

Original Research Article

PROPHYLACTIC ADMINISTRATION OF INTRAVENOUS PARACETAMOL AND ONDANSETRON FOR CONTROL OF SHIVERING DURING AND AFTER ELECTIVE CESAREAN SECTION UNDER SPINAL ANAESTHESIA: A RANDOMIZED COMPARATIVE STUDY

**Dr. Deepali Mandloi¹ (Senior Resident), Dr. Arpit Agrawal² (Consultant),
Dr. Deepali Valecha³ (Assistant Professor) & Dr. Pooja Vaskle⁴ (Associate Professor)**

Dept. of Anaesthesiology, MGM Medical College and MY Hospital, Indore, M.P.^{1,3&4}
DNS Hospital, Indore²

Corresponding Author: Dr. Deepali Valecha

ABSTRACT

Background: A sequence of repeated, involuntary skeletal muscular movements that frequently happen during spinal anesthesia is referred to as shivering. Both spinal and epidural regional anesthetic lower the shivering threshold and promote vasodilation. There have been reports recently that ondansetron (5HT₃ receptor antagonist) and paracetamol can lessen shivering following subarachnoid block. We investigate how Ondansetron and paracetamol affects shivering.

Objectives: This study aimed to compare the efficacy of paracetamol and Ondansetron in the treatment of shivering.

Methods: In this randomized comparative study, 60 patients (18-40 years) who were posted for elective caesarean section under spinal anaesthesia were randomly allocated to two groups: group P (30 patients) received 1 gram of intravenous paracetamol and group O received 8 mg of intravenous Ondansetron in operation theatre 10 min before subarachnoid block. The surface temperatures and the incidence as well as intensity of shivering were recorded.

Results: Shivering was controlled in 24 patients in group P and 17 patients in O group. Within each group, there were no significant differences among the surface temperature in recovery room but in group O had significantly lower incidence of nausea and vomiting than group P.

Conclusion: Ondansetron and paracetamol have similar effect on shivering, but Ondansetron is the drug of choice, especially in the patients with increased risk of post operative nausea and vomiting.

Keywords – Ondansetron, paracetamol, shivering, subarachnoid block.

1. Introduction

The incidence of shivering in postoperative period was reported to be 40 percent in past; however, in present era shivering is less frequent as more patient are kept in ambient temperature during peri-operative period. Shivering is a serious complication that increases oxygen consumption by about 300-400 percent.¹ It can be defined as involuntary and oscillatory muscular activities that increase the metabolic rate by two to three folds to maintain the core temperature, with the increment of heat production by only 200% in adults. However, shivering is a frequent and undesirable side effect of the procedure among a parturient woman undergoing Cesarean Section under Spinal Anaesthesia. It may be a natural thermoregulatory response to central hypothermia, or it may be the result of cytokine release during surgery². Shivering induces several complications such as interfering with standard monitoring, lactic acidosis, increased carbon dioxide production, and oxygen consumption^{3,4,5}. Now a days, a variety of pharmacologic agents including magnesium sulfate, opioids, alpha 2-agonists, N-methyl D-aspartate receptor antagonists, serotonin 5-HT₃ receptor antagonist, Paracetamol^{6,7,8,9}, and non-pharmacological interventions such as blankets, radiant heat, and forced air warmers have been used to suppress perioperative shivering¹⁰. However, the problem still exists, and investigation for novel approaches with enough safety and efficacy is strongly recommended. In this regard, in spite of considering pethidine as the gold standard of post spinal anaesthesia shivering reduction agent¹¹, it is contraindicated in breastfeeding women, which is both legally and ethically challenging. Therefore, pregnant women should particularly be considered for this issue¹². Shivering is a thermoregulatory defense mechanism. Anti-shivering drugs decreases the shivering threshold.¹³ Ondansetron is a specific 5HT₃ antagonist that may affect thermoregulation & Post Anaesthesia shivering (PAS). Studies done in this regard have shown that serotonergic pathways have a role in the regulation of PAS. It has been suggested that perhaps 5-HT₃ inhibition has a specific anti shivering effect, but given the variety of neurotransmitter systems known to be also involved in regulating shivering, an inhibitory effect at the 5HT₃ receptor probably results from a generalized thermoregulatory inhibition at the level of hypothalamus where the bulk of thermoregulatory control occurs.¹⁴ Paracetamol acts through a centrally mediated prostaglandin inhibition to decrease the hypothalamic temperature set point. Indeed, the purpose of this survey was to compare the efficacy of paracetamol and Ondansetron in the treatment of shivering in Cesarean Section under Spinal Anaesthesia.

