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Use of Administrative Data to Monitor Cardiac Implantable Electronic Device Complications

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ABSTRACT

Cardiac implantable electronic devices (CIEDs) are increasingly used in the Canadian population, because of expanding indications and an aging population. Device-related complications are a source of morbidity and mortality. There is currently no comprehensive monitoring strategy of CIED-related complications in Canada. The objective of this study was to determine the utility of administrative data in tracking CIED complications. This was a retrospective observational study in patients with newly implanted pacemakers, pacemaker system revisions, and implantable cardioverter defibrillators (ICDs) from 2011 to 2014. The study was performed at a single academic centre in Nova Scotia. A comprehensive chart review was used as the gold standard for device-related complications. This was compared with the reporting of complications identified in the Canadian Institute for

RÉSUMÉ

Les dispositifs électroniques cardiaques implantables (DECI) sont de plus en plus répandus dans la population canadienne en raison de l'élargissement de leurs indications et du vieillissement de la population. Les complications liées à ces dispositifs sont une cause de morbidité et de mortalité. Il n'existe à l'heure actuelle aucune stratégie de surveillance globale des complications liées aux DECI au Canada. L'objectif de la présente étude était de déterminer l'utilité des données administratives pour le suivi des complications liées aux DECI. Cette étude observationnelle rétrospective portait sur des patients chez lesquels avait été récemment implanté un stimulateur cardiaque ou un défibrillateur automatique implantable (DAI) ou dont le stimulateur cardiaque avait fait l'objet d'une révision entre 2011 et 2014. L'étude a été réalisée en Nouvelle-Écosse, dans un seul centre universitaire.

Cardiovascular implantable electronic devices (CIEDs) have evolved significantly, permitting an increase in their use.[1] With our aging population and the advancement of therapies for heart failure and myocardial infarction, larger numbers of patients are eligible to receive an implantable cardioverter defibrillator (ICD) for primary prevention.[2] This will pose an increased burden on the Canadian health care system, where resources are constrained.

We proposed a study to examine the feasibility of linkage using a clinical database with the Canadian of Institute Health Information (CIHI) databases to document CIED complications.

Methods

This study was a retrospective observational cohort study performed at the QEII Health Sciences Centre. Ethics approval was obtained. The study was performed in 2 phases. The first phase confirmed the International Classification of Diseases, 10th Revision (ICD-10) codes that were identified *a priori* to represent ICD and pacemaker implantation, and their complications. This phase used data from patients consented at the QEII Health Sciences Centre for use of their data for database research. This allowed patients to be identified after linkage with health records to ensure that the correct ICD-10 codes were assigned to the device and the complication. The sensitivity and specificity of the ICD-10 codes for device-related complications were derived. The second phase examined all CIEDs that were implanted (consented and nonconsented) at the QEII Health Sciences Centre, with patient information deidentified when linkage with health records was performed. Further data on accuracy of the ICD-10 codes was obtained with this population.

Patient population

In phase 1, all patients who had provided consent to participate in database research at the QEII Health Sciences Centre and underwent *de novo* ICD implantation (from January 1, 2011 to December 31, 2014), *de novo* pacemaker implantation (from January 1, 2012 to December 31, 2014),

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Health Information Discharge Abstract Database and the National Ambulatory Care Reporting System Database (NACRS). Sensitivity and specificity of Canadian Institute for Health Information/NACRS was reported. There were 1327 patients included in the study (742 pacemakers, 585 ICDs). The rate of complications in the pacemaker population was 8.0%; the sensitivity of Discharge Abstract Database/NACRS for detection of these was 83.1%, and specificity 100%. The rate of complications in the ICD population was 12.0%, with a sensitivity of 92.1%, and specificity 100%. Thirty-day mortality was 1.8% in the pacemaker population, and 0.3% in the ICD population. This study provides feasibility for use of administrative data for detection of device-related complications, showing reasonable sensitivity and excellent specificity. Further work to determine generalizability of these data across Canada is required to ensure accurate monitoring of device-related complications.

