

Effectiveness of Preoperative Force Air Warming on Perioperative Hypothermia in Patients Undergoing Caesarean Section under Spinal Anesthesia

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Abstract

Background: The incidence of inadvertent perioperative hypothermia (IPH) in Ramathibodi Hospital between 2018 and 2019. Studies evaluating the effectiveness of preoperative warming (prewarming) in preventing IPH are controversial. Especially, its effects on pregnant women undergoing cesarean section under spinal anesthesia (SB). This study aimed to assess whether the prewarming with force air warming (FAW) can prevent IPH or shivering in patients undergoing cesarean section under SB.

Methods: This prospective randomized controlled trial was performed on 44 term-pregnant women, which scheduled for elective cesarean section under SB. Subjects were randomly assigned to either control or prewarming group. The prewarming group received at least 10 min of prewarming with FAW set to 38°C, whereas the control group received standard usual care without prewarming. Using intention-to-treat analysis, the primary outcome

was the change in tympanic temperature. The secondary outcome was the incidence of shivering at post-anesthetic care unit (PACU).

Results: There was a continuous decline in the tympanic temperature after SB in both groups. Using ANCOVA adjusted for baseline, the result did not differ significantly at any time point ($P=0.939$). Although the prewarming group had a higher temperature prior to SB than control group (36.50 ± 0.31 vs 36.64 ± 0.33 , $P=0.007$), there was no difference in the incidence of hypothermia on arrival at the PACU between the groups ($P=0.531$). Shivering occurred similarly in the two groups (3 (13.64%) vs 1 (4.55%) patient for the control and prewarming group, respectively; $P=0.613$).

Conclusion: A brief 10-min of prewarming set at a moderate 38°C temperature did not prevent inadvertent perioperative maternal hypothermia and shivering. For better thermal benefits, longer period and higher temperature setting of prewarming may be considered.

Key words: Prewarming, Cesarean section, Spinal anesthesia, Hypothermia

Introduction

Inadvertent perioperative hypothermia (IPH) is defined as a decrease in core temperature below 36°C during perioperative period, consistent with the 2008 National Institute for Health and Care Excellence (NICE) guidelines.¹ The core-to-peripheral heat redistribution is the most important cause of IPH, which results from exposure to ambient temperature and impairment of thermoregulatory response during anesthesia.² Following anesthesia, the incidence of IPH in Ramathibodi Hospital between 2018 and 2019 has been reported about 20%. The potentially detrimental effects of IPH have been widely studied, included an increase of myocardial oxygen consumption and leftward shift of oxyhemoglobin dissociation curve, which may lead to myocardial ischemia.³ Moreover, it has been associated with increased rate of wound shivering,⁴ infection⁵, length of hospital stay⁶, delayed emergence from anesthesia⁷, and coagulopathy causing excessive intraoperative bleeding.^{8,9}

The etiology of IPH is multifactorial and can be influenced by extreme age, low ambient temperature, prolong duration of surgery, and massive fluid infused.¹⁰ Especially, pregnant women who are vulnerable, can be easily affected by IPH. During cesarean section under spinal anesthesia, high level of sensory blockade to achieve T4 dermatome is required, which its sympathectomy and motor blockade effects impair vasoconstriction and shivering thresholds.^{10,11} Supplementation with intrathecal morphine may further inhibit thermoregulation and exacerbate IPH.¹² Therefore, the monitoring of body temperature is essential as one of the

checklists in the surgical site infection safety checklist of the World Health Organization 2016 guidelines.¹³ More importantly, it is necessary for health care providers to maintain normothermia and emphasize prevention strategies to reduce the incidence and severity of IPH.

Preoperative warming (prewarming) of skin surface before induction of anesthetic induction, markedly increases the heat content in peripheral tissues. As a result, it may reduce the redistribution of core-to-peripheral temperature.^{14,15} Several previous studies have evaluated the effectiveness of prewarming with multiple active warming devices. Horn et al. found that 10 minutes of prewarming with force air warming (FAW) devices resulted in significantly improved core temperature of patients undergoing general anesthesia.¹⁶ However, the results of further studies evaluating the effectiveness of prewarming in cesarean section under spinal anesthesia are still controversial. At the time of this study, prewarming is not used as a routine care for preventing IPH in patients undergoing cesarean section under spinal anesthesia in Ramathibodi Hospital.

