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ORIGINAL ARTICLE

Case-Control Study of Surgical Site Infections Associated With Pacemakers and Implantable Cardioverter-Defibrillators

Jonas Marschall, MD; Diane Hopkins-Broyles, RN; Marilyn Jones, RN; Victoria J. Fraser, MD; David K. Warren, MD, MPH

OBJECTIVE. In 2000, the rate of surgical site infections (SSIs) associated with pacemaker and implantable cardioverter-defibrillator (ICD) procedures performed in the cardiothoracic operating rooms of hospital A was 16% (19 of 116 procedures resulted in infections). This study investigates risks for SSI associated with these procedures in the cardiothoracic operating room.

DESIGN. Unmatched 1 : 3 case-control study performed over a 12-month period among patients who had undergone implantation of a pacemaker and/or ICD. A standardized observation scrutinized infection control practices in the area where the procedures were performed.

SETTING. The cardiothoracic operating rooms of hospital A, which belongs to a hospital consortium in the midwestern United States.

PATIENTS. Patients with SSI were identified as case patients. Control patients were chosen from the group of uninfected patients who had procedures performed during the same period as case patients.

RESULTS. A total of 19 SSIs associated with pacemaker and ICD procedures were retrospectively identified among the patients who underwent procedures in these cardiothoracic operating rooms. Culture samples were obtained from 7 patients; 2 yielded coagulase-negative *Staphylococcus* on culture, 2 yielded *Staphylococcus aureus,* 1 yielded *Serratia marcescens,* and 2 showed no growth. In the case-control study, age, race, sex, diabetes mellitus, smoking history, timing of antibiotic therapy, and hair removal did not differ significantly between case patients and control patients. Case patients were more likely to have an abdominal device in place (odds ratio [OR], 5.5 [95% confidence interval {CI}, 1.6-19.3]; $P = .006$) and less likely to have received a new implant (OR 0.3 [95% CI, 0.1-0.8]; $P = .02$) or to have had new leads placed (OR, 0.2 [95% CI, 0.1-0.6]; $P = .003$).

CONCLUSIONS. Abdominal placement of implanted devices was associated with occurrence of an SSI after pacemaker and/or ICD procedures.

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The use of cardiac pacemakers and implantable cardioverter-defibrillators (ICDs) has increased considerably, because they reduce the incidence of both cardiac symptoms and sudden death in patients with arrhythmias.[1,2] In recent years, there has also been an expansion of indications for their use. According to a worldwide survey regarding implantable cardiac device use, 223,226 pacemakers and 48,127 ICDs were implanted in patients who underwent such placement procedures in the United States in 2001.[3]

Along with their increased use there have been increasing reports of infections associated with cardiac devices. In a survey of Medicare beneficiaries, there was a 124% increase in infections associated with cardiac devices between 1990 and 1999.[4] This increase in infections is out of proportion to the increase in the number of device implantation procedures performed during the same period. Among the possible explanations for this increase are a higher mean age at implantation[5] and a longer time at risk for infection due to longer survival of device recipients.[4] A higher number of underlying comorbidities in patients or changes in insertion practices might also play a role, as may increased awareness and reporting of infection.

There are several risk factors that have been linked to the development of surgical site infections (SSIs) and specifically to infections associated with cardiac devices. Reported risk factors for infection include congestive heart failure, diabetes mellitus, renal insufficiency and the frequency with which generators are exchanged.[6] The experience level of the person inserting the device has also been shown to influence the risk of infection.[7]

Overall infection rates for implantable cardiac device procedures have been reported to be in the range of 0.5%-5.1%.[8] However, infection rates in patients receiving ICDs are less well studied because these devices have been more recently

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introduced into cardiac therapy.[9,10] Infections associated with cardiac devices have been shown to cause substantial morbidity and they can lead to dramatic increases in healthcare costs, ranging from $10,000 to $40,000 per patient.[11]

Only a few case-control studies on infections associated with cardiac devices have been published. The purpose of this study was to provide a detailed account of infections associated with pacemaker and ICD procedures and the related risks by means of a case-control study in a hospital within an integrated healthcare system that had an increased rate of pacemaker- and ICD-associated SSI.

