Original Research Paper

Volume - 12 | Issue - 06 | June - 2022 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

EFFICACY OF INTRAVENOUS ONDANSETRON IN PREVENTION OF POST OPERATIVE SHIVERING IN LOWER SEGMENT CESAREAN SECTION

Dr.Anisha Chokshi	Associate Professor, B.J.Medical college, Ahmedabad
Dr.Vimal Thakrani*	Second year Postgraduate Resident, B.J.Medical college *Corresponding Author
Dr.Riya Shingala	First year Postgraduate Resident, B.J.Medical college
Dr.Seema Sojitra	First year Postgraduate Resident, B.J.Medical college
Dr.Sumati Sitpal	First year Postgraduate Resident, B.J.Medical college

ABSTRACT Shivering,which usually occur as a thermoregulatory response to cold, may also occur following general or neuraxial anaesthesia. Some of the causative factors of this type of shivering may be common to both, but some are particular to neuraxial anaesthesia. Although shivering may have beneficial thermoregulatory effects, it places the body under increased physiological stress. Post anaesthetic shivering is one of the leading causes of discomfort for patients recovering from anaesthesia. The study designed to determine the efficacy of intravenous ondansetron when compared to placebo for elective lower segment cesarean section under spinal anaesthesia to compare the incidence of shivering in both groups was carried out.Patients who received inj.ondansetron(Group A) shows significant decrease in incidence of shivering compared to patients who received inj.NS(Group B). Gradation of shivering was also decreased in group A compared to group B. There was no significant difference in hemodynamic variables during the intra and postoperative period in both the groups ($p>0.05$).

KEYWORDS : Shivering, inj.ondansetron, cesarean section

INTRODUCTION

Spinal anaesthesia is widely used as a safe anaesthetic technique for abdominal and lower limb surgeries for elective as well as emergency operative procedures.Shivering is defined as an involuntary, spontaneous, oscillatory mechanical activity of skeletal muscle associated with increased oxygen consumption. Shivering is a bodily function in response to cold in warm-blooded animals. When the core body temperature drops, the shivering reflex is triggered to maintain homeostasis. Skeletal muscles begin to shake in small movements, creating warmth by expending energy. Shivering can also be a response to fever. During fever the hypothalamic set point for temperature is raised. The increased

set point causes the body temperature to rise (pyrexia), but also makes the patient feel cold until the new set point is reached. Increased muscular activity results in the generation of heat as a byproduct. Most often, when the purpose of the muscle activity is to produce motion, the heat is wasted energy. In shivering, the heat is the main intended product and is utilized for warmth.

Amongst the various causes shivering can be divided into[1]

Thermoregulatory shivering occurs as a consequence of hypothermia, and in order to maintain normothermia, vasoconstriction and shivering occurs.

Non-thermoregulatory shivering is less well understood and may be associated with postoperative pain, release of endogenous pyrogens, uninhibited spinal reflexes and adrenal suppression.

Post anaesthetic shivering is one of the leading causes of discomfort for patients after spinal anaesthesia[2]. It is associated with cutaneous vasoconstriction (thermoregulatory shivering). The cause primarily include hypothermia which sets in due to thermoregulation inhibition by aesthetics. However, we also note the existence of shivering associated with cutaneous vasodilatation (non-thermoregulatory shivering) one of the origins of which is postoperative pain. Apart from the discomfort and aggravated pain, post anaesthetic shivering raises metabolic demand proportionally to the patient's cardiac capacities. In neuraxial anaesthesia, it mainly occurs due to impairment of thermoregulatory control secondary to autonomic blockade.

Shivering is very unpleasant, physiologically stressful for the patient undergoing surgery and some patients even find the accompanying cold sensation to be "worse than surgical pain".

Complications of shivering are increased metabolic rate, increased oxygen consumption[3] (upto100-600%) along with increased CO2 production[4],ventilation and cardiac output[5], interference with monitoring techniques[6], adverse post-operative outcomes such as wound infection, increased surgical bleeding and morbid cardiac events and is especially disturbing to mothers during labor and delivery.[7]. It causes arterial hypoxemia, lactic acidosis, increased IOP[8], ICT[9]as well as it interferes with pulse rate, BP, and ECG monitoring. It can hamper ongoing surgical procedure. Shivering per se may aggravate postoperative pain, simply by stretching of surgical incision.

First-line treatment consists of warming the patient; more persistent severe cases may be treated with medications[10][11] such as fentanyl[12],tramadol[13],pethidine, ketamine[14] & clonidine[15] which work by reducing the shivering threshold temperature and reducing the patient's level of discomfort.

