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Comparison of Intravenous Ondansetron and Tramadol in Prevention of Post Anesthetic Shivering in Patients Undergoing Lower Segment Cesarean Section Under Spinal Anesthesia: A Prospective Observational Study

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ABSTRACT
Temperature regulation is a complex physiological process that involves the interplay of various mechanisms within the body to maintain a constant internal temperature. Shivering is a frequent undesirable and uncomfortable event in patients undergoing cesarean delivery under spinal anesthesia. Post anesthetic shivering has a multitude of deleterious effects and different methods have been used to prevent it. We therefore compared the efficacy of ondansetron to that of tramadol in preventing post anesthetic shivering in women undergoing cesarean section under subarachnoid block. Comparison of the efficacy of ondansetron to that of tramadol in preventing post anesthetic shivering in women undergoing cesarean section under subarachnoid block. A total of 70 pregnant female patients aged between 18-40 years with ASA II scheduled for lower segment cesarean section under spinal anesthesia were included in the study. Patients were allocated to 2 groups, Group A and B of 35 patients each. Patients enrolled in Group A (ondansetron group) received 0.1 mg kg^{-1} of ondansetron and those in Group B (tramadol group) received 0.5 mg kg^{-1} tramadol immediately after clamping the cord. The use of IV ondansetron and tramadol has proved significantly effective in prevention of post operative shivering in patients undergoing caesarean delivery under spinal anesthesia with significantly less incidence of shivering in tramadol group (8.6%) as compared to ondansetron group (31.4%). This study demonstrated that both ondansetron and tramadol are effective in prevention of shivering under spinal anesthesia in women undergoing cesarean section.

INTRODUCTION

Temperature regulation is a complex physiological process that involves the interplay of various mechanisms within the body to maintain a constant internal temperature. When the patient is under anesthesia, temperature regulation becomes especially important as surgical procedures can result in significant heat loss and subsequent hypothermia. The principal defense against hypothermia includes skin vasomotor activity, non-shivering thermogenesis, shivering and sweating[1]. Heat loss is normally regulated by cutaneous vasodilatation or vasoconstriction, sweating and shivering. Thermoregulatory shivering is thus a last resort defense that is activated only when behavioral compensations and maximal arterio-venous shunt vasoconstriction are insufficient to maintain core temperature[2].

Anesthesia abolishes behavioral mechanisms and has potential to disrupt the physiological mechanisms of thermoregulation[3]. One of the common responses to hypothermia in the post operative period is shivering, which can have adverse effects on patient's recovery and overall outcome. Post-operative shivering can lead to increase oxygen consumption by approximately 5 times, metabolic rate by 100-600 times[2,4] and catecholamine release which can all contribute to cardiovascular and pulmonary complications. Additionally, shivering can be very uncomfortable and distressing for patients leading to longer recovery times and decrease patient satisfaction[5]. Regional anesthesia (spinal anesthesia) is widely used as a safe anesthetic technique for both elective and emergency cesarean sections and shivering is known to be a frequent complication, reported in 40-70% of patients undergoing surgery under regional anesthesia[3]. Risk factors that predispose the patient to hypothermia and shivering include young age, male gender, low body weight or poor nutritional status, prolonged preoperative fasting, ASA risk class higher than I combined general-regional anesthesia and the extent of induced sympathetic blockade, administration of premedication, volatile anesthetics and muscle relaxants[6-11]. Likewise, intra-operative use of cold irrigation fluids[2], transfusion of cold red blood cells and the low temperature of the operating room[12] predispose the patient to hypothermia. However, in the postoperative period, mechanisms like uninhibited spinal reflexes, sympathetic over-activity, postoperative pain, adrenal suppression, pyrogen release and respiratory alkalosis[13] may also be important. Thus, understanding the causes, risk factors and management strategies for post operative shivering is essential for optimizing patient outcome and improving quality of care in the post operative period.

Various physical and pharmacological measures have been applied in the prevention and treatment of post spinal anesthesia shivering. The physical measures are essentially aimed at attenuating peri operative core hypothermia. They include application of radiant heat, use of warm ambient air, use of heated blankets, and use of warm intravenous fluids. These physical methods are however cumbersome, expensive and yield limited success in prevention of post operative shivering. Pharmacological agents that have been used in the prevention or control of shivering mainly consists of opioids such as pethidine, tramadol and butorphanol, the majority of which have undesirable effects, which make them unsuitable for use as anti shivering agents in the parturient. Others include ondansetron, ketamine, magnesium sulfate and alpha2 receptor agonists such as clonidine. Ondansetron, a 5HT3 receptor antagonist has generated much interest because of its excellent pharmacological profile. It is a drug with a wide therapeutic index and so is devoid of toxicity even in moderately supra-clinical doses[14].

