International Journal of Infectious Diseases 36 (2015) 9–14

Contents lists available at ScienceDirect

International Journal of Infectious Diseases

journal homepage: www.elsevier.com/locate/ijid

Incidence of and risk factors for infectious complications in patients with cardiac device implantation

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ARTICLE INFO

Article history:
Received 2 March 2015
Received in revised form 27 April 2015
Accepted 7 May 2015

Keywords:
ICD
CRT
Pacemaker
CIED
infection

SUMMARY

Objectives: The use of cardiac implantable electronic device (CIED; pacemakers, implantable cardioverter-defibrillators [ICD], cardiac re-synchronized therapy [CRT]) implantation, one essential treatment for cardiac arrhythmias, is increasing. Infectious complications related to implants are the main reason for device removal and patient morbidity. We sought to identify the incidence of infectious complications among patients with cardiac device implantation and analyze the risk factors for infectious complications.

Methods: A retrospective analysis was conducted of 1307 patients (61.5±14.2 years-old, 49.6% male) with cardiac device implantation from January 1990 to April 2013. We analyzed the incidence of infectious complications during the follow-up period. To investigate risk factors associated with infectious complications, we conducted a 1:2 matched case-control study of patients with infectious complications and controls without infectious complications who had the same implantation period and physician.

Results: Among 1307 patients, 12 had a confirmed device-related infection: 7 with a pocket infection and 5 with infective endocarditis. Over a total of 9091.9 device-years, the incidence of infectious complications was 1.3/1000 device-years, based on the 12 patients with an infection. ICD (5.1/1000 device-year) had a higher incidence of infectious complications than other cardiac devices, and no infectious complications were observed among patients with CRT implantation. Mean duration from the time of implantation to infection was 2.02±1.65 years. In a multivariate analysis, the number of prior procedures including wound revision or scar revision was an independent risk factor for infectious complications (OR=10.88, 95% CI 1.11->999, p=0.040).

Conclusions: Infection was a rare complication of cardiac device implantation, but repeated procedures were associated with infectious complications.

1. Introduction

The use of cardiac implantable electronic device (CIED; pacemakers, implantable cardioverter-defibrillators [ICD], cardiac re-synchronized therapy [CRT]) implantation, an essential procedure to treat cardiac arrhythmias, is growing. Pacemaker and ICD implantation has increased by 19% and 60%, respectively, from 1997 to 2004 in the United States.[1] A rising trend has been observed globally, including in Korea.[2,3] The reported incidence of cardiac device-related infections ranges from 0.5%-4.8%.[4–7] Although infrequent, infectious complications can cause device removal and even mortality.[8–13] Recent research shows that diabetes mellitus, underlying heart disease, cardiac resynchronized therapy (CRT)/dual chamber devices and use of >1 lead are risk factors for cardiac device-related infection.[11,14,15] Most research on cardiac device-related infections has been conducted in Western countries, and studies in Asian countries are limited. The current incidence of cardiac device-related infections in South

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http://dx.doi.org/10.1016/j.ijid.2015.05.011

Korea is unknown, although implantation of cardiac devices has been performed there since 1969.[16] There were 5815 cases of cardiac device implantation in 2006 and 9208 cases in 2013 in South Korea.[17,18] A better understanding of the incidence and risk factors of infectious complications in the region would help physicians develop appropriate measures to prevent and treat cardiac device-related infections.

We conducted this study to investigate the incidence and risk factors of cardiac device-related infections in South Korea.

2. Methods

2.1. Study population

The study population was composed of patients who underwent cardiac device (including permanent pacemakers, ICD, CRT) implantation de novo in a 2000-bed, tertiary teaching hospital from January 1990 to April 2013 in South Korea. A retrospective analysis was conducted using the medical records of 1306 patients, aged 18 years or older, for whom clinical observations and laboratory findings were available. We excluded patients who did not receive regular follow-up or who received an implant in another hospital but came to our center with an infection.

2.2. Study design and variables

We analyzed the incidence of cardiac device infections among 1307 patients during the follow-up period. Person-years of follow-up were calculated from the date of cardiac device implantation until the date of cardiac device infection or the date of last follow-up visit at the hospital.