METHODS

This is a prospective, double-blinded, randomised controlled study of interventional type. Institutional ethical committee approval was obtained before starting the study. The procedure was explained to the patient and written informed consent was taken.

Pre-operative evaluation was carried out a day before the surgery. A thorough history was taken and a detailed examination carried out. Patients were subjected to routine and relevant investigations like Random blood sugar, CBC, renal and liver function tests, serum electrolytes, Chest X Ray, 12 lead ECG. The procedure was explained to the patient and written informed consent taken. The temperature of the operating room was maintained at 21°C to 22°C (measured by a wall thermometer). All patients were covered with one layer of surgical drapes over the chest, thighs, and calves during the operation and then one cotton blanket over the entire body postoperatively. No other warming device was used.

On arrival to the operation theatre, IV access was established with 18G cannula. A core temperature below 36°C was considered as hypothermia. Before performing spinal anaesthesia, each patient received 10 ml/ kg of Inj Ringer Lactate as a loading dose. The infusion rates were then continued at the rate of 10ml/kg/hr thereafter. Following the guidelines for asepsis and antisepsis, The subarachnoid anaesthesia was instituted at either the L3-4 or L4-5 interspaces. A volume of 2-2.5 ml of hyperbaric bupivacaine 0.5% was injected using a 23 G spinal needle. Group A received Inj.Ondansetron 8mg (4ml). Group B received Inj.Normal Saline 4ml. Supplemental oxygen was delivered via a facemask during the operation.Motor block was

assessed using Bromage score. Sensorial block was assessed by the pinprick test. The levels of motor and sensory blockade were assessed during the intraoperative period. The presence of shivering was assessed by an observer after the completion of subarachnoid drug injection. Shivering was graded on a scale similar to that validated by Tsai and Chu. The incidence and grade of shivering was recorded. Side effects, such as hypotension, bradycardia, nausea and vomiting were recorded.If the patient's heart rate falls below 50 bpm, 0.5 mg atropine was administered by i.v.route. Hypotension was defined as a decrease in the mean arterial pressure (MAP) of more than 20 % from baseline (baseline MAP was calculated from three measurements taken in the ward before surgery). Hypotension was treated with Inj. Mephentermine i.v. bolus and then with further i.v. infusion of lactated Ringer's solution as required.

Parameters to be observed ECG, temperature, Systolic blood pressure (SBP) ,Mean arterial blood pressure (MAP), Pulse oximetry . All parameters were recorded at following stages: Every 15 min interval intraoperatively & 60 min postoperatively upto 6 hours from the time of induction.

Bromage criteria:
O(null) :-Free movement of leg and feet
1 (partial): -Able to move knees
2 (almost complete):-Only able to move feet
3(complete):-Unable to move feet and knees

Sedation score:
1:-Fully awake and oriented
2:-Drowsy
3:-Eyes closed but open on command
4:-Eyes closed but open on mild physical stimulation
5:-Eyes closed and unresponsive to mild physical stimulation

Grades of shivering:
0:-no shivering
1:-piloerection or peripheral vasoconstriction but no visible shivering
2:-muscular activity in only one muscle group
3:-muscular activity in more than one muscle group but no generalize
4:-shivering involving the whole body

OBSERVATION AND RESULTS

No significant difference found between the groups in terms of age, weight or ASA status (Table 1)

Table 1 :- Demographic Distribution

Parameters	Group A	Group B	P value
Age (Yrs)	25.8 +- 2.80	26.16 +- 2.87	0.683
ASA Grade 1	12 (52.5%)	14 (35%)	0.602
ASA Grade 2	18 (47.5%)	16 (65%)	

Heart Rate is compared at regular interval between two groups and p value in all readings is >0.05 which is not significant. (Table 2)

Table 2:- Heart Rate wise distribution

Heart Rate	Group A	Group B	P value
Baseline	75.23 ± 2.75	76.3 ± 2.91	0.150
15 min	75.56 ± 2.82	76.5 ± 3.04	0.219
30 min	75.4 ± 3.00	76.3 ± 3.14	0.261
45 min	76.23 ± 2.75	77.63 ± 3.26	0.078
60 min	75.7 ± 2.87	76.73 ± 3.16	0.191
75 min	75.23 ± 3.03	76.56 ± 3.23	0.105
90 min	75.66 ± 3.17	76.53 ± 3.67	0.332
105 min	78.46 ± 3.21	79.8 ± 3.30	0.119
120 min	80.56 ± 3.14	81.80 ± 3.28	0.097
3 hours	79.4 ± 2.97	80.86 ± 3.59	0.091
4 hours	77.23 ± 3.13	79.93 ± 3.57	0.055
5 hours	76.46 ± 2.94	77.66 ± 3.85	0.180
6 hours	76.63 ± 320	78.46 ± 3.88	0.051

