ORIGINAL

Effect of 10-minute prewarming plus intraoperative co-warming on core temperature maintenance during breast surgery compared to intraoperative co-warming alone: a randomized controlled trial

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Abstract : Purpose : We evaluated the effect of 10-min prewarming on core temperature maintenance during general anesthesia. Patients : We randomized 40 women scheduled for breast cancer surgery into 10-min Prewarming and Control groups. In the Prewarming group, a forced-air warming system was used to warm the patients at 43℃ for 10 min immediately before general anesthesia induction. In the Control group, the patients were kept warm using cotton thermal blankets for 10 min. We measured tympanic temperature every 15 min from anesthesia induction for 90 min. Findings : Since two patients deviated from the protocol, we used the data of 38 patients (Prewarming [n=18] and Control [n=20]). There was a significant between-group difference in changes in core temperature (P=0.03), including a significant difference in core temperature decrease during the first 60 min from anesthesia induction (Prewarming : −0.3 [0.3] ℃ *vs.* Control : −0.6 [0.2] ℃, P=0.02). In addition, the duration of normal core temperature maintenance was significantly longer in the Prewarming group (66 [34] min *vs.* 39 [32] min, P=0.01). Conclusions : Ten-min prewarming decreases core temperature loss and contribute to maintaining normal core temperature during breast surgery. J. Med. Invest. 70 : 74-79, February, 2023

Keywords **:** *breast surgery, general anesthesia, ten-min prewarming, tympanic temperature*

INTRODUCTION

Intraoperative hypothermia increases blood loss and the risk of various adverse events, including surgical site infections and shivering (1-3). Enhanced Recovery After Surgery (ERAS) also recommends maintaining a normal body temperature (36.5℃ - 37.3℃) to enhance early postoperative recovery (4), which is supported by the literature (5, 6). A forced-air warming system is often used to avoid hypothermia (7, 8).

However, warming patients are generally performed after the incision, thus making it difficult to prevent a drop in core temperature after anesthesia induction. In addition, the vasodilation effect of anesthesia causes a shift in thermal energy to peripheral tissues (9). The effectiveness of prewarming before anesthesia induction has been reported (10,11), and it has been shown that 30 or 60 min of prewarming helped prevent drops in core temperature after anesthesia induction (12, 13). However, it might not be practical to take more than 30 min for prewarming before anesthesia induction in clinical practice settings.

It has also been reported that even 10 min of prewarming before entering the operating room was useful for core temperature maintenance (14). In gynecological surgery, 10 min of prewarming using a whole-body blanket immediately before anesthesia induction plus intraoperative co-warming using an upper-body blanket has been reported to reduce body temperature loss more than intraoperative co-warming alone using an upper-body blanket. (15) However, prewarming before entering the operating room and using two warming blankets is considered difficult to apply in actual clinical practice in terms of operating room efficiency and cost-effectiveness.

At our institution, patient identification is performed on the operating table before anesthesia induction ; this takes an average of 10 min. We hypothesized that 10-min prewarming during patient identification would significantly preserve core temperature and contribute to normal core temperature maintenance for breast surgery patients, and we conducted a randomized controlled trial to test this hypothesis.

After anesthesia induction, circulatory depression due to vasodilation associated with sympathetic inhibition might occur (16). In addition, prewarming before anesthesia induction may be expected to have a vasodilation effect on peripheral tissues (13). Therefore, we also evaluated whether 10-min prewarming could reduce circulatory depression during anesthesia induction.

PATIENTS AND METHODS

Ethical approval

The study protocol was approved by the Ethics Committee of Tokushima University Hospital (approval number : 3620), and written informed consent was obtained from all patients. This study was registered in the University Hospital Medical Information Network (umin.ac.jp, Receipt No. : R000044128) ; clinical trial number : UMIN000038706.

Patients

Patients scheduled for partial mastectomy or mastectomy with a scheduled operating time of more than 60 min at Tokushima University Hospital between June 2020 and September 2020 were included in this study. Inclusion criteria were women aged 20-80 years, with the American Society of Anesthesiologists

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physical status classification system : 1-2. Exclusion criteria were a scheduled operating time of less than 60 min, time from anesthesia induction to the end of surgery less than 90 min, male sex, written consent from the patient not obtained, or deviation from the established protocol (Fig. 1). Forty patients were randomly assigned to a 10-min Prewarming group or a Control group. A sealed envelope system was used for randomization. Tympanic membrane temperature was measured as an estimate of core temperature using a continuous-measuring ear thermometer (Nipro CE Thermo, Nipro®, Osaka, Japan). Non-invasive blood pressure and the perfusion index were used for hemodynamic assessment and were measured by an inbuilt monitor (Nihon Kohden®, Tokyo, Japan). In both groups, a forced-air warming system (Bair Hugger Warming Blanket System®, 3M, Minnesota, USA) was used for prewarming plus intraoperative co-warming (Prewarming group) or intraoperative co-warming alone (Control group).

