EDITORIAL COMMENTARY

Cardiac implantable device recalls: consequences, and management

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In 2021 the United States Food and Drug Administration (FDA) issued 3 Class I recalls involving a subset of St Jude (Abbott) pacemakers, Boston Scientific pacemakers, and Medtronic defibrillators. All these recalls were owing to the risk of premature battery depletion (Table 1).1

Cardiac implantable electronic devices have been and will always be subject to recalls.2 The challenge arises in their management. The type of recall and patient characteristics often dictate management strategies. While for most patients a conservative approach of close monitoring is sufficient and safe, there are subgroups of patients that might warrant a more aggressive management strategy, such as battery replacement or lead revision (in case of a lead recall).3 These interventions are not risk free and are associated with a 2.5% risk of major complications.4 Pacemaker-dependent patients or patients implanted with an implantable cardioverter-defibrillator for secondary prevention of sudden cardiac death or who have a history of recurrent ventricular tachycardia are a high-risk cohort where the equipoise of a surgical procedure might be favorable.5

Melman and colleagues report in this issue of the journal on 2 pacemaker-dependent patients implanted with recalled St Jude (Abbott) pacemakers.5 One patient had a battery longevity of around 10 years in January 2021 and was found to have a “dead” battery in April 2021. Luckily, this patient with complete heart block had a junctional escape rate of 40 beats per minute, and hence catastrophic sequelae were avoided.

The second patient had a battery longevity of >10 years in June 2021. In July 2021, the pacemaker reverted to VVI mode without an obvious reason. The device was reset to DDD mode and at that time the battery longevity was approximately 6 years. Ten days later the patient presented with symptomatic bradycardia requiring emergent battery change-out.

The authors reviewed the charts of 46 deceased patients who had a St Jude/Abbott pacemaker affected by the recall (out of a total of 169 patients with that type of pacemaker). Three pacemaker-dependent patients in this group died suddenly. While it was not possible to confirm that the cause of death was due to sudden and premature battery depletion, this causation is plausible.

This unpredictable and sudden pattern of battery depletion makes the current recommendation of close monitoring, set forth by Abbott, suboptimal in the subgroup of patients with significant conduction system disease.

It is our experience that there are several axioms that hold true in most recalls:

1. The early reported failure rates of a lead or a generator are almost always an underestimation of the true incidence of failure. An example of this is the failure rate of the Sprint Fidelis lead and the original reported failure rate of the Guidant Prizm 2DR defibrillator.6,7
2. Recalls can be managed conservatively in most patients. The rate of complications due to a preemptive procedure often tilts the balance in favor of a conservative approach.
3. Pacemaker-dependent patients and patients with frequent appropriate therapy might be the only cohort that will benefit from an invasive preemptive procedure when the nature of the recall is unpredictable and sudden.

The authors should be commended for reporting these 2 cases. When it comes to identifying problems with cardiac implantable electronic devices, the onus is not only on the device manufacturer and the FDA but also on the physicians. The latter are on the forefront and are often the first to encounter problems with these devices. Reporting these potential malfunctions will help regulatory agencies and device manufacturers identify whether these issues fall within the expected range of a malfunction or exceed it. Therefore, complacency should have no role when it comes to identifying and reporting unexpected device malfunctions. In this report, the consequences of a recently established Class I recall are highlighted.

Given the unpredictable and sudden nature of this St Jude/Abbott recall, it is probably beneficial and advisable to offer affected pacemaker-dependent patients a preemptive generator replacement after engaging in shared decision-making with the affected patient.
Table 1  Pacemaker generator Class I recall (1/2005–9/2021)

| Manufacturer                  | Device models               | Date of recall | Recall terminated | Mechanism of failure                               | Number of units subject to recall |
|-------------------------------|-----------------------------|----------------|-------------------|-----------------------------------------------------|---------------------------------|
| Guidant (Boston Scientific)   | Discovery, Meridian, Contak, Pulsar, Intelis, Virtus | 7/28/05        | 1/5/07            | Loss of hermetic seal in battery                     | 54,688                          |
| Medtronic                     | Sigma, Kappa                | 5/18/09        | 3/28/12           | Bonding wires separating from terminal               | 85,378                          |
| Medtronic                     | Adapta, Relia, Versa, Sensia, Sphera, Attesta, Vitatron | 2/14/19        | Open              | Software error                                      | 172,936                         |
| St Jude (Abbott)              | Assurity, Endurity          | 5/7/21         | Open              | Moisture ingress through header                      | 97,413                          |
| Boston Scientific             | Ingenio, Advantio, Vitalio  | 7/13/21        | Open              | High internal battery impedance                      | 72,466                          |

Search terms on FDA recall database: pacemaker; pacing; electrode; battery; generator; lead; Jan 1, 2005 to Sept 10, 2021 (Courtesy of Faisal Merchant, MD).

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