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Original Article

Canadian Registry of Electronic Device Outcomes (CREDO): The Abbott ICD Premature Battery Depletion Advisory, a Multicentre Cohort Study

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ABSTRACT

Background: Premature or rapid battery depletion may compromise the performance and reliability of an implantable cardioverter defibrillator (ICD), potentially resulting in harm or death to patients. We sought to describe the outcomes and clinical management of devices included in the Abbott ICD Premature Battery Depletion Advisory, using data from a Canadian registry.

Methods: This prospective observational study includes patients with an Abbott device subject to the advisory, from 9 centres in Canada. The incidence and outcomes related to device revision owing to premature battery depletion were identified and adjudicated by a committee.

RÉSUMÉ

Contexte : L'épuisement prématuré ou rapide de la pile pourrait compromettre le rendement et la fiabilité d'un défibrillateur cardioverteur implantable (DCI), et risque d'être dommageable ou mortel pour les patients. Nous avons voulu décrire les issues et la gestion clinique des dispositifs mentionnés dans l'avis d'Abbott sur l'épuisement prématuré de la pile de DCI, en utilisant des données tirées d'un registre canadien.

Méthodologie : L'étude observationnelle prospective a été menée auprès de patients porteurs d'un dispositif Abbott faisant l'objet de l'avis, dans neuf établissements au Canada. La fréquence des

Society guidelines recommend the implantation of implantable cardiac defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices for primary and secondary prevention of sudden cardiac death, and to improve the quality of life of patients with heart failure and reduced ejection fraction.[1] As a result of these guidelines, as well as an aging population, increasing numbers of ICDs and CRT devices are being implanted worldwide.[2,3] Cardiac implantable electronic device malfunction has the potential to affect a large number of patients.[4]

In 2016, St. Jude Medical (Sylmar, CA) issued an advisory on Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura, and Unify Quadra devices manufactured before 2015, because of the risk of premature battery depletion (PBD).[5] The underlying cause was the formation of lithium clusters, resulting in shorting of the battery, which could result in rapid battery depletion.[6] There are 398,740 implanted devices worldwide.[5] The reported rate of device failure due to PBD was 0.35% per annum.[7]

On October 11, 2017, Health Canada approved a Battery Performance Alert (BPA), which was developed to detect abnormal battery behaviours and reduce the risk of battery failure.[8] The algorithm monitored for abnormal battery voltage behaviour over the previous 32 days.[9] The BPA would

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Ethics Statement: The study was approved by each institution's research ethics board. Patient consent was obtained if required by the institutional ethics board.

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Results: There were 2678 patients enrolled with a device subject to the advisory. Devices were implanted between 2010 and 2017; follow-up time was 5.7 ± 0.7 years. Device revision occurred in 222 patients (8.3%). Revision for premature battery depletion occurred in 43 patients (1.6%). Devices were revised at physician discretion on notice of the advisory in 16 patients (0.6%), and at patient request in 5 patients (0.2%). A total of 63 (2.4%) devices reached routine end of battery life. A further 95 (3.5%) patients underwent revision for other reasons. There were no reported major complications or adverse events with device revision owing to the advisory. There were no deaths attributed to premature battery depletion.

Conclusions: The rate of premature battery depletion associated with the Abbott ICD Premature Battery Depletion Advisory is low. There were no clinically adverse events identified that were associated with the battery performance of devices under advisory.

Résultats : Ont été inscrits à l'étude 2 678 patients porteurs d'un dispositif faisant l'objet de l'avis. Les dispositifs avaient été mis en place entre 2010 et 2017; la durée du suivi avait été de 5,7 ± 0,7 ans. Une révision de dispositif a été effectuée chez 222 patients (8,3 %). Elle a été motivée par un épuisement prématuré de la pile chez 43 patients (1,6 %). Une révision de dispositif a été faite à la discrétion du médecin, après réception de l'avis, chez 16 patients (0,6 %) et à la demande de cinq patients (0,2 %). Au total, la pile de 63 (2,4 %) dispositifs avait atteint la fin de sa durée de vie habituelle. D'autres raisons ont entraîné une révision chez 95 autres patients (3,5 %). Aucune complication majeure et aucun effet indésirable n'ont été signalés avec les dispositifs révisés par suite de l'avis. Il n'y a eu aucun décès attribué à un épuisement prématuré de la pile.

