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Effect of intravenous tramadol versus pethidine on postspinal shivering control among mothers during cesarean section at Wolaita Sodo University Comprehensive Specialized Hospital, Southern Ethiopia: a prospective observational cohort study

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Background: Postspinal anesthesia shivering is a common complication during spinal anesthesia. It is very unpleasant and physiologically stressful for patients and challenging for healthcare providers. Shivering could be treated with tramadol or pethidine. However, the comparative effectiveness of one drug over the other drug has not been proven with a low-drug setup.

Objective: To compare the effect of intravenous tramadol versus pethidine on postspinal shivering control among obstetric mothers who underwent cesarean section.

Methods and materials: A prospective cohort study design was conducted on 180 ASA (American Society of Anesthesiology) I and II obstetric mothers. A systematic random sampling method was employed. Data were entered into EpiData version 4.6 and exported into SPSS version 25 for analysis. The independent sample *t* test was used to compare the difference of means between groups for normally distributed data, and the Mann–Whitney *U* test was used for non-normally distributed data. Categorical data were analyzed using the chi-squared test. Data were presented by mean ± standard deviation for normally distributed data and median and interquartile range for non-normally distributed data. Categorical data were presented as numbers and frequencies. *P* values less than 0.05 were considered statistically significant.

Results: One hundred eighty participants were used for analysis. The mean time of shivering disappearance was 5.5 ± 1.75 min and 6.6 ± 2.08 min in tramadol and pethidine groups, respectively ($P < 0.001$). The hemodynamic changes were all comparable between the two groups. The difference in the recurrence of shivering after treatment was significant between the groups ($P < 0.001$). Sedation was higher in the pethidine group, 9 (10%), than in the tramadol group, 2 (2.2%). Nausea and vomiting were found to be higher in the tramadol group, 10 (11.1%), than in the pethidine group, 5 (5.6%).

Conclusions: Tramadol controlled shivering early, and recurrence of shivering and incidence of sedation were also low in the tramadol group. Therefore, tramadol is as effective as pethidine for the treatment of postspinal shivering in obstetric mothers who underwent cesarean delivery. So tramadol can be used as an alternative for postspinal shivering in obstetric mothers.

Keywords: cesarean section, Ethiopia, postspinal, shivering

Introduction

Shivering is a spontaneous, uncontrolled, and repetitive muscular activity that results from a fall in core body temperature[1–3]. Postanesthetic shivering is one of the most common complications encountered in clinical practice[4]. The best anesthetic for treatments involving the lower abdomen and lower limbs is spinal anesthesia, which is a central neuraxial block. The likelihood of postspinal anesthesia shivering (PSAS) varies by procedure, gender, age, and kind of anesthesia[5]. It is 40–60% in regional anesthetic patients and up to 60% in general anesthetic ones[6]. Although the exact mechanism is unknown, the proposed mechanism of shivering under spinal anesthesia is because of the redistribution of the intravascular volume from the core to the peripheral compartment below the level of sympathectomy[7]. If left untreated, shivering causes increased wound pain, delayed healing, and delayed discharge from the postanesthetic care

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unit[8]. It can cause interference in monitoring hemodynamic variables and electrocardiogram and increase oxygen consumption, carbon dioxide production, lactic acid production, and metabolic rate by 400%. An increase in heart rate, cardiac output, and blood pressure may cause problems in patients with low cardiac and pulmonary reserve[9].

Preventing and treating postanesthetic shivering is a crucial part of patient perioperative management due to the related negative effects[10–13]. The American Society of Anesthesiology (ASA) guidelines recommend forced air warming as a non-pharmacological method, and pethidine as a pharmacological method received the highest validation[14]. However, non-pharmacological techniques such as forced air warmers, blankets, and radiant heat are expensive and are not being practiced in all settings[5]. Pharmacological methods using various drugs like pethidine, clonidine, tramadol, doxapram, nefopam, dexmedetomidine, alfentanil, ketanserin, magnesium sulfate, etc. have been tried; these are simple, cost-effective and easily available[15]. These drugs were not included in the study as their effectiveness for shivering treatment was not supported by works of literature adequately and have not been used commonly for the shivering treatment in our study setup.

Pethidine is an agonist at both the μ-opoid and κ-opoid receptors and closely related to the pathogenesis of shivering by reducing the shivering threshold and triggering decreased core temperature, which constitutes its antishivering effect. Studies have shown that role of κ-opioid receptors is more significant than μ-opioid receptors in the treatment of postanesthetic shivering[16].

