



A prospective comparison of four methods for preventing pacemaker pocket infections

Yao-Dong Li¹ | MaiMaiTiMin MaiMaiTiABuDuLa² | Gui-Qiu Cao² |
MaiMaiTiMin MaiMaiTiAiLi³ | Xian-Hui Zhou¹ | Yan-Mei Lu¹ | Jiang-Hua Zhang¹ |
Qiang Xing¹ | Chuang-Ju Wu¹ | Min Feng¹ | Ge-Ge Zhang¹ | Bao-Peng Tang¹

¹Pacing and Electrophysiology Department, First Affiliated Hospital of Xinjiang Medical University, Urumqi, China

²Cardiology Department, the 5th Affiliated Hospital of Xinjiang Medical University, Urumqi, China

³Emergency Department, West Branch Hospital of Hetian District People's Hospital, HeTian, China

Correspondence

Bao-Peng Tang, Pacing and Electrophysiology Department, First Affiliated Hospital of Xinjiang Medical University, NO. 137 of LiYuShan Street, Urumqi, 830054, China.
Email: tang_bp99@163.com

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Abstract

This study aims to evaluate four pacemaker pocket cleaning methods for preventing implantation-related infections. This single-center trial prospectively randomized 910 patients undergoing first-time pacemaker implantation or replacement into four pocket cleaning methods: hemocoagulase (group A, $n = 228$), gentamicin (group B, $n = 228$), hemocoagulase plus gentamicin (group C, $n = 227$), and normal saline (group D, $n = 227$). Before implanting the pacemaker battery, the pockets were cleaned with gauze presoaked in the respective cleaning solutions. Then, these patients were followed up to monitor the occurrence of infections for 1 month after implantation. Twelve implantation-related infections occurred in 910 patients (1.32%): four patients from group A (1.75%), three patients from group B (1.32%), two patients from group C (0.88%), and three patients from group D (1.32%) ($P > .05$). Furthermore, two patients developed bloodstream infections (0.22%), and both of these patients were associated with pocket infection (one patient was from group A, while the other patient was from group C, respectively). No cases of infective endocarditis occurred. The differences in the number of infections in these study groups were not statistically significant. The application of hemocoagulase, gentamicin, hemocoagulase plus gentamicin, or normal saline on the presoaked gauze before implantation was equally effective in preventing pocket-associated infections.

KEYWORDS

infection prevention, pacemaker, pocket infection

1 | INTRODUCTION

Pacemaker pocket infections are complications of an implantation procedure. These can reduce the therapeutic effects of pacemakers, which result in a decrease in a patient's quality of life. Furthermore, serious infections can be life-threatening. Intraoperative contamination of pathogenic bacteria and incomplete cessation of intraoperative bleeding are two of

the many risk factors. The application of antibiotic solutions or gentamicin powder within the pocket, the use of gentamicin-collagen patches, and electric coagulation can help prevent pocket infections.^{1,2} Each method has its own limitations and shortcomings, and there are no standard recommendations for the prevention of pacemaker pocket infections. Intraoperative gentamicin and hemocoagulase-soaked gauze have been recommended. These can clear the bacteria that

colonize the pacemaker pocket and achieve complete intraoperative hemostasis.³ However, the efficacy of this method has not been systematically evaluated. The present study evaluates the efficacies of these four different cleaning methods for preventing pacemaker pocket infections.

2 | PATIENTS AND METHODS

2.1 | Study population

Eligible patients underwent first-time pacemaker implantation or pacemaker replacement, according to the European Society of Cardiology pacemaker guidelines (2013).⁴ The procedures were performed at the First Affiliated Hospital of Xinjiang Medical University, Urumqi, China between January and December 2018. This study used a double-blind design. All patients provided a signed informed consent. The trial protocol was approved by the institutional Medical Ethics Committee (approval no. 140828-01) on the 11th of March 2014, and registered at ClinicalTrials.gov (NCT02099721) on the 31st of March 2014. Patients with contraindications to the study drugs or chronic diseases, such as cancer or tuberculosis, hematological diseases, or with an unsuccessful surgery were excluded. The patient groups were well matched, and this study excluded patients with pacemaker infection and receiving systemic antibiotics.

