



COMPARATIVE STUDY BETWEEN INTRATHECAL TRAMADOL WITH BUPIVACAINE AND INTRATHECAL BUPIVACAINE ON INCIDENCE OF PERIOPERATIVE SHIVERING

Anesthesiology

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ABSTRACT

Shivering is a common problem faced during the intraoperative and postoperative period. It is found during both regional and general anaesthesia but is more common with regional anaesthesia. Many pharmacological agents have been used to decrease and to reduce the severity of perioperative shivering. Among these pharmacological agents, tramadol which belongs to opioids has been studied. This study is designed to compare the efficacy and safety of intrathecal tramadol 0.25mg/kg-group 1 with bupivacaine 0.5% 3ml-group 2 and intrathecal bupivacaine 0.5% 3ml on prevention of perioperative shivering in patients undergoing vaginal hysterectomy under spinal anaesthesia and thereby to determine its therapeutic effect and side effects if any. There was a statistically significant decrease in the incidence of shivering in group 1. There was a statistically significant difference in temperature between Group 1 and Group 2 at 30min, 60 min and 90 min respectively. Group 2 had a lower mean temperature than Group 1.

KEYWORDS

Intrathecal Tramadol, Shivering, Spinal Anaesthesia.

INTRODUCTION

Regional anaesthesia is a safe and popular anaesthetic technique for various surgeries. Spinal anaesthesia is the most common type of anaesthesia used for vaginal hysterectomy. Ease of administration, relatively few contraindications and good relaxation make it preferred method of anaesthesia for below umbilical surgeries. Around 40-60% of patients under regional anaesthesia develop shivering¹. Shivering is a common problem faced during the intraoperative and postoperative period. It is found in both regional and general anaesthesia but is more common with regional anaesthesia. In regional anaesthesia, shivering is seen in both perioperative and postoperative period whereas in general anaesthesia it is seen in the postoperative period. The incidence of perioperative shivering is high in intraperitoneal surgical patients. Perioperative shivering causes patient and surgeon's discomfort because of severe muscle movement, and it also induces elevated blood pressure and tachycardia². This eventually leads to increased oxygen consumption, increased carbon dioxide synthesis that results in an increased pulmonary ventilation capacity and cardiac workload, and an increase in the metabolic rate by up to 400%². It increases the metabolic rate and oxygen consumption up to 100-600%. It can induce arterial hypoxemia and acidosis. It increases intraocular pressure and intracranial tension. It causes stretch on suture lines. It interferes, with monitoring like ECG, pulse oximetry and noninvasive blood pressure measurement. It can be detrimental to patients with low cardiorespiratory reserve¹. After enjoying the benefits of modern anaesthesia, patients experience shivering as an unpleasant occurrence¹.

Many physical and pharmacological interventions are used to decrease the incidence and to reduce the severity of perioperative shivering. Non-pharmacological methods like warming² the intravenous fluids, warm waterbeds, warm covers which use specialised equipment are not practical in all clinical settings³. Many pharmacological agents like Pethidine, Clonidine, Magnesium Sulphate, Amitriptyline, Urapidil, Dolasetron, Doxapram, are used to control shivering. These drugs have side effects like respiratory depression, bradycardia, hypotension

etc³. Among the pharmacological interventions, Tramadol, which belong to Opioids was found effective in many studies. Tramadol has been used as an analgesic for labour pain without adversely affecting the mother or the newborn⁴.

MATERIAL AND METHOD

The present clinical randomized prospective controlled study was conducted after obtaining due permission from the institutional ethical committee. This study was done to evaluate the efficacy of Intrathecal Tramadol in reducing the incidence of perioperative shivering in patients admitted to MVJ Medical College & Research Hospital undergoing elective vaginal hysterectomy under spinal anaesthesia. The study was undertaken during the period of November 2017 – October 2018. 100 Patients are allocated randomly into 2 groups by computer-generated randomization table. Patients belonging to ASA physical status class I and II giving consent to the study of age between 30-60 years were included. Patients with a history of allergy to the drug used with temperature more than 37 °C, failed spinal anaesthesia and any contraindication to spinal anaesthesia were excluded from this study. Preanaesthetic checkup was done 1 day prior to surgery. Patients were evaluated for any systemic diseases and routine laboratory investigations recorded. The procedure of spinal anaesthesia was explained and written consent was obtained from the patients for the study. All patients were kept nil per oral overnight and were pre-medicated on the previous night of surgery with oral tablet alprazolam 0.5 mg and tablet Rantac 150mg.

In the operation theatre ambient temperature was kept between 24 °C – 26 °C, all patients were connected to electrocardiography, arterial oxygen saturation (SpO₂) and non-invasive blood pressure monitor and all the basal parameters were recorded. Baseline temperature was noted. An IV line was secured with 18 gauge cannula and all patients were preloaded with 500 ml of Ringer lactate solution.

A normal cotton blanket was used to cover the patient. All preloading fluid and drugs were given at room temperature. No active

management was done to warm the patient. Oxygen 4 Litre/min was administered through a face mask to all patients.

