BMC Anesthesiology

RESEARCH

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Effectiveness of a new thermal insulation blanket in the control of inadvertent perioperative hypothermia and comfort: a randomized controlled trial

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Abstract

Background Disturbances in the thermoregulatory system can precipitate inadvertent hypothermia in patients undergoing surgeries lasting over 60 min, causing serious complications in the recovery process. Cutaneous thermal protection is relevant for the control of temperature of patients in the perioperative setting. The standard thermal protection widely utilized is an electric forced warm air blanket. This study compared a new layered textile blanket with the standard protection. The hypothesis posited that the textile blanket could provide cutaneous thermal protection comparable to that of the standard protection (forced-air warming blanket), in terms of temperature variation and safety.

Methods This randomized controlled trial was conducted at a Portuguese orthopedic hospital from October 2018 to January 2019, comprising 124 adult patients undergoing elective total knee arthroplasty. Participants were randomly allocated to either the intervention group, receiving the textile blanket, or to the control group, receiving standard measures. Tympanic temperature, shivering, and thermal comfort perception were evaluated at six time points. Comfort dimensions and ergonomic aspects were also assessed. Parametric statistics were performed, and independent samples *t*-tests and repeated measures were used to compare temperature variations and thermal comfort.

Results No statistically significant differences were found between groups in mean temperature variation, visual perception of thermal comfort, and thermal and perioperative comfort scales. The intervention group ($n=65$) scored significantly higher in ergonomic evaluations compared to the control group ($n=59$) for: fit to body and general comfort ($p=0.004$), touch ($p=0.005$), and feeling of comfort with the inner layer texture and shape ($p<0.001$).

Conclusion The tested blanket had a comparable performance to the standard protection, suggesting it as a potential sustainable alternative to the recommended measures for thermal protection. However, further investigations across diverse contexts and populations are needed to validate these findings.

Keywords Hypothermia, Perioperative care, Thermal insulation, Temperature, Randomized controlled trial

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Background

The human body is hypothermic when the temperature of the core thermal compartment is below 36° C [1].

Inadvertent perioperative hypothermia is a risk that ranges from 4 to more than 70% of people undergoing surgeries lasting more than 60 min, and its consequences can affect the recovery process [2–6].

Sedative and anesthetic agents induce profound alterations in human thermoregulation, raising the risk of hypothermia. This risk is further increased in individuals with pre-existing factors such as prior hypothermia, extreme ages (elderly, children, and neonates), low body mass index (BMI), female sex, multiple traumas, and comorbidities like diabetes and hypothyroidism, as well as chronic treatment with benzodiazepines and opioids. The main complications of hypothermia include an increased risk of surgical wound infection, coagulopathies, heightened blood loss, a greater need for transfusions, and prolonged duration of stay in the post-anesthesia care unit [6, 7].

The anesthetic drugs disrupt the stimulation mechanisms between the hypothalamus and the afferent neurons located in peripheral areas and the skin, resulting in two types of thermal disturbances. First, the homeothermic capacity (the ability to maintain stable body temperature regardless of environmental conditions) decreases and individuals may become poikilothermic. This means that their body temperature regulation is influenced by environmental conditions, leading to mild to moderate hypothermia when exposed to cold environments or hyperthermia when excessively bundled or in very hot conditions [3]. Second, anesthesia causes a redistribution of body heat from the core to the periphery, decreasing thermoregulatory peripheral vasoconstriction and reducing the temperature gradient between the central and peripheral compartments, as shown in Fig. 1.

This condition results in decreased blood flow to vital organs in the abdomen and brain, impairing their function [1, 8, 9].

During prolonged procedures under general anesthesia, core temperature decreases rapidly during the first hour due to the redistribution of heat from the central compartment (e.g., head, thorax, and abdomen) to the periphery (e.g., legs and arms). The redistribution of body heat from the core to the periphery due to anesthetic-induced impairment of thermoregulation accounts for 81% of the decline in core temperature during the first hour being the leading cause of hypothermia. After this initial drop, a slower, nearly linear decrease in core temperature occurs between the first and third hour. Ultimately, core temperature reaches a plateau, where heat production and loss are equal, and does not decrease further [1, 10, 11].

During the process it is possible to conduct rigorous monitoring of core temperature and following the conclusion of the anesthetic process, central thermoregulatory mechanisms are reactivated, allowing the individual to exhibit signs of hypothermia through bodily responses such as shivering and/or behavioral expressions of cold sensation.

In cases of neuroaxial anesthesia, the redistribution of heat decreases according to the same tri-phasic pattern as in general anesthesia, although the temperature decline is less pronounced (Fig. 2) and occurs below the level of the block (the lower half of the body) due to the blockade of peripheral sympathetic nerves in that region. During lengthy surgical procedures, the prolonged neural blockade caused by anesthesia facilitates the drop in temperature post-surgery, as the blockade remains active. The vasoconstriction above the level of the block, which could provide some compensation, is also impaired by the sedative drugs administered to these patients, rendering thermoregulatory responses such as shivering insufficient and inhibiting the sensation of discomfort in the unblocked areas (the upper half of the body) [12–14]. These effects may be exacerbated in older individuals, particularly those over 65 years of age, who exhibit a decreased capacity for heat production and retention and a lower thermogenic response [10]. Moreover, when

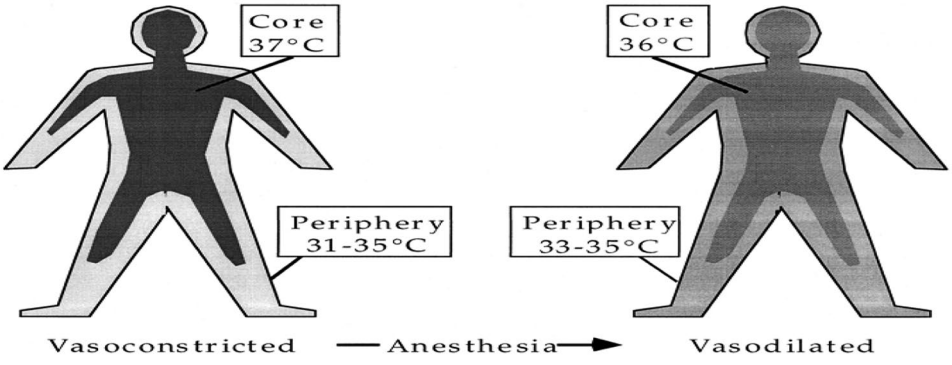


Fig. 1 Heat redistribution [1]