Conclusions : Le taux d'épuisement prématuré de la pile de DCI associé à l'avis d'Abbott est faible. Il n'y a pas eu d'incidents cliniques jugés liés au rendement de la pile des dispositifs faisant l'objet de l'avis.

be relayed through the *Merlin.net* remote monitoring system or detected on interrogation with a device programmer. For patients without remote monitoring, the triggering of the BPA would be identified only by programmer interrogation.

We sought to assess the incidence of the Abbott Premature Battery Depletion Advisory, and adverse events resulting from the advisory, in a prospective Canadian registry.

Methods

All Canadian centres (n = 22) implanting Abbott ICDs and CRT devices were approached for inclusion in the study. A total of 9 implantation sites from Canada were successfully recruited to participate in the study. The study was approved by each institution's research ethics board. Patient consent was obtained if required by the institutional ethics board.

All Abbott ICDs and CRT advisory devices that were implanted and followed in Canada from the implantation sites were included in the study.

On enrolment, device information and demographic data were obtained. A further review of outcomes was undertaken 12 months following initial enrolment. In the case of death, or device revision, further data were collected regarding the device parameters and reasons for the change.

The primary outcome was the occurrence of PBD in patients from the date of the implant until August 1, 2018. Secondary outcomes were adverse events due to the advisory, including death adjudicated to be due to PBD, complications of device replacement, and clinical sequelae of PBD. Data on cause of death were obtained from available hospital records. If the death was deemed to be due to PBD by the site investigator, the death was independently reviewed by the adjudication committee. Deaths not deemed to be due to PBD were not adjudicated for cause. Postmortem interrogation was not available for review.

PBD was defined as a loss of more than 2 years of predicted life in a span of less than 6 months without another identifiable cause (eg, high pacing output, appropriate ICD shocks). From October 11, 2017, triggering of the BPA was added to this definition. All battery changes indicated by the site to be due to premature battery depletion were adjudicated by an event committee blinded to the site of implant/follow-up. In cases in which cause of death was deemed to be attributable to the device, the information was reviewed by the adjudication committee, when this was available.

All data were entered into a computerized database by trained research personnel.

Analysis

Background and demographic information was summarized by frequency distributions for categorical variables and descriptive statistics of mean, standard deviation, minimum, median, and maximum for continuous variables. Continuous variables were tested for baseline comparability between the clinical outcome groups of interest using the Student *t* test or the Wilcoxon rank-sum test. Categorical variables were tested for baseline comparability with the χ^2 test or Fisher exact test. Time-to-event analysis was conducted using the Kaplan-Meier method.

Results

Of the 7801 advisory devices implanted in Canada, data were available for 2678 (34.3%).

Baseline patient characteristics are detailed in Table 1. The mean age of the patient at the time of device implant was 65.6 ± 11.9 years, and 80.7% were male. Devices were implanted for primary prevention in 62%, and secondary prevention in 33%; no data were available on device indication in 5%. The mean left ventricular ejection fraction was 32.2% ± 13.2%. A total of 335 patients (12.5%) were pacing-dependent at initial review. Remote monitoring was enabled in 1716 of 2678 (64.1%) at the time of enrolment into the study, and increased to 1551 of 1853 (83.7%)

Table 1. Patient demographics

Characteristic	n (%) or mean ± SD
Patient age (y)	65.6 ± 11.9
Male	2160 (80.7)
ICD indication	
Primary prevention	1665 (62)
Secondary prevention	879 (33)
Unknown	134 (5)
LVEF (%,)	32.2 ± 13.2
Previous therapy	
ATP only	276 (10.3)
Shocks only	118 (4.4)
ATP with shocks	553 (58.3)
Pacing-dependent	335 (12.5)
Remote monitoring	1716 (64.1)
Device models	
Fortify	670 (25.0)
Fortify Assura	1032 (38.5)
Quadra Assura	444 (16.6)
Quadra Assura MP	11 (0.4)
Unify	239 (8.9)
Unify Assura	167 (6.2)
Unify Quadra	115 (4.3)

ATP, anti-tachycardia pacing; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; SD, standard deviation.

patients at the last follow-up. The vibratory alert associated with device malfunction could be detected in 65% of patients.

