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*Original Article*

# Analysis of clinical efficacy and factors affecting complications of permanent pacemaker implantation

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**Abstract:** Objective: To analysis clinical efficacy and factors affecting complications of permanent pacemaker implantation. Methods: A total of 298 patients receiving permanent implantation of cardiac pacemakers were included, and simultaneously, 207 volunteers without significant cardiovascular disease were selected as the control group. The SF-36 questionnaire was used to investigate and compare quality of life in patients (6 months before pacemaker implantation, 2 weeks and 6 months after the implantation) and controls. The left ventricular end-diastolic volume (LVEDV), left ventricular end-systolic volume (LVESV) and left ventricular ejection fraction (LVEF) were measured by echocardiogram in patients (at the same time points above) and controls. The clinical efficacy of permanent pacemakers was evaluated according to comprehensive comparison. In addition, the clinical data, causes of complications and corresponding treatment methods as well as preventive measures of patients receiving different permanent pacemaker implantation were retrospectively analyzed in order to explore the factors that affected the complications of permanent pacemaker implantation. Results: Compared with the control group, patients had poorer preoperative quality of life which was significantly improved after operation, lower preoperative LVESV and LVEDV, as well as higher LVEF according to the electrocardiogram. The postoperative LVESV, LVEDV, and LVEF recovered significantly compared with before operation. After operation, there was no significant difference in the LVESV, LVEDV and LVEF between two groups, indicating that permanent pacemaker implantation could restore cardiac function with significant efficacy. Patients with single-chamber or dual-chamber pacemakers experienced postoperative complications, while patients with three-chamber pacemakers or implantable cardioverter-defibrillators had no complications. Among patients with complications, there were 13 patients with pocket infection (6 cases of single-chamber pacemaker implantation and 7 cases of dual-chamber pacemaker implantation), 3 patients with pocket hematoma (1 case of single-chamber pacemaker implantation and 2 cases of dual-chamber pacemaker implantation), 3 patients with pacemaker syndrome (1 case of single-chamber pacemaker implantation and 2 cases of dual-chamber pacemaker implantation), 2 patients of dual-chamber pacemaker with electrode lead dislocation, 1 case of single-chamber pacemaker with electrode lead breakage, 1 case of dual-chamber pacemaker with mistakenly passing through the subclavian artery, 1 case with dual-chamber pacemaker-mediated tachycardia and 1 case of dual-chamber pacemaker with myocardium perforation. Patients with complications were all treated in a timely manner. Conclusion: Permanent pacemaker implantation has significant clinical efficacy, and its main complication is pocket infection which can be improved with antibiotics.

**Keywords:** Permanent pacemaker, clinical efficacy, complication

## Introduction

With the growing aging and morbidity of chronic arrhythmias in recent years, more and more patients are treated with permanent pacemaker implantation, especially patients with cardiac conduction and sinus node dysfunction [1-4]. Relevant studies have shown that permanent pacemaker implantation can prolong survival, but as a type of traumatic treatment, this approach also increases the risk of postoperative infection and other complications [5, 6]. Pocket infection, pocket hematoma, and pacemaker syndrome are common complications after permanent pacemaker implantation [7-9].

The performance of current pacemakers is constantly improving. In this study, we aim to examine the clinical effects of this treatment. Its various postoperative complications can negatively

affect the perception of implanted pacemakers and normal pacing functions [10]. However, the clinical factors that affect the efficacy of pacemaker implantation and postoperative complications are not yet clear, so follow-up of postoperative treatment effect, analysis of factors affecting complications, active control, sufficient preoperative preparations are of great importance in improving the treatment effect and quality of life as well as reducing postoperative complications in patients [11].

This study selected patients who were treated with permanent pacemakers from 2013 to 2016 to follow up the treatment effects and analyze various factors that affect postoperative complications to help patients undergoing permanent pacemaker implantation.

