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Original Research Article

Comparison of effect of intravenous tramadol and low dose ketamine in the attenuation of post spinal anaesthesia shivering following caesarean section: a double blinded randomised trial

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ABSTRACT

Background: Intraoperative shivering is a common complication in patients undergoing caesarean section under spinal anaesthesia (SA). Various pharmacological agents including tramadol and ketamine have been used for the management of intraoperative shivering.
Methods: This double-blinded randomized trial included a total of 72 patients scheduled for elective caesarean section under SA. Patients were randomly assigned to one of two groups: Group T (received tramadol 0.5 mg/kg intravenous) and group K (received ketamine 0.2 mg/kg intravenous). The primary outcome measure was the cessation of shivering after study drug administration. Secondary outcome measures included hemodynamic changes and adverse effects of study drugs.
Results: The study compared the effects of intravenous tramadol and ketamine for treating intraoperative shivering during caesarean section under SA. Among 72 patients, tramadol 0.5 mg/kg was used in 36 patients and ketamine 0.2 mg/kg in 36 patients. The time to cessation of shivering was less with group T (2.59±0.54 s) than with group K (7.77±1.13 s). The recurrence rate of shivering with group T was significantly less (8.3%) as compared to group K (58.3%) with comparable hemodynamic parameters. No adverse effects were seen in both groups except for sedation among some in the ketamine group.
Conclusions: Tramadol offers rapid onset and less recurrence rate of shivering with no sedation as a side effect when compared to ketamine. More studies of different dose ranges of the study drugs in different surgeries need to be conducted in order to cement its position as an efficient anti-shivering agent.

Keywords: Ketamine, Tramadol, Caesarean section, Post-spinal shivering, Spinal anesthesia

INTRODUCTION

Shivering is a known complication, reported in 40 to 70% of patients undergoing surgery under SA. It can be unpleasant and physiologically stressful for the patients.[1] Shivering is defined as a spontaneous, involuntary and repetitive muscular activity. It is a common problem during and after SA due to vasodilation, which facilitates rapid heat loss from core to peripheral redistribution of body heat, which in turn results in hypothermia thus lowering the threshold for shivering.

The treatment of shivering includes both pharmacological and non-pharmacological methods. The non-pharmacological techniques which include external heating using forced air warming, warming blankets, warmed fluids etc. may not be sufficient to control the central hypothermia recovery which necessitates

pharmacological drug therapy for the prophylaxis and treatment of shivering after caesarean section.[2] Local anaesthetics impairs the centrally mediated thermoregulation by altering the afferent thermal inputs. The neurotransmitter pathways are complex and involves opioids, α-2 adrenergic, serotonergic and anticholinergic receptors. Therefore, drugs acting on these receptors could be utilized for the prophylaxis of shivering.[3] The choice of drugs is difficult considering the maternal and foetal safety.

Tramadol, an opioid receptor agonist, is an inhibitor of the re-uptake of serotonin (5-hydroxytryptamine) and norepinephrine in the spinal cord. This facilitates 5-hydroxytryptamine release, which influences thermoregulatory control. Presently it is a widely used drug for the control of shivering.[4] But tramadol may cause nausea and vomiting which is very distressing for the patient. Hence the need to find a better drug which has comparable efficacy to tramadol and at the same time has less of side effects. The aim of the study was to compare the efficacy of low-dose ketamine and tramadol in the treatment of post-SA shivering in parturient undergoing caesarean section under subarachnoid block.

METHODS

This randomized, double-blinded clinical trial was conducted in the department of anesthesiology, regional institute of medical sciences, Imphal, Manipur, India from May 2022 to June 2024. The trial was conducted after getting approval from research ethics board (REB), order no. A/206/REB COMM(SP)2015/846/184/2022, dated 29th November 2022. The trial was also registered at the clinical trials registry-India (CTRI) bearing no. CTRI/2023/08/056964 before the commencement of the study. Informed written consent were also taken from the patients concerned. Confidentiality was maintained at all levels of the study.

Inclusion criteria

Pregnant women of age group 18-45 years, American society of anesthesiologists (ASA) grade I-II undergoing elective caesarean section under spinal anesthesia were enrolled for the study.

Exclusion criteria

Patients with history of allergy to the study drugs (tramadol or ketamine), diabetes, hypertension, cardiovascular, respiratory, renal or neurological diseases, local site infection, spinal deformity and any bleeding disorder with platelet count <50,000/microliter, PT >14sec, INR >1.5 were excluded from the study.