Systolic Blood Pressure is compared between two groups at regular interval and p value in all reading is >0.05 (Table 3)

Table 3:- Systolic Blood Pressure wise distribution

SBP	Group A	Group B	P value
Baseline	115.16 ± 4.25	116.56 ± 3.97	0.194
15 min	118.33 ± 4.17	119.93 ± 3.72	0.123
30 min	117.06 ± 3.84	118.73 ± 3.82	0.097
45 min	114.13 ± 3.97	115.63 ± 3.77	0.139
60 min	116.2 ± 4.13	117.3 ± 4.07	0.304
75 min	113.16 ± 3.94	114.53 ± 4.02	0.189
90 min	113.63 ± 4.08	114.93 ± 3.94	0.215
105 min	114.83 ± 4.02	115.7 ± 4.16	0.416
120 min	115.96 ± 3.93	116.96 ± 4.02	0.375
3 hours	119.1 ± 3.89	120.66 ± 3.87	0.124
4 hours	116.26 ± 3.95	117.76 ± 3.99	0.149
5 hours	118.16 ± 3.86	119.46 ± 4.44	0.232
6 hours	115.43 ± 3.91	116.26 ± 4.64	0.455

Diastolic Blood Pressure is compared between two groups at regular interval and p value in all reading is >0.05(Table 4)

Table 4:- Diastolic Blood Pressure wise distribution

DBP	Group A	Group B	P value
Baseline	83.1 ± 2.84	83.86 ± 2.88	0.304
15 min	83.86 ± 2.88	84.7 ± 2.78	0.259
30 min	85.53 ± 2.67	86.46 ± 2.60	0.177
45 min	88.43 ± 2.86	89.3 ± 2.73	0.235
60 min	86.5 ± 2.82	87.13 ± 3.07	0.407
75 min	83.66 ± 2.56	84.56 ± 2.66	0.187
90 min	85.9 ± 2.60	86.33 ± 2.99	0.554
105 min	87.73 ± 2.93	89.16 ± 3.09	0.071
120 min	85.03 ± 2.80	86.06 ± 3.58	0.219
3 hours	85.93 ± 2.79	86.13 ± 3.55	0.809
4 hours	87.8 ± 3.06	89.23 ± 3.39	0.091
5 hours	86.96 ± 2.80	88.1 ± 3.63	0.182
6 hours	89.13 ± 2.44	90.36 ± 3.29	0.105

Mean arterial pressure was compared between the two groups and they are both comparable. There is no significant difference between the two groups. (table 5)

Table 5:-Mean Arterial Blood Pressure wise distribution

MAP	Group A	Group B	P value
Baseline	93.83 ± 2.32	94.73 ± 2.39	0.142
15 min	95.33 ± 2.26	96.40 ± 2.38	0.081
30 min	96.33 ± 1.91	97.03 ± 2.20	0.193
45 min	96.96 ± 2.02	98.03 ± 2.29	0.061
60 min	96.43 ± 2.11	97.16 ± 2.46	0.221
75 min	93.53 ± 1.88	94.46 ± 2.44	0.103
90 min	95.10 ± 1.72	95.96 ± 2.83	0.158
105 min	96.76 ± 2.02	98.01 ± 2.91	0.062
120 min	95.26 ± 1.98	96.30 ± 3.01	0.122
3 hours	96.96 ± 2.07	97.70 ± 2.93	0.271
4 hours	97.36 ± 2.05	98.43 ± 2.71	0.062
5 hours	97.40 ± 1.99	98.60 ± 2.90	0.069
6 hours	97.93 ± 2.13	99.03 ± 3.01	0.105

Respiratory rate was compared in both groups and p value is >0.05. So the difference between two groups was not significant (Table 6)

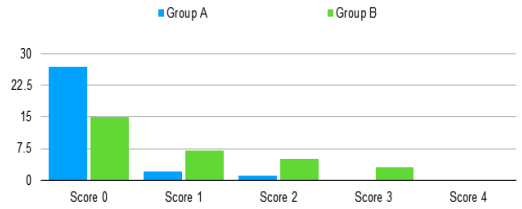
Table 6:-Respiratory Rate wise distribution

