Risk factors for lead complications in cardiac pacing: A population-based cohort study of 28,860 Danish patients

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BACKGROUND Lead complications are the main reason for reoperation after implantation of pacemakers (PM) or cardiac resynchronization therapy (CRT-P) devices.

OBJECTIVE This study sought to describe the incidence of lead complications causing reoperation after device implantation and to identify risk factors for lead complications.

METHODS A nationwide, population-based, historic cohort study was performed based on data from the Danish Pacemaker Register, which includes all Danish patients who received their first PM or CRT-P device from 1997 to 2008. Follow-up occurred 3 months after implantation.

RESULTS The study population consisted of 28,860 patients. The incidence of any lead complication was 3.6%, encompassing right atrial (RA; 2.3%), right ventricular (2.2%), and left ventricular (4.3%) lead complications. The lead complication risk declined during the first part of the study period and remained stable after 2002. Multivariate analysis identified the following significant risk factors: chronic heart failure as indication (adjusted odds ratio (aOR) 3.0; 95% confidence interval [CI] 2.1 to 4.3), implantation in a nonuniversity center (aOR 1.4; 95% CI 1.2 to 1.6), inexperienced operator with <25 implantations (aOR 1.6; 95% CI 1.3 to 2.0), single-lead RA device (aOR 1.4; 95% CI 1.1 to 1.8), dual-chamber pacing device (aOR 1.6; 95% CI 1.4 to 1.9), CRT-P device (aOR 3.3; 95% CI 2.4 to 4.4) and passive-fixation RA lead (aOR 2.2; 95% CI 1.7 to 2.9).

CONCLUSION Lead complications causing reoperation remain a clinically important problem in device therapy. Mainly procedure-related factors were identified as independent risk factors for lead complications.

KEYWORDS Lead complications; Cardiac pacemaker; Cardiac resynchronization therapy; Risk factors; Adverse events

ABBREVIATIONS **aOR** = adjusted odds ratio; **CHF** = chronic heart failure; **CI** = confidence interval; **CRS** = Danish Civil Registration System; **CRT-P** = cardiac resynchronization therapy-pacemaker; **DPR** = Danish Pacemaker Register; **LV** = left ventricular; **NHDR** = National Hospital Discharge Register; **PM** = pacemaker; **RA** = right atrial; **RV** = right ventricular

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Introduction

Permanent pacemaker (PM) treatment indications have expanded over the past decades. In addition, cardiac resynchronization therapy (CRT-P) has emerged as a new cardiac-implantable device treatment. Lead complication is a serious problem in device therapy, causing excess morbidity and increasing cost.[1] Reports on the frequency of lead complications show great variation, which may partially be explained by methodological variability, study population disparity due to strict selection criteria, and low statistical power resulting from small sample sizes.[1–4] Despite growing device implantation rates, little is known regarding the risk of lead complications and associated risk factors in the unselected, population-based, real-life setting. Insufficient knowledge of the complication risk and risk factors limits the evaluation of the quality of device treatment and restricts the ability to proactively reduce complications.

This study aims (1) to describe the incidence of short-term lead complications resulting in reoperation after device implantation in a large, nationwide, population-based cohort including all primary PM and CRT-P implantations during a 12-year study period, and (2) to identify patient- and procedure-related risk factors for lead complications.

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Methods

Study design

A nationwide, population-based, historic cohort study was performed based on prospectively gathered data from the Danish Pacemaker Register (DPR). We identified all Danish patients who underwent primary PM or CRT-P implantation from January 1997 to December 2008 (n = 29,846).