The BPA firmware update was installed in 1713 of 1853 patients (92.4%) at last follow-up. The mean follow-up time was 5.7 ± 0.7 years.

There were 222 patients (8.3%) who underwent device revision during the follow-up period until August 1, 2018. Of these, 43 (1.6%) were adjudicated to be due to premature battery failure, resulting in an annual rate of 0.36% (95% confidence interval 0.22 to 0.50; Fig. 1). The time from implant to PBD was 4.1 ± 1.3 years; the highest rate of PBD occured in the first 3 years after device implantation. By 5 years after implantation, battery depletion due to elective replacement indicator (ERI) became more likely. The time from implant to ERI in this cohort was 5.2 ± 1.2 years.

Among patients with premature battery failure, the BPA was triggered in 11 (25.6%). There were 30 patients (70%) for whom the PBD or BPA was alerted by remote monitoring; the remainder were found at an in-clinic visit (n = 13 [30%]).

There were no patients with PBD who presented with clinical symptoms. The time between device alert and a replacement was 6 days (range: 2-13 days).

Rates of PBD varied among the different device classes and models (Fig. 2). There was an increased rate of PBD with ICDs compared to CRT devices (2.0% vs 0.92%; $P = 0.026$; Table 2).

A total of 179 devices were revised for reasons other than PBD (Fig. 2). A total of 16 devices (0.6%) were revised at physician discretion, and 5 (0.2%) at patient request. Device replacement was performed in 63 patients (2.4%) due to reaching the elective replacement indicator. Other reasons for device revision in 95 patients (3.5%) were device upgrade or downgrade, lead issues, and infection.

No periprocedural complications were associated with device revisions for PBD, or when the device was exchanged at physician discretion or patient request. Among patients with device revision for ERI and other reasons, 9 patients (5.7%) experienced periprocedural complications.

There were 492 (26.6%) deaths during the follow-up period. The cause of death was deemed cardiac in 109 (22.2%), non-cardiac in 73 (14.8%), with the remainder

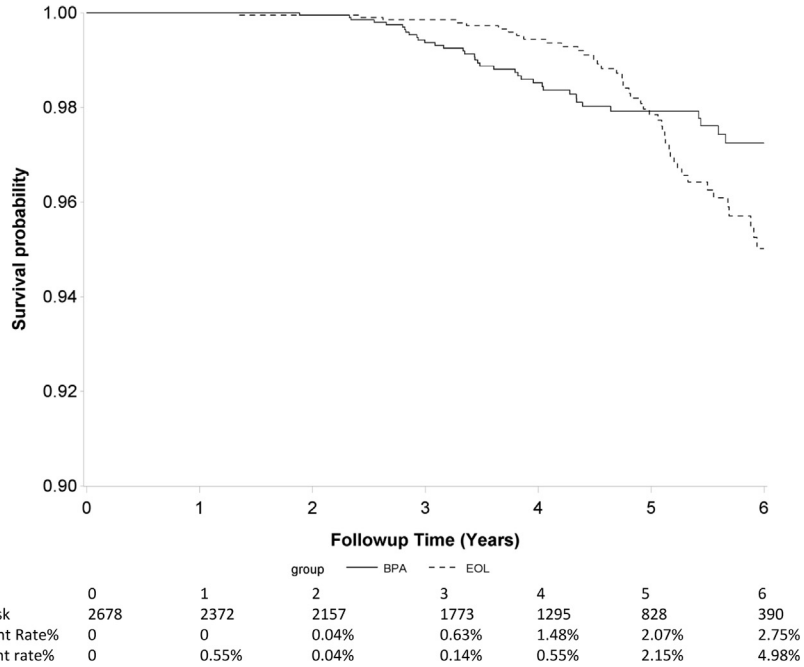

Figure 1. Outcomes for patients with Abbott Premature Battery Depletion Advisory device. PBD, premature battery depletion; ERI, elective replacement indicator.