RR	Group A	Group B	P value
Baseline	13.53 ± 1.71	14.0 ± 1.74	0.300
15 min	13.86 ± 1.65	13.66 ± 1.66	0.643
30 min	14.13 ± 1.73	14.0 ± 1.57	0.757
45 min	13.86 ± 1.73	14.4 ± 1.61	0.222
60 min	13.93 ± 1.85	13.73 ± 1.63	0.660
75 min	13.6 ± 1.69	14.06 ± 1.85	0.313
90 min	13.73 ± 1.72	13.46 ± 1.56	0.533
105 min	14.33 ± 1.66	14.06 ± 1.61	0.532
120 min	14.26 ± 1.79	14.26 ± 1.63	1.000
3 hours	14.4 ± 1.77	14.46 ± 1.63	0.880
4 hours	14.13 ± 1.73	14.26 ± 1.79	0.771
5 hours	14.46 ± 1.63	14.0 ± 1.74	0.289
6 hours	13.93 ± 1.77	14.33 ± 1.66	0.373

Shivering score

Graph 1: comparison of shivering score between two groups

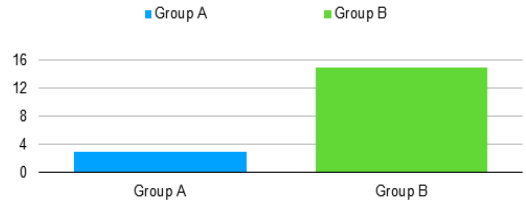
Graph 1 shows the shivering score that suggests that there was significant difference seen in both groups of patients who develop shivering. P value was <0.05.



Incidence of shivering

Graph 2: Based on Crossley and Mahajan scale for incidence of shivering

Graph 2 shows the significant difference in incidence of shivering between both groups



Incidence of adverse effects in both groups: Incidence of nausea was seen in five patients in group B while incidence of hypotension was seen in 2 and 3 patients in group A and B respectively. Bradycardia was seen in 1 patient in group A & 3 patients in group B. Incidence of nausea was significant (P Value<0.05). Hypotension and bradycardia between two groups was not significant.

DISCUSSION

Our study was designed to evaluate the efficacy of Intravenous Ondansetron in prevention of postoperative shivering after SA. Shivering is a protective response occurring as a part of centrally mediated thermoregulatory defence mechanism to hypothermia. Shivering is defined as fasciculation of the face, jaw, or head or muscle hyperactivity lasting longer than 15 secs. Postoperative shivering is an involuntary, oscillatory muscular activity during early recovery after anaesthesia. Shivering is elicited when the pre-optic region of the hypothalamus is cooled. Efferent signals radiating shivering descend in the medial forebrain bundle. Spinal alpha motor neurone & their axons are the final common path for both coordinated movement and shivering.

Shivering is a frequent complication that occurs during Spinal Anaesthesia. Shivering is believed to increase oxygen consumption, risk of hypoxemia, induce lactic acidosis & catecholamine release. Moreover, it is one of the leading causes of discomfort for post surgical patients. The etiology of shivering has been understood insufficiently. Another potential mechanism is pain & acute opioid withdrawal specially with use of short acting narcotics.

Elective cesarean delivery is most commonly carried on under spinal anaesthesia, which is commonly associated with shivering, both intra- and postoperatively. The etiology of shivering is not clearly understood, it may involve a combination of mechanisms, including modulation of thermoregulatory thresholds, change in body heat distribution,reduction in body core temperature, and the cooling effect of the fluids injected intravenously. Severe shivering interferes with electrocardiogram, pulse oximetry, and monitoring of blood pressure during the critical period of sympathetic block and aortocaval compression, when hypotension is more likely. It may also cause maternal irritability and interfere with her ability to hold her baby.

Serotonin (5-HT3) a biological amine found in the brain & spinal cord, plays a part in the neurotransmission of shivering. Serotonergic system plays an important role in the pathogenesis of postoperative shivering. Serotonin antagonism seems to lower the human thermal set range thereby reducing metabolic cold defences & discomfort associated with postoperative hypothermia. Several drugs are effective in treating or preventing post-spinal shivering, including meperidine, tramadol, and clonidine. These drugs have adverse effects on the mother and foetus, including sedation, nausea, vomiting, bradycardia, and hypotension. These unwanted effects limit the use of such drugs before delivery, because of concerns on the mother and the foetus.

We chose Ondansetron for our study. It has potential advantages in Obstetric anaesthesia because of its very low incidence of sedation, hypotension, bradycardia or risk to neonate. Ondansetron is a widely used antiemetic during both pregnancy and surgery. Some studies showed it's anti-shivering effects following both general and neuraxial anaesthesia.

