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COMPARATIVE STUDY OF EFFICACY AND SAFETY OF INTRAVENOUS TRAMADOL VERSUS INTRAVENOUS CLONIDINE IN CONTROLLING SHIVERING IN OBSTETRIC PATIENTS UNDER REGIONAL ANAESTHESIA FOR CAESAREAN SECTION

Dr Nilam Namdeo Waghmare[1], Dr Anandkumar Harishchandrarao Pande[2], Dr Hemant Shivram Pawar [3]

[1]Assistant Professor Department of Anesthesiology, Dr. Vasantrao Pawar Medical College Hospital and Research centre, Nashik, India.
[2]Professor Anesthesia Traumacare Centre, B.J.M.C. and Sasoon Hospital, Pune, India.
[3]Associate Professor Department of Anesthesiology, Dr.Vasantrao Pawar Medical College Hospital and Research Centre, Nashik, India.

Corresponding Author:
Dr Nilam Namdeo Waghmare, Assistant Professor Department of Anesthesiology, Dr. Vasantrao Pawar Medical College Hospital and Research centre, Nashik, India.

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Abstract

Background: Regional techniques are commonly used for patients undergoing caesarean and these women experience shivering frequently. Present study was aimed to compare efficacy and safety of intravenous tramadol versus intravenous clonidine in controlling shivering in obstetric patients under regional anaesthesia for caesarean section. **Material and Methods:** Present study was prospective, comparative study, conducted in pregnant women, 18-40 years age, ASA grade I & II, developing shivering intra operative or postoperative in emergency or elective section. **Results:** Among 80 cases undergoing elective caesarean section, patients were divided into two groups of 40 each as group C - Received Clonidine 0.5mcg per kg i.v & group T- Received Tramadol 0.5mg per kg i.v. There was no significant difference in pre operative temperature, HR, SBP, DBP and SpO2 in both groups and even after the control of shivering. Mean time required to control the shivering in Tramadol group is 2.77 minutes is significantly less as compared to the Clonidine group which is 5.47 minutes ($p< 0.001$). Response rate that is the percentage of patients in which shivering controlled in 15 minutes after the treatment is 95% in Tramadol group and 82.5% in Clonidine group. The difference was not significant statistically (P-value 0.155). No side effects were noted in tramadol group, while 3 patients had side effects in clonidine group (1 nausea/vomiting & 2 cases had sedation), difference was not significant statistically. **Conclusion:** Tramadol as compared to Clonidine is safe and effective in controlling the shivering in obstetric patients receiving spinal anaesthesia.

Keywords: Tramadol, clonidine, intra-operative shivering, spinal anaesthesia.

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Introduction

The combination of anaesthetic induced thermoregulatory impairment and exposure to a cool environment makes warmed surgical patients hypothermic.[1] Hypothermia during neuraxial anaesthesia develops initially from core to peripheral redistribution of body heat.

Spinal anaesthesia is known to decrease the vasoconstriction and shivering threshold. There is core to periphery redistribution of heat due to spinal induced vasodilatation and shivering is preceded by core hypothermia following spinal anaesthesia may not trigger sensation of cold as the cutaneous vasodilatation resulting from sympathetic blockade increases skin temperature leading to a sensation of warmth although accompanied by thermoregulatory shivering.[2,3]

The main cause of shivering intra or post operative are temperature loss, decreased sympathetic tone and systemic release of pyrogens.[4 Regional] techniques are commonly used for patients undergoing caesarean and these women experience shivering frequently. Since shivering can also adversely affects the patients under regional anaesthesia prompt treatment is required. Present study was aimed to compare efficacy and safety of intravenous tramadol versus intravenous clonidine in controlling shivering in obstetric patients under regional anaesthesia for caesarean section.

Material And Methods

Present study was prospective, comparative study, conducted in Department of Anesthesiology, Dr. Vasantrao Pawar Medical College Hospital and Research centre, Nashik. Study duration was of 2 years (July 2018 to June 2019). Study was approved by institutional ethical committee.

Inclusion criteria

- Pregnant women, 18-40 years age, ASA grade I & II, developing shivering intra operative or postoperative in emergency or elective section.