2.2 | Study treatments

Patients were randomly assigned to a pacemaker pocket treatment, in which the gauze was presoaked in 1 U of hemocoagulase and 10 mL of normal saline (group A, $n = 228$), 10 mL of gentamicin (group B, $n = 228$), 1 U of hemocoagulase, and 10 mL of gentamicin (group C, $n = 227$), or 10 mL of normal saline (group D, $n = 227$). The dosage of gentamicin according to body weight is 1~1.7 mg/kg, the concentration of

gentamicin used in this study is 61.0 mg/mL. The treatment for each group was performed for 10 minutes, immediately prior to the implantation of the pacemaker battery (Figure 1).

2.3 | Pocket and implantation procedures

The cardiac catheter laboratory was disinfected by ultraviolet light for 30 minutes before surgery. Patients are routinely given equal weight of second-generation cephalosporins 30 minutes before and within 24 hours after surgery, every 8 hours. Then, the patients were placed in the supine position, routine skin disinfection was performed with sterile wipes, and lidocaine (1%) was used for local anesthesia. The puncture of the left subclavian vein was performed using the Seldinger method, and a J-shaped guidewire was inserted into the subclavian vein, and into the inferior vena cava. Lidocaine (1%) was used as the infiltration anesthesia. A 4-7 cm skin incision was made along the puncture point. The subcutaneous tissues were bluntly stripped layer by layer until the superficial fascia of the pectoralis major muscle was reached, and a pocket slightly larger than the pacemaker was formed. For patients with low body weight, the pocket was made within the pectoralis major muscle. For patients with pacemaker replacement, the original pocket was used; these patients had pacemakers replaced with normal battery exhaustion. A 40 × 40 four-ply gauze pad pretreated with the respective study solutions was placed within the pocket. Then, a 7Fr venous sheath was slid along the guidewire, and a spiral electrode was positioned along the outside sheath. The distal end of the atrial electrode was implanted into the right atrial appendage or right atrial septum. The ventricular electrode was implanted into the right ventricular apex or right ventricular septum. The left ventricular electrode of three-chamber pacemakers was implanted in the cardiac or cardiac lateral vein. An intraluminal electrocardiogram and pacing analyzer were used to monitor the pacing. If the

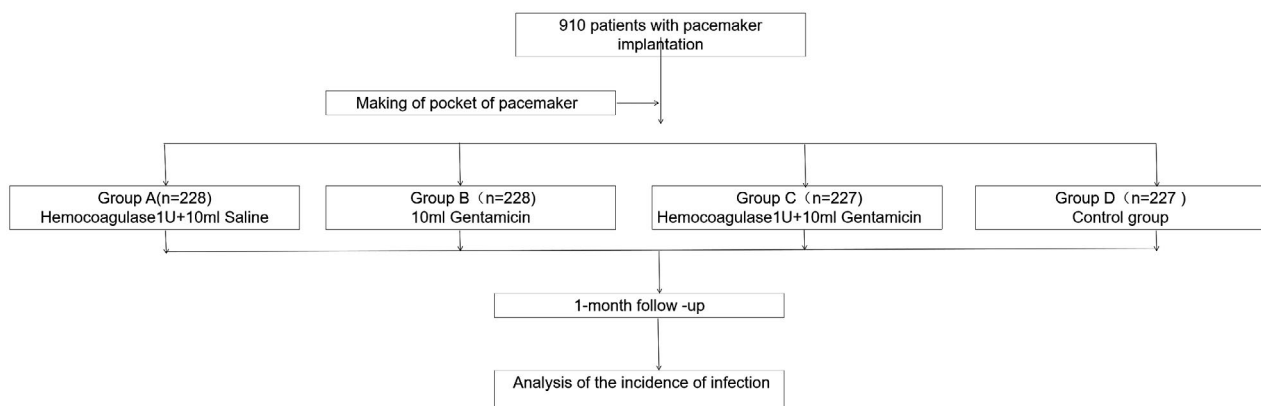


FIGURE 1 Flow diagram: evaluating four groups of patients exposed to different pocket cleaning techniques prior to pacemaker implantation



