Original Article

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THE EFFECT OF REUSABLE VERSUS DISPOSABLE SURGICAL DRAPES ON IMPLANTABLE CARDIAC ELECTRONIC DEVICE INFECTIONS

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ABSTRACT

Objective: The objective of this study was to determine if a disposable draping system is superior to reusable draping material in prevention of ICEDIs and hence lowering of the infection rate even further.

Study Design: Prospective observational study

Place and Duration of Study: The study was conducted at Armed Forces Institute of Cardiology & National Institute of Heart Diseases from November 2014 to October 2015

Material and Methods: This single-center, non-randomized, observational study included all the patients who underwent cardiac electronic device implantation and were divided into two groups on the basis of type of surgical drape used i.e. Group A (disposable drapes) and Group B (reusable drapes). Patients were followed up for at least 1 year. This study was approved by the ethical review board of AFIC&NIHD.

Results: A total of 374 cardiac devices were implanted over a period of one year. Group A comprised of 135 (36%) patients and group B comprised of 239 (64%) patients. The cumulative rate of ICEDI was calculated to be 6.6% (25 out of 374), with infection rate of 2% (5 out of 239) for group B while 14.8% (20 out of 135) for group A. A significantly greater rate of infection was reported for group A as compared to group B (p 0.0001).

Conclusion: In conclusion, efficiency of disposable surgical drapes has not been demonstrated to lower infections rates in fact to the contrary we demonstrated increase in infection rate.

Keywords: Implantable cardiac device infections, Implantable cardiac devices, Surgical drapes.

INTRODUCTION

Implantable cardiac electronic devices (ICEDs) include pacemakers for bradyarrhythmia treatment, implantable cardioverter defibrillators (ICDs) for tachyarrhythmia management, and cardiac resynchronization therapy (CRT) devices for systolic dysfunction with conduction delays[1]. The use of ICED is increasing worldwide, with over 3 million PPM and 250,000 ICD in use. Rate of implantation is increasing with rise in co-morbid conditions, aging of general population, expanding indications and increasing availability of implanting physicians[2,3]. Like any other foreign body, ICEDs can become infected. According to a recent meta-analysis the average device infection rate ranges between 1–1.3%[4]. ICED infections can be extremely challenging to diagnose and manage, and can involve any combination of the generator pocket, leads and endocardial structures. Infections are usually associated with significant morbidity and mortality which can compromise the intended benefits[5].

ICED infections can appear as early post-implantation inflammation, uncomplicated and complicated generator pocket infections, ICED-infective endocarditis and ICED-lead infections[6]. Pocket infections are characterized by swelling, discharge, localized cellulitis, dehiscence or pain. Wound inflammation occurring soon after implantation can be an early sign of pocket infection. The device should be considered infected once the skin is breached due to erosion[7]. ICED infections can be minimized by performing the implantation procedures in compliance with aseptic techniques, in an appropriately ventilated, equipped and cleaned room. This is a well established fact that complying with aseptic technique, carefully preparing the procedure field and using sterile products are crucial for

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minimizing occurrence of infection[8].

Surgical drapes are an important component of surgical items being used during device implantation. A surgical drape is defined as sterile fabric or fabric-like material used to isolate the surgical site from the rest of the body and other possible sources of contamination. Drapes are used during invasive procedures to maintain sterility of environmental surfaces, equipment, and provide patients safety by minimizing the spread of infectious agents. Drapes are recommended by the CDC to reduce surgical site infections[9]. The characteristics of an ideal surgical drape are well defined by AST

Table-1: Clinical and demographic characteristics of group A and group B.

