

SCIENTIFIC ARTICLE

The effects of crystalloid warming on maternal body temperature and fetal outcomes: a randomized controlled trial



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Apgar score

Abstract

Background and objectives: Hypothermia occurs in about 60% of patients under anesthesia and is generally not managed properly during short lasting surgical procedures. Hypothermia is associated with adverse clinical outcomes. The current study is designed to assess the effects of crystalloid warming on maternal and fetal outcomes in patients undergoing elective cesarean section with spinal anesthesia.

Methods: In this prospective randomized controlled trial, sixty parturients scheduled for elective cesarean section with spinal anesthesia were randomly allocated to receive crystalloid at room temperature or warmed at 37°C. Spinal anesthesia was performed at L3-L4 interspace with 10 mg of hyperbaric bupivacaine without adding opioids. Core temperature, shivering, and hemodynamic parameters were measured every minute until 10th minute and 5-min intervals until the end of operation. The primary outcome was maternal core temperature at the end of cesarean section.

Results: There was no difference for baseline tympanic temperature measurements but the difference was significant at the end of the operation ($p=0.004$). Core temperature was $36.8 \pm 0.5^\circ\text{C}$ at baseline and decreased to $36.3 \pm 0.5^\circ\text{C}$ for isothermal warmed crystalloid group and baseline tympanic core temperature was $36.9 \pm 0.4^\circ\text{C}$ and decreased to $35.8 \pm 0.7^\circ\text{C}$ for room temperature group at the end of the operation. Shivering was observed in 43.3% in the control group. Hemodynamic parameter changes and demographic data were not significant between groups.

Conclusions: Isothermal warming crystalloid prevents the decrease in core temperature during cesarean section with spinal anesthesia in full-term parturients. Fetal Apgar scores at first and fifth minute are higher with isothermal warming.

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PALAVRAS-CHAVE

Raquianestesia;
Aquecimento;
Cristaloides;
Temperatura central;
Tremor;
Cesariana;
Escore de Apgar

Os efeitos do aquecimento de cristaloides sobre a temperatura corporal materna e nas condições fetais: ensaio clínico randômico

Resumo

Justificativa e objetivos: A hipotermia ocorre em cerca de 60% dos pacientes sob anestesia e geralmente não é tratada adequadamente durante procedimentos cirúrgicos de curta duração. A hipotermia está associada a desfechos clínicos adversos. O presente estudo teve como objetivo avaliar os efeitos do aquecimento de cristaloides nas condições maternas e fetais em pacientes submetidas à cesariana eletiva com raquianestesia.

Métodos: Neste estudo prospectivo, randômico e controlado, 60 parturientes agendadas para cesárea eletiva com raquianestesia foram distribuídas aleatoriamente para receber cristaloides à temperatura ambiente ou aquecidos a 37°C. A raquianestesia foi realizada no interespacô L3-L4 com 10 mg de bupivacaína hiperbárica sem adição de opioides. Temperatura central, tremores e parâmetros hemodinâmicos foram medidos a cada minuto até o décimo minuto e em intervalos de 5 min até o final da operação. O desfecho primário foi a temperatura central materna ao final da cesárea.

Resultados: Não houve diferença nas mensurações basais da temperatura timpânica, mas a diferença foi significativa no final da operação ($p = 0,004$). A temperatura central foi de $36,8 \pm 0,5^{\circ}\text{C}$ na fase basal e diminuiu para $36,3 \pm 0,5^{\circ}\text{C}$ no grupo com aquecimento isotérmico de cristaloides e a temperatura basal timpânica foi de $36,9 \pm 0,4^{\circ}\text{C}$ e diminuiu para $35,8 \pm 0,7^{\circ}\text{C}$ no grupo sem aquecimento das soluções no final da operação. Tremores foram observados em 43,3% no grupo controle. Alterações nos parâmetros hemodinâmicos e dados demográficos não foram significantes entre os grupos.

