Effect of Short Duration Used of Active Prewarming for Preventing Hypothermia in Non-Anesthetized Volunteer: A Randomized-Controlled Trial

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Background: Prewarming with a forced-air warmer device at least 30 minutes before entering the operating room (OR) helps to prevent inadvertent perioperative hypothermia (IPH), although doing so on a regular schedule may be difficult. Prewarming for a short time may reduce IPH and is more practical.

Objective: To investigate the incidence of hypothermia in non-anesthetized volunteers who used a forced-air warmer device for 10 minutes before entering the OR.

Materials and Methods: The present study was a prospective, randomized-controlled trial that included 32 non-anesthetized volunteers. Sixteen volunteers were randomly assigned to receive prewarming using a forced-air warmer set at 38°C for 10 minutes as the PW group and 16 other volunteers did not receive prewarming as the NW group, before entering a 20°C OR for an hour. The primary outcome was the incidence of hypothermia in the OR. The secondary outcomes were a change in body temperature in the OR, thermal comfort, the requirement for an additional forced-air warmer device, and complications such as skin rash and burn.

Results: The incidence of hypothermia in the OR was 25% in the PW group and 18.75% in the NW group, with no statistically significant differences (p>0.999). There were no significant differences in body temperature between groups. In the waiting room, about 50% of the PW group and none of the NW group reported feeling hot discomfort (p=0.002). However, there were no significant differences in thermal comfort when entering the OR and PACU. No participant asked for an additional forced-air warmer device, and there were no observable device-related complications.

Conclusion: A short-term use of active prewarming cannot reduce the incidence of hypothermia in non-anesthetized volunteers.

Keywords: Short duration; Active prewarming; Hypothermia

Received 13 September 2022 | Revised 9 December 2022 | Accepted 20 December 2022

J Med Assoc Thai 2023;106(1):95-101

Website: http://www.jmatonline.com

Inadvertent perioperative hypothermia (IPH) is defined as a patient's core body temperature below $36^{\circ}C^{(1,2)}$. The peri-operative heat loss occurs by radiation, convection, and evaporation. These are due to the difference between peripheral tissue and ambient temperature, air circulation around the body, and vasodilatation⁽¹⁾. During the first hour of general anesthesia, the core body temperature can

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How to cite this article:

Plengpanich P, Charoensuk C, Chanthawong S, Nonphiaraj S, Prasongdee S, Suttinarakorn C, et al. Effect of Short Duration Used of Active Prewarming for Preventing Hypothermia in Non-Anesthetized Volunteer: A Randomized-Controlled Trial. J Med Assoc Thai 2023;106: 95-101.

DOI: 10.35755/jmedassocthai.2023.01.13747

decrease by 1.6°C from a redistribution of heat from the core to the peripheral compartment⁽³⁾. Surgical patients commonly experience IPH. The incidence was between 26% and 90%^(4,5).

IPH is associated with adverse effects^(5,6), such as cardiovascular events⁽⁷⁾, bleeding⁽⁸⁾, a significant increase in transfusion requirement⁽⁸⁾, altered kinetics and action of various anesthetic and paralyzing agents⁽⁹⁾, and delayed postanesthetic recovery^(6,10).

Many methods were employed to prevent IPH, including using a forced-air warming blanket, thermal insulation, warming infusion fluids and blood products, and raising the operating room (OR) temperature^(5,11,12). The standard ambient OR temperature during routine surgery is 20°C⁽¹³⁾. Increasing ambient temperature could be another option, but according to the previous studies, this method would reduce OR health care providers' performance⁽¹⁴⁾.

