Canadian Journal of Cardiology 34 (2018) 808–811

Training/Practice
Health Policy and Promotion

Canadian Registry of Implantable Electronic Device Outcomes: Surveillance of High-Voltage Leads

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ABSTRACT

Background: Cardiac implantable electrical devices (CIEDs) are subject to advisories and complications that can result in morbidity and mortality for patients; there is currently no system in Canada to track these.

Methods: This was a multicenter, prospective cohort study conducted at 5 centers to determine feasibility. Patients with a de novo high-voltage (HV) lead implantation were included and followed for a minimum of 1 year.

Results: There were 611 leads enrolled into the registry over 18 months. The mean age was 62.4 ± 12.8 years; 144 (23.6%) women were enrolled. The indication for lead implantation was for primary prevention in 65.5%. There were 497 (82.1%) de novo devices (single

RÉSUMÉ

Contexte : Les dispositifs de stimulation cardiaque implantables font parfois l'objet de mises en garde et sont susceptibles d'entraîner des complications qui peuvent être cause de morbidité et de mortalité; or il n'existe actuellement aucun système de suivi au Canada.

Méthodologie : Cette étude prospective multicentrique évaluant la faisabilité a été menée dans cinq centres. Les patients ayant subi *de novo* l'implantation de sondes cardiaques à haut voltage ont été inscrits à l'étude et suivis pendant au moins un an.

Résultats : Au total, 611 implantations de sondes cardiaques ont été consignées dans le registre au cours d'une période de 18 mois. L'âge moyen des patients était de 62,4 ± 12,8 ans; 144 (23,6 %) femmes ont été inscrites à l'étude. L'implantation des sondes avait été

Cardiac implantable electrical devices (CIEDs) have undergone revolutionary technological changes in the last decade, permitting ease of use, which has resulted in an increase in the use of both pacemakers and implantable cardioverter defibrillators worldwide, collectively known as CIEDs.[1-3] There are several issues that are unique to high-voltage (HV) leads that require a focused surveillance system, distinguishing them from other medical devices. If a HV lead malfunctions, or if there is a complication, this can result in significant morbidity or mortality due to loss of pacing. Malfunctions can also cause inappropriate implantable cardioverter defibrillator (ICD) shocks and ineffective treatment of dangerous ventricular arrhythmias. Inappropriate diagnosis of HV lead failure can also lead to unnecessary lead replacement, resulting in morbidity or death. We sought to determine the feasibility of performing post-marketing surveillance as a means of monitoring lead performance, detection of complications and lead failures, and establishing benchmarks for lead performance.

Received for publication January 3, 2018. Accepted February 12, 2018.

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See page 811 for disclosure information.

Methods

This was a multicenter, prospective, observational cohort study performed at 5 centers in Canada (See Supplemental Methods for list of centers). The study was approved by each institution's research ethics board. Patient consent was

https://doi.org/10.1016/j.cjca.2018.02.009

chamber: 54.5%, dual chamber: 20.5%, cardiac resynchronization therapy [CRT] 25.0%); the remainder of the procedures was a system revision for either upgrade (8.1%) or lead revision (9.8%). The lead revision rate at 1 year was 3.4%, with the primary reason being lead dislodgements. Mortality rate was 3.8% at 1 year. The rate of any device-related complication was 2.0% at 30 days, with the highest rate in CRT implants (4.9%, $P = 0.0105$). At 1 year, the complication rate was 4.5%, with no significant difference among device types.

Conclusions: This study demonstrates that device surveillance is feasible and highlights (1) the need for CIED surveillance to track device-related complications, (2) the scope of this should be larger, and (3) mandatory participation should be considered. This system could predict CIEDs that may be susceptible to higher than usual rates of failure, mitigating adverse outcomes in patients.

effectuée en prévention primaire dans 65,5 % des cas. Au total, 497 (82,1 %) dispositifs ont été implantés *de novo* (simple chambre : 54,5 %, double chambre : 20,5 %; thérapie de resynchronisation cardiaque : 25,0 %); dans les cas restants, des interventions de révision du système ont été pratiquées aux fins de mise à niveau des dispositifs (8,1 %) ou de révision des sondes (9,8 %). Le taux de révision des sondes a été de 3,4 % à 1 an; le déplacement des sondes ayant constitué le principal motif de révision. Le taux de mortalité a atteint 3,8 % à 1 an. Le taux de complication lié au dispositif a été de 2,0 % à 30 jours, toutes complications confondues; le taux le plus élevé a été associé aux implantations effectuées pour les besoins d'une thérapie de resynchronisation cardiaque (4,9 %, $p = 0,0105$). Le taux de complication a été de 4,5 % à 1 an, sans différence significative d'un type de dispositif à un autre.