S.No.	Variables	GroupA (disposable drape) N = 135 (36%)	Group B (reusable drape) N = 239 (63.9%)
1	Age	66.0 ± 14.5 years	63.4 ± 12.5 years
2	Gender		
	Males	84 (62.2%)	141 (58.9%)
	Females	51 (37.7%)	98 (41%)
3	Co-morbid conditions		
	Coronary artery disease	52 (38.5%)	82 (33.4%)
	Hypertension	68 (50.3%)	114 (47.6%)
	Diabetes Mellitus	64 (47.4%)	122 (51)%
	Chronic obstructive pulmonary disease	6 (4.4)%	16 (0.66%)
4	**Devices**		
	• Pacemakers	123 (91.1%)	222 (92.8%)
	• ICDs	11 (8.14%)	14 (5.8%)
	• CRTDs	1 (0.7%)	3 (1.2%)
5	**Therapy mode:**		
	• Single chamber	30 (22.2%)	59 (24.6%)
	• Dual chamber	105 (77.7%)	180 (75.3%)
6	**Indications**		
	• Complete heart block	95 (70.3%)	183 (76.5%)
	• Sick sinus syndrome	28 (20.7%)	39 (16.3%)
	• Dilated cardiomyopathy	10 (7.4%)	15 (6.2%)
	• Ventricular tachycardias	12 (8.8%)	17 (7.1%)

Table-2: Clinical presentation and signs & symptoms of patients with implantable cardiac electronic device infections (n = 27).

S.No.	Variables	Group A (disposable drape) N = 20 (14.8%)	Group B (reusable drape) N = 5 (2%)
1	Clinical presentation		
	• Pocket infection	8 (40%)	1 (20%)
	o With bacteremia	12 (60%)	4 (80%)
	o Without bacteremia		
	• Haematoma	4 (20%)	1 (20%)
	• Device / lead erosion	3 (15%)	1 (20%)
2	Signs & symptoms		
	• Fever (>38 ˚C)	12 (60%)	4 (80%)
	• Erythema	15 (75%)	5 (100%)
	• Pain at generator site	12 (60%)	4 (80%)
	• Swelling at generator site	20 (100%)	3 (60%)
	• Pus drainage	12 (60%)	2 (40%)
3	Laboratory abnormalities		
	• Leukocytosis (TLC >10x109 / L)	8 (40%)	3 (60%)
	• Positive blood culture	8 (40%)	1 (20%)

Education and Professional Standards Committee and have been approved by the AST Board of Directors. Drapes should be sterile; free of holes, tears and punctures; resistant to fluid penetration; lint free and flame resistant[10].

Surgical drapes are either reusable or disposable in nature. These two basic types of drapes have different advantages and disadvantages. There is considerable variation in design and performance characteristics which reflects the necessary trade-offs in economy, comfort, and degree of protection required for particular surgical procedures. Reusable drapes are relatively more permeable to fluids because they are most commonly constructed of tightly woven or knitted fabric, whereas on the other hand disposable drapes are made up of nonwoven materials that offer increased protection from liquid penetration[12].

Studies investigating single-use gowns and drapes versus reusable gowns report conflicting evidence[13]. Only limited data are available regarding currently available products. So, we designed a prospective comparative study to have an insight on rates of infection occurring in two different types of surgical drapes.

MATERIAL AND METHODS

All the patients who underwent cardiac electronic device implantation (either new or replacement) at Armed Forces Institute of Cardiology & National Institute of Heart Diseases from November 2014 – October 2015 were enrolled in this study. Patients were divided into two groups on the basis of type of surgical drape used during the implantation procedure i.e. Group A (disposable drapes) and Group B (reusable drapes). There were no significant differences in patients demographic data, procedural data, or the type of procedure performed between groups. Choice of drape was not influenced in any matter and it was totally left on availability, cost effectiveness and operator's will. Patients were observed for at least 7 days during their in-hospital, after device implantation, for development of any acute infections. Similarly, after discharging from the hospital, all of the patients were followed up during their routine visits to the out-patient unit of cardiac electrophysiology department for tracking of chronic infections.

