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Cardiology

# PACEMAKER POCKET TOILETING BY ANTIBIOTIC SOLUTION AND PACEMAKER POCKET INFECTION RATE

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**ABSTRACT** **Objectives:** Cardiac implantable electronic device(CIED) infections now constitute ~10% of all endocarditis cases. The incidence of CIED infection is usually <2%. Pacemaker pocket toileting by antibiotic solution is presumed to prevent pacemaker pocket contamination by microorganism.

**Methods:** Two thousand and two hundred patients were studied over a period of five years from 2011 to 2016. There were 1096 patients in study group and 1104 patients in control group. Pacemaker pockets were toileted by gentamicin solution in study group and nothing was used in control group.

**Results:** Pacemaker pocket infection occurred in 33 patients (1.5%). Seventeen patients in study group and sixteen patients in control group have suffered from pacemaker pocket infection. There were no statistical difference between study and control group in relation to pacemaker pocket infection rate.

**Conclusion:** Our data suggest that pacemaker pocket toileting by antibiotic solution have no role in preventing pacemaker pocket infection

**KEYWORDS :** Cardiac Pacemaker, Pacemaker Pocket Infection, Pacemaker Pocket Toileting By Antibiotic Solution

**Introduction:**

Permanent pacemaker was introduced in clinical practice since 1960s. Incidence of pacemaker pocket infection varies between 1-12.5%.(1) Lead dislodgement, vascular injury, pocket hematoma and pocket infection are common short term complications after permanent pacemaker implantation. Long term complications include lead fracture,

insulation failure, premature battery depletion and pocket infection. Pacemakers have both intravascular and extravascular components. Infection can occur in pacemaker pocket, pacing leads and native cardiac structures or various combinations. Several factors are implicated for pocket infection. Hypothesis is that pacemaker pocket toileting by gentamicin solution can prevent pocket infection. Our objective is to study whether pacemaker pocket toileting by antibiotic solution has any role in preventing pocket infection or not.

**Methods:**

Our centre is an university medical college hospital covering five districts of our state. Twenty two hundred patients were studied over a period of five years from January 2011 to December 2016. Informed consents were taken from all patients and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki with prior approval by institution's human research committee. This was a case control study. There were 1096 patients in study group and 1104 patients in control group. Last patient was enrolled in January 2015. Minimum follow up was one year and maximum was six years. Common risk factors like patients with diabetes, repeat procedure, chronic renal failure, chronic obstructive airway disease, immunosuppressive agents were selected equally in both groups. Different pacemaker type(single/dual chamber), male/female patients ratio were also matched in two groups. Three layers closure technique were followed for skin closure. Non absorbable monofilament suture material had been used for lead fixation and absorbable suture material were used for skin closure.

Pre and perioperative antibiotics were also given in every case. Pacemaker pockets were of liberal size and proper hemostasis were secured in all implantations. Gentamicin solution was used for pocket toileting in control group but nothing was used in study group.

**Statistical methods:**

For statistical analysis, Med Calc software for windows was used to compare the incidence rate and obtain the associated P value . A P value of less than .05 was taken as significant.

**Results:**

Majority of our implantations were single chamber pacemaker. One thousand and fifty four(70%) implantations were single chamber pacemaker and six hundred sixty (30%) were double chamber pacemaker. There were one thousand five hundred eighty four(72% ) male patients and six hundred sixty(28%) female patients. Sub pectoral pockets were done in two hundred twenty patients(10 %) of cases. It was necessary in patients with thin built stature. Many patients were suffering from different associated diseases in our study. Chronic renal failure patients were one hundred thirty in study group and one hundred twenty four in control group(11.5%). There were three hundred fifty six diabetic patients in study group and three hundred fifty in control group(32%).Repeat procedure was done in ninety five patients in study group and ninety patients in control group(9%). Eighty six patients were suffering from chronic obstructive airway disease in study group and eighty two were in control group(7%). Patients on immunosuppressive therapy were fourteen in study group and ten in control group (1.09%). Fifty four patients had pacemaker pocket haematoma in study group(4.9%) and fifty patients(4.5%) in control group. Pacemaker pocket haematoma was statistically similar in both groups.

Pacemaker pocket infection occurred in thirty three patients. Seventeen patients in study group and sixteen patients in control group suffered from pocket infection. Incidence of pacemaker pocket infection in our study was 1.5%.

