Evaluation of Warming Effectiveness on Physiological Indices of Patients Undergoing Laparoscopic Cholecystectomy Surgery: A Randomized Controlled Clinical Trial

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Purpose: *The present study aimed to evaluate the impact of warming on physiological indices of patients undergoing laparoscopic cholecystectomy.*

Design: *The study was a three-group randomized controlled clinical trial.*

Methods: *In the present study, 96 patients were assigned to three groups: forced-air warming system group; warmed intravenous fluid group; and control group. The intervention was performed immediately after the anesthesia induction. Physiological indices (core body temperature, blood pressure, and heart rate) were evaluated at 15-minute intervals, and postoperative shivering was also recorded.*

Findings: *The mean systolic blood pressure and the mean heart rate were significantly different in each warming group before, during, and after surgery, but the three groups had no significant differences in terms of physiological indices at any time (P > .05). Postoperative shivering was not seen in any group.*

Conclusions: *Both interventions had similar effects on physiological indices. Therefore, the recommendation is to use the warming method according to patient's other conditions.*

Keywords: *warming, intravenous fluid, laparoscopic cholecystectomy, physiological indices.*

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HYPOTHERMIA IS A COMMON and serious complication of anesthesia and surgery, and it is very important in perioperative care.[1] Hypothermia occurs when core body temperature drops less than 36°C (96.8 F).[2] More than 50% of patients, who undergo surgery, suffer from hypothermia.[3]

All patients, regardless of age and gender, are at risk of hypothermia after general or local

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anesthesia. Even patients with normal temperature experience 1°C to 2°C drop in core body temperature within 30 minutes after induction of anesthesia.[4]

There are several risk factors associated with hypothermia including the prolonged exposure to cold air in the operating room, disruption in body thermoregulation because of anesthesia, cold solutions, and cold intravenous fluid.[5,6]

Hypothermia causes serious problems for patients, and its prevention may reduce complications and minimize the postoperative hospital stay and subsequent therapeutic costs.[7] These complications include surgical site infections, cardiac problems, changes in drug metabolisms, and also early postsurgical complications including bleeding, hypoxia, arrhythmia, shivering, and delay in extubation.[8,9]

Physiological indices are vital symptoms that are essential in evaluating proper functions of body organs and are good indices for evaluating the patient's hypothermia.[10]

Although hypothermia is a major complication in open abdominal surgery,[4] it also occurs in laparoscopic surgery. The mechanism of hypothermia is not well known during laparoscopic surgery. This surgery requires the maintenance of normothermia and lasts for more than 60 minutes.[11] The use of warmed and humidified CO_2 is probably more suitable for long-term laparoscopic surgery and it significantly reduces hypothermia.[12] Duration of anesthesia and the volume of applied CO_2 are possible risk factors for hypothermia during the laparoscopic surgery. Therefore, these surgeries can provide evidence-based guidance on preventing hypothermia in the operating room.[13]

Patient warming methods are divided into active and passive groups for the treatment or prevention of hypothermia. Passive methods include the use of covers and blankets, whereas active methods include the use of forced-air warming system, radiant heaters, and warmed fluids. Evidence suggests that the passive warming method is less effective than the active warming in reducing the incidence or severity of hypothermia.[3]

Some studies indicate that warming patients with active methods is effective in reducing hypothermia in the operating room. A literature review indicated that numerous studies evaluated the efficacy of patient warming interventions. These studies used various methods, but there is no consensus on the best method of warming patients yet.

A great number of warming devices are now available in the operating room. Among them, the forced-air warming system and warmed intravenous fluid have been widely investigated by authors, and their effects have been evaluated on most surgeries (spinal, cesarean section, colorectal, and abdominal surgery).[13-15] Some studies have been conducted on the efficacy of forced-air systems in laparoscopic colorectal surgery.[16,17] In addition, several studies indicate the efficacy of intravenous warmed fluids in reducing hypothermia.[15,18,19] Liang et al[20] investigated 40 patients under laparoscopic total gastrectomy. The experimental group received infused fluid, and the washing fluid was heated up to 37°C before application. The control group experienced the infused liquid, and the washing fluid was put at the room temperature. Nasopharynx temperature changes were evaluated in two groups. No significant changes were observed in the experimental group, whereas the temperature reduction was significant compared with before anesthesia in the control group.[20]

Given the inconsistent results of studies and few studies on the effect of warming patients undergoing laparoscopic surgery, the present study aimed to determine and compare effects of two patient warming methods (forced-air warming system and warmed intravenous fluid) on patients' physiological indices during and after the laparoscopic cholecystectomy.