Control group

In the Control group, the room temperature was set at 26℃ before the patients entered the operating room. Immediately after entering the operating room, patients in the Control group had an ear thermometer sensor attached to the tympanic membrane and were identified for 10-min, during which they were kept warm using cotton thermal blankets. After the patients were identified, general anesthesia was induced. A cotton blanket was removed once unconsciousness was confirmed. After the surgeon disinfected the surgical field, the lower body was covered with a forced-air warming blanket and cotton blankets. At the start of surgery, intraoperative co-warming was started at a temperature of 38℃ using forced-air warming blankets placed over the lower body, and the room temperature was changed to 22℃ throughout the surgery.

Table 1. Patient characteristics

	Prewarming group (n = 18)	Control group (n = 20)	*P* value
Age (year)	56 (12)	67 (8)	0.001
Height (cm)	156 (5)	153 (6)	0.18
Weight (kg)	60 (16)	56 (8)	0.35
BMI (kg/m^2)	25 (5)	24 (3)	0.26
ASA 1/2	10 (55%) / 8 (44%)	6 (30%) / 14 (70%)	0.19
Presence of hypertension	3 (17%)	9 (45%)	0.09
Presence of diabetes mellitus	2 (11%)	4 (20%)	0.66
Core temperature at entry (℃)	36.8 (0.4)	36.8 (0.4)	0.68
Presence of menopause	12 (67%)	18 (90%)	0.08

Data are shown as mean (SD) or N (%).
Abbreviations: ASA, American Society of Anesthesiologists ; BMI, body mass index

