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Original Research Article

INTRATHECAL NALBUPHINE VERSUS MAGNESIUM SULPHATE FOR PREVENTION OF SHIVERING DURING CAESAREAN SECTION: A COMPARATIVE STUDY

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ABSTRACT

Background: Shivering is a common complication following spinal anaesthesia during caesarean section, with significant maternal discomfort and increased metabolic demand. Various pharmacological agents have been evaluated for prophylaxis, but no consensus exists regarding the optimal intrathecal adjuvant. This study compared the efficacy and safety of intrathecal nalbuphine and magnesium sulphate for prevention of shivering in parturients undergoing caesarean section under spinal anaesthesia. **Materials and Methods:** In this prospective, randomized, double-blind study, 98 ASA I–II parturients scheduled for elective caesarean section were allocated into two groups (n=49 each). Group N received intrathecal 0.5% hyperbaric bupivacaine with nalbuphine 0.8 mg, while Group M received bupivacaine with magnesium sulphate 50 mg. The primary outcome was incidence and severity of shivering. Secondary outcomes included sensory and motor block characteristics, hemodynamic changes, adverse effects, and neonatal Apgar scores. Statistical significance was set at $p<0.05$. **Result:** The overall incidence of shivering was significantly lower in Group N compared to Group M (26.5% vs 49.0%; p=0.021). Clinically significant shivering (Grade ≥3) occurred in 4.1% versus 14.3%, respectively (p=0.08). Hemodynamic parameters, incidence of hypotension (22.4% vs 28.6%; p=0.47), and bradycardia were comparable. Magnesium sulphate was associated with delayed onset of sensory block (3.8 ± 1.0 vs 3.1 ± 0.8 minutes; p=0.001). Mild pruritus occurred more frequently with nalbuphine (8.2%; p=0.04). Neonatal Apgar scores were similar between groups. **Conclusion:** Intrathecal nalbuphine significantly reduced the incidence of shivering compare3d to magnesium sulphate without compromising maternal hemodynamics or neonatal outcomes. Magnesium sulphate showed delayed onset of sensory block with modest anti-shivering efficacy. Intrathecal nalbuphine appears to be a more effective and clinically reliable adjuvant for prevention of post-spinal shivering during caesarean section.

INTRODUCTION

Shivering is a common and distressing complication of spinal anaesthesia during caesarean section, with an incidence reported between 40% and 70% in obstetric patients.[1,2] Although often considered benign, shivering increases oxygen consumption by up to 200–400%, elevates carbon dioxide production, and may precipitate hypoxemia and metabolic acidosis.[3] These physiological stresses are undesirable in parturients and may interfere with monitoring modalities such as electrocardiography and pulse oximetry, while also reducing maternal comfort and satisfaction.[3]

The mechanism of post-spinal shivering is multifactorial. Spinal anaesthesia produces sympathetic blockade and vasodilatation below the level of the block, causing redistribution of core heat to the periphery and impairment of thermoregulatory vasoconstriction.[4] Additionally, neuraxial local anaesthetics alter central thermoregulation by modifying afferent thermal input and hypothalamic set-point control.[5] Obstetric factors such as exposure during surgery and administration of unwarmed fluids may further predispose patients to hypothermia and shivering.[5]

Several pharmacological agents have been evaluated for prevention of shivering, including opioids, α2-

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agonists, serotonin antagonists, and NMDA receptor antagonists.[6] However, adverse effects such as nausea, pruritus, respiratory depression, and hemodynamic instability limit their routine prophylactic use in obstetrics.[6]

Nalbuphine, a κ-agonist and μ-antagonist opioid, exerts anti-shivering effects through modulation of thermoregulatory pathways at the spinal and hypothalamic levels.[7] It has a ceiling effect on respiratory depression and a lower incidence of pruritus compared to pure μ-agonists, making it suitable for intrathecal use in caesarean section.[7] Studies have shown its efficacy as an intrathecal adjuvant with stable hemodynamics and minimal side effects.[8]

