



Efficiency of the One-Stage Revision Hip Arthroplasty in Chronic Periprosthetic Joint Infection with Sinus Tract

Vasily A. Artyukh, Svetlana A. Bozhkova, Andrey A. Boyarov, Julia V. Muravyova, Andrey A. Kochish

Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russia

Abstract

Background. Chronic periprosthetic joint infection (PJI) remains the one among the most severe complications of total hip arthroplasty. Presence of sinus tract associated with polymicrobial infection development, complexity of bacteriological diagnostics and damage of soft tissues lead to constrictions of one-stage revision hip arthroplasty (RHA). **The aim of this study** was to assess the influence of draining sinus tract on the outcomes of one-stage RHA in patients with chronic hip PJI. **Materials and Methods.** A prospective cohort comparative study included 78 patients who underwent one-stage RHA in 2017-2020. Two groups were formed: 48 (61.54%) patients without sinus tract (WST) and 30 (38.45%) patients with sinus tract (ST). **Results.** The presence of a sinus tract significantly increased the duration of a one-stage RHA in groups of ST and WST (230 and 197.5 min respectively, $p = 0.02$), as well as blood loss (850 ml and 700 ml, respectively, $p = 0.046$). Sinus tract was a reliable symptom of soft tissue local infectious inflammation (86.67%, $p = 0.00031$), fasciitis (36.67%, $p = 0.012$), purulent cavity (66.67%, $p = 0.00027$). The structure of the pathogens was comparable. Monobacterial infections predominated in the WST group (82.98%) and in the ST group (77.78%, $p = 0.08$). In most cases staphylococci were isolated. The median follow-up was 20 months for both groups. The PJI was healed in 93.0% ($n = 28$) patients in WST group and 82.2% ($n = 43$) in ST PJI ($p > 0.05$). Postoperative evaluation in the WST and ST groups: HHS 92 and 90 points ($p = 0.79$), EQ-5D-5L – 0.82 and 0.78 points ($p = 0.84$) respectively. The proportion of patients who were indicated revision surgery with no PJI association in the ST group exceeded this indicator more than twice according to the WST group – 25 and 11.62%, respectively ($p > 0.05$). **Conclusion.** As a result of the study, there was no statistically significant difference between the outcomes of one-stage RHA in patients with and without sinus tract. Factors such as the anamnesis morbi, the soft tissues condition at the surgical site and the pathogenic microflora characteristics should be taken into account in order to achieve favourable outcomes of surgical treatment.

Keywords: periprosthetic joint infection, one-stage revision hip replacement, sinus tract.

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Introduction

Chronic periprosthetic joint infection (PJI) remains one of the most severe complications of total hip arthroplasty (THA), which requires surgical

treatment, leads to deterioration of functional results, significantly increases the financial burden on both patients and the healthcare system [1, 2]. Despite the improvement of surgical techniques

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✉ Vasily A. Artyukh; e-mail: artyukhva@mail.ru

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and prophylaxis the number of PJI cases increases in the proportion to the increase in of the THA number. The development of diagnostic tools for infectious complications identification allows to increase the life expectancy of patients [1, 3, 4, 5].

In accordance with modern ideas about the pathogenesis of PJI, the result of treatment is considered successful while having the complete elimination of the infectious inflammation symptoms and restoration of limb function [6]. In the case of chronic PJI, this goal is achieved by a one- or two-stage revision THA [7]. Both methods have their advantages and disadvantages. The two-stage method has become the most widespread. Proponents of two-stage revision THA indicate that sometimes this strategy gives an advantage in the eradication of PJI, especially combined with polyresistant pathogens or a functioning fistula [8].

One-stage revision THA is extremely attractive for both the patient and the doctor. Over ten years of practice A. Zahar et al. found out that one-stage revision THA can cure PJI in 94% of patients, and 75.9% of patients do not need a repeated surgery for instability of the endoprosthesis [9]. Among the advantages of one-stage revision THA are greater patient treatment results satisfaction, a lower mortality rate, a shorter hospitalization period, shorter duration of antibacterial therapy (ABT), and reduced financial costs. The decrease of the periprosthetic fractures frequency, dislocations, and cases of limb shortening was recorded in patients [10].

In publications devoted to the problems of one-stage revision THA, orthopedists orthopaedic surgeons usually analyze the effectiveness of a particular surgical technique or infection eradication methods. However, the functioning of the fistula as an obvious symptom of infectious soft tissue lesion, its effect on the results of treatment, has not yet been sufficiently studied. Only a few studies summarized in a systematic review have convincingly shown the negative effect of the fistula pathway on the outcomes of single-stage revision THA [11]. J. Jenny et al. presented the results of one-stage revision THA: in 6 out of 11 cases of PJI recurrence before surgery, a functioning fistula was detected in patients [12]. J. Lange et al. summarized the outcomes of one-stage revision

THA in 56 patients. During the initial examination the development of PJI was diagnosed in five cases, including a fistula in three cases and an abscess in one case [13]. According to the researchers the fistula pathway itself is not an absolute contraindication to the one-stage revision THA but it worsens the prognosis of the treatment outcome. In addition, an analysis of publications over the past decade has shown a change in the views upon the problem of fistula during the one-stage revision THA. Thus, T. Gehrke et al. consider fistula pathway (course) a contraindication for to surgery in the absence of data of the wound microbiological landscape. The deficiency of soft tissues in the area of the postoperative wound is considered be a relative contraindication [10]. Later, A. Zahar et al. considered fistula and soft tissue deficiency as a contraindication to surgery only in the absence of the surgical wound primary closure possibility [9].

Thus, the analysis of modern publications made it possible to establish that the lack of justification for one-stage revision THA surgery in patients with a functioning fistula is problematic. Perhaps insufficient attention to this problem is due to the small number of patients with fistulas (from 3 to 9) who underwent one-stage revision THA [9, 12, 13].

The aim of the study was to evaluate the effect of a functioning fistula pathway on the outcomes of one-stage revision THA in patients with chronic PJI.

