IMPLEMENTATION OF A SIMPLIFIED BUNDLE FOR THE PREVENTION OF PERIOPERATIVE HYPOTHERMIA

Espuñes-Mestres, Esther. RN, MSN, MSc, PhD St.*[1,2]; Castillo-García, Jordi. RN, MSN, PhD*[3]; Gallart Fernández-Puebla, Alberto. RN,MSN, PhD*[3,4].
*[1] Operating Room nurse Hospital Vall d'Hebron (Barcelona) Spain. *[2] Associate Professor of Nursing Science, Universitat Internacional de Catalunya, Sant Cugat del Vallès (Barcelona) Spain.
[3]Professor of Nursing Science, Universitat Internacional de Catalunya, Sant Cugat del Vallès (Barcelona) Spain.[4] Deputy director of Nursing, Universitat Internacional de Catalunya, Sant Cugat del Vallès (Barcelona) Spain.

STUDY QUESTION

Can a simplified care bundle effectively prevent hypothermia, decrease surgical site infection and shivering, and improve patient comfort in patients undergoing trauma and orthopaedics surgery in the perioperative period?

POPULATION	Patients undergoing trauma and orthopaedics surgery
INTERVENTION	*Thermal bundle*
COMPARISON	Compared not to doing so
OUTCOMES	Enhance thermal comfort, reduce hypothermia, surgical site infection and shivering
TIME	Perioperative Period

BACKGROUND INFORMATION

A well-defined approach to perioperative temperature management is essential for improving outcomes given the adverse effects that can produce. Even mild reductions in core temperature can impair immune function, increasing the risk of surgical site infection. In addition, hypothermia contributes to patient disconfort and is the primary trigger for shivering, a distressing response that may delay recovery. Unfortunately, inadvertent hypothermia continues to occur in 70% of non- cardiological surgeries, highlighting the need for improved prevention strategies.

OBJECTIVES

The **main objective** was to evaluate the effectiveness of a simplified thermal bundle on perioperative hypothermia incidence. The **secondary outcomes** were to evaluate the effectiveness of the thermal bundle on surgical site infection, shivering and comfort.

DESIGN

Open-label single center randomized controlled with two parallel groups at a University Hospital in Barcelona (Spain). Recruitment started in August 2022 and finished in June 2023.

METHODOLOGY

This study is included in the NIH U. S. National Library of Medicine registry (Clinical trials.gov) with registration number NCT05469958.

STUDY POPULATION

INCLUSION AND EXCLUSION CRITERIA

Patients undergoing osteosynthesis surgery of the upper and lower limbs, pelvis and spine.
Inclusion criteria: aged 17-65 years old, electively, or emergency surgery, general or locoregional anesthesia (Single or combined techniques).

Excluded: osteosynthesis of fingers, metacarpal, metatarsal, and distal radius fractures, Gustilo Grade III open fractures. Cognitive disorders, no admission in Post Anesthesia Care Unit (PACU). COVID-19 positive, febrile process; medical conditions: thyroid disfunction, antihypertensive (nitrates) and morbid grade III obesity. Hemodynamically unstable patients requiring massive intravenous fluids.

PARTICIPANTS AND SAMPLE SIZE

Patients were enrolled at the time their surgical procedure was scheduled in the outpatient department. A trained research nurse subsequently visited candidates in the ward to obtain written informed consent. Upon consent, participants were sequentially assigned a study identification number. On the day of surgery, an opaque, sealed envelope indicating the randomized study arm was attached to the patient's surgical preparation form to ensure allocation concealment. The sample size for this randomized controlled trial was calculated assuming bilateral contrast, an α error of 0.05, a β error of 0.20, and an anticipated 10% attrition rate, resulting in a total of 148 participants.

METHODOLOGY

INTERVENTION

Intervention group: 10 minutes pre-warming with a full-body blanket before anesthesia delivery (temperature set at 38 ºC) + maintained during surgery + environmental temperature set at 21 ºC in Operating Room (OR) + warmed irrigation fluids.
Control group: The facility typically performs procedures using unwarmed cotton blankets. Neither the environmental temperature nor the temperature of the intravenous fluids is controlled; IV fluids were administered at room temperature.

OUTCOME MEASURES

The primary outcome measure was the incidence of hypothermia, defined as a body core temperature below 36ºC and registered with a zero-heat flux sensor. Secondary outcomes included surgical site infection assessed with a telephone follow up at day 30-60 and 90; shivering, assessed with the validated *Spanish version of the* Bedside Shivering Assessment Scale *(Fig. 1 and 2)*, and comfort, with the ASHRAE scale (*Fig. 3*).

