

Effect of Intrathecal Bupivacaine kept at Room Temperature versus Body Temperature on Shivering during Lower Limb Orthopaedic Surgery under Spinal Anaesthesia: A Double-blind Randomised Controlled Trial

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ABSTRACT

Introduction: Perioperative shivering is very common after spinal anaesthesia. Shivering can cause discomfort, interfere with monitoring and lead to serious complications, particularly in patients with cardiorespiratory disorders.

Aim: To compare the effect of intrathecal bupivacaine at room temperature and body temperature on perioperative shivering in patients undergoing lower limb orthopaedic surgery.

Materials and Methods: This randomised, double-blind study was conducted at Uttar Pradesh University of Medical Sciences, Etawah, Uttar Pradesh, India, which included 70 patients of either sex, aged 18-65 years, classified as American Society of Anaesthesiologists (ASA) physical status I and II and scheduled for lower limb orthopaedic surgery under spinal anaesthesia. Patients were randomly allocated into two groups. All patients received a subarachnoid block with 3 mL of 0.5% bupivacaine heavy combined with 10 µg of fentanyl. Group W received the study drug stored at body temperature (35±1°C), while group C received the study drug stored at room temperature (20±1°C). The primary outcome measured was the incidence of shivering; the secondary outcomes measured were the onset and severity

of shivering and changes in body temperature. Side-effects of spinal anaesthesia, including bradycardia, hypotension, nausea and vomiting, were also noted. Data were expressed as mean and standard deviation for continuous variables and numbers and percentages for categorical variables. An independent t-test was used to compare the means between the groups and a Chi-square test was used for categorical variables.

Results: Both groups were comparable in terms of demographic parameters such as age, weight and height (p-value >0.05) as well as haemodynamic status. The incidence of shivering was 11 (31.43%) patients in group W and 25 (71.43%) patients in group C; the difference was statistically significant (p-value <0.001). The onset time of shivering in group W was 13 minutes compared to four minutes in group C (p-value=0.015). In group C, 40% of patients developed shivering of grade more than one, compared to 22.86% in group W.

Conclusion: Warming intrathecal bupivacaine to body temperature significantly reduces the incidence, delays the onset and decreases the severity of perioperative shivering in patients undergoing lower limb orthopaedic surgery under spinal anaesthesia, compared to bupivacaine administered at room temperature.

Keywords: Hypothermia, Incidence, Local anaesthetics

INTRODUCTION

Bupivacaine is an amide local anaesthetic characterised as a pipercoloxylidide. It is available as a racemic mixture, containing equal proportions of the S and R enantiomers. Bupivacaine hydrochloride is used for infiltration anaesthesia, as well as for peripheral, sympathetic nerve and epidural block anaesthesia. The onset of action of bupivacaine is within 20-30 minutes and the duration of action can last up to 360-720 minutes [1].

The autonomic nervous system maintains core body temperature between 36.5 and 37.5°C through physiological and behavioural changes. Anaesthesia causes a phase-like decline in core temperature, with phase 1 being the greatest at 30 minutes, phase 2 occurring after one hour and phase 3 happening after 3-5 hours, with reduced heat loss until equilibrium is reached. Due to exposure to the cold atmosphere of the operating room, the direct suppression of thermoregulation by anaesthetics, the use of cold intravenous fluids and slowed metabolism, core body temperature decreases under anaesthesia [2]. Hypothermia can lead to perioperative shivering,

which can curtail immunity, cause coagulopathy and increase the risk of cardiac morbidity [2,3].

Shivering is an involuntary, rhythmic muscular activity that increases metabolic heat production above the basal metabolic level by 600%. Up to 55% of individuals who receive spinal anaesthesia experience shivering as a complication. Shivering during anaesthesia can be managed using both non pharmacological and pharmacological techniques. Despite extensive research, it remains uncertain how to prevent and treat shivering following spinal anaesthesia due to the unclear aetiology [4,5]. While many discussions are ongoing, no consensus has been reached [6-9]. There is very limited research on the effect of the temperature of local anaesthetic on shivering after spinal anaesthesia [10].