Materials and Methods

Design of the study

A prospective comparative cohort study included patients with chronic PJI who underwent revision THA in the Vreden National Medical Research Centre of Trauma and Orthopaedics in 2017-2020.

Criteria for inclusion in the study:

- chronic PJI in the area of the hip joint, regardless of the gender and age of the patient;
- a strain of the pathogen sensitive to antibiotics with an oral form of drugs has been isolated;
- a bone defect allows implanting standard or revision endoprosthesis components: acetabulum defects of types I–IIIA according to the Paprosky classification [14], femoral defects I–IIIB according to the Mallory classification [15];
- there are enough soft tissues to cover the wound;

- limited infectious inflammation of soft tissues (fistula, abscess);
- there are no other non-sanitized foci of chronic infection;
- implant-associated osteomyelitis the first (medullary) or the second (superficial) anatomical types, the physiological class of the patient A, B (l, s) according to the Cierny – Mader classification [16].

The criterion of non-inclusion was considered to be the syndrome of systemic inflammatory reaction, sepsis.

Exclusion criteria were applied during the examination of patients or during the surgery itself:

- unlimited form of soft tissues infectious inflammation (phlegmons, leakage) or purulent leakage to the neurovascular bundles;
- implant-associated osteomyelitis of III (localized) or IV (diffuse) anatomical types, physiological class of patient C according to Cierny-Mader classification;
- defects of the acetabulum type 3B according to Paprosky and femur type 4 and more according to Mallory, which were identified before surgery or formed as a result of surgical treatment;
- soft tissue defect after excision of the fistula, which does not allow suturing the wound.

Out of 135 patients prepared for one-stage revision THA the planned surgery was performed

in 78 (57.8%). During the surgery exclusion criteria were identified in 57 (42.2%) patients, as a result of which they underwent a two-stage revision THA.

All patients who met the inclusion criteria underwent a one-stage revision THA. If exclusion criteria were found before or during the surgery, the tactics of patients treating were changed to a two-stage revision THA. During 2017-2020 the study included 78 patients. According to the presence or absence of a functioning fistula in patients at the time of treatment, two compared groups were formed. The first group included 48 (61.54%) patients who had no fistula (NFF of PJI). The second group included 30 (38.45%) patients with the fistulous form of PJI (FF of PJI) (Fig. 1).

The diagnosis of PJI was performed in accordance with the criteria of the International Consensus Meeting (ICM) in 2013 [17]. In this edition, the fistula pathway, along with the positive result of two microbiological tests, is one of the two "big" signs of PJI sufficient to confirm the diagnosis. In the absence of these criteria, three out of five "small" signs were considered sufficient for the diagnosis of PJI. The assessment of the PJI nature (acute or chronic) was performed based on the current understanding of the pathogenesis of implant-associated infection and the classification of PJI proposed by W. Zimmerli [18].

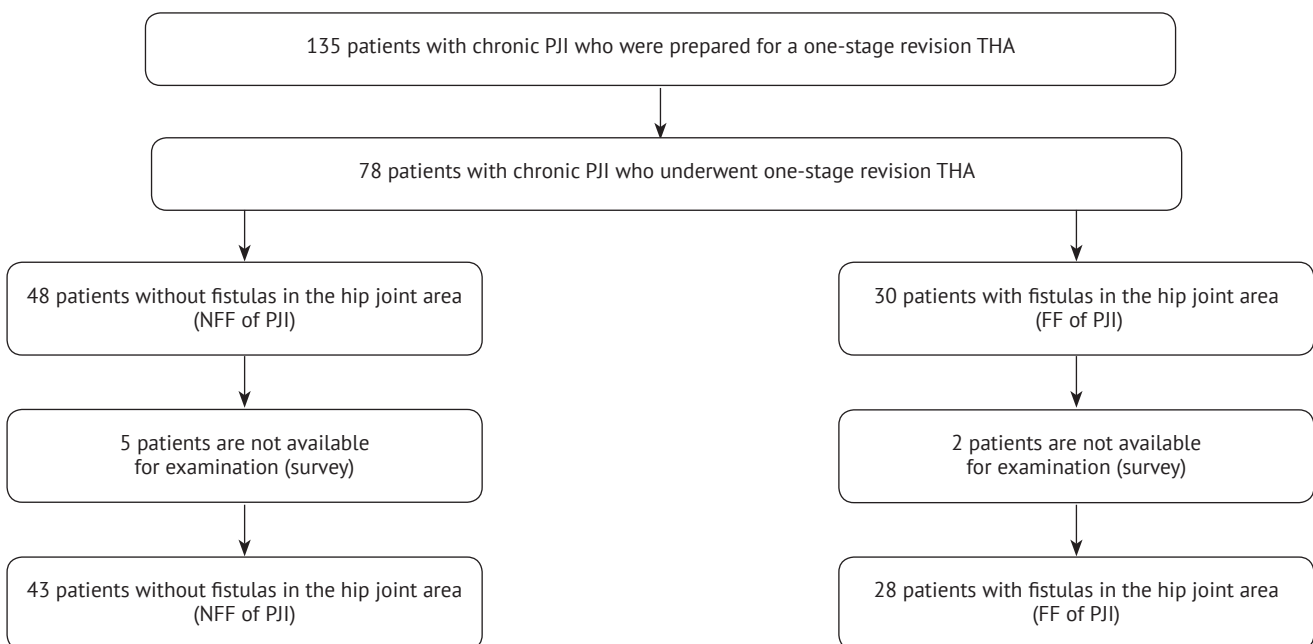


Fig. 1. Study flow chart

A prerequisite for the one-stage revision THA realization was the isolation of microbial pathogen strain sensitive to the oral antibiotics. In order to identify the pathogen, a joint puncture was performed in the preoperative period, after which a microbiological examination of the aspirate was performed. In patients with a functioning fistula, it was impossible to obtain intra-articular fluid as a result of puncture, or its amount was insufficient for the study. In these observations, tissue samples were taken from the depth of the fistula, from the surface of the bone or endoprosthesis for subsequent bacteriological analysis according to the established technique (patent for invention RU 2 698 175 C1. 2019. P).