Sample size calculation

Sample size was calculated based on the study conducted by Azam et al where the incidence of post-spinal shivering in the tramadol and ketamine group is 72% and 39% respectively.[5] Considering α value of 0.05 and power (1-β) of 80%, 36 patients were recruited for each group considering 5% drop out rate.

Procedure

Patients who fulfilled the inclusion criteria undergoing caesarean section under spinal anesthesia were explained about the purpose and procedure of the study and were enrolled after getting their written informed consents. An 18G IV cannula was secured into a vein on the dorsum of the patient's non-dominant hand and normal saline was given at 10 ml/kg. Electrocardiogram (ECG), heart rate (HR), non-invasive blood pressure (NIBP) and pulse oximetry were attached for standard monitoring. Room temperature, axillary (body) temperature and hemodynamic variables [blood pressure (BP), HR, pulse oximetry (SpO_2)] were recorded before SA. All the patients were not given any premedication. The operation room temperature was maintained at an ambient temperature of around 24°C-28°C.

Using block randomization, patient was allocated to one of the two groups. The study drug was prepared in 5ml syringe by an anaesthesiologist not directly involved in the study to keep the study blinded.

SA was given by using 25G Quincke spinal needle keeping the patient in the sitting position with the drug Inj. Bupivacaine 0.5% (Anawin heavy) 2 ml (10 mg). SA block was assessed using pinprick and Bromage scale for the desired sensory and motor block which was T6-T4 and Bromage scale 3 respectively. Then oxygen at 4L/minute was administered by face mask and patient was covered with drape, but not actively warmed. The study drug was administered as soon as the patient developed shivering. There were two groups of 36 patients each in the present study: Group T and group K. Group T patients received 0.5 mg/kg tramadol in 5 ml normal saline and group K patients received 0.2 mg/kg ketamine in 5 ml normal saline. Monitoring of the vital parameters such as heart rate (HR), blood pressure (BP), oxygen saturation (SpO_2), body temperature was done at every 5 minutes interval for the first 20 minutes and then every 10 minutes for the rest of the observation period.

The patient was closely monitored for signs of shivering at five-minute intervals during surgery and at ten-minute intervals after surgery for a period of one hour. The grading of the shivering was done as per scale by Tsai and Chu:[6]

In case of failure to control shivering by the study drug, pethidine (25 mg IV) was given as rescue drug after the delivery of fetus. Side-effects such as hypotension, nausea, vomiting, sedation and hallucination were recorded. The degree of sedation was assessed using the five-point scale by Abdelrahman:[7]

Table 1: Grade of shivering.

Grade of shivering	Clinical sign
Grade 0	No shivering
Grade 1	Piloerection or peripheral vasoconstriction, but no visible shivering
Grade 2	Muscular activity in only one muscle group
Grade 3	Muscular activity in more than one muscle group, but not generalized
Grade 4	Shivering involving the whole body

Table 2: Degree of sedation.

Score	Clinical sign
1	Fully awake and oriented patient
2	Drowsy
3	Eyes closed, arousable on command
4	Eyes closed, arousable to physical stimuli
5	Eyes closed and patients unarousable to physical stimuli

Data was collected in predesigned proforma. Baseline information like age, weight, HR, BP, SPO_2, temperature was recorded preoperatively. Intraoperatively, time of onset and disappearance of shivering, and the side effects were recorded in due time. The collected data were entered into IBM SPSS statistics version 21.0 [IBM Corp.1995,2012] for statistical analysis. Quantitative data like age, weight, height, temperature (both body and operating room), time of onset of shivering and hemodynamic parameters (BP, HR, SpO_2) were summarized in mean and SD (Standard deviation). Student's t-test was used to compare quantitative data like time of onset of shivering and hemodynamic parameters (BP, HR, SPO_2) between the groups. To compare qualitative data like grades of shivering, ASA grading and any side effects between the two groups, Chi-square test was applied and $p<0.05$ was considered as statistically significant.

RESULTS

The patients were randomly divided into two groups each having 36 patients where one group (T) was given tramadol 0.5 mg/kg intravenous and group (K) received intravenous ketamine 0.2 mg/kg.

The demographic parameters between the two groups were comparable with a $p>0.05$ as shown in Table 3.

