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Risk Factors Influencing Complications of Cardiac Implantable Electronic Device Implantation: Infection, Pneumothorax and Heart Perforation

A Nationwide Population-Based Cohort Study

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Abstract: As the number of cardiac implantable electronic devices (CIEDs) is increasing annually, CIED-related complications are becoming increasingly important. The aim of the study was to assess the risks associated with CIEDs by a nationwide database.

Patients were selected from the Taiwan National Health Insurance Database. Admissions for CIED implantation, replacement, and revision were evaluated and the evaluation period was 14 years. Endpoints included CIED-related infection, pneumothorax, and heart perforation.

The study included 40,608 patients with a mean age of 71.8 ± 13.3 years. Regarding infection, the incidence rate was 2.45 per 1000 CIED-years. Male gender, younger age, device replacement, and previous infection were risks for infection while old age and high-volume centers (>200 per year) were protectors. The incidence of pneumothorax was 0.6%, with an increased risk in individuals who had chronic obstructive lung disease (COPD) and cardiac resynchronized therapy (CRT). The incidence of heart perforation was 0.09%, with an increased risk in individuals who had pre-operation temporal pacing and steroid use.

High-volume center was found to decrease infection rate while male gender, young people, and individuals who underwent replacements were associated with an increased risk of infection. Additionally, pre-operation temporal pacing and steroid use should be avoided if possible. Furthermore, COPD patients or those who accept CRTs should be monitored closely.

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Abbreviations: CIED = cardiac implantable electronic device, CRT = cardiac resynchronized therapy, CRT-P = cardiac resynchronized therapy-pacing, CRT-D = cardiac resynchronized therapy-defibrillator, COPD = chronic obstructive lung disease, CKD = chronic kidney disease, DM = diabetes mellitus, ESRD = end-stage renal disease, ICD = implantable cardioverter-defibrillator, PM = Pacemaker.

INTRODUCTION

Cardiovascular implantable electronic devices (CIEDs), which include pacemakers (PM), implantable cardioverter-defibrillators (ICD), and cardiac resynchronized therapy (CRT), are standard therapy for bradyarrhythmias, tachyarrhythmias, and systolic heart failure with left bundle branch block.[1–3] Though the numbers of these devices have increased annually over the last decade,[4,5] as the population with implanted devices continues to grow, CIED-related complications such as infection, pneumothorax and cardiac perforation have increased as well.[6,7] Such complications not only result in prolonged hospitalization and increased costs, but also worse outcomes and mortality.[8] For this reason, many studies have attempted to investigate the factors causing CIED-related complications by evaluating baseline characteristics, procedure types, and medications.

Among the device-related complications, infection has attracted most of our attention. Some studies have reported some factors contributing to infection, such as diabetes mellitus (DM), end-stage renal disease (ESRD), corticosteroid use, early re-intervention, temporary pacing, as well as physician experience in CIED implantation and revision/replacement procedures.[9–15] However, the conclusions have been inconsistent. Baddour et al[16] pointed out that these studies had various limitations such as relatively small numbers of CIED infection patients, and individual single-center.

In addition to CIED-related infection, evaluating the risks of other complications such as pneumothorax and heart perforation is also important. Pneumothorax after implantation has supposedly shown a correlation with subclavian vein puncture, old age, female gender, and operator experience,[17] causing increased patient morbidity and substantial cost.[18] Another associated complication is heart perforation, though relatively rare with an incidence reported from between 0.09%[19] to 1.2% in the medical literature.[20] Some studies have pointed out certain risk factors for heart perforation such as temporary pacemakers, steroid use within 7 days prior to implantation, and helical screws.[20] However, compared to studies of device-related CIED

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infections, there has been little research assessing the risk of pneumothorax and heart perforation in CIED patients.

In order to fill this lacuna in the literature and evaluate CIED-related complications in Asian populations, a nationwide database was analyzed to identify possible risk factors and incidences of CIED-related complications.

