



Reimplantation surgery in patients with implantable cardioverter defibrillators: A qualitative study



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ABSTRACT

Objective: The purpose of this study was to examine the experience of recurrent surgery for patients with implantable cardioverter defibrillators (ICD).

Background: Device replacement is typically required every 4–7 years due to battery depletion. Furthermore, recurrent surgery may be related to lead malfunction or pocket infection.

Methods: Ethnographic methods were used for data collection with 23 ICD reimplanted recipients, 12 men and 11 women, 26–85 years of age. Data were analyzed using a within case and cross-case method. **Results:** Three major themes were identified: *Anticipation regarding implantation* with three sub-themes of logistics and social considerations, decisions regarding replacement, and financial considerations. *Relinquishing control* and *somatic changes* frame perceptions related to the operative and postoperative periods.

Conclusions: The frequency of ICD reimplantation differentiates it from other surgical interventions. Perceptions varied according to past experiences and present day social, financial, and somatic differences. Recipients are resolved to life-long surgery aided by their trust in health care professionals.

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Introduction

Implantation of cardioverter defibrillators (ICDs) continues to grow worldwide with the US leading in the number of both new implants and replacement devices.¹ With more than 230,000 implanted annually in the US,² ICDs are credited with decreasing the risk of mortality 30–54% in patients with high-risk cardiac conditions and are the standard of care for individuals surviving sudden cardiac death and life-threatening ventricular arrhythmias.³ Indications for ICD implantation include secondary prevention for patients who have survived a previous cardiac arrest or ventricular arrhythmia primary prevention to avert cardiac arrhythmias in high-risk patients. Patients with cardiomyopathy and heart failure are also being treated with similar devices (cardiac resynchronization therapy defibrillators (CRT-D)) that have additional pacing and sensing capabilities to improve cardiac hemodynamics thereby decreasing mortality (here after included in this article as ICD).⁴

ICDs are usually replaced because of battery depletion approximately every 3.7–5.8 years.⁵ The need for replacement is determined through periodic device interrogations (device data retrieval

and lead testing in which their heart rates are manipulated to evaluate lead sensing and pacing) performed remotely or in a device clinic.⁶ The technology itself can also present unique challenges related to device malfunctions, lead failure, infectious or noninfectious pocket-related complications.^{7–10}

ICDs are usually replaced during outpatient/same-day surgery procedures performed in an electrophysiology or catheterization lab, using conscious sedation with local anesthesia.¹¹ The old device is removed and the lead(s) are tested for sensing and pacing capabilities. A new ICD is connected to old leads and placed in the original skin pocket. Although the subject of continued debate concerning its necessity,^{12,13} a defibrillation threshold test (DFT) may or may not be performed to evaluate the new ICD's ability to detect and shock induced ventricular fibrillation.

Over time, persons living with ICDs may need to undergo multiple reimplantation procedures. Although several studies have addressed the long-term adjustment to living with an ICD,^{14–17} no studies have focused on the recipients' experience and perceptions related to reimplantation surgery. Recipients' perspectives concerning recurrent implantations, device interrogation, sedation effectiveness, or initiation of ventricular fibrillation for DVT testing are unknown. Recipients who have not had shocks, do not use their ICD for pacing (as they would with a CRT-D or with bradycardia), or are of advanced age, might question the need for a new device

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based on their experience. These perspectives may promote discussions regarding continued reimplantation. Furthermore, each experience may be unique due to changes in psychological, social, medical, or financial situations. Therefore the aim of this study was to examine the experience of recurrent reimplantation surgery among recipients with implantable cardioverter defibrillators.

Method

A micro-ethnography, focused on the events relative to perspectives of reimplantation, was used to fully understand and interpret the experience^{18,19} of reimplantation. Micro-ethnography includes directly observing the actions, behaviors, and interactions participants have with others for a limited amount of time in the cultural environment where these events occur. It “narrows the focus to one or more aspects of life known to exist” (p. 31) in a setting.¹⁹ Ethnography allowed for observations to be made during ICD implantation procedures that recipients might not be able to recall in an interview due to anxiety or intraoperative sedatives.