Surgical technique

All single-stage revisions were performed according to a single surgical protocol. The patient was placed on a healthy side on the surgical table, an incision was made along the old postoperative scar (60 (76.92%) of observations — anterior approach, 17 (21.79%) — posterior, 1 (1.28%) — another) with excision of the scar. Radical layer-to-layer surgical soft tissue debridement to the entire depth of the wound was performed. A functioning fistula (30 patients, 38.46%) was excised within the healthy tissues and was not considered a contraindication to the one-stage revision THA if the wound could be closed initially. All endoprosthesis components, bone cement and other foreign bodies were carefully removed. Osteotomy of the large trochanter was not performed. The bone wound of the acetabulum and femur was treated with cutters, rasps to a well-bleeding surface. Tissue samples (at least five) for histological and bacteriological examination were obtained from the deepest areas of the wound, as well as from under the femoral and acetabulum components of the endoprosthesis. The surgical wound was washed with 6-10 liters of antiseptic solutions 0.02% polyhexanide, 0.05% chlorhexidine bigluconate using Pulsavac (Zimmer-Biomet) pulsing jet lavage device. After the completion of radical debridement, the bone cavities were tamponed with napkins drained in 10% povidone-iodine solution (EGIS Pharmaceuticals, PLC) for 5-10 minutes. Then the change of instruments, sur-

gical sheets, gloves was performed. The choice of fixation of the endoprosthesis was carried out taking into account the type of defects of the pelvic and hip bones, as well as the surface of the bone wound. Cement fixation (62 observations, 77.8%) was chosen in cases when bone defects were insignificant or could be replaced with standard revision structures (augments). In cases where the bone surface was sclerotic and bone defects did not allow stable fixation of components, cementless endoprostheses were implanted (16 cases, 22.2%). In 19 (24.4%) patients, the fixation of the endoprosthesis was hybrid, in 9 (11.5%) — anti-hybrid. The postoperative wound was sutured in primary way in all cases, as this was the one of the criteria for patients inclusion in the study group. In most cases (70 patients, 89.7%), the wound was sutured in layers with separate interrupted sutures, 8 (10.3%) patients required plastic procedure for the soft tissue defect with local tissues. Drainage of the postoperative wound by Redon was performed in 24 patients (30.8%) for 24-48 hours. The aseptic dressing was changed daily. Laboratory control was performed twice a week, assessing the dynamics of the main homeostasis indicators of recovery, including the rate of erythrocyte sedimentation (ESR) and C-reactive protein (CRP). Mobilization of patients was started the next day after the drain removal or on the 3rd-4th day after surgery. The full weight-bearing was allowed 3-8 weeks after surgery, depending on the endoprosthesis fixation type.

Antibiotic therapy

In 76 (97.4%) cases, a wide-spectrum initial ABT was performed, but with the mandatory consideration of pathogens isolated before the surgery. On the eve of the surgery or before the start of anesthesia, the patient was fitted with a central venous catheter for parenteral administration of drugs in the perioperative period. The choice of antimicrobial agents to be added to a bone cement was also carried out based on the results of a preoperative microbiological study. If necessary, the ABT was corrected after receiving the results of the intraoperative biological material study. ABT safety control included assessment of liver transaminase activity and creatinine levels.

Assessment of results

The result of PJI eradication was studied at least 12 months after a one-stage revision THA. The appearance of infection symptoms within a year after surgery was considered as a relapse of PJI, a year or more later - an infectious complication that arose for the reasons unrelated to the previous clinical case of PJI.

Evaluation of the functional results of one-stage revision THA in patients with chronic PJI was performed by Harris Hip Score (HHS), which assumes an assessment of four parameters: pain, function, deformation, range of motions. The quality of patients life was assessed using the EQ-5D-5L questionnaire, the health profile was compiled taking into account the three levels of problems severity in five areas (mobility, self-care, normal activity, pain/discomfort, anxiety/depression) and a score obtained using a visual analog scale (VAS).

Statistical analysis

Registration, systematization of primary data and visualization of the results were performed in Microsoft Office Excel 365 spreadsheets. Statistical analysis was carried out by means of the Statistica 10 software system.

To describe quantitative indicators, the normality of the distribution according to Kolmogoro-Smirnov, Shapiro-Wilk criteria was checked. With a normal distribution, its mean value and the mean square deviation were used to describe the trait. With a distribution other than normal, the median (ME) was taken, and the lower (Q1) and upper (Q3) quartiles (25-75% MCI) were used as scattering measures. Comparison of quantitative parameters (age, duration of inpatient treatment, duration of surgery and volume of blood loss) in the study groups was carried out using Mann-Whitney criteria.

Nominal data (gender, type of PJI, comorbidity, type of spacer and outcome) were described with absolute values and percentages. Due to the small number of observations, the comparison of nominal data was carried out using the Pearson criterion χ^2 , adjusted for Yates continuity. The confidence interval (CI) for categorical data was determined based on frequency distributions. The differences between the groups were considered statistically significant at $p < 0.05$.

To quantify the dependence of the probability of outcome on the presence of a risk factor, the odds ratio (OR) indicator was calculated with a 95% confidence interval (95% CI).

Results

In the distribution of patients by gender, the predominance of females in the group of patients with NFF of PJI ($p > 0.05$) was established, while the gender distribution of patients in the group of FF of PJI was comparable (Fig. 2).

The median age of patients with NFF of PJI at the time of surgery was 67.5 (63-77.5) years, in the group with FF of PJI — 70 (62-79) years and had no significant differences ($p = 0.712$). In both groups, the majority of patients suffered from chronic hematogenous infection (Table 1). During the treatment of PJI before specialized care (one-stage revision THA), 33.3% of patients with FF and 14.58% of patients with NFF of PJI underwent various debridement surgeries ($p = 0.807$). As a rule, these were minor surgical interventions aimed to relieve the symptoms of the systemic inflammatory reaction syndrome (SIRS). After the manifestation of an infectious complication symptoms, patients in both groups did not receive specialized orthopedic care for a long time. The median waiting period for revision THA was statistically significantly higher in the FF of PJI group (256 days (180-519)) compared with patients in the NFF of PJI group (111 days (20-435)) ($p = 0.018$).