Table 4 shows the pattern of mean arterial pressure (MAP) in group T and K over different time intervals after spinal anesthesia, taking 0 minute as baseline and up to 60 minutes. The MAP between the two groups was statistically insignificant.

Table 5 shows temperature recording at the baseline (0 minute) until 60 minutes after spinal anesthesia. The mean temperature at all stages after study drugs administration was found to be statistically insignificant at 5% probability level. The time to cessation of shivering was less with group T (2.59±0.54 s) than with group K (7.77±1.13 s).

The recurrence rate of shivering with group T was significantly less (8.3%) as compared to group K (58.3%) with $p<0.05$ as shown in Table 6.

Table 7 and 8 show that there was no nausea and vomiting in our study.

Table 3: Demographic parameters.

Parameters	Mean±SD			P value
	Group T, (n=36)	Group K, (n=36)	Total, (n=72)	
Age (in years)	28.33±4.40	26.67±4.30	27.5±4.40	0.109
Weight (Kg)	64.58±12.57	62.0±7.17	63.29±10.24	0.288
Height (cm)	153.5±1.5	153.41±1.72	153.45±1.61	0.829

Table 4: Group-wise mean±SD of MAP at different stages.

Parameters	Mean±SD			P value
	Group T, (n=36)	Group K, (n=36)	Total, (n=72)	
MAP 0	98.25±7.71	100.08±6.80	99.16±7.28	0.289
MAP 5	82.00±14.08	84.58±9.13	83.29±11.85	0.359
MAP 10	80.16±10.26	77.16±8.37	78.66±9.42	0.179
MAP 15	86.00±9.05	72.50±11.75	73.75±11.68	0.170
MAP 20	85.75±6.84	82.25±13.77	83.00±11.14	0.135
MAP 30	78.41±9.74	77.00±12.60	77.70±11.20	0.595
MAP 40	78.75±10.82	75.16±16.69	76.95±14.08	0.284
MAP 50	83.58±7.15	86.41±12.06	85.00±9.95	0.230
MAP 60	83.25±6.79	84.41±8.92	83.83±7.89	0.535

Table 5: Group-wise mean±SD of axillary body temperature at different stages.

Temperature (in mins)	Mean±SD			P value
	Group T, (n=36)	Group K, (n=36)	Total, (n=72)	
Temp 0	97.30±0.40	97.97±0.68	97.14±0.58	0.064
Temp 5	97.86±0.73	97.91±0.64	97.89±0.69	0.761
Temp 10	97.50±1.21	97.56±0.48	97.28±0.96	0.072
Temp 15	96.55±1.16	96.30±0.68	96.92±1.02	0.062
Temp 20	96.95±1.65	96.50±0.97	96.72±1.36	0.164
Temp 30	96.55±0.78	96.83±1.00	96.19±0.96	0.140
Temp 40	97.93±0.47	97.33±1.26	97.13±1.24	0.068
Temp 50	97.90±0.73	97.76±0.69	97.63±0.79	0.120
Temp 60	97.00±0.41	97.58±0.96	97.29±1.02	0.110

Table 6: Comparison of shivering in both groups.

Parameters	Mean±SD			P value
	Group T, (n=36)	Group K, (n=36)	Total, (n=72)	
Onset time of shivering (min)	17.08±7.30	27.78±9.96	22.43±10.20	0.000
Time of disappearance of shivering (min)	2.59±0.54	7.77±1.13	5.18±2.75	0.000
Time of recurrence of shivering (min)	4.17±14.01	29.17±26.33	16.67±24.43	0.000
% recurrence of shivering	3 (8.3%)	21 (58.3%)	24 (33.33%)	0.000

Table 7: Group-wise adverse effect (nausea).

Nausea time (in minute)		Group T, (n=36)	Group K, (n=36)	Total, (n=36)
N0	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N5	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N10	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N15	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N20	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N30	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N40	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N50	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0
N60	No nausea	36 (100%)	36 (100%)	72 (100%)
	Nausea	0	0	0

Table 8: Group-wise adverse effect (vomiting).

Vomiting (in minutes)		Group T, (n=36)	Group K, (n=36)	Total, (n=72)
Vom 0	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 5	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 10	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 15	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0

Continued.