Conclusões: O aquecimento isotérmico de cristaloides previne a redução da temperatura central durante a cesariana com raquianestesia em parturientes a termo. Os escores de Apgar para os fetos no primeiro e quinto minutos são maiores com o aquecimento isotérmico.

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Introduction

Patients having cesarean section with spinal anesthesia are prone to hypothermia. Redistribution of heat from core to periphery occurs under regional anesthesia. Impairment of thermoregulatory control contributes to the thermal perturbations due to lack of skin afferents and vasodilation at blocked segments.^{1,2} Increased spinal block levels, lower ambient temperature and increased time of exposure to cold augment the decrease in core temperature.³

Hypothermia is estimated to occur in about 60% of patients undergoing cesarean delivery^{4,5} and is associated with several adverse outcomes including increased risk of cardiovascular events, coagulation problems and blood loss, increased incidence of wound infections, length of hospital stay, shivering, and elongated time to recover from anesthesia.⁶⁻⁹ Maternal temperature at birth is also accused for the neonatal temperature.^{10,11}

Effect of warmed IV fluids and/or active warming on thermal homeostasis was studied in previous studies.^{4,5,12-18} Former studies used preload strategy with IV fluids before induction of regional anesthesia. In most of these studies, opioids were added to intrathecal local anesthetics to increase the quality and duration of anesthesia but the effects of opioids on thermoregulation centers are conflicting their results.¹⁹ The studies that used active warming tech-

niques to maintain normothermia during cesarean section concluded that forced air warming does not prevent intraoperative hypothermia when used alone⁴ and also their use during cesarean section is not practical since covering upper half of the body prevents newborn bonding.

The aim of our study was to assess the effect of isothermic crystalloid warming on maternal core temperature and neonatal outcomes in patients scheduled for elective cesarean section with spinal anesthesia. The primary outcome was the maternal temperature at the end of surgery. We hypothesized that isothermic crystalloid warming would maintain maternal core temperature and yield to better neonatal outcomes when compared to pregnant patients hydrated with IV crystalloids at room temperature.

Methods

This prospective double blind, randomized controlled trial of healthy parturients scheduled for elective cesarean section with spinal anesthesia was conducted to assess the effect of isothermic crystalloid warming on maternal core temperature and neonatal outcomes. After approval by the Research Ethics Committee, the study was preregistered at Australian New Zealand Clinical Trials Registry.

Inclusion criteria included parturients ASA physical status II singleton pregnancies aged 18–45 years scheduled for elective cesarean section with spinal anesthesia. Exclu-

sion criteria included ASA physical status greater than II, multiple pregnancies, complicated pregnancies, presence of fetal anomaly, emergency cesarean sections, maternal or fetal cardiac disease, coagulopathy or history of anticoagulant drug use, febrile conditions, thyroid disorders, dysautonomia, Reynaud's syndrome, patients rejecting spinal anesthesia and patient refusal for the study enrollment.

After obtaining written informed consent from sixty participants, parturients were allocated randomly into two groups using computer generated randomization with Microsoft Excel. Parturients in the intervention group received isothermic Lactated Ringer's solution warmed at 37°C and the control group was hydrated with Lactated Ringer's solution at room temperature. Blinding was achieved by infusing all IV fluids via ASTOFLO PLUS eco (Gambro, Germany) which was switched off in the control group. The investigator was not allowed to touch the infusion line. ASTOFLO PLUS eco was covered with a dark green bag to keep the investigator blind for the study.

Tympanic infrared thermometer Riester ri-thermo® N (Rudolf Riester GmbH, Germany) was used to measure core temperatures. All core temperature measurements were recorded from the parturients' same tympanic membrane by the same investigator, i.e. if the baseline core temperature was measured from left ear tympanic membrane of the parturient; all core temperature measurements were done from the left ear tympanic membrane of the patient. The thermometer used for the study was same for all the participants that had a disposable sleeve for each patient. Ambient temperature was preset to 22°C throughout the study. Parturients were informed about thermal measurement with digital thermometer (the thermometer and the sleeves were demonstrated to the parturients at their pre-operative visit, they were informed that disposable sleeves would be used for every patient, the beep sound during the measurement was demonstrated to familiarize the parturients to the measurements) and they were all familiar to the procedure before they entered to operation room.

