Intraoperative bacterial contamination in total hip and knee arthroplasty is associated with operative duration and peeling of the iodine-containing drape from skin

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Abstract

Background: Surgical site infection (SSI) and periprosthetic joint infection are the most important problems after total hip arthroplasty (THA) and total knee arthroplasty (TKA). This study aimed to examine the risk factors for intraoperative bacterial contamination in THA and TKA.

Methods: One hundred and seven hips underwent THA, while 74 knees underwent TKA. After the implant was placed, a swab sample for bacterial culture was collected around the skin incision. At the time of specimen collection, patients were separated into two groups based on whether the iodine-containing drape remained adhered to the skin (group DR) or the iodine-containing drape was peeled off (group ND). Patient characteristics, including age, height, body weight, body mass index, operative duration, intraoperative blood loss, surgical procedures, and condition of the iodine-containing drape, were compared between patients with positive and negative bacterial cultures.

Results: In THA, which had a shorter operative duration than TKA ($p < 0.001$), there was one case of bacterial contamination. In TKA, there were ten cases of positive bacterial contamination, all in group ND. Postoperative SSI occurred in one case.

The binomial logistic regression analyses confirmed that TKA (OR 16.562 [95% CI 2.071 to 132.430], $p < 0.01$) compared to THA and the group ND (OR 0.000 [95% CI 0.000], $p < 0.001$) compared the group DR. were risk factors of bacterial contamination. In TKAs, operative duration was a risk factor of bacterial contamination (OR 1.026 [95% CI 1.000 to 1.054], $p < 0.01$).

Conclusions: Intraoperative bacterial contamination increases in procedures with long operating time and

22 may be suppressed by proper use of an iodine-containing drape.

23

24 **Keywords:** surgical drape, iodine, bacterial contamination, total hip arthroplasty, total knee arthroplasty

Introduction

Several complications of joint arthroplasty, including malalignment, infection, component loosening, and periprosthetic fracture, can be severe and result in poor outcome after surgery. One of the most frequent causes of revision surgery after total hip arthroplasty (THA) and total knee arthroplasty (TKA) is periprosthetic joint infection [1-7]. Despite several preventive procedures, including prophylactic intravenous administration of antibiotics, preoperative skin disinfection, and intrawound lavage with a large amount of saline [8], the risk of infection remains. The reported infection rates are approximately 1% to 2% after THA [2-6] and 2% to 3% after TKA [2, 4, 5, 7, 8]. Surgical site infection (SSI) is typically defined as infection occurring within 30 days after surgery and affecting either the incision or organs at the surgical site [9]. The World Health Organization has stated that bacterial contamination of the surgical site can lead to SSI [10]; as such, preoperative disinfection, draping around the skin incision, and intraoperative irrigation of the operating field are important countermeasures.

Intrawound lavage with a diluted povidone iodine solution before wound closure may be an inexpensive and effective means of reducing acute postoperative infection after THA and TKA [11]. Recently, to prevent SSI, covering the surgical wound with various drapes has been widely implemented. For example, when a plastic incise drape is properly applied, such that no air bubbles or pockets of fluid will form beneath or around the edge of the incision, it can aid in preventing the migration of skin microbes into the surgical wound [12]. However, if the plastic drape is not used in this appropriate manner, it can actually increase the number of bacteria [13-16]. Although iodine-containing drapes are often used, it remains controversial whether they

44 can effectively prevent SSI [17-19].

45 The purpose of this study was to examine the risk factors for intraoperative bacterial contamination in THA
46 and TKA, for example, operative duration or surgical drape. We hypothesised that operative duration and
47 condition of the iodine-containing drape (whether it remained adhered to the skin or was removed) are related
48 to bacterial contamination of the operating field.

49

50 **Materials and methods**

51 This prospective observational study was approved by the institutional review board of the authors' affiliated
52 institutions. Written informed consent was obtained from all participants. From June 2017 to December 2019,
53 consecutive patients who underwent primary THA or TKA at our hospital were included in this study.
54 Patients with previous trauma around the surgical site, those with a history of infection in the hip or knee,
55 and revision surgery cases were excluded from the study.

56

57 ***Surgical and postoperative procedures***

58 THAs were performed by three main surgeons. An anterolateral approach was used with patients in the
59 supine position. Cementless implants in a cup and a stem were used in all THAs.