location of the electrodes and pacing parameters were satisfactory, the gauze pad was removed from the pocket. The time from placement to removal was 20 minutes or less. After confirming that there was no bleeding, the pulse generator was connected, and the electrodes were fixed. Then, the pocket was sutured layer by layer, the incision was covered with 75% of ethanol gauze and sterile dressing, and pressure was applied using a sandbag. These patients were instructed to remain in the supine position for 6 hours (12 hours for patients with a three-chamber pacemaker). The dressing was changed and the wound was evaluated on day 2 and 5 after surgery. The stitches were removed on day 7.

2.4 | Definitions

The evaluation of postoperative pacemaker implantation-related infections include the clinical manifestations, bacterial culture, echocardiography, and imaging.^{5,6} The diagnosis was based on the Mayo Cardiovascular Infections Study Group guidelines.⁷ The manifestations of these pocket infections included delayed incision healing, incision tears, and the exudation of inflammatory secretions from the incision. Thinning of the skin around the pacemaker pocket, possibly with a change skin color, severe pain, or skin ulceration leading to the exposure of electrodes was also associated with pocket infections. Most of these patients did not have systemic symptoms at this stage. Infective endocarditis can occur as a complication of bacteremia, and affected patients would have obvious symptoms of systemic infection. Bloodstream infections included bacteremia and sepsis, and these patients had systemic symptoms, including high fever, chills, and rashes.

2.5 | Follow-up evaluation

Patients were followed up for 24 hours to determine whether the dressing was dry, and whether incision bleeding, exudates, or swelling and tenderness were present in the subcutaneous tissue on palpation. Body temperature was measured three times daily to monitor for fever or other systemic symptoms. Before changing the dressing on day 5, the incision margin was wiped with a sterile cotton swab, which was placed in a tube of sterile saline and sent for bacterial culture. Echocardiography and imaging were performed, as required. Adverse reactions to medications were monitored during the administration. Under normal conditions, most of the pacemaker implantation-related infections occurred within 1 week of surgery, and wound recovery took 1 month. Therefore, the routine follow-up lasted for 1 month, all patients had a follow-up of at least 1 month.

2.6 | Statistical analysis

SPSS 24.0 (IBM Corp., Armonk, NY, USA) was used for the statistical analysis. Assuming a normal distribution and homogeneity of variance, the between-group differences of continuous data were compared using the chi-square test. $P < .05$ was considered statistically significant.

3 | RESULTS

3.1 | Baseline characteristics

There were no significant study group differences in gender ratio, age, body mass index, surgical site, numbers of surgeries, operating time, pacemaker implantation depth, type of pacemaker, coagulation function, suture method, or the use of oral anticoagulant or antiplatelet agents (Table 1).