Spinal anaesthesia was given under all aseptic precautions with a 25 gauge Quincke spinal needle in sitting position.

Group 1 (n=50) received 3.0 ml of 0.5% Bupivacaine (Heavy) and 0.25 mg/kg of Tramadol.

Group 2 (n=50) received 3.0 ml of 0.5% Bupivacaine (Heavy).

Shivering was graded as follows. **Modified Crossley and Mahajan scale** were used to assessing the degree of shivering.

Grade 0	Nil	No shivering.
Grade 1	Mild	Muscular activity involving only one muscle group.
Grade 2	Moderate	Muscular activity involving two or more than two muscle groups but not involving whole body.
Grade 3	Severe	Shivering involving entire body.

Heart rate (HR), Blood pressure (BP), Oxygen saturation (SPO₂) were monitored throughout the surgery. The temperature was recorded every half hour sublingually during surgery and postoperatively for a maximum duration of 4 hours from the time of spinal anaesthesia. Heart rate of less than 20% of baseline was considered as bradycardia, mean arterial pressure less than 65 mmHg was considered as hypotension and were treated accordingly. Shivering if present, the time was noted down and was treated with Inj. Pethidine 0.5mg/kg i/v. Side effects such as nausea, vomiting, if present were noted down and treated.

RESULTS

Table: Comparison of Demographic data between 2 groups

	GROUP 1		GROUP 2		P VALUE
VARIABLE	N	MEAN	N	MEAN	
AGE	50	48.84 ± 6.02	50	48.98±6.99	0.91
WEIGHT	50	58.72± 6.62	50	58.82±6.74	0.9
ASA 1:2	50	36:14	50	30:20	0.2
SURGERY DURATION	50	84.36±4.47	50	83.50±5.40	0.38

There is no significant difference in the age, weight distribution and duration between the two groups. Samples were matching by ASA grading also.

II. Table: Comparison of Heart Rate (beats per minute) between 2 groups

TIME (IN MINS)	GROUP 1	GROUP 2	P VALUE
0	79.56±9.43	77.34±7.99	0.2
15	81.22±10.49	80.30±9.39	0.64
30	75.24±11.40	75.10±10.36	0.94
45	69.10±10.24	69.05±10.53	0.98
60	67.34±8.39	68.25±9.88	0.63
75	67.74±7.87	70.35±9.29	0.17
90	69.08±7.31	72.30±8.60	0.10
120	70.54±6.33	71.93±7.07	0.48
150	70.83±5.41	71.50±7.07	0.7
180	71.35±5.96	71.57±7.28	0.9
210	72.21±5.80	71.93±7.05	0.88
240	72.33±5.84	71.79±6.92	0.75

There is no statistically significant difference in HR between the two groups.

The analysis was done by unpaired student T-test.

III. Table: Comparison of Mean arterial pressure between 2 groups:

TIME(MIN)	GROUP 1	GROUP 2	P VALUE
0	79.96±8.68	79.84±7.57	0.94
15	70.28±7.18	70.24±7.08	0.97
30	70.64±7.04	70.60±5.35	0.97
45	71.36±5.31	71.40±4.54	0.96
60	71.90±5.19	72.45±4.40	0.59
75	72.16±4.04	74.48±5.25	0.04

90	72.61±4.53	75.00±5.10	0.04
120	72.77±4.33	75.07±5.90	0.11
150	73.77±4.33	75.21±5.96	0.33
180	74.38±4.78	75.21±6.00	0.58
210	74.65±4.55	76.07±6.55	0.35
240	74.94±4.96	76.36±4.44	0.38

There is no statistically significant difference in MAP between the two groups except at 75 and 90 min where Bupivacaine has a significant advantage over Tramadol for maintaining the MAP. The analysis was done by unpaired student T-test.

IV. Table: Comparison of incidence of shivering between 2 groups

	GROUP 1	GROUP 2
NO SHIVERING	48(96%)	14(28%)
MILD SHIVERING	2(4%)	19(38%)
MODERATE SHIVERING	0	17(34%)

Incidence of shivering was more in group2 than in group1 with a P value of 0.0001. 19 patients had mild shivering and 17 patients had moderate shivering in the bupivacaine group. 14 patients did not have shivering. 2 patients had mild shivering in group2 whereas 48 patients did not have shivering.

V. Table: Comparison of time of shivering between 2 groups

TIME	GROUP 1	GROUP 2
30-45 MIN	0	10
46-60 MIN	1	0
61-75 MIN	0	17
76-90 MIN	1	0
>90 MN	0	9

In group 2, 10 patients complained of shivering between 30- 45 min, 17 patients between 61-75min, 9 patients had shivering after 90min. In group 1, 1 patient had shivering between 45-60min and patient between 76-90min.

