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Original Article

Intraoperative Hypothermia Is Not Associated with Surgical Site Infections after Total Hip or Knee Arthroplasty

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Maintaining perioperative normothermia decreases the post-surgery surgical site infection (SSI) rate. We investigated whether SSI is associated with intraoperative hypothermia in total hip (THA) and total knee (TKA) arthroplasties by retrospectively analyzing 297 THA and TKA cases. The patients' intraoperative core body temperature (BT) was measured by bladder catheter or forehead sensor. We evaluated the associations between SSI and intraoperative BT and other variables and patient characteristics. Fifty-six patients (18.8%) had hypothermia (BT < 36°C); 43 developed SSI (14.5%); only five had hypothermia (11.6%). Intraoperative hypothermia and SSI were not significantly associated. The SSI group had more men (34.9% vs. 18.1%) and THA patients (77.4%), a longer mean surgical duration (174.3 vs. 143.5 mins), and a higher average BT (36.4°C vs. 36.2°C) than the no-SSI group. The SSI patients had a higher intraoperative BT. A multivariable analysis revealed that SSI was associated with male sex (OR 2.3, 95%CI: 1.031-4.921, p=0.042), longer surgery (OR, 1.01, 95%CI: 1.003-1.017, p=0.004), THA (OR 3.6, 95%CI: 1.258-10.085, p=0.017), and intraoperative BT > 36.0°C (OR 3.6, 95%CI: 1.367-9.475, p=0.009). Intraoperative hypothermia was not associated with SSI in adults who underwent THA or TKA. These results suggest that hypothermia might not be the problem for SSI.

Key words: hypothermia, surgical site infection, total hip arthroplasty (THA), knee arthroplasty (TKA)

H ypothermia occurs when the core body temperature is < 36°C, and it affects up to 70% of surgical patients perioperatively [1,2]. Perioperative hypothermia has been shown to be associated with numerous adverse outcomes including cardiac complications, impaired immunity, poor drug metabolism, increased blood loss, arrhythmia, coagulopathy, delayed wound healing, and increased risk of surgical site infection (SSI) [3,4]. SSI is a serious complication of orthopedic surgery, as it can lead to impaired mobility and implant losses. SSI after the replacement of a knee or hip has been a key target for epidemiological surveillance as recommended by the U.S. Centers for

Disease Control and Prevention [5-7]. The estimated rate of SSI after a total joint arthroplasty in the U.S. is 0.5-6% [8,9]. The development of an SSI increases the length of hospital stays by a week and considerably increases the cost of healthcare [10]. Considering the potential preventability of SSIs, it is important to identify risk factors during the perioperative period that may contribute to the development of an SSI.

The possible link between perioperative hypothermia and the SSI risk has been a matter of concern; it was reported that the risk of SSI is three times higher in patients whose intraoperative body temperature is 2°C lower than normal [11]. However, another research group reported that they observed no relationship

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between intraoperative hypothermia (defined as a body temperature < 35.9°C) and the incidence of SSI [12]. Given these conflicting results, further investigation is needed to ascertain whether the patients' intraoperative body temperature is related to the occurrence of SSI. We performed the present retrospective cohort study of adult patients who underwent general anesthesia for a total hip arthroplasty (THA) or a total knee arthroplasty (TKA) at a single center, our 839-bed hospital in Okayama, Japan to examine the association between intraoperative temperature during THA or TKA and the incidence of SSI. We hypothesized that intraoperative hypothermia in patients who undergo a THA or TKA is associated with SSI.

Patients and Methods

Data source, study design and setting, and partici-We collected the data of all of the patients pants. who underwent a THA or TKA at Okayama University Hospital during the 3-year period from January 2015 to December 2017. All patients 18-85 years old who underwent a THA or TKA regardless of the primary diagnosis were eligible. Patients were excluded from the study analysis if they underwent these two procedures on the same day; for patients who underwent more than one THA or TKA procedure, only the first procedure was considered in the analyses. Patients with missing intraoperative data were excluded. To identify the cohort for analysis, we used a procedural code and the surgical diagnoses for all THA and TKA procedures. Operation notes were reviewed to identify patients who had additional surgery information. We obtained the data from the Okayama University Hospital medical and anesthesia electronic records database (an institutional data repository that includes robust perioperative data and clinical details about all patients).