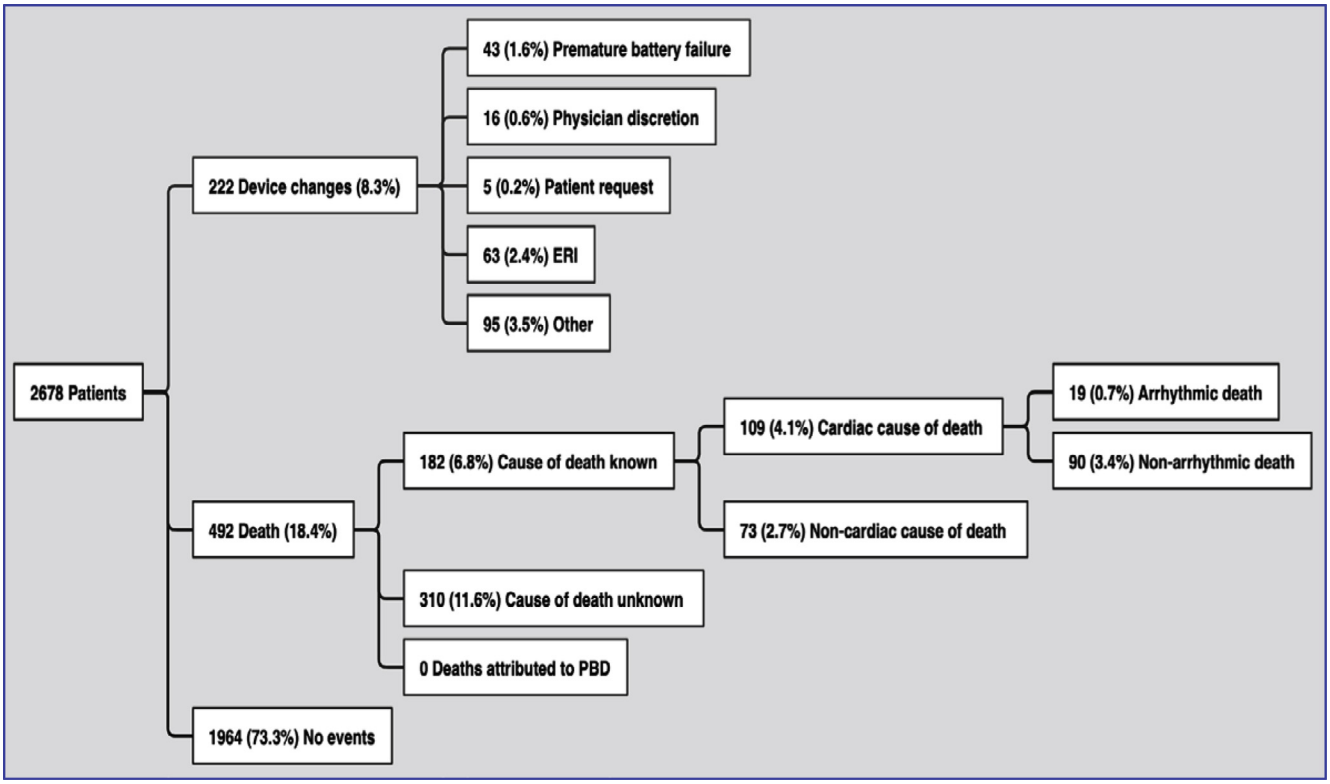

Figure 2. Cardiac device survival according to Abbott Battery Performance Alert (BPA) vs device end of life (EOL). $P = 0.053$.

having an unknown cause of death (n = 310; 63.0%). No deaths were adjudicated to be due to PBD.

Discussion

We found that the rate of PBD among devices subjected to the Abbott ICD Premature Battery Depletion Advisory was 1.6%, with an annualized rate of 0.36%. In the small numbers of patients with PBD, we found no clinical adverse events. There were no complications associated with device revisions due to the advisory.