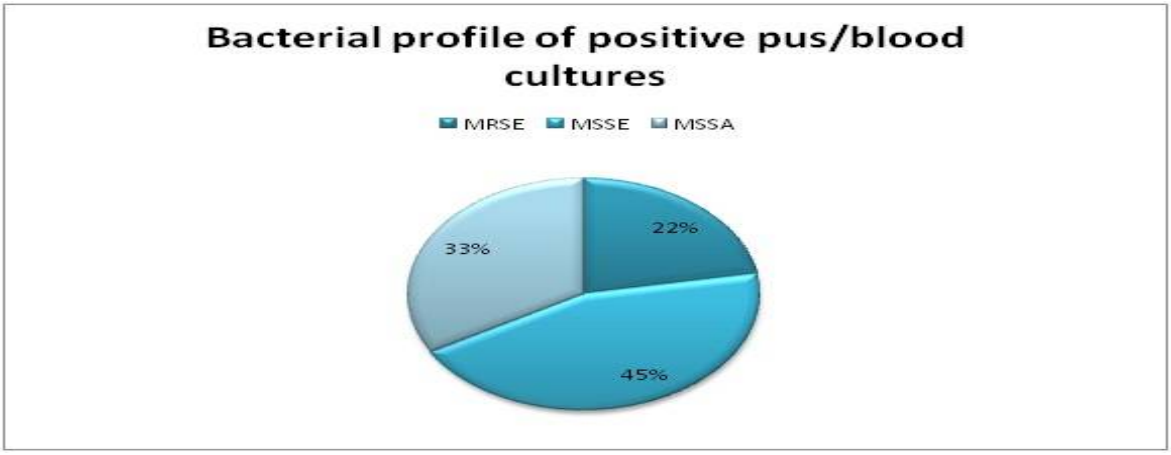

Figure-1: Bacterial profile of cumulative isolates from positive pus/blood cultures of Group A and B (n=8). Where, MRSE=Methicillin-resistant Staphylococcus epidermidis, MSSE= Methicillin-sensitive Staphylococcus epidermidis, MSSA=Methicillin-sensitive Staphylococcus aureus.

All the patients who fulfilled the criteria for implantable cardiac device infection, recruited from in-hospital wards and out-patient unit were included in analysis[5]. Infected patients were diagnosed and managed according to guidelines provided by American Heart Association in 2010[13]. Patient confidentiality was protected at all the times and an informed consent was signed by each participant prior to the participation in the study. This study was approved by the ethical review board of AFIC&NIHD.

The data were entered in IBM SPSS Statistics software (version 19). Results from continuous data were expressed as median and mean along with standard deviation values. Proportions were expressed as percentages with confidence intervals of 95%. Two groups were compared with either chi-square test or a non-parametric Fisher's exact test. Similarly groups of continuous variables were compared by using student's t-test or a non-parametric Wilcoxon - Mann - Whitney test.

RESULTS

Demographics

A total of 374 cardiac electronic devices were implanted over a period of one year (from November 2014 to October 2015) at AFIC&NIHD. Group A comprised of 135 (36%) patients for whom disposable drapes were used. Similarly, Group B comprised of 239 (64%) patients where reusable drapes were used.

The median age of patients in group A was 66 ± 14.5 years (range 25 - 92 years), whereas for group B it was 63.4 ± 12.5 years (range 27 - 81 years) years. 84 (62.2%) study participants were males in group A and 141 (58.9%) in group B, similarly 51 (37.7%) and 98 (41%) study participants were females in group A and B respectively. Table-1 summarizes the demographic and clinical characteristics of study subjects included in two groups.

Clinical characteristics

For group A cardiac devices included 123 (91.1%) pacemakers, 11 (8.14%) ICDs and 1 (0.7%) CRTDs, while in group B 222 (92.8%), 14 (5.8%) and 3 (1.2%) pacemakers, ICDs and CRTDs were implanted. 105 (77.7%) patients underwent dual-chamber cardiac device implantations while remaining 30 (22.2%) of the patients had single chamber implants in group A whereas in group B there were 180 (75.3%) dual chamber and 59 (24.6%) single chamber implants. Indications for initial device implantation included complete heart block 95 (70.3%), sinus node dysfunction 28 (20.7%), ventricular arrhythmias 12 (8.8%), and dilated / ischemic cardiomyopathy 10 (7.4%) in group A. In group B main indications for device implantation included complete heart block 183 (76.5%), sinus node dysfunction 39 (16.3%), ventricular arrhythmias 17 (7.1%), and dilated / ischemic cardiomyopathy 15 (6.2%).