Accordingly, this prospective randomized controlled trial aims to investigate the effectiveness of preoperative FAW on preventing IPH in patients undergoing cesarean section under spinal anesthesia in Ramathibodi Hospital. The primary objective of this study is to test hypothesis that pregnant women receiving the preoperative FAW for a brief period would have a lesser decrease in temperature during cesarean section under spinal anesthesia. In addition, the secondary objective is to assess if prewarming with FAW is associated with less incidence of maternal shivering.

Methods

Study Design and Patient Population

Following approval by the Research Ethics Committee of Ramathibodi Hospital (ID09-61-05), 44 pregnant women who scheduled for elective cesarean section under spinal anesthesia between November 2018 and October 2019, were enrolled in this single-center prospective open-label randomized controlled trial. Informed consent was obtained from all participants at the time of their preoperative anesthetic assessment.

Eligible patients included those who were over 18 years of age, American Society of Anesthesiologists (ASA) physical status I-III, singleton pregnancy and term ≥ 37 weeks of gestation. Exclusion criteria were patients with body mass index (BMI) $>40 \text{ kg/m}^2$, required general anesthesia during surgery, underwent emergency cesarean section and had comorbidity such as active cardiac conditions, cerebrovascular disease, hematologic conditions and hypertension included those who received antihypertensive drugs, as these might interfere with normal thermoregulatory mechanisms.

Study Protocol

According to a computer-generated randomization using Microsoft Excel random number generator (Microsoft Corp.), 44 patients were randomly assigned to either the control or the prewarming group in a ratio of 1:1. Patients in the control group received standard usual care consisting of no preoperative active warming, whereas patients in the prewarming group received preoperative full-body FAW (Bair HuggerTM model 750, 3M) set to 38°C for at least 10 minutes in the holding area before transferring

to the operative room (OR). For ethical reasons, if any patients in the control group developed hypothermia (defined as core temperature $< 36^\circ\text{C}$), active warming with FAW was instituted. During the prewarming period, patients were monitored and assessed for adverse effects related to active warming, such as diaphoresis, burn, or hyperthermia defined as core temperature $>37.5^\circ\text{C}$, which lead to a cessation of prewarming.

Following arrival to the OR, ambient OR temperature was set to $20\text{--}24^\circ\text{C}$ and routine standard monitoring (electrocardiogram, pulse oximetry and non-invasive blood pressure) was applied. After standardized intraoperative anesthetic management consisted of a co-load with intravenous (IV) warmed acetate ringer's solution (Acetar[®]) infused during the induction of spinal anesthesia using 0.5% hyperbaric bupivacaine (Marcain[®] 0.5% Spinal Heavy) with or without intrathecal morphine at the discretion of the anesthesiologists, all patients received intraoperative active warming with upper body FAW set to 38°C and IV warmed fluids (warmed to 39°C in a warming cabinet). The extent of sensory blockade was tested using a pinprick sensation until the level did not change and the surgery commenced after achieving at least level of T6 blockade. The investigators measured patients' tympanic temperature using an ear thermometer (Braun ThermoScan[®] PRO6000, Welch Allyn). Measurements were taken from both ears, which the average was recorded at these time points: at the holding area, prior to spinal anesthesia, every 15 minutes during surgery and on admission to post-anesthetic care unit (PACU).

After entering into the OR, ambient OR temperature was set to $20\text{--}24^\circ\text{C}$ and routine