Methods

The present study was a randomized controlled clinical trial that was registered at the Iranian Registry of Clinical Trials (IRCT) (www.irct.ir) with IRCT2017041533435N1 code. In this study, 96 patients underwent the laparoscopic cholecystectomy. The inclusion criteria were American Society of Anesthesiologists I-II, age from 18 to 65 years, lack of underlying diseases (hypothyroidism, hyperthyroidism, diabetes, and hypertension),

and cardiovascular disease, the absence of any infection and fever, and body mass index of 18.5 to 38 (Figure 1).

Exclusion criteria were the need for open surgery or any reason for returning patient to the operating room, the sense and expression of heat by the patient in recovery, the need for intraoperative and postoperative blood transfusions, intra-abdominal infection, and the blood loss of more than 1 L during surgery, in addition to the unexpected allergy to anesthetic drugs, intravenous fluid infusion of more than 5 L during surgery, temperature greater than 37.5°C or less than 36.5°C before surgery, the need for cardiopulmonary resuscitation, and severe hemodynamic changes during the operation.

Patients were randomly assigned to three groups. Iranian software named "Arma Random Numbers" was used for randomization. Numbers 1, 2, and 3 were first considered for the software as warmed fluids, forced-air system, and control groups, respectively, and then patients were randomly selected from three groups according to selected numbers by the software. Thirty-two subjects were selected for each group as follows:

1. The forced-air warming system group was warmed with an over-body warming blanket (Warm Touch Full Body/Multi Access Blanket) with a forced-air warming system (Warm Touch convective warming system) immediately after the induction of anesthesia with the unit set at 42°C. Patients of this group were covered by full body blankets intraoperatively just on the lower limbs and on the whole body till neck after the end of surgery and in the postanesthesia care unit (PACU).
2. The warmed intravenous fluid group was covered just with routine surgical drapes intraoperatively and in the PACU. This group was also administered prewarmed ringer's solution (38°C) immediately after induction of anesthesia and after entering the PACU.
3. The control group received routine care, which was provided for patients by covering them with routine surgical drapes intraoperatively and with blankets in the PACU.

Patients underwent routine monitoring before induction of anesthesia. The same technique of monitoring was performed on all patients. General anesthesia was done using 4 mg/kg of thiopental sodium, 2 mcg/kg of fentanyl, followed by 0.5 mg/kg of atracurium. After intubation, Patients' lungs were mechanically ventilated with 40% oxygen and air mixture to an end-tidal Pco_2 of approximately 35 mm Hg. Maintenance of anesthesia was achieved by isoflurane, O_2, and air to maintain an inspired O_2 concentration of 50%. The total gas fresh flow was limited to 1.0 L/min. Reversal agents included neostigmine (2.5 mg) and atropine (1.0 mg IV), and then the extubation was performed. Cold-dry CO_2 was used for pneumoperitoneum in all patients. The operating room temperature was maintained at 22°C to 25°C and relative humidity at 30%. Temperature and humidity in the PACU were equal and maintained at 27°C and 30%, respectively, for all patients.

The core body temperature, blood pressure, and heart rate were measured immediately before the induction of anesthesia, right after the induction of anesthesia (after intervention), and then every 15 minutes until the end of surgery. All patients received routine nursing care after surgery. In the PACU, blood pressure, heart rate, core body temperature, and shivering were recorded every 15 minutes for 30 minutes.

Blood pressure and heart rates of patients were evaluated using the monitoring device (Saadat Alborz model made in Iran). Core body temperature was measured using an infrared tympanic thermometer. The infrared tympanic thermometer is a device that is both accurate and quick for estimating the central body temperature.[21]

The described observation tool by Crossley and Mahajan[22] was used for classification of shivering as follows: no shivering = 0; no visible muscle activity, but one or more piloerection, peripheral vasoconstriction, or peripheral cyanosis = 1; muscular activity in only a muscle group = 2; moderate muscular activity in more than a muscle group, but not generalized shaking = 3; and violent muscular activity involving the entire body = 4.

