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The effects of forced air warming system on the hemodynamic status, pain intensity, tremors, nausea and vomiting in candidates of emergency laparotomy patients: a double-blind randomized clinical trial

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Abstract: **Objective:** During emergency laparotomy surgeries, a wide incision is usually created in the abdomen causing the exposure of visceral organs to cold temperatures in the operation room. Other factors such as excessive stress, intra-operation blood transfusion, and prolonged anesthesia increase the risk of hypothermia in these patients. In this study, we studied the effects of forced air warming systems on the hemodynamic status, pain intensity, tremors, nausea and vomiting in emergency laparotomy patients.

Methods: In the present double-blinded clinical trial, 80 candidates for emergency laparotomy were randomized into two groups: intervention (patients receiving forced air warming during anesthesia) and control (patients without an active warming system). Patients' hemodynamic status (during anesthesia and at post anesthesia care unit (PACU), pain intensity, opioids received, tremors, nausea, vomiting, and antiemetics administration were compared between the two groups.

Results: The amounts of opioids (P=0.041) and relaxants (P=0.039) received by the patients were significantly lower in the intervention group than in the control group. The hemodynamic status was more stable in the patients of the intervention group than those in the control group at all times measured. Pain intensity (per minute) at the PACU was significantly higher in the control group than in the intervention group (P=0.041). Among the patients admitted to the PACU, participants with no tremors (P=0.005) or nausea (P=0.005) were significantly higher in the intervention group than in the control group. Also, in the recovery unit, patients in the intervention group received significantly lower amounts of opioids (i.e., mg of pethidine, P=0.036) and antiemetics (P=0.011) compared to the control group.

Conclusion: The use of a forced air warming system in the operation room stabilizes the hemodynamic status and reduces the pain intensity, tremors, nausea and vomiting in emergency laparotomy patients. As a non-pharmacological strategy, this method was observed to have satisfactory safety.

Keywords: Emergency Laparotomy, Hemodynamic Status, Hypothermia, Pain Intensity, Tremors

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1. Introduction

Sedatives and anesthesia interfere with temperature regulatory responses and so can cause unplanned hypothermia during and immediately after surgery (1,2). Hypothermia occurs when the core body temperature falls below 36 °C (3). The prevalence of unintended hypothermia has been reported to range from 65% to 75% (4). All patients undergoing general or local anesthesia, regardless of age and gender, are at the risk of hypothermia (5). Even patients with a normal body temperature before surgery experience 1-2 °C reduction in the core body temperature within 30 minutes after anesthesia (6,7).

Several factors predispose a patient to hypothermia, such as long-term exposure of patients to cold temperature in the operating room (8), impairment of body temperature regulation due to anesthesia (9), intravenous (IV) administration of cold fluids (10), transfusion of blood products without sufficient warming, long durations of anesthesia and surgery, large surgical incisions, and the use of cold washing solutions (11).

Hypothermia decelerates the body's metabolic rate, deviates the oxyhemoglobin dissociation curve to the left, predisposes patients to myocardial ischemia (12), delays recovery (secondary to reduced metabolism of drugs) and wound healing,

causes patients to feel tremors, cold, and discomfort after the operation, nurtures coagulopathies and wound infections (13), and by increasing vascular resistance, decreases renal and hepatic blood flow thereby impairing the metabolism of some drugs (14).

Measuring vital signs, is necessary as they reflect the proper functioning of body systems (15). These parameters also offer suitable criteria for evaluating hypothermia (16). During hypothermia, there is an increase in the tendency of oxygen to bind with hemoglobin, therefore causing tissue hypoxia and an increase in demand of cardiac muscles for oxygen. This increase in demand thereby stimulates the respiratory system and increases the respiratory rate (17,18). On the other hand, hypothermia has also been reported to be associated with post-surgery tremors, episodes of nausea and vomiting at post anesthesia care unit (PACU), increased pain intensity, more need for analgesics and antiemetics, longer stay at PACU, and hemodynamic instability (19).

