e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(5); 1618-1623

Original Research Article

A Prospective Randomized Interventional Controlled Study to Compare the Effect of Intrathecal Tramadol with Placebo for Prevention of Shivering under Subarachnoid Block

Ajay Kumar Saini[1], Rajni Mathur[2], Mahima[3], Chetali Das[4]

[1]3rd Year PG Student, Department of Anaesthesia, SMS Medical College & Hospital, Jaipur

[2]Senior Professor, Department of Anaesthesia, SMS Medical College & Hospital, Jaipur

[3]3rd Year PG Student, Department of Anaesthesia, SMS Medical College & Hospital, Jaipur

[4]Senior Resident, Department of Anaesthesia, SMS Medical College & Hospital, Jaipur

Received: 26-02-2023 / Revised: 24-03-2023 / Accepted: 20-04-2023

Corresponding author: Dr. Ajay Kumar Saini

Conflict of interest: Nil

Abstract

Introduction: Peri-anaesthesia shivering is a common complication following subarachnoid block (SAB). Subarachnoid Block is the preferred means of anesthesia for lower abdomen, pelvis, and lower limb surgery.

Aim and Objective: Comparison of intrathecal tramadol versus placebo for prevention of shivering under subarachnoid block.

Material and Methods: A prospective, randomised, double-blind, controlled study was created. A total of 108 cases were chosen by the sealed envelope method and divided into two equal groups. Group A (54 cases) received intrathecal tramadol with bupivacaine, while group B (54 cases serving as a control) received intrathecal bupivacaine. The peri-operative body temperature, peri-operative hemodynamic parameters, and peri-operative shivering events were all documented.

Result: In this study, group A's mean age was 36.03 years old, whereas group B's mean age was 36.9 years old. In group A, 16.6% and 9.26% of patients experienced nausea and vomiting, respectively, while 14.8% of patients shivered both during and after surgery. Patients in group B who had peri-operative shivering and nausea made up 64.81% of the patient population.

Conclusion: When given intrathecally to patients scheduled for surgery under sub-arachnoid block, tramadol 20 mg and 3ml of 0.5% heavy bupivacaine play a significant role in the prevention of the incidence of anesthesia-induced shivering with early onset of both sensory and motor components of the sub-arachnoid block.

Keywords: Intrathecal Tramadol, Shivering, Subarachnoid Block.

Introduction

The first local anaesthetic to be isolated was cocaine (the only naturally occurring local anaesthetic), which marked the beginning of the development of regional anaesthesia. Spinal anaesthesia was the first regional anaesthetic method used. At the Royal Surgical Hospital of the University of Kiel in Germany on August 16, 1898, August Bier

(1861–1949), who is known as the father of spinal anaesthesia, carried out the first surgical procedure under spinal anaesthesia.[1,2]

The primary method of anaesthesia for lower abdominal, pelvic, and lower limb surgery is subarachnoid block. It is incredibly affordable and simple to use. Numerous studies have demonstrated that when abdominal gynecologic procedures were carried out under spinal anaesthesia rather than general anaesthesia, the return of many physiological functions occurred more quickly, with a shorter hospital stay, and with more compliance.[3]

Following subarachnoid block (SAB), peri-anesthesia shivering is a frequent consequence; the reported prevalence ranges from 40% to 70%.[4] It can be described as tremor-like hyperactivity of the skeletal muscles that is spontaneous, involuntary, and oscillatory.[5]

Opioids like pethidine, tramadol, and butorphanol have all been used pharmaceutically to stop or reduce shivering.[6] Due to its affordability, accessibility, and capacity to extend the duration of sensory block, motor block, and postoperative analgesia, tramadol is a frequently used intrathecal (IT) adjuvant.[7] Intrathecal treatments for peri-operative shivering include doxapram, ketanserin, clonidine, propofol, physostigmine, pethidine, nefopam, butorphanol, and ondansetron.[8]

The synthetic opioid tramadol was first released in the middle of the 1970s. It displays mu receptor-selective central opiate agonist action at all classes of opioid receptors. Tramadol, in contrast, has a 6000-fold lower affinity for -receptors than morphine, making it a centrally acting analgesic with less respiratory depressive effects[9]. It has no known neurological toxicity and also prevents the spinal cord's reuptake of serotonin and norepinephrine.[10]

In order to compare the effectiveness of tramadol, a medication with established anti-shivering activity, with a placebo in avoiding post-anesthesia shivering after elective surgery under the subarachnoid block, we conceptualised the current prospective study.