A comparative analysis of the concomitant diseases incidence did not reveal significant differences between the compared groups (Table 2). Among the concomitant diseases, pathology of the cardiovascular system (chronic heart failure (CHF), ischemic heart disease (IHD), arterial hypertension) and gastrointestinal tract were noted more often than others. The physical status of patients was mainly defined as mild diseases without significant functional limitations that matched the criteria of the 2nd class according to the classification of the American Society of Anesthesiologists (ASA) assessing physical status. At the same time, patients with the most severe somatic status (ASA 3) were observed only in the group with FF of PJI (2 patients, 6.67%).

Table 1

The history of the disease in patients in the study groups

Parameter	NFF of PJI n = 48	FF of PJI n = 30	p
Chronic postoperative, n (%)	14 (29,16)	11 (36,7)	> 0,05
Chronic hematogenic, n (%)	34 (70,83)	19 (63,3)	> 0,05
Debridement before one-stage revision THA, n (%)	7 (14,58)	10 (33,33)	> 0,05
Time interval: manifestation of PJI - one-stage revision THA (median, MCI)	111 (20–435)	256 (180–519)	0,018

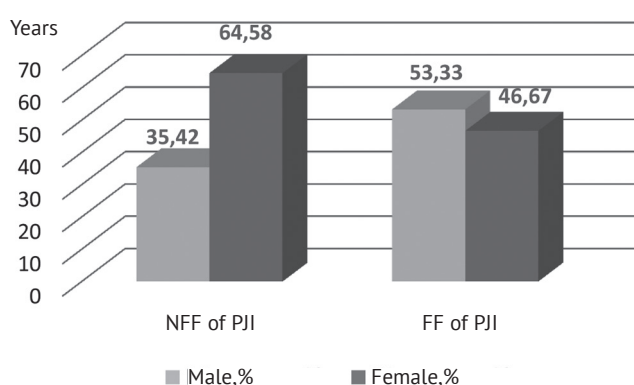


Fig. 2. Distribution of patients by gender in study groups

Median BMI exceeded the norm and amounted to 27.71 and 26.5 in the NFF and FF of PJI groups, respectively ($p > 0.05$). More than half of the patients — 32 (68.04%) in the NFF of PJI group and 18 (59.9%) in the FF of PI group - were overweight, while the distribution of patients by degree of obesity in the compared groups was similar.

The presence of a fistula pathway significantly increased the duration of one-stage revision THA: 230 and 197.5 minutes in the FF and NFF groups, respectively ($p = 0.020$), which at a comparable rate of blood loss (3.69 and 3.54 ml/min, $p > 0.05$) led to significantly greater intraoperative blood loss (850 and 700 ml, respectively ($p = 0.046$)). In the compared groups, there were no significant differences in the frequency and duration of drainage, as well as in the number of installed drains (Table 3). The median volume of drainage blood loss in the FF group was almost 1.5 times higher than in the compared group, but these differences were not statistically significant. The number of transfused erythrocyte mass doses in the NFF and FF of PJI groups of 2 doses

(2-3) and 3 doses (2-4), respectively ($p = 0.241$), as well as the volume of transfusion of freshly frozen plasma (590 (540-600) and 600 (560-890) ml, respectively ($p = 0.082$)) had no statistically significant differences, although these indicators were higher in patients with FF of PJI.

The medians of the inpatient period duration and the cost of treatment in patients in the compared groups did not differ significantly (Table 3).

Before the surgery, in the group with FF of PJI, such markers of inflammation as the number of leukocytes, ESR, and CRP levels were significantly higher than in the group with NFF of PJI (Table 4). In addition, during inpatient treatment, hemoglobin levels were slightly lower in patients with FF of PJI compared with patients with NFF of PJI ($p = 0.059$).

Information of the bone defects size was available in 71 out of 78 (91.0%) patients: in 43 out of 48 (89.6%) patients with NFF of PJI and in 28 out of 30 (93.3%) with FF of PJI. The frequency of the acetabulum bones moderate destruction detection (IIA-IIIB) in both groups was comparable. Significant defects (IIIA) were found 1.8 times more often in patients with fistulas in the hip joint area ($p > 0.05$) (Fig. 3).

The structure of femoral defects in the compared groups was close (Fig. 4).

The analysis of infectious soft tissue lesions allowed us to establish that a functioning fistula is a significant symptom of subcutaneous tissue local inflammation (86.67%, $p = 0.00031$), fibrous degeneration of subcutaneous tissue (66.67%, $p < 0.05$), fasciitis (36.67%, $p = 0.012$), purulent leakage (66.67%, $p = 0.00027$) in the area of surgical intervention. The absence of a permanent fistula in the NFF of PJI group led to the localization of infectious inflammation around metal structures (ex-

ogenous sequesters). The area of osteolysis around the acetabulum component of the endoprosthesis was found in 54.17% of patients with NFF of PJI ($p = 0.036$), around the femoral component of the endoprosthesis - in 75.0% ($p = 0.011$) (Fig. 5).

The structure of the leading pathogens was comparable — staphylococci prevailed in both groups (Table 5). Among the pathogens in the NFF group, *S. epidermidis* was more common than others, and *S. aureus* was more common in the FF group. From the number allocated before operation *S. epidermidis* the proportion of MRSE in the NFF of PJI was 41.5% (17 out of 24), and in the FF of PJI — 50% (3 out of 6) ($p > 0.05$). MRSA strains were isolated only in patients with FF of PJI, their proportion was 13.3% (2 out of 15).