When patient was accepted to the operation room, an anesthesiologist responsible for the care of the patient, other than investigator collecting data, monitorized the patient with standard ASA monitors (electrocardiogram, heart rate, pulse oximetry, non-invasive blood pressure) and introduced a 16G catheter fixed on the dorsum of left hand. Baseline hemodynamic data and core body temperature were recorded before starting intravenous infusion. Lactated Ringer's solution was used as intravenous crystalloid solution in the current study and the infusion started immediately after intrathecal injection of local anesthetic. The anesthesiologist in charge of the patient prepared the infusion line according to study protocol of the patient and covered the ASTOFLO PLUS eco with green cover. Then spinal anesthesia was performed at sitting position from L3 to L4 interspace navigated by ultrasound with a 26G atraumatic spinal needle (Atraucan, BBraun, Melsungen, Germany). 10 mg hyperbaric bupivacaine without opioids was injected after observing free flow of clear cerebrospinal fluid. After removal of spinal needle patient was placed supine with 15° left lateral uterine displacement and it was accepted as time zero for the measurements. Surgery was commenced when spinal block reached $\geq T6$ dermatome determined by

loss of sensation to pain with pinprick test. Following spinal anesthesia, data were collected for vital signs, core temperature and shivering every minute for 10 min after spinal anesthesia and with 5-min intervals until the end of surgery. In the current study hypothermia was accepted as $<36^{\circ}\text{C}$.²⁰ Shivering was graded with Wrench scale.²¹ For ethical reasons patients replying ≥ 3 to shivering scale was treated with forced air warming.

Umbilical artery sampling was done from a double clamped umbilical cord and analyzed for pH and blood gases immediately after birth. Apgar score of the newborn, recorded at 1st and 5th minutes after birth, was rated by a pediatrician who was unaware of the study protocol. The volume of IV fluids infused, need for ephedrine boluses and atropine, block height, noninvasive blood pressure, heart rate and oxygen saturation were recorded at the same data collection intervals with maternal core temperature. Other patient characteristics as age, weight, body mass index, hypotension ($>30\%$ decrease from baseline value or MAP <60) and bradycardia ($<50\text{ bpm}$), time lapse between spinal anesthesia and skin incision, duration of surgery were recorded. Hypotension was treated with incremental IV boluses of 5 mg of ephedrine and bradycardia was treated with atropine 0.5 mg as needed.

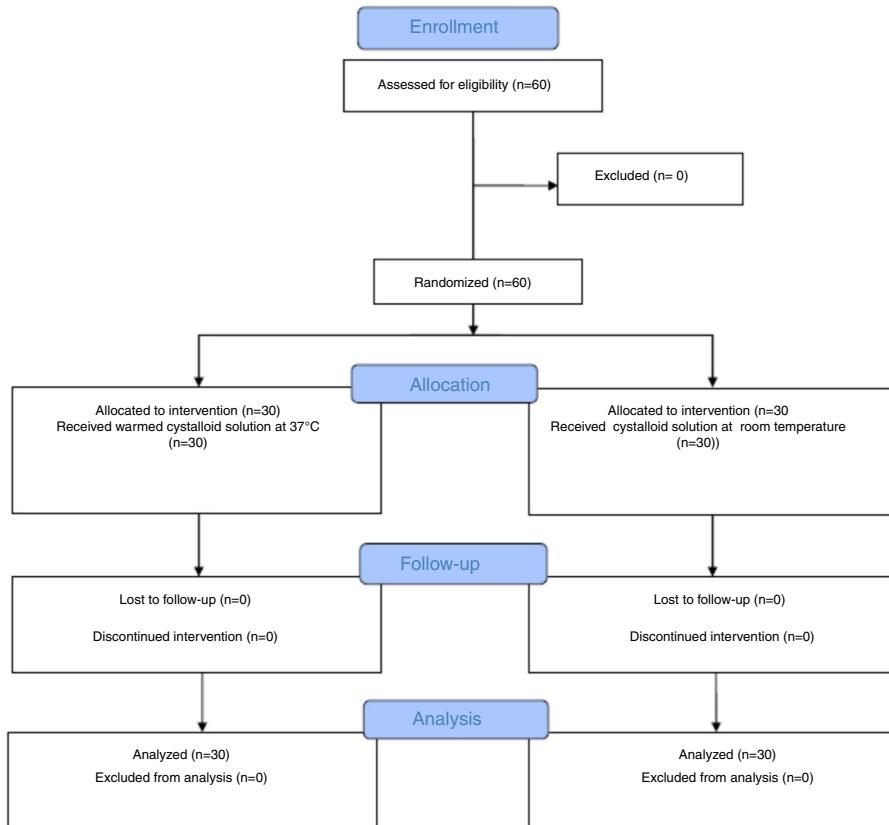
Sample size was calculated using G*Power version 3.1.9.2 package program based on previous study of Cobb.¹³ The sample size was calculated as 60 patients ($n=30$ for each group) to detect a 0.5°C decrease in maternal core temperature between groups at a significance level of 5% with a statistical power of 0.86 and an effect size $d=0.8$.