Material and Methods

This prospective, randomised, double-blind, placebo-controlled trial was carried out at the S.M.S. Medical College in Jaipur's Department of Anaesthesia. By using the sealed envelope approach, 108 cases in all were chosen and divided into two equal groups. 54 patients were given intrathecal injections of 0.5% hyperbaric bupivacaine and 20 mg of preservative-free tramadol, or 20 mg/ml, of tramadol in group A. 54 patients in Group B got intrathecal injections of 0.5% hyperbaric bupivacaine 15 mg (3ml) and normal saline (1ml) (total volume: 4ml).

Inclusion Criteria: 1. Patients of either sex are eligible. **2.** The 20–50 year old age range. 3. Having elective surgery while receiving a subarachnoid block. **3.** A history of severe anaemia, hypovolemia, or impaired renal, cardiac, or respiratory function. **4.** A history of using sedatives or opioids, or a history of mental illnesses.

Procedure: Throughout the intraoperative period, the vital signs (HR, NIBP, SpO2, body temperature, and shivering) were monitored every five minutes. Nasopharyngeal probes were used during surgery to measure body temperature. The procedure was begun once an appropriate level of sensory and motor obstruction had been reached. Using a 5-point intensity scale, patients were evaluated for shivering during the operation and for up to 3 hours afterward. Tramadol 1 mg/kg IV is given if the shivering score is greater than 2 (moderate to severe shivering). The patients were observed in the

recovery room for HR, NIBP, SpO2, and shivering scores every 15 minutes for the first three hours. For 24 hours after surgery, the patients were closely watched for any postoperative problems such hypotension, bradycardia, pruritus, respiratory depression (RR 8/min), nausea, and vomiting.

Result

Group 1's mean age was 36.03 years, whereas group 2's was 36.9 years. The bulk of the patients in groups A and B were between the ages of 31 and 40 and 41 and 50, respectively. The majority of patients in groups A and B were men: 72.2% in group A and 64.81% in group B. We discovered that group A's mean weight was 63.3 kg, while group B's was 60.87 kg.

Table 1: Comparison of intra-operative shivering between two groups.

Intra-Operative Shivering	Group A		Group B		P-Value
	No. of Patients	Percentage	No. of Patients	Percentage	
No	46	85.19	19	35.19	<0.0001(S)
Yes	8	14.81	35	64.81	
Total	54	100.00	54	100.00	

Table 1 shows that intra-operative shivering was present in the majority in 14.8% of group A patients and 64.81% of group B patients. The p-value indicated that there was a significant difference between the groups.

In our investigation, we discovered that there was no significant difference between the groups for intra-operative temperature, SBP, DBP, MAP, SPO2, and respiratory rate because the p-value was greater than 0.05.

Figure 1 shows that, up to 10 minutes, there was no discernible difference between these groups in intraoperative shivering. Then, with a p-value of 0.05, there was a significant difference between the two groups.