3.2 | Pocket infection

A total of 910 patients were included. Among these patients, 12 patients (1.32%) developed pacemaker implantation-related infections. The incidences in groups A-D were 4 (1.75%), 3 (1.32%), 2 (0.88%), and 3 (1.32%), respectively, but the differences were not statistically significant ($P > .05$). The manifestations included pocket hemorrhage, change in color and thinning of the skin around the pocket site, and severe pain. Ten of these 12 patients had no systemic symptoms, were treated with local compression and immobilization, and recovered within 1 month, these patients were treated with antibiotics, but not cultured. Two patients (one patient in group A and one patient in group C) experienced wound rupture with exudation of inflammatory secretions on day 3 after surgery. Blood culture results were positive, and *Staphylococcus aureus* was detected. These patients were treated with local debridement and stitching, but systemic symptoms occurred in both patients on day 4, which was consistent with bacteria and pacemaker-related bloodstream infection. Bloodstream infections occurred in 2 of the 910 (0.22%) patients, and both patients were associated with pocket infection. Bloodstream infections all occurred on day 4, and mainly manifested as elevated body temperature (up to 40.2°C), accompanied by chills, and increased leukocyte count, C-reactive protein, and procalcitonin. Wound secretion cultures were positive for *S. aureus* and *S. epidermidis*. In one patient in group A, the body temperature returned to normal by week 2 after surgery, and the wounds healed within 1 month, following the intravenous administration of second-generation cephalosporins. In one patient in group C, the infection was not controlled, and the symptoms worsened even after intravenous antibiotics for 2 weeks. The pacemaker was removed on day 15,



TABLE 1 Patient characteristics

	A (n = 228)	B (n = 228)	C (n = 227)	D (n = 227)	Total (n = 910)	χ^2 or F	P
Age (years)	66.79 ± 12.342	67.53 ± 12.529	67 ± 13.061	68.73 ± 11.738	67.51 ± 12.429	1.114	.342
BMI (kg/m ²)	22.261 ± 2.617	22.393 ± 2.553	22.41 ± 2.602	22.361 ± 2.626	22.356 ± 2.5966	0.149	.93
Gender						1.333	.262
Male, n (%)	124 54.39%	145 63.60%	134 59.03%	134 59.03%	537 59.01%		
Female, n (%)	104 45.61%	83 36.40%	93 40.97%	93 40.97%	373 40.99%		
Surgical location						1.739	.157
Left, n (%)	218 95.61%	216 94.74%	214 94.27%	223 98.24%	871 95.71%		
Right, n (%)	10 4.39%	12 5.26%	13 5.73%	4 1.76%	39 4.29%		
Surgery duration						0.214	.886
≤2 h, n (%)	213 93.42%	210 92.11%	208 91.63%	211 92.95%	842 92.53%		
>2 h, n (%)	15 6.58%	18 7.89%	19 8.37%	16 7.05%	68 7.47%		
Suture method						1.837	.139
Interrupted, n (%)	94 41.23%	85 37.28%	96 42.29%	109 48.02%	384 42.20%		
Subcuticular, n (%)	134 58.77%	143 62.72%	131 57.71%	118 51.98%	526 57.80%		
Depth of implantation						0.184	.907
Muscle, n (%)	204 89.47%	199 87.28%	201 88.55%	200 88.11%	804 88.35%		
Subcutaneous, n (%)	24 10.53%	29 12.72%	26 11.45%	27 11.89%	106 11.65%		
Use of antiplatelet/ anticoagulants during perioperative period						0.801	.494
No, n (%)	201 88.16%	197 86.40%	193 85.02%	189 83.26%	780 85.71%		
Yes, n (%)	27 11.84%	31 13.60%	34 14.98%	38 16.74%	130 14.29%		
Surgical history						0.86	.84
First time, n (%)	179 78.51%	177 77.63%	178 78.41%	171 75.33%	705 77.47%		
Replacement, n (%)	49 21.49%	51 22.37%	49 21.59%	56 24.67%	205 22.53%		

(Continues)



TABLE 1 (Continued)

	A (n = 228)	B (n = 228)	C (n = 227)	D (n = 227)	Total (n = 910)	χ^2 or F	P
Type of pacemaker							
Single chamber, n (%)	20 8.77%	17 7.46%	15 6.61%	11 4.85%	63 6.92%	8.45	.49
ICD, n (%)	44 19.30%	53 23.25%	60 26.43%	57 25.11%	214 23.52%		
Dual chamber, n (%)	146 64.04%	137 60.09%	130 57.27%	132 58.15%	545 59.89%		
Three chamber, n (%)	18 7.89%	21 9.21%	22 9.69%	27 11.89%	88 9.67%		
Diabetes							
No, n (%)	207 90.79%	204 89.47%	196 86.34%	198 87.22%	805 88.46%	2.777	.427
Yes, n (%)	21 9.21%	24 10.53%	31 13.66%	29 12.78%	105 11.54%		