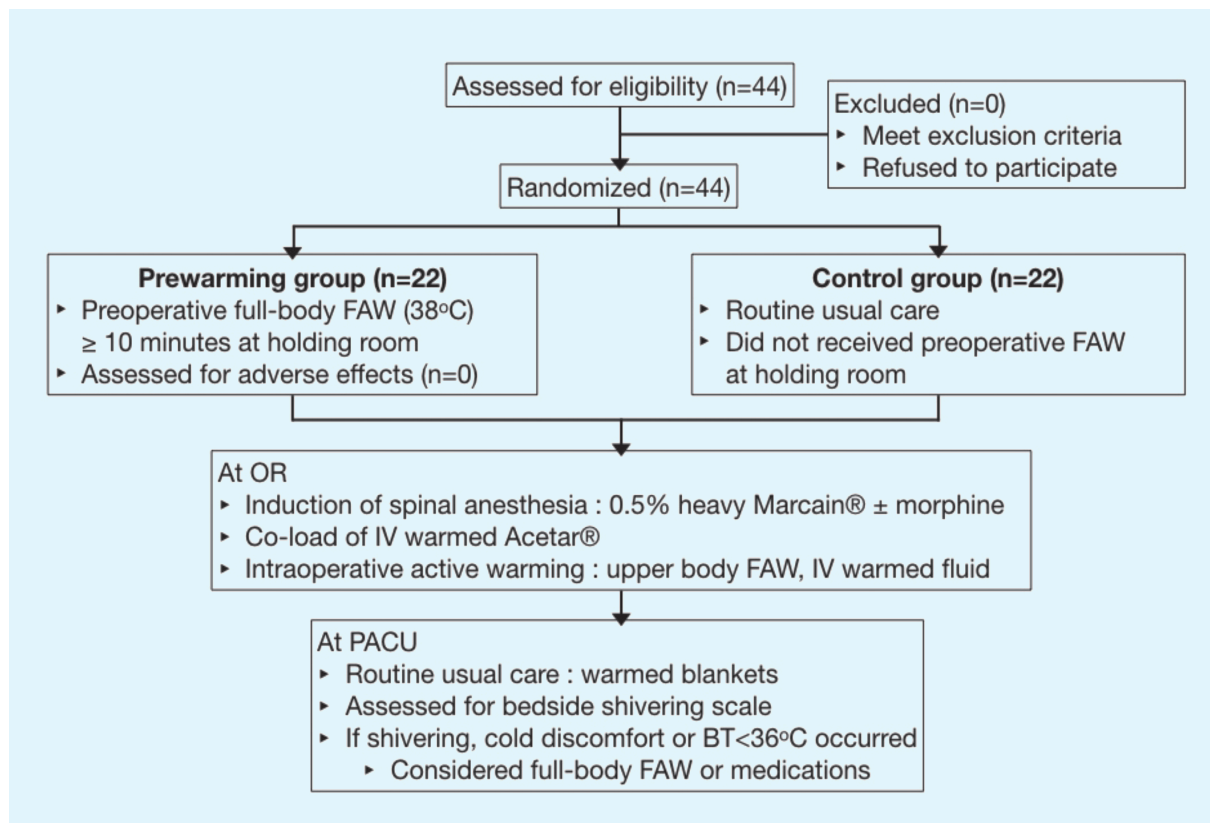


Figure 1 Study protocol

standard monitoring (electrocardiogram, pulse oximetry and non-invasive blood pressure) was applied. Then the anesthesiologists provided standardized intraoperative anesthetic management, consisting of spinal anesthesia and co-loading of intravenous (IV) warmed acetate ringer's solution (Acetar®). After the induction of spinal anesthesia, 0.5% hyperbaric bupivacaine (Marcain® 0.5% Spinal Heavy) with or without morphine was administered by intrathecal route at the discretion of the anesthesiologists. All patients received intraoperative active warming with upper-body FAW set to 38°C and IV warmed fluids (warmed to 39°C in a warming cabinet). Level of sensory blockade was tested with pinprick sensation until the level did not change.

The cesarean section commenced after achieving at least the level of T6 blockade.

After entering into PACU, a degree of shivering was observed by the investigator using bedside shivering assessment scale¹⁷, where 0 = no shivering, 1 = mild shivering localized at neck or thorax, 2 = moderate shivering involved the upper extremities, and 3 = severe shivering with whole body involvement. If shivering, cold discomfort or body temperature <36°C was experienced, active warming with full-body FAW or medications such as meperidine used to treat shivering might be offered at the discretion of the anesthesiologists, in addition to warmed blankets as routine care.

