

# Pacemaker pocket infection rate and suture technique

## Kalp pili cebi enfeksiyon oranı ve dikiş tekniği

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### ABSTRACT

**Objective:** The incidence of cardiac implantable electronic device (CIED) infection is usually <2%. The interrupted suture technique is thought to be better than a continuous suture in order to prevent pacemaker pocket infection. The aim of this study was to determine if there was a correlation between the suture techniques and the pacemaker wound infection rate.

**Methods:** The data of 2200 patients from the 5-year period of 2011 to 2016 were studied. There were 1096 patients in the study group and 1104 patients in the control group. Continuous sutures were used in the study group and interrupted sutures were used in the control group.

**Results:** Pacemaker pocket infection occurred in 33 patients (1.5%). Seventeen patients in the study group and 16 patients in the control group developed a pacemaker pocket infection. A pacemaker pocket hematoma was seen in 54 patients in the study group (4.9%) and 50 patients in the control group (4.5%).

**Conclusion:** Use of the continuous or interrupted suture technique for wound closure had no significant role in the prevention of pacemaker pocket infection.

A pacemaker pocket infection is a very serious complication in patients with a permanent pacemaker. The incidence of pacemaker pocket infection varies between 1% and 12.5%.<sup>[1]</sup> Lead dislodgement, vascular injury, pocket hematoma, and pocket infection are common short-term complications after permanent pacemaker implantation. Long-term complications can include lead fracture, insulation failure, premature battery depletion, and pocket infection.<sup>[2]</sup> Pacemakers have both intravascular and extravascular components. Infection can occur in the pacemaker pocket, pacing leads, native cardiac structures, or

### ÖZET

**Amaç:** Kardiyak implante edilebilir elektronik cihaz (KİEC) enfeksiyonunu %2'den düşük insidanda görülmektedir. Kalp pili cep enfeksiyonunu önlemede tek tek atılan dikişlerin devamlı dikişten daha iyi olduğu düşünülmektedir. Bu çalışmanın amacı, dikiş teknikleriyle kalp pili enfeksiyon oranı arasında bir ilişki olup olmadığını belirlemektir.

**Yöntemler:** 2011-2016 yılları arası 5 yıllık dönemde 2200 hastanın verileri incelendi. Çalışma grubunda 1096 ve kontrol grubunda 1104 hasta bulunuyordu. Çalışma grubunda sürekli dikiş ve kontrol grubunda tek tek dikiş atma kullanıldı.

**Bulgular:** Kalp pili cep enfeksiyonu 33 (%1.5) hastada oluşmuştu. Çalışma grubunda 17 ve kontrol grubunda 16 hastada kalp pili cep enfeksiyonu gelişmişti. Çalışma grubunda 54 (%4.9) ve kontrol grubunda 50 (%4.5) hastada hematoma görüldü.

**Sonuç:** Yara kapanmasında devamlı veya tek tek dikiş atma tekniğinin kalp pili cep enfeksiyonunu önlemede herhangi bir anlamlı rolü olmamıştır.

various combinations of these sites.

A wide skin incision and extensive tissue dissection are required for pacemaker implantation. A pacemaker wound can be closed with a continuous suture or an interrupted suture. The interrupted suture technique is presumed to be better than a continuous suture to prevent pocket infection. The objective of this study was to examine whether

### Abbreviations:

CIED	Cardiac implantable electronic device
COPD	Chronic obstructive pulmonary disease
INR	International normalized ratio
OR	Odds ratio

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the suture technique had any role in the incidence of pacemaker pocket infection.

## METHODS

The study was conducted at a university medical college hospital covering 5 districts of our state. The records of a total of 2200 patients from a period of 5 years, from 2011 to 2016, were studied. Informed consent was obtained from all of the patients and the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Approval was granted by the Burdwan Medical College human research committee. There were 1096 patients in the study group and 1104 patients in the control group. The participants were properly matched and randomized.

This was a case control study. All of the implantations were performed by assistant and associate professors from the cardiology and cardiothoracic surgery department. All of the patients received antibiotics in the pre-, peri-, and post-operative period. The antibiotics protocol of the institution consists of intravenous administration of antibiotics (ampicillin/clavulanic acid 1.2 gm thrice daily and linezolid 600 mg twice a day) on the day of the operation and the first post-operative day. The patients were discharged on the second post-operative day. They were put on the same oral antibiotics for 3 days.

Pacemaker implantation was performed for patients who were on oral anticoagulation medication without interruption of anticoagulation if their international normalized ratio (INR) was  $<3$ . No surgery was performed in any patient until the INR was  $<3$ . A few patients were on dual antiplatelet therapy following stent implantation. Pacemakers were implanted without discontinuing the use of antiplatelets if a drug-eluting stent had been implanted within 6

months. Otherwise either aspirin 150 mg/day or clopidogrel 75 mg/day was administered as needed before the procedure.

