Short- and medium-term clinical outcomes of culture-negative and culture-positive periprosthetic joint infection

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Research article

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Abstract

Purpose

The purpose of this study was to compare the clinical outcomes of culture-negative periprosthetic infection (CN PJI) with those of culture-positive periprosthetic infection (CP PJI).

Methods

The clinical data of 77 patients with prosthetic infections were collected retrospectively. The mean follow-up time was 29.2 months (12-76 months). The remission rates of CN PJI and CP PJI were compared. The effects of the culture results on the curative effect were further compared by survival analysis. The correlations between sex, age, underlying diseases, sinus, disease course, joint involvement, surgical strategy, culture results and clinical outcomes were further analyzed by logistic regression.

Results

In total, there were 24 cases of CN PJI, with an incidence of 29.63%. The overall success rate of CN PJI was 86.4% (19/22), and overall success rate of CP PJI was 87.5% (42/48). There was no significant difference in the success rate between CN PJI and CP PJI. The incidence of antibiotic-related complications for CN PJI was significantly higher than that for CP PJI, with 58.3% for CN PJI and 11.3% for CP PJI, respectively.

Conclusion

CN PJI was treated according to the strict standards for the diagnosis and treatment, and the success rate of treatment for CN PJI was similar to that for CP PJI. The incidence of antibiotic-related complications from CN PJI was higher than that from CP PJI.

Introduction

Total joint arthroplasty has been proven to be an effective treatment for improving the quality of life and relieving pain symptoms in patients with severe joint diseases\(^1\). As a rare but devastating complication, periprosthetic joint infection (PJI) seriously affects surgical quality and increases the economic burden of patients\(^1,2\). The identification of pathogenic microorganisms is an important factor in the accurate diagnosis and successful treatment of PJI and depends on the culture results of synovial fluid or tissue specimens\(^3,4\). In the clinic, CN PJIs are not uncommon. It has been reported that the incidence of CN PJI is between 0% and 42.1%\(^5\).

It has been reported that two-stage revision is the most applicable treatment method for CN PJI\(^6,7\). Other surgical strategies include DAIR with replacement of the polyethylene insert, one-stage revision, permanent joint fusion, etc.\(^5\). A systemic combination of vancomycin and third-generation cephalosporins or carbapenems is the most commonly used regimen for CN PJI\(^5\). However, complications
such as myelosuppression and liver and kidney function damage caused by the systemic application of antibiotics are not uncommon in the clinic.

The purpose of this study is to investigate 1. the incidence of CN PJI; 2. the clinical outcomes of various surgical strategies and antibiotic regimens for CN PJI; and 3. the comparison of the success rate of treatment and the incidence of antibiotic-related complications between CN PJI and CP PJI.

**Materials And Methods**

**Patients**

From January 2015 to June 2017, eighty-one patients who underwent revision surgery due to PJI after hip and knee arthroplasty in our center were retrospectively collected. Four patients who failed to follow-up were excluded (bacterial culture results were positive and underwent two-stage revision). Ultimately, 77 PJI cases of the hip and knee were enrolled.

Age, sex, body mass index (BMI), preoperative complications, American Association of Anesthesiologists (ASA) physical status, laboratory tests (routine blood test, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP)), preoperative and intraoperative synovial fluid white blood cell (SF-WBC) count and percentage of polymorphonuclear leukocytes (SF-PMN%), bacterial culture results and intraoperative frozen section results of periprosthetic tissue were collected. The incidence of PJI after total joint arthroplasty (type, sinus, pathogenic microorganism), surgical strategies (one-stage revision, two-stage revision and debridement, antibiotics, irrigation, and retention (DAIR)), antibiotic regimens and clinical results were also documented. A diagnosis for PJI were made according to the Musculoskeletal Infection Society (MSIS) criteria for PJI\(^8,9\).

All patients were classified by Tsukayama type\(^10,11\). According to the bacterial culture results of synovial fluid and pre- and intraoperative tissues, 24 cases were included in the CN PJI group, and 53 cases were included in the CP PJI group.