The patient demographic data including procedure type, intraoperative data, anesthesia, and surgical information, postoperative data, and intraoperative data were obtained, and we also collected and analyzed the patients' co-morbidities, length of hospital stay, white blood cell (WBC) data, blood/wound culture results, postoperative body temperature, and antibiotic treatment. The data regarding the patients' steroid use and tobacco-smoking habit were also obtained.

This retrospective study was approved by the Institutional Review Board of Okayama University,

Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences, and Okayama University Hospital (approval no. 2008-023). A waiver was obtained for the requirement of informed consent since all of the patients' data were anonymized. All study methods were carried out in accordance with the hospital's relevant guidelines and regulations. This manuscript also adheres to the applicable STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Anesthetic management. In each patient's case, general anesthesia was administered: total intravenous anesthesia (TIVA) or inhalational anesthesia (desflurane or sevoflurane). Electrocardiography, peripheral arterial oxygen saturation, and noninvasive blood pressure were continuously monitored. Almost all of the patients received oxygen at a concentration of 40-50%. Anesthetic induction was typically conducted using propofol (1-2 mg/kg) and remifentanil (0.2-0.4 μg/kg/ min). Regional anesthesia was not used for THA; however, a femoral nerve block or sciatic nerve block was used for the TKAs.

Each patient's intraoperative core body temperature was monitored by either a bladder sensor (BD temperature-sensing Foley catheter, Medicom Inc., Osaka, Japan) or a forehead temperature sensor probe (3M TM Bair Hugger TM Temperature Monitoring System, 3M Japan, Tokyo) and recorded continuously by an automated system. The standard care protocol for all patients included the use of forced-warm-air blankets (Bair Hugger).

With the goal of preventing postoperative infection, routine prophylactic antibiotics were administered intraoperatively and for 3 postoperative days. All other protocol aims at preventing the occurrence of SSI were accordingly implemented as recommended as follows. Acetaminophen (1.5-2 mg/kg) was used in each case to reduce postoperative pain. All patients were extubated in the operating room and transferred to the recovery room to undergo vital sign observation for 1 h after surgery. After the patient's stable condition was confirmed, he or she was transferred to the ward. Intravenous antibiotics were used for nearly 3 days except in cases of suspected infection. Oral intake started from postoperative day 1. Rehabilitation also started according to the patient's condition as soon as possible.

Each patient's intraoperative body temperature was measured and recorded at 15-min intervals from the

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start of the procedure, and the average intraoperative temperature was thus determined and used for the study analyses. Patients were considered hypothermic if they had an average intraoperative body temperature $< 36.0^{\circ}$ C.

Outcome measures. The primary outcome of this study was the incidence of SSI within 30 days of the TKA or THA surgery. SSI was defined according to the World Health Organization (WHO) Global Guidelines for the Prevention of Surgical Site Infection [13] and the WHO protocol for surgical site infection surveillance with a focus on settings with limited resources 2018 Manual [14]. We determined the presence of an SSI based on the presence of any three of the following clinical criteria: (a) elevated WBC count (> 8.60×10^9 /mL) at 3 days after the surgery, (b) a postoperative positive culture for organism isolation, (c) an unexplained postoperative increase in body temperature over 38°C for > 3 days, (d) a continued administration of antibiotics over 7 days after surgery, and (e) a change in antibiotic treatment during the patient's hospital stay. We thus considered a patient as SSI-positive if three or more of the above criteria were true. The study's secondary outcome was the length of hospital stay.

Statistical analyses. Categorical variables were evaluated and analyzed by Fisher's exact test; continuous variables were evaluated by the t-test. Data are shown as the means with standard deviation. A line plot was constructed to assess the association of SSI with intraoperative body temperature. A two-way analysis of variance (ANOVA) was performed for the determination of changes in the patients' body temperature over time. To determine predictors of the study outcome, we included the significant predictors of SSI in a multivariable regression model yielding odds ratios (ORs) and 95% confidence intervals (CIs) to determine independent or adjusted predictors of SSI. Confounding variables for the multivariable analysis included sex, duration of surgery, surgery type (THA, TKA), average body temperature, American Society of Anesthesiology (ASA) status, and anesthesia types. A line plot was also drawn of the results of the sub-group analysis by sex and surgery type. The threshold for significance was set at p < 0.05. The software programs JMP Pro 2014 (SAS, Cary, NC, USA) and Stata/SE 16.1 (College Station, TX, USA) were used to perform the analyses.