It should be noted that the methods of obtaining the material for bacteriological research differed in the compared groups. In patients with FF of PJI, an insufficient amount of intra-articular fluid was obtained during joint puncture. In this regard, tissue samples were taken from the depth of the fistula passage, in close proximity to the endoprosthesis (Patent RU 2.698.175c1). The use of this technique has significantly increased the effectiveness of preoperative bacteriological examination. In the group with FF of PJI, the number of observations in which there was no growth of pathogenic microflora, made up 7.41%, while the study of joint aspirate in patients with NFF of PJI was uninformative 14.89% of cases ($p = 0.0017$).

Table 2

The incidence of concomitant diseases and ASA in study groups

Parameter	NFF of PJI, n (%)	FF of PJI, n (%)	p
BMI, kg/m (median, MCI)	27.71 (23.43–31.2)	26.5 (22.92–30.79)	0.958
Obesity:			
normal	16 (34.04)	12 (40.0)	> 0.05
overweight:	17 (36.12)	10 (33.3)	> 0.05
1 stage	13 (27.66)	6 (20.0)	> 0.05
2 stage	2 (4.26)	1 (3.3)	> 0.05
3 stage	0	1 (3.3)	> 0.05
Ischemic heart disease	25 (53.19)	15 (55.56)	> 0.05
Chronic heart failure	27 (57.45)	18 (66.67)	> 0.05
Cardiac arrhythmia	8 (17.02)	6 (23.08)	> 0.05
Arterial hypertension	33 (70.21)	25 (86.21)	> 0.05
Peripheral vascular diseases	14 (29.79)	12 (46.15)	> 0.05
Diabetes mellitus	2 (4.26)	3 (12.0)	> 0.05
Diseases of the respiratory system	7 (14.89)	6 (21.43)	> 0.05
Malignant tumors	3 (6.38)	2 (7.69)	> 0.05
Diseases of the liver and biliary tract	9 (19.15)	5 (17.86)	> 0.05
Gastrointestinal diseases	39 (82.98)	21 (77.78)	> 0.05
Connective tissue diseases	2 (4.26)	0	> 0.05
Anemia	16 (34.04)	9 (33.3)	> 0.05
Violations of the coagulation system and taking anticoagulants	7 (14.89)	4 (15.38)	> 0.05
Kidney diseases and urinary system	9 (19.15)	4 (15.38)	> 0.05
Smoking	5 (10.64)	2 (7.69)	> 0.05
Alcoholism	17 (36.17)	6 (22.2)	> 0.05
ASA, grade:			
1	2 (4.17)	2 (6.67)	> 0.05
2	46 (95.83)	26 (86.67)	> 0.05
3	0	2 (6.67)	> 0.05

Table 3

Comparative characteristics of the perioperative period in single-stage revision THA groups

Parameter	NFF of PJI (M, MCI)	FF of PJI (M, MCI)	p
Operation time, min	197.5 (137.5–240)	230 (219–255)	0.020
Blood loss during surgery, ml	700 (400–1000)	850 (700–1300)	0.046
Drains:			
- quantity, units	0.35 (0–1)	0.8 (0–1)	0.353
- duration, day	2 (1.5–3.5)	3.5 (2–5)	0.099
- blood loss, ml	275 (150–560)	410 (350–500)	0.51
Punctures:			
- quantity, units.	2 (1–3)	1 (1–3)	1.0
- blood loss, ml	30 (15–70)	30 (10–150)	0.758
Transfusion of erythrocyte mass, dose	2 (2–3)	3 (2–4)	0.241
Transfusion of freshly frozen plasma, ml	590 (540–600)	600 (560–890)	0.082
Duration of inpatient period, days	27 (22–33)	27 (22–36.5)	0.75

Table 4

Results of laboratory tests before single-stage revision THA in study groups

Laboratory data	NFF of PJI (M, MCI)	FF of PJI (M, MCI)	p
RBC, ×10 ¹² /l	4.45 (3.98–4.7)	4.43 (3.67–4.76)	0.840
Hb, g/l	125 (107–134)	113 (99–128)	0.059
WBC, ×10 ⁹ /l	6.8 (5.5–8.4)	7.8 (6.5–9.0)	0.048
ESR, mm/h	37.5 (22–55)	60 (39–73)	0.001
CRP, mg/l	15.7 (8.8–34.24)	31.35 (20.6–78.6)	0.002

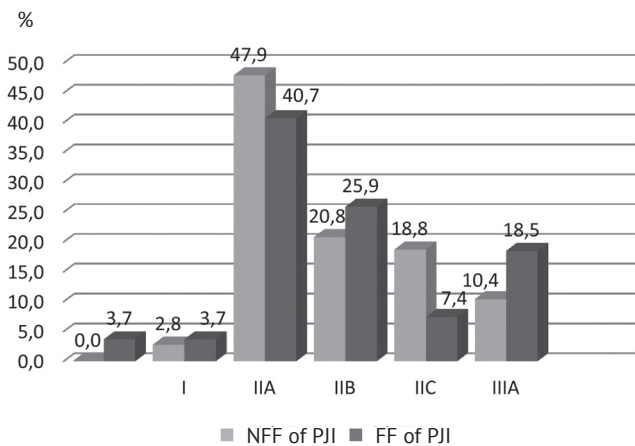


Fig. 3. Structure of the acetabulum defects according to Paprosky classification. Type IIIB femoral defects was the exclusion criteria

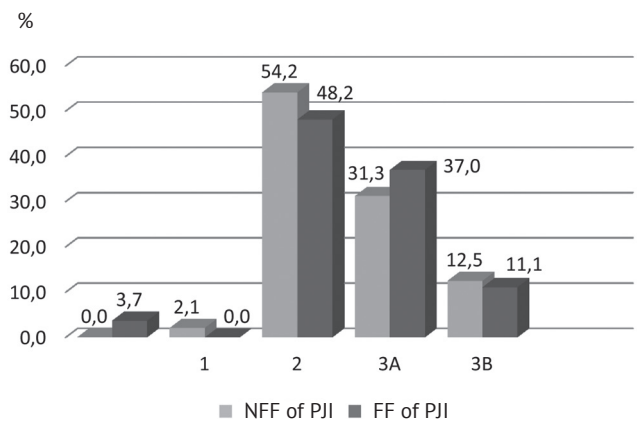


Fig. 4. Structure of femoral defects according to Mallory classification. The presence of type 4 femoral defects was the exclusion criteria

Microbiological study of biological material samples from the hip joint before the surgery showed that in both groups were dominated by

patients with monobacterial infection (group NFF of PJI – 82.98%, in the group FF of PJI – p= 77.78 %) (p = 0.084) (Fig. 6).

