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RESEARCH ARTICLE

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Self-warming blanket versus forced-air warming blanket during total knee arthroplasty under spinal anaesthesia: A randomised non-inferiority trial

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Abstract

Background: Arthroplasty patients are at high risk of hypothermia. Pre-warming with forced air has been shown to reduce the incidence of intraoperative hypothermia. There is, however, a lack of evidence that pre-warming with a self-warming (SW) blanket can reduce the incidence of perioperative hypothermia. This study aims to evaluate the effectiveness of an SW blanket and a forced-air warming (FAW) blanket peri-operatively. We hypothesised that the SW blanket is inferior to the FAW blanket.

Methods: In total, 150 patients scheduled for primary unilateral total knee arthroplasty under spinal anaesthesia were randomised to this prospective study. Patients were pre-warmed with SW blanket (SW group) or upper-body FAW blanket (FAW group) set to 38°C for 30 min before spinal anaesthesia induction. Active warming was continued with the allocated blanket in the operating room. If core temperature fell below 36°C, all patients were warmed using the FAW blanket set to 43°C. Core and skin temperatures were measured continuously. The primary outcome was core temperature on admission to the recovery room.

Results: Both methods increased mean body temperature during pre-warming. However, intraoperative hypothermia occurred in 61% of patients in the SW group and in 49% in the FAW group. The FAW method set to 43°C could rewarm hypothermic patients. Core temperature did not differ between groups on admission to the recovery room, $p = .366$ (CI: −0.18–0.06).

Conclusions: Statistically, the SW blanket was non-inferior to the FAW method. Yet, hypothermia was more frequent in the SW group, requiring rescue warming as we strictly held to the NICE guideline.

Trial Registration: Clinicaltrials.gov identifier: NCT03408197.

KEYWORDS
BairHugger, EasyWarm, primary knee replacement

Editorial Comment

Clinical efficacy of two different patient warming apparati during spinal anaesthesia and knee arthroplasty was assessed. The authors chose non-inferiority as the analysis form, but due to necessary protocol deviations, the results were mixed.

1 | INTRODUCTION

Arthroplasty patients are at high risk of developing intraoperative hypothermia[1] and resultant well-known adverse effects.[2–5] The incidence of inadvertent hypothermia can be reduced by pre-operative warming.[6] The most widely used warming method is the forced-air warming (FAW), which has been shown to be effective in perioperative settings.[7,8]

An active single-use self-warming (SW) blanket (Barrier® EasyWarm®, Mölnlycke Health Care AB, Gothenburg, Sweden, model 629900) is an option for warming patients peri-operatively.[9] The SW blanket consists of 12 warming pads (13 × 10 cm) containing iron powder which oxidises when exposed to air and heat is produced. The warming pads reach an average temperature of 40°C within 30 min, with a maximum temperature of not more than 43°C. The temperature of the pads is maintained for up to 10 h.

The SW blanket offers advantages over the FAW method in certain important aspects. For example, the SW blanket does not need additional equipment or electric current, it is noiseless, does not generate air turbulence and is readily available. The superiority of the SW blanket over standard hospital clothing has been reported elsewhere.[10] However, other randomised controlled trials which have compared the peri-operative use of the SW blanket with the FAW blanket under spinal anaesthesia (SA) or general anaesthesia (GA) have yielded conflicting results.[11–13]

The aim of this trial was to investigate whether the SW blanket is non-inferior to the FAW blanket in maintaining normothermia in patients undergoing elective unilateral total knee arthroplasty (TKA). We hypothesised that the SW blanket is inferior to the upper-body FAW blanket.

2 | METHODS

Ethical approval for this single-centre study (ETL R17136) was provided by the Regional Ethics Committee of the Expert Responsibility area of Tampere University Hospital, Tampere, Finland (Chairperson Prof. Matti Korppi) on 3 October 2017. The study was registered in ClinicalTrials.gov on 17 January 2018 (Code NCT03408197). Written informed consent was obtained from all patients prior to their inclusion in the study. The study was conducted according to rules and regulations of the Declaration of Helsinki. Personal data were processed in accordance with the European Union's General Data Protection Regulation requirements.