Magnesium sulphate acts as a non-competitive NMDA receptor antagonist and calcium channel blocker, attenuating central excitatory transmission and potentially suppressing shivering responses.[9] Intrathecal magnesium has been used to prolong analgesia, though its effectiveness in shivering prevention remains inconsistent.[10]

Despite multiple options, no standard prophylactic agent has been established.[11] Therefore, this study was aimed to compare the effectiveness of intrathecal nalbuphine and intrathecal magnesium sulphate in preventing shivering during caesarean section under spinal anaesthesia, while also evaluating associated maternal hemodynamic changes and adverse effects.

MATERIALS AND METHODS

Study Design and Ethical Considerations: This prospective, randomized, double-blind, parallel-group comparative study was conducted in the Department of Anaesthesiology in collaboration with department of Obstetrics and Gynaecology, at a tertiary care teaching hospital in North India, for a period of 2 years between August 2023 and July 2025. Written informed consent was obtained from all participants.

Study Participants: Parturients aged 18–35 years with singleton term pregnancy (≥37 weeks), classified as American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective lower segment caesarean section under spinal anaesthesia were eligible. Exclusion criteria included contraindications to neuraxial block, known hypersensitivity to study drugs, thyroid dysfunction, febrile illness, baseline core temperature <36°C or >38°C, hypertensive disorders of pregnancy with systemic compromise, significant cardiopulmonary disease, BMI >35 kg/m², coagulation abnormalities, chronic opioid use, and requirement for conversion to general anaesthesia.

Sample Size: Sample size estimation was based on recent Indian studies reporting an incidence of post-spinal shivering of approximately 55% in parturients undergoing caesarean section under spinal anaesthesia [1]. Assuming a 30% absolute reduction in shivering incidence between the two groups (from 55% to 25%), with a power of 80% and a two-sided alpha error of 0.05, the calculated minimum sample size was 44 patients per group. To compensate for possible dropouts and protocol deviations, 49 patients were enrolled in each group, resulting in a total sample size of 98 participants.

Randomization, Allocation Concealment, and Blinding: Participants were randomly allocated in a 1:1 ratio using a computer-generated randomization sequence. Allocation concealment was ensured using sequentially numbered, sealed opaque envelopes that were opened immediately prior to preparation of the study drug. Group N received intrathecal hyperbaric bupivacaine (0.5%, 2–2.2 mL) combined with Nalbuphine 0.8 mg (diluted with preservative-free normal saline to standardize total intrathecal volume). Group M received hyperbaric bupivacaine (0.5%, 2–2.2 mL) combined with preservative-free Magnesium sulphate 50 mg, with the total intrathecal volume kept identical in both groups to maintain blinding. The study solutions were prepared by an anaesthesiologist who was not involved in intraoperative management, monitoring, or data collection. Both the attending anaesthesiologist administering spinal anaesthesia and the independent observer recording intraoperative and postoperative data were blinded to group allocation throughout the study period.

Anaesthetic Technique and Perioperative Management: Standard fasting guidelines were followed. No active warming measures were instituted preoperatively. Baseline heart rate, non-invasive blood pressure, oxygen saturation, and axillary temperature were recorded. Intravenous access was secured with an 18G cannula, and patients were preloaded with 10–15 mL/kg warmed Ringer's lactate solution.

Spinal anaesthesia was administered at the L3–L4 or L4–L5 interspace using a 25G Quincke needle under strict aseptic precautions. After confirming free cerebrospinal fluid flow, the study solution was injected over 10–15 seconds. Patients were immediately positioned supine with left uterine displacement. Supplemental oxygen (4–6 L/min) was administered via face mask.