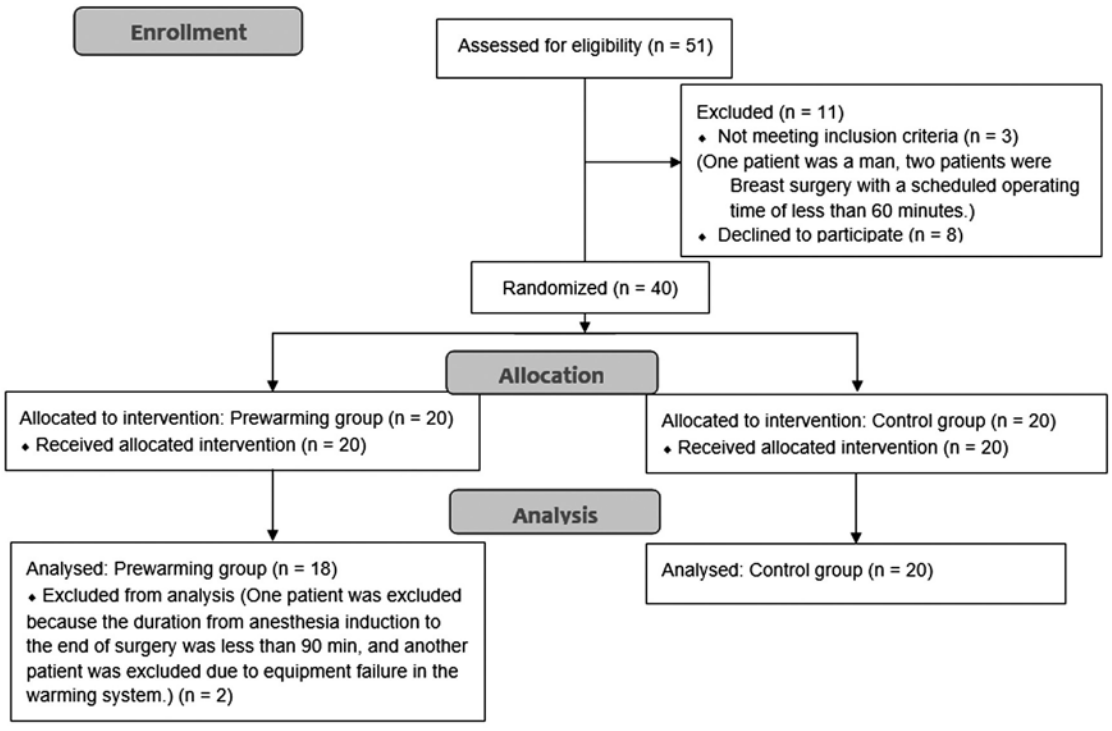

Fig 1. CONSORT flow diagram

Prewarming group

In the Prewarming group, the room temperature was set at 26℃ before the patients entered the operating room, and the same whole-body warming blanket was used for prewarming and intraoperative co-warming. After attaching the tympanic membrane temperature sensor and confirming core temperature stability, whole-body warming was initiated at a set temperature of 43℃. During the prewarming process, a thermal blanket (3M™) was placed over the forced-air warming blanket to prevent dust from being stirred up by warm air (17). After 10 min of prewarming during patient identification, general anesthesia induction was initiated. A warming blanket was removed once unconsciousness was confirmed. After the surgeon disinfected the surgical field, the patient's lower body was covered with a forced-air warming blanket and cotton blankets. At the start of surgery, intraoperative co-warming was started at a temperature of 38℃ using forced-air warming blankets placed over the lower body, and the room temperature was changed to 22℃ throughout the surgery.

Measurements and anesthesia procedure

In both groups, the tympanic temperature was measured when the thermometer sensor was first attached, at the time of anesthesia induction, and then every 15 min for 90 min. Blood pressure and perfusion index measurements were also performed every 5 min starting at the time of patient identification time.

For general anesthesia induction, propofol 1.5 mg/kg and rocuronium 0.9 mg/kg were administered 1 min after continuous administration of remifentanil 0.3 μg・kg^{-1}・min^{-1}. Tracheal intubation was performed in all patients. Mechanical ventilation was initiated after tracheal intubation. Volume control ventilation was used, with a tidal volume of 8 mL per ideal body weight, 10 cycles per min, and an inspiratory-to-expiratory time ratio of 1 : 2. Ultrasound-guided anterior chest wall block was performed immediately after intubation for pain management, in which 20 mL of 0.375 % ropivacaine was used. Anesthesia was maintained with 4 % desflurane, remifentanil 0.2 μg・kg^{-1}・min^{-1}, and additional rocuronium was administered as needed. When mean blood pressure was less than 50 mmHg, 4 mg of ephedrine was administered. All patients received 100 μg of fentanyl and 10 mg of metoclopramide during surgery, and 1000 mg of acetaminophen after surgery.

After the surgery, the anesthesiologist performed a postoperative examination and evaluated nausea and vomiting in the morning. In addition, the surgeons evaluated surgical wounds daily until discharge to assess the presence of adverse events, including surgical site infections and wound necrosis. Patients were evaluated for the presence of seromas by surgeons during outpatient post-discharge visits.

Outcomes

Primary outcomes were core temperature during 60 min after anesthesia induction, decreased core temperature from baseline, and the duration of normal core temperature maintenance after anesthesia.

Secondary outcomes included blood pressure and perfusion index changes before and after anesthesia induction and the number of times ephedrine was used during anesthesia. Secondary outcomes also comprised postoperative nausea and vomiting ; amount of blood loss ; and the incidence of shivering, wound infection, wound necrosis, and seromas.

Statistics

Continuous variables were tested for normality using the Shapiro-Wilk test. The student's t-test was used for group comparisons of normally distributed variables. The Mann-Whitney's U test was used for group comparisons of variables that were not normally distributed. The χ-squared test was used for group comparisons of categorical data, and repeated-measurement