METHODS

Setting and Patient Population

Hospital A is a hospital within BJC Healthcare, a consortium of 13 hospitals in the midwestern United States with a catchment area including the eastern part of Missouri and the southwestern part of Illinois. One of the authors (D.H.-B.) collected the data for this study.

Cardiac devices are implanted at hospital A either by cardiac surgeons in 1 of 3 cardiothoracic operating rooms or by interventional cardiologists in 1 of 3 cardiac catheterization laboratories. Procedures that are expected to be complicated (eg, removal of tightly implanted leads or procedures involving critically ill or clinically unstable patients) tend to be performed in the operating rooms. In 2000, there were 622 cardiac devices implanted at this hospital; 116 (19%) of these procedures were performed in the operating rooms and 506 (81%) in the cardiac catheterization laboratories.

Case Series Investigation

In January 2001, the BJC Healthcare Infection Control and Healthcare Epidemiology Consortium was notified by the cardiology service about a cluster of infections in patients who had had pacemakers or ICDs inserted in the cardiothoracic operating rooms during the period from January to December 2000. Up to that time, no focused surveillance for cardiac device–associated infections had been performed in any BJC Healthcare hospitals. In contrast, no increased rate of infection had been reported from the catheterization laboratories. Subsequently, an extensive search to retrospectively identify case patients with cardiac device–associated infections was performed, including a review of microbiology laboratory reports, a query regarding readmissions for infection among patients who received a pacemaker and/or ICD, and notification by the cardiology and cardiothoracic services of infected patients seen in their offices. Infected case patients were defined using standard Centers for Disease Control and Prevention National Nosocomial Infections Surveillance System definitions[12] and included those who had had a device placed at hospital A prior to infection. Briefly, SSIs were classified as superficial incisional, deep incisional, or organ space infections, depending on whether an infection was in the skin and subcutaneous tissue, in the fascia and muscle layer, or in deeper tissues. The further investigation of cardiac device–associated infections included the observation of infection control practices in the cardiothoracic operating rooms. Observations were performed using a standardized data collection instrument.

The study was approved by the Washington University institutional review board.

Case-Control Study

To better identify risk factors associated with the development of SSI in the study population, a 1 : 3 case-control study was performed. A random control population of 57 patients who had procedures to place implantable cardiac devices performed in the cardiothoracic operating rooms during the same period as the case patients, but who did not develop infections, were chosen for comparison. Data for both case and control patients were collected using a standardized data collection tool. Demographic information was collected, as was information about risk factors for infection, including diabetes mellitus, overweight status (ie, body mass index of 25 or greater), the presence of a previous implant, the site of any cardiac device implant, American Society of Anesthesiologists (ASA) score, receipt of preoperative showers, preoperative and postoperative antibiotic therapy, length of surgery, type of device implanted, irrigation fluid used, and the individual surgeon who implanted the device.

Infection Control Measures

To ensure the establishment of proper infection control techniques in the cardiothoracic operating rooms, several interventions were implemented. First, in-service training about appropriate skin preparation for the operating room staff was conducted. Second, the technique that the manufacturers' representatives used to pass devices to the operating physicians was reviewed and improved. Third, prospective surveillance for SSI in patients receiving implantable cardiac devices was initiated in January 2001 and continued until March 2002.

Analysis

The ASA score was used to define the clinical condition of patients at the time the device was implanted. Microsoft Excel 2003 (Microsoft) was used for data entry and for calculation of means and confidence intervals. For the statistical analysis, SPSS, version 11.0 (SPSS), was used. A 2-sided P value less than .05 was considered statistically significant.

RESULTS

Case Patients

The overall rate of infections associated with pacemaker and/or ICD procedures performed in the cardiothoracic operating rooms during the study period was 16%; there were 19 infections among 116 patients who underwent surgery. Of the

19 infections, 12 were superficial and 7 were deep incisional infections. Of patients with SSI, culture samples were obtained only from the 7 patients (37%) with deep infections. The organisms identified on culture were coagulase-negative *Staphylococcus* species (2 samples), *Staphylococcus aureus* (1), and *Serratia marcescens* (1); there were 2 samples that yielded no growth on culture. Prior to infection, 11 (58%) of these 19 patients had a cardiac device removed and a new device placed in the same surgical pocket. Of the remaining 8 patients (42%), a total of 7 had a device placed in a new site and 1 underwent a first-time device placement. Of the 7 patients who had a pacemaker and/or ICD replaced in a new site, 3 had an infection at the explant site and 4 had an infection at the new surgical pocket. The median time until development of infection was 9 days (range, 7-222 days). The mean age ($\pm$SD) of the case patients was 60.0 $\pm$ 16.3 years. Seventy-nine percent of the case patients were male and 90% were white.