Patient variables and demographic data were analyzed with descriptive statistics methods (frequency, %, mean, standard deviation, median, and min–max) and qualitative data was analyzed with Pearson Chi-square (χ^2), Yates (χ^2) or Fisher's (χ^2) as appropriate. Normal distribution of data was analyzed with Kolmogorov-Smirnov and Shapiro-Wilk tests. Intergroup comparison of data was tested with Independent Samples-*t* test, Mann-Whitney *U* test and Repeated Measures Analysis of Variance. Statistical significance was accepted as $p < 0.05$ and the statistical analysis was performed by IBM SPSS version 23.0 (IBM SPSS, Inc., Chicago, IL, USA).

Results

Sixty patients were recruited for the study, 30 parturient allocated in each group completed the study with spinal anesthesia (Fig. 1). Demographic variables, operation variables and obstetric characteristics were similar between groups (Table 1).

The baseline core temperature of parturients was not statistically different between groups ($36.8 \pm 0.5^{\circ}\text{C}$ in the isothermic warmed group and $36.9 \pm 0.4^{\circ}\text{C}$ in control group). The difference in core body temperature at the end of surgery was statistically significant between groups ($36.3 \pm 0.5^{\circ}\text{C}$ for the isothermic warmed group, and $35.8 \pm 0.7^{\circ}\text{C}$ for the control group, $p = 0.004$) (Fig. 2). Core temperature changes were statistically significant compared to baseline measurements after 5th minute in the isothermic warmed crystalloid group ($F = 11,928$; 95% CI: 0.32–0.66; $p < 0.05$) whereas the difference was statistically different

**Figure 1** Consort flow diagram.**Table 1** Demographic and surgical data of parturients.

	Isothermic (n = 30)	Control (n = 30)	p
Age (y)	27.8 ± 4.7	27.9 ± 4.1	0.97
Height (cm)	162.6 ± 6.3	163.5 ± 5.7	0.58
Weight (kg)	79.0 ± 10.8	79.7 ± 13.6	0.82
BMI (kg.m ⁻²)	30.0 ± 4.8	29.8 ± 4.7	0.64
IV fluid volume (L)	1.3 ± 0.4	1.3 ± 0.4	1.00
Indication for C/S			
CPD	4 (13.3%)	5 (16.7%)	
Previous C/S	19 (63.3%)	19 (63.3%)	
Other	7 (23.3%)	6 (20.0%)	
Spinal to			
Skin incision (min)	3.4 ± 1.2	3.2 ± 1.2	0.520
Uterus incision (min)	6.0 ± 1.4	5.7 ± 1.7	0.517
Umbilical clamp (min)	6.9 ± 1.5	6.8 ± 1.8	0.813
Wound dressing (min)	24.8 ± 8.8	25.6 ± 6.7	0.669

BMI, body mass index; IV fluid, the volume of crystalloid fluid administered; C/S, cesarean section; CPD, cephalo pelvic disproportion. Values are expressed as mean ± SD, and percentage as appropriate. There were no statistically significant difference between groups ($p > 0.05$ for all comparisons).

starting from the 1st minute in the control group ($F = 32,806$; 95% CI: 0.87–1.31; $p < 0.05$) (Table 2).