MATERIALS AND METHODS

Data Source and Design of outcomes

This retrospective national population-based cohort study was retrieved from the National Health Insurance Research Database (NHIRD) released by the Taiwan National Health Research Institute. The NHIRD enrols 99.91% of the Taiwanese population (about 23.20 million in 2012) and consists of all enrollees health care data. Previous studies have described it in detail[21] and validated the accuracy of the NHIRD diagnostic data.[22] The insurance reimburses all the CIED implantation, replacement, revision, and removal expenses with appropriate indication according to the clinical practice guidelines of CIEDs from 1996 to the present. All CIED procedures were enrolled including new implantation, replacement due to any cause, revisions or removal procedures, but procedures that could not be clearly defined were excluded. The CIEDs include pacemakers, ICD, and CRT. The study period was between January 1, 1997 and December 31, 2010. We inspected all admissions after CIED procedures to evaluate any CIED-related complications. The end points included device-related infection, pneumothorax, and heart perforation. The cohort was followed up until either death or December 31, 2010. The ethical approval is not necessary (approved by The Institutional Review Board of Chang Gung Memorial Hospital) because the data from NHIRD was consists of deidentified secondary data and used for research purposes only.

Definitions

The cohort was divided into 3 main groups based on the outcomes: CIED infection, CIED pneumothorax, and CIED heart perforation. The CIED infection was defined as an infection that occurred during admission for CIED-related procedures, which included implantation, replacement, revision, and removal. CIED pneumothorax was defined as a pneumothorax that occurred during admission for any CIED-related procedure. CIED heart perforation was defined as a heart perforation treated with heart repair surgery during admission for any CIED-related procedure.

Risk Factor Assessment

The analyzed risk factor parameters were separated into 4 components, including patient, device, medication, and provider factors. Patient factors included gender, age, and comorbidities, which was identified based on International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) (as listed in Table 1). Device factors referred to CIED and procedure types. Medication factors referred to the usage of antibiotics, steroid, antiplatelets, and warfarin. Finally, the hospital procedure volume and hospital level were defined as provider factors. The hospital procedure volume was a time-dependent variable and was indicative of the annual hospital CIED procedure numbers.

Statistics

Our study noted the possibility that 1 subject might suffer 1 or more infections related to CIED procedures and replacements during the study period. Hence, independent replacement risk factors due to CIED infection were identified using multiple-event per subject Cox proportional hazard analyses. This model allowed for evaluation of time-dependent prognostic factors and multiple events. The associated complications (pneumothorax and heart repair) were identified by multivariate logistic regression analyses. The results were presented as an odds ratio (OR) for logistic regression or hazard ratio (HR) for Cox regression with corresponding 95% confidence intervals (CIs). All data analyses were conducted using SPSS software version 15.0 (SPSS Inc., Chicago, IL).

TABLE 1. Patient Characteristics at First Onset (n = 40,608)

Variable	Number	Percentage
Gender		
Male	20,847	51.3%
Female	19,761	48.7%
Age, year (mean: 71.8, SD = 13.3)		
<20 years	414	1.0%
20–49 years	1923	4.7%
50–59 years	3104	7.6%
60–69 years	7754	19.1%
70–79 years	16,051	39.5%
>80 years	11,363	28.0%
Device type		
Single chamber PPM	26,443	65.1%
Double chamber PPM	12,059	29.7%
ICD	1473	3.6%
CRTP	614	1.5%
CRTD	19	0.05%
Indication		
AV block	13,802	34.0%
Congenital AV block	96	0.2%
AF	7716	19.0%
Sick sinus syndrome	18,807	46.3%
Paroxysmal ventricular tachycardia	1520	3.7%
Ventricular fibrillation	416	1.0%
Ventricular flutter	53	0.1%
Other left bundle branch block	361	0.9%
Comorbidities		
Diabetes	11,244	27.7%
Liver cirrhosis	1013	2.5%
Obstructive lung disease	3467	8.5%
Malignant neoplasm	3193	7.9%
ESRD	3617	8.9%
Heart failure	5924	14.6%
Antibiotics		
Cephalosporin	37,723	92.9%
Aminoglycoside	19,335	47.6%
Other antibiotics	11,359	28.0%
Medication		
Antiplatelet	17,190	42.3%
Warfarin	3160	7.8%
Steroid	4811	11.8%

AF = atrial fibrillation, CRTD = cardiac resynchronized therapy-defibrillator, CRTP = cardiac resynchronized therapy-pacing, ICD = implantable cardioverter defibrillator, PPM = permanent pacemaker.