The aim of our study was to assess the prophylactic effects of a single intravenous dose of Ondansetron (8 mg), compared with placebo, on the prevention of postoperative shivering during elective cesarean delivery. The study consisted of 60 patients further divided into two groups, out of which one group received injection ondansetron 8mg(4 ml) : Group A and the other was given Normal saline 4ml: Group B. A comparison of hemodynamic variables (Heart rate, SpO2, BP, RR) & shivering score was made intraoperatively and postoperatively up to 6 hours from the time of induction. There was no significant difference among the other variables; while the patients in group A had significantly less incidence of shivering as compared to group B. Among the complications that occurred (Hypotension, Bradycardia, Nausea); only nausea was significantly more in Group B.

CONCLUSION

We have concluded from our study that intravenous ondansetron when given in dose of 8 mg to patients undergoing elective cesarean section under spinal anaesthesia proved to be effective in lowering the incidence of post spinal anaesthesia induced shivering with no significant adverse effects both on mother and foetus.

REFERENCES

1. English W (2002). "Post-operative shivering, causes, prevention and treatment (letter)". Update in Anaesthesia. 1 (3). Archived from the original on 29 May 2011. Retrieved 8 September 2010.
2. Alfonsi, P (2001). "Post-anaesthetic shivering; epidemiology, pathophysiology, and approaches to prevention and management". Drugs. 61 (15):2193-205. doi:10.2165/00003495-200161150-00004. PMID11772130.
3. Ciofolo MJ, Clergue F, Devilliers C, Ben-Ammar M, Viars P: Changes in ventilation, oxygen uptake, and carbon dioxide output during recovery from isoflurane anaesthesia. Anaesthesiology 1989; 70: 737-41.
4. Just B, Delva E, Camus Y, Lienhart A: Oxygen uptake during recovery following naloxone. Anaesthesiology 1992; 76: 60-4.
5. De Courcy JG, Eldred C: Artefactual "hypotension' from shivering. Anaesthesia 1989; 44: 787-8.
6. Barker SJ, Shah NK: Effects of motion on the performance of pulse oximeters in volunteers. Anaesthesiology 1996; 85: 774 81.
7. Ostheimer GW, Datta S: Observations in the postpartum recovery room after various local anesthetic techniques. Reg Anesth 1981; 6: 13-7
8. Mahajan RP, Grover V, Sharma SL, Singh H: Intraocular pressure changes during muscular hyperactivity after general anaesthesia. Anaesthesiology 1987; 66: 419-21.
9. Rosa G, Pinto G, Orsi P, De Blasi RA, Conti G, Sanita R, La Rosa I,Gasparetto A: Control of post anaesthetic shivering with nefopam hydrochloride in mildly hypothermic patients after neurosurgery. Acta Anaesthesiol Scand 1995; 39: 90-5.
10. Kranke P, Bberhart LH, Rower N, Tramèr NIR (September 2004). "Single-dose parenteral pharmacological interventions for the prevention of postoperative shivering: a quantitative systematic review of randomised controlled 718-trials". Anesth.Analg. 99 (3):27. doi:10.1213/01.ANE.0000130589.00098.CD.PMID15333401.
11. Kranke P, Eberhart LH, Roewer N, Tramèr MR (February 2002). "Pharmacological treatment of postoperative shivering: a quantitative systematic review of randomized controlled trials". Anesth. Analg. 94 (2): 453-60. do: 10.1213/00000539-200202000-00043. PMID11812718.
12. Sevarino FB, Johnson MD, Lema M, Datta S, Ostheimer GW, Naulty JS: The effect of intravenous fentanyl on shivering and body temperature in the parturient. Anesth Analg 1989; 68: 530-3
13. De Witte J, Deloof T, De Veylder J, Housmans PR: Tramadol in the treatment of postanesthetic shivering. Acta Anaesthesiol Scand 1997; 41: 506-10.
14. Zhou, Y: Mannan, A; Han, Y; Liu, Hi; Guan, HIL; Cao, X; Dai, MS; Ca., n (30 December 2019), *efficacy and safety of prophylactie use of ketamine for prevention of postanesthetic shivering: a systematic review and meta analysis". BMC Anesthesiology. 19 (1);245. doi:10.1186/s12871-019-0910-8. PMC 6937868. PMID 31888509.
15. Hom E-P, Werner C, Sessler DI, Steinfath M, Schulte am Esch J: Late intraoperative administration of clonidine prevents postanesthetic shiverimg after spinal anesthesia. Anesth Analg 1997; 84: 613-7