Sensory block level was assessed by loss of pinprick sensation and motor block by modified Bromage scale. Hemodynamic parameters were recorded every 2 minutes for the first 10 minutes, every 5 minutes for 30 minutes, and thereafter every 10 minutes until completion of surgery. Hypotension (systolic BP <90 mmHg or >20% decrease from baseline) was treated with intravenous ephedrine 6 mg increments. Bradycardia (HR <50 bpm) was treated with atropine 0.6 mg intravenously.

Outcome Measures: The primary outcome was the incidence and severity of shivering, assessed intraoperatively and in the immediate postoperative period using a validated four-point grading scale (Grade 0–4). Clinically significant shivering was defined as Grade ≥3. Rescue therapy with

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intravenous tramadol 1 mg/kg was administered when indicated.

Secondary outcomes included onset and duration of sensory and motor block, intraoperative hemodynamic stability, perioperative temperature changes, requirement for rescue anti-shivering medication, and incidence of adverse effects such as nausea, vomiting, pruritus, respiratory depression, and sedation. Neonatal well-being was assessed using Apgar scores at 1 and 5 minutes.

Statistical Analysis: Data were analyzed using SPSS version 20.0. Continuous variables were expressed as mean ± standard deviation and assessed for normality. Between-group comparisons were performed using Student's t-test. Categorical variables were analyzed using Chi-square. A two-tailed p-value <0.05 was considered statistically significant.

RESULTS

There were no statistically significant differences between the two groups with respect to baseline demographic and obstetric characteristics. The mean age in Group N (Nalbuphine) was 26.8 ± 3.9 years compared to 27.2 ± 4.1 years in Group M (Magnesium sulphate) (p=0.62). Body weight, height, and BMI were comparable between groups (p>0.05). Mean gestational age was 38.4 ± 0.9 weeks in Group N and 38.6 ± 1.1 weeks in Group M (p=0.41). The average duration of surgery was also similar (54.6 ± 8.4 vs 56.2 ± 9.1 minutes; p=0.37), indicating homogeneity between groups at baseline [Table 1].

Table 1: Baseline Demographic and Obstetric Characteristics of Study Participants.

Variable	Group N (Nalbuphine) (n=49)	Group M (Magnesium) (n=49)	p-value
	mean ± SD		
Age (years)	26.8 ± 3.9	27.2 ± 4.1	0.62
Weight (kg)	68.4 ± 7.5	69.1 ± 8.2	0.68
Height (cm)	156.9 ± 4.8	157.4 ± 5.1	0.59
BMI (kg/m²)	27.8 ± 2.6	27.9 ± 2.9	0.88
Gestational age (weeks)	38.4 ± 0.9	38.6 ± 1.1	0.41
Duration of surgery (min)	54.6 ± 8.4	56.2 ± 9.1	0.37

BMI – Body Mass Index.

The overall incidence of shivering (Grade ≥1) was significantly lower in Group N compared to Group M (26.5% vs 49.0%; p=0.021). Absence of shivering (Grade 0) was observed in 73.5% of patients in Group N compared to 51.0% in Group M. Clinically significant shivering (Grade ≥3) occurred in 4.1% of patients in Group N and 14.3% in Group M; although numerically lower in the nalbuphine group, this difference did not reach statistical significance (p=0.08). These findings demonstrate superior shivering prophylaxis with intrathecal nalbuphine [Table 2].

Table 2: Incidence and Severity of Intraoperative Shivering among Study Participants.

Variable	Group N (Nalbuphine) (n=49)	Group M (Magnesium) (n=49)	p-value
	Frequency (%)/mean ± SD		
Shivering Grade			
Grade 0	36 (73.5%)	25 (51.0%)	0.029
Grade 1	7 (14.3%)	9 (18.4%)	
Grade 2	4 (8.2%)	8 (16.3%)	
Grade 3	2 (4.1%)	6 (12.2%)	
Grade 4	0 (0%)	1 (2.0%)	
Any Shivering (≥Grade 1)	13 (26.5%)	24 (49.0%)	0.021
Clinically significant (≥Grade 3)	2 (4.1%)	7 (14.3%)	0.08

Shivering graded on a 4-point scale (Grade 0–4). Clinically significant shivering defined as Grade ≥3.

