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Cardiac Device Related Infection: A Study from a Tertiary Care Hospital in India.

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ABSTRACT

Background: This study analyzes the incidence, associated risk factors, treatment modalities and outcomes of cardiac device related infection (CDI) in a tertiary care hospital, in India. **Methods:** Data of all consecutive devices implanted between January 1998-December 2011 and admissions related to CDI in the same period were identified from hospital information system for analysis. A total of 1751 cases of cardiac device implants were analyzed, with total surveillance of 10013 device-years. **Results:** Overall incidence of CDI was 4.69/1000 device years. Device infection occurred in 2.60% patients (36/1382) after first implantation and in 2.98% (11/369) after revision/replacement of device. 63.83% (30/47) of CDI occurred within one year of procedure whereas in 36.17%(17/47) infection occurred beyond one year. The incidence of infection was 2.72% (46/1688) in pacemaker implants and 1.58% (1/63) in high end devices (p=0.59).In multivariate analysis, independent predictors of CDI were older age (OR=2.78, 95% CI 1.59-7.23, female sex (OR=1.92, 95% CI: 1.11-3.35,), diabetes (OR=2.62, 95% CI: 1.24-4.15) and device revision (OR=1.52, 95% CI: 1.09-2.06). Rate of re-infection after new device implanted at new site were significantly less (6.5%) in comparison to reuse of the same device (26.3%) (p=0.01).Conservative antibiotic treatment with wound debridement and resuturing showed re-infection rate as high as 94.1%. **Conclusion:** CDI occurs in a small but definite number of patients. Older age, female gender, diabetes and device revision are important risk factors for CDI. Removal of infected device and implantation of a new device at new site is possibly the best treatment option, and conservative strategy is of no use.

Keywords: Pacemaker, Infection, Arrhythmias, Complications, ICD.

INTRODUCTION

There has been an increase in the number of Permanent pacemakers (PMs) and high-end device (including CRT and ICD) implantation related to both expanding indications for device therapy and the aging of the population.[1-3] Although an increased use of these therapies improves outcomes in patients with cardiovascular disease, they also subject them to risk for complications, including device-related infection.

It is estimated that worldwide there are over3.5 million patients with PMs.[4,5] The reported incidence of PM- related infection ranges from 0.5% to 6%.[6,7] A recent study reported the overall incidence of device-related infection to be 1.9 per 1,000 device-years.[8] Cardiac device infections (CDI) are associated with increased morbidity, health care costs, and even mortality.[9-11]

Information about cardiac device infections is based on the studies conducted in the West, and there were few studies in this field from India.[12]The aim of the present study was to evaluate the clinical and demographic characteristics, as well as the risk factors of patients treated for cardiac device related infections and the outcomes of different management strategies adopted at tertiary medical care centre.

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MATERIALS AND METHODS

Present study was conducted a hospital-based retrospective study to look into the incidence of device-related infection in patients implanted with PM or high-end devices (including CRT and ICD) over a thirteen year period (between January 1998 and December 2011). The clinical and demographic characteristics, as well as the risk factors associated with the infection, were studied, the different management strategies adopted and their outcomes were also analyzed.

Patient Population-All admissions of the patients with implanted cardiac device were review for device infection, device revision or replacement by using hospital electronic information system (HIS), which ensured no cases of infection were missed. A

manual, review of the records was then performed for all identified patients.

The reason for device revision was recorded as 'end of life' (EOL), 'lead-replacement/repositioning', or 'infection.' CDI was diagnosed based on local signs of inflammation at the generator pocket, including erythema, warmth, fluctuance, wound dehiscence, tenderness, purulent drainage, or erosion of the generator or lead through the skin. All infections occurring within one year after device implantation were considered to be early CDI in accordance with current guidelines.[13] Infections occurring beyond this period were categorized as late infections. A standard antibiotic prophylaxis was used in all cases as an institutional protocol.

Each case identified as a CDI had the following baseline characteristics recorded: age at implant, gender, type of procedure (new implant, generator replacement, lead repositioning, device reuse), device type (PM or high end device), past medical history (diabetes mellitus, hypertension, coronary artery disease, left ventricular ejection fraction <35%, chronic obstructive pulmonary disease), interval from latest procedure to CDI diagnosis, number of intra-cardiac leads at diagnosis and presenting symptoms of infection.