L'analyse détaillée des dossiers a été choisie comme méthode de référence pour évaluer les complications liées aux dispositifs. Cette méthode a été comparée avec la déclaration des complications recensées dans la Base de données sur les congés des patients (BDCP) et du Système national d'information sur les soins ambulatoires (SNISA) de l'Institut canadien d'information sur la santé (ICIS). La sensibilité et la spécificité de la BDCP et du SNISA de l'ICIS ont été rapportées. L'étude portait sur 1327 patients (742 portant un stimulateur et 585 un DAI). Chez les patients porteurs d'un stimulateur, le taux de complications était de 8,0 %; la sensibilité et la spécificité de la détection de telles complications de la BDCP et du SNISA étaient de 83,1 % et de 100 % respectivement. Chez les patients porteurs d'un DAI, le taux de complications était de 12,0 %, la sensibilité de 92,1 % et la spécificité de 100 %. Le taux de mortalité à 30 jours s'élevait à 1,8 % dans la population portant un stimulateur et à 0,3 % chez les porteurs d'un DAI. Cette étude démontre la faisabilité de l'utilisation des données administratives pour déceler les complications liées aux dispositifs implantables avec une sensibilité acceptable et une spécificité supérieure. Des études plus poussées sont nécessaires pour déterminer si ces données peuvent être généralisées à l'ensemble du Canada, afin de permettre une surveillance précise des complications liées aux dispositifs implantables.

or a system revision (from January 1, 2012 to December 31, 2014) were included. For phase 2, all patients at the QEII Health Sciences Centre who underwent *de novo* ICD implantation (from January 1, 2011 to December 31, 2014), *de novo* pacemaker implantation (from January 1, 2012 to December 31, 2014), or had undergone a system revision (from January 1, 2012 to December 31, 2014) were included.

Data abstraction and follow-up

Data were obtained through examination of the electronic medical record documenting follow-up of patients with these devices through 2 sources: the electronic medical record and Paceart (electronic database to capture device follow-up). Information on the type of device implanted was obtained from Paceart. Outcomes including complications and device-related hospitalizations were obtained from these 2 sources. Definitions for device-related complications are included in Table 1.

For the time periods indicated in phase 1, administrative data were queried for the patients who underwent *de novo* implantations. Hospitalizations and emergency department visits using the CIHI Discharge Abstract Database (DAD) and the National Ambulatory Care Reporting System Database (NACRS) were identified for these patients. These databases contain detailed diagnostic and procedural information for all hospital admissions and emergency department visits in the province and have been extensively validated.[3] Hospital visits for device complications were identified using the ICD-10 codes. The codes that were used for identifying *de novo* devices are as follows: single-chamber pacemaker, 1.HZ.53.GR-NM ++; dual-chamber pacemaker, 1.HZ.53.GR-NK ++; other pacemaker, 1.HZ.53.GR-NL ++; ICD, 1.HZ.53.GR-FS ++, 1.HZ.53.HA-FS ++, and 1.HZ.53.SY-FS ++; and cardiac resynchronization therapy pacemaker, 1.HZ.53.GR-FR ++ or 1.HZ.53.SY-FR ++. Codes for device complications were identified as follows: 1.YY.54.x, 1.YY.54.LA-NJ, 1.HZ.55.x, 1.HD.53.x, 1.HD.53.GR-JA, 1.HD.54.x, 1.HD.54.GR-JA, 1.HD.55.x, 1.HD.55.GP-JB, and 1.HD.55.GR-JA.

Statistical analysis

Categorical variables were summarized by means of frequency distributions and descriptive statistics by mean, SD, minimum, median, and maximum. Sensitivity and specificity of the ICD-10 codes were calculated, with the data obtained from the retrospective chart review operating as the gold standard.

Table 1. Device-related complications

Complication	Definition
Pneumothorax	An abnormal collection of air or gas in the pleural space that separates the lung from the chest wall
Lead dislodgement	Change in lead position resulting in lead repositioning
Lead perforation with cardiac tamponade	Lead perforation with collection of blood in pericardium
Infection requiring device removal	Infection requiring device removal
Death within 30 days of device implantation	Death within 30 days of device implantation
Admission to intensive care unit after device insertion	Admission to intensive care unit after device insertion
Pocket hematoma	Collection of blood in device pocket within 30 days of implantation
Pocket hematoma requiring intervention	Pocket hematoma requiring surgical intervention
Other complication leading to reoperation	For example, set screw, abnormal impedance

Table 2. Complications and sensitivity of detection using CIHI coding

Type of complication	n (%)	Sensitivity, %
Pacemaker (n = 742)		
Pneumothorax	12 (1.3)	83.3
Pocket hematoma requiring intervention	5 (0.5)	80.0
Myocardial perforation	6 (0.6)	83.3
Lead dislodgement	46 (5.1)	80.0
Device infection requiring removal	2 (0.3)	100
Total	71 (8.0)	83.1
ICD (n = 585)		
Pneumothorax	9 (1.5)	88.9
Pocket hematoma requiring intervention	4 (0.7)	75
Myocardial perforation	2 (0.4)	100
Lead dislodgement	55 (9.4)	92.7
Device infection requiring removal	5 (0.9)	100
Diaphragmatic pacing	1 (0.2)	100
Total	76 (13.0)	92.1

CIHI, Canadian of Institute Health Information; ICD, implantable cardioverter defibrillator.