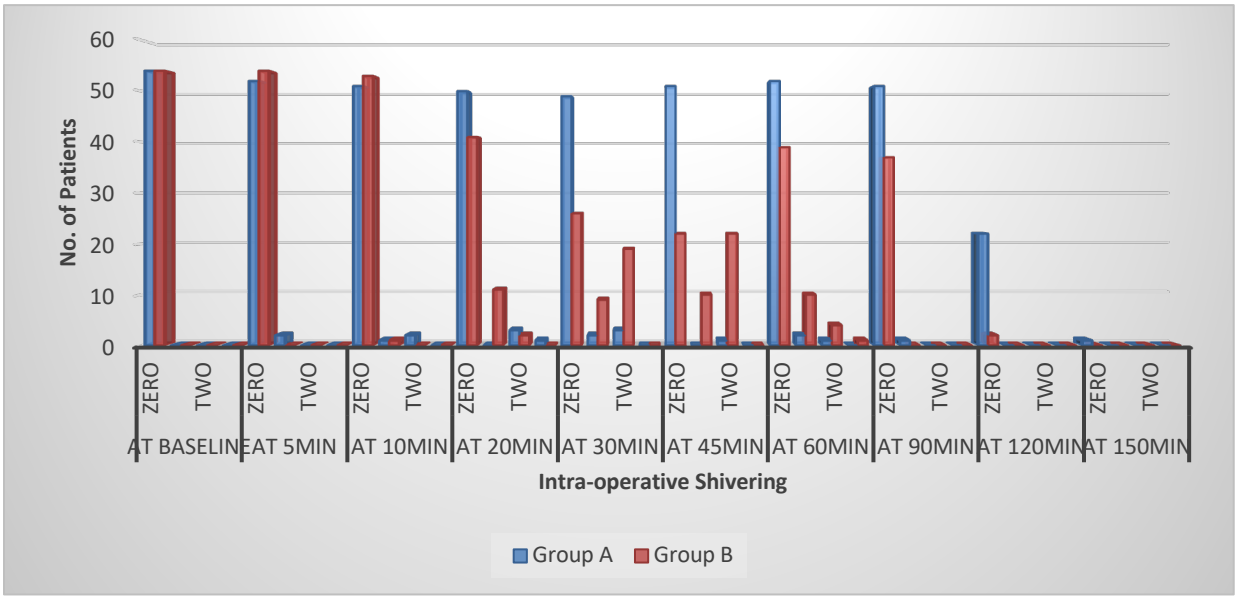

Figure 1

In terms of post-operative heart rate, SBP, DBP, MAP, SPO2, and respiratory rate, there was no statistically significant difference between the groups (p value >0.05).

Table 2: Comparison of postoperative complications between two groups

Post-op Complication	Group A		Group B		P-Value
	No. of Patients	Percentage	No. of Patients	Percentage	
Nausea	9	16.67	6	11.11	0.73(N.S)
Vomiting	5	9.26	0	0.00	
Chest Pain	0	0.00	0	0.00	
Flushing	0	0.00	0	0.00	

Table 2 shows that the majority of patients—16.6% in group A and 11.11% in group B—feel nauseous, followed by 9.26% of group A patients who vomit.

According to figure 2, there was a significant difference in post-operative shivering between these groups at all time points, including baseline, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes, 105 minutes, and 120 minutes.