Statistical Analysis

Patients' characteristics included maternal age, BMI, gestational age, and parity. Anesthetic and surgical variables were also recorded included duration of prewarming, level of sensory blockade, anesthetic drug given, incidence of hypotension (BP decline >30% from baseline value), amount of ephedrine given, total volume of IV fluid infused, duration of surgery, ambient OR temperature and total estimated blood loss. The primary outcome was the change in temperature between study groups. The secondary outcomes were the incidence of shivering at PACU.

Descriptive statistics were used to summarize demographic and outcome data. For continuous variables, means, medians and standard deviations (SD) were determined, whereas number counts and percentage were described for categorical variables. Intention-to-treat analysis was conducted, included all patients in the groups to which they were assigned, irrespective of protocol deviation. The distribution normality was tested by Kolmogorov-Smirnov test. Data were compared using independent samples t-test for normally distributed data, Mann-Whitney U test for nonparametric data, and Chi-square test or Fisher's exact test as appropriate for discrete variables. Analysis of covariance (ANCOVA) was used to examine the differences in the mean values of the dependent variables, while statistically controlling for the effects of other continuous variables. SPSS software version 20.0 (SPSS Inc., IBM Corp., NY, USA) was utilized for data analysis. A P-value of <0.05 was taken to denote statistical significance.

A data from a previous study, with a lesser decrease of $0.6 \pm 0.4^{\circ}\text{C}$ in core temperature at 45 minutes after commencement of surgery in prewarming group, was calculated in order to detect a difference of 0.3°C in mean core temperature between the groups.¹⁸ As a result, a sample size of 22 patients per group was set according to power analysis based on values for α of 0.05, β of 20% and dropout 10%.

Results

All 44 participated patients were investigated up to the end of the protocol and analysis, which the flowchart of the study progress is provided in Figure 2. Maternal demographic data included obstetric data were similar among the two groups (Table 1). Anesthetic and surgical data were statistically comparable and summarized in Table 2.

Throughout the study, there was no difference between the two groups with regard to level of sensory blockade, IV ephedrine use, incidence of intraoperative hypotension, estimated blood loss, and ambient room temperature (Table 2). The mean duration of surgery was 94.32 ± 18.15 min in control group and 86.59 ± 20.32 min in prewarming group ($P=0.191$). However, a significant difference was found for the amount of IV fluid administration, which was slightly greater in control group than prewarming group ($1,813.64 \pm 388.28$ mL vs $1,568.18 \pm 405.78$ mL; $P=0.047$).

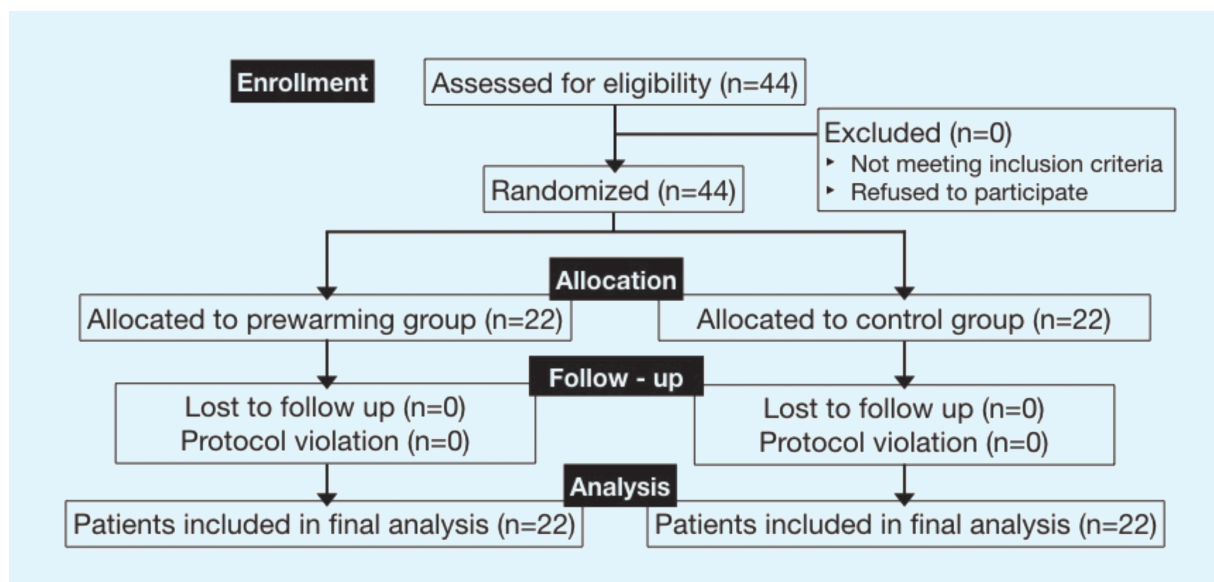
At the beginning, baseline tympanic temperature was $36.61 \pm 0.32^{\circ}\text{C}$ and $36.52 \pm 0.34^{\circ}\text{C}$ in the control and prewarming group respectively ($P=0.366$), showing no statistical difference between the two groups (Table 3).

