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ORIGINAL RESEARCH

A Comparative Study on the Efficacy of Intrathecal Nalbuphine and Magnesium Sulfate in Preventing Shivering During Caesarean Sections

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ABSTRACT

Background:SA is the preferred choice due to its numerous benefits compared to General Anaesthesia (GA), including quick onset, better blockade, minimal physiological changes, reduced stress response, cost efficiency, and lower likelihood of postoperative complications. The present study was conducted to compare intrathecalNalbuphine and Magnesium Sulphate for prevention of shivering in caesarean section.**Materials & Methods:**70parturients between the ages of 20-40 years were divided into 2 groups of 35 each. Group I received 0.7 mg nalbuphineintrathecally, while group II received 25 mg of magnesium sulfate intrathecally, both with 0.5% bupivacaine (10 mg). Parameters such as onset of sensory block (mins), time to reach sensory level of T5 (mins), motor block onset (time to reach MBS-3) (mins), time to regress motor blockade to MBS-1 (mins), duration of sensory block (mins), side effects and severity of shivering were recorded.**Results:**T h e mean age was 25.2 years and 24.8 years, weight was 64.6 kgs and 64.8 kgs, height was 1.42 meters and 1.45 meters, duration of surgery was 51.3 minutes and 53.7 minutes. ASA grade I was seen in 24 and 23 and II in 11 and 12 patients in group I and II respectively. The difference was non- significant (P> 0.05). Onset of sensory block (mins) was 1.62±3.3 and 4.51±6.4, time to reach sensory level of T5 (mins) was 6.34±1.2 and 6.12±2.1, motor block onset (time to reach MBS-3) (mins) was 5.40±2.5 and 7.62±2.1, time to regress motor blockade to MBS-1 (mins) was 217.5±15.3 and 219.4±14.2 and duration of sensory block (mins) was 230.7±20.4 and 228.5±23.5 in group I and II respectively. The difference was significant (P< 0.05). Grade of shivering was 3 seen in 2 in group I and 3 in group II and 4 in 1 in group I and 2 in group II patients. The difference was non- significant (P> 0.05). Side effects were nausea seen in 3 in group I and 1 in group II, vomiting 2 in group I and 1 in group II, sedation 4 in group I and 3 in group II and hypotension 1 in group I respectively. The difference was non-significant (P> 0.05).**Conclusion:** Both medications are safe and reduce the frequency and severity of shivering in women undergoing LSCS under SA, without causing any serious side effects.

Keywords: General Anaesthesia, Nalbuphine, Shivering

INTRODUCTION

The selection of anaesthesia for LSCS is based on several factors: the rationale for the surgery, how urgent it is, the patient's preferences, and the anaesthesiologist's assessment.[1,2] SA is the preferred choice due to its numerous benefits

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compared to General Anaesthesia (GA), including quick onset, better blockade, minimal physiological changes, reduced stress response, cost efficiency, and lower likelihood of postoperative complications.[3] Nevertheless, hypothermia and shivering are frequent complications following SA due to its effects on thermoregulation, tonic vasoconstriction, and core heat distribution. In patients who undergo LSCS, shivering linked to SA is a frequent issue. Approximately 55% of patients undergoing neuraxial anaesthesia exhibit shivering.[4]

It is quite uncomfortable for patients and can disrupt the monitoring of Electrocardiogram (ECG), Blood Pressure (BP), and oxygen saturation (SpO2). Shivering raises oxygen consumption, lactic acidosis, and carbon dioxide production, leading to distress in parturients with low cardiopulmonary reserves and high metabolism.[5] Various agents such as meperidine, doxapram, nalbuphine, dexamethasone, tramadol, nefopam, ketanserin, clonidine, propofol, physostigmine, magnesium sulfate (MgSO4), and fentanyl have been used to eliminate postoperative shivering.[6] MgSO4 serves as a non-competitive antagonist of N-methyl-D-aspartate (NMDA) receptors. Its blocking of these receptors results in reduced levels of epinephrine and 5-HT, both of which are involved in thermoregulation. Nalbuphine and MgSO4 administered intravenously (IV) are effective in managing shivering post-regional anaesthesia.[7] Only a small number of studies have compared intrathecal nalbuphine and magnesium sulfate for lower abdominal surgeries. Furthermore, the authors are not aware of any research that compares the effects of intrathecal injections of nalbuphine and MgSO4 in preventing post-SA shivering during LSCS.[8]

AIM AND OBJECTIVES

Aim of the Study

To compare the effectiveness of intrathecal nalbuphine versus magnesium sulfate in preventing post-spinal anaesthesia shivering in patients undergoing lower segment caesarean section (LSCS).