Demographic data (age and gender), duration of anesthesia, duration of surgery, the volume of CO_2, duration of pneumoperitoneum, volume of received fluid, and administration of
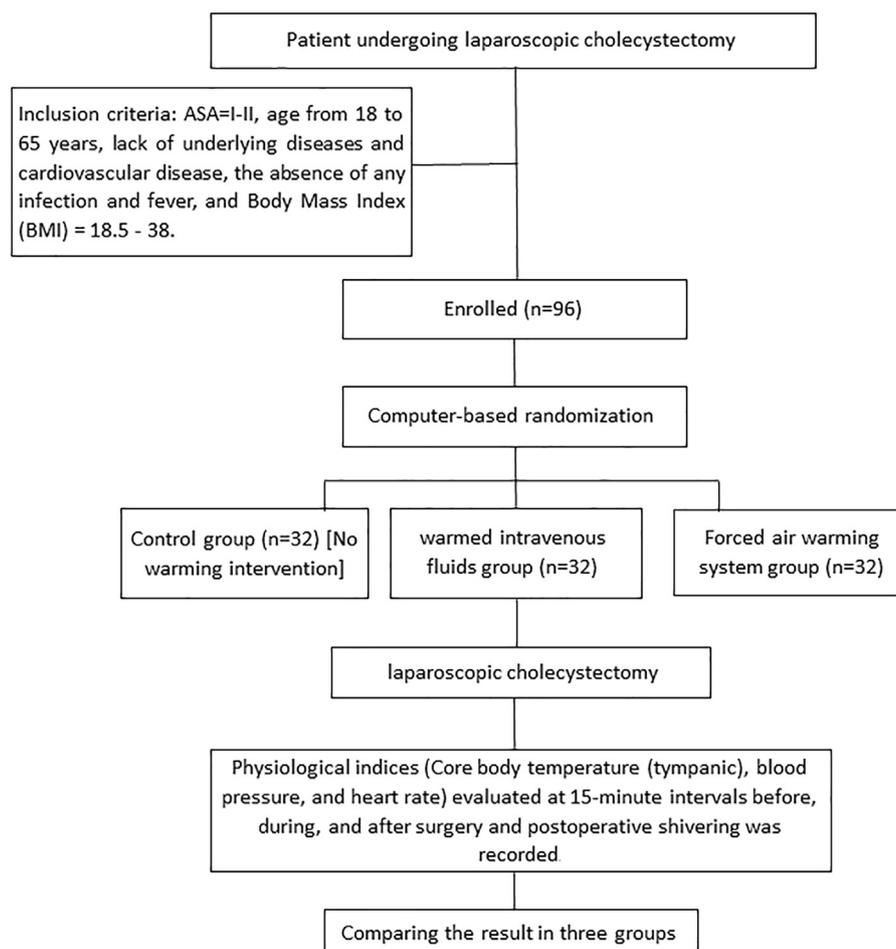
Figure 1.   CONSORT diagram. ASA, American Society of Anesthesiologists.

meperidine were also recorded for each patient by the researcher. Reliability of measurement tools was confirmed using the careful measurement and confirmation of their calibration and sensitivity.

Ethical Considerations

The present study was approved by the Research Council of the Faculty of Nursing and Midwifery and the Ethics Committee at Isfahan University of Medical Sciences with IR.MUI.REC.1390.30947 code. Objectives and methodology were explained to qualified patients and informed consent forms were obtained by them.

Statistical Methods

Demographic characteristics of these aforementioned groups were compared using the χ^2 or t tests. Repeated measures analysis of variance (ANOVA) was used to compare physiological indices in each group at any time. The one-way ANOVA was used to compare physiological indices of groups. After the data collection, all statistical analyses were performed using SPSS 21. Thirty-two subjects were selected for each group considering the test power of 80% and confidence interval of 0.95 ($\alpha < 0.05$, $z1 = 1.96$, $z2 = 0.84$, $d = 7$ s).