**Surgical strategies and postoperative antibiotic regimens**

Generally, for cases of Tsukayama type II or III without a sinus tract, DAIR was selected. For cases classified as Tsukayama type I or IV without a sinus tract and where multiresistance bacteria was isolated from the preoperative synovial fluid, as well as cases involving elderly populations and poor economic conditions combined with the wishes of the patients, one-stage revision surgery was chosen. For cases classified as Tsukayama type IV with poor soft tissue conditions and where multiresistance bacteria was isolated from preoperative synovial fluid as well as the existence of a sinus, two-stage revision was selected. And patient's willingness was also taken into consideration.

**Antibiotic regimens**
If the bacterial culture results were negative, the administration of vancomycin and third-generation cephalosporin or carbapenem antibiotics were combined intravenously. If the bacterial culture results were positive, proper sensitive antibiotics were selected. All patients received intravenous antibiotics for two to six weeks (mean time: 20 days for DAIR, 16 days for one-stage revision, and 31 days for two-stage revision). After that, the antibiotic regimens were switched to oral antibiotics. Rifampicin combined with sensitive antibiotics was selected for staphylococcal infections and only sensitive antibiotics for other positive cultures, quinolone antibiotics were selected for negative culture, and the course of antibiotics administered was six to ten weeks, with a total of 12 weeks. Antibiotics were administered intravenously for 7–14 days after the second stage of reimplantation. If the pathogenic microorganism culture was positive during reimplantation, antibiotics were orally taken for eight to ten weeks after two to four weeks of sensitive antibiotic administration according to drug-sensitive veins, with a total course of treatment of 12 weeks.

Prognostic evaluation

All patients underwent routine blood tests, liver and renal function tests, and ESR and CRP measurements. The patients were followed regularly (3 months, six months, one year after the operation, and once a year thereafter, with a minimum follow-up of 2 years). The ESR and CRP level were reexamined at each follow-up.

Successful treatment was evaluated according to the definition established by the international consensus in 2013: 1. infection eradication, characterized by good wound healing and no exudation, sinus or wound pain; 2. no infection-related surgical intervention after reimplantation; and 3. no infection-related death (caused by septicemia, necrotizing fasciitis, etc.).

Antibiotic-related complications: 1. myelosuppression: a preoperative routine WBC count of > 4*10^9/L and a maximum value of WBCs during intravenous or oral antibiotics < 3 * 10^9/l; 2. liver function damage: before the operation, the liver function alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels were all normal, and the peak value of ALT or AST during intravenous or oral antibiotics increased more than 1.5 times; 3. renal function damage: the creatinine level characteristic of renal function was within the normal range before the operation, and the creatinine value increased more than 1.5 times the initial value during intravenous or oral antibiotic administration.

Statistical analysis

The χ² test and F-test were used to compare the differences in demographic characteristics and comorbidities between CN PJI and CP PJI. Continuous variables such as age, body mass index and ASA between groups were analyzed by independent sample t test if they obeyed a normal distribution; otherwise, the Mann-Whitney U test was performed. Kaplan-Meier survival analysis and log-rank tests were used to compare the success rates of CN PJI and CP PJI. The χ² test and F-test were used to compare the incidence of antibiotic complications. Logistic regression was used to further analyze the
correlation between sex, age, basic diseases, sinus tract, joint involvement, surgical strategies, culture results and clinical outcomes. All statistical analyses were conducted with IBM SPSS version 22.0, and all tests were conducted with bilateral tests. P < 0.05 was considered statistically significant.

This study was approved by the Ethics Committee of the First Affiliated Hospital of Fujian Medical University.

**Results**

Seventy-seven PJI cases of the hip and knee were enrolled, including 24 cases of CN PJI and 53 cases of CP PJI. There was no significant difference in age, sex, body mass index (BMI), preoperative complications or ASA grade between the groups (Table 1). Nineteen patients in the CN PJI group had used antibiotics prior to surgery, which was significantly different from that in the CP PJI group. The administration of antibiotics prior to surgery might be the reason for the negative culture. The microbiology of CP PJI included methicillin-resistant *Staphylococcus* (MRS) in 25 cases, methicillin-sensitive *Staphylococcus* (MSS) in 16 cases, *Streptococcus* in four cases, gram-negative bacilli in three cases, fungi in three cases, and polymicrobial infection in two cases (Fig. 1). The incidence rate of CN PJI in this study was 31.17% (24/77). Six patients with CN PJI underwent one-stage revision, 11 patients underwent two-stage revision (two patients did not undergo reimplantation of the prosthesis due to the poor economy), and seven patients underwent DAIR. Seven patients with CP PJI underwent one-stage revision, 32 patients underwent two-stage revision (five patients did not undergo reimplantation of the prosthesis due to other reasons), and 14 patients underwent DAIR.