60 TKAs were performed by two other main surgeons. A medial parapatellar or midvastus approach was used
61 with patients in the supine position. A computed tomography-free navigation system (Stryker Knee
62 Navigation System; Stryker Leibinger) was used in all TKAs. A posterior-stabilizer implant was used, and

63 femoral and tibial components were fixed with cement. A tourniquet was used during cementing, and
64 the antibiotic cement was not used in all TKAs. The patella was not replaced in all TKAs.
65 In both THA and TKA, the suction drain was removed, and patients were allowed to ambulate on the first
66 day after surgery.
67
68 ***Standard procedure to prevent SSI***
69 All patients underwent a standard protocol to prevent infection in both THA and TKA. Perioperative
70 intravenous administration of antibiotics (2 g cefazolin) was initiated prior to the skin incision and repeated
71 at 3 and 6 hours (1 g cefazolin) after the first administration on the day of surgery. From the first day after
72 surgery, cefazolin (1 g) was administered intravenously every 12 hours for 2 days after surgery. Preoperative
73 skin preparation was performed with 10% povidone iodine. A skin drape with the povidone iodine was
74 applied on the skin before the incision. Care was taken to ensure that the iodine-containing drape was in
75 intimate contact with the skin. Suction drains placed intraoperatively were removed within 24 hours.
76
77 ***Preparation for bacterial culture with a swab***
78 In THA and TKA, after the implant was placed and the wound was washed with saline solution, a culture
79 sample was collected with a swab at the edge of the skin incision. Culture sample was collected within 2 cm
80 of the skin incision in the area defined with a 20 mL syringe (Fig. 1). When the iodine-containing drape
81 remained adhered to the skin at the time of specimen collection, the drape was removed, and the swab sample

was collected from the skin under the drape (group DR). If the drape was unintentionally peeled from the skin during the operation, the swab sample was collected directly from the exposed skin (group ND). Then, the skin incision was closed with nylon suture.

Bacterial contamination was judged by the results of microscopic examination with Gram stain and enrichment culture examination. SSI was defined according to the report by Petherick et al. [20]. SSI was investigated within 30 days after surgeries.

Patient characteristics, including age, height, body weight, body mass index (BMI), operating duration, intraoperative blood loss, surgical procedure (THA vs TKA), and condition of the iodine-containing drape (DR vs ND), were compared between patients with positive and negative bacterial cultures.

Statistical analysis

On the basis of results of the intermediate analysis in the rate of positive culture with swab for 50 cases, a power analysis was performed. Seventy-four subjects in each group (total 148 joints) were needed to detect a minimal clinically important difference in each group as a primary outcome, with >80% statistical power and an alpha cut-off of 5% (0.05) as the probability of a type-I error.

For statistical analysis, the Student *t*, Mann-Whitney U, or chi-square test including Fisher's exact probability test was used. *P* values < 0.05 were considered statistically significant. Based on the results of an intermediate analysis (30 cases in each group), a power analysis for bacterial contamination was performed. A total of 56 cases in each group were needed to detect a minimally clinically important

101 difference in the primary outcome (THA vs TKA or DR vs ND), with >80% statistical power and an alpha
102 cut-off value of 5% (0.05) as the probability of a type I error.
103
104 **Results**
105 One hundres and seven hips underwent THA, which included 23 men and 84 women with an average age
106 of 61.8 ± 14.2 years. Seventy-four knees underwent TKA, including 13 men and 61 women with an average
107 age of 72.5 ± 6.9 years. Demographic characteristics of the patients are shown in Table 1. Significant
108 differences in age, body weight, BMI, operative duration, intraoperative blood loss, and distribution of drape
109 condition were found between THA and TKA. In THA, there was one case of bacterial contamination
110 including *Staphylococcus coagulase-negative* and no SSI. In TKA, there were ten cases of positive bacterial
111 contamination, including *Staphylococcus coagulase-negative* (six cases), methicillin-susceptible
112 *Staphylococcus aureus* (two case), *α-Streptococcus* (one case), and gram-negative *bacilli* unknown in detail
113 (one case). Postoperative SSI due to *Staphylococcus coagulase*-negative occurred in one patient who
114 underwent TKA and had positive bacterial contamination, which was treated by lavage and debridement.
115 The binomial logistic regression analyses confirmed that TKA was a significant risk factor of bacterial
116 contamination by swab culture (OR 16.562 [95% CI 2.071 to 132.430], $p < 0.01$), and the group DR that had
117 the iodine-containing drape remained adhered to the skin introduced significantly less bacterial
118 contamination than the group ND that had the drape peeled (OR 0.000 [95% CI 0.000], $p < 0.001$). Age, sex,
119 body height, weight, BMI, operative duration, and intraoperative blood loss were not factors of bacterial

