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Perspectives in managing recalls of cardiac implantable electronic devices

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Implantable cardioverter defibrillators (ICDs) have proven survival benefit and their use continues to increase worldwide. Being devices dependent on a range of sophisticated electronic and mechanical components, there is an inherent risk of device-related complications. Any compromise in system (generator/lead) integrity demands prompt evaluation. Fortunately, current era cardiac implantable electronic devices (CIEDs) are very reliable and component failure infrequent. Advisories and recalls signal a greater than expected malfunction rate and are a source of anxiety to physicians, patients and to industry alike. Questions regarding prevalence of the problem vs. the danger(s) posed, the technical solution (if any), and management, initially may not have clear cut answers.

Advisories and recall notices surface with regular – perhaps increasing-frequency. Why is this? Possibly, increasing awareness coupled to improved surveillance techniques are contributory. Nevertheless, as device complexity increases, so does risk of malfunction. The best intentioned efforts to improve performance (e.g. battery technology, thinner leads) and pre-market testing carry risks of unanticipated problems occurring downstream. Each advisory or recall poses a unique management challenge. The most important question is the anticipated risk to the recipient. Any proposed treatment should not be more dangerous than the condition being addressed. One single center study of 1644 consecutive ICD recipients over 9 years reported that ICD advisories impacted an astounding 43% of the patients [1]. However, within this group, advisory-related malfunctions affected 4% of patients. Based on a conservative management strategy, ICDs under advisory were not associated with increased mortality over a background of significant disease-related mortality, whether designated Class 1 or II. This experience indicates that advisories largely do not translate into patient morbidity. Deaths due to the device malfunction are scant in the literature. However, interventional procedures in response to advisories may be harmful. Systematic review indicated that prophylactic replacement of recalled CIED generators is associated with a low mortality rate but nontrivial rates of other major complications [2]. Complications associated with (simple) box changes may range from 5–10%, of which one half are considered "major" [2a–2c]. These rates are magnified considerably when it comes to lead replacement. Given the complexity of the decision process, it is not surprising that opinions regarding best management strategy differ [3].

This does not argue that system components subject to recall should be ignored. Rather each patient be treated on individual merit. Malfunctioning software functions seldom pose-life threatening problems and may have software fixes (including disabling them). Advisories associated with battery, high voltage circuitry and lead failure potentially are more serious e.g. battery or lead failure in a patient who is pacemaker dependent may be catastrophic, but not in another with non-ischemic cardiomyopathy receiving an ICD for primary prevention. The former may be treated with replacement, the latter not. Extraction of leads with a long dwell time should be considered carefully, particularly in centers with low extraction volumes. Age, frailty and comorbidities should be included in this decision. These may influence not only acute procedural safety but also determine long term survival, perhaps more so than therapy from the implantable cardiac device itself. These are important points to be discussed with the patient. Rarely, is the psychological stress of living with a recalled device unacceptable to a degree warranting explantation [4]. Well informed patients will choose the conservative management if this represents their best interests.

Central to all management decisions regarding devices subject to advisories or recalls is prompt identification of the problem, if it occurs. Responsibility involves manufacturer and patient, but ultimately rests with the physician. A system of rigorous post-implant monitoring is necessary. Conventionally, this rests on regular calendar-based appointments, assuming consistent patient adherence. In practice, this method will miss potentially serious problems occurring between interrogations (which is when they are most likely to occur) and is vulnerable to patient attrition. This situation was highlighted in 2005, when efforts to follow a large number of recalled devices from several manufacturers were undermined by the loss of patients to follow up care and lack of contact details. This prompted the HRS to advocate the necessity of post-implant follow up, and in recognition of the workload posed to clinics and inconveniences to patients, a call for wireless remote monitoring (RM) [5]. Embedded technologies have created the ability for devices to monitor their own function and communicate this information wirelessly to health care

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providers without needing clinic or patient involvement [6]. Alert transmissions are triggered as and when out of bounds conditions occur. These wireless automatic remote monitoring platforms have been developed and tested in trials yielding favorable results, and well accepted by patients. Regarding device management in particular, the TRUST trial illustrated that automatic remote monitoring was a powerful instrument for detection of disintegration of high voltage circuitry, lead integrity and battery depletion occurring in a general population of ICD recipients, particularly since the majority of such events were asymptomatic and underreported by conventional follow up [7]. RM facilitated prompt decisions regarding interventional or conservative management for issues as and when they occurred. The same spectrum of abnormalities and management decisions apply to the majority of recalls or advisories. Thus, recent consensus statements indicate Class 1 recommendations for remote patient management to be initiated soon after implant and adopted as standard of care (i.e. preferable to in-person follow-up) for maintaining device surveillance in general and for recall or advisories in particular [8]. For recall management, RM provides significant operational efficiencies compared to simply increasing the frequency of in-person follow up, which are onerous and still likely to miss dangerous interim problems.