Management strategies offered to patients with CDI were analyzed, and their outcome was compared in terms of re-infection or final success.

Statistical Analysis:

Descriptive statistics is presented as number (percent) for categorical variables and mean (± standard deviation [SD]) or median (25th–75th percentile) for continuous variables. Pearson chi-squared tests and Student's t-tests were used to compare categorical and continuous variables, respectively. Multivariate analysis was used to determine possible predictors of CDI. All tests were two-tailed, with $p \leq 0.05$considered to be statistically significant. All analyses were performed using SPSS 16.0 software.

RESULTS

Baseline characteristics:

Data were available for all 1751 patients who had one or more device implantation between January 1998 and December 2011, with total surveillance of10013 PM-years. Baseline characteristics of the patients are shown in [Table 1].

Of the 1751 patients analyzed, 1382 patients were of the first implant and 369 patients under went device revision or replacements.

Infections:

A total of 47 patients had 67 CDI episodes, with an overall incidence of 4.69/1000 device years. In 36 patients device infection occurred after the first PM implantation (incidence2.60 %) and in 11 patients after device revision (incidence2.98 %). The number of days between procedure and the time of diagnosis of infection ranged from 7 to 2600 days (average 456 ± 552 days, median 302).

'Infection' was listed as a reason for removal of these devices. Removals were attributed to clinical presentations of infection, indicated as 'Discharge' in 25 cases (37.37%),'Hematoma' in 3 cases (4.47%), 'Pocket Erosion' in 23 cases (34.3%),Swelling 8 cases (11.9%), Erythema in 4 cases (5.97%) and tenderness in 4 cases (5.97%).When the patients were evaluated with respect to signs of infection, discharge and pocket erosion (71.6%) was determined to be the most frequent presentation in general as detailed in [Table 2].

The incidence of infection was 2.72% (46/1688) in pacemaker implants, and 1.6% (1/63 devices) in high-end devices, the device type was not significantly (p=0.59) associated with CDI. In 30 patients (63.82%) of CDI occurred within one year of procedure whereas in 17 patients (36.17%) infection occurred after one-year post-implantation. The risk of CDI relative to the risk of late infection did not differ significantly between first implantations and replacement procedures (p=0.46).

Primary antibiotic prophylaxis was administered in all patients. There was no significant difference between the groups in terms of the type, doses and duration of antibiotic prophylaxis used with no difference in the incidence of CDI (OR=0.90, 95% CI 0.39 -2.02).

Risk factors associated with CDI:

Univariate and multivariate logistic regression analyses indicated that the following factors were associated with an increased risk of CDI viz device replacement/revision, female sex, older age and diabetes. Other variables including pacing indication, number of intracardiac leads and antibiotic protocol used were not found to be significant [Table 3].

Management strategy for Pacemaker infection and outcomes:

A. For the 67 episodes of CDI, the management strategy included: A new device at new site with the removal of the infected device and leads as much possible 31/67(47.3% cases).
B. Same device sterilized and re-implanted with new leads at new site 19/67(31.1%).
C. Conservative antibiotic treatment with wound debridement and re-suturing in 16/67(23.6%).

Incidence of re-infection with a given treatment strategy was 6.5% (2/31) in strategy A, 26.3% (5/19) in B and 94.1% (16/17) in C, (p =0.01 for A vs B and P=0.001 for A+ B vs C).

Table 1: Baseline characteristics of Patients with device implant.

* Bundle Branch Block

Age			**59yr(9-89)**
Sex	Male	1253	71.56%
	Female	498	28.44%
Pacing Mode	VVI	950	54.25
	DDD	570	32.55%
	ICD	63	3.60%
	OTHER	168	9.59%
Indication	AV Block	858	49.00%
	Sinus node disease	457	26.10%
	Atrial fibrillation	22	1.26%
	LV Dysfunction	112	6.40%
	BBB*	302	17.25%
Associated Co-morbities	Diabetes	494	28.21%
	Hypertension	803	45.86%
	Left ventricular ejection fraction <35%,	103	5.88%
	Chronic obstructive pulmonary disease	98	5.60%
		Total no=1751	

Table 2: Presenting symptoms in patients with CDI.

Symptom	**N=67, Frequency (%)**
Discharge	25(37.31)
Hematoma	3(4.48)
Pocket Erosion	23(34.33)
Swelling	8(11.94)
Erythema	4(5.97
Tenderness	4(5.97)

Table 3: Risk factors associated with infection.