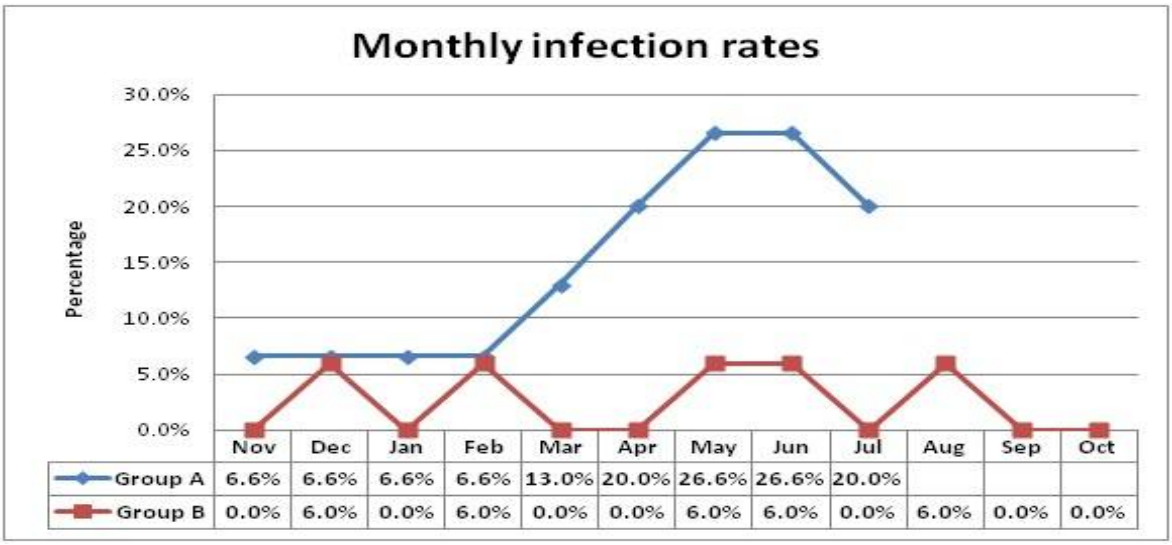

Figure-2: Comparison of monthly infection rates in Group A and Group B over a period of one year (Nov 2014 to Oct 2015).

Implantable cardiac electronic device infections

27 out of 374 (6.6%) cases of implantable cardiac electronic device infections occurred and all of them fulfilling the case definition were included in the study. 24 out of 27 (88.8%)

infected patients were diabetic. In group A, 20 out of 135 (14.8%) patients developed implantable cardiac electronic device infections, where as in group B, 5 out of 239 (2%) infected cases were observed. The number of infections in group A was significantly higher as compared to group B with a *p*-value of 0.0001.

Acute infections occurred in 10 (50%) patients of group A with fresh implants; while 2 (10%) acute infections occurred with re-implants due to generator replacements, system upgrades and lead repositions. In group B there was only 1 (20%) acute infection due to fresh implant. Chronic implantable cardiac device infections were observed in 8 (40%) patients in group A, where median time from device implantation to infection was 31.7 ± 55 days. For group B, chronic implantable cardiac device infections were observed in 4 (80%) cases with median time from device implantation to infection was 96.7 ± 75 days.

