Thermal Suit or Forced Air Warming in Prevention of Perioperative Hypothermia: A Randomized Controlled Trial

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Purpose: To prevent perioperative hypothermia, forced air warming blanket was compared with a passive insulation suit.

Design: Prospective, open, randomized controlled trial.

Methods: Thirty patients were scheduled for orthopedic spinal surgery. The intervention group (group TS) received the thermal suit T-Balance before premedication and throughout the perioperative period, whereas the control group (group C) received forced air warming (FAW) during surgery.

Findings: No statistically significant difference (ns) was found between the groups for core temperature 30 minutes after induction of general anesthesia. Perioperative hypothermia occurred in 10 (66.7%) patients in group TS and 6 (40%) in group C (ns). For hypothermic patients, re-establishment of normothermia took significantly longer in group TS, mean 108 ± 111 minutes, than in group C, 33 ± 59.5 minutes (P = .03).

Conclusions: The thermal suit did not prevent hypothermia in this study. FAW was significantly more efficient in re-establishing normothermia.

Keywords: unintended hypothermia, thermal suit, forced air warming, zero-heat-flux thermometry.

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surgery is reported to be the preferred method of preventing unintentional hypothermia. Hypothermia during general anesthesia is initially caused by internal redistribution of body heat from the core to the periphery, followed by heat loss exceeding metabolic heat production. Furthermore, the administration of room temperature intravenous fluids, skin disinfection with vaporizing chemical agents, and the area of exposure for surgery also contribute to heat loss and the development of hypothermia. Prewarming of peripheral tissues and skin surfaces before induction of general anesthesia decreases the core to peripheral temperature gradient, thereby reducing redistribution hypothermia. In recently published guidelines, the effect of prewarming patients before induction of general anesthesia was emphasized as important in prevention of perioperative hypothermia. Studies with forced air warming (FAW) support active prewarming and demonstrate that patients were warmer during the perioperative period with FAW applied in advance, although negative findings were reported in a single study.

Prevention of unintended hypothermia during orthopedic spinal surgery is still challenging. The patients are exposed to cool environments without effective prevention against hypothermia before and during induction of general anesthesia and are further exposed during prolonged preparation for surgery when positioned into the prone position. A randomized controlled trial which tested a method of FAW in prewarming patients undergoing orthopedic spinal surgery still had a hypothermia incidence rate of 32%.

We wanted to test a full-body thermal suit, T-Balance (Telespro Finland Ltd., Kuopio, Finland), in the perioperative setting. The thermal suit is constructed especially for preoperative, intraoperative, and postoperative use. The material for passive insulation is a three-layer laminate, and the suit is a one piece. Several concealed zippers make it possible to reveal parts of the patient’s body surface as required for anesthesia, monitoring, and access for surgery. For spine surgery, the zippers may adjust the skin exposure to just the level and area needed for access in the individual cases. An open randomized trial with T-Balance concluded that the suit was a good alternative to conventional warming devices in reducing heat loss. No randomized controlled trials evaluating the efficacy of the thermal suit versus other efficient methods of warming, such as FAW, have been carried out.

**Purpose**

The objective of this trial was to compare the effectiveness of passive heat retention with the thermal suit versus FAW in prevention and treatment of hypothermia, as measured by the noninvasive zero-heat-flux forehead patch thermometer (ZHF thermometer, the Bair Hugger Temperature Monitoring System; 3M, St Paul, Minnesota) in patients undergoing spinal vertebrae surgery. A secondary aim of the study was to evaluate conventional temperature readings with esophageal temperature, to the ZHF device during surgery.

**Methods**

This prospective, open-label, randomized controlled trial was carried out at Oslo University Hospital, Ullevaal. The study was approved by the Regional Ethics Committee in September 2014 (2014/1159-3) and registered with ClinicalTrials.gov (Protocol Record Varmedrakt.OUS.15.1. NCT02336152). All equipment used in this study was approved and CE marked (European consumer goods quality control system).