Table 1 Demographic and obstetric data

	Control (n=22)	Prewarming (n=22)	<i>P</i> value
Age (years)	32.27±4.89	31.45±3.70	0.535
Body mass index (kg/m ²)	28.82±3.13	27.77±3.21	0.280
ASA PS II (n, %)	22 (100)	22 (100)	1.000
Gestational age (days)	269.18±3.17	268.27±2.23	0.278
Parity (n, %)	1 [1-1]	1 [0-1]	0.659

Data are mean±SD, median [interquartile range] or number (%)

Abbreviation; ASA PS: American Society of Anesthesiologists physical status

**Figure 2** Flowchart of the study progress

Preoperative FAW was well tolerated by the patients in the prewarming group with the median prewarming period of 10 minutes. No adverse events or cessation of the prewarming intervention were reported. Subsequently, tympanic temperature prior to induction of spinal anesthesia exhibited a greater increase in the prewarming than the control group (36.64 ± 0.33 vs 36.50 ± 0.31 , respectively; $P=0.007$). Although the prewarming group had higher

mean temperature during the first 30 minutes of the surgery, this was not statistically significant (Figure 3).

At the beginning, baseline tympanic temperature was $36.61 \pm 0.32^\circ\text{C}$ and $36.52 \pm 0.34^\circ\text{C}$ ($P=0.366$) in the control and prewarming group respectively, showing no statistical difference between the two groups (Table 3). Preoperative FAW was well tolerated by the patients with the median prewarming duration of 10 min.

Table 2 Anesthetic and surgical data

	Control (n=22)	Prewarming (n=22)	<i>P</i> value
Prewarming time (minutes)	-	10 [10-11]	<0.001*
Ambient OR temperature (°C)	21 [21-21]	21 [20-21]	0.054
IT bupivacaine (mg)	2.3 [2.2-2.4]	2.35 [2.2-2.4]	0.555
IT morphine (mg)	0.2 [0.2-0.2]	0.2 [0.2-0.2]	>0.999
Level of sensory blockade (n, %)			0.737
T3	1 (4.55)	1 (4.55)	
T4	21 (95.45)	19 (86.36)	
T6	0	2 (9.09)	
IV ephedrine (mg)	32.05±13.56	31.36±12.34	0.862
Total IV fluid (mL)	1,813.64±388.28	1,568.18±405.78	0.047*
MAP below baseline >20% (n, %)	14 (63.64)	17 (77.27)	0.322
Estimated blood loss (mL)	400 [300-500]	300 [300-400]	0.196
Time before SB (min)	29.45±7.49	25.14±7.40	0.061
Time before PACU (min)	94.32±18.15	86.59±20.32	0.191

Data are mean±SD, median [interquartile range] or number (%).