Baseline systolic blood pressure was comparable between Group N (118.6 ± 9.4 mmHg) and Group M (119.8 ± 8.9 mmHg) (p=0.51). The lowest recorded SBP intraoperatively was 98.4 ± 10.1 mmHg in Group N and 95.6 ± 9.8 mmHg in Group M (p=0.16). Incidence of hypotension (22.4% vs 28.6%; p=0.47) and bradycardia (6.1% vs 8.2%; p=0.69) were similar in both groups. Mean ephedrine requirement did not differ significantly (5.8 ± 3.2 mg vs 6.4 ± 3.7 mg; p=0.38), indicating comparable hemodynamic stability [Table 3].

Table 3: Intraoperative Hemodynamic Parameters among Study Participants.

Parameter	Group N (Nalbuphine) (n=49)	Group M (Magnesium) (n=49)	p-value
	Frequency (%)/mean ± SD		
Baseline SBP (mmHg)	118.6 ± 9.4	119.8 ± 8.9	0.51
Lowest SBP (mmHg)	98.4 ± 10.1	95.6 ± 9.8	0.16
Incidence of hypotension	11 (22.4%)	14 (28.6%)	0.47
Incidence of bradycardia	3 (6.1%)	4 (8.2%)	0.69
Ephedrine requirement (mg)	5.8 ± 3.2	6.4 ± 3.7	0.38

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SBP – Systolic Blood Pressure.

The onset of sensory block was significantly faster in Group N (3.1 ± 0.8 minutes) compared to Group M (3.8 ± 1.0 minutes) (p=0.001). Similarly, time to achieve T6 sensory level was shorter in Group N (5.6 ± 1.2 vs 6.4 ± 1.3 minutes; p=0.002). Duration of sensory block (128.5 ± 15.6 vs 134.2 ± 18.4 minutes; p=0.09) and motor block (142.6 ± 20.8 vs 148.3 ± 22.5 minutes; p=0.18) were comparable between groups. These findings suggest delayed onset with magnesium sulphate without significant prolongation of block duration [Table 4].

Table 4: Sensory and Motor Block Characteristics among Study Participants.

Variable	Group N (Nalbuphine) (n=49)	Group M (Magnesium) (n=49)	p-value
	mean ± SD		
Onset of sensory block (min)	3.1 ± 0.8	3.8 ± 1.0	0.001
Time to T6 level (min)	5.6 ± 1.2	6.4 ± 1.3	0.002
Duration of sensory block (min)	128.5 ± 15.6	134.2 ± 18.4	0.09
Duration of motor block (min)	142.6 ± 20.8	148.3 ± 22.5	0.18

Time measured in minutes.

Incidence of nausea and vomiting was comparable between Group N (12.2%) and Group M (14.3%) (p=0.76). Pruritus was observed in 8.2% of patients in Group N and none in Group M (p=0.04). Sedation (Ramsay score ≥3) occurred more frequently in Group N (18.4%) compared to Group M (8.2%), though this difference was not statistically significant (p=0.14). No cases of respiratory depression were recorded in either group. Neonatal Apgar scores at 1 minute (8.1 ± 0.6 vs 8.0 ± 0.7; p=0.48) and 5 minutes (9.3 ± 0.5 vs 9.2 ± 0.6; p=0.39) were comparable, indicating no adverse neonatal effects [Table 5].

Table 5: Adverse Effects and Neonatal Outcomes among Study Participants.