Results

Overall, we identified a total of 379 patients who underwent a THA or a TKA during the study period. After the exclusion of patients with missing data, those who underwent a double operation procedure or repeated surgery, and those who were outside the stated age range, 297 patients met our criteria for the study (Fig. 1). The mean age of this patient population was 63.9 (10.9) years, the mean body mass index (BMI) was 26.5 (4.4) kg/m², and 79.5% of the patients were female. Other demographic information, comorbidities, and operative characteristics are shown in Table 1.

An SSI occurred in 14.5% of the patients. The comparison of the baseline and surgical characteristics of the patients who developed an SSI (n=43) and those who did not (n=254) is summarized in Table 1. The patients in the SSI group had a higher average intraoperative temperature compared to the no-SSI group (36.4°C (0.5) vs. 36.2°C (0.2) and a significantly longer surgery time (174.3 (92.4) min vs. 143.5 (45.1) min). The incidence of SSI in the THA patients (n=230) was 16.1% and that in the TKA patients (n=67) was 7.5%.

The ASA status, BMI, age, steroid use, and rate of tobacco-smoking habit were not significantly different between the SSI and no-SSI groups. The patients with SSIs had longer hospital stay than those without SSIs (21.9 (4.5) vs. 19.5 (4.7) days; p = 0.002). Our analysis also revealed that the rate of SSI declined over the study period: 17.3% in 2015, 15.6% in 2016, and 10.2% in

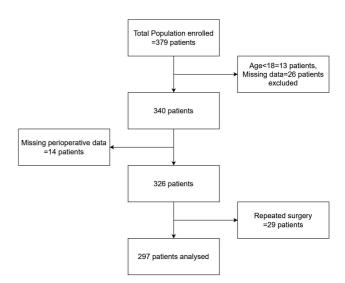


Fig. 1 Flowchart of the study's patient selection process.

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Table 1 Comparison of the patients' clinical variables and outcomes with respect to SSI

Patient characteristics	Total population=297	SSI=43	No SSI=254	P-value
Sex, female; no. (%)	236 (79.5)	28 (65.1)	208 (81.9)	0.012
Age, mean (SD) years.	63.9 (10.9)	65.0 (10.4)	63.8 (11)	0.47
BMI, mean (SD)	26.5 (4.4)	24.6 (4.4)	24.5 (4.4)	0.92
Current smoking status, no. (%)	29 (7.1)	4 (9.5)	17 (6.7)	0.50
Steroid use, no. (%)	29 (9.8)	7 (16.7)	22 (8.6)	0.10
DM, no. (%)	30 (10.1)	3 (7.1)	27 (10.6)	0.49
CVD, no. (%)	5 (1.7)	0 (0.0)	5 (1.9)	0.36
Hypertension; no. (%)	54 (18.8)	5 (11.9)	49 (19.2)	0.25
ASA, no. (%)				
1	76 (25.6)	8 (19.1)	68 (26.7)	0.26
2	183 (61.6)	25 (59.5)	157 (61.8)	
3	37 (12.5)	9 (21.4)	28 (10.9)	
4	1 (0.3)	0 (0.00)	1 (0.4)	
Anesthesia Type; no. (%)				
TIVA	138 (46.5)	16 (38.1)	122 (47.8)	0.24
Volatile	159 (53.5)	26 (61.9)	132 (51.9)	
Oxygen; no. (%)				
<50% >50%	236 (79.8) 61 (20.2)	32 (76.2) 9 (23.8)	205 (80.4) 50 (19.7)	0.85
				0.02
Average intraoperative temperature, mean (SD)	36.3 (0.4)	36.4 (0.5)	36.2 (0.2)	0.03
Patients with hypothermia, no. (%)	56 (18.8)	5 (11.6)	51 (20. 0)	0.21
Operation type, no. (%)				
ТНА	230 (77.4)	37 (88.1)	193 (75.7)	0.07
ТКА	67 (22.6)	5 (11.9)	62 (24.3)	
DOS, mean (SD) (mins)	148.2 (55.5)	174.3 (92.4)	143.5 (45.1)	0.04
LOS, mean (SD) (Days)	19.8 (4.7)	21.9 (4.5)	19.5 (4.7)	0.002