Aims and Objectives:

This study aimed to compare the efficacy of paracetamol and Ondansetron in the treatment of shivering.

2. Methodology

It is a prospective, randomized, comparative study. This study was conducted in the Department of Anaesthesiology, M.G.M Medical College and M.Y Hospital, Indore after approval by the Institutional Ethics and Scientific Review Committee. A written informed

consent was taken from all the patients after explaining the procedure, its associated risks and side effects. 60 adult patients (30 in each group) between 18–40 years of age belonging to American Society of Anesthesiologists (ASA) physical status I or II, of female sex, who were admitted for elective cesarean section, were recruited for the study. Patients with known allergy or hypersensitivity to paracetamol, hepato-renal and cardiorespiratory co-morbidities, alcohol abuse, and body temperature $>38^{\circ}\text{C}$ and $<36^{\circ}\text{C}$ were excluded from our study.

Patients were randomly allocated to two groups: group P (30 patients) received 1 gram of intravenous paracetamol and group O received 8 mg of intravenous Ondansetron in operation theatre 10 mins prior to planned induction of Sub arachnoid block.. The surface temperature was recorded at axilla by a skin thermometer. Intraoperative hypothermia was minimized by several techniques, including warming all infused fluids, and the operating room temperature was adjusted to 22°C - 24°C . The shivering was assessed by Bedside assessment shivering scale (BSAS)¹⁷ from a score of 0 to 3, where 0 implies no shivering on palpation of the masseter, neck or chest wall; 1 implies mild shivering localized to neck/thorax only; 2 implies moderate shivering involves gross movement of the upper extremities and 3 implies severe shivering involves upper and lower extremities. During the surgery vitals and shivering grade were noted at a regular interval of 15mins for the purpose of study.

If the shivering scale was more than grade 2, ketamine 0.25mg/kg was given intravenously as a rescue agent and subsequently recorded.

Patients were transferred to the recovery room and covered with a cotton blanket. The temperature of the post-op anesthesia care unit was kept the same as that of the operating room by adjusting the air conditioner settings. Patients were observed for 1-hour post-surgery in recovery room, the vitals and shivering grade were recorded at an interval of 15 mins. Any complication (nausea, vomiting, hypotension, bradycardia etc.) if present during the perioperative period were also recorded.

Statistical analysis

Data analyses were performed using the SPSS software (was used for calculating P values). The incidence of shivering and side effects were compared using t-test and chi-square test. P value < 0.05 was considered to be significant.

3. Result

Table No. 1: Demographic and surgical characteristics of the study

Parameter	Paracetamol	Ondansetron	P Value
Age (years)	24.63±5.582	25.58±4.894	.697091
Weight (kg)	63.55±5.268	64.67±5.306	
Duration of surgery (min)	53.18±7.885	54.11±8.139	

The chi-square statistic is 0.0058. The *p*-value is .697091. The result is *not* significant at *p* $< .05$.

Table No. 2: Incidence of shivering and side effects

Parameter	Paracetamol	Ondansetron	Total (60)	P Value
Shivering Grades (S0/S1/S2/S3/S4)	24/4/1/1/0	14/10/3/2/1	38/14/4/3/1	.544635
Nausea/vomiting	4/1	1/1	5/2	
Required Ketamine	01	03	04	
Hypotension	04	03	07	
Braycardia	01	02	03	

The chi-square statistic is 1.2153. The *p*-value is .544635. The result is *not* significant at $p < .05$.