Results

A total of 96 patients (the forced-air warming system group, n = 32, the warmed intravenous fluid group, n = 32, and control group, n = 32) participated in the study and underwent laparoscopic cholecystectomy surgery. The research results indicated that 77.08% of patients were female (n = 74), 22.92% of patients were male (n = 22), and there was no difference between genders in

Table 1. Distribution of Means of the Quantitative Variables in Three Groups

Variable	Warmed Intravenous Fluids Group (n = 32)		Forced-Air Warming System Group (n = 32)		Control Group (n = 32)		ANOVA	
	Mean	SD	Mean	SD	Mean	SD	F	P
Volume of carbon dioxide (L)	120.2	63.7	145.9	117.8	123.1	72.9	0.81	.45
Duration of anesthesia (min)	101.87	26.2	106.1	24.8	109.4	32.2	0.60	.55
Duration of pneumoperitoneum (min)	60.9	21.9	57.9	17.5	62.3	23.7	0.35	.70
Duration of surgery (min)	76.6	19.9	74.5	19.2	77.3	25.9	0.14	.87
Volume of received fluids (mL)	1,053.7	548.2	993.5	348.3	921.9	447.4	0.67	.51

ANOVA, analysis of variance.

three groups ($P = .49$). The mean age of patients was 42.7 ± 13.04 years in the forced-air warming system group, 41.8 ± 9.04 years in the warmed intravenous fluid group, and 40.4 ± 13.3 years in the control group, and they were not statistically different.

The variables namely the duration of anesthesia, duration of surgery, volume of CO_2, duration of pneumoperitoneum, and volume of received fluid were analyzed by statistical tests (ANOVA) and were not statistically significant ($P < .05$; Table 1). Moreover, prescription was not provided for any of the three groups.

The one-way ANOVA indicated no significant differences in systolic and diastolic blood pressure, heart rates, and body temperatures of three groups at any time (before the induction of anesthesia, immediately after induction of anesthesia, every 15 to 30 minutes after the end of surgery) ($P > .05$).

The repeated measures ANOVA indicated that mean diastolic blood pressure had no significant difference in any of the three groups at different times (before induction of anesthesia, after induction of anesthesia, or during operation and after the operation) ($P > .05$). Moreover, the mean systolic blood pressure did not significantly differ in the control group over time ($P > .05$). However, it was significantly different in two intervention groups, the warmed intravenous fluid and the forced-air warming system groups, at different times ($P < .001$), so that the mean systolic blood pressure was significantly higher in the warmed intravenous fluid group in the PACU than before the induction of anesthesia ($P = .003$) and during

the operation ($P < .001$), but there was no significant difference between the induction of anesthesia and during the operation ($P = .98$).

In the forced-air warming system group, the mean systolic blood pressure was significantly higher in the PACU than during the operation ($P < .001$), but there were no significant differences between other times ($P > .05$; Table 2). The mean heart rate was not significantly different in the control group at three times ($P > .05$), but there was a significant difference between the warmed intravenous fluid group and the forced-air warming system group at three times ($P < .05$). The mean heart rate was significantly lower in the warmed intravenous fluid group during the operation than the preinduction of anesthesia ($P = .001$) and recovery ($P = .03$), but no significant difference was seen between before induction of anesthesia and recovery ($P = .06$). The mean heart rate was significantly lower in the forced-air warming system group during the operation than before induction of anesthesia ($P = .03$) and recovery ($P = .04$), but there were no significant differences before induction of anesthesia and recovery ($P = .47$; Table 3).

There was no significant difference in mean body temperature in any of the three groups at different times ($P > 0.05$; Table 3). It should be noted that postoperative shivering was not observed in any of the three groups.