The DPR

In Denmark, device implantations are done in only 13 centers, and all procedures are performed by cardiologists, except a small fraction of mainly pediatric device implantations performed by thoracic surgeons. Since 1982, all Danish PM and CRT-P implantations and replacement procedures have been recorded in the DPR. All centers have been dedicated participants of the DPR for a period of nearly 30 years. Regular meetings among the centers and the DPR ensure a constant focus on the reporting of complete and accurate data to the DPR. The implanting cardiologist records details regarding the implantation procedure, technical specifications, and patient-related factors. Since 1997, details regarding in-hospital complications after primary PM or CRT-P implantations have been prospectively reported to the DPR. In addition, complications occurring within the period from hospital discharge to the first planned outpatient visit after 3 months have been reported. For all patients, a complication status should be reported to the DPR at this first outpatient visit. In case no report on complication status was received in the DPR, a reminder was sent. This practice resulted in a yearly response rate of 98% for PM patients and 90% for CRT-P patients.

The National Hospital Discharge Register (NHDR)

Since 1977, the NHDR has recorded nationwide data on all hospital admissions, including information such as diagnoses and treatment dates. Since 1995, it also has included all outpatient visits. Diagnoses and procedures are coded by the treating physician according to the International Classification of Disease (8th revision until 1993 and 10th revision thereafter). Recording in the NHDR is a requirement for financial reimbursement.

The Danish Civil Registration System (CRS)

The CRS is the national register of all Danish citizens, and contains information on the date of death. The Civil Registration Number, an unique personal identification number assigned to each Danish citizen, was used to link data from the DPR, the NHDR, and the CRS.

Complications

Any treating cardiologist who diagnosed a complication reported this to the DPR categorized into the following categories: (1) lead complications requiring reoperation (dislodgements, insulation defects, lead fractures, sensing or threshold problems) or (2) nonlead complications (infection, myocardial perforation, pneumothorax requiring a chest tube, lead connection malfunction [e.g., incorrect placement of the lead in the generator], hematoma requiring a reoperation, procedure-related deaths, failed attempt to place a left ventricular [LV] lead and other [e.g., PM syndrome]). The outcome in this study was any lead complication requiring reoperation after PM or CRT-P implantation.

Risk factors

Variables thought to be associated with lead complications after device implantation were selected a priori and included: gender; age; indication for device implantation (atrioventricular block, sinus node dysfunction, atrial fibrillation with bradycardia, chronic heart failure [CHF] or other); device type (single-lead atrial, single-lead ventricular, dual-chamber or CRT-P device); center type (university centers, which also implanted cardioverter-defibrillator devices, or nonuniversity centers); operator experience (total number of procedures: 0 to 24, 25 to 49, 50 to 99 or >100); procedure type (elective or urgent); venous access (cephalic vein, subclavian vein, both cephalic and subclavian veins, or other); lead fixation method (passive or active); and procedure duration. In the NHDR, we identified patients with a prior history of CHF and used the Charlson Comorbidity Index to establish a measure for known comorbidity prior to device implantation. This index has been validated based on hospital discharge diagnoses.[5] A Charlson Comorbidity Index score was computed and further divided into 3 comorbidity groups: 0 (low), corresponding to no registered comorbidity; 1 to 2 (medium); and 3 or above (high). The date of death was identified in the CRS.

Statistical analysis

Differences among groups were evaluated with the Student *t* test or the χ^2 test. The Spearman test for trends was used to test differences in ordered categorical variables. Odds ratios were used to estimate the association between risk factors and lead complications after device implantation. Multiple logistic regression analysis was used to adjust for possible a priori–selected confounders and adjusted odds ratios reported (aOR). We adjusted for age group, gender, center type, date of procedure, and device type. We chose not to adjust for procedure duration because we judged it to be an intermediate factor rather than a confounder. Odds ratios were presented with 95% confidence intervals (CI). A *P* value (2-sided) below .05 was considered statistically significant. STATA software (STATA IC for Windows, version 11.0, StataCorp LP, College Station, Texas, USA, 2009) was used for all statistical analyses. The Danish Data Protection Board approved the study. No informed consent was required by Danish law to conduct this register-based cohort study.

Results

Study population

All patients undergoing primary PM (n = 28,820) or CRT-P (n = 1,026) implantations during the years 1997 to 2008 were eligible as study candidates. We excluded patients without any complication status (n = 787), those with 2