The incidence of shivering was statistically significant between groups ($p = 0.000$). 13 of 30 patients in control group had shivering but none of the patients in isothermic warmed group had shivering (Table 3). Of

the 13 patients in control group, only one patient had a shivering score >3 and she was warmed with active warming.

Fetal outcomes are summarized in Table 4. Umbilical cord blood pH values and rectal temperature measurements were similar between groups but the difference in Apgar scores

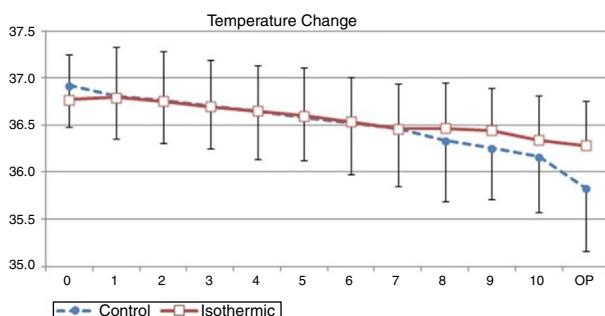


Figure 2 Core body temperature at the end of surgery between groups.

Table 2 Temperature changes: in-group and between groups.

	Isothermic (n = 30)	Control (n = 30)	p ^a
T 0	36.8 ± 0.5	36.9 ± 0.4	0.221
T 1	36.8 ± 0.5	36.8 ± 0.4 ^c	0.937
T 2	36.8 ± 0.5	36.8 ± 0.5 ^c	0.979
T 3	36.7 ± 0.5	36.7 ± 0.4 ^c	0.935
T 4	36.7 ± 0.5	36.7 ± 0.5 ^c	1.00
T 5	36.6 ± 0.5 ^c	36.6 ± 0.5 ^c	0.895
T 6	36.5 ± 0.5 ^c	36.5 ± 0.5 ^c	0.939
T 7	36.5 ± 0.5 ^c	36.5 ± 0.6 ^c	0.981
T 8	36.5 ± 0.5 ^c	36.3 ± 0.6 ^c	0.380
T 9	36.4 ± 0.4 ^c	36.3 ± 0.5 ^c	0.146
T 10	36.3 ± 0.5 ^c	36.2 ± 0.6 ^c	0.206
T 15	36.4 ± 0.6 ^c	36.2 ± 0.6 ^c	0.199
T 20	36.2 ± 0.5 ^c	35.9 ± 0.7 ^c	0.128
T 25	36.2 ± 0.5 ^c	35.8 ± 0.8 ^c	0.110
T 30	36.2 ± 0.6 ^c	36.1 ± 0.6 ^c	0.739
T OP	36.3 ± 0.5 ^c	35.8 ± 0.7 ^c	0.004
p ^b	0.000	0.000	

T, tympanic membrane temperature (°C), numbers after T indicating minutes after spinal anesthesia; T OP, tympanic membrane temperature at the end of surgery (°C).

^a Independent samples *t* test.

^b Repeated measures ANOVA.

^c Presence of in-group statistically significant difference compared to baseline measurement (*p* < 0.05).

Table 4 Fetal outcomes.

	Isothermic (n = 30)	Control (n = 30)	p
Apgar 1st minute	8.8 ± 0.4	8.4 ± 0.6	0.006
Apgar 5th minute	9.9 ± 0.1	9.8 ± 0.2	0.045
pH	7.4 ± 0.1	7.4 ± 0.0	0.065
Rectal temperature (°C)	37.0 ± 0.7	36.9 ± 0.9	0.675

Values are expressed as mean ± SD, and percentage (%) as appropriate. There were no statistically significant difference between groups for pH and rectal temperature. Apgar scores were significantly different at first and fifth minute after delivery.

at 1st and 5th minute were statistically significant (*p* = 0.006 and *p* = 0.045 respectively).