Because the definition of successful treatment in this study was aimed at patients who underwent reimplantation of the prosthesis, the patients who did not receive reimplantation (two patients with CN PJI and two patients with CP PJI) were excluded when analyzing the success rate of treatment. The overall success rate of CN PJI treatment was 86.4% (19/22). In one of the failed cases, the wound continued to ooze fluid after reimplantation surgery, and DAIR was performed 11 days after reimplantation. One patient experienced infection reoccurrence four months after one-stage revision, and another patient experienced infection reoccurrence six months after DAIR. There was no sign of infection recurrence at till now. The overall success rate of CP PJI treatment was 87.5% (42/48). Among the failed cases, three patients received additional DAIR within two weeks after primary DAIR due to wound discharge, and the other two patients received additional DAIR treatment 35 days and 13 months after primary DAIR due to infection recurrence. One patient received DAIR five months after two-stage revision, and no signs of infection recurrence were found till now. The overall success rates of CN PJI and CP PJI (Fig. 2) and the success rate among various surgical strategies did not reach statistical significance (Table 2).

CN PJI was associated with an overall antibiotic complication rate of 58.3% (14/24): myelosuppression occurred in five cases (20.8%), renal dysfunction in four (16.7%), liver dysfunction in one (4.0%), simultaneous liver and renal dysfunction in three (12.5%), and simultaneous myelosuppression and renal dysfunction in one (4.2%). CP PJI was associated with an overall antibiotic complication rate of 11.3%
(6/53): liver injury occurred in four cases (7.5%) and renal function damage in two (3.7%) without concurrent damage. The incidence of CN PJI and CP PJI antibiotic-related complications was significantly different, and the incidence of CN PJI antibiotic-related complications was higher than that of CP PJI antibiotic-related complication.

To further analyze the factors related to the clinical outcomes of PJI, factors such as sex, age, basic diseases, sinus tract, joints involved, surgical strategies, and bacterial culture results were included, and logistic univariate and multivariate analyses were used. The results showed that there was no correlation between the bacterial culture results and clinical outcomes (OR = 1.26, \(P = 0.75\)). Diabetes was the only factor that may be related to failure (adjusted OR = 48.8, \(P = 0.006\)).

**Discussion**

A total of 77 cases of hip and knee PJIs were included in the study. Nineteen patients in the CN PJI group had used antibiotics prior to surgery, which was significantly different from the CP PJI group. This may be the main cause of the negative bacterial results, so it is necessary to stop antibiotics for a few weeks before specimen collection for culturing. In the present study, the overall treatment success rate of PJI was 87.1%, and the average follow-up period was 29.2 months (12–76 months). The overall treatment success rates of CN PJI and CP PJI were 86.4% and 87.5%, respectively. There was no significant difference between the two groups (\(P = 1.000\)), which was consistent with the conclusions reported in most previous studies\(^{13-17}\). It has been reported that DAIR and two-stage revision are the two main surgical strategies for CN PJI, and the rate of infection eradication can reach 73–94%\(^{17}\). There was no significant difference in the success rate of one-stage revision between the groups. However, the sample size was small in the present work, and whether one-stage revision is applicable for CN PJI needs to be further investigated. In the present work, the antibiotic regimens for CN PJI that were typically used were an intravenous combination of vancomycin with third-generation cephalosporin or carbapenem. This kind of antibiotic regimen is effective for all pathogenic microorganisms except Mycobacterium tuberculosis and fungi (including G+/G-/ drug-resistant bacteria)\(^{17}\), which might be the reason why the success rate in the CN PJI group was similar to that in the CP PJI group in the present work.