Observation in Operating Rooms

Observations in the cardiothoracic operating rooms revealed instances of inadequate skin preparation technique as well as pacemaker manufacturers' representatives reaching across the sterile field to hand off devices, potentially contaminating the surgical site.

Risk Factor Analysis in the Case-Control Study

There were no significant differences in age, sex, or race between case and control patients (Table). Only a few (11%) of the case patients had documentation of a preoperative shower in their records (11% of control patients had similar documentation). Interestingly, case patients were somewhat more likely to be outpatients at the time of the procedure, compared with control patients ($P = .06$).

The majority of patients in both groups (16 [84%] of 19 case patients and 43 [75%] of 57 control patients) received perioperative antibiotic prophylaxis in a timely manner, that is, within 30-120 minutes before incision. There was no significant difference between the 2 groups with respect to this factor ($P = .53$).

Case patients were less likely to have undergone procedures involving implantation of a new device, compared with control patients (42% vs 74%; $P = .02$), or to have undergone placement of only new leads (32% vs 72%; $P = .003$). Case patients were, however, more likely to have an abdominal cardiac device in situ at the time of surgery, compared with control patients (74% vs 33%; $P = .006$). The rate of retention of leads was not significantly different between case and control patients (21% vs 26%; $P = .77$).

Changes in Recommendations and Policy

As a result of the increase in the incidence of infection during 2000, the following recommendations were made to improve practices and reduce the risk of infection: (1) ensure timely administration of preoperative antibiotics prior to incision, (2) ensure preoperative shower with an antimicrobial soap, (3) ensure adequate skin preparation, and (4) obtain wound culture samples from patients who have wound or device drainage after cardiac devices are placed prior to initiation of antibiotics.

Subsequently, prospective surveillance for SSI following placement of implantable cardiac devices in the cardiothoracic operating rooms was initiated. Case patients were identified by communication with the cardiothoracic clinic, the cardiology clinic, by readmission reports, and by microbiology laboratory data. From January 2001 through March 2002, there were 7 infections identified following 93 procedures (infection rate, 8%).

DISCUSSION

The number of studies on SSI associated with implantable cardiac devices has increased in recent years.[13,14] This reflects the increasing size of the problem because more and more pacemakers and ICDs are implanted in the United States.[4] However, to our knowledge, few of these studies have investigated the risk factors for infection by means of a case-control study.[6] We give a detailed account of an infection control investigation and the risk factors associated with the development of SSI in patients who received pacemakers and ICDs. In brief, the infection investigation found that aspects of preoperative skin preparation and antibiotic prophylaxis, and procedures involving an in situ abdominal device, were significantly associated with subsequent infection.

The overall rate of infection in patients who received implantable cardiac devices observed in this study was 16%. This rate is above the range of infection rates in the recent literature, which has been reported as 0.4%-5.4% for pacemakers[15,16] and 0.2%-5.7% for ICDs.[17,18] However, infection rates after pacemaker implantation as high as 19.9% were reported in the 1970s, which were related to abdominal implantation.[19] In the last 2 decades, however, a transition to prepectoral implantation for most cardiac devices has taken place, and rates of infection have been lower in comparison.[20]

In the current study, implantation of a device in the abdominal wall was strongly associated with an increased risk of infection ($P = .006$). This finding correlates with the findings of Mela et al.,[20] who found a higher rate of infection associated with abdominal placement (3.2%), compared with pectoral placement (0.5%). Possible explanations are differences in the vascular supply, the adipose tissue, and the local skin flora.