A continuous suture was used in the study group and an interrupted suture was applied in the control group. A 3-layer closure technique was used for skin closure. Non-absorbable monofilament suture material (Prolene 2.0; Ethicon, Inc., Somerville, NJ, USA) was used for lead fixation, and absorbable non-braided suture material (Monocryl 2.0; Ethicon, Inc., Somerville, NJ, USA) was used for skin closure. Standard, meticulous surgical asepsis methods were observed in all cases. Pre- and peri-operative antibiotics were administered in every case. The pacemaker pockets were of liberal size and proper hemostasis was secured in all of the implantations.

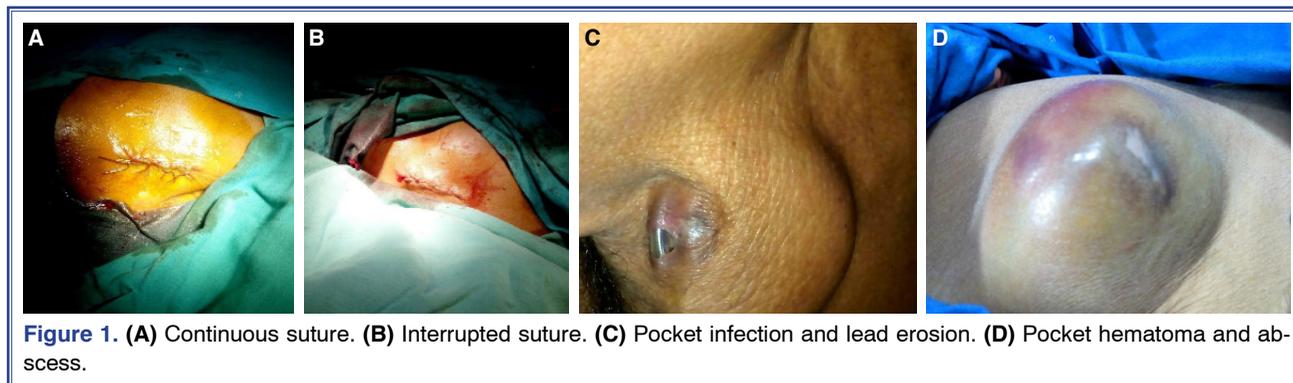
## Statistical methods

Med Calc statistical software (MedCalc Software, Ostend, Belgium) was used to compare the incidence rate and obtain the associated p value. A p value  $<0.05$  was considered significant.

## RESULTS

Of the implantations in this study, 1054 (70%) were a single-chamber pacemaker and 660 (30%) were double-chamber pacemakers. There was a clear male predominance among the patients: 1584 (72%) were male while 660 (28%) were female. Subpectoral pockets were created in 220 patients (10%). It was determined to be necessary in thin patients.

Many of the patients had comorbidities. There were 130 patients with chronic renal failure in the study group and 124 in the control group (11.5%). There were 356 diabetic patients in the study group and 350 in the control group (32%).



**Figure 1.** (A) Continuous suture. (B) Interrupted suture. (C) Pocket infection and lead erosion. (D) Pocket hematoma and abscess.

**Table 1. Characteristics of the study group and control group**

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 years)	218	222	19.8	20.1
Age (50–80 years)	791	790	72	71.6
Age >80 years	87	90	7.93	8.1

**Table 2. Incidence of different types of infection**

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

A repeat procedure was performed in 95 cases in the study group and 90 in the control group (9%). Chronic obstructive pulmonary disease (COPD) was present in 86 patients in the study group and 82 in the control group (7%). There were 14 patients on im-

munosuppressive therapy in the study group and 10 in the control group (1.09%).

In all, 54 patients had a pacemaker pocket hematoma in the study group (4.9%) and there were 50 (4.5%) in the control group. The incidence of pacemaker pocket hematoma was statistically similar in the 2 groups. A pacemaker pocket infection occurred in a total of 33 patients: 17 patients in the study group and 16 patients in the control group. The incidence of pacemaker pocket infection in our study was 1.5%.

Table 3 illustrates the difference in the rate of infection between the study group and the control group when risk factors were compared. The difference in the rate of infection was not statistically significant

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

Group	Frequency of infection (n)	Rate of incidence	Incidence rate ratio	<i>p</i>
Control group	17	0.0154	0.948	0.8782
Study group	16	0.0146		

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

Category of sample	Frequency		Percentage		Difference between the rates and associated <i>p</i> value		<i>p</i>
	Study group	Control group	Study group	Control group	No of infection in study group	No of infection in control group	
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 pulmonary disease	86	82	7.8	7.4	2	2	0.962
Immunosuppressive therapy	14	10	1.2	0.9	1	1	0.811

\*Difference between the two rates and associated *p*-value.

between the 2 groups. This was true for all of the risk factors.

Evaluation of all of the cases in the present series indicated that the difference in the rate of infection was not statistically significant between the 2 groups ( $p=0.878$ ) (Table 4).