Table 2. Outcomes

	Prewarming group (n = 18)	Control group (n = 20)	*P* value
Operation time (min)	123 (54)	95 (40)	0.06
Anesthesia time (min)	163 (55)	134 (38)	0.05
Amount of bleeding (g)	10 [4, 31]	8 [0, 21]	0.46
Ephedrine use frequency	1 [0, 2]	2 [1, 2]	0.13
Core temperature 60 min after anesthesia induction (℃)	36.5 (0.4)	36.1 (0.2)	0.008
Core temperature changes during 60 min after anesthesia induction (℃)	−0.3 (0.3)	−0.6 (0.2)	0.02
Duration of normal core temperature maintenance for 90 min after anesthesia induction (min)	66 (34)	39 (32)	0.01
Mean blood pressure (mmHg) :			
at the time of induction / 5 min after / 15 min after	101 (9) / 102 (21) / 69 (9)	105 (12) / 98 (25) / 65 (6)	0.65
Perfusion index :			
at the time of induction / 5 min after / 15 min after	3.5 (2.0) / 5.2 (2.5) / 6.6 (2.0)	3.4 (2.2) / 5.5 (1.5) / 6.0 (1.8)	0.86
Time from anesthesia induction to restart of warming (min)	31 (5)	32 (4)	0.56
Shivering	1 (6%)	0 (0%)	0.47
Surgical site infection	1 (6%)	0 (0%)	0.47
postoperative nausea and vomiting	5 (28%)	8 (40%)	0.51
Wound necrosis	3 (17%)	1 (5%)	0.32
Seromas	8 (44%)	10 (50%)	0.75

Data are shown as mean (SD), median [interquartile range], or N (%).

ANOVA was used for group comparisons of changes in core body temperature. All statistical analyses were performed using IBM SPSS Statistics for Windows version 25 (IBM Corp., USA) and were considered significant at $P < 0.05$. Data are shown as mean (SD), median (interquartile range), and number (%). Power analysis was performed to calculate the required sample size. Previous studies have shown that core body temperature decreases after anesthesia induction by an average of 1.6 ± 0.3℃ (9). If 10-min prewarming effectively maintains core body temperature by 0.3℃ 60 min after anesthesia induction compared to the Control group, the required number of patients would be 17. Considering potential dropouts, this study recruited 40 patients : 20 in each group. We also conducted a multiple regression analysis to identify patient background factors affecting core temperature loss during 60 min after anesthesia induction.

RESULTS

Two patients were excluded from the Prewarming group : one patient was excluded because the duration from the anesthesia induction to the end of surgery was less than 90 min ; another patient was excluded due to equipment failure in the warming system. Therefore, 18 patients in the Prewarming group and 20 patients in the Control group were included in the analysis.

Even after randomization, there was a significant difference in patient age (Prewarming : 56 (12) years *vs.* Control : 67 (8) years, $P = 0.001$). There was a significant between-group difference in changes in core temperature ($P = 0.03$) (Fig. 2) and in core temperature decrease during 60 min after anesthesia induction (Prewarming : −0.3 (0.3)℃ *vs.* Control : −0.6 (0.2)℃, $P = 0.02$). For 90 min after anesthesia induction, the duration of normal core temperature maintenance was significantly longer in the Prewarming group (Prewarming : 66 (34) min *vs.* Control : 39 (32) min, $P = 0.01$).

In both groups, changes in core temperature from initiation of tympanic temperature measurement to anesthesia induction were 0.1 (0.1)℃. The maximum fluctuation value of core temperature during 10-min prewarming was 0.4℃. There were no significant between-group differences in the mean value of mean blood pressure ; rate of mean blood pressure changes during anesthesia induction ; mean value of the perfusion index ; rate of perfusion index changes during anesthesia induction ; or amount of blood loss. In addition, there was no significant difference in the presence of shivering, postoperative nausea and vomiting, surgical site infection, wound necrosis, or seromas.

Patients in both groups were asked questions regarding warmness and coldness every 5 min during the 10 min required for patient identification. No patient in the Control group requested warming due to coldness, and no patient in the Prewarming group requested to stop warming because it was too hot.

A multi-regression analysis revealed that factors that had a statistically significant effect on core temperature loss during 60 min after anesthesia induction were core temperature at entry (standardized β-coefficient : −0.57, $P = 0.00$) and the presence of prewarming (standardized β-coefficient : 0.41, $P = 0.00$) at the 0.05 level, (adjusted R^2 : 0.45, *P*-value of prediction equation : 0.00 ; Table 3). The standardized β-coefficient for age was 0.05 ($P = 0.76$) (Table 4).

DISCUSSION

We showed herein that 10-min prewarming immediately before general anesthesia induction plus intraoperative co-warming in patients undergoing breast surgery significantly improved core body temperature maintenance. We also found that 10-min prewarming significantly prolonged the duration of normal core temperature maintenance for 90 min anesthesia induction. However, there were no significant differences in the incidence of postoperative nausea and vomiting, shivering, wound infection, wound necrosis, seromas, or amount of blood loss.

