

## Intravenous Ondansetron Efficacy in Preventing Post Spinal Shivering during Lower Segment Caesarean Section

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### ABSTRACT

**Objective:** To determine IV Ondansetron efficacy in preventing post-spinal shivering during LSCS.

**Study Design:** Quasi-experimental study.

**Place and Duration of Study:** Department of Anaesthesiology, Combined Military Hospital, Rawalpindi Pakistan, from Sep 2018 to Mar 2019.

**Methodology:** A total of 60 women undergoing LSCS under spinal anaesthesia were included. Group-A was given 8 mg/4 ml Ondansetron, while Group-B was given 4 ml Normal Saline 0.9% IV immediately before induction of spinal anaesthesia. Body temperature, level of sensory block, and shivering scores during the peri-operative period were recorded. After surgery, patients were shifted to Post Anaesthesia Care Unit (PACU). Shivering was graded using Crossley and Mahajan 5-item scale. Injection Tramadol 1mg/kg intravenously was used as a rescue anti-shivering drug.

**Results:** The majority of the patients 33(55.0%) were between 18-25 years of age. Efficacy of Intravenous Ondansetron in preventing post-operative shivering during spinal anaesthesia in patients undergoing caesarean section was seen in 26 86(67%) patients (Group-A) as compared to 17(56.67%) patients in the Control Group (Group-B) ( $p$ -value=0.010).

**Conclusion:** The study concluded that there was less post-operative shivering with intravenous Ondansetron during spinal anaesthesia in patients undergoing caesarean section as compared to the Control Group.

**Keywords:** Intravenous ondansetron, Spinal anaesthesia, Post-operative shivering,

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### INTRODUCTION

Spinal block is the most commonly used anaesthesia modality for lower-segment caesarean section (LSCS) across the globe.<sup>1</sup> However; it has associated side effects like hypotension, nausea, vomiting, etc.<sup>2</sup> Shivering is also common following spinal anaesthesia, with an incidence of 40%, leading to psychological stress and a physiologic increase in oxygen consumption by 200%-600%, increased carbon dioxide production, lactic acidosis, increased chances of bleeding, infection, myocardial ischemia, and increased minute ventilation, which can be detrimental in patients with limited reserves.<sup>3,4</sup>

Prevention of shivering is important to avoid intra-operative and post-operative complications.<sup>5</sup> Hypothermia and shivering during the operative period are usually prevented by physical methods such as using warmers, which are not widely available in Pakistan, and pharmacologically by drugs such as Tramadol, Clonidine, Pethidine and Ketamine.<sup>6,7</sup>

Many studies support the evidence that the serotonergic system is vital in the pathogenesis of peri-operative shivering.<sup>8,9</sup> Ondansetron, a 5HT<sub>3</sub> antagonist, is a safely implicated antiemetic drug used during pregnancy and surgery. Some foreign studies showed an anti-shivering effect following both general and regional anaesthesia. It is potentially a safe drug in obstetric anaesthesia owing to the very low incidence of bradycardia, hypertension and risk to neonates. Ondansetron has been used in preventing post-operative nausea, vomiting, and hypotension in lower segment caesarean section. It also decreases the incidence of post-dural puncture headache (PDPH).<sup>10</sup>

However, no data on its use in preventing post-spinal shivering during LSCS in Pakistan was available. The efficacy of Ondansetron in reducing post-spinal shivering in pregnant patients undergoing elective LSCS under spinal block was evaluated in this study. The results of this study would be helpful in future practice.

### METHODOLOGY

The quasi-experimental study was conducted at the Main Operation Theatre, OT Complex, Department

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## Preventing Post Spinal Shivering

of Anaesthesiology, Combined Military Hospital, Rawalpindi, Pakistan from September 2018 to March 2019 after IERB approval. The sample size was calculated based on using the WHO sample size calculator with expected efficacy of Ondansetron in reducing the incidence of post spinal shivering to 10% in comparison with the controls 42.5%.<sup>11</sup>

**Inclusion Criteria:** Female patients aged 18-35 years suffering from full-term parturient, elective lower segment caesarean section and normal coagulation profile were included in the study.

**Exclusion Criteria:** Patients contraindicated to spinal anaesthesia, with emergency lower segment caesarean section, with CVS disease or thyroid disease, and with psychological disorders were struck off from the study.

