Effects of Different Thermal Insulation Methods on Nasopharyngeal Temperature in Patients Undergoing Laparoscopic Hysterectomy: A Prospective Randomized Controlled Trial

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Research Article

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Abstract

**Background:** The purpose of this study was to compare the thermal insulation effect of incubator and infusion thermometer in laparoscopic hysterectomy.

**Methods:** 75 patients were enrolled and were assigned randomly to three groups: group A used warming blanket, group B used warming blanket and infusion thermometer, group C used warming blanket and incubator. The primary outcome was nasopharyngeal temperature at different time points during the operation.

**Results:** The nasopharyngeal temperature of the infusion heating group was significantly higher than that of the incubator group 60min at the beginning of surgery (T3): 36.10±0.20 vs 35.81±0.20 (P=0.001) 90min at the beginning of surgery (T4): 36.35±0.20 vs 35.85±0.17 (P=0.001), and the incubator group was significantly higher than that of the control group 60min at the beginning of surgery (T3): 35.81±0.20 vs 35.62±0.18 (P=0.001); 90min at the beginning of surgery (T4): 35.85±0.17 vs 35.60±0.17 (P=0.001). The wake-up time of the control group was significantly higher than that of the infusion heating group: 23.88±3.86 vs 20.56±3.80 (P=0.004), and the incubator group: 23.88±3.86 vs 21.52±4.02 (P=0.035).

**Conclusion:** Warming blanket (38°C) combined infusion thermometer (37°C) provides better perioperative thermal insulation, and in hospitals without infusion thermometer, an incubator can be used as a substitute.

**Trial registration:** This trial was registered with http://www.chictr.org.cn/index.aspx, ChiCTR2000039162, 20 October 2020.

Background

Perioperative hypothermia is defined as a core temperature below 36°C [1], previous studies have demonstrated that the occurrence rate of perioperative hypothermia is between 25 to 90% [2], perioperative hypothermia may lead to a range of complications, including intraoperative coagulation dysfunction, delayed postoperative recovery, incision infection, etc [3,4].

Laparoscopic surgery has the advantages of less trauma, less bleeding, rapider postoperative recovery, fewer surgical complications, etc [5,6]. Compared with open surgeries, the abdominal cavity is relatively closed, but anesthetic factors, persistent CO₂ pneumoperitoneum during surgery, and the use of large amounts of irrigating fluid can also lead to hypothermia [7,8].

This study aimed to compare the effects of two different thermal insulation methods in laparoscopic hysterectomy.

Methods
This prospective, single-blind, randomized, controlled study was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University and was registered at http://www.chictr.org.cn/index.aspx(ChiCTR2000039162) on 20 October 2020. All patients signed the informed consent. Our methodology was executed in accordance with the international guidelines for randomized clinical studies according CONSORT Guidelines.

75 patients scheduled for elective laparoscopic hysterectomy. Inclusion criterion: 1) Aged 40-65 years; 2) American Society of Anesthesiologists' physical status class of I to III; 3) No serious heart, liver, kidney disease; 4) No history of severe respiratory or cerebrovascular disease. Exclusion criterion: 1) preoperative anemia; 2) intraoperative blood transfusion; 3) switch to open surgery. 75 patients were randomly divided into 3 groups using a random number table: control group(A), infusion heating group(B) or incubator group(C).

**Study protocol**

No patients were premedicated and the operating room was kept at 22-24°C. All three groups use warming blankets and turn them on an hour in advance so that the warming blanket reaches the preset temperature(38°C). After entering the operating room, patients in the three groups were first injected with 500ml Ringer's lactate solution and then with 500ml succinylated gelatin, the infusion speed was controlled at 10ml/min. In group A, the infusion fluid was not treated and the temperature was room temperature; In group B, the infusion fluid was heated by the infusion thermometer, and the target temperature of the infusion thermometer was set at 37°C; In group C, the infusion fluid was stored in an incubator with the target temperature set at 37°C.

Nasopharyngeal temperature was monitored after anesthesia induction in all three groups, and vital signs were kept stable during the operation. If the intraoperative nasopharyngeal temperature of the patient is lower than 35°C, the temperature of the warming blanket will be increased to maintain the nasopharyngeal temperature of the patient above 35°C.