Objectives

1. Evaluate the incidence and severity of shivering following spinal anaesthesia in both study groups.
2. Assess the onset and duration of sensory and motor blockade in patients receiving either nalbuphine or magnesium sulfateintrathecally.
3. Monitor and compare perioperative side effects such as nausea, vomiting, sedation, and hypotension between the two groups.

MATERIALS AND METHODS

Study Design

This was a prospective, randomized, comparative clinical study conducted to evaluate the efficacy of intrathecal nalbuphine versus magnesium sulfate in the prevention of perioperative shivering in patients undergoing caesarean section under spinal anaesthesia.

Study Population

The study was carried out on a total of 70 parturients, aged between 20 to 40 years, who were scheduled for elective lower segment caesarean section (LSCS).

Study place

The study was conducted in the Department of Anaesthesia in collaboration withDepartment of Obstetrics & Gynaecology, Himalaya Medical College, Hospital, Patna, Bihar, India.

Study Duration

The study was conducted over a period of 10 months from February 2024 to November 2024.

Inclusion Criteria

- Parturients aged between 20 to 40 years.
- ASA (American Society of Anaesthesiologists) Physical Status I and II.
- Scheduled for elective caesarean section under spinal anaesthesia.
- Provided written informed consent.

Exclusion Criteria

- Known allergy to any of the study drugs.
- Contraindications to spinal anaesthesia.
- Patients with febrile illness or infections.
- History of pre-eclampsia, eclampsia, or chronic hypertension.
- Neurological or psychiatric disorders.
- Coagulation abnormalities.
- Any opioid or magnesium therapy within 24 hours preoperatively.

Ethical Considerations

- Ethical approval was obtained from the Institutional Ethics Committee prior to the commencement of the study.
- Written informed consent was obtained from all participants after thoroughly explaining the nature, purpose, and potential risks of the study.
- The study adhered to the principles of the Declaration of Helsinki.

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Study Procedure

- The 70 participants were randomly divided into two groups (n = 35 each) using a computer-generated randomization table:
  - Group I (Nalbuphine Group): Received 0.7 mg of nalbuphine intrathecally along with 10 mg of 0.5% hyperbaric bupivacaine.
  - Group II (Magnesium Group): Received 25 mg of magnesium sulfateintrathecally along with 10 mg of 0.5% hyperbaric bupivacaine.
- All patients were preloaded with 10 mL/kg of Ringer's lactate prior to spinal block.
- Spinal anaesthesia was administered in the L3–L4 or L4–L5 interspace with a 25G Quincke spinal needle in the sitting position under aseptic conditions.

Surgical Technique

- Following the establishment of adequate block height (T5), the caesarean section was performed using a standardized surgical technique.
- All surgeries were carried out by the same surgical team to minimize variability.

Outcome Measures

The following parameters were recorded and analyzed:

- Onset of sensory block (minutes): Time from intrathecal injection to first loss of pinprick sensation.
- Time to reach T5 level (minutes): Time to attain T5 dermatome sensory level.
- Onset of motor block (MBS-3, minutes): Time to achieve modified Bromage score of 3.
- Time to regress motor blockade to MBS-1 (minutes).
- Duration of sensory block (minutes).
- Incidence and severity of shivering, assessed using a standardized 4-point scale.
- Side effects and complications, such as hypotension, nausea, vomiting, pruritus, sedation, or respiratory depression.

Statistical Analysis

- Data were compiled and statistically analyzed using SPSS software version 25.0.
- Descriptive statistics were calculated as mean ± standard deviation (SD) for continuous variables.
- Categorical data were expressed as percentages.
- Comparison between the two groups was done using:
  - Unpaired t-test for continuous variables.
  - Chi-square test or Fisher's exact test for categorical variables.
- A p-value < 0.05 was considered statistically significant.

RESULTS

Table 1: Demographic Data

Parameters	Group I	Group II	P value
Age (years)	25.2	24.8	0.91
Weight (kg)	64.4	64.8	0.35
Height (meter)	1.42	1.45	0.72
Duration of surgery (mins)	51.3	53.7	0.84
ASA I/II	24/11	23/12	0.63

Table 1 shows that mean age was 25.2 years and 24.8 years, weight was 64.6 kgs and 64.8 kgs, height was 1.42 meters and 1.45 meters, duration of surgery was 51.3 minutes and 53.7 minutes. ASA grade I was seen in 24 and 23 and II in 11 and 12 patients in group I and II respectively. The difference was non-significant (P> 0.05).