**Table 1. Different population characteristics**

| Category of sample | Study group | Control group | Percentage study group | Percentage control group |
|---|---|---|---|---|
| Male | 789 | 798 | 72 | 72.5 |
| Female | 307 | 304 | 28 | 27.5 |
| Single chamber pacemaker | 760 | 768 | 69 | 70 |
| Double chamber pacemaker | 336 | 334 | 31 | 30 |
| Age(20-50) | 218 | 222 | 19.8 | 20.1 |
| Age (50-80) | 791 | 790 | 72 | 71.6 |
| Age >80 | 87 | 90 | 7.93 | 8.1 |

**Table 2. Different types of infection in two groups**

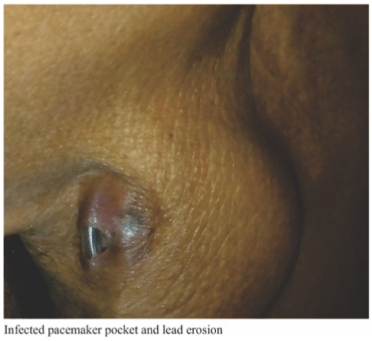
| Types of infection | Study group | Control group |
|---|---|---|
| Type1 | 4 | 5 |
| Type 2 | 3 | 4 |
| Type 3 | 5 | 3 |
| Type 4 | 3 | 4 |
| Type 5 | 1 | 1 |

**Table 3. Different risk factors and comparison of infection rate for each**

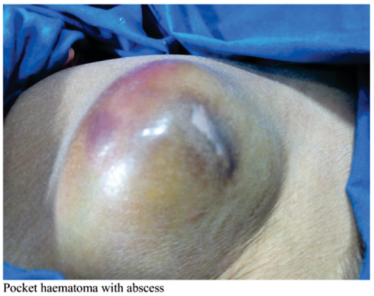
| Category of sample | Frequency | | percentage | | | | Difference between the two rates and associated P value |
|---|---|---|---|---|---|---|---|
| | Study group | Control group | Study gr | Control gr | No of infection in study group | No of infection in control group | P value |
| Diabetes | 356 | 350 | 16.18 | 15.90 | 4 | 5 | 0.719 |
| Chronic renal failure | 130 | 124 | 5.90 | 5.64 | 3 | 2 | 0.693 |
| Repeat procedure | 95 | 90 | 27.74 | 28.64 | 6 | 7 | 0.707 |
| Chronic obstructive airway disease | 86 | 82 | 7.8 | 7.4 | 2 | 2 | 0.962 |
| Immuno suppressive therapy | 14 | 10 | 1.2 | .9 | 1 | 1 | 0.811 |

**Table 4. Study and control group infection rate comparison**

| Group | Frequency of infection | Rate of incidence | Incidence rate ratio | P value |
|---|---|---|---|---|
| Control group | 17 | .0154 | 0.948 | 0.8782 |
| Study group | 16 | .0146 | | |



Infected pacemaker pocket and lead erosion



Pocket haematoma with abscess

From Table 3 it is seen that the difference in the rate of infection between the study and control group was compared for each risk factor separately. The difference in the rate of infection was not statistically significant between the two groups. This was true for all the risk factors.

Taking all the cases in the present series, it was seen that the difference in rate of infection was not statistically significant between the two groups[ p=0.878 ( Table 4)]

**Discussion:**

Permanent pacemakers have been used for over 50 years. infection is a serious complication of cardiac device implantation and is associated with increased morbidity, mortality, and healthcare costs. In- hospital mortality rates have been reported to be 3.7–11.3%.(2)The standard-of-care requires device removal and systemic antibiotic therapy. The additional admission costs of an infected device can exceed $15 000 in the USA and €7000 in Europe.(3) An analysis of the Nationwide Inpatient Sample discharge records from 1993 through 2008 showed a 96% increase in Cardiac implantable electronic device(CIED) implantations in the USA. During the same period, the incidence of CIED infection increased by 210% (from 1.5% in 1993 to 2.4% in 2008).(4) Pacemaker pocket infection rate varies between 1-12.5%.(5) In our institution, infection rate was 1.5%. Multicenter U.S. and European data from the MOST (Mode Selection in Sinus Node Dysfunction Trial) and FOLLOWPACE (Cost-Effectiveness of Routine Follow-up Visits in Patients With a Pacemaker) studies report 30- and 60-day complication rates of 4.8% and 12.4%, respectively, and 3-year and 5-year complication rates of 7.5% and19.7%,respectively. Short- term complication of single- and dual-chamber pacemakers include lead revision (2.5% and 3.7%), infection (1.2% and 1.1%), cardiac perforation (0.3% and 0.6%), venous thrombosis (0.4% and 0.5%), pocket complications (0.3% and 0.3%), and generator complications (0.1% and 0.1%). Lead removals, which comprise 1.4% of all lead- related complications, were associated with infection in 22.9% of the cases.(6)

Permanent pacemakers are implanted commonly through cephalic vein or subclavian vein, rarely via jugular or axillary vein. Pulse generator is kept in pacemaker pocket which requires extensive fascial plane dissection. Dissected tissue and skin should be closed properly for better wound healing. Wound contamination by microorganism is the root cause of early or primary infection. Secondary infection may be caused by wound or device seeding by blood borne organisms. Gentamicin is an amino glycoside antibiotic.Many operators use gentamicin solution to toilet the subcutaneous pocket at the time of device implantation. (7) Early El Cajone and University of Oklahoma experience of combination of prophylactic systemic antibiotics and topical pocket irrigation with povidone-iodine has been reported useful in the prevention of infection.(8) Early infections after pacemaker implantation are thought to result from wound contamination at the time of surgery and most of these seem to happen within the first sixty days after the implantation.