Clinical characteristics were compared with respect to the presence of a surgical site infection during hospitalization. BMI, body mass index; SD, standard deviation; CVD, cardiovascular disease; LOS, length of stay; DOS, duration of surgery; ASA, American Society of Anaesthesiology physical status classification; no., number, DM, diabetes mellitus; THA, total hip arthroplasty; TKA, total knee arthroplasty.

2017.

In all, 56 of the 297 patients (18.8%) had an average intraoperative body temperature below 36.0°C (hypothermia). Figure 2 provides a line plot with the 95%CI

values of intraoperative body temperature in the SSI and no-SSI groups over time. The patients in the SSI group were observed to have had intraoperative body temperatures during their procedures that differed from

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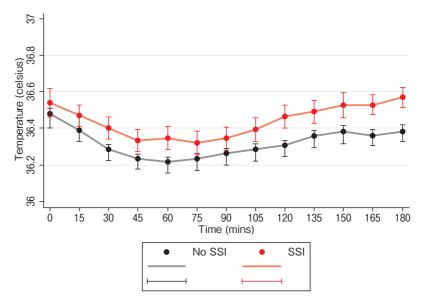


Fig. 2 A line plot of average body temperature (°C) over the surgery time course (min) with a 95% confidence interval for all patients by the presence/absence of surgical site infection (SSI). The time course of intraoperative body temperatures was examined by a two-way ANOVA. Temperature measurements were taken at 15-min intervals during the surgeries.

those in the no-SSI group. At most stages of the procedures, a complete separation of body temperature was observed between the SSI and no-SSI group at each time point; however, the changes in intraoperative body temperature over the time course were not significantly different between the SSI and no-SSI groups (p = 0.49).

Table 2 summarizes the results of the multivariable logistic regression analysis of SSI predictors. Of the potential patient- and procedure-related risk factors included in the multivariable logistics regression analysis, male sex was significantly associated with the development of an SSI (OR 2.3, 95%CI: 1.031-4.921, p=0.042), as was a surgery duration > 100 min (OR 1.01, 95%CI: 1.003-1.017, p=0.004). Undergoing a THA was significantly associated with SSI (OR 3.6, 95%CI: 1.258-10.085, p=0.017), and patients with an average intraoperative body temperature > 36.0°C had a higher risk of developing an SSI (OR 3.6, 95%CI: 1.367-9.475, p=0.009). No association was found between SSI and ASA > 2 (OR 1.9, 95%CI: 0.785-4.757, p=0.151).

Figures 3 and 4 illustrate the results of the sub-group analysis by sex and surgery type, respectively. The analysis by sex demonstrated that male patients with an SSI had a higher intraoperative body temperature than the male patients without SSI, and a complete separation of

Variables	Odds ratio	95% CI	P-value
Sex: Male	2.3	1.031-4.921	0.042
Operation Type: THA	3.6	1.258-10.085	0.017
DOS >100 min	1.01	1.003-1.017	0.004
ASA >2	1.9	0.785-4.757	0.151
Average intraoperative temperature > 36.0° C	3.6	1.367-9.475	0.009

Independent predictors of surgical site infection (SSI) were assessed by multiple variable logistic regression. 95% CI, 95% confidence interval; ASA, American Society of Anaesthesiology physical status classifications; DOS, duration of surgery; TKA, total knee arthroplasty.

these subgroups' body temperature values at each time point throughout the procedure was observed. However, the changes in body temperature over the time course were not significantly different between the male SSI and no-SSI patients (p = 0.09) (Fig. 3A).