Two major warming methods are implemented in the operating room to prevent and treat hypothermia: active and passive (20). Passive methods include the use of covers and blankets, while active methods include air-source heating systems, radiator heaters, and warm fluids (21). Evidence shows that active warming methods are more effective than passive strategies in reducing the incidence and severity of hypothermia (22). Numerous studies have assessed the effects of various thermal interventions on patients; however, controversies regarding the best patient warming method still persist (23).

Emergency laparotomy requires creating a wide abdominal incision, causing visceral tissues to be exposed to the ambient temperature in the operating room (24,25). The risk of hypothermia is also exaggerated in patients undergoing emergency laparotomy due to factors such as excessive stress, intra-operation blood transfusions, and the long duration of anesthesia. A meta-analysis study performed by Lee Y et al., showed that the use of a forced air warming system can be effective in preventing hypothermia during surgery; but there were several limitations in this study: 1) the study focused only on a forced air warming system, the use of warm fluids administration and room temperature were not taken into consideration. 2) post-surgery hypothermia was not studied. 3) the forced air warming system only covered a limited part of the body leaving the upper limbs uncovered, and 4) hemodynamic status during and after surgery was not discussed (26). Considering the various limitations in this study, we conducted this present study in order to be able to reach more desirable results. This study is designed to assess the effects of using a forced air warming system on the hemodynamic status, pain intensity, tremors, nausea and vomiting among emergency laparotomy patients.

2. Methods

2.1. Study design and setting

The present study is a randomized double-blinded clinical trial conducted on 84 emergency laparotomy patients admitted to the Imam Reza Hospital affiliated with the Tabriz University of Medical Sciences, for a time period of 18 months, from March 21, 2018, to September 23, 2019. All patients fulfilling the eligibility criteria were enrolled in this study.

2.2. Sample size estimation and patient recruitment

In order to estimate the sample size, a similar study by Pu et al., 2014 (27), and the sample size estimation formula were used for two independent groups; for this purpose, default assumptions such as S1=2.21, S2=2.86, μ1=9.97 and μ1=10.4, α=0.05, study power=80 and probability of 5% dropout, 42 people in each group were determined; a total of 84 participants were included in the present study. The participants were enrolled in this study using the convenient sampling method.

2.3. Eligibility criteria

Inclusion criteria included: aged between 18 and 60 years, being a candidate for emergency laparotomy surgery, American society of anesthesiologists (ASA) classes I-II, body mass index between 18 and 38.5 Kg/m^2, willing and able to sign informed consent.

Exclusion criteria were: patient history of thyroid disorders, diabetes mellitus and intra-abdominal infections, (patients with symptoms of abdominal infection such as pain, abdominal cramps and observation of intra-abdominal infection by the surgeon during surgery), receiving blood products three hours before surgery or excessive intravenous fluid administration (more than five liters), surgery time exceeding 180 minutes, body temperature above 37.5 °C or below 36.5 °C, unstable hemodynamic status.

2.4. Randomization and blinding

Excel software was used to randomize the participants into two study groups. First, the groups were assigned letters A and B, written in the same column. As the number of samples in each group was n=42, each letter was sequentially repeated 42 times in the column beneath each other. Then random numbers were generated in the opposite column using the RAND command. Next, using the sort command, the generated random numbers were sorted from small to large or vice versa, so a random order of letters A and B (i.e., groups) was generated, which was used as a basis to assign people to different groups. The intervention started after the induction of anesthesia and ended immediately after extubation of the patient; therefore, the patients were completely unaware of the type of intervention received. Results were analyzed by a statistician (outside the authors' group) to analyze them. Therefore, this study was conducted