## Methods

### *Clinical data*

This study was approved by the Ethics Committee of Xingtai People's Hospital. A total of 298 patients with permanent pacemaker treated from January 2013 to April 2016 were selected, including 152 females and 146 males (aged 21-89 years old, with an average of 58±6.4 years). Among them, there were 196 cases of sick sinus syndrome, 73 cases of third-degree atrioventricular block, 18 cases of ventricular tachycardia and ventricular fibrillation, 11 cases of heart failure; 104 cases were implanted with single-chamber pacemaker, 189 cases with dual-chamber pacemaker, 4 cases with three-chamber pacemaker and 1 case with implantable cardioverter-defibrillator (ICD). Electrode leads were implanted by subclavian vein puncture in all patients. The atria were fixed in the right auricle. The right ventricular electrode was fixed to the right ventricular apex, and the left ventricular electrode was fixed to the vena cava via the coronary sinus. All cases met the indications of ACC/AHA as well as Types I and II in *Guideline for Medical Electrophysiology in China (2002)*. In this study, 207 volunteers without obvious cardiovascular disease were selected as control group. Informed consents were obtained from all patients and their families, volunteers.

### *Surgical methods*

The patients were connected to the electrocardiograph monitor on DSA platform to detect the preoperative vital signs such as blood pressure, heart rate and oxygen saturation. Lidocaine 1% was used for local infiltration anesthesia, which was followed by subclavian vein puncture and successful insertion of two J-shaped guide wire. Along the left side of the left thoracic pectoralis, major, flexural incision was performed, with blunt separation to the subcutaneous tissues (made as pacemaker pockets). The J-shaped guide wire was sent into pull-apart sheath, and the pacemaker electrode was implanted under fluoroscopy. The intracardiac electrocardiogram was recorded, and the pacemaker electrode was tested. All the patients were implanted with the passive endocardial electrode, and the ventricular electrode implantation site (including single-chamber pacemakers, dual-chamber pacemakers, three-chamber pacemakers) was at the right ventricular apex. The right auricle was selected as cardiac pacing site in patients with dual-chamber pacemaker or three-chamber pacemakers. An electrode of three-chamber pacemaker reached the coronary vein branch through the coronary sinus orifice. Left cephalic vein was chosen for implanting the defibrillator electrode in patients with ICD implantation. Conventional pacing thresholds, impedance and sensitivity test thresholds required atrial pacing threshold < 1.5 V, P-wave amplitude > 2 mV, current < 3 mA and right ventricular pacing threshold < 1 V, R-wave amplitude > 5 mV, current < 2 mA. The patients were asked to take a deep breath and cough to confirm a satisfied electrode position, and the test result of diaphragmatic muscle stimulation was negative. Confirmation of all the procedures above meant that the electrode test was completed. The pulse generators of the pacemaker were connected, and the pacemaker was in the pocket. Raised pacemaker indicating a normal sensory function. Then the pocket was closed, and the skin was sutured layer by layer. The incision was covered by gauze with alcohol. After surgery, patients were lying in bed for 48 hours, sandbags compressing for 8 hours, and their left upper limbs were immobilized for 3 days. Changing fresh dressing for the wound was performed regularly. The stitches were removed 1 week after operation as there was no dislocation of the pacing electrodes and the pacemaker wounds healed well.

### *Outcome measures*

The SF-36 questionnaire (recommended by WHO) was used to evaluate the changes of pre-

**Table 1.** Quality of life scores in controls and in patients before and after pacemaker implantation (mean ± sd)

| Item | Control group | Single-chamber pacemaker | | | Dual-chamber pacemaker | | |
|---|---|---|---|---|---|---|---|
| | | 6 months before operation | 2 weeks after operation | 6 months after operation | 6 months before operation | 2 weeks after operation | 6 months after operation |
| PF | 86.06±8.04 | 57.21±15.14* | 79.43±7.26# | 77.12±9.08# | 54.74±16.39* | 87.89±11.86#,& | 86.71±11.24#,& |
| RP | 81.04±8.03 | 33.54±15.47* | 74.32±8.17# | 70.27±10.58# | 32.99±15.87* | 81.35±10.22#,& | 80.67±9.48#,& |
| BP | 96.03±2.02 | 72.84±4.91* | 89.33±8.04# | 88.98±5.26# | 71.3±5.31* | 95.79±2.49#,& | 94.74±1.37#,& |
| GH | 89.28±4.21 | 38.06±10.79* | 79.19±10.45# | 74.23±11.3# | 38.58±10.47* | 84.22±5.13#,& | 83.27±4.67#,& |
| VT | 87.94±8.05 | 32.41±12.88* | 77.87±5.86# | 75.15±12.37# | 34.41±12.44* | 83.01±6.43#,& | 81.02±8.56#,& |
| SF | 91.05±4.22 | 27.15±14.73* | 84.87±12.47# | 81.45±14.03# | 28.35±15.40* | 90.24±8.36#,& | 89.18±9.43#,& |
| RG | 88.64±8.05 | 47.92±8.66* | 77.04±11.24# | 75.18±12.18# | 47.33±9.37* | 87.98±7.47#,& | 86.68±8.07#,& |
| MH | 87.46±8.03 | 50.57±7.34* | 73.52±12.86# | 71.14±14.59# | 49.54±9.48* | 86.21±10.94#,& | 84.88±11.85#,& |
| HT | 84.97±9.22 | 38.85±12.37* | 76.01±10.37# | 71.77±11.38# | 40.52±12.61* | 88.92±7.03#,& | 82.47±8.88#,& |