In addition to the fact that the shivering mechanism is poorly understood, the best standard for treatment and prevention is not known[17,18]. The use of pethidine and tramadol for the treatment of shivering is indicated by many studies. However, studies have not proven which of the two drugs is better concerning the treatment of shivering, its severity, and its adverse effects[19–21].

Although these medications have been used interchangeably to treat shivering, anesthetists have made this decision without considering the side effects, recurrence rate, or early shivering control. Because of this, our goal was to identify a medication that would stop shivering quickly after administration, have fewer adverse effects, and have a lower recurrence rate. The aim of this study is to compare the effectiveness of tramadol versus pethidine on PSAS.

HIGHLIGHTS

- Tramadol controlled shivering early.
- Recurrence of shivering and incidence of sedation were also low in the tramadol group.
- Tramadol can be used as an alternative for postspinal shivering in obstetric mothers.

Methods and materials

Study design, period, and area

An institution-based prospective cohort study was employed in Wolaita Sodo University Comprehensive Specialized Hospital from June 2021 to September 2021GC. The study was registered at https://www.researchregistry.com with the UIN: research registry 8640. The work has been reported in line with the STROCSS (strengthening the reporting of cohort, cross-sectional and case–control studies in surgery) criteria[22].

Inclusion criteria

Pregnant mothers of ASA class I and II who underwent either elective and emergency cesarean section (C/S) who developed grade II and above shivering following spinal anesthesia and were treated either with tramadol or pethidine were included in the current study.

Exclusion criteria

- Clients who developed shivering even before the administration of spinal anesthesia;
- Mothers treated with either of the two drugs before spinal for labor pain;
- Patients having opioid and steroidal premedication;
- Patients taking non-steroidal anti-inflammatory drugs (NSAIDs) and tricyclic antidepressants;
- Patients who have psychiatric disorders and are taking antipsychotic drugs.

Study variables

Time of controlling postspinal shivering, recurrence of shivering.

Independent variables

Sociodemographic variables, ASA physical status, operating room temperature, the experience of the surgeon, duration of surgery, amount of blood loss, body mass index, and parity.

Sample size determination

The sample size (n) for this study was determined by applying the formula which is applied in case data are on an interval/ratio scale, and the mean is a parameter of the study and user response time to treatment as the primary outcome variable. In a previous study, the mean (M) and standard deviation (SD) of each drug to control PSAS in the pethidine and tramadol groups were ($M = 4.45$, $SD = 3.18$) and ($M = 3.08$, $SD = 1.3$), respectively, at 95% CI and 80% power of the study[23].

Sample size (n):

$$n = \frac{\left(\sigma_1^{\,2} + \sigma_2^{\,2}\right)^2 \left(Z_{1-\beta} + Z_{1-\alpha/2}\right)^2}{d^2},$$

where d is the difference in means of the two groups (effect size); σ_1 is the SD of group 1; σ_2 is the SD of group 2; $Z_{1-\beta}$ is the desired power, 0.84; and $Z_{1-\alpha/2}$ is the critical value and a standard value for the corresponding level of confidence (at 95% CI it is 1.96, and at 99% CI, or 1% type I error, it is 2.58):

$$n = \frac{(3.18 + 1.3)^2 (0.84 + 1.96)^2}{(4.45 - 3.08)^2} = 82.$$

Adding 10% of the loss to follow-up, $n = 82 + 8 = 90$. Therefore, 90 subjects in each group with a total of 180 mothers in two groups, participated in the study.

Table 1

Comparison of demographic and clinical parameters between the two groups

Parameter	Tramadol group	Pethidine group	*P*
Age (median, IQR)	26 (22–30)	27 (25–30)	0.2
BMI (mean, SD)	(24.3 ± 17.12)	(24.93 ± 9.63)	0.56
Physical health status: ASA I:ASA II	72:18	65:25	
Parity: /nulli/primi/multiparous/	/13/43/34/	/7/34/49/	
C/S type: /elective/emergency/	/33/57/	/35/55/	
Fluid type given: /cold/warm/	/89/1/	/87/3/	
Fluid amount given: /below 1000/ 1000–1500/1501–2000/ 2001–2500/25 001–3000/	/0/20/63/7/	/3/19/64/4/	0.83
Blood loss: /below 500 ml/ 500–1000 ml/above 1000 ml/	/40/41/9/	/52/30/8/	0.56
Duration of surgery: /below 45 min/ 45–60 min/	/78/12/	/80/10/	0.69

IQR, interquartile range.