Hypotension was observed in 22 patients (73.3%) in isothermic warmed group and in 23 patients (76.7%) in the control group (*p* = 0.964). The total dose of ephedrine was 27.4 ± 18 mg in isothermic warmed group and 20.6 ± 10 mg in the control group (*p* = 0.480). Bradycardia was observed in 3 patients (10%) in the isothermic warmed group and in 2 patients (6.7%) in the control group (*p* = 0.642) and they were treated with atropine.

Number of blocked segments at third minute was 12.30 ± 2.47 (number of blocked segments are counted starting from L5 where 12 segments corresponds to T6) in isothermic warmed group and 12.00 ± 1.81 segments were blocked at third minute in control group (*p* = 0.595). Number of blocked segments at the end of the operation was 14.70 ± 1.36 segments in isothermic warmed group and 15.13 ± 1.59 segments were blocked in control group at the end of the operation (*p* = 0.263). Four parturient (13.33%) in isothermic warmed group and five parturient (16.67%) in control group reached a sensory block level above T4 dermatome but none of them complained about respiratory difficulty.

Discussion

In the current study isothermic warmed crystalloid infusion attenuated the decrease in core body temperature and incidence of shivering as well as resulting in higher Apgar scores at first and fifth minutes in term parturients undergoing elective cesarean section with spinal anesthesia.

Spinal anesthesia results in redistribution of heat from core to periphery due to peripheral vasodilation as a result of sympathetic block. The degree of vasodilation is parallel to the level of sympathetic block. Since vasodilatation is due to blockage of the sympathetic nervous system which has a blockage level above the sensory block and achieving a sensory block level between T6–T4 dermatomes is necessary for cesarean section,^{5,7,13,14} sympathectomy affects a large proportion of the body during cesarean section with spinal anesthesia. Shivering threshold is also reduced by 0.6 °C under regional anesthesia favoring vasoconstriction and shivering above the sympathetic block.¹⁴ Afferent input block from the blocked segments prevents vasoconstriction and shivering and also interferes with the conscious recognition of cold feeling.²² As a result of these factors parturients

Table 3 Distribution of shivering according to Wrench scale.

Shivering	Isothermic (n = 30)	Control (n = 30)	p
0	30 (100.0%)	17 (56.7%)	0.000
>0	0 (0.0%)	13 (43.3%)	
1	0 (0.0%)	4 (13.3%)	
2	0 (0.0%)	4 (13.3%)	
3	0 (0.0%)	4 (13.3%)	
4	0 (0.0%)	1 (3.3%)	

Shivering score graded according to Wrench scale (0 = no shivering; 1 = no muscular activity with one or more of the following: piloerection, peripheral vasoconstriction, peripheral cyanosis without other cause; 2 = visible single muscle group activity; 3 = visible muscular activity in more than one muscle group; 4 = muscular activity involving whole body).

are predisposed to hypothermia during cesarean section with spinal anesthesia.

Forced air warming was used to prevent hypothermia but timing to start warming of the patient was a debate.^{4,12,13,23} Using a thermal gown or forced air warming blanket was unpractical for the mother and newborn bonding. Bernardis²³ studied the effect of thermal gown to maintain maternal hypothermia in combination with intravenous fluid infusion at 37°C and Cobb¹³ also studied active warming combined with intravenous fluids warmed to 41°C and they both concluded warmed fluid combined with forced air warming is effective in attenuating perioperative hypothermia incidence. Horn¹⁵ showed >1°C temperature difference promoting the use of active warming but his results could not be replicated by Fallis.²⁴ However Butwick reported the use of intraoperative forced air-warming was not sufficient to prevent intraoperative maternal hypothermia in patients undergoing cesarean section with spinal anesthesia. The conflicting results on active warming as a single intervention modality to reduce the decrease in maternal core temperature implies that the use of warmed intravenous fluids is the key in their success to prevent hypothermia.