The purpose of this study was to evaluate the hypothesis that "intrathecal bupivacaine at body temperature is associated with less shivering than intrathecal bupivacaine at room temperature during lower limb orthopaedic surgery under spinal anaesthesia."

MATERIALS AND METHODS

This randomised double-blind control study was conducted at Uttar Pradesh University of Medical Sciences, Etawah, Uttar Pradesh, India, between November 2021 and November 2022 after receiving approval from the UPUMS, Saifai ethical committee (ethical clearance number: 150/2020-21 dated 21-06-2021) and informed consent from all the patients.

Inclusion criteria: Patients with the ASA Physical Status (ASA-PS) classification I and II, aged 18 to 65 years, scheduled for lower limb orthopaedic surgery under spinal anaesthesia were included in this study.

Exclusion criteria: Patients with spinal abnormalities, mental retardation, neurological problems, cardiorespiratory illnesses, coagulation disorders, or those using anticoagulant drugs; those with hypersensitivity to local anaesthetics; and those with a localised infection at the block site. Patients requiring blood transfusions and those whose body temperatures were recorded as lower than 36.5°C or greater than 38°C preoperatively, were also excluded from the study.

Sample size: The sample size was calculated using the following formula:

$$n = 2 \times (Z_{\alpha/2} + Z_{1-\beta})^2 \times \sigma^2 / (\mu_1 - \mu_2)^2$$

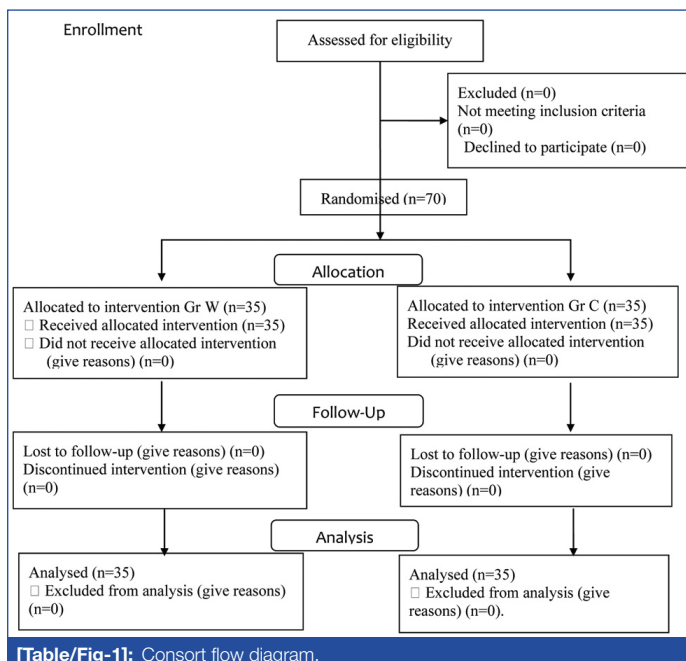
$$= 2 \times (1.96 + 0.84)^2 \times (2.9)^2 / (2)^2$$

$$= 2 \times 7.84 \times 8.41 / 4 = 32.9$$

where n=sample size per group, $Z_{\alpha/2}$ =standard normal z-value for significance level $\alpha=0.05$, $Z_{1-\beta}$ =standard normal z-value for the power of 0.8, μ_1 =mean effect at baseline, μ_2 =mean effect after the drug is administered and σ =standard deviation.