Table 5

Spectrum of PJI pathogens isolated from biomaterial before surgery

Pathogenic microflora	NFF of PJI, n (%)	FF of PJI, n (%)	p
<i>S. epidermidis</i>	24 (58.5)	6 (20.7)	>0.05
<i>S. aureus</i>	4 (9.8)	15 (51.7)	>0.05
<i>Enterococcus spp.</i>	6 (14.6)	3 (10.3)	>0.05
Gram-negative bacteria	1 (2.4)	1 (3.4)	>0.05
Other	6 (14.6)	4 (13.8)	>0.05
Total	41 (100)	29 (100)	-

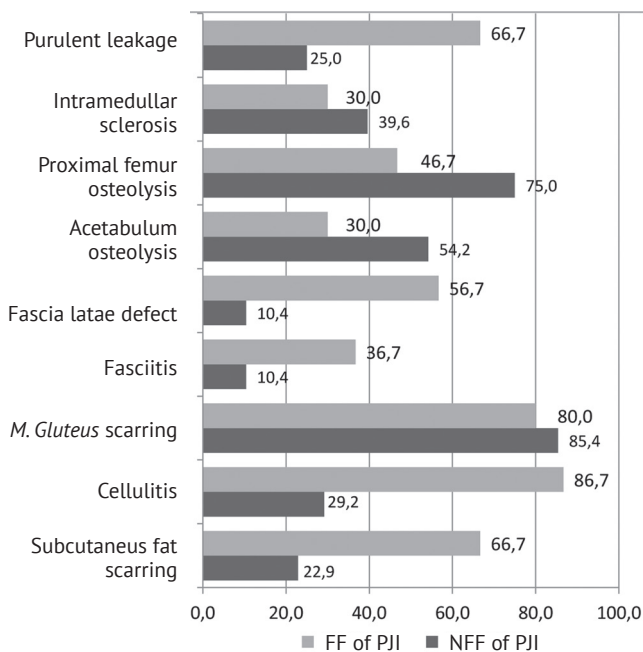


Fig. 5. Structure of soft tissues and bone infectious lesions in the groups (p<0.05)

Comparison of the biological material study results obtained before and during surgical intervention, showed that the proportion of matched results was 40.00 and 56.25%, respectively in groups FF and NFF of PJI (p = 0.081) (Fig. 7).

While still at 33.3 and 12.5% of cases (p>0.05), respectively, for groups FF and NFF of PJI results of tissue samples preoperative studies from fistula partially coincided with the data obtained from specimens obtained during surgery. The proportion of "incorrect" preoperative data on the pathogen in both groups was comparable (p>0.05).

Information on delayed treatment outcomes was obtained from 71 out of 78 patients (43 from the NFF of PJI group and 28 from the

FF of PJI group). Median follow-up duration was 20 months (12-29) in the NFF group and 23 months (12-34) in the FF group (p = 0.685). It was found that the eradication of infection was achieved in 43 (93.03%) patients with NFF of PJI and 28 (82.15%) — in the group FF of PJI (p>0.05) (Fig. 8). All cases of PJI recurrence developed up to one year after one-stage revision THA.

The proportion of patients who needed revision surgery unrelated to PJI (hematoma of the postoperative wound, dislocation of the endoprosthesis head) in the FF of PJI group was more than twice higher than this indicator in the NFF of PJI group - 25% and 11.62% (p>0.05).

The number of deaths among the patients of the studied groups was comparable. In the NFF of PJI group, the death of patients in 2 (4.65%) cases occurred 90 days and 1.5 years after surgery and was not associated with a recurrence of PJI. In the group with FF of PJI, the cause of death of one patient (3.57%) was the generalization of chronic recurrent PJI 6 months after surgery.

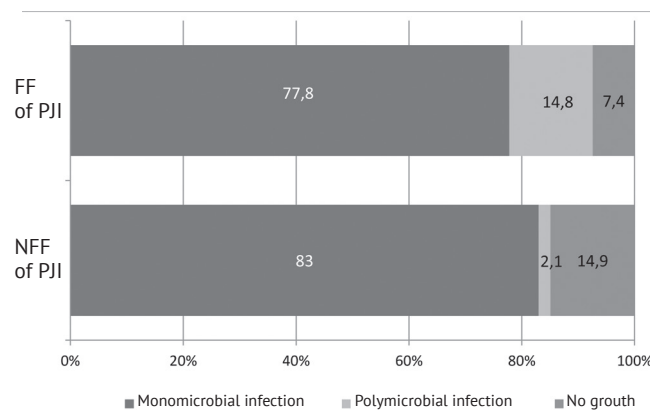


Fig. 6. Etiology of the hip PJI in the groups

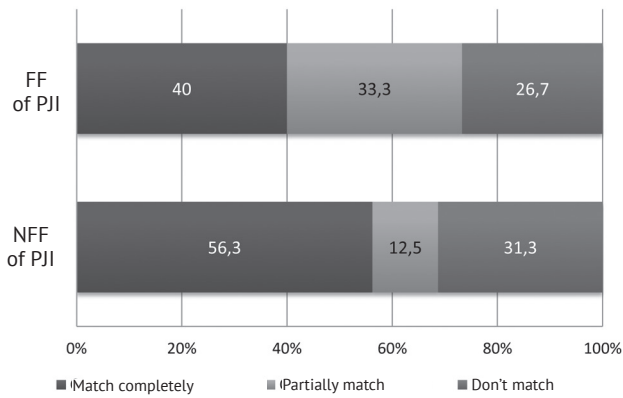


Fig. 7. Comparability of the microbiological study results up to- and intraoperative samples of biological material in groups