Variable		**Devices**	**Events**	**Univariate**	**Multivariate**
				Odds Ratio	
Implantation	First Implant	382	46	1	1
	Device revision	369	21	1.75(1.03-2.97)	1.52(1.09-2.06)
Infection	< 1 year		30		
	>1 year		17		
Sex	Male	1253	27	1	1
	Female	498	20	1.89(1.05-3.41)	1.92(1.11-3.35)
Age (in years)	<50	347	3	1	
	>50	1410	44	3.69 (1.14-11.96)	2.78(1.59-7.23)
Diabetes	No	1257	28	1	1
	Yes	494	20	1.86(1.04-3.34)	2.62(1.24-4.15)
Preoperative antibiotics	Cefazolin + gentamycin	286	17		
	Teicoplanin	1465	50		
Device type	CRT/ICD	63	1		
	Pacemaker	1688	46		
Indications	AV Block	858	35		
	Sinus node disease	457	6		
	Atrial fibrillation	22	0		
	on				
	LV Dysfunction	112	1		
	BBB*	302	5		

* Bundle Branch Block

Best treatment strategy for CDI was a new device at new site with the removal of the infected device and leads as much possible.

Antibiotic treatment was given on the basis of culture and sensitivity obtained from local site and blood which was positive only in 19.4% cases (13 out of 67 patients). S.aureus was the most common organism (46%) isolated in cases of CDI followed by E.coli (30%) and Klebsiella (23%).

DISCUSSION

The present study represents one of the largest hospital-based studies of device related infection and associated risk factors to date from India. This single-center study reports rates of infection after first implant and device revision or replacements. Although study methodology may have missed a few cases of infections among patients who did not present back to our center for follow-up but mostly patients done by us do get followed at our center, hence we feel confident that the actual rate of device-related infection would be no different from what is in our study. The reported incidence of PM-related infection ranges from 0.5% to 6% in previous studies.[6,7] Other epidemiological studies that include long-term follow-up have calculated cumulative rates per 1000 patient or device years with the reported infection rates of 2.2 to 1.6, with presentstudy results being not much different viz 4.69/1000 device years.[9-11]

The incidence of infection was similar in pacemaker implants and high-end devices in the present study. This correlates with other studies where rate of infection in ICD systems has been reported to be similar to the rates observed for PM systems,[9,10,14] with the exception of few study that demonstrated a higher risk of infection in ICD patients,[10,15] probably because of larger study population.

Male sex and absence of diabetes were associated with a lower risk of CDI. The patient age, indication for pacing, number of intra cardiac leads, and preoperative antibiotic use were not independently associated with the risk of CDI, similar risk profile have been reported in previous studies.[16,17] In contrast, a recent large prospective study reported male sex and younger age as important risk factor for device infection.[18]

Repeated operative procedures after the first implant were associated with a high risk of infection in our study. It is recognized that revision surgery is an important risk factor for the infection of the implanted prosthesis or device.[19] Probable explanation given is that the increase in infection

rates might be due to decreased immunologic defense in the preformed pacemaker pocket and inadequate visualization of the surgical field.[20]

One important finding of this cohort study is that a significant number of infections (36%) were found to occur during the late follow-up period1 year post-procedure. This late onset of infection is consistent with the findings from other studies that consider extended follow-up periods and with the current understanding of slowly progressing, implant-related infection.[9,14,21,22] The defined one-year period post-implant surgery for early CDI may be more or less arbitrary,[13] and present study was not able to distinguish between CDI and lead endocarditis. The significant number of infections occurring later than one year after implantation highlights the continued need for long-term clinical follow-up and patient-education to identify patients presenting with CDI during the late postoperative period of device patients.

As far as management of CDI is concerned present study shows the limited usefulness of conservative management strategy. Best option is to implant a new device with new lead at new site. Strategy of using the same device after sterilization and implanting at fresh site does work to a reasonable extent, but re-infection rates were high contrary to the reports from other studies where similar re-infection rates were observed with device reuse or implantation of the new device.[23-25] It may be a smaller number could be responsible for this difference.

CONCLUSION

This study concludes that CDI is not uncommon despite current broad spectrum antibiotic prophylaxis and once occurs implanting a new device at new site is possibly the best management strategy. The risk factors for the occurrence of the CDI include female sex, older age, PM replacement/revision and diabetes.

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