Discussion

The present study aimed to compare effects of two warming methods on physiological indices of patients during and after laparoscopic cholecystectomy. According to χ^2 test and ANOVA, samples

Table 2. Comparison of Systolic and Diastolic Blood Pressure in Three Groups at Three Different Times

Variable	Time	Warmed Intravenous Fluids Group (n = 32)		Forced-Air Warming System Group (n = 32)		Control Group (n = 32)	
		Mean	SD	Mean	SD	Mean	SD
Systolic blood pressure (mm Hg)	Before inducing of anesthesia	125.3	20.6	128.5	22.8	126.3	16.6
	During the operation	124.2	14.6	124.9	8.8	126.2	12.7
	In recovery	137.2	16.2	134.6	15.3	132.6	22.4
Repeated measures	F	12.35		9.96		1.89	
ANOVA	P	< .001		< .001		.17	
Diastolic blood pressure (mm Hg)	Before inducing of anesthesia	78.1	15.2	82.7	17.3	84.8	15.6
	During the operation	81.2	10.6	79.1	8.8	79.7	10.8
	In recovery	85.2	11.9	81.2	12.1	82.3	12.4
Repeated measures	F	2.60		1.23		1.64	
ANOVA	P	.09		.31		.21	

ANOVA, analysis of variance.

of all three groups were homogeneous in terms of age, gender, and duration of anesthesia, duration of surgery, the volume of carbon dioxide, duration of pneumoperitoneum, the volume of received intravenous fluid, and meperidine administration.

Some previous studies also found evidence on relationships of hypothermia and some of the aforementioned variables. Older age, female gender,

type of surgery, duration of anesthesia, operating room temperature, the low weight of patient, and the history of hypothermia at room temperature fluid injection in previous surgeries were related factors to hypothermia.[23-25]

In a study on the effect of prewarmed intravenous fluid therapy on the prevention of postoperative shivering after caesarean section, Oshvandi

Table 3. Comparison of Heart Rate and Body Temperature in Three Groups at Three Different Times

Variable	Time	Warmed Intravenous Fluids Group (n = 32)		Forced-Air Warming System Group (n = 32)		Control Group (n = 32)	
		Mean	SD	Mean	SD	Mean	SD
Heart rate	Before inducing of anesthesia	94.2	17.3	90.7	15.8	87.7	17.3
	During the operation	84.1	14.2	82.7	12.4	84.7	11.3
	In recovery	88.01	13.5	88.01	11.5	85.3	10.5
Repeated measures	F	7.95		4.01		0.77	
ANOVA	P	.002		.03		.47	
Body temperature	Before inducing of anesthesia	36.6	0.14	36.6	0.16	36.7	0.25
	During the operation	36.4	0.16	36.5	0.20	36.4	0.16
	In recovery	36.3	0.20	36.4	0.25	36.2	0.22
Repeated measures	F	2.81		2.07		3.82	
ANOVA	P	.17		.25		.10	

ANOVA, analysis of variance.

et al[25] found that the volume of received fluids was an important factor, but there was no significant difference in the control and intervention groups ($P = .86$). In addition, Liang et al[20] revealed that factors such as long duration of operation, CO_2 pneumoperitoneum time, and infusion of a large amount of room temperature fluid caused the patient hypothermia. Pu et al (2014) also found that anesthesia time ($P = .003$), length of operation time ($P = .001$), volume of CO_2 ($P < .001$), and volume of infused fluid ($P = .034$) were possible risk factors for hypothermia during laparoscopic surgery.[13]

Results of the present study indicated that the mean body temperature was not significantly different in any of the three groups at different times ($P > .05$). Pu et al examined the impact of forced-air warming system method on patients undergoing laparoscopic gastrointestinal surgery and pointed out the positive impact of this system during surgery. They also reported that if the active warming system was not applied, core body temperature decreased after 30 minutes from the start of surgery and at the end of surgery compared with the start of anesthesia.[13] These are not consistent with findings of the present study.

Nicholson[16] found no significant differences between ratio of patients who had hypothermia before, during, and after surgery in two groups when comparing prewarming with cotton blankets and forced-air warming in patients undergoing colorectal surgery ($P > .05$). This is consistent with findings of the present study. In addition, Leeth et al[26] found no significant differences between preoperative and postoperative patient temperatures in the control group and those who were warmed before surgery.

In a study by Kim et al, the forced-air warming system was used to warm patients in the operating room before induction of anesthesia. Their findings indicated that patients' body temperature was higher in the operating room ($P < .05$). It should be noted that hypothermia was defined as a body temperature lower than 35°C (95 F) in their study,[27] whereas the body temperature lower than 36°C (96.8 F) was defined as hypothermia in the present study.