Study Procedure

Randomisation was conducted by generating a random number table for 70 patients [Table/Fig-1] and concealment was achieved using sequentially numbered opaque sealed envelopes. Patients were allocated to one of two groups. In group W, patients received 3 mL of 0.5% bupivacaine heavy with 10 µg of fentanyl stored at body temperature (35±1°C), while in group C, patients received 3 mL of 0.5% bupivacaine heavy with 10 µg of fentanyl stored at room temperature (20±1°C). In this study, group C was considered the control group. The injection of fentanyl and syringes were also stored at the same temperature as the study drug. Both the patients and the anaesthesiologist involved in the study were unaware of the group allocation. A designated nurse, who was not involved in the patient care in the operating room, prepared the study drug.



[Table/Fig-1]: Consort flow diagram.

The nurse opened the opaque sealed envelope containing the group allocation and drew the study medication into syringes. The investigators were not given access to the randomisation codes until all patient measurements and computations was recorded in the database. All data were entered into an Excel sheet before the randomisation series was decoded.

The operating room temperature was maintained at 20±1°C for all cases and all intravenous fluids were prewarmed to 35±1°C. The fluids were transferred directly to the operating room from the fluid warming cabinet. An in-line fluid warming system was not used. After the preanaesthesia assessment, the patients were shifted to the operating theatre. Preloading was conducted with 10 mL/kg of warm Ringer's lactate after securing an 18 G intravenous cannula.

Standard ASA monitors, such as the Electrocardiogram (ECG), non invasive blood pressure monitor, pulse oximetry and temperature probes, were connected and monitored throughout the surgery. Both rectal and peripheral temperatures were recorded. The core temperature was measured using a rectal probe, while the peripheral temperature was measured using an axillary probe. A soft rectal temperature probe compatible with the Mindray temperature module 5 was gently inserted into the rectum to a predetermined length (10-12 cm) after lubricating the probe with a local anaesthetic jelly. Additionally, another skin temperature probe was applied to the axilla to measure the peripheral temperature.

After all aseptic precautions, a subarachnoid block was performed at the L3-L4/L4-L5 intervertebral space using a 25 G Quincke needle in a sitting position. The study drug was injected according to group allocation after confirming free flow of Cerebrospinal Fluid (CSF). This time was considered as time zero. For blinding purposes, a separate anaesthetist who was not involved in the study performed the spinal procedure.

The height of the sensory block was assessed using cotton soaked in 70% isopropyl alcohol and the maximum height attained was noted. Block success was defined as a lack of sensation to pinprick up to T10-T12. The modified Bromage scale was used to evaluate motor blockade (Grade 0: No motor block; Grade 1: Inability to raise the extended leg, but able to move the knees and feet; Grade 2: Inability to raise the extended leg and move the knee, but able to move the feet; Grade 3: Complete motor block of the lower limbs).

Haemodynamic parameters (heart rate, respiratory rate, non invasive blood pressure, pulse oximetry and temperature) were continuously monitored throughout the surgery and data entry for temperature was carried out. The temperature values for both rectal and axillary sites were noted every 10 minutes. The patient was covered with a cotton blanket throughout the procedure, as forced air warmers were unavailable. The patient was closely observed for the onset and grades of shivering during the intraoperative period. Shivering was defined as the presence of fasciculation in the face, chest and limbs for at least 15 seconds and it was graded using a 4-point scale by Vanderstappen and Vandermeersch [Table/Fig-2] [11]. The time of onset and grade of shivering were recorded.

Grading	Characteristics
Grade 0 (None)	No perceptible tension of muscles was observed.
Grade 1 (Mild)	Slight muscle tonus of masseter muscle.
Grade 2 (Moderate)	Real shivering of proximal muscles.
Grade 3 (Severe)	Generalised shivering of the whole body.

[Table/Fig-2]: Vanderstappen and Vandermeersch shivering scale [11].