Table 2:Assessment of Parameters

Parameters	Group I	Group II	P value
Onset of sensory block (mins)	1.62±3.3	4.51±6.4	0.02
Time to reach sensory level of T5 (mins)	6.34±1.2	6.12±2.1	0.05
Motor block onset (time to reach MBS-3) (mins)	5.40±2.5	7.62±2.1	0.01
Time to regress motor blockade to MBS-1 (mins)	217.5±15.3	219.4±14.2	0.35
Duration of sensory block (mins)	230.7±20.4	228.5±23.5	0.48

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Table 2 shows that onset of sensory block (mins) was 1.62±3.3 and 4.51±6.4, time to reach sensory level of T5 (mins) was 6.34±1.2 and 6.12±2.1, motor block onset (time to reach MBS-3) (mins) was 5.40±2.5 and 7.62±2.1, time to regress motor blockade to MBS-1 (mins) was 217.5±15.3 and 219.4±14.2 and duration of sensory block (mins) was 230.7±20.4 and 228.5±23.5 in group I and II respectively. The difference was significant (P< 0.05).

Table 3: Severity of Shivering

Shivering	Group I	Group II	P value
0	0	0	0.59
1	0	0	
2	0	0	
3	2	3	
4	1	2	

Table 3 shows that grade of shivering was 3 seen in 2 in group I and 3 in group II and 4 in 1 in group I and 2 in group II patients. The difference was non- significant (P> 0.05).

Table 4: Assessment of Side-Effects

Side-effects	Group I	Group II	P value
Nausea	3	1	0.81
Vomiting	2	1	
Sedation	4	3	
Hypotension	1	0	

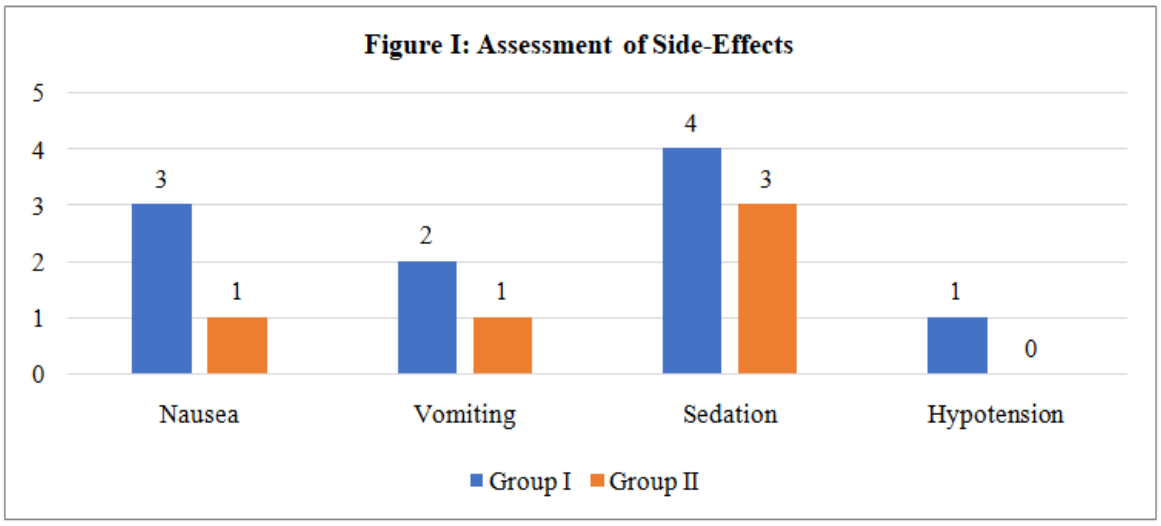

Table 4, figure I shows that side effects were nausea seen in 3 in group I and 1 in group II, vomiting 2 in group I and 1 in group II, sedation 4 in group I and 3 in group II and hypotension 1 in group I respectively. The difference was non- significant (P> 0.05).

DISCUSSION

Patients undergoing SA commonly experience postoperative shivering (POS) as a complication.[9]Although shivering acts as a protective reflex to raise core temperature via involuntary muscle contractions, it can also lead to negative consequences. Included among these effects is heightened oxygen consumption, which may affect wound healing.[10] In addition, shivering disrupts intraoperative and postoperative monitoring because of the involuntary oscillatory muscular activity.[11]The present study was conducted to compare intrathecal Nalbuphine and Magnesium Sulphate for prevention of shivering in caesarean section.