## DISCUSSION

Permanent pacemakers are commonly implanted through the cephalic vein or the subclavian vein, and rarely, via the jugular or axillary vein.<sup>[3]</sup> A pulse generator is maintained in the pacemaker pocket, which requires extensive fascial plane dissection. Dissected tissue and skin must be closed properly for better wound healing. There are different techniques of wound closure; however, a 3-layer wound closure method is typically used. The first layer consists of deep fascia and muscle. Subcutaneous tissue is the second layer, and skin constitutes the final layer. Non-absorbable sutures were used for lead fixation in this study, and absorbable monofilament sutures were used for skin closure. When using the continuous suture technique, all of the layers are closed simultaneously without cutting the suture material. In the interrupted suture method, the 3 layers are closed separately. Interrupted sutures are believed to be a better method of skin closure that leads to better wound healing and less pocket hematoma formation. The interrupted suture technique leaves little or no dead space for pocket hematoma formation and skin apposition is better. The continuous suture technique is technically demanding and requires more expertise. It may lead to improper skin apposition, causing poor wound healing. This method may also preserve more dead space in the tissue plane or pocket for hematoma formation.

A repeat procedure is always more difficult because it involves most extensive tissue dissection through the fibrous capsule of the previous pacemaker pocket.<sup>[4]</sup> Infection is a dreaded complication in patients with a permanent pacemaker. It increases morbidity, mortality, and healthcare costs.<sup>[5]</sup> The reported pacemaker pocket infection rate varies between 1% and 12.5%. In our institution, the infection rate was 1.5%. There was no significant statistical difference between the continuous and interrupted suture groups. The rate of pocket hematoma was also similar in both the study group and the control group (4.9% vs 4.5%, respectively).

The infection rate may differ significantly according to whether or not the patient develops a pacemaker pocket hematoma. Lee et al.<sup>[6]</sup> found that the incidence of infection was 11% in patients with a pocket hematoma and 1.5% in those who did not have a pacemaker pocket hematoma. It can be inferred from their study that pocket hematoma and poor wound healing are 2 important contributors to pacemaker pocket infection. In our study, pocket hematoma was observed in 35% of infected patients in the study group and 31% of infected patients in the control group. Gleva and Poole<sup>[7]</sup> demonstrated in the BRUISE CONTROL (Bridge or continue coumadin for device surgery randomized controlled trial extended follow-up for infection) study that a clinically significant pocket hematoma was associated with increased risk of infection (hazard ratio: 7.7). The infection rate was 2.4% in their study. Lakkireddy et al.<sup>[8]</sup> analyzed 2564 patients from an 8-year period who had a new device implantation and/or lead/generator replacement. Eighteen patients (0.7%) developed pocket infection. In their series, 33% had diabetes, 5% had renal insufficiency, 7% had an autoimmune disorder, and 17% were on systemic steroids. In our series, 11.5% had chronic renal failure, 32% had diabetes, 9% had a repeat procedure, 7% had COPD, and 1.2% were on immune suppressive therapy.

Pacemaker pocket infection is characterized by localized erythema, cellulitis, swelling or pain over the pocket. This may progress to wound dehiscence, purulent discharge, skin erosion or sinus formation. It may be accompanied by systemic signs of infection.

There are different types of pacemaker pocket infection: 1) Spreading cellulitis affecting the generator site, 2) incision site purulent exudate (excluding simple stitch abscess), 3) wound dehiscence, 4) erosion through skin with exposure of the generator or leads, 5) abscess or fistula formation.<sup>[9]</sup> Complicated pocket infection is associated with evidence of lead or endocardial involvement, systemic signs or symptoms of infection, or positive blood cultures. Darouiche et al.<sup>[10]</sup> reported that Gram-positive bacteria were by far the most commonly isolated microorganism (67%). Coagulase-negative *Staphylococci* was the most consistently isolated bacteria, followed closely by *Staphylococcus aureus*. Gram-negative bacilli were isolated in 1% to 17% of patient episodes. Fungal

infection was uncommon, occurring in no more than 2% of patients.

A variety of patient characteristics and procedural issues have been associated with pacemaker infections. Polyzos et al.<sup>[11]</sup> described several risk factors for infection in their study. With respect to host-related factors, the most significant predictors of infection were diabetes mellitus (odds ratio [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 included New York Heart Association functional class  $\geq 2$ , fever prior to implantation, oral anticoagulation, heparin bridging, and chronic skin disorders. Regarding procedure-related factors, post-operative hematoma (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 long procedure duration were all significant predictors of CIED infection. Among device-related characteristics, an abdominal generator pocket (OR: 4.01), the presence of epicardial leads (OR: 8.09), positioning of 2 or more leads (OR: 2.02), and a dual-chamber system (OR: 1.45) were predictors of CIED infection. Post-operative hematoma has been repeatedly associated with the risk for CIED infection and was a strong predictor of infection in their analysis.

## Conclusion

Our study suggests that the suture technique does not affect the pacemaker infection rate. Pocket hemostasis is an important factor for the prevention of pacemaker pocket infection. Our research revealed no correlation between the suture technique and the pacemaker pocket infection rate.

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**Conflict-of-interest:** None.

**Authorship contributions:** Concept: G.D.; Design: G.D.; Supervision: G.D.; Materials: G.D.; Data: G.D.; Analysis: G.D.; Literature search: G.D.; Writing: G.D.; Critical revision: G.D.

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**Anahtar sözcükler:** Kalp pili; kalp pili cebi enfeksiyonu; suture tekniği.