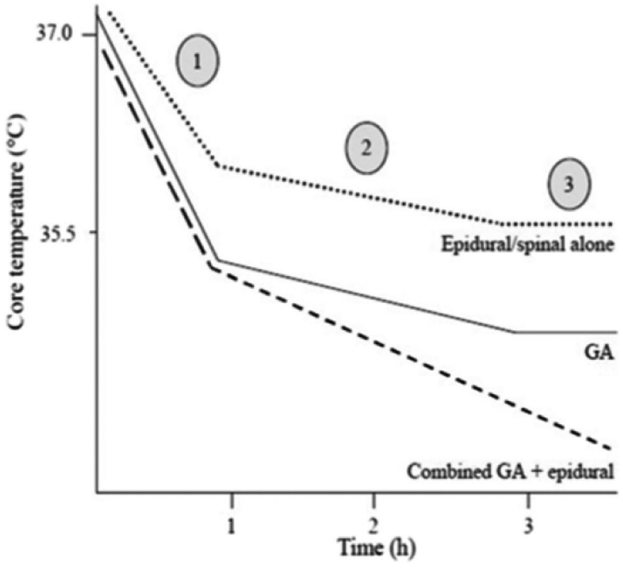


Fig. 2 Characteristic triphasic patterns of hypothermia under regional, general, or combined regional and general anesthesia [12]

shivering does occur, it is often pharmacologically managed to reduce oxygen demands, further diminishing its thermogenic function. Therefore, in the absence of effective temperature monitoring, hypothermia may go unnoticed [1, 14].

In addition to the effects of anesthetics, exposure of the surgical area to the cold perioperative environment increases the risk of temperature drop and trigger changes in the perception of comfort [1, 3, 5]. Thus, during the intraoperative phase, it is crucial to keep patients protected since they are more exposed in the operating room.

Cutaneous protective measures play a crucial role in managing hypothermia [15, 16]. These measures encompass two primary types of protection: thermal insulation systems, such as sheets, blankets or covers, and warming systems which are blankets that utilize a heat source to warm the patient.

Previous research has demonstrated the higher effectiveness of active warming systems in managing perioperative hypothermia when compared to passive insulation methods [15–18].

However, a study has shown that the effectiveness of preheated cotton blankets placed over maternal women's upper bodies during cesarean delivery under neuroaxial anesthesia is comparable to forced warm air systems in terms of temperature variation. It is stated that in the control group, although the temperature to which the blankets were heated is not specified, patients reported feeling thermal discomfort after 30 min due to the cooling of the blankets. In the intervention group, it is noted that the forced-air warming blanket started at 43 °C, but 56% of participants requested a lower temperature, which was adjusted to 38 °C. These results highlight that heated thermal insulation systems can achieve the same level of effectiveness as warming systems in managing inadvertent perioperative hypothermia in short-duration surgeries, but they are less effective in terms of thermal comfort, leading to cold discomfort [19].The heating of the patient undergoing surgery contributes to the control of body temperature, even when only applied to a part of the body [20]. While forced warm air systems are recommended for perioperative use [15, 16, 21], both patients and healthcare providers have reported several drawbacks associated with their application [17]. These include the instability of blankets due to their lightweight composition, the need for constant temperature adjustment, equipment space requirements, waste generated by single-use consumables, the noise generation, and the increased risk of contamination associated with the design of warm air transport sleeves which complicates thorough cleaning, may discourage professionals from utilizing this system [17, 22].

Considering these practical challenges and the aim to investigate alternative approaches to current cutaneous warming systems, it seemed pertinent to question and explore whether a more advanced passive system could compete with active heating solutions while avoiding their disadvantages.

This inquiry prompted the authors to develop and evaluate, in a previous study, the thermal properties of a new insulation system. This system consists of a blanket inspired by layered clothing commonly used in mountaineering and sailing, composed of three different fabric layers - one for comfort, one for insulation, and one external waterproof layer. The blanket is made from these three overlapping textile fabrics designed to be worn over the upper body [23].

This study aimed to assess the effectiveness of the textile layered thermal insulation blanket on temperature variation, on shivering incidence and on the perception of thermal and general comfort, compared to the standard protection, in patients undergoing total knee arthroplasty during the intraoperative phase. The study hypothesized that the textile blanket under investigation could provide a level of cutaneous thermal protection comparable to that of the standard protection, in terms of temperature variation and safety.

Methods

Participants

This parallel single-blinded randomized clinical trial (RCT) study includes patients diagnosed with gonartrosis admitted for surgery at a hospital in northern Portugal from October 2018 to January 2019. The first participant was recruited on October 19 and the last one on January 29.

The study protocol was approved by Ethics Committee of the hospital under the code number "CEUOSS-CMP/20.14". Moreover it has been registered in the Registry of Clinical Trials under the reference number: NCT05131568.

The blanket tested in this study is classified as a low-risk medical device according to EU Regulation 1223/2009.

The study protocol was explained by the anesthesia nurse to all participants, ensuring the protection of their rights and the confidentiality of their personal information.

Adult volunteers scheduled for elective total knee arthroplasty under neuraxial anesthesia were enrolled in the study. Exclusion criteria included patients with a temperature below 36ºC, pregnancy, or those scheduled for general anesthesia or revision surgery. After obtaining written and informed consent, participants were randomly assigned to either the intervention group (IG), or the control group (CG) in a ratio 1:1 using a simple randomisation method through a coin toss process [24] carried out by the anesthesia nurse. After being allocated to a group, each patient was assigned an alphanumeric code linked to their data collection form. This study was blinded for the participants, ensuring that the group to which they were assigned remained unknown, meaning they did not know whether the protection applied was experimental or control.

The textile layered blanket under test was applied in the IG, while the CG received usual care using an electric (an electric forced warm air blanket). Both blankets were suitable for use on the upper body considering the surgical site.

Based on assumptions derived from an estimated of 0.8 and employing a t-test for independent samples, sample size calculation using G*Power 3.1 [25] indicated that a total of 84 participants with 42 participants per group were required to achieve 95% test power at a significance level of 0.05. The noncentrality parameter was 3.6660606, the critical t value was 1.9893186, and the degrees of freedom were 82. The actual power of the test was 0.9518269. To prevent losses, a sample size of 130 participants was deemed appropriate. The study ended when the predetermined number of subjects was reached.

Intervention

The intervention took place in an operating room during the intraoperative phase and adhered to perioperative hypothermia control guidelines. The procedures for all patients followed a predefined protocol that included parameters such as surgical setting, environmental conditions and data collection methods.

The patients underwent neuroaxial anesthesia at the L2-L3 level with ropivacaine and sedation with 1 mg of midazolam and 0.05 µg of fentanyl, which allowed them to remain conscious and awake throughout the surgery. After completing the anesthesia procedure and transferring the patient to the operating room, cutaneous protection was applied by the anesthesia nurse based on their assigned group. In the IG, a three-layered textile blanket was used, comprising three overlapping fabrics: an outer layer of 80% polyester and 20% polyurethane, an intermediate layer of 100% polyester fabric, and an inner layer of fabric consisting of 61% polypropylene, 34% polyamide, and 5% elastane as shown in Fig. 3.