**Patient Selection**

Patients scheduled for orthopedic spinal surgery were recruited after written informed consent was obtained. Inclusion criteria were patients aged 18 to 80 years with surgery expected to last from 60 to 120 minutes. Exclusion criteria were American Society of Anesthesiologists physical status (ASA) IV, known diabetes mellitus, fever, subjects with a medical history or current medication interfering with normal thermoregulation, pregnancy, body mass index < 17 or > 35, or a baseline core temperature < 36.0°C measured using the ZHF thermometer in the preoperative holding area. All patients received general anesthesia, and the choice of anesthetic agent was not dictated by the protocol. Patients were randomly assigned using a computer-generated randomization sequence, in which the group assignment was kept in sequentially numbered opaque envelopes, to 1 of 2 groups in a 1:1 ratio: thermal suit,
group TS, or the department’s standard method with FAW during surgery, group C. The researcher, a registered nurse anesthetist (RNA), opened the sealed envelopes in numerical order after written informed consent was obtained.

**Intervention**

In both groups, patients were checked on the ward for inclusion and exclusion criteria and then asked for study participation, if eligible. After informed consent was given and signed, patients were randomized to one of the two groups.

Baseline temperature measurement was performed in group TS after the patients were dressed in the correctly sized thermal suit for 30 minutes and before premedication was given. For the patients in group TS, the thermal suit was continued for the entire perioperative period. A flap of the suit was opened to allow access for disinfection, draping, and surgery and then closed by the zippers at the end of the surgical procedure to cover the skin surface and ensure maximum passive insulation.

In group C, baseline temperature measurement was obtained before patients received premedication. Patients in group C were dressed in standard cotton shirts, underwear, stockings, and bath robe, all made of one-layer cotton textile, before they were transferred to the operating room (OR). The patients in group C were covered with room temperature cotton blankets during preparation and induction of anesthesia and no active pre-warming device.

After premedication was given, patients in both groups were transferred to the OR, and standard monitoring including electrocardiogram, pulse oximetry, and noninvasive blood pressure was established.

In group C, FAW was applied and started after positioning and draping the patients on the operating table in the prone position. They received FAW from under-body, upper-body, or lower-body blankets, depending on the design of the operating table and the surgical procedure. Bair Hugger Temperature Management Blanket Spinal Underbody Model 57501 (3M, St. Paul, Minnesota) and Level 1 Snuggle Warm Convective Warming Blanket Upper and Lower Body (Smiths Medical, Inc., Rockland, Massachusetts) were used. The spinal under-body blanket is designed to open frame tables and provides full unrestricted patient access with the size 213 cm × 91 cm. The upper-body blanket provides coverage to the torso, arms, neck, and head and is 203 cm wide and 102 cm long. The lower-body blanket covers the lower half of the body and is 102 cm wide and 163 cm long. For the spinal under-body blanket, convective warming with Bair Hugger Model 775 (3M, St Paul, Minnesota) was used at the setting “High 43°C” for all patients. Equator Convective Warming Level 1 (Smiths Medical, Inc., Rockland, Massachusetts) was used for upper and lower blankets at the setting “44°C”. FAW was continued until the end of surgery or when the patient reached a core temperature of 37.0°C during surgery. The total time of active warming was recorded. All patients in both groups were extubated before transfer to postanesthesia care unit (PACU).

**Measurements**

Before routine oral premedication with paracetamol and oxycodone, baseline temperature measurement was obtained in all patients using the ZHF thermometer, attached to the patient’s forehead and connected to a monitor for continuous measurements. Core temperature was recorded when entering the OR, at induction of general anesthesia, and then at 10-minute intervals throughout the intraoperative period. The ZHF thermometer was used as our primary method for all temperature readings. However, during general anesthesia, after intubation, the core temperature was also monitored by the esophageal probe Level 1 Esophageal/Rectal Temperature Probe 9 FR (Smiths Medical, Inc., Rockland, Massachusetts) and recorded parallel to ZHF-thermometry measurements for secondary analyses. Readings with the ZHF thermometer were continued until 15 minutes after admittance to the PACU if the patient had a core temperature ≥36.0°C. For patients with temperature <36.0°C 15 minutes after arriving in the PACU, measurements were continued and recorded every 30 minutes until normothermia was re-established with a core temperature reading ≥36.0°C. Time of re-establishing normothermia was recorded in all hypothermic patients.
All patients were scored on a thermal comfort scale at the same time as baseline preoperative core temperature was obtained and 15 minutes after admittance to the PACU. They were asked to mark thermal comfort on a 100-mm visual analog scale in which 0 mm was labeled as “worst imaginable cold”, 50 mm as “neither warm nor cold”, and 100 mm as “insufferably hot”.