Our observed rate of device failure is comparable to that in previous reports. A meta-analysis of device failures reported in device registries found a failure rate associated with ICDs of 26 per thousand patient-years.[7] Device failure was found to be due to battery failure in 80% of cases.[7] The Abbott Product Performance Report 2018 reported that the failure rate for advisory ICDs was between 0.13% and 0.49% for ICDs, and 0.12% and 0.38% for CRT devices.[10]

The pattern of device failure associated with the PBD indicates a low rate of failure in the first 2.5 years, followed by an increasing rate of failure. There was, however, no statistical difference between the rate of failure due to premature battery depletion and elective replacement interval at 6 years. Over time, it will become more likely that a device will be revised due to routine ERI rather than PBD.

Previous studies have found that PBD has been associated with symptoms in up to 25% of patients with pacemakers.[11] In our study, we found no adverse clinical presentations for PBD, which is similar to previous reports of rapid battery depletion with ICDs.[12] The current advisory may indicate some factors that reduce complications compared to previous advisories. First, there is more widespread use of remote monitoring, alerting clinicians to the triggering of ERI or PBD immediately on occurrence. There has been much claimed about remote monitoring and its ability to promptly detect lead and device malfunction.[13,14] Previous experience with ICDs, however, has demonstrated that rapid battery depletion is not always detected by remote monitoring.[12] Second, vibratory alerts were reported as the reason for the presentation for the PBD detected in a number of patients. Although this alert is useful, only 65% of patients were able to feel the vibratory alert when it was demonstrated. Ozcan et al. previously reported that in rapid battery depletion, no patients

Table 2. Abbott advisory premature battery depletion rate by device model and device class

Model	Failure (n, %)
ICD (n = 1701)	34 (2.0)
Fortify (n = 669)	13 (1.9
Fortify Assura (n = 1032)	21 (2.0)
CRT device (n = 974)	9 (0.9)
Quadra Assura (n = 442)	7 (1.6)
Quadra Assura MP (n = 11)	0 (0)
Unify (n = 239)	1 (0.4)
Unify Assura (n = 167)	0 (0)
Unify Quadra (n = 115)	1 (0.9)

CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator.

were able to detect the vibratory alert.[12] Third, the development of a novel battery performance algorithm allowed prediction of battery depletion before it actually occurred. The use of firmware updates previously was shown to be beneficial in the management of battery malfunction in devices.[11] Finally, a low percentage of patients were pacing-dependent, with only 12.5%, compared with previous pacemaker studies in which patients are more likely to be symptomatic in the event of device failure.

We found no deaths attributable to PBD of the device. Although postmortem device interrogation was not undertaken as part of this study, as has been suggested by guidelines,[13] a clinical review of the circumstances of death did not find any deaths associated with device failure. For 310 patients, the cause of death was not able to be obtained, or was unknown. It is possible that in this subgroup, there were deaths that could have been attributable to device failure.

The management of device advisories requires a balancing of the harm of continuation with the device, with the risk of device failure, on one hand, with the risks of complications associated with device revision.[15] Gould et al. reported a 9.1% risk of complications associated with replacement of ICDs, which was subjected to an advisory over a 12-month period.[16,17] We found that there were no clinically adverse events associated with device revisions related to this advisory.

In this study, a small number of patients had devices exchanged at physician discretion or patient request, despite the recommendations from St. Jude[5] and also guidelines recommending against the routine elective replacement of the device for advisory.[13] Exchange of the device due to advisory was variable amongst implanting centers, similar to that found in previous reports.[16]

The limitations of this study include the fact that this is a mixed prospective and retrospective study due to the nature of the device advisory. This mixture in itself may influence the results that we achieved with low rates of mortality and complications, particularly for the cases in which cause of death was unknown. Finally, this study was unable to enrol all patients in Canada that were subject to advisory; it is possible that there was clustering of events at centres that were not included in this study. This possibility could be a source of bias in the results, but given that our data are comparable to those reported globally, it is unlikely to have affected this report substantially.

Conclusion

The rate of PBD associated with the Abbott is low. With the current practice of active surveillance, vibratory alert and remote monitoring, and a novel battery monitoring system, no clinical adverse events associated with PBD were found. This study reaffirms the Abbott reports on the incidence of this advisory and did not find any evidence of adverse clinical events, supporting the current Canadian Heart Rhythm Society recommendations of enhanced monitoring, without the need for early device replacement.

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Disclosures

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