Vomiting (in minutes)		Group T, (n=36)	Group K, (n=36)	Total, (n=72)
Vom 20	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 30	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 40	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 50	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0
Vom 60	No vomiting	36 (100%)	36 (100%)	72 (100%)
	Vomiting	0	0	0

Table 9: Group-wise adverse effect (sedation).

Sedation score		Group T, (n=36)	Group K, (n=36)	Total, (n=72)	P value
SED 0	1	36 (100%)	36 (100%)	72 (100%)	-
SED 5	1	36 (100%)	36 (100%)	72 (100%)	-
SED 10	1	36 (100%)	36 (100%)	72 (100%)	-
SED 15	1	36 (100%)	36 (100%)	72 (100%)	-
SED 20	1	36 (100%)	33(91.66%)	69 (95.83%)	0.239
	2	0 (0.0)	3 (8.33%)	3 (4.16%)	
SED 30	1	36 (100%)	30 (83.33%)	66 (91.66%)	0.025
	3	0 (0.0)	6 (16.66%)	6 (8.33%)	
SED 40	1	36 (100%)	30 (83.33%)	66 (91.66%)	0.038
	2	0 (0.0)	3 (8.33%)	3 (4.16%)	
	3	0 (0.0%)	3 (8.33%)	3 (4.16%)	
SED 50	1	36 (100%)	30 (83.33%)	66 (91.66%)	0.025
	2	0 (0.0%)	6 (16.66%)	6 (8.33%)	
SED 60	1	36 (100%)	36 (100%)	72 (100%)	-

Table 9 shows the comparison of adverse effects of sedation among the group T and K. On 0^{th}, 5^{th}, 10^{th}, 15^{th} and 60^{th} minutes after administration of study drug no sedation was present. On the contrary, at 20^{th}, 30^{th}, 40^{th} and 50^{th} minutes sedation was present in group K.

DISCUSSION

Postoperative shivering is one of the unwanted and common complications during both spinal and general anesthesia. In addition to the fact that shivering is poorly understood, the gold standard for the treatment and prevention of shivering has not been defined yet.[8] Though the exact mechanism of shivering during spinal anesthesia has not been fully recognized, the possible mechanisms include impairment of central thermoregulation, internal redistribution of body heat and heat loss to the environment. Potential risk factors for hypothermia in spinal anesthesia include ageing, level of sensory block, temperature of the operation theatre and IV fluids.[9] In this study, operation theatre was maintained at ambient temperature of 24-28°C and all fluids and drugs were kept at room temperature during the surgery.

The neurotransmitter pathways involved in shivering are multiple and involve opioids, α2 adrenergic agonists, serotonergic and anticholinergic receptors. Hence drugs acting on these systems which includes opioids (pethidine, tramadol or nalbuphine), propofol, ketamine, clonidine and nefopam are utilized in the treatment of shivering. Many studies have been done in the past to compare different drugs for the prevention and treatment of the post spinal shivering but till now no drug for the treatment of post spinal shivering has been standardized.

In our study, we have taken 72 patients who were divided into two groups, group T received 0.5 mg/kg tramadol and group K received 0.2 mg/kg ketamine intravenous after the onset of shivering. The result of this study indicates that both tramadol and ketamine were effective for the control of post spinal anesthesia shivering. However, most of the patients had cessation of shivering after single bolus dose of tramadol compared to patients in ketamine group. Cessation of shivering was faster in tramadol group (2.59±0.54s) than ketamine group (7.77±1.13s). The percentage of recurrence of shivering was less with tramadol group (8.3%) compared to ketamine group (58.3%).

The findings in our study are in line with the study done by Zia Uddin et al on comparative study of tramadol versus ketamine for postoperative shivering which concluded that the frequency of intraoperative shivering with intravenous 1 mg/kg tramadol is less than 0.5 mg/kg ketamine in patients undergoing infra-umbilical surgery under spinal anesthesia.[10] According to the study done by Jouryabi et al

on comparing the effects of low dose of ketamine, tramadol, and ondansetron in prevention of post spinal anesthesia shivering in cesarean section, shivering was witnessed in 68(53.5%), 26(20.5%) and 75(59.1%) patients in K (ketamine 0.2 mg/kg IV), T (0.2 mg/kg tramadol IV) and O (Ondansetron 4 mg IV) group respectively, hence concluding tramadol as the most effective one, followed by a low dose of ketamine and ondansetron.[14] Their observations are in concurrence with the present study. In a study conducted by Faraz et al comparing the effects of low doses of ketamine (0.2 mg/kg) and tramadol (0.5 mg/kg) in the prevention of post-spinal anesthesia shivering in cesarean section found out that tramadol is the most effective medication for managing shivering, followed by a lower dosage of ketamine.[12]