Abbreviation; OR: operating room, IT: intrathecal, IV: intravenous, MAP: mean arterial pressure, SB: spinal block, PACU: post-anesthesia care unit

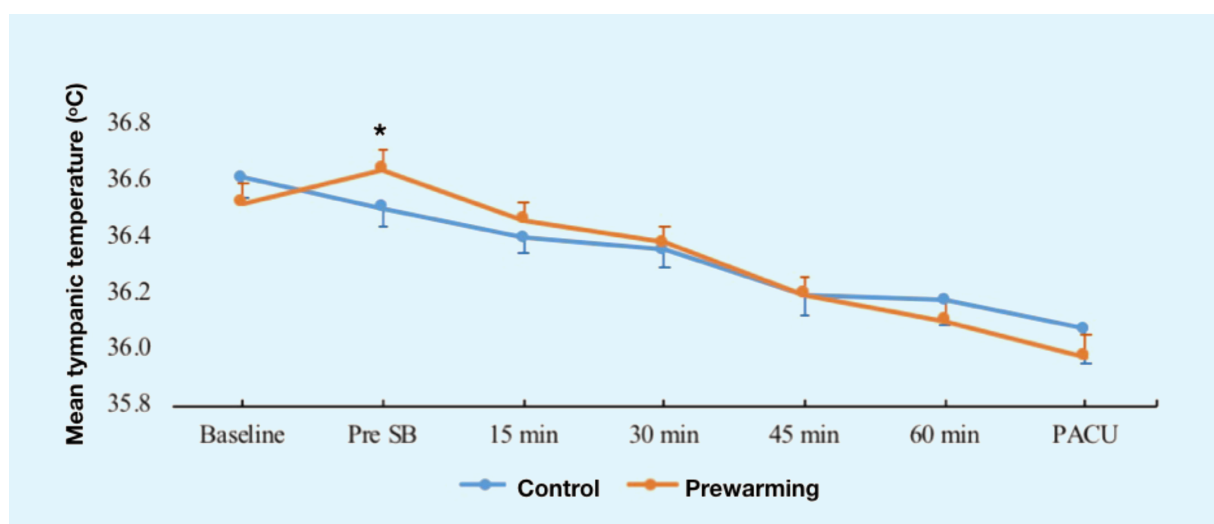


Figure 3 Mean tympanic temperatures (°C) by time in patients received preoperative FAW (prewarming; orange) or no prewarming (control; blue). Vertical bars are SD. **P* value < 0.05.

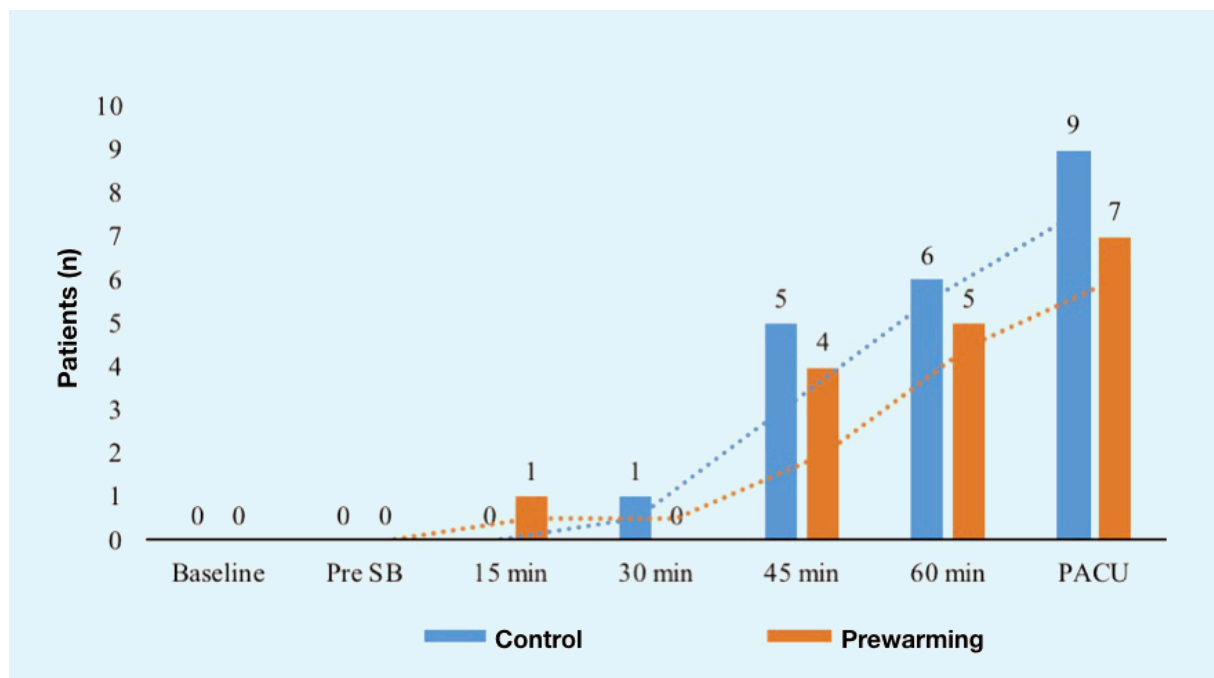
Table 3 Primary maternal outcome; tympanic temperature change (°C)