For a shivering grade of more than 2, Inj. Tramadol 0.5 mg/kg was administered intravenously. Any episodes of bradycardia, hypotension, nausea and vomiting were noted. A heart rate of less than 20% of baseline was defined as bradycardia. Injection atropine 600 µg was given intravenously if the heart rate fell below 50 beats per minute. Hypotension, characterised by a reduction

in Mean Arterial Pressure (MAP) exceeding 20% from baseline, was managed with intravenous crystalloids and a 6 mg bolus of intravenous mephentermine. If any patient developed nausea and vomiting, intravenous metoclopramide 10 mg was administered. Patients were monitored postoperatively for up to two hours after surgery and were also observed for any episodes of recurrence of shivering.

STATISTICAL ANALYSIS

The statistical data analysis was performed using the Statistical Package for the Social Sciences evaluation version 17.0 (SPSS, Inc., Chicago, IL, USA). Data were expressed as mean and standard deviation for continuous variables and as numbers and percentages for categorical variables. An Independent t-test was used to compare the means between the groups, while a Chi-square test was applied for categorical variables. Changes in rectal and peripheral temperatures, as well as haemodynamic parameters between the groups from baseline over time, were analysed using factorial repeated measures Analysis of Variance (ANOVA). A p-value of 0.05 or less was considered significant for statistical analysis.

RESULTS

All enrolled participants completed the study and none were excluded until the end of the trial. Both groups were comparable in terms of demographic and clinical characteristics. Statistically, no significant differences were observed in age, weight, height, Body Mass Index (BMI), duration of surgery, ASA grade and the modified Bromage scale [Table/Fig-3]. Out of 35 patients in each group, shivering was reported in 11 (31.4%) patients in group W and in 25 (71.4%) patients in group C. The mean time of onset of shivering was shorter in group C (4.71±9.92 minutes) compared to group W (13.29±20.51 minutes) (p-value <0.015) [Table/Fig-4].

Demographic parameters		Group W (n=35) Mean±SD	Group C (n=35) Mean±SD	p-value ¹
Age (years)		41.00±13.42	37.49±12.41	0.130
Weight (kg)		54.86±4.33	56.34±4.26	0.076
Height (cm)		153.89±3.2	155.14±4.51	0.092
BMI (kg/m²)		23.15±1.5	23.42±1.71	0.244
Duration of Surgery (mins)		113.29±29.73	105.86±28.91	0.147
ASA class, n (%)	I	21 (60)	23 (65.7)	0.771
	II	14 (40)	12 (34.3)	
Modified Bromage Scale, n (%)	Grade II	13 (37.1)	15 (42.9)	0.808
	Grade III	22 (62.9)	20 (57.1)	

[Table/Fig-3]: Distribution of demographic characteristics of the patients.
¹Unpaired Student t-test for age, Weight, Height, BMI and duration of surgery, Chi-square test for ASA class and Bromage scale, Group W=Warm bupivacaine group (35°C); Group C=Cold bupivacaine group (20°C), ASA: American society of anaesthesiologists; BMI: Body mass index; SD: Standard deviation

Variables	Group W (n=35)	Group C (n=35)	p-value ¹
Incidence of shivering (%)	11 (31.4)	25 (71.4)	<0.001*
Onset time of Shivering in min (Mean±SD)	13.29±20.51	4.71±9.92	0.015*

[Table/Fig-4]: Incidence and onset time of shivering.
¹Unpaired Student t-test for onset time of shivering and Chi-square test for incidence of shivering, *=statistically significant, SD=Standard deviation, Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C)

Significantly higher grades of shivering were noted at 5, 10, 15 and 20 minutes after spinal anaesthesia in group C compared to group W, as shown in [Table/Fig-5]. In group W, grade 1 shivering was present in 14.3% of patients, while grade 2 shivering was seen in 22.9%. In group C, grade 1 shivering was present in 31.4%, grade 2 shivering in 28.6% and grade 3 shivering in 11.4% of patients, though the differences were not statistically significant (p>0.05) [Table/Fig-6].