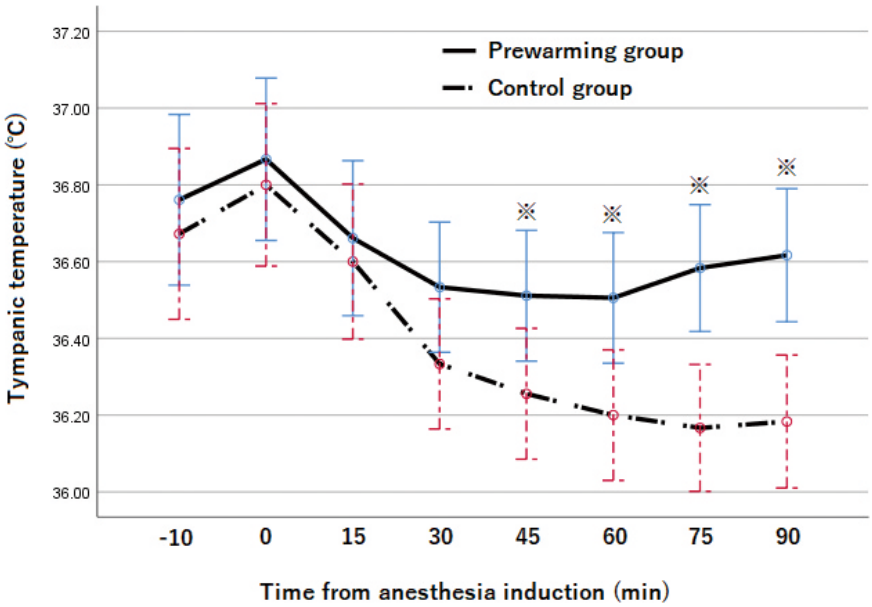

Fig 2. Changes in core temperature
Error bars indicate 95% confidence intervals.
* indicates a significant difference between the two groups.

Table 3. Coefficients of explanatory variables determined significant by multiple regression analysis (N = 38)

Variables	Standardized β-coefficients	*P* value
Core temperature at entry	−0.57	0.00
Presence of prewarming	0.47	0.00

Objective variables: core temperature loss during 60 min after anesthesia induction, $P < 0.05$, $R^2 = 0.45$, $P = 0.00$

Table 4. Coefficients when the removed variables are input (N = 38)

Variables	Standardized β-coefficients	*P* value
Presence of hypertension	−0.25	0.07
Height	−0.20	0.11
ASA (PS)	−0.18	0.17
Weight	−0.16	0.24
BMI	−0.14	0.30
Presence of diabetes mellitus	−0.05	0.70
Age	0.05	0.76

Abbreviations : ASA, American Society of Anesthesiologists ; PS, physical status ; BMI, body mass index

Previous studies have shown that intraoperative hypothermia leads to increased intraoperative blood loss and wound infection (1, 3). In addition, a prospective study of 400 patients found that prewarming reduced wound infections (11). Many studies have shown that prewarming effectively reduces body temperature loss after anesthesia induction, and one report even mentions the potential effect of prewarming on preventing wound infection (12). These studies also investigating the impact of prewarming on adverse events had relatively large sample sizes, whereas our study had a smaller sample size. In addition, our study included breast surgery in the population ; this procedure is associated with fewer adverse events such as bleeding and wound infections ; thus, it may have been more appropriate to investigate other procedures that are associated with more adverse events. However, to demonstrate the effectiveness of 10-min prewarming, it was first necessary to show the significant core temperature maintenance effect : we considered that the duration from general anesthesia induction to surgery would influence core temperature loss because the body surface is exposed. To minimize the effect of a body surface exposure, we selected breast surgery because it was the procedure with the least variation in time from anesthesia induction to surgery at our institution. In addition, we also showed that 10-min prewarming significantly maintained core temperature and prolonged the duration of normal core temperature maintenance, which is recommended by ERAS (4).

Similar to our results, the thermoregulatory effect of prewarming for 10 min on gynecological laparoscopic surgery was reported in 2020 (15). In that study, the rate of intraoperative hypothermia and other factors were evaluated. However, the investigators changed how the core temperature was measured before and after the anesthesia induction. Therefore, they did not examine core temperature loss. Our study consistently measured tympanic membrane temperature, which showed that prewarming had a thermoregulatory effect of about 0.3℃ compared with that in the control group. In addition, their study did not examine the duration of normal core temperature maintenance following 10-min prewarming. However, we showed that 10-min prewarming prolonged the duration of normal core temperature maintenance, which we believe is a new and unique finding.