In the CG, standard thermal protection was applied using the Warmair®135 electric forced warm air system, FilteredFlo® Upper Body Warming Blanket (non-woven fabric:198.12×60.96 cm) set at a temperature of 38 °C at the output of the power source according to the manufacturer and confirmed by the anesthesia team.

The blanket remained positioned over the participants' upper body throughout the intraoperative phase, up until the patient left the operating room. Upon leaving the operating room, the blanket was removed, and the patient was provided with standard and appropriate protection before being transferred to the post-anesthesia care unit.

Pre-warming was not used, nor was the textile blanket pre-warmed.

A detailed description of potential adverse effects was outlined and the replacement of the blanket under test with the electric forced warm air blanket was scheduled whenever the patient's temperature fell below 36ºC for more than 5 min.

Outcomes and measures

To assess the primary outcome - temperature variation - the tympanic method was selected and a 400-Series Thermistor Tympanic Temperature Sensor from Smiths Medical (-400) accurate to ±0.1˚C at 37˚C and ±0.2˚C at 5˚C to 45˚C, was placed in the ear canal according to the manufacturer's instructions and connected to a vital signs monitor to measure the patient's core body temperature via the tympanic membrane. The sensor is protected by soft foam that conforms to the ear canal, minimizing the risk of injury to the tympanic membrane and acting as a barrier to seal out ambient air and reduce the influences of environmental temperature.

Temperature was assessed and recorded at six specific time points. Secondary outcomes, including thermal comfort perception measured via a visual analog scale and the presence of shivering, were also assessed and documented at these same time points throughout the study. Time 1 served as the baseline assessment, conducted upon admission to the operating room department. Time 2 occurred at the beginning of the surgery. Times 3, 4, and 5 were designated at intervals of fifteen, thirty, and forty-five minutes respectively, after Time 2.

Fig. 3 Three-layered textile blanket

Finally, Time 6 occurred before the patient left the operating room. At Time 4, both thermal and general comfort aspects were also evaluated once for each participant using two comfort scales.

The visual perception of thermal comfort was evaluated using the Visual Analog Scale of Thermal Comfort [26], a ruler-shaped instrument which allows to access the perception of thermal comfort in a bidirectional way and consists of two main components: a numerical scale ranging from 0 (strong cold discomfort) to 10 (strong heat discomfort), with thermal neutrality, or comfort, identified at the midpoint (5); and a graphical representation featuring five expressive faces. The first face, corresponding to the range 0–2, indicates strong cold discomfort, while the second (2–4) represents cold discomfort. The third face, positioned at 5, signifies thermal comfort. The fourth face (6–8) indicates heat discomfort, and the fifth face (8–10) represents strong heat discomfort. The Thermal Comfort Scale [27], which categorizes thermal comfort into two dimensions - physical (PD) and emotional (ED) - was employed to assess differences between groups. This instrument consists of 9 items rated on a 5-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree). General aspects of comfort were evaluated using the Perioperative Comfort Scale [28]. The instrument consists of 15 items and assesses overall perioperative comfort and encompasses the three states (relief, ease, and transcendence) and four contexts of comfort (physical, psychospiritual, sociocultural, and environmental) as proposed by Kolcaba [29]. The responses to items are recorded on a 6-point Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree).

Shivering was measured using the scale developed by Leslie and Sessler [30], categorized into three levels: 0 (no shivering), 1 (light shivering), and 2 (vigorous shivering).

The ergonomic aspects related to comfort were recorded using a dedicated form comprising 10 items: fit to the body, weight, comfort in the neck, comfort in the arms, comfort in the trunk, overall comfort, tactile feel, comfort with the inner layer texture, blanket color, and blanket shape. Responses were rated on a 5-point Likert scale ranging from 1 (not adequate) to 5 (completely adequate). Table 1 summarizes the instruments used.

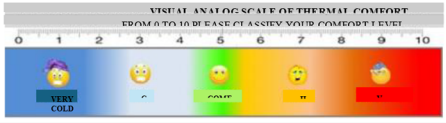
In addition to continuous monitoring and responding to questionnaires, all participants were encouraged to promptly notify researchers of any discomfort they experienced at any time.

The relative humidity and temperature of the operating room was assessed at the beginning of the surgery (approximately T2).

Statistical analysis

Data analysis was conducted using IBM SPSS Statistics, version 27.0. Descriptive statistics were utilized, and an exploratory univariate analysis of each variable was

Table 1 Instruments used in the study

Instrument	Dimension	Nº Items	Time
Visual Analog Scale of Thermal Comfort		1	T1 to T6
Thermal Comfort Scale	Physical Emotional	6 3	T4
Perioperative Comfort Scale	Ease Relieve Transcendence	5 5 5	T4
Shivering Scale		1	T1 to T6
Ergonomic Evaluation Questionnaire		10	T5

performed, including measures of central tendency, dispersion, symmetry, and kurtosis. Outliers and missing values were also examined. The normality of distributions was assessed using the Shapiro-Wilk test. Parametric statistics were applied after verifying assumptions specific to each test. The strength of association between temperature and thermal comfort variables was evaluated using Pearson's correlation coefficient. Correlation values were interpreted as follows: very weak (≤0.2), weak (0.2 to 0.4), moderate (0.4 to 0.6), and strong (>0.6).

The t-test for independent samples was employed to compare means between independent groups (control and intervention), with degrees of freedom reported in parentheses [31].

A repeated measures ANOVA was used to assess the variation in temperature and thermal comfort across six time points, considering both time as a within-subject factor and group as a between-subject factor. The assumption of sphericity was tested using Mauchly's test, and if violated, the Greenhouse-Geisser correction was applied. Interaction effects between time and group were specifically evaluated to determine whether the patterns of variation differed between groups. For all statistical tests, a significance level of $p<0.05$ was adopted.

Results

Out of the 130 eligible participants for inclusion in the sample, only 124 participated in the study. The reasons are depicted in the CONSORT flow diagram of the study population presented in Fig. 4.

As illustrated, the exclusion of patients from the study was not associated with any negative outcomes resulting from the intervention.

All baseline data were analyzed. Demographics, anthropometric measurements, and clinical data of the 124 participants are summarized in Table 2.

There were significant differences in the characteristics of the two participant groups regarding age, BMI, and diastolic blood pressure. In the IG, participants were significantly older and had lower BMI compared to the CG. Diastolic blood pressure values were also lower in the CG.

Regarding environmental variables, the mean room temperatures were 21.53 °C (SD=0.72) for the IG and 22.00 °C (SD=0.61) for the CG, while relative humidity was 51.08% (SD=8.31) for the IG and 45.68% (SD=8.34) for the CG, with p-values of 0.0001, indicating statistical significance.

Temperature and thermal comfort variation – visual analog scale

Table 3 provides detailed variations in mean temperatures and visual perception of thermal comfort across the six evaluation time points for both groups.