**Outcome measurements**

The primary outcome was nasopharyngeal temperature at 5min after anesthesia induction(T1), 30min(T2), 60min (T3), and 90min (T4) at the beginning of surgery in the three groups. Secondary outcome was wake-up time in three groups.

**Statistical analyses**

SPSS was used for all statistical analysis (version 22.0, SPSS Inc, Chicago, IL, USA), measurement data were expressed as mean ± standard deviation, and analysis of variance was used for comparison between groups, the nasopharyngeal temperature was compared at different time points by repeated measurement ANOVA, Chi-square test was used to compare counting data, and P < 0.05 was considered statistically significant.
The sample size was calculated using GPower (version 3.1.9.2, Franz Faul, Universitat Kiel, Germany), studies have shown that a core temperature difference of 0.5°C is clinically significant because 0.5°C is the smallest difference associated with hypothermic complications [9]. With the significance level(\(\alpha\)) set at 0.05, power(1-\(\beta\)) at 0.9, then each group needs to include 22 patients, assuming that the rate of withdrawal is 10%, then each group will eventually have 25 patients enrolled.

**Results**

A total of 75 patients were included and randomly divided into three groups (Fig. 1). No intraoperative nasopharyngeal temperature was lower than 35°C.

**Primary outcome**

The nasopharyngeal temperature of the infusion heating group was significantly higher than that of the incubator group 60min at the beginning of surgery(T3):36.10±0.20 vs 35.81±0.20(\(P<0.001\)) at 90min at the beginning of surgery(T4):36.35±0.20 vs 35.85±0.17(\(P<0.001\)), and the incubator group was significantly higher than that of the control group 60min at the beginning of surgery(T3):35.81±0.20 vs 35.62±0.18(\(P<0.001\));90min at the beginning of surgery(T4):35.85±0.17 vs 35.60±0.17(\(P<0.001\))(Table 2)(Fig. 3).

**Secondary outcomes**

The wake-up time of the control group was significantly higher than that of the infusion heating group: 23.88±3.86 vs 20.56±3.80(\(P=0.004\)), and the incubator group:23.88±3.86 vs 21.52±4.02(\(P=0.035\)) (Table 1) (Fig. 2).

**Table 1** Descriptive variables of the group A–group B and group C

|                      | Group A n=25 | Group B n=25 | Group C n=25 | F value | P value |
|----------------------|--------------|--------------|--------------|---------|---------|
| Age (years)          | 53.28±6.91   | 51.52±7.6    | 54.32±6.30   | 1.034   | 0.361   |
| BMI (kg/m²)          | 23.31±3.07   | 23.50±2.91   | 23.62±3.01   | 0.066   | 0.936   |
| ASA grade /1/1       | 13/12        | 16/9         | 12/13        | /       | 0.497   |
| Surgery time (min)   | 108.36±8.33  | 111.20±8.45  | 109.00±8.68  | 0.770   | 0.467   |
| Blood loss (ml)      | 38.60±6.70   | 39.80±6.69   | 40.28±8.84   | 0.335   | 0.717   |
| Urine output (ml)    | 338.00±96.05 | 340.00±76.38 | 358.00±89.77 | 0.394   | 0.676   |
| Wake-up time (min)   | 23.88±3.86   | 20.56±3.80   | 21.52±4.02   | 4.816   | 0.011   |

Values are presented as mean (standard deviation) or counts

ASA American society of anesthesiologists; BMI Body Mass Index
Table 2 Nasopharyngeal temperature at different points in three groups

| Group | n  | T1       | T2       | T3       | T4       |
|-------|----|----------|----------|----------|----------|
| A     | 25 | 36.40±0.19 | 35.88±0.21\(^t\) | 35.62±0.18\(^t\) | 35.60±0.17\(^t\) |
| B     | 25 | 36.37±0.24 | 35.92±0.24\(^t\) | 36.10±0.20\(^*\) | 36.35±0.20*      |
| C     | 25 | 36.35±0.21 | 35.88±0.18\(^t\) | 35.81±0.20\(^\#\)\(^t\) | 35.85±0.17\(^\#\)\(^t\) |