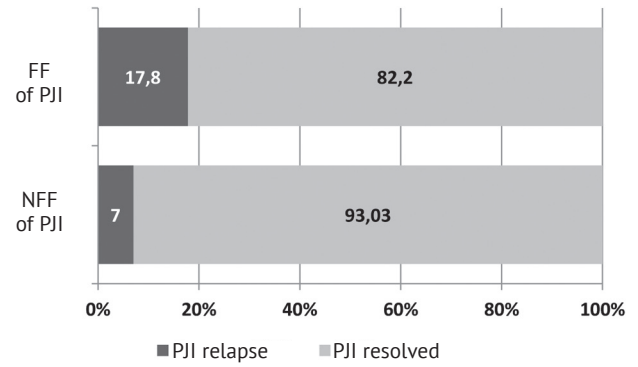


Fig. 8. Results of a single-stage revision in comparison groups

Before the surgery, patients in the FF of PJI group felt better than patients with NFF of PJI, which is confirmed by the results of the survey on the EQ-5D-5L scale - 0.49 and 0.28 points, respectively ($p = 0.031$) (Table 6).

After the surgery, the final results of the patients functional capabilities assessment in the two groups were comparable on a scale of HHS

(92 and 90 points, $p = 0.79$) and social adaptation scale EQ-5D-5L (0.82 and 0.78 points, $p = 0.84$).

It should be noted that subjective assessment by patients of their general condition on VAS before surgery (50 points, $p < 0.05$) and after (75 points, $p = 0.47$) was higher in the group of patients with FF of PJI.

Table 6

Results of one-stage revision THA in patients with chronic PJI in the groups

Scale	NFF of PJI (M, MCI)	FF of PJI (M, MCI)	p
Follow-up period, months	20 (12–29)	23 (12–34)	0.685
HHS:			
– before the surgery	32 (26–44)	36 (25–49)	0.525
– after the surgery	92 (71–95)	90 (74–93)	0.790
EQ-5D-5L:			
– before the surgery	0.29 (0.15–0.5)	0.49 (0.22–0.64)	0.031
– after the surgery	0.82 (0.58–0.88)	0.79 (0.71–0.88)	0.845
VAS:			
– before the surgery	30 (20–50)	50 (40–60)	0.000
– after the surgery	70 (50–85)	75 (50–85)	0.474

Discussion

After the publication of H.W. Buchholz et al. [16], dedicated to the ten-year experience of one-stage revision THA, the surgery gained many convinced supporters and opponents. Since then, thematic meta-analyses and reports on the study of international consensus meetings have been published, and the severity of the discussion has significantly decreased, and a unified approach to the choice of surgical tactics is being

formed in the orthopedic community [7, 20, 21]. Nevertheless, not an obvious solution has been found for all problems. The influence of a functioning fistula pathway on the results of treatment is one of such issues.

In our prospective comparative cohort study of delayed results for single-stage revision THA in 71 patients with chronic PJI, infection was depressed in 43 (93.03%) patients with NFF of PJI and in 28 (82.15%) patients with FF of PJI ($p > 0.05$).

S. Marmor et al. believe that a fistula is not an obstacle to surgery if there is enough soft tissue after its excision for primary suturing of the wound [9, 21]. In the study of A. Zahar et al., 10.6% of patients had one or more fistula pathways, but 94% of them had no recurrence of PJI for 10 years [9]. Moreover, as shown by a systematic review carried out by S. Kunutsor et al., among the candidates for one-stage surgery there were more patients with a history of debridements, a higher level of CRP, more patients with abscesses, fistula pathways and granulating wounds compared with the group of two-stage revision THA. These results were unexpected, since it is generally believed that patients with complications of PJI are more likely to undergo two-stage surgery in order to realize the benefits of additional surgery and a course of ABT [7]. In our study, 30 (38.5%) patients had fistula pathways, and postoperative wounds were sutured by the end of the surgery in all cases. At the same time, the presence of a fistula significantly reduced the chances of PJI relief during the first two years after a one-stage revision THA (OR = 0.806; 95% CI = 0.396-1.642).

Perhaps, the degree of infectious soft tissue injury in the hip joint area may have greater importance for predicting the outcomes of single-stage revision THA. F. Rowan et al. consider infectious soft tissue injury to be one of the contraindications to single-stage revision THA [22]. M. Wolf et al., based on the McPherson classification, showed that with 3 stage of soft tissue damage, it was not possible to achieve eradication of PJI in any of the cases of single-stage revision THA [23]. The authors believe that patients with extensive soft tissue injury need a two-stage revision THA. In our study, patients with both FF of PJI and NFF of PJI had no statistically significant association between recurrence of PJI and infectious inflammation of subcutaneous fat (OR = 1.0; 95%CI = 0.26-3.88 and OR = 1.0 95% CI = 0.19-5.22, respectively), as well as the fascia lata (OR = 2.9; 95% CI = 0.86-9.75 and OR = 1.7; 95% CI = 0.93-7.74, respectively). Along with this, a statistically significant relationship was revealed between the presence of purulent leakage and recurrent PJI in the group of patients with FF of PJI (OR = 10.0, 95% CI = 2.94-34.0), as well as in the NFF group (OR = 4.46; 95% CI = 1.16-17.18).

Currently, the presence of an open fistula communicating between the joint and the external environment, as well as unsuccessful de-

bridements in the anamnesis are considered to be factors predisposing to the development of polymicrobial infection [21]. As we have established, the proportion of patients with polymicrobial infection in the group FF of PJI (14.8%) was 6.9 times higher than the same indicator in the group of NFF (2.1%). The study of the material obtained during the surgery allowed us to establish statistically significant differences ($p = 0.034$) in the frequency of cases of polymicrobial infection in patients of the NFF of PJI (17.02%) and FF of PJI (42.86%) groups. The data we obtained in the FF of PJI group significantly exceeded the results of D. Rudelli et al. (22% of observations) and S. Marmor et al. (21% of observations) [21, 24]. Despite the polymicrobial infection, the effectiveness of one-stage revision THA was high, which is probably due to the timely appointment of empirical broad-spectrum antibacterial therapy until the results of bacteriological examination of the intraoperatively collected material were obtained. A statistically significant association of polymicrobial infection and recurrence of PJI was established in patients of the FF of PJI (OR = 3.3; 95% CI = 1.00-11.14). Regardless to the species composition of bacterial associations, polymicrobial infection did not significantly affect the chances of recurrence of PJI in the NFF of PJI (OR = 3.0; 95% CI = 0.75-12.09). It should be noted that in the observation groups there were no patients with PJI caused by pathogens difficult to eradicate.