Diagnosis of cardiac device infection was made clinically or microbiologically. We defined clinical evidence of cardiac device infection as one of the following signs: erythema, tenderness, fluctuance, warmth, wound dehiscence, skin erosion or discharge over the generator site.[19] Microbiological diagnosis was made based on positive culture of typical causative agents from the pocket of the device or its leads.[19] We applied modified Duke Criteria for the diagnosis of infective endocarditis for the detection of device-related endocarditis.[20]

In addition, to identify risk factors for cardiac device infection, we performed a matched case-control study. Cases included 12 patients with device-related infections during the study period. The control group consisted of 24 patients who underwent cardiac device implantation during the same period without infections during follow-up. Two controls were matched to each case according to implantation period within a month and the physician who did the procedure.

The following variables were assessed: (1) demographic and clinical characteristics (age at cardiac device implantation, gender, body mass index and Charlson comorbidity index.[21] Presence of arterial hypertension, diabetes, myocardial infarction, heart failure (ejection fraction $< 50\%$), valve disease (significant regurgitation or stenosis in transthoracic echocardiography), chronic obstructive pulmonary disease (FEV1/FVC $<70\%$), renal insufficiency (estimated glomerular filtration rate <60 mL/min/1.73m^2), malignant neoplasm and smoking were assessed.; (2) perioperative circumstances (use of prophylactic antibiotics, presence of signs of infection, anticoagulants use); (3) device characteristics (type of device - pacemaker, implantable cardioverter-defibrillator, cardiac resynchronized therapy, number of intracardiac leads); (4) number of procedures before the infection occurred (generator change, wound revision, lead repositioning and temporary pacemaker use).

2.3. Data analysis

Normally distributed continuous variables were expressed as mean ± standard deviation (SD).

Statistical significance of the comparisons was assessed using the paired t-test and χ^2 test. Uni- and multi-variate logistic regression analyses were used to analyze the cause of device-related infection between cases and controls. Variance inflation factors (VIF) were used to measure co-linearity in the multivariate logistic analysis; parameters with VIF$\geq$10 were considered to be co-linear. Parameters with co-linearity were excluded from the multivariate logistic regression analysis. A p-value <0.05 was considered statistically significant. Analyses were performed using SPSS v19 (SPSS Inc., Chicago, IL, USA) and SAS version 9.2 (SAS Institute Inc., Cary, NC, USA.)

3. Results

A total of 1307 patients underwent cardiac device implantation during the study period. Of these, 49.6% were male, and the mean age was 61.5±14.2 years. There were 1130 patients (86.5%) who received pacemaker implantation, 147 (11.2%) who received an ICD and only 30 patients (2.3%) who received CRT. Over a total of 9091.9 device-years, the incidence of infectious complications was 1.3/1000 device-years (Table 1), based on the 12 patients with an infection. There was a higher incidence of infectious complications with ICD (5.1/1000 device-year) than other cardiac devices, and no infectious complications were observed among the patients with CRT implantation. Of the 12 patients with infection, 7 patients (0.5%) had a pocket infection only and 5 patients (0.4%) had infective endocarditis. The mean duration from the time of implantation to infection (range) was 2.02±1.65 years (6 days to 2481 days) (Table 1).

Table 2 compares demographic and clinical characteristics between patients with and without infections complications. There were no significant differences in gender, echocardiographic findings or lab findings between the two groups. The proportion of patients with renal insufficiency and valvular heart disease was higher in the control group than the case group, and there was no

Table 1
Incidence of infectious complications of cardiac implantable electronic devices

		Device type			
	Total	PM	ICD	CRT	p-value
Number (n,%)	1,307	1,130 (86.5)	147 (11.2)	30 (2.3)	
Age (Years)	61.5±14.2	62.5±13.7	53.6±14.7	64.1±13.6	<0.001
Gender (male; n,%)	634 (49.6)	496 (44.0)	123 (83.7)	15 (50.0)	<0.001
Total FU duration (Device-yr)	9,091.95	8,442.27	579.99	69.68	
No. of infection complications (n,%)	12 (0.9)	9 (0.8)	3 (2.0)		
Incidence (/1,000Device-yr)	1.3	1.0	5.1		
Type of infection					
Pocket infection (n,%)	7 (0.5)	5 (0.4)	2 (1.4)		
Endocarditis (n,%)	5 (0.4)	4 (0.4)	1 (0.7)		

PM: Pacemaker, ICD: implantable cardioverter defibrillator, CRT: cardiac resynchronized therapy, FU: follow-up.