2.1 | Participants and randomisation

The study population comprised patients who were scheduled for primary unilateral TKA under SA in Coxa Hospital for Joint Replacement, Tampere, Finland. Inclusion criteria were age 40–90 years, American Society of Anesthesiologists ASA physical status I–III and body mass index from 25 to 40.[14] Exclusion criteria were GA or inability to give written consent. Assessment for eligibility was verified in advance (S-LL). After arriving at the lounge of the surgical ward on the day of the surgery, patients were recruited (S-LL, JK, AA) and equally and randomly allocated to have either an SW blanket (SW group) or an upper-body FAW blanket (3M™ Bair Hugger™, Arizant Healthcare Inc, Eden Prairie, MN, USA; model 62200; FAW group) according to a sealed randomisation envelope which was opened after consent was obtained. A computer-generated list of random numbers was used.

2.2 | Study design

In accordance with the hospital's standard of care, patients were given paracetamol 1 g and cetirizine 10 mg per os as pre-medication. In addition, two thirds of the patients were given extended-release oxycodone/naloxone 5/2.5 mg or 10/5 mg per os. Patients waited for the surgery in the lounge where they were picked up to the preoperative holding area. Before SA induction, patients were pre-warmed in supine position for 30 min in a preoperative holding area. After pre-warming, standard monitoring (non-invasive blood pressure, electrocardiography and pulse oximetry) was applied, intravenous access was opened, and SA was induced with isobaric bupivacaine (Bicain Spinal 5 mg/mL, Orion Pharma, Espoo, Finland) in lateral position. After ensuring the complete motor block of the lower limb to be operated, patients were transferred to the operating room. During surgery, patients received propofol sedation, if desired, which was induced and maintained with target-controlled infusion with Schnider model effect site initially set to 1.0 μg/mL (TCI, Asena™ PK, Alaris Medical Systems, Basingstoke, UK) and raised when needed. To verify the adequate positioning of the knee prosthesis, antero-posterior and lateral radiographs of the operated knee were taken outside the OR. Thereafter, patients were transferred to the recovery room (RR).

2.3 | Warming and temperature control

The SW blanket was opened and unfolded at least 30 min before use. It was placed on the patient's entire body for pre-warming.

The upper-body FAW blanket was set to 38°C and placed longitudinally on the patient for pre-warming. To ensure sterile conditions, active warming was discontinued during induction of SA. The FAW was turned off during transfer of the patient to the OR and the RR. Both blankets were applied on the upper-body and arms, and a warm cotton blanket was placed over the non-surgical limb in the OR. The FAW was turned on at 38°C after surgical draping. The patient's head was left uncovered. Intravenous fluids were taken from the warming cabinet (Termaks AS, Bergen, Norway, model B 9420) set to 37.5°C, but the fluids were not warmed in the OR.

Core temperature was measured with a non-invasive zero heat flux (ZHF) method (3M™ Bair Hugger™ Temperature Monitoring System, Arizant Healthcare, Eden Prairie, MN, USA). The sensor was placed on the right side of the forehead. Skin temperature (Skin Temperature Probe®, GE Healthcare Oy, Helsinki, Finland) was measured from the chest and upper arm on the right side, and from the thigh and leg contralateral to the site of the surgery.[15] Core and skin temperatures were continuously measured from the beginning of the pre-warming period up to 1 h postoperatively. The data were retrieved for statistical analyses at the beginning and the end of pre-warming, and thereafter at 10-min intervals. The ambient temperature of the lounge, preoperative holding area and OR was controlled and measured.

Hypothermia was defined as core temperature below 36.0°C, as indicated in the NICE guideline.[16] If intraoperative hypothermia existed, the patient, regardless of the study group, was warmed with an upper-body FAW blanket set to 43°C. Postoperatively, FAW was initiated when a patient shivered or felt cold, or the measured core temperature was below 36.0°C. Active warming was discontinued at any time when the core temperature exceeded 37.0°C or the patient complained of discomfort.

