

PREVENTION OF INTRAOPERATIVE SHIVERING UNDER SPINAL ANAESTHESIA- A COMPARATIVE STUDY BETWEEN INTRAVENOUS DEXMEDETOMIDINE AND MAGNESIUM SULPHATE

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Abstract

Background: Intraoperative shivering is a common complication during spinal anaesthesia and is caused by various factors including a decrease in core body temperature, changes in neurotransmitter activity and peripheral vasoconstriction. Dexmedetomidine and magnesium sulphate are two agents that have been used to prevent shivering, but the effectiveness of these drugs remains controversial. **Materials and Methods:** After obtaining an institutional ethical clearance prospective randomised double blinded study was conducted on 90 patients divided in 3 groups A,B,C of 30 each. These group received 0.5mcg/kg of dexmedetomidine, 30 mg/kg of magnesium sulphate, 100 ml normal saline respectively. Severity of shivering, grade of sedation, temperature, any side effects, hemodynamic changes were monitored and recorded. **Result:** The incidence of shivering was noticed among 8 (26.6%) patients in group A, 10 (33.3%) patients in group B and 19 (63.3%) patients in group C. Among 30, 4 (13.33%) patients in group C reported grade 3 shivering, while 22(73.33%) patients in group A reported grade 0 shivering. Out of 30 patients in group B, 9 (30%) patients had hypotension and 2 (6.66%) patients reported incidence of bradycardia in group A. Incidence of hypothermia was reported in 6 (20%) patients in group A, 9 (30%) patients in group B and 4 (13.3%) patients in group C. **Conclusion:** Dexmedetomidine at 0.5mcg/kg prevents shivering and induces sedation, but magnesium sulphate at 30 mg/kg is recommended due to its availability and lower cost. Both are effective options for preventing shivering.

INTRODUCTION

Post anaesthetic shivering is a spontaneous, involuntary, rhythmic, oscillatory tremor-like muscle hyperactivity increasing metabolic heat production up to 600%. It is one of the commonest problems and is observed in 19- 33% of patients.^[1,2] It causes several undesirable physiologic consequences especially an increase in oxygen consumption by 100-600%, with an increase in carbon dioxide production and minute ventilation.^[3] It may induce arterial hypoxemia, lactic acidosis, increased intraocular and intracranial pressure, and interfere with patient monitoring like Electrocardiogram (ECG), Non-invasive blood pressure (NIBP), Oxygen saturation (SPo2) etc.^[4] Spinal anaesthesia prevents peripheral

vasoconstriction and increases cutaneous heat loss. The threshold for vasoconstriction and shivering is decreased by 0.6° C above the block level; this reduction is directly proportional to the number of segments blocked.^[5,6] There is a core-to-periphery redistribution of heat due to spinal anaesthesia induced vasodilatation and shivering is preceded by core hypothermia and vasoconstriction above the level of block.^[7]

Other causes of shivering include pre-existing fever or septicemia, exposure to a cold environment which is commonly seen in operation theatre, rapid infusion of cold intravenous fluids, drug allergies, and blood transfusion reactions. Various pharmacological or non-pharmacological methods are practised to prevent and to treat shivering. The non-pharmacological methods include the use of

heaters, forced air warming blankets, radiant heat, infusing warm fluids, surgical drapes etc.^[8-10]

The pharmacological methods include use of various opioid and non-opioid agents including pethidine, tramadol, butorphanol, clonidine, dexmedetomidine, magnesium sulphate, ondansetron, and ketamine are used to control shivering.^[11-13] All these drugs are not free from certain side effects. Hence, in search of a safer, more effective and faster-acting drug, we conducted this study. We compared the efficacy, haemodynamic alterations, and adverse effects of intravenously administered dexmedetomidine and magnesium sulphate for prevention of shivering occurring during spinal anaesthesia.

MATERIALS AND METHODS

After obtaining institutional ethical clearance, and written informed consent this prospective randomized double blinded study was conducted in the department of Anaesthesia, Rajendra Institute of Medical Sciences, Ranchi and was registered in Clinical Trial Registry India (CTRI/2022/09/045440).

The sample size was calculated as $27.23 \sim 30$ approximately in each Group Using the formula $n = [P1 (1 - P1) + P2 (1 - P2)] / (P1 - P2)^2 \times F$, where n = sample size per group, $P1 = 35\%$ or 0.35 , $P2 = 75\%$ or 0.75 from previous studies and $F = 7.9$ for 80% power and 10.5 for 90% . Taking 5% as the level of significance ($\alpha = 0.05$) and 90% as the power of the study.^[14]

Patients of either gender, between 20 and 50 years of age, weighing between 30 to 80 kgs with ASA grade I or II were included in this study. The surgical procedures selected were, lower abdominal and lower limb surgeries under spinal anaesthesia. Patients developing shivering during preloading, one who requires blood transfusion during surgery, patients with an initial temperature greater than 37.5°C or less than 36.5°C , patients having contraindications to spinal anaesthesia or study drugs were excluded from study.