Note: PF: physical functioning, RP: role physical, BP: body pain, GH: general health, VT: vitality, SF: social functioning, RG: role emotional, MH: mental health, HT: health transition. *represents compared with control group, $P < 0.05$; #represents compared with 6 months before operation, $P < 0.05$; &represents compared with patients with single-chamber pacemaker implantation, $P < 0.05$.

operative and postoperative quality of life; it was used to evaluate quality of life in both groups. SF-36 questionnaires were performed 6 months before surgery, 2 weeks and 6 months after surgery in all patients; questionnaire surveys were also conducted in volunteers to assess patients' quality of life from 6 months pre-implantation to 6 months post-implantation [12]. The subjects of evaluation were the patients themselves, and explanation was given based on their educational level. The SF-36 quality of life scale included 9 aspects: physical functioning, role physical, body pain, general health, vitality, social functioning, role emotional, mental health and health transition. When scoring, each item was dealt positively, and then the scores were converted to 100% according to the SF-36 standard integral conversion formula. The higher the score was, the better the quality of life was. Standard score = (actual score - the lowest score of the aspect)/(the highest score of the aspect - the lowest score of the aspect) * 100.

*Echocardiographic detection*

Electrocardiogram examinations were performed in patients 6 months preoperatively, 2 weeks and 6 months after operation and in all controls. The efficacy of permanent pacemaker implantation was determined by testing left ventricular end diastolic volume (LVEDV), left ventricular end systolic volume (LVESV) and left ventricular ejection fraction (LVEF).

*Postoperative follow-up*

All patients were followed up at the 1st, 3rd, 6th, 9th and 12th months respectively. Pacemaker parameters were tested after 3 months of pacemaker implantation. All complications were cause-identified and timely treated with detailed sampling records.

Common complications included pocket infection (local pain, red and swollen, high skin temperature and fluid wave), pocket hematoma (partially swollen of pocket with ecchymosis, increased pressure in the pocket and dark red blood drawn out by sterile syringe) and pacemaker syndrome (palpitations, shortness of breath, syncope, throbbing pain and fullness in head and neck, chest pain, cold sweats, and low blood pressure, which patients did not suffer before and showed after pacemaker implantation).

*Statistical analysis*

Data processing was performed by SPSS 18.0 (IBM Corp, Armonk, NY, USA) statistical software. Measurement data are expressed as mean ± standard deviation; pairwise measurement data with normal distribution were processed by t test. Count data are expressed as n or % and were tested by $X^2$. One-way ANOVA followed by Bonferroni post-hoc test was conducted for analysis of variances among multiple groups. $P < 0.05$ is considered statistically significant.

**Table 2.** Results of electrocardiogram test

| Index | Control group | Single-chamber pacemaker | | | Dual-chamber pacemaker | | |
|---|---|---|---|---|---|---|---|
| | | 6 months before operation | 2 weeks after operation | 6 months after operation | 6 months before operation | 2 weeks after operation | 6 months after operation |
| LVESV | 72.18±6.82 | 44.83±8.32* | 68.43±6.14# | 67.98±6.13# | 49.31±9.15* | 75.27±6.75# | 74.98±7.25# |
| LVEDV | 99.16±9.02 | 88.19±7.25* | 97.27±8.15# | 96.46±9.24# | 92.01±7.97* | 106.99±8.96# | 103.29±9.87# |
| LVEF | 50.17±5.22 | 72.08±7.18* | 54.16±5.18# | 55.19±5.67# | 79.29±7.89* | 59.58±5.69# | 57.34±5.86# |

Note: LVEDV: left ventricular end-diastolic volume, LVESV: left ventricular end-systolic volume and LVEF: left ventricular ejection fraction. Compared with control group, *P < 0.05; compared with 6 months before operation, #P < 0.05.