RESULTS

From January 1, 1997 to December 31, 2010, this study included 46,506 CIED procedures, which comprised of 40,608

patients during the study period (Supplementary, http://links.lww.com/MD/A84). There were 35,308 patients accepted for the first CIED implantation during the study period; 10,731 replacement procedures were carried out in 4840 patients. Reoperations consisting of lead replacements without generator replacement were performed in 467 procedures (out of 461 patients). In those patients with mechanical complications during the same CIED procedure admission, there were 279 episodes of pneumothorax and 43 episodes of heart perforation requiring surgical correction. The total follow-up was 170,299 device-years; mean follow-up for each subject was 4.19 person-years. A total of 417 CIED-related procedures due to infection were found during the study period: 290 after first CIED implantation (incidence 2.19/1000 CIED-years), 120 after replacement (incidence 3.39/1000 CIED-years), and 7 after revision/replacement (incidence 3.08/1000 PPM-years). The infection incidence rate was 2.45/1000 CIED-years and the most events happened in the first 6 months. The time to the CIED infection was illustrated by Kaplan–Meier plots in Figure 1.

The baseline characteristics of patients are shown in Table 1. The mean age of CIED patients was 71.8 ± 13.3 years old (y/o) and the age distribution skewed toward elderly participants (>70 y/o; 67.5%). Male gender was predominant (51.3%). Patients who underwent pacemaker implantations were in the majority (94.8%), and the major criteria for CIED were sick sinus syndrome (46.3%) and atrioventricular (AV) block (34%). In addition, prophylactic antibiotics were prescribed in nearly all the types of procedures.

Risk Factors Associated With Infection

Several CIED infection risks were found (shown in Table 2). There were no significant differences in patient factors, except for gender and age: male patients had higher incidence of infection than females ($P < 0.001$; HR: 1.68, 95% CI: 1.37–2.05); Relative to middle age (20–49 y/o), young age (<20 y/o) ($P = 0.027$; HR: 1.84, 95% CI: 1.02–3.32) was a risk for infection, while old age (all staged aged period >60 y/o; all $P < 0.01$; HR: around 0.53–0.59) prevented patients from CIED-related infection. In addition, patients with a greater frequency of previous CIED infections had a higher incidence of CIED infection. Regarding device factors, replacement procedures ($P < 0.001$; HR: 1.71, 95% CI: 1.37–2.14) were an increased risk for CIED infection when compared to new implantation; dual chamber PM was a protector for CIED infection when compared to single chamber PM ($P = 0.021$; HR: 0.79, 95% CI: 0.62–1.01). Among provider and medication factors, high center volume (>200 vs ≤50; $P = 0.002$; HR: 0.54, 95% CI: 0.36–0.80) was a protector from infection; cephalosporin also trended toward preventing devices from infection ($P = 0.078$; HR: 0.74, 95% CI: 0.54–1.03).

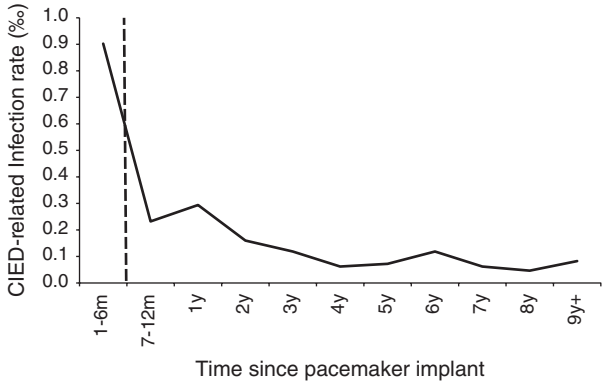

FIGURE 1. Time to cardiac implantable electronic device (CIED) infection event.

Risk Factors Associated With Complications—Pneumothorax and Heart Perforation

The CIED pneumothorax incidence was 0.60% (279/46,506) and CIED heart perforation incidence was 0.09% (43/46,506) in this study. Regarding CIED pneumothorax, chronic obstructive lung disease (COPD) ($P = 0.025$; HR: 1.52, 95% CI: 1.05–2.18) was a risk while DM ($P < 0.001$; HR: 0.56, 95% CI: 0.40–0.77) and chronic kidney disease (CKD) ($P = 0.034$; HR: 0.54, 95% CI: 0.31–0.96) might be protectors (see the left panel in Table 3). The CIED pneumothorax incidence was lower in patients accepting CIED replacement than those accepting new devices ($P = 0.012$; OR: 0.66 CI: 0.48–0.91): the incidence was also lower in patients accepting pacemakers than those accepting cardiac resynchronized therapy-pacing/cardiac resynchronized therapy-defibrillator (CRT-P/CRT-D) ($P = 0.02$; OR: 3.15 CI: 1.54–6.41). Regarding CIED heart perforation, there were only 2 risks identified under logistic regression analyses. One was the pre-operation temporal pacing system ($P = 0.013$; OR: 2.20 CI: 1.18–4.09) and the other was steroid use ($P = < 0.001$; OR: 9.85 CI: 5.07–19.14), as seen in the right panel of Table 3.