2.4 | Statistical analysis

The primary outcome measure was the core temperature value on admission to the RR. Secondary outcomes were core and peripheral temperature changes peri-operatively, the usability and convenience of the warming methods, related costs and postoperative complications.

The non-inferiority design was chosen with the widely used FAW method as an active control.[17] We predetermined an inferiority margin to be 0.2°C, since the margin had to be narrower than usually used 0.5°C in superiority trials[12] and further, 0.2°C was the accuracy of the ZHF thermometer.[18] For the sample size calculation, a SD of 0.4°C was chosen[10] with an alpha error of 0.05 and a power of 0.9. The sample size of 69 patients per group was calculated. To allow for dropouts, 75 patients were enrolled for each study group.

Initially, all patients were allocated the warming blanket according to randomisation and there were no changes between groups. The results were analysed using intention-to-treat analysis.

Statistical analyses were performed using SPSS Version 27.0 (IBM Corp: Armonk, NY). Continuous data are reported as mean (SD) or median with quartiles (Q_1–Q_3). Categorical data are expressed as

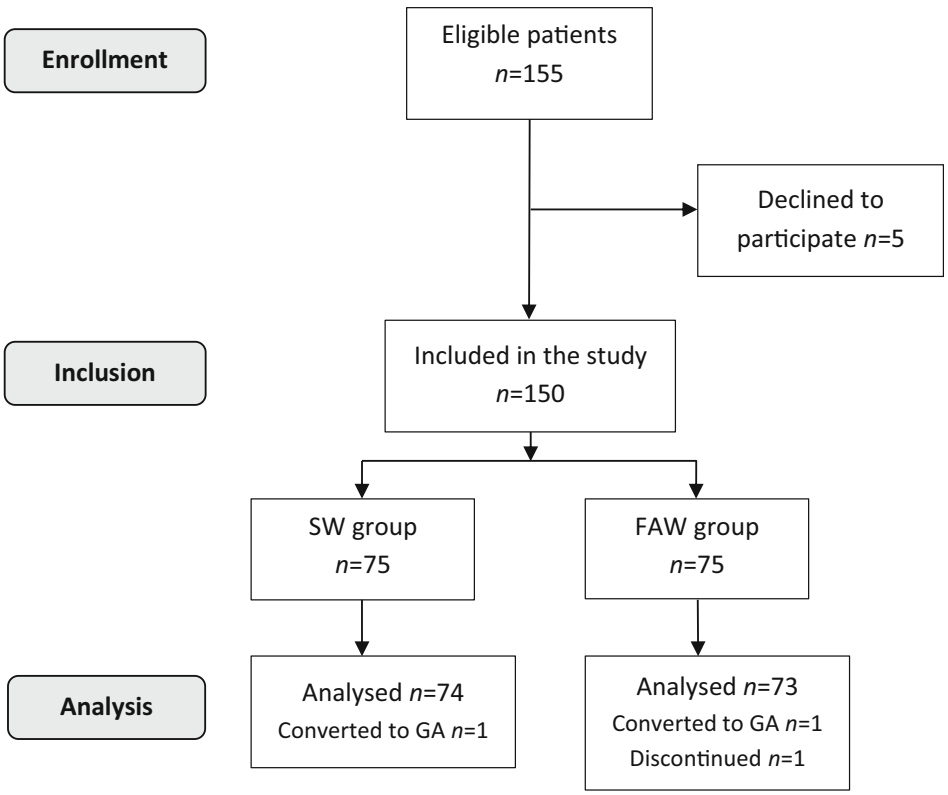

FIGURE 1 SW, self-warming; FAW, forced-air warming; GA, general anaesthesia.

n (%). Independent samples *t*-test or paired samples *t*-test were used for parametrical continuous data, Mann–Whitney test for non-parametrical data and χ^2 test for binominal data. The effect size and CI were calculated.