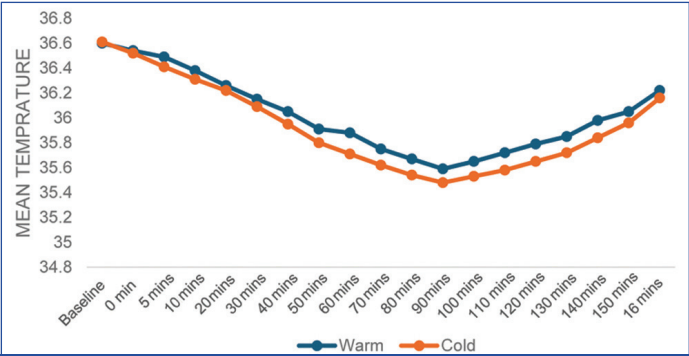
Shivering grade	Group W (n=35) Mean±SD	Group C (n=35) Mean±SD	p-value ¹
Baseline	0	0	-
At the time of spinal	0	0	
Just after spinal	0	0.11±0.47	0.078
5 mins	0.06±0.34	0.89±1.3	<0.001*
10 mins	0.06±0.34	1.06±1.3	<0.001*
15 mins	0.06±0.34	0.74±1.17	<0.001*
20 mins	0.11±0.53	0.57±1.04	0.012*
25 mins	0.11±0.53	0.29±0.89	0.166
30 mins	0.26±0.74	0.26±0.9	0.485
40 mins	0.35±0.98	0.71±1.29	0.104
50 mins	0.35±0.98	0.68±1.27	0.122
60 mins	0.32±0.84	0.50±0.93	0.208
70 mins	0.12±0.54	0.18±0.58	0.321
80 mins	0.24±0.79	0.19±0.6	0.391
90 mins	0.17±0.65	0.41±1.05	0.148
100 mins	0.13±0.61	0.41±1.1	0.140
110 mins	0.11±0.46	0.30±0.8	0.181
120 mins	0	0.13±0.52	0.163
130 mins	0	0	
140 mins	0	0	
150 mins	0	0	
160 mins	0	0	

[Table/Fig-5]: Comparison of mean grading of shivering in both groups at various time points.
Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C), ¹=Anova test, *Significant p<0.001

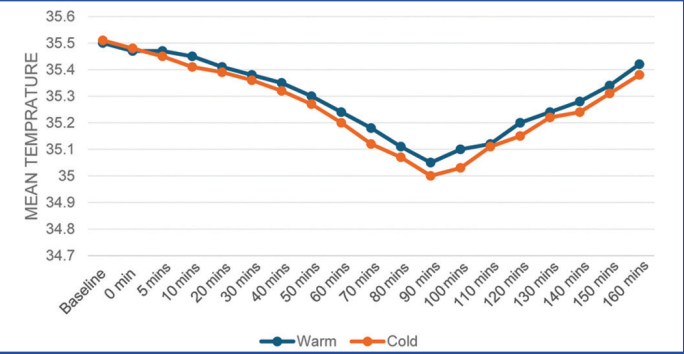
Grade of shivering	Group W (N=35) n (%)	Group C (N=35) n (%)	p-value ¹
	n (%)	n (%)	
Grade 0	22 (62.9)	10 (28.6)	0.008*
Grade 1	5 (14.3)	11 (31.4)	0.154
Grade 2	8 (22.9)	10 (28.6)	0.78
Grade 3	0	4 (11.4)	0.35

[Table/Fig-6]: Grades of shivering between the groups.
¹Chi-square test, *=statistically significant, Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C),

Both baseline peripheral and rectal temperatures were comparable. The temperature recordings showed a decreasing trend in both groups over time, which was more pronounced in group C, as shown in [Table/Fig-7,8], although this was not statistically significant. Nineteen patients in group W and three patients in group C had sensory block levels up to T6. T8 level sensory blockage was present in 15 patients in group W and 24 patients in group C. Eight patients in group C and one patient in group W experienced a sensory block level up to T10 [Table/Fig-9].