Pacemaker pocket irrigation by antibiotic solution is believed to reduce pacemaker pocket contamination by micro organism. Thereby infection rate can be reduced.

Two thousand five hundred and sixty four patients were studied by Dhanunjaya Lakkireddy el al over a period of eight years who had either new device implantation and or lead/generator replacement. Of these patients, 1,359 (53%) had their pockets irrigated with povidone-iodine solution versus 1,205 (47%) with saline, prior to device placement.

Eighteen patients (0.7%) developed pocket infection.(9) In their series 33% had diabetes, 5% had renal insufficiency, 7% had autoimmune disorders, and 17% were on systemic steroids. In our series 11.5% had chronic renal failure, 32 % had diabetes, 9% had repeat procedure, 7 % had chronic obstructive airway disease and 1.2 % patients were on immune suppressive therapy. Pacemaker pocket infection occurred in 33 patients (1.5%) in our series.

Seventeen patients in study group and sixteen patients in control group have suffered from pacemaker pocket infection. There were no statistical difference between study and control group in relation to pacemaker pocket infection rate.

Pacemaker pocket infection is characterized by localized erythema, cellulitis, swelling or pain over the pocket. It may progress to wound dehiscence, purulent discharge, skin erosion or sinus formation. There are different classification of pacemaker pocket infection.Type1) Spreading cellulitis affecting the generator site. Type 2) Incision site purulent exudate (excluding simple stitch abscess). Type 3) wound dehiscence. Type 4) erosion through skin with exposure of the generator or leads. Type 5) abscess or fistula formation. Complicated pocket infection is associated with evidence of lead or endocardial involvement, systemic signs or symptoms of infection or positive blood cultures. Gram-positive bacteria were by far the most commonly isolated microorganisms(67%). Coagulase negative staphylococci is the most consistently isolated bacteria followed closely by *Staphylococcus aureus.* Gram-negative bacilli were isolated in 1%–17% of patient episodes. Fungal infection is uncommon, occurring in no more than 2% of patients.(10) An important finding of a

study by Sohail MR et al is that 50% of pocket infections occurred late or a full year after pocket manipulation and most were due to coagulase-negative staphylococci (CoNS).Unlike infections due to staphylococcus aureus, infections due to CoNS are more indolent and present with subtler findings. This suggests that CoNS infections were likely acquired during pocket intervention.(11)

A variety of patient characteristics and procedural issues have been associated with pacemaker infections. Konstantinos A el have described several risk factors for infection in their study.(12)

Regarding host-related factors, the most significant predictors of infection are diabetes mellitus (OR 2.08), end-stage renal disease (OR 8.73), COPD (OR 2.95), corticosteroid drug use (OR 3.44), history of previous device infection (OR 7.84), renal insufficiency (OR 3.02), malignancy (OR 2.23) and congestive heart failure (OR 1.65).

Other significant host factors include New York Heart Association (NYHA) functional class ≥2, fever prior to implantation, oral anticoagulation, heparin bridging, and chronic skin disorders. Regarding procedure-related factors, post-operative haematoma (OR 8.46), reintervention for lead dislodgement (OR 6.37), device replacement/revision (OR 1.98), lack of antibiotic prophylaxis (OR 0.32 ), temporary pacing (OR 2.31), generator change (OR 1.74), inexperienced operator (OR 2.85) and increased procedure duration were all significant predictors of CIED infection. Among device-related characteristics, abdominal generator pocket (OR 4.01), the presence of epicardial leads (OR 8.09) , positioning of two or more leads (OR 2.02), and dual-chamber system (OR 1.45) were predictors of CIED infection. Post-operative haematoma has been repeatedly associated with the risk for CIED infections and was a strong predictor of infection in their analysis.

**Conclusion:**

Pacemaker pocket toileting by antibiotic solution is a popular practice. But our data suggest that it does not have any role in preventing pacemaker pocket infection rate. During implantation, there is a risk of device contamination with the patient's own skin flora, introduced into the wound at the time of skin incision and it can be prevented by ideal surgical asepsis technique, pre and perioperative use of antibiotics.

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