To evaluate the thermal redistribution, we applied Ramanathan's formula,[15] where four peripheral temperatures are used to calculate mean skin temperature (MST): $MST_R = 0.3 \times (T_{chest} + T_{arm}) + 0.2 \times (T_{thigh} + T_{leg})$. To evaluate body heat content, mean body temperature was calculated by using Burton's formula[19]: $MBT_B = 0.64 \times T_{core} + 0.36 \times T_{MST}$.

Temperatures were measured as degrees Celsius. A $p < .05$ was considered statistically significant.

3 | RESULTS

The data were collected between November 2018 and November 2019. The follow-up lasted until May 2020. During the study period, 155 patients were screened for eligibility. Of these, five declined to participate in the study. Enrolled patients were randomised to either the SW group ($n = 75$) or the FAW group ($n = 75$). Data of three patients were excluded from the final analyses (Figure 1).

Both study groups had similar patient characteristics (Table 1). Moreover, there was no difference between groups in the length of the waiting, pre-warming, surgery and transition times (Table 2). The ambient temperature did not differ between the study groups on admission to the OR. However, intraoperative ambient temperature differed statistically significantly between groups. The other relevant peri-operative data were the same in each group (Table 3).

Similar core temperature changes were observed in both groups (Figure 2). Core temperature did not change in initially normothermic patients but rose to more than 36°C in all, but one hypothermic patient during pre-warming. Core temperature remained unchanged after SA induction but decreased after admission to the OR. Intraoperative hypothermia was common: 45 patients (61%) in the SW group and 36 patients (49%) in the FAW group became hypothermic intra-operatively and needed rescue warming with the upper-body FAW set to 43°C (Table 3). Hypothermia developed during the first 30 min in the OR and persisted, on average, for 40 min in each group. Core temperature was 36.1°C (0.3) in the SW group and 36.1°C (0.4) in the FAW group on admission to the RR (primary outcome), $p = .366$ (CI: −0.18–0.06, effect size 0.15). The core temperature of intraoperatively normothermic patients who only were warmed with a randomised blanket was 36.3°C (0.3) in the SW group ($n = 29$) and 36.3°C (0.4) in the FAW group ($n = 37$) on admission to the RR, $p = .538$ (CI: −0.23–0.12, effect size 0.15). Figure 3 presents these results with the predetermined inferiority margin.

Similar changes in MST and MBT were observed in both groups peri-operatively. MST rose statistically significantly during pre-warming: 1.0°C (0.6) in the SW group, $p < .001$, and 2.0°C (0.6) in the FAW group, $p < .001$. The peri-operative changes in MBT are presented in Figure 4.

Most patients felt comfortable during the perioperative period. In some patients the objective core temperature and the

TABLE 1 Patients' characteristics.

	SW group $n = 74$		FAW group $n = 73$	
	n/mean	%/SD	*n*/mean	%/SD
Sex, female	38	51.4	48	65.8
Age (*y*)	69	9	67	8
BMI	30	4	30	3
ASA				
I	6	8.1	6	8.2
II	37	50.0	42	57.5
III	31	41.9	25	34.2
Side of surgery, right	44	59.5	36	49.3
Core temperature[a]	36.2	0.4	36.3	0.3

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; FAW, forced-air warming; SW, self-warming.
[a]Measured with an infrared thermometer after a patient had changed to hospital cotton clothes.

TABLE 2 The duration (min) of each perioperative episode.

	SW group $n = 74$		FAW group $n = 73$		
	Median	Q_1–Q_3	Median	Q_1–Q_3	*p*-Value
Time in the lounge	60	45–81	60	47–79	.927
Pre-warming period	30	30–38	30	30–36	.741
Spinal anaesthesia induction	11	8–15	10	7–13	.169
Transfer to operating room	18	14–27	19	14–26	.852
Incision	20	17–23	20	17–24	.941
End of surgery	60	49–68	60	52–70	.737
Transfer to recovery room	15	14–17	16	14–18	.886

Abbreviations: FAW, forced-air warming; SW, self-warming.