Active prewarming has emerged as a method

for preventing IPH by using a forced-air warmer device to blow warm air to the patient before entering the OR⁽⁵⁾. Forced-air warmers work by transferring heated air from a power unit via a specifically designed downstream blanket, which transfers heat to the covered body surface. The mechanism of this method is to decrease central to peripheral temperature gradient, thereby minimizing heat loss from thermal redistribution⁽¹⁵⁾. The previous studies regarding the active prewarming method found various optimal duration of active prewarming, ranging from 15 to 120 minutes⁽¹⁶⁾. Studies showed that prewarming using a force-air warming device between 30 to 60 minutes could prevent IPH^(17,18), but this remains unclear. However, using more extended period of prewarming may be impractical in clinical routine due to thermal discomfort⁽³⁾, congestion in the waiting room⁽¹⁹⁾, and delayed surgery⁽¹⁹⁾. A short-term prewarming is more practical and may reduce IPH. Previous studies showed that 43°C of prewarming for 10 minutes reduced the incidence of $IPH^{(3,20)}$. The temperature of prewarming lower than 43°C for 10 minutes has not been studied.

Objective

The present study aimed to determine the effect of short-term active prewarming using a forced-air warmer device at 38°C for 10 minutes before entering the OR on reducing the incidence of hypothermia in the OR. The authors studied non-anesthetized volunteers to control the other factors affecting body temperature changes.

Materials and Methods Design and participants

The authors conducted a prospective, randomized controlled trial in non-anesthetized volunteers at Srinagarind Hospital, Khon Kaen University. The study protocol was approved by Khon Kaen University Ethics Committee in Human Research (HE631521) and registered at the Thai Clinical Trials Registry (TCTR20220712003). The authors had put up an announcement for volunteers at Srinagarind Hospital, Khon Kaen University between December 2020 and January 2021. The present study was conducted between February 2021 and May 2021. Volunteers aged between 18 and 60 years were eligible for participation. Exclusion criteria included volunteers with body mass index (BMI) less than 18.5 or more than 30 kg/m², body temperature more than 38°C, diabetes, thyroid disease, peripheral vascular disease, peripheral neuropathy, skin lesion, skin disease, psychiatric disorders, and those unable to measure body temperature by tympanic membrane thermometer. All participants gave their written informed consents before enrollment in the study.

All participants were randomly allocated into the active prewarming (PW) group or non-active prewarming (NW) group. Volunteers in the PW group received prewarming using a forced-air warmer device at 38°C for 10 minutes, while the NW group did not receive any prewarming before entering the OR. Randomization was performed using a computer-generated in a block of four lists (http:// www.randomizer.org/). Allocation concealment was performed using opaque, sealed envelopes. Investigator opened the envelope for the group assignments on the day of the study.

Procedure

On the study date, all volunteers were instructed on how to assess the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) thermal comfort scale⁽²¹⁾ as -3 for cold, -2 for cool, -1 for slightly cool, 0 for comfortable, +1 for slightly warm, +2 for warm, +3 for hot. Volunteers changed their apparel to the standard operating room gown, then lay down on a stretcher in the waiting room. All participants received a forced-air warmer device connected through a full body covered blanket, 3M Bair Hugger model 30000, length 213 centimeters, width 91 centimeters (Figure 1) for 10 minutes before entering the OR. Volunteers in the PW group received active prewarming at 38°C, while the NW group, received a forced-air warmer device at room temperature. All volunteers were transferred to the OR, which was maintained a 20°C and stayed for an hour. If volunteers felt cold, they could request for extra warming device with a 38°C forced-air warmer through a full body blanket, 3M Bair Hugger model 30000. After spending one hour in the OR, they were transferred to post-anesthetic care unit (PACU) and stayed in PACU for 15 minutes. The ambient temperature at waiting area, OR, and PACU were kept constant, which is controlled by the hospital control system.

Data collection

Demographic data such as age, gender, weight, BMI, and comorbidities were recorded. Core body temperature was measured using a calibrated tympanic thermometer (LEVERTM Model no. TD-1261) by a non-researcher nurse anesthetist blinded



Figure 1. Demonstrates the use of a forced-air warmer device through a full body blanket on a volunteer in the waiting room.

to the group assignment. The core body temperature was measured at 15 minutes after the volunteers entered the waiting room as a baseline, then 0-, 15-, 30-, 45-, and 60-minute after entering the OR for T0, T15, T30, T45, and T60, respectively, and then 15 minutes after resting in PACU. Thermal comfort scales were evaluated after 10 minutes of stay in the waiting room, 60 minutes in the OR, and 15 minutes after being transferred to PACU. A request for an extra forced-air warmer and complications of forced-air warmer device such as skin rash and burn were collected.