The total incidence rate of antibiotic-related complications was 25.9%, and the incidence rates of CN PJI and CP PJI were 58.3% and 11.3%, respectively; the difference was significant. In the CN PJI group, the incidence rate of bone marrow suppression complicated by antibiotics was 20.8%, which was higher than the 2% ~ 8% reported in previous studies\(^{18,19}\). The incidence rate of concurrent renal impairment was 16.7%, and the incidence of renal impairment related to vancomycin treatment alone has been reported in the literature to be 6.5% ~ 10.7\(^{20,21}\). Some scholars have also shown that the incidence of renal damage increases from 6–21% with vancomycin treatment intravenously for more than one week, and the incidence of renal failure can reach 30\(^{22,23}\) when the antibiotic treatment course is extended to more than two weeks. Although there was no significant difference in clinical outcomes between the CN PJI group and the CP PJI group, the incidence of antibiotic-related complications in the CN group was
relatively higher than that in the CP PJI group. Therefore, the isolation of pathogenic bacteria and the proper administration of antibiotics were of great significance in reducing the incidence of antibiotic-related complications.

The advantages of this study were as follows: The cases of PJI in this study were included from January 2012 to June 2017, with uniform diagnosis and treatment standards, and the surgery was performed by doctors of the same medical team. The definition of successful treatment was judged by the international consensus made in 2013 and was well representative. This study is the first to compare the incidence of antibiotic-related complications between CN PJI and CP PJI as an evaluation of clinical outcome. There were also some limitations of this study. The present study was a retrospective study. The data of patients were collected via the electronic case system of this institution, so there was a certain degree of data deficiency. This study involved a single center, so the sample size was small. In addition, the minimum follow-up time was one year, and a few cases of recurrent infection may have been missed. Furthermore, this study focused on the short-term and medium-term clinical outcomes of CN PJI and CP PJI, and we should prolong the follow-up time to compare whether there are differences in long-term clinical outcomes. Finally, in the present study, the patients who did not undergo reimplantation of their prosthesis were excluded when comparing the success rate, and four patients in the CP PJI group who were treated with two-stage revision were lost to follow-up, which may have affected the results. Future prospective randomized controlled studies and longer follow-up time periods are warranted in order to evaluate clinical outcomes.

In conclusion, this study showed that if the CN PJI patients were treated strictly according to Tsukayama type, with a combination of two to six weeks of intravenous vancomycin and ceftazidime or carbapenem antibiotic administration with oral quinolone antibiotics for six to ten weeks, the overall success rate was similar to that of CP PJI, and there was no significant difference between the success rates of various surgical strategies in CN PJI and CP PJI. However, the incidence rate of antibiotic-related complications in CN PJI was higher than that of antibiotic-related complication in CP PJI. Due to a lack of etiological basis, the selection of suitable antibiotics is unclear for CN PJI. The empirical administration of a combination of vancomycin and ceftazidime or carbapenem antibiotics, which covers almost all pathogenic microorganisms except Mycobacterium tuberculosis and fungi, can achieve a good treatment success rate while at the same time also increasing the incidence rate of antibiotic-related complications.

**Abbreviations**

CN PJI: culture-negative periprosthetic infection

CP PJI: culture-positive periprosthetic infection

PJI: periprosthetic joint infection

BMI: body mass index
ASA: American Association of Anesthesiologists

ESR: erythrocyte sedimentation rate

CRP: C-reactive protein

SF-WBC: synovial fluid white blood cell

SF-PMN%: percentage of polymorphonuclear leukocytes

DAIR: debridement, antibiotics, irrigation, and retention

MSIS: Musculoskeletal Infection Society

ALT: alanine aminotransferase

AST: aspartate aminotransferase

**Declarations**

**Ethics approval and consent to participate:** This study was approved by the Ethics Committee of the First Affiliated Hospital of Fujian Medical University. Informed consent was obtained from all individual participants included in the study.

**Consent for publication:** Not applicable.

**Availability of data and materials:** The datasets used in the current study are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they have no competing interests.