TABLE 3 Relevant perioperative data.

	SW group $n = 74$		FAW group $n = 73$		
	n/median	%/Q_1–Q_3	*n*/median	%/Q_1–Q_3	*p*-Value
Bicain spinal 5 mg/mL (mL)	1.5	1.5–1.7	1.5	1.5–1.8	.905
Intravenous fluids (mL)	500	400–600	400	300–600	.293
Blood loss (mL)	150	100–200	150	100–200	.393
Propofol sedation	63	85.1	63	86.3	1.000
Propofol mL/kg/h	3.2	2.6–4.0	3.5	2.8–4.2	.061
Holding area temperature (°C)	21.0	20.6–21.3	21.1	20.8–21.6	.170
OR temperature (°C)					
On admission	19.5	18.9–20.2	19.7	19.2–20.3	.439
Intraoperatively	18.8	18.3–19.4	19.1	18.7–19.8	.008
Core temperature (°C)					
Drop in the OR	0.7	0.4–0.9	0.6	0.5–0.9	.921
Lowest in the OR	35.9	35.7–36.1	36.0	35.8–36.2	.282
Last in the OR	36.0	35.9–36.2	36.1	35.9–36.4	.338
Hypothermia					
On admission to the OR	1	1.5	3	4.3	.620
Intraoperative	45	60.8	36	49.3	.186
On admission to the RR	32	43.2	25	34.2	.309
One hour postoperatively	4	5.5	4	5.5	1.000
Postoperative complication	1	1.4	4	5.5	.209

Abbreviations: FAW, forced-air warming; OR, operating room; RR, recovery room; SW, self-warming.

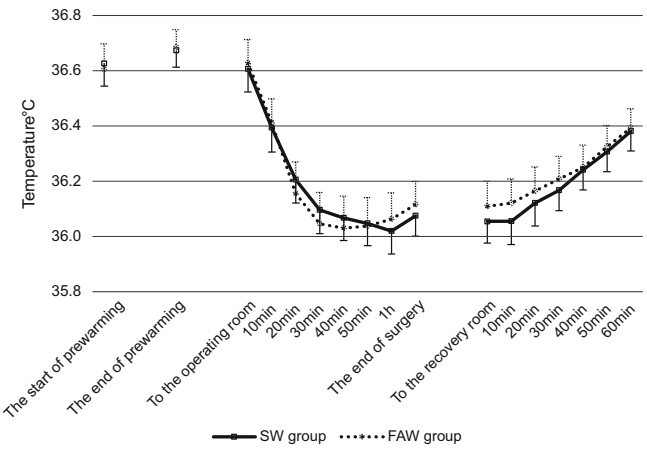

FIGURE 2 Mean with 95% CI; SW, self-warming; FAW, forced-air warming.

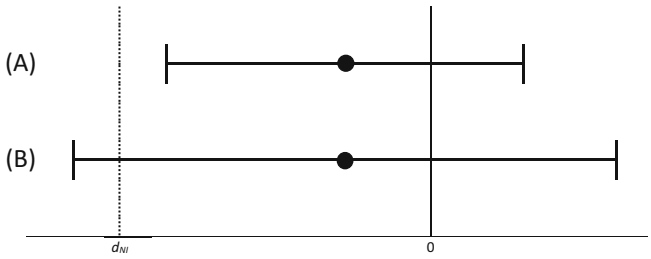

FIGURE 3 Mean with 95% CI; d_{NI}, inferiority margin 0.2°C; SW, self-warming; FAW, forced-air warming. (A) Difference between the SW group and the FAW group according to the randomisation. (B) Difference between intraoperatively normothermic patients who only were warmed either with the SW blanket or the FAW blanket set to 38°C.

subjective feeling did not correlate. Seven normothermic patients in each group felt hot after pre-warming. A few patients in each group regarded the FAW set to either 38°C or 43°C as uncomfortable. Postoperative shivering occurred in three patients, two of which were normothermic.