DISCUSSION

In this nationwide cohort study, some risk factors of the 3 catastrophes (CIED related infection, pneumothorax, and cardiac rupture) were found. Male gender, young age, CIED replacement, and previous CIED-related infection were contributors of CIED infection while old age and high-volume center were protectors. In individuals with pneumothorax, the incidence was higher in COPD patients than those without COPD, as well as the incidence was higher in patients who accepted CRT-P/CRT-D than those who accepted single chamber PM. A pre-operation temporal pacing and steroid use increased the risk of heart perforation.

Factors Contributing to Infection

The incidence of CIED infection has been evaluated since the early 1970s and has varied widely between 0.13% and 19.9%. Gould et al[23] reported that a study demonstrated increasing infection rates year by year. Baddour et al[16] also observed that the numbers of CIED infection-related hospitalizations increased out of proportion to rates of new device implantation. Although these conditions were not evident in our study, which showed constant infection rates per year (the incidence was around 1%) (Supplementary, http://links.lww.com/MD/A84), our findings corresponded to a large registered study from Danish.[11] In terms of risk factors of CIED infection, more comprehensive parameters, such as baseline characteristics, the type of procedures, providers and medications, were analyzed in our study when comparison with another nation cohort study (a registry study in Danish).[11]

Regarding patient factors, male gender was important and an inverse relationship between age and infection risk also was found, showing that the infection rate was highest in children and lowest in the elderly. Although several hypotheses have

TABLE 2. Associated Factors Related to CIED Infection

	Replacement Due to Infection						
Variable	**Devices**	**Device-Years**	**Event**	**HR (95% CI)**	***P*-Value**	**Adjusted HR (95% CI)**	***P*-Value**
Patient factor							
Gender							
Male	23,906	86,191	263	1.66 (1.36–2.02)	<0.001	1.68 (1.37–2.05)	<0.001
Female	22,600	84,108	154	1		1	
Age							
<20 years	639	2452	17	1.92 (1.08–3.42)	0.027	1.84 (1.02–3.32)	0.043
20–49 years	2313	9977	36	1		1	
50–59 years	3593	14,843	60	1.10 (0.73–1.66)	0.656	1.16 (0.77–1.76)	0.482
60–69 years	8708	38,114	74	0.53 (0.36–0.79)	0.002	0.58 (0.38–0.86)	0.008
70–79 years	18,060	69,523	145	0.56 (0.39–0.81)	0.002	0.59 (0.41–0.87)	0.007
>80 years	13,193	35,390	85	0.59 (0.40–0.87)	0.008	0.60 (0.40–0.90)	0.013
Diabetes							
No	33,762	132,547	330	1		1	
Yes	12,744	37,752	87	0.86 (0.68–1.10)	0.230	0.91 (0.71–1.17)	0.467
Liver cirrhosis							
No	45,353	167,608	410	1		1	
Yes	1153	2691	7	0.93 (0.44–1.97)	0.853	0.84 (0.39–1.78)	0.644
Obstructive lung disease							
No	42,464	159,300	388	1		1	
Yes	4042	10,999	29	1.01 (0.69–1.47)	0.972	0.93 (0.63–1.37)	0.698
CKD							
No	42,462	162,338	397	1		1	
Yes	4044	7961	20	0.85 (0.54–1.33)	0.467	0.72 (0.45–1.15)	0.171
Heart failure							
No	39,682	153,368	363	1		1	
Yes	6824	16,931	54	1.21 (0.91–1.62)	0.190	1.19 (0.88–1.61)	0.257
Malignant neoplasm							
No	42,770	160,742	391	1		1	
Yes	3736	9557	26	1.01 (0.68–1.51)	0.942	1.03 (0.69–1.54)	0.897
Previous infection							
No	39,776	152,722	338	1		1	
1 time	4972	13,958	46	1.40 (1.03–1.91)	0.031	1.32 (0.96–1.81)	0.085
2 times	1159	2445	19	3.09 (1.94–4.91)	<0.001	2.86 (1.77–4.61)	<0.001
More than 3 times	599	1174	14	4.73 (2.77–8.07)	<0.001	3.79 (2.16–6.64)	<0.001
Device factors							
Type of procedure							
New implant	35,308	132,617	290	1		1	
Replacement	10,731	35,406	120	1.71 (1.37–2.14)	<0.001	1.97 (1.54–2.52)	<0.001
Revision or removal	467	2276	7	1.52 (0.72–3.21)	0.277	1.13 (0.52–2.42)	0.760
Device type							
Single chamber PPM	29,344	127,632	317	1		1	
Double chamber PPM	14,494	36,712	82	0.79 (0.62–1.01)	0.062	0.71 (0.53–0.94)	0.017
ICD	1839	4212	15	1.27 (0.75–2.13)	0.369	1.01 (0.58–1.77)	0.965
CRTP/CRTD	829	1744	3	0.61 (0.19–1.89)	0.388	0.53 (0.16–1.70)	0.283
Temporal PPM							
No	32,041	114,374	267	1		1	
Yes	14,465	55,925	150	1.16 (0.95–1.42)	0.140	1.19 (0.97–1.47)	0.095
Provider factors							
Year of procedure							
1997–2000	8233	50,189	127	1		1	
2001–2005	15,217	75,329	155	0.83 (0.65–1.05)	0.118	0.80 (0.62–1.03)	0.078
2006–2010	23,056	44,781	135	0.93 (0.72–1.19)	0.549	0.92 (0.68–1.24)	0.591
Center volume (quartile)							
≤50	12,055	43,585	128	1		1	
51–100	11,598	45,597	108	0.82 (0.64–1.06)	0.137	0.78 (0.57–1.06)	0.108
101–200	12,274	45,061	113	0.86 (0.66–1.10)	0.226	0.79 (0.56–1.10)	0.164
>200	10,579	36,056	68	0.64 (0.47–0.86)	0.003	0.54 (0.36–0.80)	0.002