Sampling technique

From situational analysis, Wolaita Sodo University Comprehensive Specialized Hospital provides ~1210 caesarian section (C/S) services under spinal anesthesia annually. Utilizing systematic random sampling, each subsequent patient from both emergency and elective (C/S) was included in the study. The clients who developed grade II and above PSAS and received either of the treatment agents were observed in one of the two groups. They were followed for 60 min each until the required number of study participants was reached during the data collection period.

Data collection technique and instrument

English language structured questionnaires containing preoperative, intraoperative, postoperative, and sociodemographic information were developed from different literatures as well as assessment tools: classification of physical state by the American Society of Anesthesiologists (ASA)[24]. Five-point scale for grading shivering has been approved by Crossly and Mahajan[25]. Ramsay sedation score to determine the level of sedation[26]. To evaluate the effectiveness of treatment for PSAS, the visual suppression scale was employed[27].

Before data collection, training was given for four BSc in anesthesia data collectors and two MSc in anesthesia supervisors about the objective and process of data collection by the principal investigator. A pretested structured questionnaire was used for data collection. The data were collected using this structured questionnaire both from observation and the client's clinical response status during the follow-up period. After they were taken to the operating room, standard monitoring was applied, and baseline vital signs such as heart rate, mean arterial pressure (MAP), and peripheral oxygen saturation (SpO_2) were recorded before spinal anesthesia administration and then after at 10, 20, 30 through 60 min. The injection time was after the patient developed grade II and above shivering, and the patients were followed for 60 min in order to get adequate time to measure the recurrence rate of shivering and posttreatment side effects. The starting time of cessation of shivering and the complete cessation of shivering time was recorded. Then the drug that treated shivering early with few side effects and less recurrence rate was judged as effective. In both groups, the patients in whom shivering recurred were given the second dose of a similar drug. The patients were given 0.9% normal saline (NS), lactated Ringer's (LR) solution, oxytocin, and ergometrin after the baby was out as needed, and no adverse drug reaction occurred. Shivering cessation time, recurrence, side effects, and sedation were recorded.

Data quality control

Training and orientation were provided for data collectors and supervisors. During data collection, regular supervision and follow-up were undertaken. Supervisors checked questionnaires for completeness and consistency of data collected.

Data analysis and interpretation

Data were entered into EpiData version 4.6 and exported into SPSS version 25 for analysis. Data were tested for normality using the Shapiro–Wilk normality test, and homogeneity of variance was tested for normally distributed quantitative data. The independent sample *t* test and Mann–Whitney *U* test were used for quantitative data that are distributed normally and non-normally, respectively. The collinearity of predictor variables was also checked. The comparison of categorical parameters was analyzed using the χ^2 test. Data were presented as mean ± SD for normally distributed, median ± interquartile range (IQR) (25th–75th percentile) for non-normally distributed; and categorical data were presented as numbers, frequencies, and percentages. *P* values less than 0.05 were considered statistically significant.

Results

Participant's sociodemographic and preoperative parameters

A total of 180 ASA I and II pregnant mothers participated in the study. The results indicated a nonstatistically significant difference in the distribution of age ($P = 0.2$) and BMI ($P = 0.56$) between the two groups. The values of C/S type, ASA status, parity, amount of fluid administered, amount of intraoperative

Table 2

Comparison of shivering characteristics after treatment between the two groups

Parameter	Tramadol group	Pethidine group	*P*
Shivering cessation time (M ± SD)	(5.53 ± 1.756)	(6.63 ± 2.085)	< 0.001, $d = 0.404$
Reoccurrence of shivering, *n* (%)	16 (17.8)	25 (27.8)	0.001, $d = 1.93$
Grade of shivering /grade two/grade three/grade four/	/26/50/14/	/36/46/8/	0.35, $d = 0.2$
Sedation	2 (2.2%)	9 (10%)	
/Nausea only/nausea and vomiting/	/45/10/	/20/5/	
Dizziness, *n* (%)	6 (6.7)	2 (2.2)	

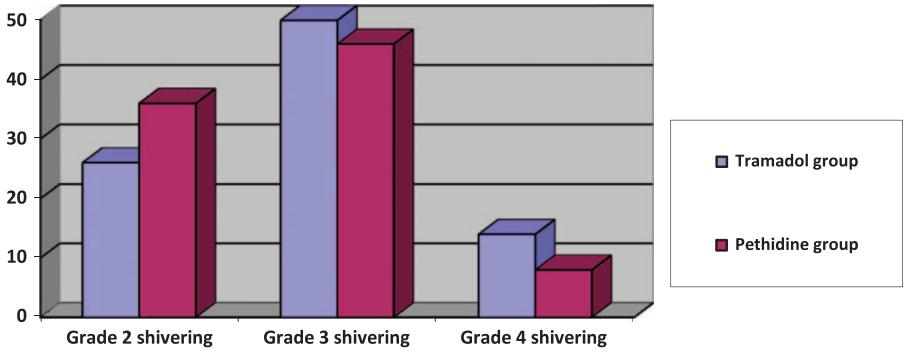

Figure 1. Distribution of severity of shivering before treatment between two groups.