Demographic details such as age, sex, ASA grade, height, and weight were registered, as well as duration of time from baseline to last measurement, duration of time spent in the OR, duration of anesthesia (the time from induction to extubation), duration of surgery (the time from incision to application of dressing), volume of administrated intravenous (IV) fluid, urine output, and estimated blood loss. Ringer’s acetate was prewarmed to 40°C before IV administration, according to the local guidelines. The incidences of shivering and hypothermia, as defined by a core temperature < 36.0°C, were recorded.

Hemodynamic parameters were registered as the highest and lowest measurement in noninvasive blood pressure, heart rate, and pulse oximetry. The surgical procedure; room temperature in the preoperative unit, OR, and PACU; and type of warming device for the control group were also recorded. At 15 minutes after admittance to the PACU, the investigator assessed whether the patients were awake, awake by touching, awake by shaking, or unconscious.

Primary and Secondary Endpoints

The primary outcome of this study was the difference in mean core temperature between the two groups at 30 minutes after induction of general anesthesia measured with ZHF-thermometry.

Secondary outcomes of the study were incidence of perioperative hypothermia with any core body temperature < 36.0°C measured using the ZHF thermometer, duration of hypothermia, changes in perioperative core temperature, patients’ experiences of thermal comfort preoperatively and postoperatively, incidence of postoperative shivering, observed level of consciousness, and a comparison between ZHF-thermometry measurements and esophageal temperature readings.

Sample Size and Statistical Methods

This study was powered to detect a difference in core temperature of 0.3°C between the groups at 30 minutes after induction of general anesthesia, with a standard deviation (SD) ± 0.3°C for both groups, to be clinically relevant. Sample size was calculated based on earlier studies in our department and parametric tests. A sample size of 11 patients in each group was sufficient to detect the difference of 0.3°C and SD of 0.3 for a power of 0.9, with alpha value 0.05 in parametric testing. We decided on 30 patients, to allocate for dropouts; thus, 15 in each group were to be recruited.

Data were analyzed using the Statistical Package for the Social Sciences (IBM SPSS, version 22, for Macintosh). Normally distributed continuous data were compared using independent sample t test. Categorical variables were tested using χ² tests.

All data are expressed as mean ±SD, number, or percentage as appropriate. Differences were considered statistically significant at P-value ≤ .05. We did not correct for multiple secondary outcome comparisons.

Findings

In the period from January 1st to May 31st, 2015, a total of 32 patients were asked to participate in the study (Figure 1). Two patients declined, and 30 patients entered the study, with no drop-outs. There were no statistically significant differences (ns) in demographic characteristics and anesthetic/surgical details between the two groups (Table 1).

The core temperatures at baseline and induction of general anesthesia were comparable between the two groups (ns). There was no statistically significant difference between the groups for the primary endpoint, core temperature 30 minutes after induction of general anesthesia: mean core temperature and SD was 36.2°C ± 0.4°C in group TS and 36.4°C ± 0.5°C in group C (P = .355) (Table 2).

The core temperature was comparable between the groups until the primary endpoint. After this point, there was a trend favoring group C, reaching statistically significance at the end of surgery and
anesthesia and further into the early postoperative period (Table 2 and Figure 2).

Perioperative hypothermia occurred in 16 patients (53.3%): 10 (66.7%) patients in group TS and 6 (40%) in group C (ns). The duration of hypothermia was significantly longer in group TS, 108 ± 111 minutes (mean ± SD), than in group C, 33 ± 59.5 minutes (P = .03).

Patients in group TS wore the suit for 349 ± 91.4 minutes (mean ± SD). In the control group, the patients were actively warmed for 101 ± 61 minutes. The mean time from induction of anesthesia to activation of FAW was 38.5 ± 10.3 minutes in group C. One patient in group C had a 40-minute prolonged time from the end of surgery to the end of anesthesia because of hypothermia with a core temperature of 35.2°C at the end of surgery. In group C, six patients received FAW from an under-body blanket, eight patients from an upper-body blanket, and one from upper and lower-body blanket. There was no use of any extra warming device.