The results of the repeated measures tests suggest a significant effect on the patients' temperature over the six assessment points ($F(5,610)=152.794$, $p<0.001$), regardless of the group to which they belonged. A significant interaction was observed between time and allocation group ($F(5,610)=2.881$, $p=0.014$), indicating that the variation in temperature across the six moments differed between the two groups, becoming more pronounced from moment 3, as shown in Table 4.

However, when evaluating between-subject effects, no statistically significant differences were found in the average temperature between the experimental and control

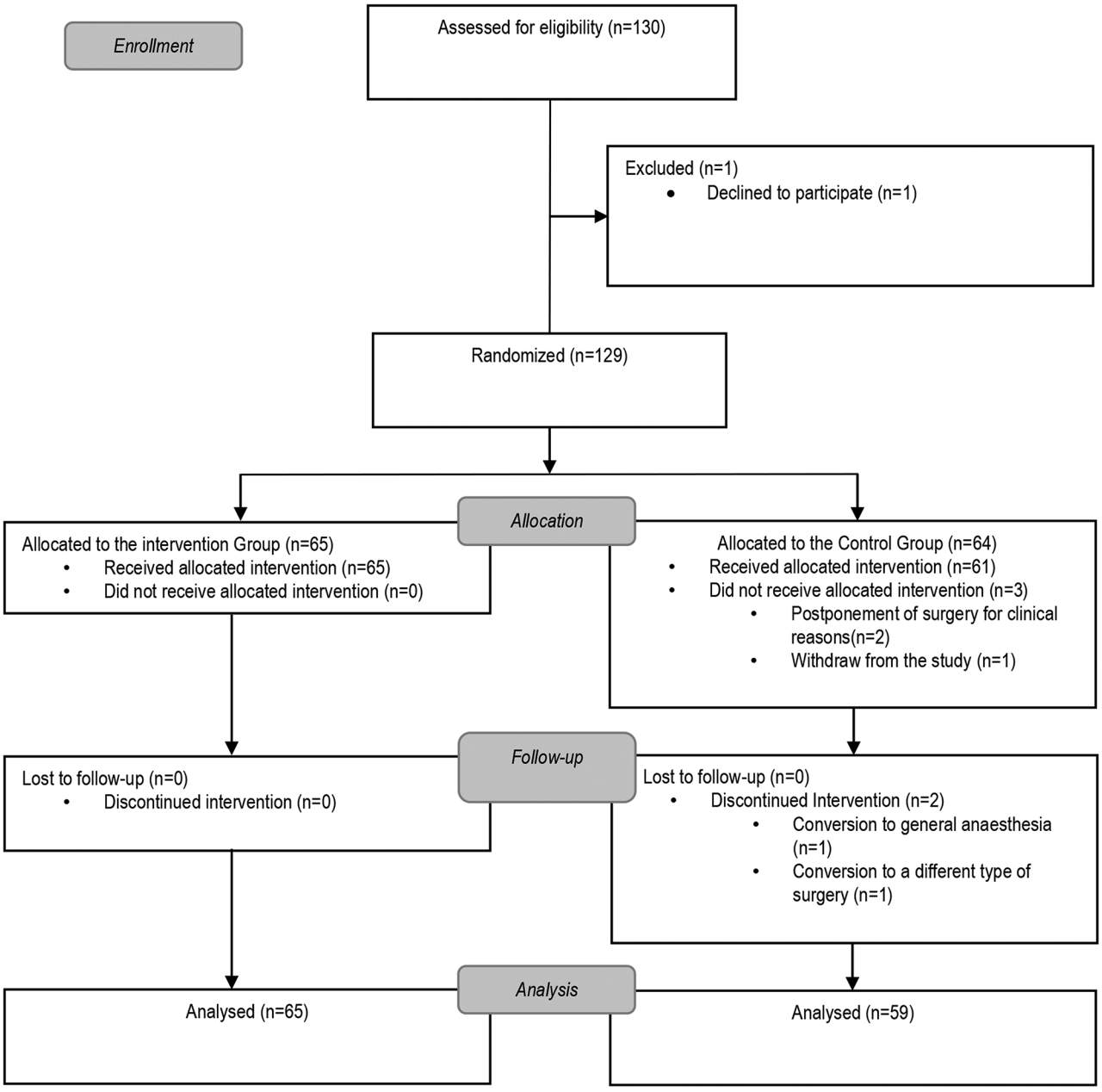


Fig. 4 CONSORT flow diagram

groups (F(1,122)=0.689, $p=0.408$), suggesting that, overall, the average temperatures between the two groups did not differ significantly. These results indicate that, although temperature varied over time in both groups, the pattern of variation differs between them, suggesting that each group may have responded differently to the intervention. The results are graphically presented in Fig. 5.

Regarding the perception of thermal comfort assessed through a visual scale, the analysis of variance for repeated measures indicated a significant violation of sphericity, as determined by Mauchly's test. Corrections were made using the Greenhouse-Geisser adjustment. The results demonstrated that thermal comfort has a significant effect over time (F(2.051, 250.216)=11.409, $p<0.001$). However, the interaction between thermal comfort and allocation group was not statistically significant after adjustment ($p=0.072$), indicating that the changes over time do not differ significantly between groups.

No correlation was found between tympanic temperature variation and the perception of thermal comfort variation.

Table 2 Sample characterization

Variable	IG ($n=65$)	CG ($n=59$)	t(df)	p
	Mean (SD)	Mean (SD)		
Age	70.18 (8.10)	66.90 (6.71)	2.468 (122)	0.015
Comorbidities	1.58 (1.07)	1.50 (0.95)	0.508 (122)	ns
Education	4.60 (2.18)	4.24 (2.05)	0.953 (122)	ns
Body mass index (BMI)	28.95 (4.16)	30.76 (4.10)	-2.432 (122)	0.016
Fasting hours	11.40 (1.80)	11.61 (2.03)	-1.371 (122)	ns
Systolic blood pressure	142.40 (18.14)	142.20 (14.89)	0.072 (122)	ns
Diastolic blood pressure	80.77 (9.92)	75.92 (11.66)	2.504 (122)	0.014
Heart rate	69.52 (10.37)	69.07 (7.22)	0.286 (122)	ns
Oxygen saturation	97.29 (1.72)	97.47 (1.28)	-0.664 (122)	ns
Surgery duration (mn)	72.46 (13.59)	69.32 (12.40)	1.339 (122)	ns
	Number (%)	Number (%)		
Gender				
Female	55 (84.6)	48 (81.4)		ns
Male	10 (15.4)	11 (18.6)		ns
ASA classification				
I	4 (6.2)	3 (5.1)		ns
II	61 (93.8)	51 (93.2)		ns
III	0 (0)	1 (1.7)		ns

Abbreviations: IG, Intervention Group; CG, Control Group; SD, Standard Deviation; ASA, American Society of Anaesthesiologists; df, degrees of freedom