Exclusion criteria

- Cardio pulmonary, renal, liver disorder.
- Known case of hypersensitivity to tramadol and clonidine.
- Hypo or hyper thyroidism.
- Severe PIH or eclampsia.
- Psychological disorder.
- Known case of alcohol or drug abuse.
- Receiving drug for labour analgesia or other medication likely affect thermoregulation.

A written informed consent was obtained in each case after explaining surgical procedure, anaesthesia procedure & drugs to be used in their vernacular language. Patients underwent thorough preoperative assessment including detailed case history, physical examination, and all necessary investigations. Fit patients received spinal anaesthesia as per departmental standard operating procedures.

Among 80 cases undergoing elective caesarean section, patients were divided into two groups of 40 each using computerized randomization charts. Drug therapy started as per patient group after delivery of baby

1. Group C - Received Clonidine 0.5mcg per kg i.v
2. Group T- Received Tramadol 0.5mg per kg i.v

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Intraoperatively shivering was recorded at 5-minute interval up to 60 minutes of surgery, using a scale validated by Wrench.[5] Patients developing grade 3 or 4 shivering as per Wrench criteria are included.

Grade 0: No shivering,

Grade 1: Piloerection but no visible muscular activity,

Grade 2: Visible muscular activity confined to one muscle group,

Grade 3: Visible muscular activity in more than one muscle group but not generalized,

Grade 4: Gross muscular activity (Shivering) involving the whole body.

Variables studied were time of appearance of shivering, response rate (Percentage of patients in which shivering controlled within 15 minutes), failure to control the shivering, recurrence of shivering & side effect and complications are noted. Pulse rate, blood pressure, oxygen saturation and body temperature (in axilla) recorded before commencement of surgery and there after every 5min for one hour, every 15min for rest of procedure. Post operative side effects/adverse events noted were

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

In present study, age, weight, ASA grade, type of surgery (elective/ emergency) was comparable among both groups & difference was not significant statistically.

Table 1: General parameters

Parameters	**Group T (Mean ± SD)**	**Group C (Mean ± SD)**	**P-value**
Age (years)	25.10 ± 5.66	25.28 ± 5.52	0.889
Weight (kg)	62.90 ± 2.19	63.20 ± 2.70	0.587
ASA grade			0.820
I	23	24	
II	17	16	
Surgery			0.823
Emergency	20	21	
Elective	20	19	

There was no significant difference in pre operative temperature, HR, SBP, DBP and SpO2 in both groups and even after the control of shivering. Mean time required to control the shivering in Tramadol group is 2.77 minutes is significantly less as compared to the Clonidine group which is 5.47 minutes ($p< 0.001$).

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Table 2: Mean time required to control shivering (min.) after treatment

Parameter	Group T (Mean ± SD)	Group C (Mean ± SD)	P-value
Mean time required to control shivering (min.) after treatment	2.77 ± 3.19	5.47 ± 5.11	< 0.001

Response rate that is the percentage of patients in which shivering controlled in 15 minutes after the treatment is 95% in Tramadol group and 82.5% in Clonidine group. The difference was not significant statistically (P-value 0.155).

Table 3: Response rate

Time required to control shivering	Group T	Group C	Total
≤ 15	38 (95.0%)	33 (82.50%)	71
> 15	2 (5.0%)	7 (17.50%)	9

In present study, no side effects were noted in tramadol group, while 3 patients had side effects in clonidine group (1 nausea/vomiting & 2 cases had sedation), difference was not significant statistically.

Table 4: Comparison of occurrence of side effect in group 1 and group 2.

Side effect	Group T	Group C	Total	P-value
Present	0	3	3	0.255
Absent	40	37	77	

Discussion

Intra-operative hypothermia can be minimized by any technique that limits cutaneous heat loss to the environment such as those due to cold operating room, evaporation from surgical incisions and conductive cooling produced by administration of cold intravenous fluids.