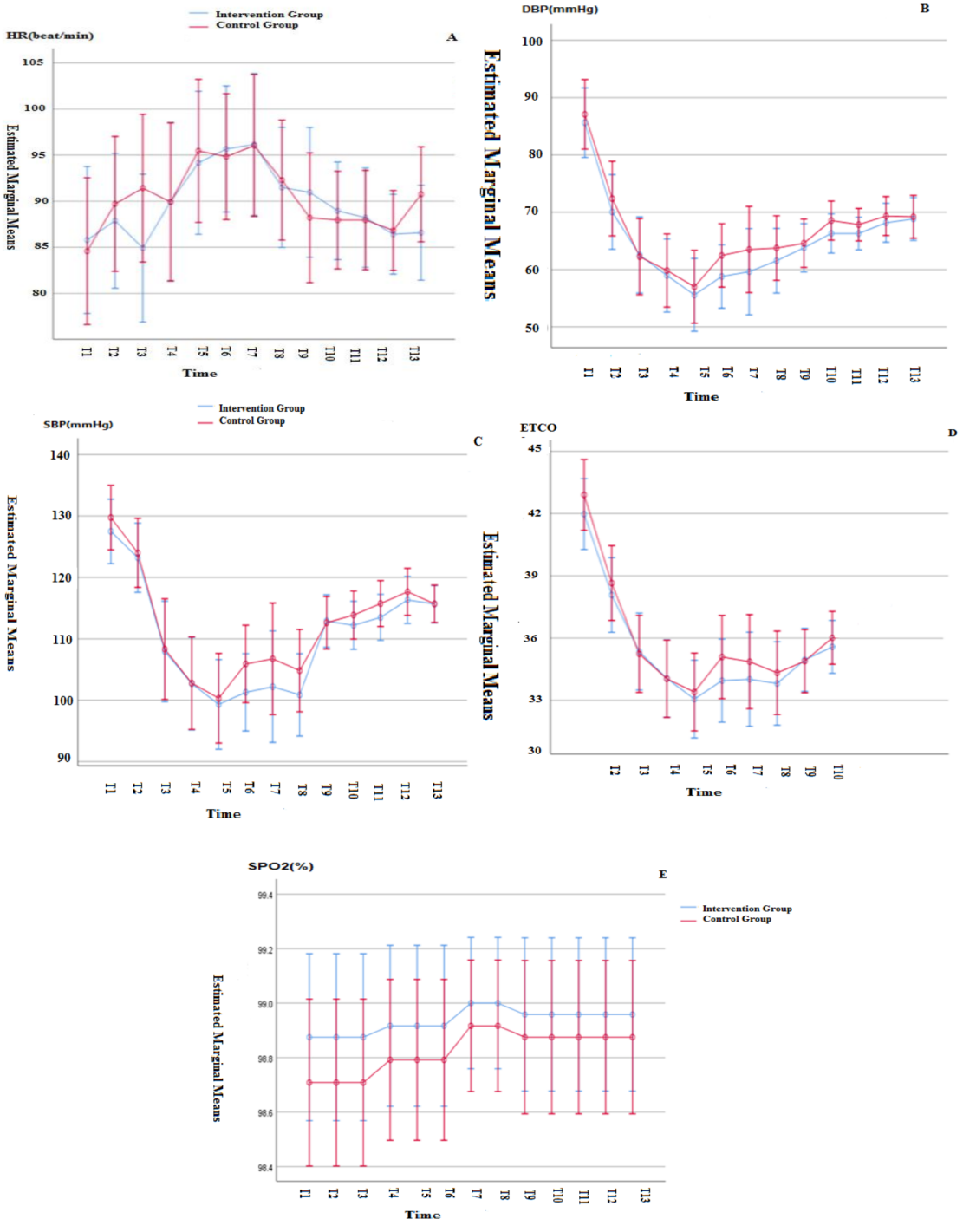

Figure 1 A-E Comparison of HR, SBP, DBP, ETCO2, and SpO2 during time between study groups

HR: Heart rate; DBP: Diastolic blood pressure; SBP: Systolic blood pressure; SpO2: Saturation of peripheral oxygen; ETCO2: End-tidal carbon dioxide; T1: Baseline; T2: Before intubation; T3: 15 min after intubation; T4: 30 min after intubation; T5: 45 min after intubation; T6: 60 min after intubation; T7: 75 min after intubation; T8: 90 min after intubation; T9: 105 min after intubation; T10: 120 min after intubation; T11: Admission at PACU; T12: 15 minutes after transferring to PACU; T13: At discharge from PACU