	Control (n=22)	Prewarming (n=22)	<i>P</i> value
Baseline ^a	36.61±0.32	36.52±0.34	0.366
Pre-SB ^b	36.50±0.31	36.64±0.33	0.007*
Procedural time ^b			0.939
15 min in OR	36.40±0.26	36.46±0.29	
30 min in OR	36.35±0.30	36.38±0.27	
45 min in OR	36.20±0.37	36.20 ±0.30	
60 min in OR	36.17±0.42	36.10±0.34	
at PACU	36.07±0.57	35.97±0.38	

^aPerformed by independent samples t-test^bPerformed by ANCOVA adjusted for baseline temperature

Data are mean±SD

Abbreviation; Pre-SB: prior to spinal block, OR: operating room, PACU: post-anesthesia care unit

**Figure 4** The number of patients with perioperative tympanic temperatures below 36°C by time. There was no significant difference between the group.

No adverse events related to the prewarming intervention were reported. Subsequently, the temperature prior to spinal anesthesia

exhibited a greater increase in prewarming group than control group with a mean difference of 0.14°C ($P=0.007$). Although the prewarming group

had a higher mean temperature during the first 30 min of the operation, this was not statistically significant (Figure 3).

Thereafter, there was a continuous decline in tympanic temperature in both groups. Using ANCOVA adjusted for baseline temperature, the comparison was not statistically significant at any time point (Figure 3). There were 9 (40.9%) patients in the control group and 7 (31.8%) patients in the prewarming group had a temperature below 36°C at the time of arrival in the PACU, but there was no significant difference between the groups ($P=0.531$; Figure 4). Lastly, the maximum change in tympanic temperature was not significantly different too (0.54°C versus 0.55°C in control and prewarming group, respectively).

After arrival in the PACU, shivering was observed in 3 (13.6%) of 22 patients of the control group, which 1 of 3 patients had a moderate shivering (shivering assessment scale=2) and intervention with full-body FAW was needed. When considering postoperative shivering, there was no statistically difference in the incidence of shivering between the two groups (Table 4).

Discussion

According to intention-to-treat analysis, the main finding of this study reveals that the changes in tympanic temperature from baseline to the time of arrival in PACU between the control and prewarming group did not differ significantly. In spite of an increase in temperature prior to induction of spinal anesthesia in prewarming group, there was still a decrease in temperature thereafter. Consequently, the trends of decreasing temperature were not significantly different between the groups ($P=0.939$), indicating that 10 minutes of prewarming at 38°C with FAW was not associated with a prevention of perioperative hypothermia during cesarean section under spinal anesthesia. Similarly, the incidence of shivering also was not prevented by taking this intervention.

The optimal periods and temperature of prewarming have been studied. The study of Horn et al. proved that at least 10 minutes of prewarming at a high 44°C temperature could improve core temperature of patients undergoing general anesthesia.¹⁶ Likewise, Chung et al. found that patients who received 15-min prewarming with 43°C upper-body FAW and underwent

Table 4 Secondary maternal outcomes

	Control (n=22)	Prewarming (n=22)	P value
Shivering (n, %)	3 (13.64)	1 (4.55)	0.613
Shivering assessment scale (n, %)			
0	19 (86.36)	21 (95.45)	
1	2 (9.09)	1 (4.55)	
2	1 (4.55)	-	

Data are number (%).