and the antibiotic treatment was continued. At 2 days after pacemaker removal, the patient's body temperature returned to normal. Blood count and the inflammatory factor level returned to normal after 5 days. The pacemaker was successfully implanted into the contralateral side on day 20 after the initial surgery, without the occurrence of any procedure-related complications. No cases of infective endocarditis were observed in the 910 patients during the 1-month follow-up period (Table 2 and Figure 2).

4 | DISCUSSION

Pacemakers have a key role in treating arrhythmia and heart failure, preventing sudden cardiac death, and improving patient quality of life.^{8,9} The number of devices implanted is estimated at 1.2 million pacemakers and 0.4 million implantable cardioverter defibrillators each year, worldwide.¹⁰ However, instrumentation, perioperative conditions, patient characteristics, surgeon-related factors, and the surgical environment all contribute to infection risk. Intraoperative exposure to *S. aureus* and other pathogens, and incomplete intraoperative hemostasis^{11,12} can be reduced by preoperative antibiotic prophylaxis and the discontinuation of antiplatelet and anticoagulant therapy.¹³ The routine use of intravenous antibiotics has not eliminated pacemaker pocket infections, and the condition of patients who need pacemakers is frequently complicated by coronary artery disease, atrial fibrillation, and ischemic myocardial disease. The perioperative withdrawal of antiplatelet and anticoagulant agents in patients with high risk of thrombosis resulted in a threefold increase in incidence of myocardial infarction and systemic thrombosis.^{14,15}

The intraoperative treatment of pacemaker pockets with sterile gauze presoaked in gentamicin or hemocoagulase solution is recommended for several reasons: The hospital suites used for interventional cardiology, such as catheterization, may not achieve the same level of sterility as operating suites. The pacemaker wires and pulse generator are exposed to air before implantation, and may introduce pathogenic bacteria into the body. Furthermore, the environment surrounding the implanted pulse generator, which is a foreign metal body, facilitates bacterial growth. Gentamicin-treated gauze can clear bacteria that colonize the pacemaker pocket.¹⁶ Incomplete hemostasis can result in the formation of pocket hematomas, increase the risk of pocket infection, prolong the hospital stay of patients, and increase medical costs. The use of thrombin can promote platelet aggregation at the bleeding site, release a series of coagulation factors, and then, cross-link and polymerize into insoluble fibrin to promote thrombosis and hemostasis at the bleeding site. Using thrombin-soaked gauze can prevent pocket hematoma and further prevent infection.

TABLE 2 Infections after pacemaker implantation

		A (n = 228)	B (n = 228)	C (n = 227)	D (n = 227)	Total (n = 910)	χ^2	P
Pocket infection, n (%)	No	224	225	225	224	898	0.221	.882
		98.25%	98.68%	99.12%	98.68%	98.68%		
	Yes	4	3	2	3	12		
		1.75%	1.32%	0.88%	1.32%	1.32%		
Type of bacteria	<i>S. aureus</i>	2	2	1	1	6	0.418	.723
		50.00%	66.67%	50.00%	33.33%	50.00%		
	<i>S. epidermidis</i>	1	0	1	1	3		
		25.00%	0.00%	50.00%	33.33%	25.00%		
	<i>S. schleiferi</i>	1	1	0	1	3		
		25.00%	33.33%	0.00%	33.33%	25.00%		

(A)**(B)****FIGURE 2** A patient developed a bloodstream infection that resulted in pacemaker removal. A, Infected pocket and with white purulent secretions and (B) removed pacemaker

The intraoperative treatment of pacemaker pockets with gentamicin plus hemocoagulase-soaked gauze can thereby be expected to clear bacteria and help achieve complete hemostasis. The occurrence of pocket infections should decrease, but the efficacy of this pretreatment has not been validated in randomized trials.