This study was designed primarily to compare and evaluate the efficacy of ondansetron to that of tramadol in preventing post anesthetic shivering in patients undergoing cesarean section under spinal anesthesia and secondary aim was to compare sedation score between the two groups.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of anesthesiology and critical care, SKIMS, srinagar. After obtaining Institutional ethical clearance, a total of 70 pregnant female patients after a thorough and detailed history and physical examination, randomized on the basis of days of week, aged 18-40 years with ASA II scheduled for lower segment cesarean section under spinal anesthesia were included in the study. A written informed consent was taken from all subjects. Patient refusal, allergy to ondansetron or tramadol, patients with contraindications to spinal anesthesia such as hypovolemia, coagulopathy, allergy to local anesthetic agents, raised intra-cranial pressure, fixed cardiac output states, local sepsis around the site of injection, patients with abnormal psychological profile, patients with initial body temperature less than 36 or more than 38°C were excluded. All relevant investigations were noted and patient was kept fasting for 6 hrs prior to surgery.

Patients were allocated to two groups, group A and B of 35 patients each. Patients enrolled in group A (ondansetron group) received 0.1 mg kg^{-1} of ondansetron and those in group B (tramadol group) received 0.5 mg kg^{-1} tramadol immediately after clamping the cord. The drugs were prepared by a single person in 5 mL syringes and all study medications were diluted in normal saline to make 5 mL of total medication.

After shifting the patients to the operation theatre, all the standard ASA monitors were attached to the patient. Axillary temperature probe was used to measure the temperature. Baseline heart rate (HR), noninvasive blood pressure (NIBP), mean arterial pressure (MAP), oxygen saturation (SPO2), electrocardiography (ECG) and axillary temperature were recorded. Venous access was secured with 18 and 20G intravenous (IV) cannula. Spinal anesthesia was administered in the sitting position. Using an aseptic technique, a 27-gauge Quincke needle e (B-Braun Medical, Inc., Bethlehem, PA) inserted through a midline approach into the L3-L4 or L4-L5 interspace. Anesthesia was established with a single bolus of 3.0 mL out of a mixture of 3.5 mL 0.5% hyperbaric bupivacaine and 25 mcg of fentanyl (as adjuvant). Patient was immediately kept in supine position. The level of sensory blockade was assessed regularly by the level of touch sensation before surgical incision (T6-T8 was considered adequate). Supplemental oxygen 5 L min^{-1} through a face mask was administered during the surgery. Estimated fluid requirement and maintenance fluid was replaced with Ringer's lactate or 0.9% normal saline.

The attending anesthesiologist observed shivering after spinal anesthesia at Zero min (time of clamping of cord), 5, 10, 15, 20, 30, 45 min, 1 and 2 hrs. Shivering grade 3 or 4 after the administration of the tested prophylactic drug was considered as severe shivering and was treated with additional dose of 0.25 mg kg^{-1} IV tramadol as the rescue agent. Hemodynamic parameters, oxygen saturation and sedation were recorded. Sedation was assessed using the Ramsay sedation scale[15]. Grading of shivering was done as per Tsai and Chu[16] which is as follows:

- **Grade 0:** No shivering
- **Grade 1:** 1 or more of the following; piloerection or peripheral vasoconstriction but no visible muscle shivering
- **Grade 2**: Visible muscle activity confined to one muscle group
- **Grade 3:** Visible muscle activity in more than one muscle group
- **Grade 4:** Gross muscle activity involving the upper part of body

Statistical analysis: The data was recorded and compared between the two groups. The recorded data was compiled and analyzed using SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expressed as Mean (±SD) and categorical variables were summarized as frequencies and percentages. Student's independent t-test or Mann-Whitney U-test, whichever feasible was employed for comparing continuous variables. Chi-square test or Fisher's exact test, whichever appropriate was applied for comparing categorical variables. A p-value of less than 0.05 was considered statistically significant. All p-values were two tailed.

RESULTS

All the demographic parameters of both the groups were comparable in terms of age of the patient, weight of the patient and duration of surgery. The mean duration of surgery was 48.9±4.86 in group A and was comparable to time taken for surgeries in group B which was 48.3±5.93 with no statistical significance (p = 0.661) (Table 1).

The axillary temperature was measured at various intervals of time till the end of surgery in both the groups and no significant change in temperature was observed in either group and the difference was of no statistical significance (p>0.05) (Table1).

The hemodynamic parameters, heart rate, systolic, diastolic and mean arterial pressures (SBP, DBP, MAP) all the parameters were comparable and had no statistical significance with the p>0.05 in all the hemodynamic parameters.