Table 3 Temperature and thermal comfort variation

	IG ($n=65$)	CG ($n=59$)	t(df)	p
	M(SD)	M(SD)		
Temperature variation				
T1	36.59 (0.22)	36.59 (0.26)	-0.026 (122)	ns
T2	36.34 (0.20)	36.33 (0.22)	0.820 (122)	ns
T3	36.28 (0.18)	36.30 (0.20)	0.221 (122)	ns
T4	36.27 (0.17)	36.29 (0.21)	0.615 (122)	ns
T5	36.25 (0.16)	36.32 (0.20)	-1.869 (122)	ns
T6	36.28 (0.19)	36.35 (0.22)	-1.963 (122)	ns
Thermal comfort (visual analog scale)				
T1	4.80 (0.44)	4.90 (0.31)	-1.456 (122)	ns
T2	5.00 (0.00)	4.95 (0.22)	1.1763 (122)	ns
T3	5.00 (0.00)	5.00 (0.00)	-	ns
T4	4.97 (0.25)	5.05 (0.22)	-1.925 (122)	ns
T5	5.00 (0.00)	4.98 (0.13)	1.000 (122)	ns
T6	5.00 (0.00)	5.00 (0.00)	-	ns

Abbreviations: IG, Intervention Group; CG, Control Group; M, Mean; DP, Standard Deviation; df, degrees of freedom; IT1 to T6, Time 1 to Time 6. Legend: T1, baseline values; T2, beginning of surgery; T3 to T5, 15, 30 and 45 min after Time 2; T6, before the patient left the operating room

Thermal and general comfort scores

The results of the scores obtained from the Thermal Comfort Scale, including dimensions and the total scale, and general aspects of comfort from the Perioperative Comfort Scale, indicate minor differences without statistical significance between the IG and CG, as depicted in Table 5.

Table 4 Temperature parewise comparations

Temperature		Differences	Standard error	p^b
1	2	0,252*	0,014	0,0001
	3	0,299*	0,015	0,0001
	4	0,304*	0,016	0,0001
	5	0,302*	0,018	0,0001
	6	0,267*	0,019	0,0001
2	3	0,047*	0,008	0,0001
	4	0,052*	0,012	0,0001
	5	0,050*	0,014	0,007
	6	0,015	0,016	1,000
3	4	0,005	0,008	1,000
	5	0,003	0,012	1,000
	6	-0,032	0,015	0,486
4	5	-0,002	0,009	1,000
	6	-0,037	0,013	0,082
5	6	-0,035*	0,009	0,001

* The mean difference is significant at the 0,05 level

[b] Adjustment for multiple comparisons: Bonferroni

Participant responses regarding ergonomic aspects of comfort for both protection systems revealed statistically significant differences in eight out of the ten items evaluated. Blanket weight and color were the only aspects showing similar results between groups, as shown in Table 6.

Discussion

This study aimed to compare the effectiveness of a new thermal insulation system to the standard protection in the perioperative context, specifically during the intraoperative phase.

Several differences were observed in individual and environmental variables.

Despite random allocation, the study groups were not homogeneous in terms of age and BMI. The intervention group (IG) exhibited significantly lower BMI values, and a higher average age compared to the control group (CG). Although these differences are significant, participants in both groups had BMI values above the normal range, with no patients classified as underweight. Consequently, we believe that even though BMI is recognized as a risk factor [5, 10, 15, 16, 32, 33], it should not significantly affect temperature variation for either the patients or the groups. Regarding age, it remains unclear whether the slightly lower temperature values of temperature observed in the intervention group are a result of the tested blanket's effect or are influenced by the higher age values.

The diastolic blood pressure values were significantly lower in the CG. However, these findings cannot be definitively supported or refuted due to a lack of corroborating

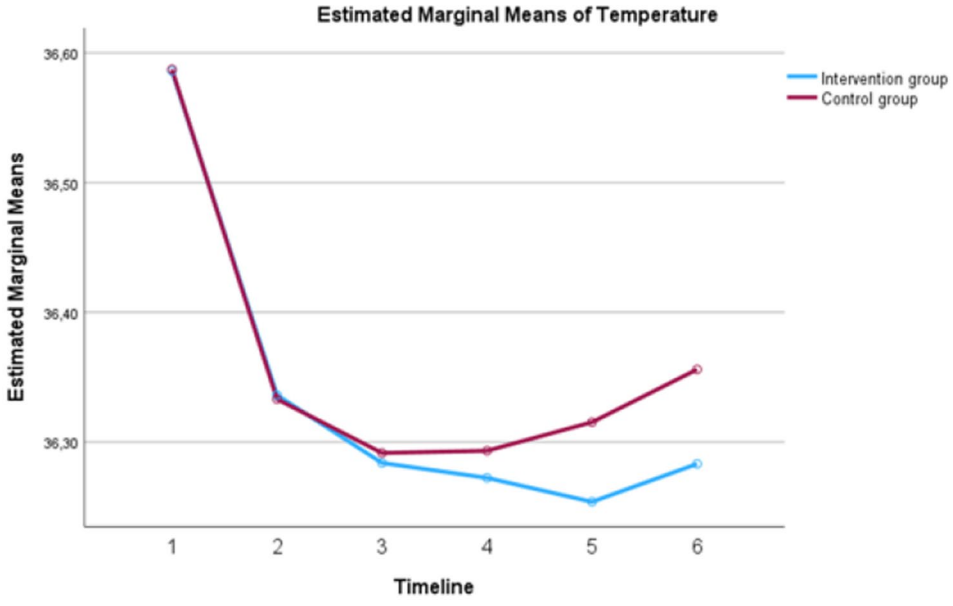


Fig. 5 Repeated measures analysis of temperature

Table 5 Thermal and general comfort scores

	IG (*n* = 65)	CG (*n* = 59)	t (df)	*p*
	M (SD)	M (SD)		
Thermal comfort scale				
Physical dimension	26.75 (2.39)	27.25 (2.23)	1.203 (122)	ns
Emotional dimension	12.27 (1.51)	12.78 (1.19)	0.293 (122)	ns
Total	39.46 (3.59)	40.03 (2.88)	0.974 (122)	ns
Perioperative comfort scale				
Relief	25.89 (2.19)	26.41 (2.59)	1.199 (122)	ns
Ease	16.71 (2.18)	16.86 (1.85)	0.429 (122)	ns
Transcendence	21.09 (2.02)	21.47 (1.99)	1.061 (122)	ns
Total	59.12 (5.44)	60.20 (5.06)	1.141 (122)	ns

Abbreviations: IG, Intervention Group; CG, Control Group; M, Mean; DP, Standard Deviation; df, degrees of freedom

Table 6 Ergonomics evaluation

	IG (*n* = 65)	CG (*n* = 59)	t (df)	*p*
	M (SD)	M (SD)		
Fit to body	4.40 (0.55)	4.10 (0.58)	2.928 (122)	0.04
Weight	4.46 (0.50)	4.31 (0.50)	1.376 (122)	ns
Comfort in the neck	4.43 (0.50)	4.03 (0.59)	4.039 (122)	0.0001
Comfort in the arms	4.46 (0.50)	4.03 (0.59)	4.340 (122)	0.0001
Comfort in the trunk	4.43 (0.50)	4.15 (0.49)	3.148 (122)	0.02
General comfort	4.45 (0.50)	4.19 (0.47)	2.786 (122)	0.04
Touch	4.38 (0.49)	4.15 (0.41)	2.876 (122)	0.005
Comfort with the Inner layer texture	4.46 (0.50)	4.12 (0.42)	4.142 (122)	0.0001
Comfort with the Colour	4.32 (0.53)	4.27 (0.49)	0.567 (122)	ns
Comfort with the Shape	4.43 (0.53)	4.07 (0.53)	3.799 (122)	0.0001

Abbreviations: IG, Intervention Group; CG, Control Group; M, Mean; DP, Standard Deviation; df, degrees of freedom

evidence. Existing literature only identifies systolic blood pressure below 140 mmHg as a risk factor [15].