TABLE 2. (*Continued*)

	Replacement Due to Infection						
Variable	**Devices**	**Device-Years**	**Event**	**HR (95% CI)**	***P*-Value**	**Adjusted HR (95% CI)**	***P*-Value**
Hospital level							
Medical center	28,942	109,023	253	1		1	
Metropolitan	16,427	58,108	151	1.10 (0.90–1.34)	0.374	0.95 (0.71–1.25)	0.702
Local community	1137	3168	13	1.64 (0.94–2.87)	0.081	1.35 (0.72–2.50)	0.346
Medication factors							
Antibiotics							
Cephalosporin							
No	3353	11,083	45	1		1	
Yes	43,153	159,216	372	0.59 (0.43–0.80)	0.001	0.74 (0.54–1.03)	0.078
Aminoglycoside							
No	24,735	81,183	213	1		1	
Yes	21,771	89,116	204	0.92 (0.75–1.11)	0.366	0.88 (0.72–1.08)	0.229
Other antibiotics							
No	33,671	129,561	291	1		1	
Yes	12,835	40,738	126	1.32 (1.07–1.63)	0.009	1.16 (0.92–1.46)	0.209
Steroid							
No	41,301	156,358	374	1		1	
Yes	5205	13,941	43	1.19 (0.86–1.63)	0.289	0.92 (0.66–1.29)	0.632
Warfarin or Anti platelet							
No use	25,396	95,696	237	1		1	
Antiplatelet only	17,525	61,987	140	0.90 (0.73–1.11)	0.309	0.96 (0.77–1.19)	0.678
Warfarin only	2347	8434	24	1.14 (0.75–1.73)	0.547	0.98 (0.64–1.52)	0.937
Both	1238	4182	16	1.51 (0.91–2.50)	0.112	1.45 (0.86–2.43)	0.161

AF = atrial fibrillation, AHR = adjusted hazard ratio, CIED = cardiac implantable electronic device, CKD = chronic kidney disease, CRTD = car-cardiac resynchronized therapy-defibrillator, CRTP = cardiac resynchronized therapy-pacing, ICD = implantable cardioverter defibrillator, PPM = permanent pacemaker.