Seventy-one patients in each group considered the blanket to be convenient. Moreover, 77% of nurses considered the SW blanket to be suitable and 97% of nurses considered the FAW blanket to be suitable. The costs of an SW blanket and an upper-body FAW blanket were 12.60 € and 8.10 €, respectively. In the FAW group costs include also acquisition of the attached warming unit and the required electric current.

Postoperative recovery data were available for 145 patients (Table 3). In the FAW group, one patient required a revision arthroplasty due to deep infection and two patients had superficial infections at the surgical site. One patient in the SW group had deep vein thrombosis and another patient in the FAW group had pulmonary embolism.

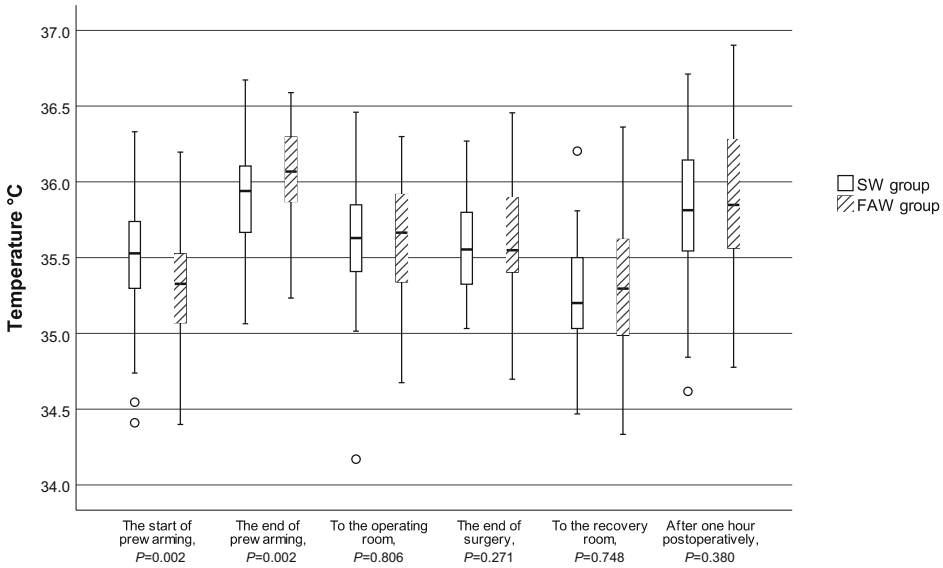

FIGURE 4 SW, self-warming; FAW, forced-air warming.

4 | DISCUSSION

To the best of our knowledge, this is the first study comparing the SW blanket and the FAW blanket used in a similar manner during the pre-warming and intraoperative periods. The results of our study reveal that the SW blanket and the upper-body FAW blanket set to 38°C both were capable of increasing MBT and warming up initially hypothermic patients during pre-warming. Despite active pre-warming, intraoperative hypothermia was unexpectedly common in both groups, and rescue warming with the FAW method was needed in 61% of patients in the SW group and in 49% of patients in the FAW group. The primary outcome of the study, the core temperature value on admission to the RR, did not differ between groups.

SA is known to predispose patients to hypothermia.[20,21] However, the induction of SA has been shown to decrease core temperature less than the induction of GA.[22] In our study, the core temperature remained unchanged in both groups after SA induction. This might have resulted from reduced heat redistribution due to effective pre-warming and from the moderate amount of isobaric bupivacaine limiting the level of spinal block.

The high incidence of hypothermia observed in the present study might have been the result of the over 20 min interruption between pre-operative and intraoperative warming.[23] This was most evident in the FAW group, as active warming was discontinued during transfer to the OR and during surgical preparation. In contrast, patients in the SW group had the blanket without interruption. The patients in our study became only slightly hypothermic. Our findings are therefore in accordance with those of previous studies that pre-warming does not prevent intraoperative hypothermia completely, but reduces its severity.[24,25]

Intraoperative hypothermia might also be caused by the ambient temperature being colder than recommended,[16] as the core temperature drop was only observed in the OR. However, when patients are warmed with forced air, the ambient temperature has been shown to have a negligible effect on core temperature.[26] Yet, since both blankets were placed over the patients' upper body and the FAW was discontinued for the first 20 min in the OR, the effect of ambient temperature and laminar air flow cannot be ignored.