There were no differences in the level of wakefulness between the groups when arriving in PACU. The thermal comfort scale rating did not differ between the groups and was comparable at the preoperative test and in the PACU (Table 3).

Core temperature readings were similar, at one decimal given, in 28% of the measurements between the ZHF thermometer and the esophageal temperature probe. In the remaining measurements, the ZHF thermometer read a higher temperature in 66% and the esophageal probe in 6%. Data from one patient were excluded in this comparison because of problems with positioning of the esophageal temperature probe.
The findings in this study showed that wearing the thermal suit did not have any effect in prevention of unintended hypothermia at 30 minutes after start of general anesthesia.

Both groups had a similar decrease in core temperature after induction of general anesthesia to the primary endpoint (Figure 2). This trend was an expected result for group C because they did not receive any prewarming. For group TS, we expected a smaller decrease in core temperature as a result of the passive insulation of body heat in the preanesthesia period. However, our findings indicate that the thermal suit is no more effective than standard hospital clothing with a cotton blanket that covered the patients in the control group during the preoperative period.

Hirvonen and Niskanen tested the thermal suit in a previous study of patients in regional anesthesia with a control group wearing hospital clothing, where both groups received active warming if the patient felt cold or the temperature dropped below 35.0°C. They found significantly less hypothermia in the recovery unit when the thermal suit was used. The major difference from our study was that FAW was only used as a rescue measure at established hypothermia in their study, whereas we used FAW for all patients in our control group, in accordance with the local guideline.
The overall high incidence of hypothermia in more than half of our patient groups demonstrates that patients undergoing orthopedic spinal surgery are at risk of developing unintended perioperative hypothermia. With active FAW, normothermia was usually restored by the end of 60 to 120 minutes of surgery, whereas normothermia was not restored to the same extent with the thermal suit. In a study of mixed types of surgery and active prewarming with a self-warming blanket, there was less temperature drop initially after start of anesthesia than with passive insulation; however, 38% of the patients still had hypothermia. Andrzejowski et al demonstrated that active prewarming in patients undergoing spinal surgery resulted in a smaller decrease in core temperature between 40 and 80 minutes after induction, although 32% of patients still became hypothermic. After this time, the differences between groups did not achieve statistical significance.

In our study, the FAW in the control group was started late, for 12 of 15 patients after the primary endpoint, when the patients were in the prone position prepared for surgery. This approach reflects the clinical practice of not starting active FAW until the patient is intubated and repositioned into the prone position for this particular surgical procedure.

Table 2. Comparison of Core Temperatures Between the Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group TS (n = 15)</th>
<th>Group C (n = 15)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline temperature</td>
<td>36.7 ± 0.4</td>
<td>36.8 ± 0.23</td>
<td>ns</td>
</tr>
<tr>
<td>Induction of anesthesia</td>
<td>36.8 ± 0.36</td>
<td>36.9 ± 0.24</td>
<td>ns</td>
</tr>
<tr>
<td>Primary endpoint (30 min after induction)</td>
<td>36.2 ± 0.42</td>
<td>36.4 ± 0.47</td>
<td>ns</td>
</tr>
<tr>
<td>Start of surgery</td>
<td>36.1 ± 0.42</td>
<td>36.2 ± 0.5</td>
<td>ns</td>
</tr>
<tr>
<td>End of surgery</td>
<td>36.1 ± 0.44</td>
<td>36.6 ± 0.55</td>
<td>.008</td>
</tr>
<tr>
<td>End of anesthesia</td>
<td>36.0 ± 0.45</td>
<td>36.6 ± 0.44</td>
<td>.001</td>
</tr>
<tr>
<td>PACU 15 minutes</td>
<td>35.9 ± 0.48</td>
<td>36.6 ± 0.53</td>
<td>.001</td>
</tr>
<tr>
<td>End of study</td>
<td>36.1 ± 0.25</td>
<td>36.6 ± 0.49</td>
<td>.005</td>
</tr>
<tr>
<td>Average decreased core temperature from baseline to primary endpoint</td>
<td>0.54 ± 0.26</td>
<td>0.51 ± 0.32</td>
<td>ns</td>
</tr>
</tbody>
</table>

PACU, postanesthesia care unit; SD, standard deviation.