Table 1 Comparison of participants' baseline characteristics

Variables		Study group (n=84)		P-value
Age (years) *, mean±SD		43.19±3.88	42.21±3.10	0.714
BMI * (kg/m^2), mean±SD		27.79±3.40	28.29±3.53	0.669
Duration of anesthesia (minutes)*, mean±SD		150.76±15.51	170.63±16.49	0.093
Duration of surgery (minutes)*, mean±SD		115.03±8.14	145.84±9.86	0.088
Opioids used (μg of fentanyl) *, mean±SD		105.66±25.33	190.11±50.26	0.041
Relaxants used (mg of atracurium) *, mean±SD		20.71±8.64	39.09±14.40	0.039
Gender **, n (%)	Male	24 (57/14%)	27 (64/28%)	0.399
	Female	18 (42/86%)	15 (35/71%)	
ASA class **, n (%)	I	29 (69/04%)	30 (71/42%)	0.803
	II	13 (30/95%)	12 (28/57%)	

*: t-test; **: Chi-squared test; BMI: Body mass index; ASA: American association of anesthesiologists; mg; Milligram

Table 2 Comparison of temperature of rectal probe, esophageal probe and tympanic trimester at different times between two groups participating in the study

Temperature, °C		Study group (n=84)		P-value*
		Intervention group (n=42), mean±SD	Control group (n=42), mean±SD	
Rectal probe	30 minutes after intubation	36.65±0.69	35.74±0.25	0.014
	60 minutes after intubation	36.89±0.85	35.61±0.19	0.011
	90 minutes after intubation	37.01±0.88	35.50±0.25	0.009
	End of surgery	37.19±0.96	35.42±0.29	0.005
Esophageal probe	30 minutes after intubation	36.85±0.33	35.90±0.45	0.019
	60 minutes after intubation	37.03±0.96	35.78±0.36	0.015
	90 minutes after intubation	37.25±0.27	35.65±0.30	0.010
	End of surgery	37.70±0.75	35.30±0.33	0.008
Tympanic trimester	30 minutes after intubation	34.76±0.25	34.65±0.41	0.225
	60 minutes after intubation	34.90±0.41	34.80±0.49	0.319
	90 minutes after intubation	34.92±0.39	34.83±0.25	0.203
	End of surgery	34.99±0.27	34.86±0.14	0.114

*: t-test; SD: Standard deviation

Table 3 Comparison of the safety of the warming procedure in the patients transferred to the PACU between the two study groups

Variables		Study groups (n=84)		P-value
		Intervention group (n=42)	Control group (n=42)	
Pain intensity (VAS) *, mean±SD	Admission at PACU	3.66±1.36	4.24±1.14	0.093
	15 minutes after transferring to PACU	4.25±1.12	6.55±1.66	0.041
	At discharge from PACU	3.03±1.11	3.96±1.97	0.059
Opioids used (mg of pethidine) *, mean±SD		18.44±5.96	32.96±9.22	0.036
Tremor intensity **, n (%)	No tremor	21 (50%)	9 (21/42%)	0.005
	Score 1	13 (30/95%)	9 (21/42%)	
	Score 2	5 (11/90%)	11 (26/19%)	
	Score 3	3 (7/14%)	8 (19/01%)	
	Score 4	0 (0/0%)	5 (11/90%)	
Nausea and vomiting **, n (%)	No nausea	25 (59/52%)	10 (23/80%)	0.005
	Score 1	9 (21/42%)	14 (33/33%)	
	Score 2	7 (16/66%)	15 (35/71%)	
	Score 3	1 (02/38%)	3 (07/14%)	
Dose of antiemetic infused *, mean±SD		2.29±1.44	6.35±2.59	0.011

*: t-test; **: ANOVA; PACU: Post anesthesia care unit ;SD: Standard deviation; mg: Milligram.

in a double-blind manner.