There was a 12 percentage point difference in incidence of hypothermia (61% in the SW group vs. 49% in the FAW group, $p = .186$) but the lowest core temperature differed between groups by only 0.1°C. The difference in incidence of hypothermia can be considered clinically, economically and environmentally important, as the workload of anaesthesia nurses, the costs of warming and the amount of waste all increase when more than one warming method is used on a single patient. Instead, a change from medium to maximum set temperature of the FAW device can only be achieved by pushing the 43°C button.

On the other hand, using the SW blanket for pre-warming during waiting and transferring to the OR seems to keep the core temperature more balanced than the FAW, which has to be interrupted for the course of transfer and surgical draping. Also, the same FAW blanket seldom lasts from the OR to the RR due to staining and tearing.

In the present study, active warming was well tolerated, although a few patients in each group felt excessively warm regardless of the core temperature value. Subjective thermal perception is largely determined by skin temperature.[27] Therefore, the FAW device was set to 38°C during pre-warming to avoid discomfort and sweating. In addition, the medium set temperature has been shown to be as effective as the high set temperature in increasing the heat content of peripheral tissues.[28]

It has been argued that the FAW may increase the risk of surgical site infection (SSI).[29,30] However, hypothermia itself is known to be a risk factor for SSI.[31] In our study, three patients had SSI in the FAW group but none in the SW group. Notably, most patients in the SW group also had the FAW blanket. Nevertheless, given the sample size, this study was not targeted at analysing postoperative complications.

The main strengths of this study are the continuous core and skin temperature monitoring. The ZHF method has been shown to be accurate enough for clinical use.[32] The method is non-invasive and thus suitable for conscious patients. The measurement of peripheral temperatures allowed us to calculate MBT which can reflect a person's thermal status more closely than core temperature alone. Moreover, this was a pragmatic study, comparing the two accepted warming methods in our hospital. Both of these have their strengths and inconveniences: FAW has been shown to be very effective, the temperature is modifiable, but it has to be attached to electric current whereas the SW is all the time at the same temperature and may be worn on the patient also during transfers and surgical site disinfection.

There are some significant limitations in our study that should be considered. The choice of primary outcome seemed to be unsuitable since intraoperative core temperature change and the duration of hypothermia have been used to assess the thermal condition or the hypothermia burden of surgical patients rather than a single temperature value.[33] Further, the incidence of intraoperative hypothermia was unexpectedly high and according to the study protocol, all hypothermic patients, regardless of study group, were warmed with the upper-body FAW blanket set to 43°C. Thus, core temperature on admission to the RR does not reflect the warming effect of the SW blanket and the upper-body FAW blanket set to 38°C. Moreover, our clinical practise resulted in long interruptions between pre-warming and intraoperative warming, leading to temperature decrease especially in the FAW group. Although the schedule of the day was predetermined, the actualised course of a single patient depended on the time schedules of the operative unit.

In this study, non-inferiority of the SW blanket was not demonstrated when comparing intraoperatively normothermic patients, that is patients who only were warmed either with the SW or FAW blanket, as the lower CI −0.23 was outside the predetermined inferiority margin. In future, to assess the non-inferiority of the SW blanket to the FAW method more reliably, the threshold core temperature for inadvertent hypothermia should be defined as 35.5°C, since according to the latest findings this temperature has been shown to be sufficient for surgical patients.[34]

In conclusion, based on our results, both methods were effective in raising MBT during pre-warming. However, although the SW blanket was statistically non-inferior to the FAW method, hypothermia was more frequent in the SW group, requiring rescue warming as we strictly held to the NICE guideline.

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The authors have no conflicts of interest.

FUNDING INFORMATION

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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