Outcome measures

The primary outcome was the incidence of hypothermia, defined as the patient's core body temperature below 36°C during the stay in the OR. The secondary outcomes included the incidence of hypothermia in the waiting room and PACU, the changes in core body temperature, thermal comfort scale, extra forced-air warmer used, and complications of a forced-air warmer device such as skin rash and burn.

Statistical analysis

The sample size was calculated based on the study of Horn EP that showed the rate of hypothermia at 13% in patients who used a force-air warmer and 69% in patients who did not use one⁽²⁰⁾. With 90%

Table 1. Baseline characteristics of the study population

Variables	NW group (n=16)	PW group (n=16)
Age (years); mean±SD	38.38 ± 9.91	$34.94{\pm}11.93$
Female; n (%)	13 (81.25)	11 (68.75)
BMI (kg/m ²); mean±SD	23.76 ± 3.85	24.36 ± 3.80
Comorbidities; n (%)		
Allergic rhinitis	1 (6.25)	1 (6.25)
Dyslipidemia	0 (0.00)	1 (6.25)
Hepatitis B infection	0 (0.00)	1 (6.25)
Hypertension	2 (12.50)	1 (6.25)
Ischemic heart disease	0 (0.00)	1 (6.25)
Baseline BT (°C); mean±SD	36.6 ± 0.4	36.5 ± 0.4

SD=standard deviation; BMI=body mass index; BT=body temperature

power and a level of significance of 5%, the sample size needed with an anticipated dropout rate of 5% was 16 participants per group. Data were analyzed using Stata Statistical Software, version 16 (StataCorp LLC, College Station, TX, USA). For continuous data, results were presented as mean and standard deviation (SD) or the median and interquartile range (IQR) as appropriate, and as a number (percentage) for categorical data. An independent Student t-test or Mann-Whitney U-test was applied for continuous data, and chi-square test or Fisher's exact test was applied for categorical data. A two-way repeated ANOVA followed by Tukey's post hoc test were used to evaluate the effects of time on core body temperature changes. A p-value of less than 0.05 was considered statistically significant.

Results

Thirty-two non-anesthetized volunteers were enrolled between February 2021 and May 2021, with 16 participants in each group, PW and NW group, and there was no dropout (Figure 2). Both groups had similar baseline characteristics, including age, gender, BMI, comorbidities, and baseline body temperature (Table 1). The ambient temperature was $22.6\pm0.3^{\circ}$ C in the waiting room, $19.9\pm0.5^{\circ}$ C in the OR, and $22.9\pm0.3^{\circ}$ C in PACU. The humidity in the OR was 61.3 ± 12.8 g/m³.

The incidence of hypothermia is shown in Table 2. At waiting area, there was only one volunteer or 6.25% in PW group that experienced hypothermia. In the OR, the overall incidence of hypothermia was 21.88% (7/32) including three volunteers in PW and four volunteers in NW group, with no statistically significant difference (p>0.999). No participant experienced hypothermia at PACU.



Figure 2. CONSORT flow diagram showing patient selection and randomization.

Variables	NW group (n=16); n (%)	PW group (n=16); n (%)	p-value
Incidence of hypothermia			
Waiting room	0 (0.00)	1 (6.25)	>0.999
Operating room	3 (18.75)	4 (25.00)	>0.999
PACU	0 (0.00)	0 (0.00)	N/A

Table 2. Incidence of hypothermia between groups (n=32)

PACU=post-anesthetic care unit; N/A=not applicable

* p<0.05 was statistical significance

The changes in body temperature are shown in Figure 3. There was no difference between groups at any of the measurement points for the changes in body temperature throughout the study period. The effects of time on core body temperature were not different between the groups (p=0.812 by repeated ANOVA). The maximum reduction in body temperature from baseline in OR was $0.5\pm0.4^{\circ}$ C in the NW group and $0.3\pm0.3^{\circ}$ C in the PW group (p=0.227).