been proposed explaining the increased pediatric infection risk, including more abdominal approaches in children and a greater frequency of replacement, no studies have decidedly verified any hypothesis. In our study, we found CIED replacement is an independent risk for infection and more epicardial leads and higher prevalence of replacement were noted in younger-aged participants than older-aged ones (Supplementary, http://links.lww.com/MD/A85, and http://links.lww.com/MD/A86). This study can thus indirectly confirm 1 hypothesis. As for provider factors, high risk of ICD infection associated with lower physician volume was reported by Al-Khatib et al[24] but high hospital volume was proven to decrease the risk of ICD implantation complications in a retrospective study.[25] Unfortunately, no previous study could establish an effect of hospital volume in other CIEDs.[11,14] In this study, we showed that hospital volume had a significant effect on overall CIED-related infection. When combining the Danish registry data[11] and ours, both hospital volume and operator experience were important factors in CIED-related infection control.

As for medication factors, a meta-analysis study[26] concluded that prophylactic antibiotics could reduce CIED-related infections and guideline for CIED infection[16] also recommends pre-procedure antibiotics. But no large study has concluded which antibiotics is the most beneficial in reducing infection rates. Therefore, this is the first large study to mention what antibiotics impact on the CIED-related infection and to find that the cephalosporins might be more efficacious than others, especially in replacement procedures (Supplementary, http://links.lww.com/MD/A87). At last, other potential risks of infection published in the literature, such as DM, heart failure,[9,27,28], corticosteroid[13] and anticoagulation,[29] did not achieve statistical significance but they nonetheless did correspond to another large prospective multicenter study.[14]

Factors Contributing to Pneumothorax

The incidence of CIED related pneumothorax was reported as 1.7% in a single center [30] and was 0.60% over a 14-year observation period in a national registry.[17] In this study, our result (0.60% (279/46,506)) was comparable to presented incidence in the literature. Regarding of risks for pneumothorax, the Danish registry showed that COPD and dual chamber device were important risks for pneumothorax and they also supposed CRT may be a risk. In our study, CRT-P/D was proven as a risk of pneumothorax. Similarly, our study also was able to confirm the hypothesis that replacement is a protector (given the absence of lead insertions). Other protective factors for pneumothorax were in this study, such as diabetes and CKD, but no evidence has emerged to show why the above variables became predictors. A possible explanation is that the previously mentioned comorbidities are notorious risks for cardiovascular disease, making cardiologists pay greater attention to patients undergoing procedures with these comorbidities.

Factors Contributing to Heart Perforation

Heart perforation has been a rare but significant complication after CIED implantation. Khan et al[31] summarized event rates ranging from 0.1% to 0.8% for pacemakers and 0.6–5.2%

TABLE 3. Associated CIED-Related Complication Factors: CIED Pneumothorax and CIED Heart Perforation