Patients were enrolled through non-probability consecutive sampling, and two equal-size groups were formed through random tables (Figure). Informed written consent was obtained from all patients in the study after the purpose of the study, and the advantages and disadvantages of each technique used were explained to them.

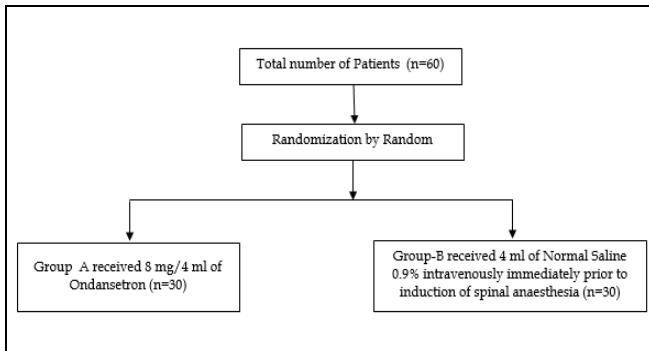


Figure: Patient Flow Diagram (n=60)

The female nursing staffs were present in the operation theatre during the spinal block, surgery, and shift to the Post-Operative Anaesthesia Care Unit (PACU) for all the patients. Patients were selected from Gynecological & Obstetric OPD and Pre-Anesthesia Clinic, randomized and divided into two equal Groups (A and B). To optimize the study, confounding factors are addressed in the exclusion criteria, and it was strictly followed to decrease bias in the results. Group-A received 8 mg/4 ml of Ondansetron, and Group-B received 4 ml of Normal Saline 0.9% intravenously immediately prior to induction of spinal anaesthesia. The anaesthesiologist performed a block and observed the patient, and the patient was blinded to the treatment. Patients were kept NPO as per ASA Fasting

Guidelines and pre-medicated with ranitidine 150 mg orally a night before surgery. Standardized monitoring was attached to the operation room. Heart rate (HR), three lead ECG, NIBP, respiratory rate, and SpO<sub>2</sub> were monitored throughout the peri-operative period. Body temperature was measured by the tympanic thermometer. Operation theatre temperature was maintained at 25C by air conditioning/heating. After securing peripheral intravenous access using an 18-gauge cannula on the dorsum of the non-dominant arm, all patients were preloaded with warm Ringer's Lactate 10ml/kg before spinal anaesthesia. Respective drugs were injected intravenously just before the initiation of spinal anaesthesia. Supplemental oxygen (4L/min) was given to all patients through a simple Face Mask till the end of the procedure. No other warmers/devices were used. Body temperature, level of sensory block and shivering score during the peri-operative period were recorded. Body temperatures would be monitored just before intrathecal injection and then with 15-minute intervals every 15-minutes for up to 6 hours. After surgery, patients were shifted to PACU. Shivering was graded using Crossley and Mahajan 5-item scale. Injection Tramadol 1mg/kg intravenously was used as a rescue anti-shivering drug.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Quantitative variables were expressed as Mean±SD and qualitative variables were expressed as frequency and percentages. Chi-square test and Independent sample t-test were applied to explore the inferential statistics. The *p*-value of ≤0.05 was set as the cut-off value for significance.

## RESULTS

The age range in this study was from 18 to 35 years, with a mean age of 28.60±4.57 years. The mean weight of patients was 75.53±7.31kg, as shown in Table-I.

Table-I: Baseline Characteristics of Study Groups (n=60)

Charact eristics	Group A (n=30)		Group B (n=30)		Total	
	No.	% age	No.	% age	No.	% age
<b>Age (years)</b>						
18-25	17	56.67%	16	53.33%	33	55.0%
26-35	13	43.33%	14	46.67%	27	45.0%
	28.53±4.42 years		28.67±4.89 years		28.60±4.57 years	
<b>Weight (kg)</b>						
≤70	10	33.33%	12	40.0%	22	36.67%
>70	20	66.67%	18	60.0%	38	63.33%
	75.87±6.88 kg		75.20±7.82 kg		75.53±7.31 kg	

Efficacy of intravenous Ondansetron to pre-vent post-operative shivering during spinal anaesthesia in patients undergoing caesarean section was seen in 26(86.67%) patients as compared to 17(56.67%) patients in the control Group ( $p$ -value=0.010), shown in Table-II.