The patients were randomly assigned into three groups, based on computer generated randomization as: Group A - Intravenous (I.V) injection of 0.5mcg/kg of dexmedetomidine in 100ml Normal saline (NS), Group B - I.V injection of 30 mg/kg of magnesium sulphate in 100ml NS and Group C - Control group-intravenous injection of 100 ml NS. Double blinding was done by blinding the patients and the investigator who was assessing the severity of shivering.

The temperature of the operating room was maintained at 21°C to 22°C . 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.

A core temperature below 36°C will be considered hypothermia. Before performing spinal anaesthesia, each patient received 10 ml/kg/h of lactated Ringer's solution. The infusion rates were then reduced to 6 ml kg/h . An independent investigator, who was not a part of the study, prepared the study drug based on randomization and administered intravenously to the patient over a period of 20 minutes after successful spinal anaesthesia.

The presence of shivering and intensity of shivering was recorded according to the Crossley and Mahajan scale of Shivering [Table 1].

The severity of shivering was recorded at 5-min intervals during the operation and in the recovery room. If the score was two or greater at 20 minutes after spinal anaesthesia, the prophylaxis was regarded as ineffective, and 50 mg tramadol was administered intravenously (I.V) and the side effects if any were recorded.

The bradycardia, hypotension and nausea or vomiting were treated with Inj Atropine, Inj Mephentermine and or with I.V fluids and Inj Ondansetron 4mg IV respectively as per the institutional protocol. Postoperatively, all patients were monitored, given oxygen via a facemask (6L/min) and covered with one layer of drapes and one cotton blanket.

The post-anaesthesia care unit temperature was maintained at 25°C to 26°C . The heart Rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP), oxygen saturation (SpO₂), severity of shivering, grade of sedation, temperature, any side effects were continuously monitored and recorded before induction, during induction and every 5 minutes till 30 min and then every 10 min after giving spinal anaesthesia. [Figure 1]

Means and standard deviations were used to analyse the similarity of the data collected about the group. Chi square test was done for categorical data and ANOVA test was used for parametric data. The normal distribution was presented as frequencies and percentages.

RESULTS

Among 90 patients, 23(25.55%) were female and 67(74.4%) were male. The most common weight range was $61\text{-}70\text{ kg}$, accounting for 35(38.88%) of patients. 38 (42.22%) patients were in the age range of 21-30 years and 74 (82.22%) patients belonged to ASA I physical status as shown in [Table 2]. The incidence of shivering was noticed among 8 (26.6%) patients in group A, 10 (33.3%) patients in group B and 19 (63.3%) patients in group C as depicted in Graph 1. Among 30, 4 (13.33%) patients in group C reported grade 3 shivering, while 22(73.33%) patients in group A reported grade 0 shivering. [Graph 2]

Side effects were noted in our study groups. Out of 30 patients in group B, 9 (30%) patients had

hypotension and 2 (6.66%) patient reported incidence of bradycardia in group A. Incidence of hypothermia was reported in 6 (20%) patients in group A, 9(30%) patients in group B and 4(13.3%) patients in group C. 4 (13.33%) patients in group C had grade 3 severity of shivering while no patient in group A and B reported grade 3 shivering. (Table 3)18 (60%) patients in group A out of 30 (100%) had grade I sedation. [Graph 3]

Total rescue Tramadol consumption for shivering in Group C was (31.66 ± 24.09) mgs as compared to Group A (13.33 ± 22.11) mgs and Group B (16.66 ± 23.57) mgs. [Table 4]

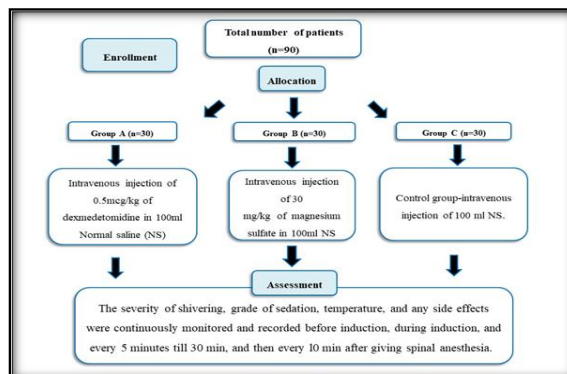


Figure 1: Consort diagram for study

Table 1: Shivering grade and sedation scale.