[Table/Fig-7]: Change in rectal temperature at different time intervals after spinal anaesthesia.
All temperatures were measured in degree Celsius and expressed as mean. Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C)



[Table/Fig-8]: Change in peripheral temperature at different time intervals after spinal Anaesthesia.
All temperatures were measured in degree Celsius and expressed as mean, Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C)

Level of sensory block	Group W (n=35)	Group C (n=35)	p-value
	n (%)	n (%)	
T-6	19 (54.3%)	3 (8.6%)	<0.001*
T-8	15 (42.9%)	24 (68.6%)	0.015*
T-10	1 (2.9%)	8 (22.9%)	0.006*

[Table/Fig-9]: Level of block achieved in two groups.
*Chi-square test, *statistically significant, Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C), T thoracic level

Nausea was observed in five patients (14.3%) in group W and three patients (8.6%) in group C. Hypotension was observed in six patients (17.2%) in group W and four patients (11.4%) in group C. The mean values were not statistically significant [Table/Fig-10]. No patient had a recurrence of shivering in either group.

Side-effects	Group W (n=35)	Group C (n=35)	p-value ¹
	n (%)	n (%)	
Nausea and vomiting	5 (14.3%)	3 (8.6%)	0.226
Hypotension	6 (17.2%)	4 (11.4%)	0.247

[Table/Fig-10]: Comparison of side-effects among two groups.
¹Chi-square test, Group W=Warm bupivacaine group (35°C) Group C=Cold bupivacaine group (20°C)

DISCUSSION

Shivering is a common challenge for anaesthetists. It is an involuntary oscillatory muscular activity that increases metabolic heat production and acts as a compensatory mechanism for core hypothermia. Clinically, it is associated with hyperactivity of the skeletal muscles at different frequencies (clonic or tonic). While under spinal anaesthesia, changes in body temperature and hypothermia are primarily caused by three main mechanisms. The first mechanism is vasodilation resulting from the sympathetic block, which causes heat to shift from the central to the peripheral areas of the body. The second mechanism is the loss of thermoregulation; temperature-related sensory input cannot travel from blocked areas to the brain, leading to altered thermoregulation. A decrease in the thresholds for shivering and vasoconstriction has been observed with spinal block. The third mechanism involves increased heat loss due to reduced thermoregulatory vasoconstriction below the level of the sympathetic block [12].

Depending on the patient's age and the extent of the sensory block, this effect is greatest in the first 60 minutes, resulting in a core body temperature drop of approximately 1-2°C [13]. In addition to being uncomfortable, this increased muscle activity can lead to hypoxemia, hypercarbia and lactic acidosis, which may be detrimental to patients with poor cardiopulmonary reserve [6]. Present study compared the impact of changes in the temperature of intrathecal bupivacaine on shivering.

In the present study, group C exhibited a higher incidence of shivering (71.4%) compared to group W (31.4%) and this difference was statistically significant. Present study findings were in line with

a previous study by Al-Mandhari KM et al., who noted that the cold bupivacaine group had a greater incidence of shivering. They reported shivering in 31 (62%) patients in the room temperature group and in 7 (14%) patients in the body temperature group, which was statistically significant (p-value=0.0001) [13]. This was consistent with a study conducted by Herniques K et al., who found that shivering was present in 57.5% of patients in group I (0.5% hyperbaric bupivacaine at 22°C) and in 32.5% in group II (0.5% hyperbaric bupivacaine at 37°C), with this difference also being statistically significant [14]. Similarly, Golboyu BE et al., recorded a higher incidence of shivering among the 37°C bupivacaine group compared to those in the 23°C bupivacaine group [15].

Shivering began earlier in group C than in group W in present study and this difference in onset was statistically significant. This aligns with the results of a previous study by Kishore N et al., who observed that shivering started earlier in a group that received intrathecal hyperbaric bupivacaine stored at 4°C than in a group that received intrathecal hyperbaric bupivacaine stored at 22°C during lower segment caesarean section surgeries [16]. Similarly, Elsharkawy RA et al., found that the onset of shivering was significantly earlier in the Levobupivacaine 24°C group compared to the levobupivacaine 30°C and levobupivacaine 37°C groups [17].