**Table 3.** Complications

| Implantation | Cases with complications | Incidence of complications (%) |
|---|---|---|
| Single-chamber pacemaker (n=104) | 9 | 8.65 |
| Dual-chamber pacemaker (n=189) | 16 | 8.47 |
| Three-chamber pacemaker (n=4) | 0 | 0 |
| ICD (n=1) | 0 | 0 |

Note: ICD: implantable cardioverter-defibrillator.

## Results

*Quality of life*

In order to evaluate the clinical effect of permanent pacemaker implantation, the SF-36 questionnaires were conducted 6 months before operation, 2 weeks and 6 months after operation, and results were compared with the results of SF-36 questionnaire in the control group. Patients with three-chamber pacemaker and ICD were not included in quality of life assessment for the sample size was too small. Compared with the control group, quality of life in patients with single-chamber pacemaker and dual-chamber pacemaker was poorer than that in the control group at 6 months before operation ($P < 0.05$), but there was no significant difference between them at 2 weeks and 6 months after operation. Also, there was no significant difference between patients with single-chamber pacemakers and patients with dual-chamber pacemakers in preoperative quality of life ($P > 0.05$). While quality of life was significantly improved at 6 months after the implantation in patients with single-chamber pacemakers and dual-chamber pacemakers; quality of life was better in patients with dual-chamber pacemakers than that in patients with single-chamber pacemakers ($P < 0.05$). The results indicated that permanent pacemakers had significant effects. See **Table 1**.

*Echocardiographic detection*

Electrocardiogram was performed in controls and in the patients at 6 months before operation, 2 weeks and 6 months after operation. Results showed that compared with the control group, LVESV and LVEDV decreased significantly and LVEF increased significantly in patients at 6 months before operation (all $P < 0.05$). Compared with 6 months before operation, LVESV and LVEDV in patients implanted with single-chamber or dual-chamber pacemakers were significantly increased at 2 weeks and 6 months after operation, and simultaneously, LVEF of which decreased significantly. There was no significant difference in LVESV, LVEDV and LVEF between patients with single-chamber pacemaker implantation and patients with dual-chamber pacemaker implantation at 2 weeks and 6 months after implantation. The results indicated that permanent pacemaker implantation could obviously restore the cardiac function of patients. See **Table 2**.

*Complications*

Patients who were implanted with permanent cardiac pacemakers were followed up and examined 6 months after operation, and the incidence of complications in patients with single-chamber pacemaker was 8.65%, and 8.47% in patients with dual-chamber pacemaker. No complications occurred in patients with three-chamber pacemakers or ICD. There was no significant difference in the incidence of complications between patients with single-chamber pacemakers and those with dual-chamber pacemakers ($X^2=0.002$, $P=0.959$), indicating that the occurrence of complications was not related to the way of implantation. See **Table 3**.

*Theory and treatment methods of complications*

There were 13 cases with pocket infection (6 cases of single-chamber pacemaker implantation and 7 cases of dual-chamber pacemaker implantation). All of them were chronic infection; 8 cases improved after general and local use of antibiotics; 3 cases were performed with thoroughly recleaning up of wounds, placing of drainage strips, pressure dressing, reproducing of pocket and implanting the pacemakers into the contralateral side; they got better and discharged after intravenous antibiotics and strengthening nutritional support. Two patients were hospitalized repeatedly because of pacemaker infection and fever. Negative pressure drainage and systemic antibiotic therapy were performed after repeated debridement, which was ineffective. So, their pacemakers and electrode leads were removed, followed by continuously sensitive antibiotic treatment, and they recovered and discharged 10 days later.

There were 3 cases of pocket hematoma (1 cases of single-chamber pacemaker implantation and 2 cases of dual-chamber pacemaker implantation). In 1 severe case, replacement of the pacemaker was performed with new incision and blood clots removal; drainage strips were placed after pressure dressing, and hematoma was removed after the use of antibiotics. The incision was healed. The other 2 cases were treated by local puncture blood drawing, salt bag compression and wet compress of magnesium sulfate.

There were 3 cases of pacemaker syndrome (1 cases of single-chamber pacemaker implantation and 2 cases of dual-chamber pacemaker implantation) occurred in one year after surgery. For non-pacemaker-dependent patients, pacing frequency was reduced, and patients' own rhythm was the dominant factor. For pacemaker dependent patients, different types of pacemakers were implanted for replacement.