Score	Definition
0	**None:** no shivering noted on palpation of the masseter, neck or chest wall
1	**Mild:** shivering localized to the neck and/or thorax only
2	**Moderate:** shivering involves gross movement of the upper extremities (in addition to neck and thorax)
3	**Severe:** shivering involves gross movements of the trunk, and upper and lower extremities

FIGURE 1: Shivering occurrence (Bedside Shivering Assessment Scale).

Puntos	Definición
0	**Ningún temblor:** Ningún temblor apreciable en musculatura mesetera, cuello o tórax
1	**Temblores leves:** Temblores apreciables en cuello y tórax
2	**Temblores moderados:** Temblores que afectan extremidades superiores, cuello y tórax
3	**Temblores severos:** Temblores que afectan extremidades superiores e inferiores generalizados

FIGURE 2: Shivering occurrence (Bedside Shivering Assessment Scale –Spanish version).

-3	-2	-1	0	+1	+2	+3
Cold	Cool	Slightly Cool	Neutral	Slightly warm	Warm	Hot

FIGURE 3: Thermal comfort Scale, by *American Society of Heating, Refrigerating and Air-Conditioning Engineers* (ASHRAE)

RESULTS

RESEARCH VARIABLES	n=148	CONTROL GROUP (n=71)	INTERVENTION GROUP (n=77)	P Value
AGE	46.6 ± 10.7	46.9 ± 10.3	46.4 ± 11.0	0.759
GENDER	MALE	MALE	MALE	0.740
	102 (68.99%)	48 (67.6%)	54 (70.1%)	
	FEMALE	FEMALE	FEMALE	
	46 (31.1%)	23 (32.4%)	23 (29.9%)	
MEDICAL CONDITIONS: DIABETES MELLITUS	NOT	NOT	NOT	0.551
	139 (93.9%)	67(94.4%)	72 (93.5%)	
	YES	YES	YES	
	9 (6.1%)	4 (5.6%)	5 (6.5%)	
PREOPERATIVE CAPILLARY BLOOD GLUCOSE	96.3 ± 16.8	95.6 ± 15.4	96.8 ± 18.1	0.667
BODY MASS INDEX	27.2 ± 4.5	27.6 ± 4.3	26.8 ± 4.7	0.272
ASA PHYSICAL STATUS	ASA P. STATUS I	ASA P. STATUS I	ASA P. STATUS I	0.880
	76 (51.4%)	36 (50.7%)	40 (51.9%)	
	ASA P. STATUS II	ASA P. STATUS II	ASA P. STATUS II	0.942
	60 (40.5%)	29 (40.8%)	31 (40.3%)	
	ASA P. STATUS III	ASA P. STATUS III	ASA P. STATUS III	0.883
	12 (8.1%)	6 (8.5%)	6 (7.8%)	
SMOKING HABIT	NOT	NOT	NOT	0.589
	95 (64.2%)	44 (62.0%)	51 (66.2%)	
	YES	YES	YES	
	53 (35.8%)	27 (38%)	26 (33.8%)	
CORE TEMPERATURE AT OR ARRIVAL	37.1 ± 0.4	37.0 ±0.4	37.1 ± 0.4	0.350
ANESTHESIA PERFORMED	GENERAL ANESTHESIA	GENERAL ANESTHESIA	GENERAL ANESTHESIA	0.341
	17 (11.5%)	10 (14.1%)	7 (9.1%)	
	NEURAXIAL PROCEDURE	NEURAXIAL PROCEDURE	NEURAXIAL PROCEDURE	0.720
	16 (10.8%)	7 (9.9%)	9 (11.%)	
	NEURAXIAL + PERIPHERAL NERVE BLOCK	NEURAXIAL + PERIPHERAL NERVE BLOCK	NEURAXIAL + PERIPHERAL NERVE BLOCK	0.561
	62 (41.9%)	28 (39.4%)	34(44.1%)	
	PERIPHERAL NERVE BLOCK	PERIPHERAL NERVE BLOCK	PERIPHERAL NERVE BLOCK	0.335
	14 (9.5%)	7 (5%)	11.7 (9%)	
	PERIPHERAL NERVE BLOCK + GENERAL ANESTHESIA	PERIPHERAL NERVE BLOCK + GENERAL ANESTHESIA	PERIPHERAL NERVE BLOCK + GENERAL ANESTHESIA	0.392
	39 (26.3%)	21 (29.6%)	18 (23.4%)	

TABLE 1: Sample Characteristics; Data are presented with mean± standard deviation; or n (%). Body Mass Index: Kg/m²; ASA: American Society of Anesthesiologists; Core Temperature: (ºC) Celsius; OR: Operating Room SPSS V28.0

RESULTS

Core Temperature

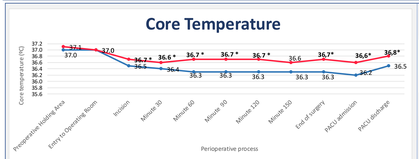

FIGURE 4: Bundle effectiveness on hypothermia, **** in bold statistically significant.***

	Control Cum. Inc.	Intervention Cum. Inc.	RRR [CI95%]
Hypothermia risk	25.3%	10.4%	59% [11.7 to 81]

TABLE 2: Calculation of risk for hypothermia depending on whether the bundle was performed or not. Cum Inc: Cumulative Incidence, CI: Confidence Interval, RRR: Relative Risk Reduction.