Workhoven studied the effect of intravenous fluid warming on patients undergoing elective cesarean section with single injection lumbar epidural in a small group of patients.¹⁸ He reported no difference in patients' core temperature which is in contrast to our results. This may be due to the intravenous fluid used in the warmed fluid group was warmed up to 30–33.9°C which was still hypothermic. Second reason may be the small sample size of his study. And third, fentanyl was administered to 68% of patients in Group 1 and 73% of patients in Group 2. Administration of opioids may alter the threshold levels of thermoregulatory centers.¹⁹ Our results on the maintenance of core temperature with isothermic crystalloid warming was in accordance with the results of Woolnough and Yokoyama^{5,17} who reported the infusion of warmed fluids resulted in a reduced decrease in maternal core temperature when compared to control group.

Our primary endpoint was the core temperature at the end of the operation. In the current study, patients in the isothermic warmed group resulted in higher core temperatures than control group at the end of the operation. Previous studies evaluating the impact of warmed intravenous fluids used preload strategy to prevent regional anesthesia induced hypotension.

Shivering is reported to occur in up to 60% of patients under regional anesthesia. The mechanism of shivering under anesthesia is not clearly understood. Our intervention decreased the incidence of shivering (Table 3). The core temperature mean values were above 36°C in isothermic warmed crystalloid group at all measurement times and none of the patients shivered. In the control group, however, the mean core temperature was below 36°C 20 min after spinal anesthesia (Table 2) and 13 patients in control group (43.3%) shivered (Table 3). A previous study by Workhoven¹⁸ used warmed infusion as a single intervention modality and concluded that increased intravenous fluid temperature reduces the incidence of shivering.

There were no differences in fetal cord blood pH values and rectal temperature between groups. In a meta-analysis

by Sultan et al.,²⁵ 209 patient results were assessed for pH and they concluded that there were no significant difference in neonatal outcomes when comparing active warming to no warming, with the exception of umbilical artery blood pH. Although the pH values of umbilical arterial sampling was statistically different between the warmed infusion receiving group and the control group, venous cord blood sampling pH results were comparable between groups.

Apgar scores at first and fifth minute favored warmed infusion of crystalloids (Table 3). Although the difference in Apgar scores was statistically significant between groups, the difference does not imply to clinical condition in daily practice. Woolnough reported no difference in the Apgar scores between the control and the intervention group.¹⁷ The difference between the current study and that of Woolnough may arise from the time elapsed between the induction of spinal anesthesia and delivery. In our study time from the induction of anesthesia to skin incision was 3.4 ± 1.2 min and the delivery was completed within 6.9 ± 1.5 min whereas in the study by Woolnough, time from combined spinal epidural anesthesia to skin incision was 29 ± 5.1 min which is even longer than the time until the completion of surgery in our study. In the current study cesarean section time was 24.8 ± 8.8 min for the isothermic group whereas 78 ± 25 min for the hotline group of Woolnough.

The National Institute for Health and Clinical Excellence (NICE) guidelines states that intravenous fluids should be warmed to 37°C if the amount of infusion would exceed 500 mL to prevent inadvertent intraoperative hypothermia.²⁶ In the current study, intravenous fluids are warmed to 37°C to maintain core temperature of the parturients undergoing scheduled cesarean section with spinal anesthesia and the results of the study demonstrated that isothermic crystalloid warming is nice for the mother and the newborn.

There were some limitations in our study as we did not collect data for patient satisfaction or other possible adverse effects of spinal anesthesia as nausea and vomiting. In the current study warming intravenous crystalloids was the only active warming modality. Further studies are needed to assess the effect of combined use of active warming modalities on maternal and fetal outcomes.

In summary, our study results showed that hydrating the parturients with warmed crystalloids attenuates the incidence of intraoperative hypothermia and shivering and also increases the Apgar scores of the newborn.

Conflicts of interest

The authors declare no conflicts of interest.

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