There are many pharmacological and non-pharmacological methods used to prevent heat loss and decrease shivering. Non-pharmacological methods include radiant heat warmers, warming the operation theatre, warm IV fluids, blankets, and using anaesthetic drugs at body temperature.[6] It has been mentioned that hypothermia may cause postanesthetic shivering by alteration of thermoregulatory mechanism. However, no relationship has been shown between axillary temperature and occurrence of shivering.[7]

Pharmacological intervention does not raise body temperature, but resets the shivering threshold to a lower level, thereby decreasing rigors and its episodes. Various pharmacological therapies[8] have been tried to prevent or treat shivering, including opioids (e.g., pethidine, nalbuphine, butorphanol or tramadol), ketanserin, propofol, ondansetron, granisetron, doxapram, physostigmine, clonidine, and nefopam etc., but debate for an 'ideal anti-shivering drug' still continues.

Mathew et al.,[9] study used tramadol 1mg/kg for treating post operation shivering and no, undesirable side effects (nausea and vomiting) were noted. In addition, tramadol had no

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effect on blood pressure, arterial oxygen saturation percentage and body temperature. These results are in accordance with our study results.

Zahedi et al.,[10] reported tramadol 1mg/kg was more effective due to a faster onset, no recurrence of shivering, shorter duration of recovery, and fewer adverse effects. In our study we used Tramadol in 0.5mg/kg dose. Even at this dose the results are in accordance with the study of Zahedi.

In Talakoub et al.,[11] study efficacy and harm of tramadol for treatment of post spinal anesthesia shivering in cesarean section were evaluated. They compared tramadol (0.5mg/kg) with pethidine (0.5mg/kg) to control shivering and concluded that tramadol is more effective to control shivering. Time elapsed from treatment to cessation of shivering was 2.5+/-1.07 min in Tramadol group where in our study the mean response time from administration of Tramadol to cessation of shivering was minutes is 2.77 with standard deviation of 3.19min.

Usha Shukla et al.,[12] used tramadol and clonidine in dosages of 0.5mg/kg and 0.5mcg/kg intravenously. They concluded both clonidine (0.5 μg/kg) and tramadol (0.5 mg/kg) effectively treated patients with post–spinal anaesthesia shivering. Complication rates were significantly higher in group T than in group C. Nausea, vomiting and dizziness were higher in group T than in group C. More patients of group C were sedated than of group T. Even in our study both drugs are effective in controlling the shivering. We observed that there are nil side effects in Tramadol group while patients in Clonidine group are more sedated.

Wason R et al.,[13] used Tramadol in doses of 0.5mg/kg. They concluded that tramadol is effective in preventing shivering during neuraxial anaesthesia without causing any major untoward side-effects. Results similar to our study results.

Velayudha Reddy et al.,[14] studied the Clonidine and Tramadol for post spinal shivering during caesarean section. They concluded that time required for control of shivering in Tramadol shorter than the Clonidine group. Even in our study mean time required for control of shivering is 2.77 minutes in Tramadol group and 5.47 minutes in Clonidine group.

Sias et al.,[15] found clonidine to be an effective drug when used prophylactically at 1 mcg/ kg i.v. to control shivering under neuraxial blockade. In accordance with above study even in our study Clonidine is effective in controlling the shivering.

Capogna G et al.,[16] studied efficacy of intravenous clonidine to control shivering in parturient even our study includes same group patients. They observed shivering ceased within 5 min after only one dose of clonidine 30 micrograms. Even in our study mean time required for control of shivering is 5.47 minute. We conclude that a small dose of i.v. clonidine may be useful to suppress post-spinal shivering in parturient.

Intra-operative shivering during regional anaesthesia especially in parturient undergoing caesarean section needs to be treated actively as shivering is not only troublesome but also increases the oxygen demand which can adversely affect both maternal and fetal outcome. Tramadol and Clonidine both are easily available in peri-operative set up, are found to be useful drugs for their antishivering effect.

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Conclusion

Tramadol & clonidine, both were found to be effective in controlling the shivering. But the mean time required to control the shivering in Tramadol was significantly less as compared to the Clonidine & no any side effects noted with tramadol, patients in Clonidine groups were more sedated. There was no recurrence of shivering in both the groups. Tramadol as compared to Clonidine is safe and effective in controlling the shivering in obstetric patients receiving spinal anaesthesia.

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