Microbial profile of implantable cardiac electronic device infections

Pocket infection with positive pus/blood culture growth 8 out of 20 (40%) [Group A], 1 out of 5 (20%) [Group B] or with negative pus/blood culture growth 12 out of 20 (60%) [Group A], 4 out of 5 (80%) [Group B] was the most common clinical presentation. In group A, Methicillin-sensitive Staphylococcus aureus (MSSA), Methicillin-resistant Staphylococcus epidermidis (MRSE) and Methicillin-sensitive Staphylococcus epidermidis (MSSE) were isolated in 3 (37.5%), 2 (25%) and 3 (37.5%) out of 8 positive pus/blood culture growths respectively. For group B the only positive pus/blood culture growth isolate was Methicillin-sensitive Staphylococcus epidermidis (MSSE) as shown in fig-1. It has been observed that majority of the infections caused by Staphylococcus epidermidis species occur > 2 weeks after device implantation while most of the infections caused by Staphylococcus aureus species occur within 2 weeks of device implantation (*p* 0.03)

The device was explanted in 8 (40%) patients in group A while 2 (40%) patients in group B presented with signs of inflammation/infection. All patients received intravenous antimicrobials right after they were admitted in the hospital with signs of infection. Most patients remained on antibiotics for 2 weeks after removal of infected device. All of the generator re-implantations were done on the opposite side of the infected pocket.

Infection rates

The cumulative rate of ICEDI was calculated to be 6.6%, with infection rate of 14.8% for group A while 2% for group B. Monthly infection rates for group A and group B are shown in fig-2. A significantly greater rate of infection was reported for group A as compared to group B (*p* 0.001). As the study progressed, a significantly rising trend of infection was observed in group A. At the point when infection rate shot to 26.6% in the month of April, we deliberately had to stop the usage of disposable drapes and the study was terminated. All the SOPs and procedures followed during device implantation were cross-checked for any recent changes that might have caused sudden fluctuation in infection rates. But all of the procedures were being followed in usual manner except the difference in type of drape for both the groups. A significant decrease in infection rates was observed after switching to reusable drapes.

DISCUSSION

Implantable cardiac electronic device infection remains a serious challenge, despite improvement in device design, implantation technique and prevention strategies. Rates of ICEDI ranges between 1 – 1.3% [4, 14]. In our study, the overall rate of (ICEDI) was 6.6% (25/374), with an infection rate of 14.8% for disposable drapes and 2% for reusable surgical drapes.

Most patients with (ICEDI) present with only localized inflammatory signs at the generator pocket, and a lack of systemic signs should not sway clinicians away from a suspicion of (ICEDI). Nonspecific laboratory abnormalities such as leukocytosis, anemia, and high sedimentation rate were present in less than one-half of the cases. In the current study Coagulase-negative staphylococci (CoNS) and Staphylococcus aureus are the most common

causes of ICEDIs[15-17]. In our study the most common identified organism was staphylococcus species including 33.3% of Staphylococcus aureus isolates and 66.6% Staphylococcus epidermidis isolates. Staphylococcal species account for more than two-thirds of (ICEDI) cases in most published series[1-5,17,18].

The use of sterile gowns and drapes in the operating room has been a standard infection control practice to prevent SSIs, because they act as barriers to bacteria that are shed by the patient or the surgical team members into the open wound during the operation. Studies investigating single-use gowns and drapes versus reusable gowns report conflicting evidence in terms of infection rates[13]. At our institution sterilized reusable drapes were in practice because of their cost effectiveness[16,19] and easy availability. In order to study whether we can further reduce the infection rate and to check the feasibility and acceptance of disposable surgical drapes, a prospective study was designed and conducted. To cut off the price, disposable drapes were bought in bulk. As the study progressed, a significant number of infections started to occur in patients for whom disposable drapes were used. As an unacceptably high number of infections came into notice the study was terminated and the use of disposable drapes was ceased. By stopping the use of disposable drapes, rate of infection reduced significantly. Before drawing this conclusion all processes were cross-checked in order to rule out other possible incriminating factors.

CONCLUSION

In conclusion, efficiency of disposable surgical drapes has not been demonstrated to lower infections rates in fact to the contrary we demonstrated increase in infection rate.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author

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