A small percentage of patients in our study (11%) had documentation of receiving a preoperative shower with an antiseptic solution. Explanations for this low rate might be deficits in the instruction of patients, deficits in patient compliance, or simply inadequate documentation of established practices. The efficacy of a chlorhexidine gluconate solution as a skin antiseptic was demonstrated by Paulson,[21] who

TABLE. Comparison of Demographic Characteristics and Risk Factors for Cardiac Device-Associated Infections in Case and Control Patients

Variable	Case patients (n = 19)	Control patients (n = 57)	Crude OR (95% CI)	P
Age, mean ± SD, years	60 ± 16.3	63 ± 16.2		.4
White race	17 (90)	49 (86)	1.4 (0.2-10.5)	.99
Male sex	15 (79)	33 (58)	2.7 (0.7-11.2)	.2
Smoking status				
Current	1 (5)	7 (12)	0.4 (0.1-3.5)	.7
Former	8 (42)	26 (46)	0.9 (0.3-2.5)	.99
Overweight (BMI ⩾25)	5 (26)	12 (22)	1.3 (0.4-4.3)	.99
Diabetes mellitus	7 (37)	14 (25)	1.8 (0.6-5.4)	.99
Previous implant	17 (90)	42 (74)	3.0 (0.6-14.7)	.2
Outpatient prior to procedure	14 (74)	27 (47)	3.1 (0.99-9.8)	.06
Received preoperative shower	2 (11)	6 (11)	1.0 (0.2-5.4)	.5
Preoperative antibiotic prophylaxis received				
Vancomycin	4 (21)	11 (19)	1.1 (0.3-4.0)	.99
Cefazolin	15 (79)	44 (77)	1.1 (0.3-3.9)	.99
Not documented	0	2 (4)		
Timely preoperative antibiotic prophylaxis[a]	16 (84)	43 (75)	1.7 (0.4-8.8)	.5
Body hair removed with electric shaving	10 (53)	17 (30)	2.6 (0.8-8.7)	.1
Skin prepared with tincture of iodine[b]	10 (53)	20 (35)	2.1 (0.7-5.9)	.2
ASA score				
2	1 (5)	3 (5)	Reference	
3	14 (74)	37 (65)	1.1 (0.1-11.8)	.99
4	4 (21)	17 (30)	0.7 (0.1-8.7)	.99
Operating room where surgery took place				
A	3 (16)	5 (9)	2.0 (0.4-9.1)	.99
B	9 (47)	32 (56)	0.7 (0.3-2.0)	.6
C	4 (21)	14 (25)	0.8 (0.2-2.9)	.99
Received general anesthesia	18 (95)	50 (88)	2.5 (0.3-21.9)	.7
Device type received				
ICD	11 (58)	19 (33)	2.8 (0.95-8.0)	.7
Pacemaker	6 (32)	21 (37)	0.8 (0.3-2.4)	.8
Procedure undergone[c]				
Surgical pocket revision	4 (21)	10 (18)	1.3 (0.3-5.3)	.7
Generator change	10 (53)	16 (28)	2.8 (0.98-8.3)	.09
Device removal	8 (42)	29 (51)	0.7 (0.3-2.0)	.6
Lead removal	7 (37)	26 (46)	0.7 (0.2-2.0)	.6
New implant	8 (42)	42 (74)	0.3 (0.1-0.8)	.02
New lead placement	6 (32)	41 (72)	0.2 (0.1-0.6)	.003
Device location				
Same site[d]				
Pectoral	3 (16)	23 (40)	0.3 (0.1-1.1)	.2
Abdominal	8 (42)	11 (19)	3.0 (0.9-10.8)	.07
Abdominal site				
Old[e]	14 (74)	19 (33)	5.5 (1.6-19.3)	.006
New	8 (42)	12 (21)	2.5 (0.8-7.8)	.99
Moved from abdominal to pectoral	6 (32)	8 (14)	2.8 (0.8-9.6)	.99
Old leads retained	4 (21)	15 (26)	0.8 (0.2-2.6)	.8
Radiography used intraoperatively	6 (32)	21 (37)	0.8 (0.3-2.4)	.8
Laser used intraoperatively	3 (16)	21 (37)	0.3 (0.1-1.2)	.2

(Continued)