2.5. Procedures

Patients were made to lay down on a surgery bed upon entry to the operation room. The patient's hemodynamic status was regularly measured from the time of their entrance to the operating room until their exit and transfer to the PACU. These parameters included heart rate, arterial oxygen saturation, systolic blood pressure, diastolic blood pressure, and end tidal CO2 (ETCO2) (performed during intubation). After primary hemodynamic status monitoring, all patients received 500 milliliters (mL) of intravenous crystalloids through IV cannula no. 15. The temperature of the IV solution for all patients reached 37 °C by being placed into a water bath (a Bain-Marie with a circulating flow) before infusion. Then all patients underwent general anesthesia performed the same method by the same anesthesiologist. General anesthesia was induced by administering midazolam (0.02 mg/kg), fentanyl (2 mcg/kg), lidocaine (1-2 mg/kg), propofol (3-5 mg/kg), atracurium (0.5 mg/kg) using tracheal tube size 7 mm for women or 7.5 mm for men. Isoflurane gas (1-1.2 MAC) and a mixture of air and N2O gas were used to maintain anesthesia. During surgery, fentanyl (50 mcg) and atracurium (10 mg) were repeated at 30 and 45-minute intervals, respectively. For patients experiencing an elevation in blood pressure and heart rate during the surgery (indicating pain), an additional 50 mcg of fentanyl was administered. Upon request of the surgeon during surgery for an increase in relaxation of the surgery site, 10 mg of atracurium was administered. At the end of the surgery, the effects of the relaxants were reversed using atropine (0.02 mg/kg) and neostigmine (0.04 mg/kg), and then the patient was extubated. In the intervention group, a forced air warming system at a maximum temperature of 40 °C (Warm Touch™ convective warming system) and full-body blankets (Warm touch™ Full Body Multi Access Blanket) was applied for patients only on the limbs immediately after the induction of anesthesia and full body surface after the end of the surgery or immediately after extubation. The patients in the control group received routine care such as covering the patient's hands with normal cloths and not using an air cooler. The temperatures of the patient's body and the operating room were measured and recorded by a tympanic infrared thermometer manufactured in Germany (model FT55). Also, the humidity of the operating room was measured and recorded by a hygrometer (model TFA55, Germany). The operating room's temperature was maintained at 22-25 °C and humidity at 30%. Body temperature was measured in three areas. An electric rectal probe (Exacon Scientific A/S, Geeichbis, D-RS2 series, Denmark) wrapped in a disposable cover was inserted 5 cm into the patient's anus. An esophageal electrical thermometer probe (Exacon Scientific A/S, Geeichbis, D-RS2 series, Denmark), covered in a disposable shield, was inserted into the patient's mouth corresponding to the length of the tracheal tube through the esophagus. An ear canal trimester (Mona-therm Tympanic YSI 400 Series, Tyco Healthcare, CA, USA) was also inserted into the patient's ear canal to measure the ear temperature, while ambient air was prevented from entering the ear canal to avoid its influence on the measurement.

All probes have the capacity to measure temperature with a precision of 0.1, and their accuracy and performance has been approved by the food and drug association (FDA) and European Union. All the probes were connected to the spacelab monitor under regular calibration programs. For all patients, the probes were inserted by the same anesthesiologist (the main researcher in this study). Also, body temperature was recorded at different times (30 minutes after intubation, 60 minutes after intubation, 90 minutes after intubation and at the end of surgery) by each probe separately. Required data, including patients' basic features such as age, gender, body mass index (BMI), ASA class, duration of anesthesia, duration of surgery, the amount of opioid use during anesthesia (μg of fentanyl), and the amount of relaxant administration during anesthesia (mg of atracurium), were recorded for all patients. During surgery, changes in hemodynamic status indicators were measured every five minutes for the initial 15 minutes and then every 15 minutes and before extubation. These parameters were also measured upon transferring patients to the PACU (i.e., at admission, first 15 minutes after admission, and at discharge). During admission at the PACU, pain intensity was determined using the visual analogue scale (VAS) at the entrance and after 15 and 30 minutes. Tremor was assessed and categorized using an observational tool developed by Grossely & Mahajan (28) as follows: no tremor=0; goosebumps+peripheral cyanosis without observable tremor=1, visible tremors in a group of muscles=2, tremors in more than one group of muscles=3, and tremors in all body muscles=4. Nausea and vomiting (Bellville scale) were defined based on their frequencies as lack of nausea and vomiting (score=0), feeling nauseous (score=1), nausea plus vomiting twice or less than twice (score=2), and nausea plus vomiting twice or more than twice (score=3) (29).