blood loss, and duration of surgery between the pethidine and tramadol groups were also compared, and the differences were not statistically significant between the groups. The results indicated that 72 (80%) participants in the tramadol group and 65 (72.2%) in the pethidine group were those having ASA I health status (Table 1).

Shivering characteristics before and after treatment between the two groups

Recurrence of shivering was more common in the pethidine group, 25 (27.8%) than in the tramadol group, 16 (17.8%), and the difference was both statistically and clinically significant ($P < 0.001$, Cohen's $d = 1.93$). Sedation was also higher in the pethidine group, 9 (10%), than in the tramadol group 2 (2.2%), but nausea and vomiting were higher in the tramadol group. The difference in the severity of shivering distribution before PSAS treatment was not statistically significant but was clinically significant between the two groups (Cohen's $d = 2$). There were significant differences ($t(178) = 3.823$, $P < 0.001$, two-sided) in the score, with the mean score for the pethidine group ($M = 6.63$, SD = 2.085) being higher than that of the tramadol group ($M = 5.53$, SD = 1.756). The magnitude of the differences in the means (mean difference = 1.1, 95% CI: 0.533–1.667) was medium (Cohen's $d = 0.404$) (Table 2) (Fig. 1).

Comparison of hemodynamic parameters between the two groups

The mean difference in baseline MAP was not statistically significant between the two groups. However, it was clinically significant (Cohen's $d = 0.65$). The mean difference was statistically significant at 10 min after treatment throughout the follow-up period between the two groups (Table 3).

Comparison of body temperature between the two groups at different time intervals

The test outcomes in the following table demonstrate a statistically significant difference in baseline temperature across groups but only a small clinically meaningful difference between the two groups ($P = 0.022$, Cohen's $d = 0.24$). However, the difference in body temperature at different time intervals after treatment of PSAS was not significant both statistically and clinically between the two groups (Table 4).

Discussion

The current study found that the mean time of shivering disappearance was 5.5 ± 1.75 min and 6.6 ± 2.08 min in tramadol and pethidine groups, respectively ($P < 0.001$). The hemodynamic changes were all comparable between the two groups. The difference in the recurrence of shivering after treatment was significant between the groups. Sedation was higher in the pethidine group than in the tramadol group. Nausea and vomiting were found to be higher in the tramadol group than in the pethidine group.

The baseline hemodynamic parameters like heart rate, MAP, SpO_2, and body temperature were compared between the pethidine and tramadol groups. The results revealed that there was no statistically significant difference between the groups except for a clinically significant difference in the baseline MAP. In addition, hemodynamic parameters after treatment of PSAS were measured at different time intervals and were found to be comparable between the two groups except for a statistically significant difference in MAP at 10 min after treatment throughout the follow-up period. This difference may be attributed to stress-induced catecholamine release and noradrenaline reuptake inhibition action of tramadol[28].

Table 3

Comparison of mean arterial pressure (MAP) between the two groups

MAP	Tramadol group ($n = 90$)	Pethidine group ($n = 90$)	*t* value	*P*
Baseline MAP	(91.91 ± 10.65)	(93.01 ± 12.039)	0.65	0.52
MAP at 10 min	100.6 ± 85.5	93 ± 8.8	2.2	0.03
MAP at 20 min	89.38 ± 7.4	92 ± 8.14	2.3	0.023
MAP at 30 min	86.9 ± 7.76	91 ± 8.29	3.37	0.001
MAP at 40 min	84.8 ± 7.57	89.3 ± 8.4	3.75	0.001
MAP at 50 min	82.5 ± 7.4	88 ± 9.1	4.46	0.001
MAP at 60 min	81.9 ± 7.4	86.7 ± 8.9	3.85	0.001