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We found that mean age was 25.2 years and 24.8 years, weight was 64.6 kgs and 64.8 kgs, height was 1.42 meters and 1.45 meters, duration of surgery was 51.3 minutes and 53.7 minutes. ASA grade I was seen in 24 and 23 and II in 11 and 12 patients in group I and II respectively. Angralet al[12] compared the effect of intrathecal injection of nalbuphine and magnesium sulfate on the prevention of postspinal anaesthesia shivering during LSCS. Both study groups were comparable in terms of age (p-value=0.081), height, weight (p-value=0.079), ASA grade (p-value=0.072), and duration of surgery (p-value=0.077). In group N, 5 patients (16.67%) had POS, while in Group M, 6 patients (20%) had POS, but the difference was not statistically significant. In Group N, 3 patients (10%) had a shivering score of 3 and 2 patients (6.67%) had a shivering score of 4, while in group M, 3 patients (10%) had a shivering score of 3 and 3 patients (10%) had a shivering score of 4. The difference was statistically insignificant. Perioperative complications (sedation, hypotension, nausea, and vomiting) were comparable in both groups with no statistically significant difference.

We found that onset of sensory block (mins) was 1.62±3.3 and 4.51±6.4, time to reach sensory level of T5 (mins) was 6.34±1.2 and 6.12±2.1, motor block onset (time to reach MBS-3) (mins) was 5.40±2.5 and 7.62±2.1, time to regress motor blockade to MBS-1 (mins) was 217.5±15.3 and 219.4±14.2 and duration of sensory block (mins) was 230.7±20.4 and 228.5±23.5 in group I and II respectively. Amulya N[13] assessed the effectiveness of intrathecal magnesium sulphate as an adjuvant in preventing shivering in parturients undergoing caesarean section. 80 parturients of age 18-45 years of American Society of Anaesthesiologists (ASA) grade II undergoing caesarean section were randomised into two groups of 40 each. Group M received 2ml 0.5% heavy bupivacaine+ 0.1ml 25mg MgSo4. Group P received 2ml 0.5% heavy bupivacaine + 0.1ml saline. Intraoperative Shivering score was assessed as primary outcome, Vital signs, temperature, sensory and motor blockade were recorded as secondary outcome. Overall incidence of shivering in Magnesium sulfate group was low, though during 10, 15, 20, 30, 40 minutes post spinal, it was statistically significant ($p < 0.001\%$). Core body temperature was significantly reduced in Magnesium sulfate group compared to the normal saline group30minutes post spinal ($p < 0.001\%$).

We found that grade of shivering was 3 seen in 2 in group I and 3 in group II and 4 in 1 in group I and 2 in group II patients. We found that side effects were nausea seen in 3 in group I and 1 in group II, vomiting 2 in group I and 1 in group II, sedation 4 in group I and 3 in group II and hypotension 1 in group I respectively. Nirala DK et al[14] compared the clinical efficacy, hemodynamic parameters, and side effects of nalbuphine and tramadol for control of postspinal anaesthesia shivering. This study was conducted on 90 American Society of Anaesthesiologists Physical Status I and II patients of either gender, aged between 18 and 60 years, who subsequently developed shivering grade 3 or 4, scheduled for different surgical procedures under spinal anaesthesia. The patients were randomized into two groups of 45 patients each to receive either nalbuphine 0.06 $mg.kg^{-1}$ (Group N) or tramadol 1 $mg.kg^{-1}$ (Group T). The time taken for cessation of shivering was significantly less with nalbuphine in comparison with tramadol ($P < 0.05$). It was observed that the response time at 5 and 30 min and rescue dose requirement for control of shivering were not much difference ($P > 0.05$).

LIMITATIONS OF THE STUDY

- Small sample size (n=70) may limit the generalizability of the findings.
- The study was single-centre, which may not reflect practices in other institutions.
- Short follow-up duration limited assessment of delayed side effects or late-onset shivering.
- The subjective nature of shivering assessment may introduce observer bias.
- Lack of blinding could influence results; a double-blind design would have improved the robustness of the findings.

CONCLUSION

The study concluded that both intrathecal nalbuphine (0.7 mg) and magnesium sulfate (25 mg) are effective in reducing the incidence of post-spinal shivering in women undergoing LSCS under SA, without causing any serious side effects.Both drugs demonstrated comparable safety profiles with minimal perioperative complications, making them viable, cost-effective options for shivering prevention in clinical practice

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