Andrzejowski et al[14] used a forced-air warming system before and during spinal surgery and found that 68% of patients had temperatures greater than 36°C after the operation. Kim et al compared the effectiveness of warming with a forced-air warming system and circulating-water mattress in patients who underwent spinal anesthesia. They stated that both methods had same effects on maintaining core body temperature, but the incidence of shivering in recovery was lower in the use of warming with forced-air warming system,[28] whereas none of the patients suffered from shivering in the present study.

The use of a forced-air warming system in laparoscopic colorectal surgery has also attracted the attention of some researchers.[16] Lynch et al[17] found that most studies focused on patients undergoing colorectal surgery, but the use of a forced-air warming system achieved the best results in patients undergoing laparoscopic cholecystectomy. They also concluded that after using this system, core body temperatures of 75% of patients reached to 36°C and greater until 15 minutes after leaving the operating room. They also suggested that the forced-air warming system should be used before, during, and after surgery to maintain normothermia.

Warming the intravenous fluid can prevent hypothermia, but the use of warmed intravenous fluid had no effect on patients' core body temperatures in the present study. Choi et al[15] reported the usefulness of warmed intravenous fluid at 38°C in laparoscopic colorectal surgery. On the contrary to the present study, they used warmed and humidified CO_2, which affected body temperatures, and thus they reported the usefulness of warmed intravenous fluids.

Chung et al[19] found that the infusion of warmed intravenous fluid (37°C to 38°C) and a forced-air warming system caused higher core body temperatures and lower incidence of shivering. Yokoyama et al[29] studied the impact of warmed intravenous fluid (38°C) on mothers who were candidates for cesarean section under spinal anesthesia, and it was found that their core body temperature was 0.5°C higher in the experimental group.

In the present study, core body temperatures of three patients (9.37%) in the control group versus one patient (3.12%) in the warming group, who

were warmed by intravenous fluid at 30 minutes after the end of the operation, dropped less than 36°C. Despite the fact that this finding was statistically insignificant, it was clinically significant, so that even mild body temperature reduction led to unwanted serious effects such as lethal cardiac complications and coagulation disorders in many patients.[30] Choi et al[15] stated that 28.0% of patients in the warming group were warmed by intravenous fluid versus 53.8% of patients in the control group who suffered from hypothermia, and the incidence of shivering between two groups was not statistically significant.

Other affected indices by hypothermia were blood pressure, heart rate, and oxygen mixing tendency with hemoglobin. After hypothermia, the tissue access to oxygen decreased and the oxygen need for heart muscle increased resulting in higher blood pressure and tachycardia (higher heart rate than 100).

The present study did not show any significant difference in the mean heart rate, systolic and diastolic blood pressure, and core body temperature between patients of three groups at any time ($P > .05$). In a study by Kiekkas et al,[24] there was no difference in heart rates in the group of patients with hypothermia and patients with normothermia, and only the mean arterial blood pressure was affected by hypothermia. However, the mean systolic blood pressure in the warming group, who were warmed by intravenous fluid in recovery, was significantly higher than before induction of anesthesia ($P = .003$) and during the operation ($P < .001$) in the present study. The average systolic blood pressure in PACU was significantly higher than during the operation ($P < .001$) in the warming group via the forced-air warming system.

On the other hand, the average heart rate in both warming groups was significantly lower during the operation than the recovery. In fact, higher systolic blood pressure and heart rates could be related to mild hypothermia in patients.[10]

Limitations and Suggestions

Limitations of this study included the small number of samples, the impossibility of complete coverage of patients during the operation using forced-air warming blankets, and the inability to control the speed of receiving intravenous fluid in various patients during surgery.

Conclusions

According to results of the present study, hypothermia did not occur during a short-time laparoscopic surgery (less than 120 minutes), and the efficacy of the forced-air warming system was similar to warmed intravenous fluid in preventing hypothermia. The use of a conventional method of warming with routine blankets was still a useful way for warming patients. It seems that forced-air warming system blankets could not be significantly effective because of heat dissipation and incomplete coverage of patient body during the operation.

Using the underbody warming blanket along with forced-air warming system blankets to cover a larger part of body may achieve better results. However, further research is necessary to provide evidence on the effectiveness of warming methods in patients undergoing laparoscopic surgery.

Acknowledgment

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