Some authors suggest that environmental temperatures below 21 °C increase the risk of hypothermia, potentially leading to a decrease in body temperature of up to 1 °C [24, 34]. In our study, while the room temperatures in the intervention group (IG) were significantly lower, they remained above 21 °C, which may have mitigated the potential for body temperature reduction.

Despite the differences between the groups, according to the American Society of Heating, Refrigerating and Air-Conditioning Engineers standards [35] the values of ambient relative humidity range between 20% and 60%. Guidelines indicate that this is not an important variable in relation to variations in core temperature and no evidence was found regarding the correlation between ambient relative humidity and perioperative hypothermia [16]. Some authors also reported in a study that ambient relative humidity was not correlated with the incidence of surgical site infection, even when ambient relative humidity was outside the established standards [36].

Regarding the primary outcome, body temperature variations during the measurement periods were similar between the groups, indicating minor differences in the descent pattern. These findings suggest comparable efficacy between the two skin thermal protection methods in this specific context, which contrasts with previous studies that demonstrated significantly superior effectiveness of forced warm air systems compared to thermal insulation systems [37, 38].

The temperature variations across six evaluation time points showed higher baseline temperatures with significant differences compared to subsequent evaluations. These results underscore the link between core temperature decline and heat redistribution during anesthesia and surgical exposure [3].

The temperature variation observed in this study follows the usual pattern of temperature decline seen in neuroaxial anesthesia and supports the evidence that the temperature does not drop as much as in general anesthesia or combined anesthesia (general + epidural) [12]. Furthermore, the pharmacological evolution and the minimal doses of drugs administered may also contribute to a lesser decline in temperature and a reduction in the incidence of hypothermia in these specific contexts.

The difference observed between time point 5 and 6, showing stabilization or a slight temperature rise, suggests that the closure of the surgical wound, complete protection of the operated limb with surgical dressing, and initiation of full-body protective measures contribute to the body's rewarming process.

Regarding the visual perception of thermal comfort, baseline values (T1) were slightly lower in the IG but tended to equalize in both groups over the course of the study. This suggests an association between increased thermal comfort sensation and the effects of sedative drugs, which reduce anxiety and inhibit the brain's thermoregulatory responses [3]. However, data indicate that the blockade of the cerebral thermoregulatory system was not sufficient to completely suppress thermal comfort perception: Three participants in the control group reported mild heat discomfort at time point 4, prompting an adjustment of the blanket temperature to 32 °C. Additionally, one participant in the intervention group experienced slight cold discomfort but reported feeling comfortable again after 5 min. The peak values of visual perception of thermal comfort observed between time points 5 and 6 in both groups may be related, on one hand, to the stabilization or slight temperature rise and, on the other hand, to the positive emotional effect of anticipating successful anesthesia and surgery, as well as nearing the moment of leaving the operating room.

The differences in scores on the comfort and thermal comfort scales were not statistically significant between groups, both in their dimensions and overall values. According to Kolcaba [29], the three types of comfort experience (relief, ease, and transcendence) depend on four contexts (physical, environmental, sociocultural, and psychospiritual). Given that all participants were from the same geographic region with similar habits, beliefs, traditions, and lifestyles, these findings suggest that these factors contribute to a uniform comfort experience.

The lack of correlation between temperature variation and the perception of thermal comfort supports the notion that neuroaxial block reduces patients' sensations of thermal discomfort, regardless of body temperature values [39].

The temperature was measured using the tympanic method, which is recognized as one of the four primary sites for assessing core temperature [11, 39] and a comfortable non-invasive approach for use in awake patients during surgery. However, evidence suggests that the effectiveness depends on the care taken during the assessment process [11, 12, 39]. In this study, the manufacturer's instructions were followed in its application.

While perioperative shivering alone is not a reliable indicator of hypothermia [40], its pharmacological treatment is often necessary to reduce oxygen demands, thereby reducing thermogenesis [38, 39]. In this study, no incidence of shivering was observed in either group, which is beneficial physiologically for patient comfort. These results may be attributed to the lower level of neuroaxial block [41].

The observed differences in ergonomic aspects of perceived comfort suggest that the tested blanket is more comfortable for participants, likely due to its better body fit, overall comfort, and ergonomic shape compared to the forced warm air system. The inflated hot air in the forced warm air system makes it challenging to conform to the patient's body and stabilize the blanket. These findings imply that the characteristics of the tested blanket align with patients' preference for a cozy feeling.

Neuraxial anesthesia triggers heat redistribution from the core to the periphery of the body, increasing heat loss to the environment [1, 3, 8]. In the textile blanket under test the heat source is the patient's own internal basal metabolic rate (around 80 watts). When properly fitted to the patient's body, the blanket may capture as much of this metabolic energy as possible, helping to maintain insulation of the body's surface and, consequently, controlling hypothermia while active warming systems tend to not conform well to the patient's body when inflated with warm air and a portion of the heat emitted from the source is lost to the environment, which may not contribute to control hypothermia.

Study limitations

Throughout this study, an attempt was made to exclude or, when this was not possible, minimise the factors influencing its rigour. However, some limitations need to be acknowledged. The study was conducted at a single center and involved a limited number of participants. Small sample sizes can diminish result accuracy and the ability to detect significant differences. Therefore, the replication of this study in various populations and surgical contexts, would be beneficial for validating and establishing consistency in the results obtained.

Regarding the variables of BMI and age, there were significant differences between the groups in this study. It remains unclear whether the outcomes would differ in homogeneous groups.

Although all participants had a BMI above the normal range, this study was conducted with a population of relatively older men and women. Further research is needed to examine subjects with diverse thermoregulatory responses and insulation properties, including factors such as weight, age, and sex, to determine potential differences and correlations.

The configuration of the three-layered textile blanket is designed to apply to the upper body. Therefore, it would be interesting to test its effects and its thermal behaviour in different configurations (whole body or lower body).