Table 4

Comparison of body temperature at different time intervals

Body temperature	Tramadol group ($n=90$)	Pethidine group ($n=90$)	*t* value	*P*
Baseline temperature	36.4 ± 0.47	36.6 ± 0.43	2.3	0.022
Temperature at 10 min	36.5 ± 0.22	36.5 ± 0.4	1.4	0.15
Temperature at 20 min	36.47 ± 0.21	36.4 ± 0.38	0.21	0.83
Temperature at 30 min	36.3 ± 0.2	36.3 ± 0.37	0.46	0.64
Temperature at 40 min	36.3 ± 0.37	36.2 ± 0.36	0.7	0.48
Temperature at 50 min	36.2 ± 0.19	36.1 ± 0.34	1.4	0.15
Heart rate at 60 min	36.1 ± 0.17	36.1 ± 0.44	0.16	0.87

In the present study, shivering disappeared earlier in the tramadol group (5.53 ± 1.75 min) than in the pethidine group (6.63 ± 2.085 min), with $P < 0.001$. The mean difference between the groups was both statistically and clinically significant ($P = 0.001$, Cohen's $d = 1.93$). A recent prospective cohort study conducted on a similar topic in Ethiopia revealed results comparable to those of the present study[23]. These results were also in line with the results of the study done by Talakoub and Noori[29] and the study done in Bangladesh[30]. Similarly, tramadol is more effective in comparison to pethidine for the control of shivering, as noted by earlier studies[31,32]. Furthermore, tramadol is considered to be more effective than pethidine in shivering control, as evidenced by a study conducted by Dhimar and colleagues and another similar study[5,33]. In contrast to the current study, earlier research evaluated the superiority of one medicine over another for controlling shivering across intervals of 10 and 15 min. In order to compare the relative efficacy of one medication versus another in controlling shivering, this study examined mean time difference, the incidence of side effects, recurrence, and severity of shivering prior to treatment rather than durations of 10 and 15 min.

A relatively higher mean time difference in this study compared to the previous study could be attributed to the inclusion of mothers who underwent elective and emergency cesarean sections. Recurrence of shivering was more frequent in the pethidine group (27.8%) than in the tramadol group (17.8%), which was a finding similar to results reported by Al Maruf *et al.*[30]

Regarding side effects, the current study showed that the incidence of sedation was higher in the pethidine group (10%) than in the tramadol group (2.2%). This finding is similar to the results of a previous study in Ethiopia[23]. However, this is contrary to a study result by Talakoub and Noori[29]. The finding of this study also indicates that nausea and vomiting occurred more frequently in the tramadol group (11.1%) than in the pethidine group (5.6%), but the difference was not significant ($P > 0.05$). This result is in line with a study done by Fern La *et al.*[34] The difference may be due to the direct effect of tramadol on the chemoreceptor trigger zone in the brain, thereby stimulating vomiting through activation of the μ-opoid receptor. Contrary to this, the study done by Manouchehrian *et al.*[33] and another study indicated that pethidine could increase the incidence of nausea and vomiting and induce respiratory depression[35].

Strength of the study

The relatively large sample size and employing the probability sampling method are strengths of the present study. The homogeneity of the study participants could increase the validity of the results.

Limitations of this study

The present study did not tightly control the various factors which might have an effect on the incidence of shivering, like the temperature of drugs, intravenous fluids, and blood and the temperature of the operating room. However, this may not have affected the validity of the results since the current study focused on the response rate after treatment rather than the incidence of shivering and, by randomization, the two study groups were subjected to a similar degree of influence of these factors. The study design employed was not as strong as clinical trials.

Conclusion

In this study, early disappearance and less recurrence of shivering, and minimum side effects were observed in the tramadol group compared to the pethidine group. Due to its weak sedative property, mothers in the tramadol group remained fully alert and awake, which facilitated maternal–newborn bonding after delivery. In addition, shivering ceased earlier in the tramadol group despite the greater number of participants with a higher shivering grade in the pethidine group. Therefore, we conclude that the fact that tramadol 'can be' as effective as pethidine with reduced side effects, which can potentially increase its clinical benefits. So, tramadol can be used as an alternative for postspinal shivering in obstetric mothers.

Ethical approval

The study protocol was approved and ethically cleared by the Institutional Review Board of Wolaita Sodo University, College of Medicine and Health Sciences.

Consent

Informed written consent was obtained from every participant.

Sources of funding

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Author contribution

M.M. and G.D.: conception, study design, execution, acquisition of data, analysis, and interpretation of data and took part in drafting the article or revising it critically for important intellectual content; Z.Z., W.A., M.T., B.D., M.S., M.G., M.Y.,

T.D. and A.S.: study design, execution, acquisition of data, interpretation, drafting, and final manuscript writing.

Conflicts of interest disclosure

The authors declared that they have no conflicts of interest.

Data availability statement

Datasets used and analyzed during the study are accessible from the authors upon reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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