Currently, the isolation of pathogenic microflora sensitive to available antibiotics for prolonged ABT remains the leading requirement for candidates for single-stage revision THA [9]. It is known that in 5-35% of cases, the data of microbiological examination before surgery are not informative [22]. In our study, the results of bacteriological examination of pre- and intraoperative samples of biological material were the same in 56.25% of patients in the NFF of PJI group and 40.00% in the FF of PJI group.

The Second International Consensus Meeting (2018) did not recommend to use the biological material from the superficial parts of the fistula, obtained with the help of a cotton swab for the research due to the high risk of samples contamination [26]. However, the technique we have developed allows us to take the tissue biopsies from the depth of the wound, from the surface of the bone or the endoprosthesis. Therefore, in the ab-

sence of fluid in the hip joint in patients of the FF of PJI group, we received soft tissue samples for bacteriological analysis through the fistula pathway. The effectiveness of the technique, in our opinion, was sufficient, despite the fact that there were more observations in the FF of PJI group in which the preoperative microbiological diagnosis was incomplete (33.3% vs. 12.5%, respectively). Probably, these data were associated with contamination of tissue samples during the passage along the fistula. At the same time, the proportions of correct diagnoses in the FF of PJI and NFF of PJI groups were comparable (40.0 and 56.3%, respectively), in the FF of PJI group there were fewer microbiological diagnostic mistakes (26.7 and 31.3%, respectively). Thus, the implemented technique not only gave a general idea of the true nature of the pathogens of PJI, but in some cases was the only way of microbiological diagnosis.

Obviously, in order to increase the number of favorable outcomes of surgery, more factors should be evaluated, such as the history of the disease, the condition of soft tissues in the area of surgery, concomitant diseases of the patient. It is likely that the implementation of such an approach will require the use of another classification of PJI, for example, such as that of E. McPherson [27].

In our study, after a one-stage revision THA, a number of patients had indications for revision surgery for reasons unrelated to an infectious complication (removal of a hematoma of a post-operative wound and managing of the endoprosthesis head dislocation). In both groups, there was no significant effect of additional surgeries on treatment outcomes: in the FF of PJI group - OR = 0.652; 95% CI = 0.179-2.372, in the NFF of PJI group - OR = 0.57, 95% CI = 0.127-2.551.

Study limitations

The performed study has limitations that are associated with a small number of observations in the FF of PJI group (30 patients), which reduces the possibilities of statistical data processing. In addition, we did not analyze such factors as the time interval between the manifestation of PJI and the provision of specialized surgical care, the use of endoprostheses with cement and cement-free fixation, the creation and benefits of antibiotics local depot. In addition, the study used our patented technique for obtaining tissue samples from the hip joint cavity through the fistula pathway,

which has not yet been widely used, and the advantages of which need further study. Multivariate statistical analysis was not carried out.

Additional studies are required to study these factors, which, of course, will affect the determination of the causes of unsatisfactory treatment outcomes.

Conclusion

In the treatment of chronic PJI, one-stage revision THA has demonstrated effectiveness regardless to the presence or absence of a fistula. Optimization of microbiological diagnostics, reasonable expansion of indications for surgery, including in patients with functioning fistula, allows to achieve high results of eradication of PJI. At the same time, the outcomes of one-stage revision THA in patients with fistulas are inferior to those observations where the selection of patients was stricter. Determining the boundaries of the possible use of one-stage revision THA requires further study in more numerous cohorts of patients and, possibly, multicenter studies.

Ethical expertise

All manipulations performed in the study with the participation of people complied with the standards of the local ethics committee, as well as the Helsinki Declaration of 1964 and later amendments thereto or comparable ethical standards. Formal consent of the local ethics committee is not required for this type of research.

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AUTHORS' INFORMATION:

Vasily A. Artyukh — Cand. Sci. (Med.), Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russia
 e-mail: artyukhva@mail.ru
<https://orcid.org/0000-0002-5087-6081>

Svetlana A. Bozhkova — Dr. Sci. (Med.), Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russia
 e-mail: clinpharm-rniito@yandex.ru
<https://orcid.org/0000-0002-2083-2424>

Andrey A. Boyarov – Cand. Sci. (Med.), Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russia
e-mail: Bojaroffaa@mail.ru
<https://orcid.org/0000-0003-0493-7784>

Julia V. Muravyova – Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russia
e-mail: julia-muraveva@yandex.ru
<https://orcid.org/0000-0002-9535-6661>

Andrey A. Kochish – Vreden National Medical Research Center of Traumatology and Orthopedics, St. Petersburg, Russia
e-mail: aakochish@rniito.ru
<https://orcid.org/0000-0001-8573-1096>

Authors' contribution:

Artyukh V.A. – a significant contribution to the development of the concept and design of the study, collection, analysis and interpretation of the data obtained, statistical data processing, writing the text of the article.

Bozhkova S.A. – development of the concept and design of the study, writing and editing the text of the article, interpretation of the data obtained.

Boyarov A.A. – development of the research concept, collection, interpretation of the obtained data, writing the text of the article.

Muravyeva J.V. – collection, interpretation of the received data, statistical data processing.

Kochish A.A. – collection, interpretation of the received data, writing the text of the article.

All authors have read and approved the final version of the manuscript of the article. All authors agree to bear responsibility for all aspects of the study to ensure proper consideration and resolution of all possible issues related to the correctness and reliability of any part of the work.

Conflict of interest:

The authors declare that there is no conflict of interest.