The standard protection is composed of disposable materials, while the tested textile blanket is washable and reusable, which gives it an ecological advantage. The three-layered textile blanket underwent disinfection treatment in the laundry. Therefore, gathering data on the traceability, strength, and durability of these textile materials would elucidate how long their properties remain unchanged and ensure their safety effects persist. Additionally, a study has been conducted focusing on the costs associated with production, laundering, and maintenance, although without considering the cost of textile materials. However, this information would be valuable for conducting a more thorough cost analysis and gaining deeper insights into the comprehensive economic advantages and disadvantages of its utilization.

Only tympanic temperature was assessed in this study. Future research could benefit from incorporating additional methods, such as skin temperature measurements, to evaluate, correlate, or compare results. This approach would help identify any differences and enhance the consistency and robustness of the findings.

Implications and conclusion

This randomized clinical trial evaluated the effectiveness of a new and innovative three-layered thermal insulation blanket in patients undergoing total knee arthroplasty under neuraxial anesthesia during the intraoperative phase.

Although it is widely accepted that an experiment does not conclusively confirm a hypothesis but rather subjects it to scrutiny, the minor differences in temperature variation and thermal comfort as measured by visual scales, along with the comparable scores on general comfort and thermal comfort scales between the two studied groups, regardless of the protective system used, suggest that the tested textile blanket performs comparably to the recommended standard system in this specific context. The redistribution of body heat due to anesthesia decreases core temperature while increasing peripheral temperature in patients and the gradient between peripheral temperature and the environment also increases, leading to greater heat loss through radiation. Additionally, the wind chill effect from air movement in the operating room increases the potential for heat loss via convection [1]. Based on the results obtained, we believe that although there is no external heat source connected to the blanket under study, its composition, design, and fit to the body and arms can enhance the retention of heat emitted by the patient, thereby preventing radiant heat loss to the environment in the protected body area and facilitating thermal insulation and protection. Since no harms related to its application were observed, the tested blanket appears to possess qualities that make it well-suited for use on the upper body of patients in the studied perioperative setting, particularly during the intraoperative phase.

Moreover, the blanket's washable and reusable nature aligns it with sustainability principles, and its independence from external power sources enhances its flexibility and portability, making it potentially suitable for use in diverse surgical settings, including resource-constrained environments like developing countries, field hospitals, and disaster relief scenarios.

Research has been unequivocally demonstrated the superior effectiveness of active warming systems in managing perioperative hypothermia compared to passive insulation methods, such as cotton sheets, blankets and reflective blankets. Our objective was to explore whether a more advanced passive system could compete with active heating solutions. We developed a blanket inspired by layered clothing commonly used in mountaineering and sailing, consisting of three different fabric layers—one for comfort, one for insulation, and one waterproof layer. It should be noted that this blanket is not a high-tech solution; rather, it is constructed from readily available materials, aimed at enhancing patient insulation through the strategic layering of these fabrics.

Despite active heating systems remaining the gold standard, the findings of this study suggest that this innovative passive approach may offer a viable alternative worth further exploration. During the study, researchers observed impacts on healthcare professionals beyond the clinical outcomes, even though these aspects were not within the scope of the study and were not specifically investigated. The introduction of the new system eliminated heat discomfort among the surgical team, contributing to enhanced concentration and overall satisfaction during procedures. This change also heightened awareness among the team about the criticality of managing

perioperative hypothermia, prompting beneficial shifts in daily practices and institutional protocols.

Author contributions
All listed authors were involved in the study conception and design. Teresa Martins analyzed the data. Isaura Carvalho analyzed the data and wrote the initial draft of the manuscript. Miguel Carvalho and Fernando Abelha commented on and substantively revised the manuscript. All authors participated in the interpretation of the results, in the development of the study and approved the manuscript final version to be published.

Funding
This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. This article was supported by National Funds through FCT - Fundação para a Ciência e a Tecnologia, I.P., within CINTESIS, R&D Unit (reference UIDB/4255/2020 and reference UIDP/4255/2020).

Data availability
The datasets used and/or analysed during the current study are available from thecorresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study protocol was approved by Ethics Committee of the Hospital da Prelada, Porto, Portugal under the code number "CEUOSSCMP/20.14".

Consent for publication
Non applicable.

Competing interests
The authors declare no competing interests.

Received: 13 August 2024 / Accepted: 21 November 2024
Published online: 19 December 2024