Success of RM is dependent on several factors. The problem being monitored needs to be one that can trigger an alert and this usually depends on detection of electrical abnormalities. Thus "inside-out" lead breakdown which does not affect electrical parameters (though some do) will not be detected. Conditions which progress rapidly may not give sufficient notice for pre-emptive intervention. For example, one third of patients with Fidelis lead failure receive inappropriate shocks within 3 hours of lead fracture. In some battery recalls, progression to complete depletion has occurred in less than 48 hours. Possibly, in such cases, these may be anticipated by other changes in device circuitry, that may be signalled earlier by remote monitoring, and permit intervention. Notably, to maintain early reaction ability to within 48h, there is a requirement for significant infrastructure [9] including trained personnel.

The points raised above are reflected in the management plan for the recent recall affecting ICD batteries from one manufacturer (SJM) and the guidelines proposed by Indian Heart Rhythm Society [10]. This affects a minority (<1%) of implanted devices. Sudden (<48h) battery depletion occurs in an even smaller minority. Given the hazards posed by the procedure, which outweigh the risk of device failure, generator replacement is not recommended *en masse.* Elective replacement may be considered for those patients who are pacemaker dependent. However, it is preferable to keep all patients with the affected device on remote monitoring. In this regard, automatic continuous remote monitoring represents an early warning system which can provide assurance to both patients and their physicians.

In summary, although advisories and recalls occur with alarming frequency and pose real risks, management centers on early detection by remote monitoring and device replacement individualized according to the problem discovered in the context of patient's condition. For the future, RM offers as stringent method of post-implant ICD evaluation in which system components are automatically tested, reported and databased longitudinally ie a system permitting characterization of device behavior, determination of reliability, and definitions of abnormality (and recalls) [9].

References

[1] Sengupta J, Kendig AC, Goormastic M, Hwang ES, Ching EA, Chung R, et al. Implantable cardioverter-defibrillator fda safety advisories: impact on patient mortality and morbidity. Heart Rhythm 2012;9:1619–26.

[2] Zeitler EP, Patel D, Hasselblad V, Sanders GD, Al-Khatib SM. Complications from prophylactic replacement of cardiac implantable electronic device generators in response to United States food and drug administration recall: a systematic review and meta-analysis. Heart Rhythm 2015;12:1558–64.
a Moore III John W, Barrington William, et al. Complications of replacing implantable devices in response to advisories: a single center experience. Int J Cardiol 2009;134:42–6.
b Gould Paul A, Gula Lorne J, et al. Outcome of advisory implantable cardioverter-defibrillator replacement: one-year follow-up. Heart Rhythm December 2008;5(12).
c Lewis Krystina B, Dawn Stacey RN, et al. Estimating the risks and benefits of implantable cardioverter defibrillator generator replacement: a systematic review. PACE July 2016;39.

[3] Grazia Bongiorni M, Dagres N, Estner H, Pison L, Todd D, Blomstrom-Lundqvist C. Management of malfunctioning and recalled pacemaker and defibrillator leads: results of the european heart rhythm association survey. Europace 2014;16:1674–8.

[4] Larsen JM, Riahi S, Johansen JB, Nielsen JC, Petersen HH, Haarbo J, et al. The patient perspective on the riata defibrillator lead advisory: a danish nationwide study. Heart Rhythm 2014;11:2148–55.

[5] Carlson MD, Wilkoff BL, Maisel WH, Carlson MD, Ellenbogen KA, Saxon LA, et al. Recommendations from the heart rhythm society task force on device performance policies and guidelines endorsed by the american college of cardiology foundation (accf) and the american heart association (aha) and the international coalition of pacing and electrophysiology organizations (cope). Heart Rhythm 2006;3:1250–73.

[6] Varma N, Ricci RP. Telemedicine and cardiac implants: what is the benefit? Eur Heart J 2013;34:1885–95.

[7] Varma N, Michalski J, Epstein AE, Schweikert R. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the lumos-t safely reduces routine office device follow-up (trust) trial. Circ Arrhythm Electrophysiol 2010;3:428–36.

[8] Slotwiner D, Varma N, Akar JG, Annas G, Beardsall M, Fogel RI, et al. Hrs expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm 2015;12:e69–100.

[9] Varma N, Brugada P. Automatic remote monitoring: milestones reached, paths to pave. Europace 2013;15(Suppl 1):i69–71.

[10] Bhargava K, Arora V, Jaswak A, Vora A. Premature battery depletion with St.Jude Medical ICD and CRT-D devices. Indian Heart Rhythm Society guidelines for physicians. Indian Pacing Electrophysiol J 2016;6:194–6.

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