The authors divided the ASHRAE thermal comfort scale into cold discomfort with -3 for cold and -2 for cool, thermal comfort with -1 for slightly cool, 0 for comfortable, and +1 for slightly warm, and hot discomfort with +2 for warm and +3 for hot, as shown in Table 3. In the waiting room, all





Data are expressed as mean±SD (p=0.812 by repeated ANOVA) BT=body temperature; T=time after entering the operating room; PACU=post-anesthetic care unit

volunteers in the NW group felt thermal comfort, while 50% of volunteers (8/16) in the PW group significantly reported hot discomfort (p=0.002). In the OR, volunteers in the PW group reported a higher rate of thermal comfort than the NW group at 81.25% versus 68.75%, respectively, but there was no statistically significant difference (p=0.685). In the operating room, eight volunteers had cold discomfort including five in the NW group and three in the PW group. However, no participant asked for extra

Table 3. Therma	l comfort scale	between	groups	(n=32)
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Thermal comfort scale	NW group (n=16) n (%)	PW group (n=16) n (%)	p-value
At the waiting room			0.002*
Cold discomfort (-3 to -2)	0 (0.00)	0 (0.00)	
Thermal comfort (-1 to +1)	16 (100)	8 (50.00)	
Hot discomfort (+2 to +3)	0 (0.00)	8 (50.00)	
At the operating room			0.685
Cold discomfort (-3 to -2)	5 (31.25)	3 (18.75)	
Thermal comfort (-1 to +1)	11 (68.75)	13 (81.25)	
Hot discomfort (+2 to +3)	0 (0.00)	0 (0.00)	
At the PACU			0.776
Cold discomfort (-3 to -2)	1 (6.25)	3 (18.75)	
Thermal comfort (-1 to +1)	9 (56.25)	8 (50.00)	
Hot discomfort (+2 to +3)	6 (37.50)	5 (31.25)	

PACU=post-anesthetic care unit

Thermal comfort scale: -3=cold, -2=cool, -1=slightly cool, 0=comfortable, +1=slightly warm, +2=warm, +3=hot

* p<0.05 was statistical significance

forced-air warmers device. In PACU, thermal comfort scale was similar between groups (p=0.776). There was no complication such as skin rash and burn that occurred throughout the present study.

Discussion

The principal mechanism of body temperature reduction in the first hour is a redistribution of heat from the central part of the body to the periphery via vasodilatation effects⁽²²⁾. Prewarming prevents redistribution by increasing peripheral temperature and reducing heat loss⁽¹⁵⁾.

The present study revealed that prewarming using a forced-air warmer device setting at 38°C for 10 minutes before entering the OR was ineffective in raising body temperature to prevent hypothermia in non-anesthetized volunteers. Additionally, half of the participants in prewarming group complained of hot thermal discomfort.

The overall incidence of hypothermia in the present study was 21.9%, which was lower than 26% to 90% in earlier published research^(4,5), and there was no significant difference in the incidence of hypothermia and core body temperature between groups. On the contrary, prior studies reported that using a short duration prewarming was an effective technique to prevent hypothermia and core body temperature reduction^(19,20,23,24). It may be caused by the present study conducting the study in non-anesthetized volunteers who have a normal thermoregulation process to prevent hypothermia, while the previous

study was conducted in anesthetized patients whose process of thermoregulation was interrupted by anesthetic agent effects⁽²⁵⁾. Moreover, the present study set a forced-air warmer device temperature at 38°C, which was lower than 43°C to 44°C in the previous studies^(19,20,23).