References

1. Sessler D, Perioperative Heat. Balance Anesthesiology. 2000;92:578–578. https://doi.org/10.1097/00000542-200002000-00042.
2. Abelha FJ, Castro MA, Neves AM, Landeiro NM, Santos CC. Hypothermia in a surgical intensive care unit. BMC Anesthesiol. 2005;5:1–10. https://doi.org/10.1186/1471-2253-5-7.
3. Insler SR, Sessler DI. Perioperative Thermoregulation and temperature monitoring. Anesthesiol Clin North Am. 2006;24:823–37. https://doi.org/10.1016/j.atc.2006.09.001.
4. Poveda V, de B, Galvão CM. Hipotermia no período intra-operatório: é possível evitá-la? Rev Da Esc Enferm Da USP. 2011;45:411–7. https://doi.org/10.1590/S0080-62342011000200016.
5. Sessler D, Schroeder M, Merrifield B, Matsukama T. Optimal duration and temperature of prewarming. Anesthesiology. 1995;82:674–81. https://doi.org/10.1097/00000542-199503000-00009.
6. Rauch S, Miller C, Bräuer A, Wallner B, Bock M, Paal P. Perioperative hypothermia—a narrative review. Int J Environ Res Public Health. 2021;18. https://doi.org/10.3390/ijerph18168749.
7. Wang J, Deng X. Inadvertent hypothermia: a prevalent perioperative issue that remains to be improved. Anesthesiol Perioper Sci. 2023;1:1–13. https://doi.org/10.1007/s44254-023-00022-6.
8. Kurz A, Sessler DI, Narzt E, Lenhardt R, Lackner F. Morphometric influences on intraoperative core temperature changes. Anesth Analg. 1995;80:562–7. https://doi.org/10.1097/00000539-199503000-00023.
9. Matsukawa T, Sessler D, Christensen R, Ozaki M. Heat flow and distribution during epidural anesthesia. Anesthesiology. 199;83(5):961–7.
10. Cho SA, Yoon S, Lee SJ, Jee YS, Cho CK, Sung TY. Clinical efficacy of short-term prewarming in elderly and adult patients: a prospective observational study. Int J Med Sci. 2022;19:1548–56. https://doi.org/10.7150/ijms.77578.
11. Sessler DI, Perioperative Temperature. Monit Anesthesiology. 2021;134:111–8. https://doi.org/10.1097/ALN.0000000000003481.
12. Riley C, Andrzejowski J. Inadvertent perioperative hypothermia. BJA Educ. 2018;18:227–33. https://doi.org/10.1016/j.bjae.2018.05.003.
13. Allen T, Habib A. Inadvertent perioperative hypothermia induced by neuroaxial anesthesia for cesarean delivery might be more significant than we think: are we doing enough to warm our parturients? Anesth Analg. 2018;126:7–9. https://doi.org/10.1213/ANE.0000000000002604.
14. Hynson J, Sessler D, Glosten B, McGuire J. Thermal balance and tremor patterns during epidural anesthesia. Anesthesiology. 1991;74:680–90.
15. Association of Perioperative Registered Nurses. Recommended practices for the prevention of unplanned perioperative hypothermia. AORN J. 2007;85:972–88. https://doi.org/10.1016/j.aorn.2007.04.015.
16. National Institute for Health and Clinical Excellence. Clinical practice guideline The management of inadvertent perioperative hypothermia in adults National Collaborating Centre for Nursing and Supportive Care commissioned by National Institute for Health and Clinical Excellence; 2008. https://doi.org/https://www.nice.org.uk/guidance/cg65/resources/hypothermia-prevention-and-management-in-adults-having-surgery-pdf-975569636293
17. Conway A, Gow J, Ralph N, Duff J, Edward KL, Alexander K, et al. Implementing a thermal care bundle for inadvertent perioperative hypothermia: a cost-effectiveness analysis. Int J Nurs Stud. 2019;97:21–7. https://doi.org/10.1016/j.ijnurstu.2019.04.017.
18. Bolt LB, Stannard D. Thermal insulation for preventing Inadvertent Perioperative Hypothermia. J Perianesthesia Nurs. 2015;30:427–9. https://doi.org/10.1016/j.jopan.2015.08.002.
19. Fallis WM, Hamelin K, Symonds J, Wang X. Maternal and newborn outcomes related to maternal warming during cesarean delivery. JOGNN - J Obstet Gynecol Neonatal Nurs. 2006;35:324–31. https://doi.org/10.1111/J.1552-6909.2006.00052.x.
20. Granum MN, Kaasby K, Skou ST, Grønkjær M. Preventing Inadvertent Hypothermia in patients undergoing major neuroaxial surgery: a Nonrandomized Controlled Study of two different methods of preoperative and intraoperative warming. J Perianesthesia Nurs. 2019;34:999–1005. https://doi.org/10.1016/j.jopan.2019.03.004.
21. Hooper VD, Chard R, Clifford T, Fetzer S, Fossum S, Godden B, et al. ASPAN 's evidence-based clinical Practice Guideline for the Promotion of Perioperative Normothermia, 2nd Ed. J PeriAnesthesia Nurs. 2010;25:346–65. https://doi.org/10.1016/j.jopan.2010.10.006.
22. Ng V, Lai A, Ho V. Comparison of forced-air warming and electric heating pad for maintenance of body temperature during total knee replacement. Anaesthesia. 2006;61:1100–4. https://doi.org/10.1111/j.1365-2044.2006.04816.x.
23. Carvalho I, Carvalho M, Fontes L, Martins T, Abelha F. Development of a perioperative thermal insulation system: testing comfort properties for different textile sets. PLoS ONE. 2023;18:1–12. https://doi.org/10.1371/journal.pone.0291424.
24. Ferreira JC, Patino CM, Randomization. Beyond tossing a coin. J Bras Pneumol. 2016;42:310. https://doi.org/10.1590/S1806-37562016000000296.
25. Faul F, Erdfelder E, Axel Buchner A-G. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39:175–91. https://doi.org/10.3758/bf03193146.
26. Gomes C. Escala visual do conforto térmico: estudo das propriedades métricas. Escola Superior de Enfermagem do Porto; 2015.
27. Martins AC. Adaptação Da Escala do conforto térmico para a população portuguesa. Escola Superior de Enfermagem do Porto; 2015.
28. Carvalho I, Martins A, Gomes C, Martins T, Abelha F, Apóstolo J. Development and psychometric evaluation of the Perioperative Comfort Scale. Perioper Care Oper Room Manag. 2018;12:11–5. https://doi.org/10.1016/j.pcorm.2018.09.004.
29. Kolcaba K. Comfort Theory and Practice: a Vision for Holistic Health Care and Research. 1st ed. New York: Springer Publishing Company; 2002.
30. Leslie K, Sessler D. Reduction in the shivering threshold is proportional to neuroaxial block height. Anesthesiology. 1996;84:1327–31. https://doi.org/10.1097/00000542-199606000-00008.
31. Polit D, Cheryl B, Baltimore. New York, London, Buenos Aires, Hong Kong, Sydney, Tokyo: Wolther Kluwer; 2021.
32. Biazzotto CB, Brudniewski M, Schmidt AP, Costa Auler JO. Perioperative hypothermia. Rev Bras Anestesiol. 2006;56:89–106. https://doi.org/10.1590/s0034-70942006000100012.
33. Tramontini CC, Graziano KU. Hypothermia control in elderly surgical patients in the intraoperative period: evaluation of two nursing interventions. Rev Lat Am Enfermagem. 2007;15:626–31. https://doi.org/10.1590/s0104-11692007000400016.

34. Morris R, Wilkey B. The effects of ambient temperature on patient temperature during surgery not involving body cavities. Anesthesiology. 1970;32:102–7. https://doi.org/10.1097/00000542-197002000-00003. PMID: 5414287.
35. ASHRAE. Humidity Control Events in Perioperative Care Areas. ASHRAE Tech Comm 96, Heal; 2019.
36. Usiak S, Yas J, Reyes M, Martin A, Bubb T. Temperature and humidity variations in the operating rooms: a risk assessment. Open Forum Infect Dis. 2023;10:5. https://doi.org/10.1093/ofid/ofad500.1266.
37. Ng S-F, Oo C-S, Loh K-H, Lim P-Y, Chan Y-H, Ong B-C. A comparative study of three warming interventions to determine the most effective in maintaining Perioperative Normothermia. Anesth Analg. 2003;96:171–6. https://doi.org/10.1097/00000539-200301000-00036.
38. Shaw CA, Steelman VM, DeBerg J, Schweizer ML. Effectiveness of active and passive warming for the prevention of inadvertent hypothermia in patients receiving neuraxial anesthesia: a systematic review and meta-analysis of randomized controlled trials. J Clin Anesth. 2017;38:93–104. https://doi.org/10.1016/j.jclinane.2017.01.005.
39. Sessler DI. Perioperative Thermoregulation and heat balance. Lancet. 2016;387:2655–64. https://doi.org/10.1016/S0140-6736(15)00981-2.
40. Koeter M, Leijtens B, Ko S. Effect of Thermal Reflective Blanket Placement on Hypothermia in primary unilateral total hip or knee arthroplasty. J PeriAnesthesia Nur. 2013;28:347–52. https://doi.org/10.1016/j.jopan.2012.08.007.
41. Frank SM. Consequences of hypothermia. Curr Anaesth Crit Care. 2001;12:79–86. https://doi.org/10.1054/cacc.2001.0330.

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