TABLE. *(Continued.)*

Variable	Case patients (n = 19)	Control patients (n = 57)	Crude OR (95% CI)	P
Fluoroscopy	8 (42)	30 (53)	0.7 (0.2-1.9)	.4
Irrigation fluid used				
Any	19 (100)	52 (91)	…	…
With antibiotics	18 (95)	51 (90)	2.1 (0.2-18.8)	.7
With vancomycin	4 (21)	8 (14)	1.6 (0.4-6.2)	.99
Closure method				
Sutures plus adhesive[f]	7 (37)	13 (23)	2.0 (0.7-6.0)	.99
Sutures only	13 (68)	44 (77)	0.6 (0.2-2.0)	.99
Mean procedure time, min	42.6	35.7		.3
IV antibiotic therapy after surgery	9 (47)	37 (65)	0.5 (0.2-1.4)	.2
Antibiotic therapy after discharge	5 (26)	13 (23)	1.2 (0.4-4.0)	.99

NOTE. Data are no. (%) of patients, unless otherwise indicated. ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; ICD, implantable cardioverter-defibrillator; IV, intravenous; OR, odds ratio.

[a] Administered 30-120 minutes before incision.

[b] Versus other formulations, eg, povidone-iodine (with 0.75% available iodine).

[c] Patients could undergo multiple procedures (ie, the categories are not mutually exclusive).

[d] Patients who had a device removed and new device placed in the same site.

[e] When patient went to the OR, the device was abdominally placed (ie, the old site was abdominal).

[f] Cyanoacrylate tissue adhesive (Dermabond; Ethicon) used to replace or reinforce conventional sutures.

showed significant reduction in the concentration of microbial flora on healthy volunteers after using chlorhexidine gluconate body washes. Seal et al.[22] advocated the inclusion of such an antiseptic shower as part of a system of prevention before surgery, and the procedure has been advocated by national guidelines.[23] However, chlorhexidine gluconate was not found to reduce the incidence of SSI in a recent meta-analysis of existing studies.[24]

Twenty-two percent of the study population did not receive timely perioperative antibiotic prophylaxis (ie, within 30-120 minutes prior to incision).[25] Antibiotic prophylaxis is an established part of the standard-of-care to prevent SSI[23] and a meta-analysis has previously shown it to be efficient in reducing the incidence of SSIs in pacemaker recipients.[26] Reasons for the suboptimal timing of antibiotic prophylaxis may include anesthesiologists' lack of awareness of the importance of reducing the microbial load perioperatively, insufficient processes for ensuring preoperative administration of antibiotics, or failure to document administration properly. On the basis of substantial evidence of inconsistent perioperative administration of antibiotics, the Institute for Healthcare Improvement is advocating the intransigent and healthcare-wide implementation of ideal perioperative care practices to reduce the risk of SSI.[27]

Only a third of infected patients (37%) had wound cultures performed, which precluded a detailed examination of the microbiology of these infections. It is not surprising that coagulase-negative staphylococci and *S. aureus* were found in 4 of the 7 infections for which culture samples were obtained. These bacteria are the most common causes of cardiac device–associated infections.[28] We have no detailed information about the 2 case patients who had negative culture results. One explanation might be that they had already received antibiotics when samples were obtained, or the culturing technique might be responsible.[29] We have also no sound explanation for the low frequency of microbiological workups for case patients, other than the perception of the surgeon that superficial infections might not require culture samples to be obtained before empirical antibiotic therapy is started.

This study has some limitations. The sample size was small. We also have no data on infection rates in the respective services before January 2000 to determine the baseline infection rate. Furthermore, we did not determine the indication for implantation, or the indication for performing a procedure in the cardiothoracic operating room, nor did we observe long-term outcomes.

The results of our investigation did not identify a common source to explain the high rate of implantable cardiac device–associated infections among patients in the cardiothoracic operating rooms. The explanation for the infection rate was most likely multifactorial, particularly in light of the multiple causative organisms identified. During the course of our investigation, basic infection control measures were taken (eg, in-service training was provided to operating room staff about appropriate skin preparation procedures; also, the role of manufacturers' representatives in the operating room and the process they used for handling and passing devices to the surgeon during surgery were reviewed), and surveillance was implemented in the affected units. After implementing fundamental infection control measures in a unit not previously audited, we observed decreased infection rates.

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Potential conflicts of interest. V.J.F. reports serving as a consultant for Steris and Verimetrix and serving as a member of the speakers' bureau for Pfizer, Merck, and Cubist Pharmaceuticals. D.K.W. reports receiving research support from Sage and serving as a consultant for Enturia and 3M Healthcare. All other authors report no relevant conflicts of interest.

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