Results

There were 1327 patients included for analysis, with 742 patients with pacemakers and 585 patients with ICDs.

Pacemaker population

In the pacemaker population, there were 407 men (54.9%) and 335 women (45.1%). The mean age was 75 ± 11 years. Most pacemaker procedures were performed as inpatient (n = 575; 77.5%). There were 513 (69.1%) dual-chamber and 219 single-chamber pacemaker procedures performed. There were 71 (8.0%) complications in 67 patients (Table 2). The sensitivity of CIHI coding was 83.1% overall, with 100% specificity (Table 2). Device infection requiring removal was found to have 100% sensitivity and specificity. Thirty-day mortality in the population was 1.8%.

ICD population

In the ICD population (n = 585), there were 466 men (79.7%) and 119 women (20.3%). The mean age was 63 ± 13 years. The procedures were performed as inpatient in 55.4% (n = 324). There were 323 (55.2%) single-chamber, 114 (19.5%) dual-chamber, and 148 (25.3%) cardiac resynchronization therapy with defibrillators performed. There were 76 (13.0%) complications in 74 patients (Table 2). The sensitivity of CIHI coding was 92.1% overall, with 100% specificity (Table 2). Device infection requiring removal was found to have 100% sensitivity and specificity. Thirty-day mortality in the population was 0.3%.

Discussion

In this study, we compared the use of a comprehensive chart review with data obtained from the DAD and NACRS to show the feasibility and accuracy of using administrative data to monitor and track device-related complications. The overall sensitivity for detection of pacemaker complications was 83.1%, whereas in the ICD population it was 92.1%. Specificity for both groups was 100%. Importantly, sensitivity and specificity for device-related infection was 100%.

A focused surveillance system is critical to CIED follow-up because of some properties that are unique, and disparate from other medical devices. First, CIEDs often provide therapies that are life-saving.[4] Malfunction or complication of a CIED can result in significant morbidity and/or mortality. Infection is a major concern, because they are contained within the vasculature and can result in seeding within the heart, thereby causing bacterial endocarditis. Treatment of device-related infection is usually done with complete system removal, using either laser or other tools, and can be associated with a 1% mortality risk.[5] Appropriate and timely detection can mitigate such adverse outcomes. Complications from initial implantation of CIEDs can range from 2.5% to 13% and are higher with more complex devices, such as cardiac resynchronization therapy.

In this study, the sensitivity and specificity of detecting periprocedural complications was excellent, particularly for device infection requiring removal. The remaining complications including lead dislodgment, perforation, pocket hematoma, and pneumothorax had a sensitivity ranging from 80% to 92%. These complications were either missed (n = 9), or the complication was noted but did not meet coding standards (n = 8) as set by CIHI. Because of these findings, it is important to review the coding standards set by CIHI as they pertain to these complications, to ensure agreement among implanting physicians and CIHI. If this process were to be adopted by provincial ministries as a method to perform quality assurance and postmarket surveillance for CIEDs, then establishing these standards are of utmost priority.

The Canadian Cardiovascular Society has developed a Canadian Cardiovascular Society Quality Project to establish cardiovascular care quality indicators in the areas of heart failure, cardiac rehabilitation and secondary prevention, cardiac surgery, atrial fibrillation, percutaneous coronary intervention, and transcatheter aortic valve implantation (https://www.ccs.ca/en/ccs-data-definitions-quality-indicators). There are currently no established quality indicators for CIEDs. This study provides feasibility for the use of administrative data to monitor CIED quality indicators, with current definitions in the DAD and NACRS. Further refinement of coding might improve the sensitivity of these databases.

There are some limitations to this study. It was performed in a single centre and whether the sensitivity and specificity of this approach would remain stable across jurisdictions is unknown. Minor complications data such as wound infection, pain after device implantation, or venous thrombosis were not collected as part of this study. These remain important for patients' quality of life and should be part of any comprehensive monitoring or tracking of device-related complications. This study did show reasonable sensitivity and excellent specificity to monitor complications using the DAD and NACRS. These data are collected across Canada and could be used to improve and monitor implant-related complications, in particular device-related infection, which is associated with worse outcomes and increased mortality.

Conclusion

Device-related complications are known to increase morbidity and in some cases mortality. Ongoing monitoring of these is important to ensure optimal use and performance

of these devices for the cardiac device patient population. Reduction of these complications would likely be associated with reduced costs that would be substantial, particularly in the face of increasing use of ICDs and pacemakers. National strategies to reduce device-related complications are required to ensure safe and efficacious use of CIEDs. The effective use of administrative databases might provide a viable alternative to more costly registries or chart reviews to obtain this information. Future research needs to address the generalization of our findings in Canada, and worldwide.

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