In the female patients, the intraoperative body temperatures at each time point throughout the procedure were completely separated between the SSI and no-SSI patients. The subgroup of female patients who developed an SSI showed a downward trend of intraoperative

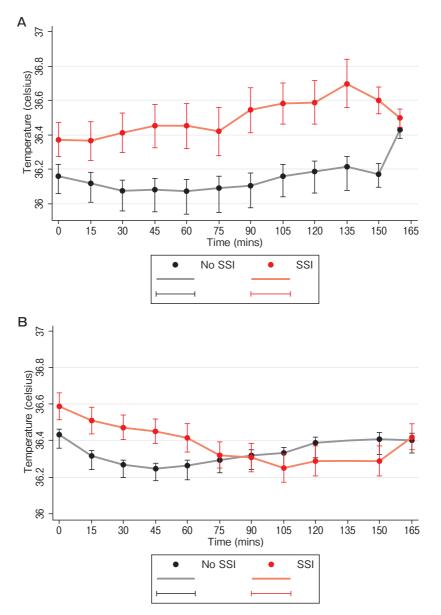


Fig. 3 Adjusted line plot to compare the trend of intraoperative temperature course (°C) over surgery time (min) by male/female sex with 95%CIs. The changes in the intraoperative body temperature course were examined by a two-way ANOVA. A, Average body temperature during surgery over surgery time by SSI for the male patients (n=61); B, Average body temperature over surgery time by SSI for the female patients (n=236). For both analyses, temperature was measured at 15-min interval during the surgery.

body temperature during the procedure, and their temperature values overlapped with those of the female no-SSI patients at the 90th min; however, the changes in the intraoperative body temperature course was not significantly different between these subgroups (p=0.91) (Fig. 3B). As in the males, among the group of female TKA patients there was a complete separation of intraoperative body temperature at almost all time

points during the procedure between the SSI and no-SSI subgroups; however, their changes in the intraoperative body temperature course were not significantly different (p=0.18) (Fig. 4A). In contrast, the female THA patients' intraoperative temperatures at each time point overlapped during the procedure and started separating toward the end of the procedure, but the changes in the intraoperative temperature course were

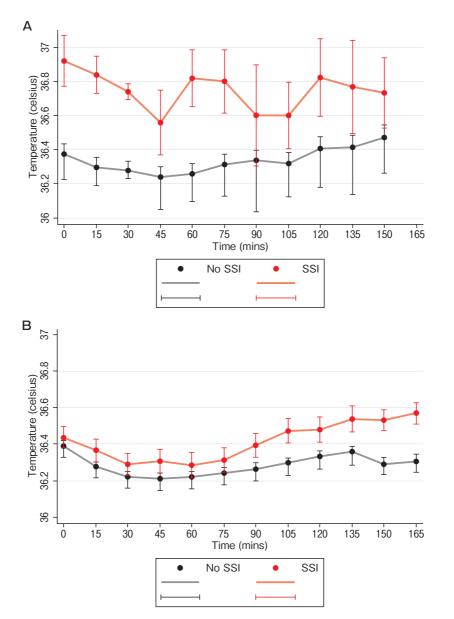


Fig. 4 Adjusted line plot to compare the trend in the intraoperative body temperature course over surgery time by the type of surgery (TKA, THA) with 95%CIs. The changes in the intraoperative body temperature course were examined by a two-way ANOVA. A, Average intraoperative temperature over surgery time by SSI in the total knee arthroplasty patients (n=67); B, Average body temperature over surgery time by SSI in the total hip arthroplasty patients (n=230). For both analyses, temperature was measured at 15-min interval during the surgery.

not significantly different (p = 0.41) (Fig. 4B).

Discussion

We evaluated the association between intraoperative hypothermia and surgical site infection in patients who underwent a THA or TKA. An SSI occurred in 43 (14.5%) of the 297 patients over the 3-year period that we examined. No significant association was detected between intraoperative hypothermia and SSI. However, a line plot demonstrated both slightly higher intraoperative body temperatures in the SSI patients and a complete separation of temperature values at several time points between the SSI and no-SSI groups. This trend was also observed in the male and TKA populations, but not in the female and THA populations. A multivariate analysis revealed that the surgery type, surgery duration, and average intraoperative body temperature > 36.0°C were important factors in the SSIs.