VI. Table :Comparison of Mean temperature in the two groups (in centigrade)

TIME (MIN)	GROUP 1	GROUP 2	P VALUE
BASELINE	36.69±0.27	36.64±0.21	0.31
0 MIN	36.57±0.33	36.49±0.33	0.23
30 MIN	36.07±0.35	35.30±0.66	0.0001
60 MIN	35.68±0.33	34.90±0.60	0.0001
90 MIN	35.68±0.33	35.13±0.66	0.001
120 MIN	35.80±0.27	35.80±0.33	0.94
150 MIN	35.97±0.26	36.08±0.33	0.21
180 MIN	36.18±0.30	36.24±0.25	0.53
210 MIN	36.28±0.30	36.31±0.21	0.75
240 MIN	36.37±0.25	36.32±0.14	0.48

There was statistically significant difference in temperature between Group 1 and Group 2 at 30min, 60 min and 90 min respectively with a P Value of 0.0001. Group 2 had a lower mean temperature than Group 1.

VII. Table: Comparison of incidence of Bradycardia between 2 groups

	GROUP 1	GROUP 2
ABSENT	43(86%)	41(82%)
PRESENT	7(14%)	9(18%)

Incidence of bradycardia was comparable within 2 groups with a P-Value of 0.60.

VIII. Table: Comparison of incidence of Hypotension between 2 groups

	GROUP 1	GROUP 2
ABSENT	38(76%)	35(70%)
PRESENT	12(24%)	15(30%)

Incidence of Hypotension was comparable within 2 groups with a P-Value of 0.510.

DISCUSSION:

Regional anaesthesia is emerging as a safe and popular technique both in elective and emergency situations in modern anaesthesia practice. Incidence of post anaesthesia shivering is high during regional anaesthesia⁵. It occurs both in the perioperative and postoperative

period. Shivering continues to be a common problem faced by the anesthesiologist during intraoperative and postoperative periods. Shivering occurs both during general and regional anaesthesia. Unfortunately, there is no gold standard drug or definitive strategy drawn in the management of this commonly encountered problem. Shivering is a very unpleasant experience for the patients receiving comforts of modern anaesthesia. At times it is described as a sensation worse than surgical pain. It is physiologically stressful; it increases oxygen consumption, which may go up by 100-600%. It increases intraocular and intracranial pressures.

It interferes with routine monitoring like ECG, pulse oximeter and NIBP. It causes tension on suture lines. Shivering is detrimental to patients with low cardiorespiratory reserve. It is uncomfortable for the patients as well as to the operating room personnel, especially during regional anaesthesia^{5,6} as patients will be conscious and surgery will be ongoing.

Tramadol is a synthetic, centrally acting analgesic agent. It acts as an opioid agonist with selectivity to mu-opioid receptors and also binds weakly to kappa and delta receptors. Tramadol inhibits 5-HT₃ reuptake and promotes its release. It also inhibits synaptosomal noradrenaline reuptake⁷. Neuropharmacologic experiments in animals have established the role of Noradrenaline and 5HT₃ in the control of body temperature. Activation of nucleus Raphe Magnus, where 5-HT₃ acts as a neurotransmitter have an inhibitory effect on shivering. It is thus possible the anti-shivering effect of Tramadol is mediated by its effect on these receptors. The exact mechanism of development of post anaesthesia shivering is not known. Many hypotheses like perioperative heat loss, the direct effect of certain anaesthetics, hypercapnia and hypoxia, uninhibited spinal reflexes, early recovery of a spinal reflex activity and sympathetic over activity⁸.

Prasad RB conducted a randomized controlled study on one hundred parturients undergoing cesarean section who were randomly divided into two groups of 50 each. Group T received 0.2 mL (10 mg) of tramadol with 2 mL of 0.5% bupivacaine, while Group S received only 2ml of 0.5% Bupivacaine. The presence of shivering was noted intraoperatively and postoperatively. Shivering was noted in 66% of the patients in Group S as against the 16% noted in Group T with a majority of the cases (88%) noted in the intraoperative period. He concluded that Tramadol (10 mg), along with bupivacaine given intrathecally plays a significant role in reducing the incidence of anaesthesia-induced shivering in parturients while prolonging both the sensory and motor components of the subarachnoid block⁹.

Sarvesh Jain et al in 2014 conducted a study on Intrathecal Tramadol for prevention of shivering in Anorectal surgeries under Subarachnoid anaesthesia. In this study, patients received 12.5 mg of bupivacaine mixed with 10 mg Tramadol at L3-L4 interspace with 23 gauge spinal needle in sitting position. They concluded Intrathecal Tramadol is safe, reliable and cost-effective adjuvant to spinal anaesthesia. It effectively prevents intra and postoperative shivering¹⁰.

In my study, there was a statistically significant difference between 2 groups in the incidence of shivering. Incidence of shivering was more in Group 2 than in Group 1. 19 patients had mild shivering and 17 patients had moderate shivering in group 2. 14 patients did not have any incidence of shivering. 2 patients had mild shivering in Group 1 whereas 48 patients did not have any incidence of shivering. There was a statistically significant difference in temperature between Group 1 and Group 2 at 30 min, 60 min and 90 min respectively. Group 2 had a lower mean temperature than Group 1.

CONCLUSION:

From the findings of the study, it can be concluded that Tramadol in a dose of 0.25mg/kg intrathecally is an effective drug for the control of shivering in patients undergoing spinal anaesthesia with a less fall in body temperature and no increased incidence of side effects.

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