There were 2 patients of dual-chamber pacemaker with electrode lead dislocation. One was found during the operation. The reason might be improper separation of pocket, so traction of the skin outed and then shifted the electrode lead. It was found in time, and was reset and fixed in time. The complication occurred within 1 months after the pacemaker implantation in the other case, mainly manifested as poor pacing and sensory dysfunction, combined with the diaphragmatic muscle stimulation. According to the symptoms, we examined the patients by chest X-ray examination, and the symptoms were confirmed as electrode dislocation, so surgical reposition was carried out.

There was 1 case of single-chamber pacemaker with electrode lead breakage. The chest radiography showed that the breakage site was located at the junction of the right clavicle and the first rib, partially broken, so the catheter was excised through the side of bone vein. The new electrode was reset through the cephalic vein. After that, no other complications including infection occurred.

There were 1 case of dual-chamber pacemaker with mistakenly passing through the subclavian artery, 1 case of dual-chamber pacemaker-mediated tachycardia and 1 case of dual-chamber pacemaker with myocardium perforation. The complications were found in time, without progress and serious consequences. Pacemaker mediated tachycardia was detected in 1 patient with atrial tachycardia and triggered ventricular pacing. The atrial refractory period was prolonged, and drugs were given to control atrial arrhythmia. Myocardial perforation in 1 patient occurred in acute myocardial infarction pacemaker, which was related to ischemic necrosis of ventricular wall after myocardial infarction. The suture was taken back after the operation, without occurrence of pericardial tamponade.

## Discussion

In recent years, the proportion of patients with chronic or intermittent arrhythmias has been increasing; patients often have symptoms such as insufficiency of cerebral blood supply, bradycardia and congestive heart failure, and in severe cases, arrhythmia can cause sudden death [13, 14]. Pacemaker implantation offers a favorable treatment for patients with arrhythmias, but this approach is associated with certain complications because it is a traumatic treatment [15, 16]. How to improve the postoperative effect and reduce complications of permanent pacemaker implantation has always been a focus in clinic [17-19].

We evaluated the efficacy of patients undergoing permanent pacemaker implantation in our

hospital, and their complications were also followed up. The SF-36 questionnaire was used to evaluate the clinical efficacy in patients. We found that patients had significantly lower quality of life scores than the control group 6 months before they received single-chamber or dual-chamber pacemaker implantation; there was no significant difference in the quality of life scores between patients and controls 2 weeks and 6 months after the pacemaker implantation. Six months after surgery, the quality of life scores of patients undergoing single-chamber or dual-chamber pacemaker implantation were significantly improved compared with before surgery, suggesting that permanent pacemakers could significantly improve outcomes. Monitoring of cardiac function parameters by electrocardiography revealed that patients undergoing permanent pacemaker implantation had significantly improved postoperative cardiac function compared with preoperative parameters, further confirming that pacemakers could improve outcomes and cardiac function in patients.

Analysis of complications revealed that there was no significant difference in the incidence of complications between patients implanted with single-chamber and dual-chamber pacemakers. No complications occurred in patients undergoing three-chamber pacemaker and ICD implantation. There was no significant difference in the incidence of complications between patients with different implantations, indicating that there was no relationship between complications and implantation methods. In this study, postoperative complications of patients mainly included pocket infection, pocket hematoma and pacemaker syndrome; there were also a small number of patients with dislocation and breakage of electrode leads, mistakenly passing through the subclavian artery, tachycardia and myocardial perforation. The causes of complications were considered to be mainly related to the advanced age, poor nutritional and immune status as well as the use of antiplatelet and anticoagulant drugs after surgery [20-22]. Therefore, during operation, attention should be paid to normative operation and strict prevention of bleeding. Postoperative follow-up of patient outcomes and complications should be strengthened, and targeted measures should be taken in time [23-25]. This study analyzed the clinical efficacy and postoperative complications of patients with permanent pacemaker implantation. However, long-term effects of this approach need to be further observed, and for postoperative complications, preventive measures need to be constantly improved.

In summary, permanent pacemaker implantation has significant clinical efficacy, with pocket infection as its main postoperative complication. Patients should be properly evaluated during clinical treatment. They should be timely informed, and targeted measures should be taken for possible complications to reduce the occurrence of complications and further improve the efficacy and quality of life.

## Disclosure of conflict of interest

None.

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