Data presented as mean values of core temperature in °C ± SD measured with ZHF thermometer.
procedure. Our data highlight the potential of improving with FAW if the device is applied in the preoperative period and also during induction of anesthesia and positioning of the patient.

Several investigators have evaluated the effectiveness of passive and active warming devices and strategies, with conflicting results.\(^2,13,20-26\) The challenges of preventing unintended hypothermia manifest differently depending on surgery type; hence, it is difficult to develop standard guidelines to suit all types of surgery.

Unintended perioperative hypothermia may be underestimated because of inadequate temperature monitoring and management. In clinical practice, there is a challenge with reliable monitoring of core temperature, especially in the awake patients preoperatively and postoperatively. Our study showed minor differences in core temperature between the ZHF thermometer and esophageal thermometer. However, when differences occurred, they were mostly higher readings obtained using the ZHF thermometer. As the ZHF thermometer has proved very reliable in scientific and clinical testing,\(^27,28\) our interpretation is that esophageal probes may sometimes show low values because they are exposed to cooling from the ventilation of the patients or variable position in the esophagus.

The ZHF thermometer should not be placed over the sinuses to avoid interruptions from cooler parts of the forehead.\(^27\) This may explain the few cases of lower readings with ZHF-thermometry in our study. An advantage is that ZHF thermometer is a reliable measurement of core temperature in conscious patients as well and may be kept for monitoring during the entire perioperative course.

The strength of the present study is that we conducted a randomized controlled trial using patients scheduled for orthopedic spinal surgery, with a duration of general anesthesia and surgery expected to render them hypothermic if no prevention measures were applied.

**Limitations**

The nonblinded design of the study may be a limitation because it may have influenced how staff handled patients, as may the open recording of core temperatures. Another limitation may be that we did not measure skin temperature as a parameter of peripheral conservation of heat. However, core temperature is the main outcome measure in clinical practice. Patients in the control group received FAW from three different blankets, and the area of skin surface covered was not standardized. Interpretations of our findings may be limited because we used the sample size calculation for perioperative changes in core body temperature and not the incidence of hypothermia, which would require a larger sample size.

**Conclusion**

The present study shows that the thermal suit did not prevent perioperative hypothermia at 30 minutes after induction of general anesthesia for orthopedic spinal surgery in the prone position. Neither the thermal suit nor the late application of FAW could prevent unintended perioperative hypothermia occurring in more than half of the patients. FAW was significantly more efficient in re-establishing normothermia. The ZHF thermometer seems to be a promising method for obtaining perioperative core temperature readings.

### Table 3. Patients Self-reported Level of Thermal Comfort and Postanesthetic Observation of Shivering

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group TS (n = 15)</th>
<th>Group C (n = 15)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal comfort, preoperative (mm)</td>
<td>50.0 ± 5.1</td>
<td>52.3 ± 6.8</td>
<td>ns</td>
</tr>
<tr>
<td>Thermal comfort, 15 minutes PACU (mm)</td>
<td>47.4 ± 14.3</td>
<td>51.2 ± 2.6</td>
<td>ns</td>
</tr>
<tr>
<td>Shivering, number of patients (%)</td>
<td>1 (6.7)</td>
<td>2 (13.3)</td>
<td>ns</td>
</tr>
</tbody>
</table>

PACU, postanesthesia care unit; SD, standard deviation.
Data presented as mean values ± SD or numbers of patients.
Further studies should address the strategy of active prewarming with more efficient means than the present type of passive heat-conserving thermal suit to avoid hypothermia in patients undergoing orthopedic spinal surgery.

Implications for Clinical Practice

It is crucial that perianesthesia nurses are continually educated in the prevention of perioperative hypothermia. The findings in this study can be used in the decision-making of implementing new devices for prevention of unintended perioperative hypothermia. It is important that perianesthesia nurses keep the surgical patient warm throughout the perioperative period because of the severity of unintended hypothermia.

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References