Table No. 3: Body temperature values in two groups

Parameter	Paracetamol	Ondansetron	P Value
Basic Body Temp.	34.36±4.82	36.58±4.19	.07412
Post Anaesthesia Body Temp.	34.05±5.68	36.67±5.36	
Post Anaesthesia Body Temp. after 15 min	34.93±4.96	36.47±4.46	
Body Temp. in recovery room	34.69±7.85	36.11±8.13	
Body Temp. after exit of recovery room	34.68±7.75	36.91±8.92	

The chi-square statistic is 0.1768. The *p*-value is .07412. The result is *not* significant at $p < .05$.

4. Discussion

The results of the current study show that ondansetron and paracetamol both have comparable effects on shivering; nevertheless, ondansetron is the recommended medication, particularly for patients experiencing nausea and vomiting along with post-operative shivering.

Shivering is a very common complication of surgery owing to postoperative pain and post anesthesia hypothermia, is distressing for both patients and clinicians. Furthermore, it may interfere with the monitoring devices. Thus, prevention of shivering is important especially in patients with cardiopulmonary disease or elderly patients¹⁵. Although many pharmacological agents have been used to treat or prevent postanaesthetic shivering, the ideal treatment has not yet been found.

The result of this study showed that intravenous paracetamol was effective in preventing shivering due to spinal anaesthesia. Paracetamol is an effective, safe and widely used analgesic agent with antipyretic properties that inhibits prostaglandin synthesis to reduce the

hypothalamic temperature set point¹⁶. It has a rapid onset of action about 15-20 min after the injection and declines after 4 h. Unlike other anti-shivering drugs, paracetamol does not cause adverse effects such as sedation, respiratory depression, constipation, or vomiting. Moreover, a study conducted by Gholami and Hadavi¹⁷ also supports our study results, where prophylactic IV paracetamol was used during surgery on 110 pregnant women to prevent POS in cesarean delivery using general anesthesia. The results showed a favorable response to prophylactic paracetamol regarding post-anaesthetic shivering; thus, it might replace opioids that have many side effects. Ondansetron, a specific 5-HT₃ antagonist, has generated much interest because of its excellent pharmacological profile. It has a wide therapeutic index. It is usually prescribed to prevent and manage nausea and/or vomiting during the perioperative period. The exact mechanism of 5-HT₃ antagonists in preventing postanesthetic shivering has not been clarified, but it might be related to the inhibition of serotonin reuptake in the hypothalamus. Serotonin receptors also affect heat production and heat loss pathways, as well¹⁸. The results of the present study are similar to a trial carried out by Mahoori et al¹⁹, who had compared the efficacy of ondansetron and meperidine for treating shivering in 83 patients randomly divided into three groups: The first group was given 4 mg of IV ondansetron, the second group was given 8 mg of IV ondansetron, and the third group received 0.4 mg kg⁻¹ of intravenous meperidine at the recovery room, and they found that 8 mg of IV ondansetron could control shivering and this is the dose of choice, especially in patients with POS in association of postoperative nausea and vomiting. These results were confirmed by Teymourian et al.²⁰, where ondansetron was administered 10 min before the end of surgery to 40 patients for the prevention of post-anesthesia shivering after elective craniotomy, and they found that ondansetron was of great value in preventing POS.

Limitations.

This study has several limitations. Initially, the trial was conducted at a single centre, and the participants were only evaluated for post-operative symptoms for 60 minutes. On the other hand, POS incidence can persist up to 10 h²¹. Secondly, although it might not be feasible, we did not measure the plasma levels of ondansetron or paracetamol. More research is required to assess the late effects of ondansetron and paracetamol on POS and identify the best time to administer these medications for the greatest possible benefit. The axilla region was used to take temperature; however, the bladder is the optimum place because it is known to reflect the body's core temperature more precisely. However, the investigation was carried out using axilla temperature monitoring because there was no bladder temperature monitoring sensor available.

5. Conclusion

Ondansetron and paracetamol have similar effect on shivering, but Ondansetron is the drug of choice, especially in the patients with post-operative shivering with nausea and vomiting.

6. References

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