\(^*\)P<0.05 compared to the same time of Group A

\(^\#\)P<0.05 compared to the same time of Group B

\(^t\)P<0.05 compared to T1

Values are presented as mean ± standard deviation

5min after anesthesia induction(T1), 30min at the beginning of surgery(T2), 60min at the beginning of surgery(T3), 90min at the beginning of surgery(T4)

Discussion

The results of this study showed that nasopharyngeal temperature decreased significantly in the three groups from T1 to T2. On the one hand, general anesthesia leads to peripheral vasodilation, which inhibits the function of blood vessels to regulate body temperature through contraction; meanwhile, general anesthesia also inhibited the body's central thermoregulation, and anesthetic drugs also decreased the metabolic rate[10,11]. On the other hand, the operating room temperature is relatively low, and a lot of heat will be absorbed by preoperative disinfection and intraoperative infusion, as well as heat will be taken away by continuous CO₂ infusion during the operation[8,12].

The nasopharyngeal temperature of the T2 to T3 control group and the incubator group continued to decrease, and the decrease degree of the incubator group was less than that of the control group. The nasopharyngeal temperature of the infusion heating group began to increase, indicating that the use of a warming blanket alone (38°C) could not maintain the patient's body temperature, and might require a higher temperature. The infusion fluid in the incubator group was not continuously heated, and the temperature gradually decreased over time. Only the infusion heating group made the patient's body temperature rise by warming blanket and infusion thermometer.

The nasopharyngeal temperature of the T3 to T4 control group began to stabilize, and the nasopharyngeal temperature of the incubator group began to rise, but was lower than T1. The nasopharyngeal temperature of the infusion heating group continued to rise, with no significant difference from T1, indicating that the temperature of the patients could be maintained to the
preoperative level when the warming blanket (38°C) combined infusion thermometer (37°C) was used for 90min.

The wake-up time of the control group was significantly higher than that of the infusion heating group and the incubator group, mainly because of the low temperature status, which reduced the capacity of the liver to uptake drugs and the capacity of the kidney to excrete drugs, which affected the metabolism of anesthetic drugs in the body and led to prolonged wake-up time [13,14].

As one of the important vital signs, body temperature has attracted more and more attention in the perioperative period in recent years. However, the protection of body temperature during perioperative period is not good. On the one hand, this is due to the insufficient attention paid by medical staff to body temperature protection; on the other hand, there is no protective device for body temperature in hospitals, such as infusion thermometer [15,16]. The incubator is used as a necessary equipment for hospitals, usually to preserve the irrigating fluid used during the operation. This study makes full use of the equipment to preserve the fluid injected during the operation to achieve the effect of fluid heating. Although the patient has hypothermia during the operation, the temperature drop is slight and the wake-up time was not prolonged. Therefore, for hospitals without better insulation device, this method is easy to use, low cost and worth popularizing.

The observation time in this study was limited to 90min, for longer duration of surgery, it is not clear whether the temperature of the warming blanket and infusion thermometer should be adjusted, and further research is still needed.

**Conclusions**

Warming blanket (38°C) combined infusion thermometer (37°C) provides better perioperative thermal insulation, and in hospitals without infusion thermometer, an incubator can be used as a substitute.

**Abbreviations**

BMI: Body Mass Index; ASA: American Society of Anesthesiologists

**Declarations**

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**Author’s contributions**

Study design: GY, ZZ, ZS. Study conduct: GY, HZ, SH. Data analysis: GY, ZZ, WZ, ZS. Writing paper: GY, ZZ, HZ, SH, WZ, ZS. All authors read and approved the final manuscript version.
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Availability of data and materials

The raw data of this study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University on May 31, 2020 (2020-KY-176). All patients signed the informed consent.

Consent for publication

Not applicable.

Competing interests

None.

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Figures
Figure 1

Participant flowchart

Figure 2

Wake-up time (min)

Group A  Group B  Group C
Figure 3

Nasopharyngeal temperature at different points in three groups. Time point, 5min after anesthesia induction(T1), 30min at the beginning of surgery(T2), 60min at the beginning of surgery(T3), 90min at the beginning of surgery(T4); +statistical significance between the group A and group B; *statistical significance between the group A and group C; #statistical significance between the group B and group C.