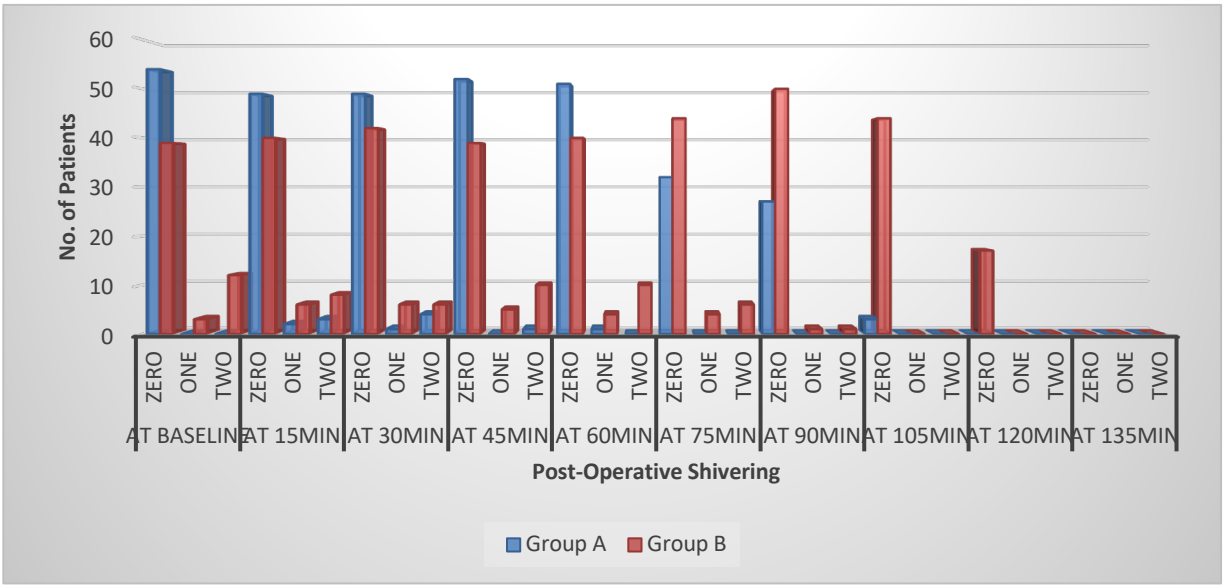

Figure 2: Comparison of post-operative shivering between two groups.

Discussion

Most patients' shivering is caused by hypothermia. It happens as a result of a combination of the anaesthetic medications' competitive reduction of thermoregulatory responses, lowered metabolism, and exposure to a cold environment. Internal redistribution, which occurs right away when anaesthesia is induced, is the process by which core heat is moved from the centre to the periphery. The second stage is the decrease in core temperature brought on by heat losses (via the skin, through visceral exposure, or through the perfusion of cold liquids). Depending on the anaesthetic agents and concentrations utilised, a different amount of body temperature loss occurs. In this study, group A's mean age was 36.03 years, whereas group B's was 36.9 years. The bulk of the patients in groups A and B were between the ages of 41 and 50. Male patients made up 72.2% of patients in group A and 64.81% of patients in group B.

According to a study by Badhe V K *et al.*[11], group C's mean age was 45.56 years old and group T's mean age was 42.48 years old. By

dividing the 60 cases into two groups of 30, Bansal A. P. *et al*[12]. Regarding demographic traits like age, sex, and ASA grade, both groups were comparable. Group C had a mean age of 24.74 years, whereas group T had a mean age of 25.32 years.

Similar to Agarwal K *et al* [13], our study found that the mean pre-operative, intra-operative, and post-operative vital signs (SBP, DBP, MBP, Pulse rate, SPO2, RR, and Temperature) did not significantly differ between the two groups when P-value was 0.05. In this investigation, there was no discernible difference between the groups in terms of the mean heart rate, systolic blood pressure, or diastolic blood pressure. Similar findings for hemodynamic data, such as baseline heart rate and blood pressure, operating room and recovery room temperatures, were found in a study by Mohta M *et al* [14].

We discovered that 16.6% of patients in group A and (11.11%) of patients in group B experience nausea, with 9.26% of group A patients experiencing vomiting.

In the study of Subedi *et al* [15], nausea was present in 26% of patients and vomiting was present in 18% of the patients intra-operatively, whereas in the study done by Verma *et al* [16] nausea was seen in 10% and 6.6% patients experienced vomiting.

We also analyzed post-operative shivering in this study. We found that there was a significant difference found in post-operative shivering between these groups at all the time intervals i.e at baseline, 15 min, 3o min, 45 min, 60 min, 75 min, 90 min, 105 min, 120 min. Similar results were seen by Agarwal K *et al* [13] who found that there is a significant decrease in the incidences of shivering in group T (both intra-operatively and post-operatively) as compared to group B. Gupta P *et al* [17] sought to compare the anti-shivering efficacy of two commonly used doses of intrathecal tramadol (10 and 20 mg) to find the dose with the best anti-shivering efficacy with the least adverse effects.

They observed a significant reduction in the incidence and severity of post-spinal shivering. Post-spinal shivering has been hypothesized to be a physiological response to intraoperative hypothermia.4 Subarachnoid block associated sympathetic blockade induces loss of thermoregulatory vasoconstriction below the level of block; causing core-to-peripheral redistribution of the body heat and core hypothermia.[18]

Conclusion

Based on the findings of this study, we can conclude that administering intrathecal tramadol 20 mg in combination with 3ml of 0.5% heavy bupivacaine to patients undergoing surgery with a subarachnoid block significantly reduces the occurrence of anesthesia-induced shivering. Furthermore, this treatment approach promotes early onset of both the sensory and motor components of the subarachnoid block.