Lee et al. used 10 minutes of prewarming in patients who underwent gynecologic laparoscopic surgery and found the overall incidence of IPH to be 49%, 24% in prewarming and 73% without prewarming⁽²⁴⁾. They also noted that patients who received prewarming had a significant higher core body temperature. In addition, the OR temperature was set at 22°C, which was higher than the present study protocol, but the incidence of hypothermia was also higher. This result could explain why anesthesia had a significant impact on thermoregulation⁽²⁶⁾.

Horn et al. compared the duration between 10, 20, and 30 minutes of prewarming with a 44°C forced-air warmer device in patients who underwent general anesthesia for 30 to 90 minutes and reported that longer prewarming duration was associated with a decrease the incidence of IPH⁽²⁰⁾. Andrzejowski et al. found that prewarming at 38°C for 60 minutes reduced a decline of core body temperature intraoperatively and decreased the incidence of IPH in patients undergoing spinal surgery under general anesthesia⁽¹⁵⁾. Prewarming duration should therefore be extended if it did not disrupt the routine OR flow, especially when prewarming at low temperatures.

The present study found that prewarming volunteers showed a lesser decline in core body temperature when compared with the non-active prewarming group at 0.3°C versus 0.46°C, respectively, with no statistically significant difference. Contrasting to Kaufner et al. finding that studied on patients scheduled for cytoreductive surgery with 43°C prewarming during epidural catheter placement. A reduction in core body temperature was 0.35°C in prewarming and 0.9°C without prewarming with statistically significant difference⁽²³⁾. Shin et al. performed 43°C prewarming for about 15 minutes, during interscalene brachial plexus block in patients undergoing arthroscopic shoulder surgery and demonstrated a significantly higher body temperature during intraoperative period⁽¹⁹⁾. The difference of the present study result from Kaufner et al. and Shin et al. could be a combination of higher prewarming temperature, longer prewarming duration during the performed regional block, and impaired thermoregulation in anesthetized patients.

In the present study, 50% of the volunteers experienced hot thermal discomfort during the 38°C prewarming, which is similar to the study from Sessler et al. conducted on non-anesthetized volunteers, many of the volunteers felt uncomfortably warm when a forced-air warmer device was set at 40°C, and all of the volunteers felt an excessive heat when it was set to $43^{\circ}C^{(3)}$. Although prewarming volunteers were significantly overheated, there was still some volunteers who felt uncomfortably cold when they entered the OR. Participants were advised to request a forced-air warmer device if they felt cold, but the participants in the present study did not request for it.

There were no complications of a forced-air warmer device, which was consistent with the previous studies showing that complications were very rare if used properly, therefore, it is safe to use in surgical patients without contraindications⁽²⁷⁾. According to the previous studies, patients who received prewarming had a significant lower rate of shivering^(20,24). However, shivering was not included in the present study outcome.

Limitation

Non-anesthetized volunteers remain a thermoregulation mechanism that may not be applied to surgical anesthetized patients in clinical routine practice. Further study should be conducted.

Conclusion

A 10-minute active prewarming using a 38°C forced-air warmer device cannot decrease the incidence of hypothermia in non-anesthetized volunteers and increases uncomfortably heat to the participants in the waiting room.

What is already known on this topic?

Intraoperative hypothermia is a common complication that increases morbidity and mortality among surgical patients. Prewarming by using a forced-air warmer device at least 30 minutes before entering the OR can decrease the incidence of hypothermia. However, prewarming for a long time may be impractical in clinical practice. A short duration of 10 minutes prewarming at 43°C can reduce the incidence of IPH, however, a lower temperature at 38°C of prewarming has not been studied.

What this study adds?

Active prewarming with a 38°C forced-air

warmer device for 10 minutes may not be sufficient to increase body temperature to prevent intraoperative hypothermia.

Surgical patients with a risk of IPH should receive longer duration and higher temperature prewarming before induction of anesthesia if thermal comfortable prewarming did not delay the surgery.

Acknowledgment

The present study was supported by the Faculty of Medicine Research Affairs unit, Khon Kaen University, Thailand (Grant number IN64239).

Conflicts of interest

The authors declare no conflict of interest.

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