Surgical Site Infection (SSI)

Six SSIs were diagnosed, three in each group.

	Control Cum. Inc.	Intervention Cum. Inc.	RR [95% CI]
Surgical site infection	4.2%	3.9%	0.92 [0.19, 4.42]

TABLE 3: Calculation of risk for hypothermia depending on whether the bundle was performed or not. Cum Inc: Cumulative Incidence, CI: Confidence Interval, RR: Relative Risk.

Variable	Odds Ratio	95% CI	p value
Bundle implementation	0.35	0.04 to 2.92	0.332
Average preoperative stay (days)	1.27	1.03 to 1.56	**0.027**
Operating room occupancy (minutes)	1.02	1.00 to 1.03	**0.021**
Post Anesthesia Unit occupancy (minutes)	1.03	1.01 to 1.06	**0.014**

TABLE 4: Mixed multivariate logistic regression analysis of variables associated with SSI CI, confidence interval; p < .05 in **bold**.

Shivering

	Control Cum. Inc.	Intervention Cum. Inc.	RR [CI95%]
Shivering risk	9.9%	6.5%	0.66 [0.2 to 2.0]

TABLE 3: Calculation of risk for shivering depending on whether the bundle was performed or not. Cum Inc: Cumulative Incidence, CI: Confidence Interval, RR: Relative Risk.

Patients who experienced shivering had a mean temperature difference of –0.27 °C throughout the perioperative period compared with those who did not.

Variable	ß	CI 95%	P value
Mean body temperature differences during T1-T15 (ºC)	0.27	0.10 to 0.44	**0.002**

TABLE 5: Mixed multivariate logistic regression analysis for shivering in relation to mean differences in core temperature across the entire perioperative period. ß: beta value, CI: Confidence Interval. p < .05 **in bold**

Thermal Comfort

	Control Cum. Inc.	Intervention Cum. Inc.	RR [CI95%]
Thermal discomfort risk	19.7%	7.8%	0.39 [0.1 to 0.9]

TABLE 6 Calculation of risk for thermal discomfort depending on whether the bundle was performed or not. Cum Inc: Cumulative Incidence, CI: Confidence Interval, RR: Relative Risk.

Variable	Odds Ratio	CI 95%	p value
Implementation of the thermal bundle	4.61	1.84 to 11.58	**0.001**
Core temperature at min. 30 of surgery	6.80	2.87 to 16.12	**<0.001**
Shivering	0.19	0.05 to 0.71	**0.014**

TABLE 7: Mixed multivariate regression analysis of variables associated with thermal comfort prior to post-anesthesia care unit (PACU) discharge. CI: Confidence Interval, p < .05 **in bold** .

DISCUSSION

The thermal bundle significantly reduced the incidence of inadvertent perioperative hypothermia with sustained improvements in core temperature throughout surgery and recovery. However, no significant effect was observed on surgical site infection in contrast with findings reported by other authors. Nevertheless, average preoperative stay, OR and PACU occupancy were identified as SSI risk factors, consistent with current surgical site infection prevention guidelines.
Although the relative risk of shivering was 0.66 (95% CI [0.2 to 2.0]), this difference was not statistically significant. Further research with longer pre-warming periods may be required. Patients with higher core temperatures showed reduced shivering, in line with previous studies. Additionally, patients who experienced shivering demonstrated that temperature loss during the first 30 minutes of surgery had a significant impact on its occurrence (p = 0.001), highlighting the importance of early preventive strategies upon OR entry.
The bundle and the core temperature achieved at minute 30 were positively associated with thermal comfort. Shivering was also identified as a contributor to patient discomfort and should be addressed to improve the overall patient experience.

CONCLUSION

The bundle is easy to implement with significant effect on hypothermia prevention and thermal comfort improving patient safety and patient reported experience.

RELEVANCE FOR CLINICAL PRACTICE

Implementing simple hypothermia-prevention measures, such as pre-warming, is essential to improve both patient satisfaction and patient safety and should be a priority for every perioperative nurse.

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AUTHOR CONTACT INFORMATION