The Canadian Experience with Device and Lead Advisories

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KEYWORDS

• Arrhythmias • Implantable cardioverter defibrillator • Device • Advisory • Complications

KEY POINTS

- Device/lead advisories have become increasingly common and pose significant management challenges.
- Complications caused by device/lead advisories can have serious effects on patient outcomes.
- A collaborative approach using a virtual network can provide an excellent mechanism to respond rapidly to advisories in a uniform manner.

INTRODUCTION

Cardiac implantable electrical devices (CIEDs) have undergone revolutionary changes in the last decade, linked to growth in both indications and capability. These changes have led to an increase in the use of both pacemakers and implantable cardioverter defibrillators (ICDs), collectively known as CIEDs.[1–3] It is projected that the population with heart failure will double by the year 2025, and the absolute number of patients eligible to receive an ICD for primary prevention or cardiac resynchronization therapy will likely increase accordingly.[4–6] These epidemiologic observations will translate into a significantly increased burden on the health care system, with fiscal pressures that will be hard pressed to cope with this projected demand.

THE CANADIAN EXPERIENCE WITH DEVICE AND LEAD RECALLS

Because of the recent increase in device and lead advisories,[7] the Canadian Heart Rhythm Society (CHRS) responded by establishing the Device Advisory Committee, now termed the Device Committee (DC). The purpose of this committee was to coordinate a network of Canadian arrhythmia device physicians to provide a system of device and lead surveillance, reporting, and uniform response to advisories in a timely and consistent manner.[8]

Establishment of the Canadian Device Advisory System

History has proved instructive in providing the basis of response to advisories before the last

The authors have nothing to disclose.

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Card Electrophysiol Clin 6 (2014) 327–334
http://dx.doi.org/10.1016/j.ccep.2014.02.003
1877-9182/14/$ – see front matter

decade. The Accufix lead advisory (Telectronics Pacing Systems, Englewood, CO) was a prime example of how intervention proved more dangerous than observation.[9] Using this concept of harm versus benefit in dealing with device advisories, the CHRS established a subcommittee dedicated to this issue. This committee was initially tasked with promoting a unified approach and providing guidelines for device follow-up centers in Canada for device advisories. Before the establishment of the CHRS-DC, response to advisories in Canada was handled in a varied fashion from center to center. Several ICD generator advisories were announced in 2005, including the Medtronic Marquis (Medtronic, Minneapolis, MN) and Ventak Prizm (Boston Scientific, Natick, MA).[10–12] The risk of generator failure in these advisories was from 1/1000 to 1/10,000 (Table 1),[12] yet many centers responded by replacing the pulse generator earlier than would otherwise occur, as dictated by battery replacement indicators. To provide evidence-based management in this regard, a group of investigators began a collaboration to collect and report a Canadian perspective on the outcome of generator replacement caused by an advisory ICD.[12] The results were remarkable in that the risk of early generator replacement outweighed any risk that may result from generator failure caused by the advisory (Table 2). At least as compelling was the variability in replacement rates across centers, ranging from 0% to 45%.[12] This situation resulted in a change in management of ICD generators under advisory. This format of using evidence to guide decision making provided the basis for further work carried out by the CHRS-DC.

Canadian Device Advisory Structure

The CHRS-DC consists of a Chair, appointed by the CHRS executive, and a member from each ICD implanting and follow-up center across Canada (Fig. 1). In addition, there is a working group that consists of the Chair, Deputy Chair (appointed by the Chair of the CHRS-DC), CHRS President, and a member at large. Advisories are considered by the committee when a greater degree of intervention beyond simple increased surveillance

Table 1
Current ICD advisories included in the survey and associated risk

Company/Device[a]	Date of Advisory	Advisory Issue[b]	Current Risk of Failure (%)[b]
Medtronic Marquis ICD	February, 2005	Accelerated battery depletion caused by internal battery short	0.001
Guidant Ventak Prizm 2 DR ICD	June, 2005	Short circuit caused by wire insulation problem within lead connector block	0.1
Guidant Ventak Prizm AVT, Vitality AVT, and Contak Renewal AVT ICDs	June, 2005	Random memory error, limiting delivery of therapies	0.0095
Guidant Contak Renewal 3, 4 Renewal 3, 4 AVT and Renewal RF ICDs	June, 2005	Magnetic switch faulty, impairing delivery of therapies	0.009
St Jude Photon DR, Photon Micro VR/DR, and Atlas VR/DR ICDs	October, 2005	Memory chip affected by atmospheric radiation, which can impair pacing and delivery of therapies	0.167
ELA Alto ICD	August, 2001	Migration of metal, which can impair pacing and delivery of therapies	2.6[c] 0.1[d]

[a] Predominantly subpopulation of listed devices affected by advisory.
[b] Data obtained from physician communications and public statement releases such as those from Medtronic and Guidant. The current risk of failure represents the number of failures divided by the number of devices implanted at the time of advisory disclosure.
[c] Manufactured between April and July, 2003.
[d] Manufactured between August, 2003 and August, 2004.
From Gould PA, Krahn AD. Complications associated with implantable cardioverter-defibrillator replacement in response to device advisories. JAMA 2006;295:1907–11; with permission.