Ahirwar et al also conducted a study on efficacy of intravenous tramadol and low-dose ketamine in prevention of post-spinal anesthesia shivering in lower segment caesarean section and concluded that low-dose intravenous ketamine (0.2 mg/kg) is more effective than tramadol (0.5 mg/kg) in reducing post-spinal shivering, with a lower incidence of intraoperative side effects.[13] Our study result is in line with the findings observed in a study conducted by Seyam and Hamdy on prevention of post-spinal anesthesia shivering: low-dose ketamine (0.2 mg/kg) versus tramadol (0.5 mg/kg) in which the study recommends low-dose IV ketamine or tramadol for post spinal shivering with high priority to tramadol (p=0.003).[14] The hemodynamics of the patients in our study were comparable in both the groups with the mean HR of 87.58±11.12-104.25±20.88 in group T and 86.58±11.46-97.91±16.51 in group K and the MAP ranging from 78.41±9.74-98.25±7.71 in group T and 75.16±16.69-100.08±6.80 in group K. These findings are in accordance with the study conducted by Seyam and Hamdy.[14] There was no case of nausea or vomiting in either tramadol or ketamine group. Few patients in ketamine group had sedation but there was no case of sedation in tramadol group. Similar findings were reported by the study conducted by Lema et al in which a few parturient who received 0.2 mg/kg intravenous ketamine for the prevention of post-spinal anesthesia shivering in caesarean section developed grade 2 sedation.[15] Ketamine causes hallucination and sedation, but these side effects are dose dependent. However, in the study conducted by Dal et al where 0.5 mg/kg ketamine was used for prevention of shivering and there were no side effects at this dose.[16] The anti-shivering effect of tramadol may be linked to serotonergic and noradrenergic effects or both.[17] It inhibits the neuronal uptake of nor-adrenaline and serotonin in the spinal cord and triggers the secretion of hydroxyl-tryptamine, which modulates the human temperature regulation center.

Ketamine is an NMDA receptor antagonist, also obstructs and averts peri-operative shivering. It is probable that NMDA receptor antagonist controls thermoregulation at different levels. Additionally, being competitive NMDA receptor antagonist, ketamine has numerous other properties. Consequently, it possibly controls shivering by non-shivering thermogenesis either by exploiting on hypothalamus or by β-adrenergic effects of nor-epinephrine. Ketamine causes direct central sympathetic stimulation and deters nor-epinephrine acceptance into post-ganglionic sympathetic nerve endings and can decline head-to-toe re-distribution of heat. Honarmand et al concluded that ketamine 0.5 mg/kg prophylactically was effective in prevention of postoperative shivering compared to placebo and reported frequency of shivering in ketamine group was 23.3% versus placebo 60%.[18] There is a significant disparity between the outcomes of different investigations due to disparities in methodology, the investigated populations, operating room settings, genealogy, fluid preheating, drug room temperature, and the extent of sensory block. Finally, it has been demonstrated that the degree of shivering in pregnant women is highly connected to their level of anxiousness before surgery.[19]

The major limitation of our study is the short duration of the surgeries as the mean duration of the surgeries was less than one hour in both the groups. Furthermore, failure to assess the neonatal outcome by Apgar score is another limitation of this study. Further studies are needed to know the effectiveness of tramadol 0.5 mg/kg IV and ketamine 0.2 mg/kg IV in other lower abdominal surgeries (non-parturient) as this study was done only in parturient undergoing cesarean section.

CONCLUSION

In conclusion, both tramadol (0.5 mg/kg IV) and ketamine (0.2 mg/kg IV) are effective in treating patients with post-spinal anesthesia shivering during cesarean section. However, the time taken for complete cessation of shivering was shorter with tramadol as compared to ketamine. The percentage of recurrence of shivering was less with tramadol as compared to ketamine, the difference being statistically significant. Furthermore, adverse effects like nausea and vomiting were not observed in both groups, except for sedation among some in the ketamine group. Hence, tramadol offers rapid onset, less recurrence and no sedation as a side effect when compared to ketamine.

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