept described by Goldstein et al.,\(^\text{52}\) was shared by a large percentage of patients in our focus groups and by almost every cardiologist in the SP interviews, who used words such as safety net and friend. As in one of the prior studies, patients “did not seem to fully comprehend the nuances and intricacies of these devices.”\(^\text{52,61}\) Also consistent with prior research,\(^\text{13}\) our patients voiced optimistic estimates of ICD efficacy, likely reflecting physician minimization or denial of risks. Discussion of such key issues as the effect of the ICD on quality of life typically was prompted by SPs; without such prompting, many SP interviews would have ended without meaningful coverage of the topic. We posit that a lack of accurate information exchange can lead to patient uncertainty and may negatively influence quality of life.

We encountered several methodological challenges related to patient uncertainty about the indication for implantation and the actual type of device implanted. Because a combined ICD–biventricular pacemaker can affect heart failure symptoms, patient responses may be different than if an ICD alone is implanted. Focus groups bring together a heterogeneous collection of patients based on educational background, duration since implantation, history of a shock, and ability to distinguish real from phantom shocks,\(^\text{53}\) as well as other factors that might influence the risk for increasing psychological distress.\(^\text{54}\) In addition, our study was not powered to analyze the effect of key patient variables such as race/ethnicity or age. Nevertheless, patient responses on key questions were fairly uniform across focus groups.

Although the SP interview participants included cardiologists who implant ICDs and those who refer, the sample was too small to draw inferences about the influence of practice type, physician age, or other characteristics on quality of communication. Similarly, we cannot draw conclusions about the effect of the specific SP profiles because they differed by multiple characteristics, including age, sex, race/ethnicity, and underlying etiology of disease.

For future directions, it is important to develop and validate questions that can be used to identify patients who might be at risk for decrements in health-related quality of life following implantation. A greater focus on patient-physician communication is required. The content of such discussions needs to be more fully developed\(^\text{55}\); at the same time, the decision to implant an ICD is just one of multiple difficult discussions encountered in the contemporary care of patients with chronic and advanced heart disease. We hypothesize that communication skills can be taught in a formal educational initiative, with favorable effect on patients, as demonstrated in the oncology model.\(^\text{56}\)

In summary, our study demonstrates that patient-physician communication about ICDs is characterized by patient misinformation and a lack of attention to psychosocial and long-term risks by the prescribing physician. Separate qualitative investigations with patients and cardiologists supported these conclusions. Given the high volume of ICD implant procedures, the present findings suggest that failure to fully engage patients in bidirectional communication may be widespread. Training of cardiologists about information exchange with patients may be beneficial to informed decision making and preempt threats to patient quality of life.

Accepted for Publication: July 15, 2012.
Published Online: February 18, 2013. doi:10.1001/jamainternmed.2013.3171
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Conflict of Interest Disclosures: None reported.
Funding/Support: This study was funded by the President’s Research Fund and the Joseph C. Sansone Fund in Cardiovascular Outcomes Research, both at Saint Louis University.

Role of the Sponsors: The funding agencies had no role in the design and conduct of the study; collection, management, analysis, and interpretation of data; and preparation, review, or approval of the manuscript.


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