On comparison of incidence of shivering between group A and B at 0, 5, 10, 20, 30, 45 min, 1 and 2 hrs, there was no incidence of shivering in any patients of either group at 0 min. However, at 5 min the incidence of shivering was 11.4% of patients in group A and in 2.9% patients in group B but the difference was statistically insignificant with p = 0.351. At 10 min, the incidence of shivering was 17.1% in group A and 5.7% in group B and again this difference was not of any statistical significance with p = 0.259. At 20 min, incidence of shivering was 2.9% in group A and 0% in group B with no statistically significant comparison between the two groups (p = 1.000). At 30, 45, 60 min and 2 hrs shivering was not present in either of the group.

Although, there was no significant difference in incidence of shivering at different intervals of time among the two groups, the overall incidence of shivering (Table 2) did show a statistically significant difference (p = 0.004) between the two groups with the overall incidence of 31.4% of patients experiencing shivering in group A, while only 8.6% patients in group B experienced shivering. Overall, less incidence of shivering was observed in patients of group B as compared to group A.

Similarly, on comparing the grades of intensity of shivering among the two groups, the difference was found to be statistically significant, with the p-value of 0.029. Grade 2 shivering was seen in 20% patients in group A and 2.9% patients in group B, grade 3 shivering was seen in 8.6% patients in group A and 0% patients in group B and grade 4 shivering was not seen in any patient in any of the groups. The higher grade of

Table 1: Duration of surgery, axillary temperature of patients of both the groups

Parameters	Group A (n = 35)	Group B (n = 35)	p-value
Weight of patients (kg)	70.70±4.56	69.70±3.85	0.339
Mean duration of surgery (min)	48.90±4.86	48.30±5.93	0.661
Axillary temperature	36.68±1.46	36.68±1.53	>0.05

Table 2: Overall incidence of shivering, grades of shivering and need of rescue drug in two groups

	Group A		Group B		
Parameters	No.	Percentage	No.	Percentage	p-value
Incidence of shivering	11	31.4	3	08.6	0.004
Grades of shivering					0.029
Grade 0	24	68.6	32	91.4	
Grade 1	1	02.9	2	05.7	
Grade 2	7	20.0	1	02.9	
Grade 3	3	08.6	0	00.0	
Treatment with rescue drug	3	08.6	0	00.0	0.239

Table 3: Ramsay sedation score in two groups

	Group A		Group B		
Ramsay sedation score	No.	Percentage	No.	Percentage	p-value
Grade	4	11.4	3	08.6	0.013
Grade 2	30	85.7	22	62.9	
Grade 3	1	02.9	10	28.6	
Grade 4	0	00.0	0	00.0	
Grade 5	0	00.0	0	00.0	
Total	35	100.0	35	100.0	

shivering was observed in patients of group A as compared to group B. The need of rescue anti shivering agent was also studied in both the groups. It was observed that, 3 patients (8.6%) in group A required the rescue treatment, while none of the patients in group B felt any need of rescue agent and the difference was also statistically insignificant with p>0.239 (Table 2). Sedation score was assessed on the basis of ramsay sedation score (Table 3) and it was observed that 11.4% in group A and 8.6 % in group B had grade 1 of sedation, 85.7% in group A and 62.9% in group B has grade 2 sedation and 2.9% in group A and 28.6% in group B has grade 3 sedation, which were statistically significant with p = 0.013. Patients in the group B (tramadol) had higher grades of sedation compared to group A (ondansetron).

DISCUSSIONS

Post operative shivering, though a common phenomenon (incidence ranging from 40-60%) is an undesirable side effect in both regional and general anesthesia that should be prevented in all patients[17,18]. Several factors have been identified as potential cause of post operative shivering in patients undergoing cesarean section under regional anaesthesia many of which are related to patients like, age, gender, body mass index (BMI) etc.[6].

The present study was designed primarily to evaluate and compare the efficacy of ondansetron and tramadol for control of shivering in patients undergoing Lower segment caesarean section under spinal anesthesia. This was a prospective observational study, conducted in department of anesthesiology and critical care, SKIMS, srinagar over a period of two years. A total of 70 female subjects, aged between 18-40 years with ASA II, undergoing lower segment cesarean section under spinal anesthesia were included in the study and were allocated into two groups, group A and B of 35 patients each. Patients in group A received ondansetron 0.1 mg kg^{-1} and those in group B received 0.5 mg kg^{-1} tramadol immediately after clamping the cord. All the demographic parameters in both the groups were comparable with no statistical significance (p>0.05) (Table 1).

While comparing the hemodynamic parameters, it was observed that there were no significant changes in hemodynamic parameters in any group that were recorded at regular intervals between the two groups (p>0.05) and this finding was similar to a study done by Lakhe *et al*.[17], wherein also no significant difference in hemodynamic parameters were observed.