Crossley and Mahajan grades of shivering	
Grade	Clinical Signs
0	No shivering
1	Piloerection, peripheral vasoconstriction, peripheral cyanosis without other cause but without visible muscular
2	Visible muscular activity confined to one muscle group
3	Visible muscular activity in more than one muscle group
4	Gross muscular activity involving the entire body
Sedation scale	
0	Alert
1	Arouse to voice
2	Arouse with gentle tactile
3	Arouse with vigorous tactile
4	No awareness

Table 2: Demographic details and ASA status of study participants.

Parameter	Scale	Group A n=30 N (%)	Group B n=30 N (%)	Group C n=30 N (%)	Total n=90 N (%)
Gender	Female	5 (16.7)	11 (36.7)	7 (23.3)	23 (25.5)
	Male	25 (83.3)	19 (63.3)	23 (76.7)	67 (74.4)
Age range in years	11-20	6 (20)	3 (10)	6 (20)	15 (16.7)
	21-30	11 (36.7)	17 (56.7)	10 (33.3)	38 (42.2)
	31-40	6 (20)	3 (10)	10 (33.3)	19 (21.1)
	41-50	6 (20)	7 (23.3)	3 (10)	16 (17.8)
	51-60	1 (3.3)	0	1 (3.3)	2 (2.2)
Weight of patient in kg	31-40	1 (3.3)	0	0	1 (1.1)
	41-50	7 (23.3)	5 (16.7)	5 (16.7)	17 (18.9)
	51-60	10 (33.3)	13 (43.3)	7 (23.3)	30 (33.3)
	61-70	10 (33.3)	11 (36.7)	14 (46.7)	35 (38.9)
	71-80	2 (6.7)	1 (3.3)	4 (13.3)	7 (7.8)
ASA Status	I	24 (80)	27 (90)	23 (76.7)	74 (82.2)
	II	06 (20)	03 (10)	07 (23.3)	16 (17.8)

Table 3: Severity of shivering and incidence of adverse outcomes of study drug among participants.

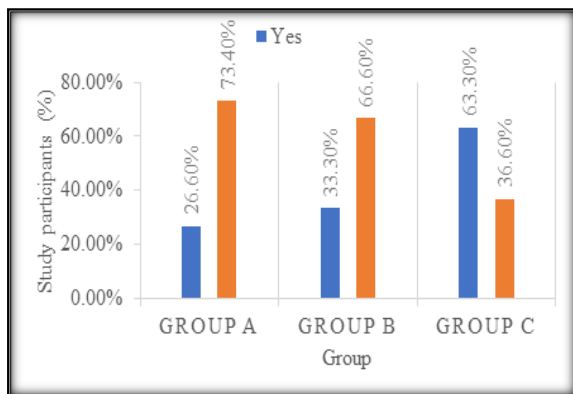
Parameter	Scale	Group A N (%)	Group B N (%)	Group C N (%)	p value
Severity of shivering	0	22 (73.3)	20 (66.7)	11 (36.7)	0.0001
	1	4 (13.33)	8 (26.7)	2 (6.66)	
	2	4 (13.33)	2 (6.66)	13 (43.3)	
	3	0	0	4 (13.33)	
Incidence of hypotension	Yes	7 (23.3)	9 (30)	8 (26.7)	0.8433
	No	23 (76.7)	21 (70)	22 (73.3)	
Incidence of Bradycardia	Yes	2 (6.66)	0	0	0.1293
	No	28 (93.3)	30 (100)	30 (100)	
Incidence of Hypothermia	Yes	6 (20)	9 (30)	4 (13.3)	0.2815
	No	24 (80)	21 (70)	26 (86.7)	

p value less than 0.05 is considered significant.

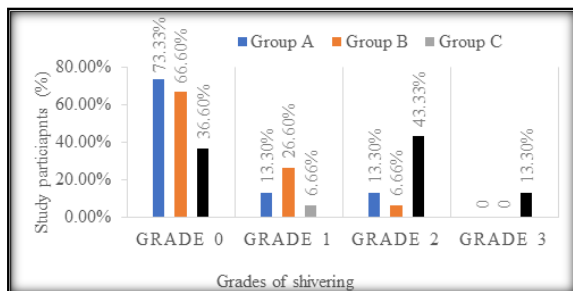
Table 4: Total consumption of rescue tramadol (in mgs)