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**Authors' contributions:** All authors contributed to the study conception and design. Experiment design, data collection and analysis were performed by Zhiyang XU and Yuanqing Cai. The first draft of the manuscript was written by Zhiyang XU and Yuanqing Cai, and translated by Xinyu Fang, Zida Huang and Chaofan Zhang, final edition was completed by Wenbo Li and Wenming Zhang. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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**Tables**

*Table 1* Demographic characteristics of all patients

| Variable            | CN-PJI (n=24) | CP-PJI (n=53) | P value |
|---------------------|---------------|---------------|---------|
| Sex (male)          | 12            | 25            | 0.818   |
| Age                 | 62.50         | 64.15         | 0.613   |
| BMI                 | 23.84         | 24.13         | 0.729   |
| ASA                 | 0.92          | 0.79          | 0.604   |
| Hypertension        | 14            | 33            | 0.743   |
| Diabetes            | 4             | 14            | 0.349   |
| Sinus               | 7             | 16            | 0.928   |
| Intraoperative suppuration | 15          | 27            | 0.526   |
Table 2 Comparison of the treatment success rates of PJIs

| Surgical strategies | CN-PJI (n= number of successful, success rate) | CP-PJI (n= number of successful, success rate) | \( \chi^2 \) value | \( P \) value |
|---------------------|---------------------------------------------|---------------------------------------------|----------------|----------------|
| Total               | 22/19 86.4%                                | 48/42 87.5%                                | 0.017          | 0.897*         |
| One-stage revision  | 6/4 66.7%                                  | 7/7 100%                                   | 2.560          | 0.110*         |
| Two-stage revision  | 9/9 100%                                   | 27/26 96.3%                                | 0.333          | 0.564*         |
| DAIR                | 7/6 85.7%                                  | 14/9 64.3%                                 | 1.079          | 0.299*         |

Table 3 Logistic regression analysis of factors related to the clinical outcomes of PJI

| Sex         | Successful | Failed | OR | \( P \) value | Adjusted OR (95%CI) | \( P \) value |
|-------------|------------|--------|----|---------------|---------------------|---------------|
| Male        | 29         | 4      | 1  |               |                     |               |
| Female      | 30         | 7      | 1.69 | 0.44         |                     |               |
|                  |       |     |       |      |
|------------------|-------|-----|-------|------|
| **Age**          |       |     |       |      |
| <60              | 20    | 2   | 1     |      |
| 60-70            | 22    | 3   | 0.283 | 0.15 |
| >70              | 17    | 6   | 0.386 | 0.22 |
| **BMI**          |       |     |       |      |
| <24              | 29    | 8   | 1     |      |
| 24-28            | 22    | 2   | 2.20  | 0.46 |
| ≥28              | 8     | 1   | 0.72  | 0.81 |
| **Diabetes**     |       |     |       |      |
| No               | 49    | 4   | 1     |      |
| Yes              | 10    | 7   | 8.57  | 0.003 |
|                  |       |     | 48.8±3.13-761.63±0.006 | 0.006 |
| **Hypertension** |       |     |       |      |
| No               | 26    | 3   | 1     |      |
| Yes              | 33    | 8   | 2.1   | 0.31 |
| **Sinus**        |       |     |       |      |
| No               | 42    | 9   | 1     |      |
| Yes              | 17    | 2   | 0.55  | 0.47 |
| **Joint involved** |     |     |       |      |
| Hip              | 39    | 4   | 1     |      |
| Knee             | 20    | 7   | 3.41  | 0.073 |
| **Administration of preoperative antibiotics** |       |     |       |      |
| No               | 23    | 5   | 1     |      |
| Yes              | 36    | 6   | 0.77  | 0.69 |
| **Surgical strategies** |     |     |       |      |
| DAIR             | 10    | 4   | 1     |      |
| One-stage revision | 11   | 2   | 3.04  | 0.15 |
| Two-stage revision | 38   | 5   | 1.38  | 0.72 |
| **Bacterial culture results** |       |     |       |      |
### Figures

**Figure 1**

Microbiology of CP-PJI
Kaplan-Meier survival analysis showing that the overall success rates of CN PJI and CP PJI are similar (P=0.897)

Figure 2

Kaplan-Meier survival analysis showing the success rates of different procedures.

Figure 3
Kaplan-Meier survival analysis showing the success rate of CN PJI treated with various surgical strategies.