	CIED Pneumothorax		CIED Heart Perforation	
Variable	**AOR (95% CI)**	***P*-Value**	**AOR (95% CI)**	***P*-Value**
Patient factors				
Gender, male	1.07 (0.84–1.36)	0.566	0.59 (0.31–1.10)	0.097
Age				
<20 years	0.71 (0.24–2.11)	0.542	3.45 (0.70–16.89)	0.127
20–49 years	1		1	
50–59 years	0.60 (0.32–1.14)	0.118	0.59 (0.12–2.98)	0.521
60–69 years	0.53 (0.30–0.92)	0.024	0.81 (0.21–3.13)	0.758
70–79 years	0.69 (0.42–1.12)	0.135	0.41 (0.10–1.60)	0.199
>80 years	0.91 (0.55–1.49)	0.699	0.90 (0.24–3.34)	0.870
Diabetes	0.56 (0.40–0.77)	<0.001	1.23 (0.61–2.48)	0.568
Liver cirrhosis	0.96 (0.42–2.19)	0.927	0.97 (0.13–7.27)	0.977
Obstructive lung disease	1.52 (1.05–2.18)	0.025	0.34 (0.08–1.43)	0.141
Malignant neoplasm	1.00 (0.65–1.54)	0.999	0.58 (0.14–2.43)	0.453
CKD	0.54 (0.31–0.96)	0.034	0.76 (0.26–2.22)	0.611
Heart failure	0.82 (0.56–1.20)	0.309	0.73 (0.32–1.70)	0.471
Device factors				
Type of procedure				
New implant	1		1	
Replacement	0.66 (0.48–0.91)	0.012	1.75 (0.81–3.76)	0.152
Revision or removal	0.30 (0.04–2.19)	0.237	2.32 (0.52–10.36)	0.270
Device type				
Single chamber PPM	1		1	
Double chamber PPM	1.29 (0.95–1.74)	0.106	0.41 (0.16–1.06)	0.065
ICD	1.55 (0.84–2.84)	0.160	NA	NA
CRTP/CRTD	3.15 (1.54–6.41)	0.002	3.74 (0.74–18.89)	0.110
Temporal PPM	0.87 (0.67–1.15)	0.331	2.20 (1.18–4.09)	0.013
Provider factors				
Year of procedure				
1997–2000	1		1	
2001–2005	0.76 (0.53–1.10)	0.146	1.78 (0.73–4.30)	0.204
2006–2010	0.91 (0.62–1.33)	0.618	1.21 (0.45–3.23)	0.706
Center volume (quartile)				
≤50	1		1	
51–100	1.07 (0.74–1.55)	0.718	0.86 (0.34–2.15)	0.740
101–200	1.13 (0.74–1.72)	0.570	1.23 (0.48–3.17)	0.665
>200	0.94 (0.59–1.51)	0.810	0.58 (0.16–2.05)	0.397
Hospital level				
Medical center	1		1	
Metropolitan	1.14 (0.81–1.60)	0.450	1.64 (0.74–3.66)	0.227
Local community	1.34 (0.63–2.83)	0.445	1.66 (0.19–14.51)	0.645
Medication factors				
Steroid	1.38 (0.97–1.97)	0.072	9.85 (5.07–19.14)	<0.001
Warfarin or antiplatelets				
No use	1		1	
Antiplatelet only	0.97 (0.75–1.25)	0.827	1.36 (0.67–2.76)	0.394
Warfarin only	0.48 (0.22–1.02)	0.058	2.23 (0.81–6.18)	0.122
Both	0.39 (0.12–1.23)	0.107	2.05 (0.57–7.38)	0.271

AF = atrial fibrillation, AOR = adjusted odds ratio, CIED = cardiac implantable electronic device, CKD = chronic kidney disease, CRTD = cardiac resynchronized therapy-defibrillator, CRTP = cardiac resynchronized therapy-pacing, ICD = implantable cardioverter defibrillator, PPM = permanent pacemaker.

for ICD. In our study, the event rate for heart perforation was lower than rates reported in literature at 0.09%, though the major reason may be our restricted definition focusing on the complications requiring intervention. In addition, some studies have mentioned that heart perforation incidence may be underestimated due to the fact that many perforations lack clinical symptoms.[32] Regarding the risk of heart perforation, a cohort study from the Mayo clinic[20] noted 2 strong predictors: temporary transvenous pacemaker installation and steroid use. These 2 risks were proven again in our study. In the Mayo clinic

study, the researchers proposed that temporary pacing leads were usually placed in emergencies and more leads in the right ventricle[20] increased the perforation risk. In our clinical practice, we agree with that explanation. In terms of steroid use, although Mahapatra et al[20] proposed that steroid use will make cardiac muscle weaker and atrophy as it does to skeletal muscle,[33] there has been no published research to support this hypothesis, and thus requires further study.

Study Limitations

This retrospective analysis bears the inherent limitations of these types of studies. First, the information of the severity of the complications and procedures was not available, since the data were from an insurance system where diseases were classified according to ICD-9 codes and payment was made according to procedure type. Therefore, some complications may have been underestimated. Nonetheless, the complications requiring treatment were likely to be more important clinically than those without therapy. Second, information for some potential risks, including preoperative infections and procedure type (ie, cut-down vs puncture method) were not available in the analysis. However, the data were from the national insurance system that covers nearly every citizen in a country that may reduce systematic bias caused by a single operator or center and uncover factors that may not be readily found in studies of single clinics or with a small sample size. Therefore, such large number of patients and the complete follow-up should counterbalance the inherent study weaknesses.

CONCLUSION

In the CIED related infection, high-volume center can lower it and clinicians should pay more attention to young male patients and those who undergo device replacements. Preprocedure antibiotics remain important and cephalosporins should be considered a priority, especially in CIED replacement patients. As for heart perforation, temporary pacing should be avoided whenever possible after taking into account patient stability and timing to permanent pacing device. Careful attention should be paid when patients on steroids receive CIED implantations, due to the higher risk of heart perforation and it is recommended that steroids be discontinued if possible. Clinicians also should pay more attention to COPD patients and CRT patients in order to prevent pneumothorax.

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