We used participant observation of patients during pre-operative, operative, and post-operative ICD replacement procedures, ICD follow-up and device interrogation procedures; semi-structured interviews with ICD patients; and medical record review. The principal investigator has clinical expertise in cardiac electrophysiology and performed data collection and analysis, in collaboration with a second investigator who had methodological expertise. To minimize bias, a health care facility was chosen that was unfamiliar to the principal investigator. Patterns and elements of physical, social, and psychological experiences of patients with recurrent implantation surgery were identified.

Participants and setting

A stratified purposive sampling strategy was used in which cases were selected that varied on pre-selected parameters.²⁰ Participants were adult ICD patients with either a single- or double-lead ICD or CRT-D who were planning, undergoing or had previously undergone ICD replacement for any reason, including lead failure, infection, or device recall. We recruited participants through an electrophysiology device clinic within a large teaching hospital in the southeastern US.

Data collection

Nurses and physicians from the cardiac electrophysiology service facilitated participant recruitment in collaboration with the primary investigator. The device clinic nurses identified potential participants who were scheduled for an upcoming appointment and a letter was sent to introduce the study. Willing participants mailed their contact information back to the hospital giving permission to be contacted by the researcher. IRB approval was obtained prior to the study, and informed consent was obtained from participants prior to data collection. Recruitment and data collection were conducted over a one-year period and discontinued when data saturation was identified by both researchers and no new themes or patterns emerged.

The foci of all observations were adapted from the dimensions of social situations¹⁹ that include the space and objects in the scene, the sequence of activities, the goals being accomplished, the interactions, and the feeling and emotions felt or expressed by the actors in the scene. Informal questions were posed to the actors (hospital personnel) to understand what they were doing (e.g., goals they were attempting to accomplish) or clarify observed behaviors. To minimize influence in the setting, these questions were asked when the procedure was completed.

Observations during device interrogation and lead testing procedures lasted approximately 10–15 min, unless there were problems pertaining to medications or errant heart rhythms. Attention was focused on the patient’s non-verbal and verbal communication as they were positioned in the chair, connected to the ICD programmer and monitoring equipment and as the lead-tests were conducted. Observations in the clinic yielded information on the influence these procedures might have had on patients’ ICD experience.

After the participants’ ICD follow-up appointment (for both those who were observed in surgery and those having routine follow-up), semi-structured interviews were conducted to obtain accounts of reimplantation experiences from the patient’s perspective.

All interviews were audiotaped and transcribed by the researcher. Interviews opened with a question, “*Can you tell me the story of how you came to have an ICD?*” Questions were asked to clarify, expand, or focus on specific aspects of what they had talked about. Additional questions were asked to address the aspects of the reimplantation experience. An interview guide was used with questions to reflect topics relative to the study focus (see [Appendix](#)).

Medical records were reviewed. Data were collected on the demographic and clinical characteristics of the sample and details of the device implantation including diagnosis, time since implantation, the reason for the initial implantation, the number of and reason for ICD replacements, and frequency of antitachycardia pacing (ATP) or shocks.

Data analysis

Analysis was conducted simultaneously with data collection. All data were entered into a Microsoft® Word computer file and organized by case number. A case was composed of all observations, interviews, and medical record information obtained from and about an index patient. Each case was linked to the data collection method (e.g., interview, observation), and the place and time it occurred (e.g., pre-surgical, post-surgical, EP lab, device clinic). All recordings and the field notes were reviewed and corrected. The transcripts were proofed against audio files for accuracy. Codes were assigned to words or segments of data that were descriptive or inferential in nature. Coding was organized according to the interview guide and helped to identify key variables and themes that were later examined across cases. While coding was in process, memos were written in which ideas and thoughts were developed. Both researchers met weekly and collaborated on coding selection and memo interpretation. Ultimately, memos were used to explore ideas and relationships, and to identify gaps in the data. Data matrices were created to organize data, which allowed for comparisons to be made within and across cases.²¹ These matrices displayed patient characteristics, reimplantation and ICD events, physiological, psychological and social interactions and thematic lines were developed using these matrices in the course of analysis. A reflexive journal was maintained to track analytical moves throughout the course of the study.

Results

A total of 23 patients were recruited who varied on age, race, sex, and number of reimplantations. The length of time participants had ICDs was from 4 to 13 years. The number of reimplantation procedures varied between one and three and were due to battery deletion, lead revisions, ICD upgrades to biventricular ICDs, or device recalls. Details of participants’ demographic and clinical characteristics are displayed in [Table 1](#). Five of 23 patients were the

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