The axillary temperature which was measured at various intervals of time in both the groups showed no significant change in temperature in either group (p>0.05) (Table1). Similar results were observed in a study done by Chowdhury *et al*.[18] comparing IV ondansetron and tramadol for control of shivering during spinal anesthesia and found that the difference in fall of core body temperature between two groups was not significant statistically (p>0.05).

Similarly, in an another study done by Siddhartha Chagaleti *et al*.[19], comparing ondansetron and tramadol in prevention of post-anesthesia shivering following cesarean section under spinal anesthesia found that the difference in fall of core body temperature between two groups was statistically insignificant (p>0.05). These results were also similar to the study done by Mohammadzadeh Jouryabi *et al*.[20] who in their study compared the effects of low dose of

ketamine, tramadol and ondansetron in prevention of post spinal anesthesia shivering in cesarean section. Although the exact mechanism of action of ondansetron and tramadol with regard to changes in thermoregulation during anesthesia and surgery is still not clear much has been attributed to serotonergic activity in the anatomic and physiologic pathways of both central and peripheral thermoregulation[17].

In our study, incidence of shivering was compared between the two groups and the difference in incidence of shivering at various intervals of time was statistically insignificant with p>0.05. Although, there was no significant difference in incidence of shivering at different intervals of time among the two groups, the overall incidence of shivering (Table 2) did show a statistically significant difference (p = 0.004) between the two groups with the overall incidence of 31.4% of patients experiencing shivering in group A, while only 8.6% patients in Group B experienced shivering.

Similarly, on comparing the grades of intensity of shivering among the two groups, the difference was found to be statistically significant, with the p-value of 0.029. The higher grade of shivering was observed in patients of group A as compared to group B (Table 2). The incidence of shivering was higher for ondansetron group of parturients compared to tramadol group and the probable reason for that could be anti-shivering properties of tramadol that include inhibiting noradrenaline and serotonin uptake in the spinal cord, activating the monoaminergic receptors of the descending neuraxial inhibitory pathways and triggering the secretion of hydroxyl-tryptamine, which modulates the human temperature regulation center[21].

Our results are in concordance with the study done by Chowdhury *et al*.[18] who in their study observed that the complete disappearance of shivering took a mean of 3.4 min in tramadol group while 5.1 min in ondansetron group ($p \leq 0.05$) concluding that IV tramadol is superior to ondansetron for control of shivering with an early onset. Similar, results were obtained by the study done by Mohammadzadeh Jouryabi *et al*.[20] and Lakhe *et al*.[17] indicating that the prophylactic use of ondansetron and tramadol was effective in preventing shivering in ondansetron and tramadol groups but tramadol fared marginally better. Although many studies support the findings of our study, contradicting results were noted in the study done by Onyekwulu *et al*.[14] in which they found that patients in tramadol group had slightly higher incidence of shivering (39.4%) as compared to Ondansetron group (5.9%). The difference in results can be due to different time of administration of the study drugs and their onset and duration of action as in their study the drugs were administered to the patients just immediately after depositing the local anesthetic into the intrathecal space, while patients in our study received the study drug after clamping of the cord and also there was difference in dosage of the drugs used, while they used a fixed drug amount (50 mg for tramadol and 4 mg for Ondansetron) for each patient irrespective of the weight of the patients and we in our study used the study drugs as per weight of the patient (0.5 mg kg^{-1} for Tramadol and 0.1 mg kg^{-1} for Ondansetron).

The need of rescue anti-shivering agent was also compared between the two group but the difference was found to be statistically insignificant (p>0.05). Similar results were also observed by Ejiro *et al*.[21] in their study comparing the two drugs in prevention of post anesthesia shivering following caesarean section under spinal anesthesia. Our results were also in concordance with the study done by Chowdhury *et al*.[18] and Nallam *et al*.[22] who in their respective studies also required the need of rescue treatment with tramadol even after giving the study drugs which however also was of no statistical significance.

Sedation score was compared between the two groups and the difference was found to be statistically significant (p = 0.013). Sedation score of grade 3 was observed in 28.6% in tramadol group and 2.9% in ondansetron group, which was statistically significant (p<0.05). Grade 4 and 5 sedation was not found in any group.

Similar results were obtained by the study done by Lakhe *et al*.[17] and Onyekwulu *et al*.[14] who also in their studies found more incidence of sedation in tramadol group and as compared to ondansetron group. The possible explanation for tramadol's tendency to cause more sedation than ondansetron may be because of its partial agonist action at mu-opioid receptors and inhibition of serotonin and noradrenaline reuptake in the CNS.

CONCLUSION

This study concluded that the use of both ondansetron and tramadol is an effective way of preventing shivering under spinal anesthesia in women undergoing cesarean section. However, the overall incidence and grade of shivering is lesser with tramadol as compared to ondansetron and tramadol has an additional advantage of higher sedation score which keeps the patients calm.

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