Conclusions : Cette étude démontre la faisabilité de la surveillance des dispositifs de stimulation cardiaque implantables et met en lumière les points suivants : 1) la surveillance des dispositifs de stimulation cardiaque implantables est nécessaire pour assurer le suivi des complications qu'ils peuvent occasionner; 2) la surveillance des dispositifs de stimulation cardiaque implantables doit être élargie; 3) la participation obligatoire au processus doit être considérée. Le système envisagé pourrait permettre de connaître à l'avance les dispositifs de stimulation cardiaque implantables susceptibles de présenter un taux anormalement élevé de défaillance et ainsi limiter les résultats défavorables chez les patients.

obtained (if required) by the institution's ethics board. The study was conducted between June 2014, and July 2016. Patients who underwent new HV lead implants at the participating sites were included, regardless of lead or generator manufacturer. Subcutaneous leads were not included. Patients were followed for 1 year from the time of implant. Each center complied with the current guidelines for CIED follow-up.[4] For further details on methodology, please see Supplemental Methods.

Results

There were 611 HV leads implanted in 611 patients included in the study during the enrollment phase; 7 leads were implanted at a pediatric ICD implant center. Follow-up at 12 months was completed for 99.0% of the leads. The distribution of enrollment by center is shown in Supplemental Figure S1. The baseline characteristics of the enrolled patient population are shown in Supplemental Table S1. The mean age was 62.4 ± 12.8 years, and 144 (23.6%) were women. The indication for ICD was for primary prevention in 399 (65.5%) patients. The mean left ventricular ejection fraction (LVEF) was 34.0 ± 14.5%. Ischemic heart disease was the underlying etiology in 446 (73.0%) of patients. The HV lead manufacturers included Medtronic (n = 319), Abbott (previously St Jude, n = 112); Boston Scientific (n = 86); and other (Livanova and Biotronik, n = 94).

Procedural Characteristics

The characteristics of the lead and index procedure are presented in Supplemental Table S2. The majority of leads (n = 582, 95.3%) were implanted by cardiac electrophysiologists. Venous access was noncephalic in the majority (n = 435, 71.3%); active fixation (n = 610, 99.8%), single coil (n = 603, 98.7%) HV leads were predominantly used. De novo implants accounted for 82.1% of the procedures, with single-chamber devices being the most common (54.5%); cardiac resynchronization therapy (CRT) devices were implanted in 25.0% of the de novo procedures. System revisions included upgrade from pacemaker to ICD or to cardiac resynchronization therapy defibrillator (CRT-D) in 49 patients (8.1%), and lead revision alone occurred in the remainder (n = 59, 9.8%).

Complications

At 1 year, 3.8% of patients had died; 1 patient suffered cardiac tamponade periprocedurally due to lead perforation and requested system removal 3 months after implantation. There were 28 complications at 1 year in 27 patients in the cohort (4.5%). The most common complication was lead dislodgement requiring revision, occurring in 16 (2.6%) patients. Of the pediatric leads included in the study, there was 1 (6.7%) lead dislodgement. There was no significant difference in complications between patients who underwent a system revision vs a de novo implant in this cohort (Table 1). When examined by device type at 30 days, the number of complications was highest in patients undergoing CRT implants owing to a higher rate of lead dislodgements and pocket hematomas before 30 days (4.9% vs 1% in single chamber, 0.8% in dual chamber, $P = 0.0105$) (Table 1). At 1 year, complications that occurred beyond 30 days by device type were similar, owing primarily to lead dislodgement in single- and dual-chamber devices. The cumulative incidence for lead revision is shown in Figure 1. Electrical abnormalities occurred in two leads: 9 months post-implant, the HV lead was found to have an elevated threshold and was explanted and replaced; the second lead had T-wave oversensing seen at the same admission as