Psychological Aspects of Cardiac Devices and Recalls in Patients With Implantable Cardioverter Defibrillators

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The product recall of an implantable cardioverter defibrillator (ICD) creates a potentially stressful event for patients. This study briefly describes the psychological adjustment of patients with implantable devices and makes recommendations for the management of device recalls and adverse outcomes to minimize psychological distress. Because the occurrence of ICD-specific fears and symptoms of anxiety are the most common psychological symptoms experienced by ICD recipients, a comprehensive care plan to attend to recall procedures and patient distress is needed. It is suggested that recalls do not affect all ICD patients equally, with risk factors for poor psychological adjustment to ICDs including younger age (<50 years), shock experience, and female gender that may be associated with increased recall anxiety. Specific recommendations for device recall management include formalizing clinic responses to recall before and after implantation and innovative uses of patient support systems to communicate recall responses. © 2006 Elsevier Inc. All rights reserved. (Am J Cardiol 2006;98:565–567)

The recall of an implantable cardioverter defibrillator (ICD) is a stressful event for patients. The effectiveness of ICDs in randomized clinical trials in reducing mortality has inspired great confidence in medical technology in ICD patients. These patients report desirable quality of life and have a perception of protection from sudden cardiac death.1 However, these same patients must cope with the prospect of a potentially life-threatening arrhythmia, rely on a device for the precise delivery of therapy, and live with the potential for ICD shock. The emergence of multiple device recalls highlights a new psychological challenge for ICD patients.

A substantial body of research indicates that anxiety can be problematic for patients with ICDs.2–5 Psychological distress continues to be examined as a precipitant and a consequence of ICD shock.4–7 As Wilkoff8 noted, device recalls are a common and predictable result of manufactured items. This reality confronts patients who must trust in their ICDs to support them in their return to full functionality. Similar to other undesired courses, such as bouts of congestive heart failure or ICD shocks, patients with ICDs can and will cope with a recall as an expected challenge, if the key stakeholders manage the information and process it well. Unfortunately, very few data exist to guide the processes and procedures of recalls and their impact on patients in published research on biomedical devices and/or ICDs. Although “disclosure, disclosure, disclosure” is a likely sounding call, patients should not be expected to decipher the subtleties of advisories, recalls, and “Dear Doctor” communications. This editorial briefly describes the psychological adjustment of patients with implantable devices and makes recommendations for ongoing device recalls and adverse outcomes.

Initial efforts to understand the psychological adjustment of patients with ICDs relied on traditional paradigms seeking to “find and fix” diagnosable psychopathology. The occurrence of ICD-specific fears and symptoms of anxiety (e.g., excessive worry, physiologic arousal) are the most common psychological symptoms experienced by ICD recipients, with approximately 13% to 38% of recipients experiencing diagnosable anxiety. ICD-specific fears include the shock experience, device malfunction, and/or death. Depressive symptoms are reported at rates that are generally consistent with other cardiac populations (24% to 33%).9 Standard diagnostic approaches lack the sensitivity necessary to detect subdiagnostic yet important concerns, calling for more disease-specific methods and paradigms.10 We have promoted a disease-specific concept of adjustment to an ICD called “patient acceptance” that avoids the pitfalls of psychopathology detection alone and suggests a more normative adjustment model in most patients. The Florida Patient Acceptance Survey measures 4 factors, including positive appraisal, body image concerns, device-related distress, and return to function, which are summed to provide a patient acceptance total score. It is a fundamental and inescapable principal that patients with ICDs must have faith in their devices, or their psychological acceptance of the devices is altered. Security is the primary benefit for ICD recipients. Only cardiac resynchronization therapy devices are likely to produce an independent functional capacity benefit. In fact, 24% of an ICD sample reported “low treatment satisfaction,” an outcome that was associated with psychological distress and shocks.11 Device

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Recalls are very unlikely to produce profound psychopathology, but more specific approaches to patient outcomes may allow the detection of changes in “faith” in a device.

The ICD patient community is no longer a homogeneous group of survivors of cardiac arrest, as in the 1990s. During those years, the prototypical patient with an ICD expressed relief and gratitude to the electrophysiology community for the lifesaving technology of ICDs. The new population of ICD recipients is populated by a diverse set of patients with a “drive-through” experience of ICD implantation and a security-backup mentality, compared with the life-support mentality of secondary prevention patients. Our follow-up processes are less demanding, including the use of remote technologies, and represent success as a health care system that is less intrusive to patients’ lives. Progress has increased the health care community’s expectations regarding the quality of life, which we welcome but may not always exceed. Device recalls represent a chink in our armor that reminds us to acknowledge with our patients that faith in a device is crucial but not unyielding.

Recalls likely do not affect all patients with ICDs equally. Risk factors for poor psychological adjustment to ICDs have been defined and include younger age (<50 years), shock experience, female gender, a poor understanding of a condition or device, severe co-morbidities, and a history of psychological difficulties. Similar risk groups would likely be differentially affected by news of a recall. The means and manner of communication may also be a critical aspect of device recall procedures. Clearly, the presumption that recall information is best disseminated through the doctor–patient relation is likely valid. However, this ideal circumstance may no longer be feasible with the increased size of the device population and the need for rapid communications. This scenario suggests the need for increased attention to a systematic communication system to patients from multiple sources. Research is needed to examine how patients may best respond to recall information and its implications.

Because virtually no data exist on the impact of implantable device recalls on patients, recommendations are offered with a degree of caution. Nonetheless, patients with ICDs are currently dealing with these issues, and awaiting data does not allow us to address current needs. Because ICDs have a very desirable rate of functioning, the possibility of device malfunction or recall remains low but will likely be a more prominently voiced concern by future patients. Acknowledgment of the news of recalls and a statement about how recalls are handled in each clinic seems appropriate as a degree of preparation. The informed consent process also now needs inclusion of the risk for recalls as an adverse outcome. After implantation, information related to recalls is increasingly more likely to reach patients through alternative sources than the doctor–patient relation. Specific information about who is affected and what action patients should take should accompany any news release to limit emotional reactivity and costly and unneeded crisis calls and to facilitate optimal professional, planned care. Currently, the United States Food and Drug Administration or a device company provides some information related to level of risk, but this recommendation is focused primarily on what action patients should take, as opposed to communicating the degree of risk. Furthermore, it is our hope that technologic solutions could be further developed, such as using the established clinic-patient links associated with home monitoring technologies to efficiently provide information related to recalls or field advisories deemed important by their physicians.

Many patients with implantable devices regularly have access to either virtual support groups through the Web or local support groups facilitated by health care providers. These informal networks may serve as local patient-to-patient information networks that could be formally harnessed to disseminate information and reduce hysteria and rumors. Professional leadership is needed to provide the appropriately measured tone and response. Currently, some Web sites for patients with ICDs have spontaneously attempted to be clearinghouses of recall information. The community of patients with ICDs has a capacity for information dissemination, unlike other cardiac disease related patient groups.

Clearly, ICDs have achieved great success in preventing cardiac arrest in at-risk patients. The emergence of recalls should not be interpreted as an abject failure but rather as a signal for the need to more closely attend to the full continuum of device-based patient care.