120 contamination with the binomial logistic regression analyses. However, in only TKAs, the drape condition
121 (OR 0.0 [95% CI 0.0], $p < 0.01$) and operative duration (OR 1.026 [95% CI 1.000 to 1.054], $p < 0.01$) were
122 risk factors of bacterial contamination with the binomial logistic regression analyses.
123
124 **Discussion**
125 The most important finding of this study is that bacterial contamination occurred in cases with a longer
126 operative duration and in those that had the iodine-containing drape peeled from the skin. There was no case
127 of positive bacterial contamination in THA despite greater intraoperative blood loss and higher frequency of
128 drape peeling. It is considered that bacterial contamination was not observed in THA because the operating
129 time was very short, averaging 103.4 min.
130 Gibbons et al. previously reported that operating time was related to the incidence of SSI [21]. In the
131 department of surgery, surgical duration is regarded as an independent predictor of SSI [22-24]. Similarly,
132 Willis-Owen et al. reported that prolonged operating time was associated with increased incidence of
133 infection in THA and TKA [25]. In previous studies of orthopedic surgery, the risk of periprosthetic joint
134 infection demonstrated an odds ratio of 7.4 in joint replacement surgery lasting >180 min [26], while thoracic
135 and lumbar spine surgeries with a duration >3 h were reported to be independent risk factors for SSI [27].
136 Based on our results, shorter operating time was associated with a decrease in bacterial contamination.
137 Not only shorter operating time but also use of an iodine-containing drape is considered a modifiable SSI
138 prevention factor, unlike patient comorbidities, such as diabetes mellitus or chronic kidney disease. In this

study, there were cases of positive bacterial contamination in group ND, but no cases in group DR. Previous studies reported the effect of iodine-containing drapes on SSI prevention [17, 18, 28, 29]. Milandt N. et al. reported that similar quantities of bacteria were found between the knees with or without Iodine-impregnated incision drapes after simulated knee surgery [30]. However, they evaluated bacterial recolonization after 75 minutes. That duration was relatively short compared our study. In addition, the number of subjects was small, such as 20 knees. Rezapoor M. et al. reported the iodophor-impregnated adhesive draping significantly reduces bacterial colonization of the incision during hip surgeries [31]. Based on our results showing all eleven cases of positive bacterial contamination, in which the iodine-containing drape was peeled off during surgery, it seems that the drape might not be effective without intimate contact with the skin. Thus, the iodine-containing drape must be adhered to the skin properly and be maintained. We considered that if the drape is peeled off intraoperatively, measures such as re-disinfection and repasting of the drape are required. This study had several limitations. First, this study involved a relatively small number of patients. However, we had a sufficient number of cases to evaluate the effect of the iodine-containing drape according to the power analysis. Second, only 1 of 5 patients with a positive bacterial culture later experienced SSI. Therefore, it is controversial whether all cases with positive cultures need to be treated for the prevention of infection.

Conclusion

SSI can be caused by a small number of bacteria when artificial materials are used. Based on the results of this study, further attention to SSI is encouraged because bacteria are still identified in swab culture even at

158 the time of wound closure. There is no doubt that surgical duration is associated with bacterial contamination

159 of the operating field. In conclusion, our results indicate that growth of bacteria in the operating field can be

160 suppressed by proper use of an iodine-containing drape, especially in procedures with a long operating time,

161 such as TKA, which could help prevent SSI.

Declaration of interest

All authors declare that they have no conflict of interest.

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253
254 **Figure caption**
255 Fig. 1. Procedure to obtain a swab sample for bacterial culture.
256 Culture sample was collected within 2 cm of the skin incision in the area defined with a 20 mL syringe.

Table 1

Demographic characteristics of the patients.

	THA	TKA	
Number of surgery (men / women)	107 (23 / 84)	74 (13 / 61)	n.s.
Age (yr)	61.8 ± 14.2	72.5 ± 6.9	p <0.001 *
Body height (cm)	155.6 ± 10.4	152.8 ± 8.7	n.s.
Body weight (kg)	58.1 ± 11.7	63.7 ± 13.5	p <0.001 *
Body mass index (kg/m^2)	24.0 ± 4.0	27.1 ± 4.1	p <0.001 *
Operative duration (min)	102.6 ± 58.2	177.4 ± 24.4	p <0.001 *
Intraoperative blood loss (g)	373.3 ± 192.3	170.2 ± 80.4	p <0.001 *
Drape condition (DR / ND)	42 / 65	34 / 40	n.s. **
Swab culture (positive / negative)	1 / 106	10 / 64	p <0.01 ***
Comorbidities			
Diabetes mellitus (%)	7.5	17.6	n.s.
Chronic kidney disease (%)	8.4	5.4	n.s.

Values are presented as numbers, mean or percentage, and standard deviation.

*: Student's t-test

**: chi-square for independent test

***: Fisher's exact probability test

THA, total hip arthroplasty

TKA, total knee arthroplasty

DR, the group that the drape was remained when the swab sample was collected.

ND, the group that the drape was peeled off when the swab sample was collected.


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