In group W, grade 1 shivering was observed in 14.3% of patients, grade 2 shivering in 22.9% of patients and grade 3 shivering in 0% of patients. In group C, grade 1 shivering was present in 31.42% of patients, grade 2 shivering in 28.6% of patients and grade 3 shivering in 11.4% of patients. This was similar to a study conducted by Malleswari R and Reddy KBV, which showed 22.5% of patients exhibited grade-I shivering, 20% grade-II, 12.5% grade-III and 2.5% grade-IV in group I (bupivacaine at 22°C). In group II (bupivacaine at 37°C), 15% showed grade-I shivering, 10% grade-II, 7% Grade-III and none exhibited grade-IV shivering [18]. Another study by Chalabi M et al., also found higher grades of shivering in patients receiving bupivacaine at lower temperatures [19].

Both basal peripheral and rectal temperatures were similar in both groups. Over time, both groups showed a decreasing trend in temperature of around 0.5°C to 0.6°C from the baseline, with a more pronounced decline in group C. The decrease in both rectal and peripheral temperatures in the two groups was comparable. These findings were consistent with a previous study by Thakur N et al., who investigated the effect of the addition of fentanyl to bupivacaine on shivering and measured peripheral and nasopharyngeal temperatures. The temperatures at which shivering was noted were not significantly different in both groups [2].

In the present study, the level of block showed statistically significant differences between the groups. Group W exhibited an increased cephalad level of the block compared to group C. The levels of block achieved at the T6, T8 and T10 levels in group W were 19, 15 and one patient, respectively, whereas in group C, the numbers were three, 24 and eight patients, respectively. This finding was consistent with the study conducted by Arai YC et al., who investigated the impact of spinal anaesthesia spread and the temperature of hyperbaric bupivacaine [20]. In their study, the viscosity and density of hyperbaric 0.5% bupivacaine were tested at 25°C and 37°C and the duration of spinal anaesthesia produced by these solutions was observed. They found that increasing the temperature of bupivacaine from 25°C to 37°C enhanced the cephalad level of spinal anaesthesia, which was reported to be statistically significant.

Callesen T et al., conducted a study on 30 patients using 0.5% bupivacaine at 4°C (group 1), room temperature (group 2) and 37°C (group 3). They found that in group 3, the height of the block was significantly greater than in groups 1 and 2. The different densities of bupivacaine 0.5% at 4°C, 20°C and 37°C seem to be the most reasonable explanation for these findings [21].

In present study, five patients in group W and three patients in group C experienced nausea or vomiting, while six patients in group W and four patients in group C experienced hypotension. However, these findings were deemed statistically insignificant.

Limitation(s)

This study was conducted exclusively on lower limb orthopaedic surgeries, which limits its generalisability to other populations. Additionally, the temperature of the study drug could have fluctuated during handling. Since we did not employ an inline warmer, it was impossible to determine the precise temperature of the warmed crystalloids that were administered. This could have resulted in variations in the temperatures of the fluids used for resuscitation. Further multicentric studies with larger sample sizes would facilitate the clinical extrapolation of the findings.

CONCLUSION(S)

It can be inferred that the onset of shivering was earlier and the incidence and grade of shivering were higher in group C (cold bupivacaine) compared to group W (warm bupivacaine). Group W demonstrated a higher level of sensory and motor block compared to group C. Therefore, warming intrathecal bupivacaine to body temperature before administration significantly reduces the incidence, delays the onset and lessens the severity of perioperative shivering in patients undergoing lower limb orthopaedic surgery under spinal anaesthesia. This approach represents a simple, effective and low-cost strategy to enhance patient comfort and safety.

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