cesarean section, had a lesser decrease of core temperature at 45 min after spinal anesthesia than control group (-0.6 vs -0.9°C , $P=0.004$).¹⁸ Recently, Jun et al. evaluated the effects of 20-min prewarming at 45°C in patients undergoing prostate surgery under spinal anesthesia, and found that the prewarming group had a higher temperature on admission to the PACU (35.9 vs 35.6°C , $P=0.023$). Nevertheless, the high temperature setting of prewarming may relate to some adverse effects such as burn, diaphoresis, hyperthermia and maternal thermal discomfort.¹⁹

In our study, we performed 10 minutes of prewarming at a moderate temperature setting (38°C) to decrease the risk of adverse effects related to prewarming. As a result, our findings were different from other previous studies. Because the magnitude of heat redistribution that is the major initial cause of core hypothermia, depends on the gradient of core to peripheral temperature, we assume that the insignificant thermal changes of this study are attributable to the insufficient temperature setting and prewarming time. There was a failure in raising the heat content of the peripheral tissue to the amount that can prevent perioperative hypothermia. After prewarming at the holding area, patients received a warm blanket, the same as patients in control group did. There was a period of time between the end of prewarming and the start of the operation, which might attenuate the benefits of prewarming.

As a result, our findings were different from other previous studies. We assume that the insignificant thermal changes were attributable to insufficient temperature setting and prewarming period. The gradient

of core-to-peripheral heat redistribution is an important cause of hypothermia.² There was a failure in raising the heat content of peripheral tissues to the amount that can prevent perioperative hypothermia. Also, there was a delay period of time from the end of prewarming to the operation, which might attenuate the thermal benefits of prewarming. Therefore, we suggest that intraoperative active warming, such as FAW and IV warmed fluid, are still beneficial to maintain normothermia and prevent maternal IPH.

Unlike general anesthesia, spinal anesthesia can cause residual sympathectomy and vasodilation below the level of blockade during postoperative period.¹⁴ The study of Szmuk et al. showed that core temperature after operation in patients given spinal anesthesia increased significantly faster than those who given general anesthesia ($1.2 \pm 0.1^{\circ}\text{C/h}$ vs $0.7 \pm 0.2^{\circ}\text{C/h}$, $P<0.001$). They also concluded that residual peripheral vasodilation could speed the rewarming of postoperative core temperature.²⁰ The results from our study demonstrated that the temperature dropped the most at the time of arrival in the PACU, which IPH and shivering also occurred. Active cutaneous warming with full-body FAW can increase peripheral heat content¹⁴, so we guess that it is an efficient method at rewarming and reducing shivering at the PACU.

Our limitations are that the anesthesiologists and investigators who assessed shivering were not blinded to the group assignment, because it was difficult to hide FAW. This would influence the shivering assessment results. For the primary outcome, tympanic temperature

was unlikely influenced by this bias. We did not measure the heat content in peripheral tissues directly. Additionally, clinical acceptance of the infrared ear thermometer was limited. Despite its accuracy of $\pm 0.2^{\circ}\text{C}$ for the range 35.0 to 42.0°C , it still has some variations in comparison to other invasive core temperature measurements, including user error.¹⁸ Lastly, we did not evaluate maternal satisfaction, cost-effectiveness, and potential neonatal outcomes, then further investigation should be taken.

Conclusion

A brief 10 minutes of prewarming set at a moderate 38°C temperature did not prevent inadvertent perioperative maternal hypothermia and postoperative shivering during cesarean section under spinal anesthesia. We suggest that intraoperative and postoperative active warming are needed to maintain normothermia. For better thermal benefits, the longer period and higher temperature setting of prewarming may be considered.

Clinical Implication

1. What is already known on this topic?

At least 10 minutes of forced-air prewarming set to a high 44°C temperature could improve core temperature during general anesthesia. In addition, 15 minutes of forced-air prewarming set to 43°C had a lesser decrease in core temperature during cesarean section under spinal anesthesia.

2. What does this study add?

According to intention-to-treat analysis, 10 minutes of forced-air prewarming set to a

moderate 38°C temperature was not effective to reduce perioperative hypothermia during cesarean section under spinal anesthesia and postoperative shivering.

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