2.6. Statistical analysis

After the completion of data collection, the data were entered into SPSS 25 statistical software and analyzed by a statistician who was not a member of the research team. Mean±standard deviation and frequency (%) were used to display the data, and for within- and between-group comparisons, the t-test, Chi-squared test, and ANOVA were utilized. A P-value of less than 0.05 was considered as the statistical significance level.

2.7. Ethical consideration

This study was approved by the ethics committee of Tabriz University of Medical Sciences (no: IR.TBZMED.REC.1396.901) and registered in the Iranian Registry for Clinical Trials (no: IRCT2017041533435N1). The research objectives were explained to the patients at the beginning of the study, and they were requested to sign a consent form if willing to participate in the study. The participants did not pay any extra fee, and the research team

resolved any complications they encountered as soon as possible and free of charge.

3. Results

The average age of the participants was 42.84±3.69 years, and most of the participants were male (n=51, 60.71%). The mean BMI was equal to 28.14±3.96 Kg/m^2. Also, most of the participants had ASA class I (n=59, 70.23%). None of the mentioned variables were significantly different between the two groups (P>0.05) (Table 1). The overall means±SDs of the duration of anesthesia and surgery were 159.85±15.63 and 125.44±8.69 minutes, respectively, both of which were insignificantly lower in the intervention group than in the control group. Also, the amount of opioid (115.24±40.96 μg of fentanyl) and relaxant (30.19±10.37 mg of atracurium) administered were significantly lower in the intervention than in the control group (P values of 0.041 and 0.039, respectively) (Table 1).

Baseline hemodynamic variables showed no statistically significant differences between the two study groups. The heart rate was significantly lower in the intervention than in the control group during anesthesia, before extubating (except for the first 15 minutes), and during the entire time of stay at PACU. Moreover, the heart rate during the entire study period showed more stability (according to the difference in the P-values) in the participants of the intervention group (P=0.569) compared to control subjects (P=0.096) (Figure 1-A). There was no significant difference between the two study groups regarding systolic blood pressure measured initially and during the first 15 minutes after anesthesia; however, this parameter was significantly lower in the intervention than in the control group at other time points. Also, systolic blood pressure showed more stability (according to the difference in P-values) in the intervention group (P=0.749) compared to the control group (P=0.079) at all times (Figure 1-C).

Similar results were noticed when comparing diastolic blood pressure between the two groups, and diastolic blood pressure also displayed higher stability (according to the difference in P-values) in the intervention group (P=0.773) compared to the control group (P=0.085) at all time points (Figure 1-B).

The comparison of the arterial oxygen saturation showed no statistically significant differences between the two groups at any time point; however, the stability (according to the difference in P-values) of arterial oxygen saturation was higher in the patients of the intervention group (P=0.880) than in patients of the control group (P=0.349) (Figure 1-E). The amount of ETCO2 measured did not show a statistically significant difference between the two study groups during the first 15 minutes after anesthesia, but this parameter was significantly higher in the control group compared to the intervention group during anesthesia and before extubating (Figure 1-D) During all time points (30 minutes after intubation, 60 minutes after intubation, 90 minutes after intubation and at the end of surgery), the body temperature measured by the rectal probe (P<0.05) and esophageal probe (P<0.05) in the in-tervention group was significantly more close to normal than in the control group (Table 2).

We also observed that patients in the control group experienced significantly more severe pain than those in the intervention group 30 minutes after anesthesia and in the PACU. Also, the number of patients who did not experience tremors in the PACU was significantly higher in the intervention group than in the control group (P=0.005). On the other hand, the incidence of nausea and vomiting was higher in the control group compared to the intervention group (P=0.005); however, this difference was not statistically significant. Finally, in the recovery unit, the patients of the intervention group received significantly lower amounts of opioids (mg of pethidine, P=0.036) and antiemetics (P=0.011) in comparison with their counterparts in the control group (Table 3).