The incidence of SSI after a THA or TKA usually varies from 0.5% to 6% [8,9]. The incidence in the present patient population (14.5%) is thus rather high. We suspect that this result could be due to our liberal definition of SSI, *i.e.*, not restricted to only organism isolation. In fact, only 18.6% of all of the present cases of SSI had positive blood- or wound swab-culture results. This might be the result of the routine use of antibiotics (3-7 days) after TKAs and THAs at our hospital. Expanding our definition of SSI to include other clinical criteria would thus help identify SSI events that might have been missed with the use of blood- and/or wound swab-culture criteria only. Our analyses also revealed that the incidence of SSI in the THA patients was significantly higher than that in the TKA patients. This finding supports earlier reports that THA poses a higher risk of a post-arthroplasty SSI than TKA [15, 16].

Perioperative hypothermia has been established as a risk factor for SSI in surgical procedures such as head and neck surgery, general surgery (*e.g.*, major open abdominal surgery), and trauma surgeries [11,17,18], but evidence of the relationship between intraoperative hypothermia and SSI after a THA or TKA procedure has been insufficient. Williams *et al.* reported a relationship between intraoperative hypothermia and SSI after of SSIs in their study was relatively small (n=3) [19]. Our present analyses did not show an association between the occurrence of SSI and intraoperative hypothermia in THA or TKA.

Most of the clinical reports and research articles describing an association between intraoperative hypothermia with SSI — which mostly support perioperative normothermia as a quality measure — were published well over a decade ago [11,20]. In recent years, an increasing number of studies have either suggested the lack of such an association or obtained unclear evidence to support the concept that the maintenance of intraoperative normothermia will lead to a reduction in the occurrence of SSI [21-23]. However, a recent systematic review indicated that the maintenance of normothermia may help prevent other adverse outcomes [24]. Although some of the present study's patients had a core body temperature < 36.0°C during the first hour of sur-

gery, the average temperature at the end of the procedure was \geq 36.0°C, which is consistent with the WHO recommendation [25].

It is also important to note that the interference of forced-air warming devices in the surgical suite's airflow could be a prospective contaminant to a surgical site. Our analyses did not reveal any significant risk of SSI associated with intraoperative hypothermia after THA or TKA. Our findings thus corroborate those of recent studies that reported the absence of a significant association between perioperative hypothermia and SSI.

Nevertheless, the present results demonstrate that male sex, duration of surgery, and THA were risk factors associated with the development of an SSI after a total hip or knee arthroplasty. Male sex was associated with a higher incidence of SSI, which is consistent with earlier findings regarding SSI after orthopedic surgeries [26]. This could be due to biological differences between the sexes. It was also suggested that male patients usually have higher activity levels and a greater chance of infection than female patients [27]. A longer duration of surgery was also a risk factor associated with SSIs following a THA or TKA in our present investigation; this is also consistent with previous findings of longer surgery and anesthesia times as risk factors for infection after various types of orthopedic surgery [28-31].

Although our findings suggest that an intraoperative body temperature > 36.0°C is associated with the development of an SSI after a total hip or knee arthroplasty, we agree that the maintenance of intraoperative normothermia is very important for some physiological purposes. Hypothermia can impair drug metabolism, affect cardiac morbidity, and lead to coagulopathy [32]. A substantial drop in a patient's temperature occurs during the induction of anesthesia, and pre-warming is essential to reduce the initial redistribution of hypothermia [33]. We thus emphasize that clinicians should pay very close attention to the maintenance of normothermia intraoperatively (from the induction of anesthesia through to the end of the procedure).

This study has some limitations. It is limited by its retrospective nature and a relatively small number of events, in addition to the robust nature of intraoperative temperature management. However, the number of patients (n=297) is larger than those of some of the studies on which many national and international guidelines have been based (although some of the studies were randomized clinical trials). Second, the accu-

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racy of both the patients' body temperature data pertaining to the positioning of the temperature probe (*e.g.*, a probe falling off) and the readings of the temperature monitors was difficult to control and verify in a retrospective study. Finally, although we attempted to exclude patients with any pre-operative infection, there might have been a few patients with ongoing inflammation processes that could have increased their core body temperature.

In conclusion, our results indicate that intraoperative hypothermia is not associated with the development of a surgical site infection in adults who underwent a THA or TKA. Although perioperative normothermia is vital to the postoperative outcome, comprehensive care for other potential risk factors for SSI merits equal attention toward a reduction of the incidence of this morbidity in patients who undergo a total hip or knee arthroplasty.

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