In the present study, even after randomization, there was a significant difference in age between the two groups. Therefore, we did multiple regression analysis to assess variables that affect core temperature loss during 60 min after anesthesia induction. This analysis revealed that the factors that had a statistically significant effect on core temperature loss during 60 min after anesthesia induction were core temperature at entry and the presence of prewarming. This result suggests the importance of prewarming for core temperature maintenance. The β-coefficients for age suggest that the effect of age on core temperature loss is negligible ; thus, the difference in age groups likely did not affect the results. The third factor with the highest β-coefficient, although it was not statistically significant, was the presence of hypertension. These results suggest that significant temperature reductions are more likely to occur in patients whose hypertension or nervousness causes a concentration of thermal energy in the central region, resulting in an increase in central temperature at entry. Previous reports have also indicated a strong association between the degree of nervousness and intraoperative hypothermia (18). In addition, 30-min prewarming has been reported to suppress the decrease in blood pressure caused by anesthesia induction (19). These results suggest that prewarming is expected to supply heat energy to peripheral tissues and relieve nervousness, resulting in significant body temperature retention effects, even though it only takes about 10 min.

In the present study, both groups underwent intraoperative lower body warming, as has been recommended (20). In the Control group, core temperature loss during 60 min after general anesthesia induction was −0.6 ± 0.2℃. Previously, core temperature loss during 60 minutes after general anesthesia induction was shown to be −1.6 ± 0.3℃ (9), indicating that intraoperative co-warming might be highly effective in core temperature maintenance during breast surgery.

According to previous reports (9), core temperature loss in the early period after general anesthesia induction was mainly due to thermal energy transfer to peripheral tissues associated with vasodilation. In the present study, it was also observed that there was a significant decrease in core temperature in the early period after anesthesia induction. Prewarming did not significantly increase core temperature during administration and effectively maintained core temperature in the early period after general anesthesia induction. Prewarming raises the amount of thermal energy in the peripheral tissues (9) that cool when patients move to the operating room, which may explain why prewarming might be effective. Accordingly, after general anesthesia induction, prewarming may have inhibited thermal energy transfer to peripheral tissues.

At our hospital, patient clothing for entering the operating room consists of half-dressed, knee-high disposable paper gowns for cleanliness and ease of undressing after anesthesia introduction. We may need to consider switching to material and size that might be more effective in body temperature maintenance.

In the present study, the temperature setting of the forced-air warming system was 43℃ for prewarming. Previous studies have reported that the optimum temperature of forced-air warming systems for prewarming was 38 - 43℃ (13). Our study also showed that no interruptions were requested during the 10-min prewarming period. Previous reports (13) showed that warming at more than 40℃ for more than 60 min could cause sweating and other problems. Therefore, we used 43℃ only for the 10-min prewarming and 38℃ for intraoperative warming.

The increase in core temperature during the 10-min patient identification was 0.1 (0.1)℃ in both groups, suggesting little concern about excessive increases in core temperature. However, a core temperature increase of up to 0.4℃ was observed during

prewarming. Therefore, Prewarming under non-invasive continuous temperature monitoring, such as tympanic membrane and anterior forehead temperature measurement, has been considered necessary (21).

Limitations

The present study was a single-center study. This enabled keeping factors that affect core temperature reduction as constant as possible, such as the time of warming interruption from prewarming to intraoperative co-warming. In addition, there was a between-group difference in age ; however, the multivariate analysis suggests that the effect of age is minimal. Moreover, prewarming does not enable blinding patients to the assigned group ; previous studies have also been conducted in an unblinded manner. Furthermore, we were unable to show the effectiveness of prewarming on factors other than core temperature, such as wound infection and shivering. A more extensive study is needed to demonstrate efficacy against adverse events.

In conclusion, our results suggest that 10-min prewarming and intraoperative co-warming suppresses core temperature loss during breast surgery compared with intraoperative co-warming alone. Moreover, 10-min prewarming contributes to normal core temperature maintenance during breast surgery. As there was no patient discomfort or adverse events associated with prewarming, prewarming should be indicated for all patients whenever possible, even if only for a short time.

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CONFLICT OF INTEREST

The authors declare no competing interests

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None

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