4. Discussion

The aim of this study was to evaluate the effects of a forced air warming system on the hemodynamic status, pain intensity, tremors, nausea, and vomiting, among emergency laparotomy patients. The results of our study indicated that this method, as a non-pharmacological strategy, could desirably stabilize patients' hemodynamic status during surgery and at the PACU and therefore reduce the duration of anesthesia and surgery, the need for analgesics, relaxants, and antiemetics during anesthesia, as well as the incidence of sequelae such as nausea, vomiting, and tremors.

Using this heating system during anesthesia primarily reduced the duration of surgery and anesthesia and the need for opioids and relaxants during anesthesia (30). Our results showed that patients exposed to the heating system during anesthesia required significantly lower amounts of fentanyl (as an analgesic) and atracurium (as a relaxant) (31). It is believed that hypothermia during surgery can accentuate tissues' need for oxygen and metabolic rate, increasing requirements for opioids. Besides, hypothermia has been shown to promote muscular and tissue stiffness, explaining the higher need for relaxants during surgery (32). We found no study investigating the effects of patient heating during anesthesia on the need for opioids and relaxants, a topic addressed in the present study for the first time.

The results of our study showed that the central temperature (rectal and esophageal) remained significantly constant during the intervention, while in the control group patients, this temperature decreased over time; but the temperature measured in the tympanic (ambient temperature) remains unchanged and the intervention has no effect on the ambient temperature. The results of our study are consistent with the results of previous studies (33,34). In this regard, it is believed that the decrease in core temperature leads to the occurrence of hypothermia and shivering after unconsciousness, which was also observed in this study.

As mentioned, patient heating during anesthesia could stabilize patients' hemodynamic status. It is believed that hy-

pothermia increases the cardiac muscle's demand for oxygen, which is provided by increasing blood pressure, blood flow, heart rate, and metabolic rate. An increase in metabolism encourages the utilization of oxygen reserves in tissues such as muscles, and extricating oxygen from these tissues increases blood pressure and decreases tissues' carbon dioxide content (31,35,36). The results of our study agree with those of several previous studies (37-39). Nevertheless, several other studies have detected no significant differences in hemodynamic parameters between patients exposed or not exposed to heat, which could be due to different anesthetic methods used (spinal anesthesia, general anesthesia, etc.), variability in anesthesia maintenance, as well as different heating methods or surgical incisions (13,18,40).

Our results indicated that after transferring to the PACU, the patients exposed to heating experienced significantly milder pain than the control subjects. Hypothermia, secondary to accelerating the body's metabolic rate and tissues' physiological needs, reduces the body's resilience (9,41). Therefore, hypothermic patients perceive more severe pain than normothermic individuals due to muscle contractions, explaining their higher requirements for analgesics and opioids (27). On the other hand, hypothermia during anesthesia paves the ground for tremors after anesthesia. One of the most important determinants of post-anesthesia tremors is body temperature during anesthesia (42,43). A drop in body temperature during anesthesia activates the cerebral temperature control center, which nurtures tremors to respond to increased tissue oxygen demands (44,45). On the other hand, an increase in the body's carbon dioxide levels triggers nausea and vomiting, leading to higher need for antiemetics. In this regard, our results are in line with that of prior studies (46,47).

A consequence of surgery is a decrease in the core body temperature, which results from heat loss due to exposure to cold air, impaired function of temperature regulatory mechanisms due to vascular dilatation, and anesthetics-induced loss of muscular tone.

Hypothermia and subsequent tremors can lead to tachycardia, the release of catecholamines, vascular contraction, reduced blood flow, and metabolic acidosis, demanding immediate coping measures. In this study, we could prevent and reverse these adverse consequences by applying an air-source heating system (48,49).

5. Limitations

Not measuring arterial blood gases to assess acidosis and being conducted in a single center were among the limitations of this study, which are recommended to be obviated in future studies.

6. Conclusion

Using a forced air warming system stabilized hemodynamic status parameters and reduced pain intensity, tremors, nausea, and vomiting in emergency laparotomy patients. Our results confirmed the safety of this method as a non-pharmacological strategy.

7. Declarations

7.1. Acknowledgement

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7.2. Authors' contribution

All the authors passed four criteria for authorship contribution based on recommendations of the International Committee of Medical Journal Editors.

7.3. Conflict of interest

We declare no conflict of interest.

7.4. Funding

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