**Table-II: Efficacy of Intravenous Ondansetron Severity of Shivering (n=60)**

Variables	Group A		Group B		p-value
	No.	% age	No.	% age	
<b>Efficacy of IV Ondansetron</b>					
Yes	26	86.67%	17	56.67%	0.010
No	04	13.33%	13	43.33%	
<b>Severity of Shivering</b>					
I	02	50.0%	03	23.08%	0.010
II	01	25.0%	02	15.38%	
III	01	25.0%	04	30.77%	
IV	00	0.0%	04	30.77%	

## DISCUSSION

Post-anaesthetic shivering is a highly common complication in the recovery period after spinal anaesthesia. After general anaesthesia, its occurrence varies from 5%-65%.<sup>2</sup> Among various side effects of shivering are blood pressure, carbon dioxide production, increased oxygen consumption and distressing patients with coronary artery disease, besides causing discomfort and pain.<sup>3,4</sup> Shivering can be reduced in two ways, either by using pharmaceutical agents or with forced warming of patients. In this study, the efficacy of intravenous Ondansetron to prevent post-operative shivering during spinal anaesthesia in patients undergoing C-sections was seen in 26(86.67%) vs 17(56.67%) patients compared to the Control Group with  $p$ -value=0.010. Nallam *et al.*<sup>11</sup> reported that post-spinal shivering incidence in the Ondansetron 8 mg Group was 10% compared to 42.5% in the control Group. The importance of Ondansetron as a prophylactic agent to prevent shivering was reported by Badawy *et al.* and Kelsaka *et al.*<sup>12,13</sup> Contrary to our findings, Browning and colleagues observed no significant difference.<sup>14</sup>

Two doses of Ondansetron (4 mg vs 8 mg) were compared with placebo by Powell *et al.*<sup>15</sup> for preventing shivering after anaesthesia, in which 82 patients (age 18-60 years) were randomized into three Groups. Post anaesthetic shivering was noticed in 16/28 (57%) patients in Group C in comparison with 9/27(33%) in Group O 4 ( $p$ =0.13) and 4/27(15%) patients in Group O 8 ( $p$ =0.003). Similarly, the efficacy of treatment was shown by Kim *et al.* in such patients.<sup>16</sup>

Sagir *et al.*<sup>17</sup> reported the efficacy of Ketamine and Granisteron both separately and in combination to prevent shivering after anaesthesia. Sajedi *et al.*<sup>18</sup> concluded that granisetron was as effective as Pethidine in preventing postanesthetic shivering, comparable to our study. Narayan *et al.*<sup>19</sup> reported that Ondansetron at 8mg dose was effective in reducing bradycardia and hypotension.

In the study conducted by Marashi *et al.*<sup>20</sup> patients undergoing spinal anaesthesia were studied, and 70 patients were in the saline Group. In other Groups, 70 patients received 6 mg of Ondansetron, and 70 patients received 12 mg of Ondansetron. In this study, Ondansetron significantly prevented low blood pressure, which was not the case in our study. Patients receiving Ondansetron were also more likely to develop low blood pressure than the Saline Group. Eldaba *et al.*<sup>8</sup> in their study on 52 patients undergoing elective caesarean section, 26 patients received normal saline, and 26 other patients received 4 mg of Ondansetron before surgery. The study also found that Ondansetron reduces blood pressure drop and the need for blood pressure medication in patients.

## LIMITATIONS OF STUDY

The limitation of this study was the non-inclusion of intra-operative blood pressure patients, which is strongly recommended for study in future research.

## CONCLUSION

This study concluded that there is less post-operative shivering with Intravenous Ondansetron during spinal anaesthesia in patients undergoing caesarean section as compared to the Control Group. We recommend that Intravenous Ondansetron in patients during spinal anaesthesia be used routinely in our general practice for preventing post-operative shivering and managing patients undergoing spinal anaesthesia.

**Conflict of Interest:** None.

## Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

KA & RI: Conception, study design, drafting the manuscript, approval of the final version to be published.

SARS & ST: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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# Preventing Post Spinal Shivering