References

1. Bier, A. Experiments in cocainization of the spinal cord. Dtsch Zschrf Chir. 1899; 51:363–369.
2. David LB. Spinal, epidural and caudal anesthesia. In: Miller RD, ed. Millers Anesthesia, 6th edn, Vol. 63. New York: Elsevier Churchill Livingstone
3. Ghirardini G, Baraldi R, Bertellini C, *et al*. Advantages of spinal anesthesia in abdominal gynecologic surgery. Clin Exp Obstet Gynecol. 1998; 25:105– 106.
4. De Witte J, Sessler DI. Perioperative shivering: Physiology and pharmacology. Anesthesiology 2002; 96:467-84.
5. Prasad RB, Joel CJ, Zachariah VK. Effectiveness of addition of intrathecal tramadol with hyperbaric bupivacaine in prevention of shivering in parturients undergoing caesarean section under

spinal anaesthesia: A randomized placebo-controlled study. Karnataka Anaesth J. 2015; 1:123-7.
6. Bharti N, Dontukurthy S, Bala I, Singh G. Postoperative analgesic effect of intravenous clonidine compared with clonidine administration in wound infiltration for open cholecystectomy. Br J Anaesth. 2013; 130:1093-9.
7. Chakraborty S, Chakrabarti J, Bhattacharya D. Intrathecal tramadol added to bupivacaine as spinal anesthetic increases analgesic effect of the spinal blockade after major gynecological surgeries. Indian J Pharmacol. 2008; 40:180-2.
8. Kranke P, Eberhart LH, Roewer N, Tramèr MR. Pharmacological treatment of postoperative shivering: A quantitative systematic review of randomized controlled trials. Anesth Analg. 2002; 94:453-60.
9. Vickers MD, O'Flaherty D, Szekely SM, Read M, Yoshizumi J. Tramadol: pain relief by an opioid without depression of respiration. Anaesthesia 1992; 47: 291±6.
10. Tsai YC, Chang PJ, Jou IM. Direct tramadol application on sciatic nerve inhibits spinal somatosensory evoked potentials in rats. Anesth Analg. 2001; 92: 1547-51.
11. Badhe V K, Swami N R, Gore S K, Badhe V K, Vinayak S R. Comparative study of efficacy of intrathecal tramadol added to bupivacaine in prevention of intraoperative shivering. Pravara Med Rev. 2019;11(2).
12. Bansal A P, Chakole V, Singam A, Latwal B S. Evaluation of Efficacy of Intra Thecal Tramadol for Prevention of Shivering Post Spinal Anaesthesia in Patients Undergoing Caesarian Section. Biomedical & Pharmacology Journal. 2020;13(3):1305-1310.
13. Kanika Agrawal, Tejash H Sharma, Kirti D Patel. Comparison of Intrathecal Tramadol with Bupivacaine and Bupivacaine alone to Control Shivering in Patients Undergoing Caesarean Surgery. Indian J Anesth Analg. 2019;6(2):449-453.
14. Mohta M, Kumari N, Tyagi A, Sethi A.K. Tramadol for prevention of postanaesthetic shivering: a randomised double-blind comparison with pethidine. Anaesthesia, 2009, 64, pages 141–146.
15. Subedi A, Biswas Bk, Tripathi M. Analgesic effects of intrathecal tramadol in patients undergoing caesearean section: a randomised, double-*blind* study. Int J Obstet anesth. 2013;22(4):316-21. Epub 2013 Aug 17.
16. Verma D, Naithani U, Jain DC, Singh A. Postoperative analgesic efficacy of intrathecal tramadol versus nalbuphine added to bupivacaine in spinal anaesthesia for lower limb orthopaedic surgery. J evol med densci. 2013;2(6):196-206.
17. Gupta P, Gupta M. Intrathecal tramadol for prevention of postanesthesia shivering after subarachnoid block: A prospective randomized placebo-controlled comparison of two different doses (10 and 20 mg). Anesth Essays Res. 2018; 12:495-500.
18. Rastegarian A, Ghobadifar MA, Kargar H, Mosallanezhad Z. Intrathecal meperidine plus lidocaine for prevention of shivering during cesarean section. Korean J Pain. 2013; 26:379-86.