Groups	Mean	SD	p Value
Group A	13.33	22.11	0.008
Group B	16.66	23.57	
Group C	31.66	24.09	

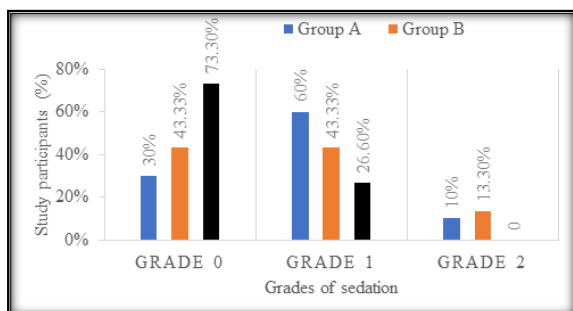
p value less than 0.05 is considered significant.



Graph 1: Incidence of shivering



Graph 2: Grades of shivering



Graph 3: Grades of sedation

DISCUSSION

The exact mechanism of shivering during regional anaesthesia has not been fully established. The possible mechanisms include cessation of central thermoregulation, internal redistribution of body heat, and heat loss to the environment.^[15] Redistribution of core temperature during regional anaesthesia is typically restricted to the legs, and therefore core temperature decreases about half as much during regional anaesthesia as during general anaesthesia.^[16] Vasoconstriction and shivering are restricted to the upper body during spinal anaesthesia, as they are inhibited below the level of blockade through the sympathetic and somatic neural block.^[17] Various drugs have been used to treat or prevent postoperative shivering. However, dexmedetomidine may be a good choice among them because of its dual effects of anti-shivering and sedation. Pharmacological therapies, such as pethidine, tramadol, physostigmine, clonidine, ketamine, and magnesium, have been used to prevent shivering.^[18]

Bicer and colleagues found the incidence of shivering as 15% with dexmedetomidine and 55% with placebo following general anaesthesia. Our results are similar to their study, with the incidences being 10% and 56.7%, respectively.^[19] The lower incidence of shivering in the dexmedetomidine group may be related to the depression of the thermoregulation threshold.

The hemodynamic effects of dexmedetomidine are biphasic. When it is administered intravenously, it causes hypotension and bradycardia until the central sympathomimetic effect is achieved, and then it causes moderate decreases in MAP and HR.^[20,21]

On the other hand, Magnesium (Mg²⁺) is a naturally occurring non-competitive antagonist of N-methyl-D aspartate (NMDA) receptors with a good safety profile and neuro-protective properties under the condition of hypothermia.^[22] The current study demonstrated that prophylactic i.v infusion of both dexmedetomidine (0.5 mcg/kg) and MgSO₄ (30 mg/kg) significantly reduced the incidence of post-spinal shivering. 8 patients (26.65%) were in group A, 10 patients (33.3%) in group B, and 19 patients (63.3%) in group C developed shivering. The number of patients who developed shivering and required Tramadol administration in group A group was 8 (26.6%), in group B was 10 (33.3%), and in group C was 19 (63.3%). Furthermore, while the incidence of bradycardia was 6.65% in group A, none of the patients developed bradycardia in group B and group C. One of the main objectives of using sedative agents is that the drug should not cause respiratory depression. In previous studies, it has been shown that α -2 adrenergic agonists cause no or minimal respiratory depression.^[23] None of our patients had respiratory depression during the operation or in the recovery room. Botros et al. compared the prophylactic effects of an intravenously infused placebo, 1 μ g/kg of dexmedetomidine, and 8 mg of ondansetron on the prevention of post-spinal shivering in 120 patients undergoing different lower body surgeries and found that IV dexmedetomidine and ondansetron were equally as effective in reducing the incidence of post spinal shivering as the placebo.^[24] In a study by Sachidananda et al, a prophylactic IV infusion of Magnesium sulphate and tramadol effectively reduced shivering during caesarean section under spinal anaesthesia and the shivering intensity.^[25] Intravenous infusion of both dexmedetomidine and MgSO₄ were effective in reducing the incidence of post-spinal anaesthesia shivering however one should note that the MgSO₄ is easily available, cost effective with no sedative property.

Limitation of the study

We did not assess different doses of dexmedetomidine and MgSO₄ and their effect on shivering intra and postoperatively. Further studies are needed to evaluate the effects of dexmedetomidine with various doses.

CONCLUSION

Dexmedetomidine at 0.5mcg/kg effectively prevents shivering and induces sedation without increased side effects. Magnesium sulphate at 30 mg/kg intravenously reduces shivering incidence and its severity. However, we recommend using MgSO₄ due to ready availability, and lower cost compared to dexmedetomidine.

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