The 910 patients in the present study were randomly assigned to pocket pretreatment with hemocoagulase or gentamicin alone, gentamicin plus hemocoagulase, or normal saline. The 1.32% incidence of pocket infection (12/910) was consistent with that in a previous study, which reported a 1%-7% incidence of pocket infection.¹⁷ Differences in the occurrence of pocket infections were not significant. Pocket treatment with gauze presoaked in hemocoagulase and/or gentamicin did not significantly prevent pocket infections, when compared to normal saline alone. Using gauze moistened with physiological saline to clean the pouch can reduce friction, reduce damage to small blood vessels in the pouch, and reduce the risk of infection. At the same time, this method can save operating time and cost, and is worthy of further

clinical promotion and verification. There were several ways to account for the lack of difference in effect. The sterility of the catheterization suite, surgical and procedural environment, and the experience of the surgeons, who all perform more than 100 pacemaker implantations every year, may have effectively reduced the risk of bacterial contamination. The use of small incisions and vascular puncture techniques for pacemaker implantation reduced the operation field, operation time, and contamination risk. However, it is difficult to achieve an effective inhibitory concentration of gentamicin with the local use of gentamicin-soaked gauze, and some of the included patients may have had other systemic diseases that influenced the trial results.

There is no agreement on the continued use of anticoagulant and antiplatelet drugs during the perioperative period. Some studies have shown that bleeding risk may be decreased by replacing warfarin with low molecular weight heparin before the implantation.^{18,19} A study revealed that perioperative heparin is associated with a 20% bleeding risk, which is higher than the 2%-4% risk associated with warfarin.²⁰ In



addition to the effects of anticoagulant and antiplatelet drugs, surgical, or anatomical errors, such as intraoperative injury of small arteries or the pectoralis major fascia, and incomplete hemostasis contribute to bleeding complications. Surgical experience and techniques are of great significance in preventing these complications. During surgery, the anatomical level must be known, in order to avoid damaging the pectoralis major fascia. Excessive local skin tension should also be avoided, and in addition to suturing the bleeding sites, it is also important to suture the subcutaneous tissues where electrode wires penetrate. This fixes the electrode wires, and prevents the reflux of exudative venous blood into the pocket along the wires.

4.1 | Study limitations

The limitations of the present single-center study include its small sample size and the relatively small number of infections. Nevertheless, these results warrant the conduction of multicenter studies with larger patient samples. Furthermore, the follow-up was only performed for 1 month, and this was performed mainly in the acute stage. Residual bacteria that colonized the pacemaker pocket could have led to infection, if the immune system was compromised. A longer follow-up period would have been more beneficial for longer term outcomes. The most common pathogens that cause postoperative pacemaker infections include *S. aureus*, *S. epidermidis*, and *S. schleiferi*. Gram-negative bacteria, *Candida spp.*, *Corynebacterium spp.*, and other microorganisms accounted for a small proportion of the infections. The pathogens that caused pocket infections may change as the environment changes, and adjusting the antibiotics used for prophylaxis may reduce the incidence of infection. The present study was prospective, and the calculation of the incidence of infection was derived from patients with pacemaker implantation in a single period, which may underestimate the actual incidence.

5 | CONCLUSION

The local treatment of pacemaker pockets with gentamicin, hemocoagulase, or gentamicin plus hemocoagulase-soaked sterile gauze had no significant effect in preventing pocket infection, when compared with saline controls. Proper perioperative management can help reduce the risk of bleeding and hematoma formation. Furthermore, strict attention to the aseptic surgical environment, technique, and appropriate procedures reduce the incidence of pocket infections. The present study provides valuable clinical data for determining effective methods for preventing pacemaker pocket infection.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

ORCID

Bao-Peng Tang  <https://orcid.org/0000-0002-2704-712X>

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