Variable	Group N (Nalbuphine) (n=49)	Group M (Magnesium) (n=49)	p-value
	Frequency (%)/mean ± SD		
Nausea/Vomiting	6 (12.2%)	7 (14.3%)	0.76
Pruritus	4 (8.2%)	0 (0%)	0.04
Sedation (Ramsay ≥3)	9 (18.4%)	4 (8.2%)	0.14
Respiratory depression	0 (0.0%)	0 (0.0%)	—
Apgar score (1 min)	8.1 ± 0.6	8.0 ± 0.7	0.48
Apgar score (5 min)	9.3 ± 0.5	9.2 ± 0.6	0.39

Apgar scores assessed at 1 and 5 minutes.

DISCUSSION

Post-spinal shivering during caesarean section remains a clinically relevant problem in obstetric anaesthesia, with reported incidence ranging between 40–70% in parturients in studies by Khanna et al., Subramani et al., and Shrivastava et al.[12-14] In the present randomized double-blind study involving 98 patients, intrathecal nalbuphine significantly reduced the overall incidence of shivering compared with intrathecal magnesium sulphate (26.5% vs 49.0%; p=0.021), with a significant difference in overall grade distribution (p=0.029). The absolute risk reduction of 22.5% corresponds to a clinically meaningful benefit in routine obstetric practice.

Our findings are consistent with previous studies by Deetayart et al., and Mostafa et al., evaluating intrathecal nalbuphine as an adjuvant to bupivacaine.[15,16] Deetayart et al., and Mostafa et al., reported shivering incidences ranging from 20–30% in patients receiving 0.8–1 mg intrathecal nalbuphine, significantly lower than control groups (p<0.05).[15,16] Similarly, international studies by Nair et al., and Tudimilla et al., evaluating κ-opioid agonists have demonstrated reduced thermoregulatory responses due to hypothalamic modulation.[17,18] The anti-shivering effect of Nalbuphine is attributed to κ-receptor activation, which increases the shivering threshold and suppresses cold-induced thermogenesis while preserving respiratory drive because of its μ-antagonist property.[17] This dual mechanism makes nalbuphine particularly suitable in obstetric populations where respiratory safety is paramount.[18] In contrast, although Magnesium sulphate possesses NMDA receptor antagonistic properties and attenuates central excitatory neurotransmission, its intrathecal anti-shivering efficacy appears less consistent.[19] Previous studies by Lenil et al., and Kathuria et al., assessing intravenous magnesium have shown moderate reduction in shivering incidence (approximately 30–40%), but intrathecal studies report variable outcomes.[20,21] The present study observed a 49% incidence of shivering in the magnesium group, suggesting that while magnesium may modulate spinal nociceptive pathways, its influence on hypothalamic thermoregulation may be indirect and less robust compared to opioid receptor modulation.[21]

Clinically significant shivering (Grade ≥3) was lower in the nalbuphine group (4.1% vs 14.3%), although this did not achieve statistical significance (p=0.08). This trend aligns with prior obstetric studies by Shraddha et al., and Liu et al., where nalbuphine

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reduced severe shivering episodes but sample sizes were insufficient for statistical confirmation.[22,23] Larger multicentric trials may clarify this difference. Hemodynamic stability was comparable between groups. The incidence of hypotension (22.4% vs 28.6%; p=0.47) and bradycardia did not differ significantly, which parallels findings from previous studies by Kapdi et al., and Chandrappa et al., where intrathecal nalbuphine did not exacerbate sympathetic blockade.[24,25] Magnesium has been associated with vasodilatory effects when administered intravenously; however, the low intrathecal dose (50 mg) used in our study did not significantly alter blood pressure or vasopressor requirements.

A noteworthy finding was the delayed onset of sensory block in the magnesium group (p=0.001). Similar observations have been reported in studies by Saraiva et al., and Zhang et al., evaluating intrathecal magnesium as an adjuvant, where NMDA receptor blockade may alter synaptic transmission and delay local anaesthetic action at the dorsal horn.[26,27] However, the duration of sensory and motor blockade remained comparable (p>0.05), indicating that magnesium's effect on block kinetics is limited primarily to onset rather than prolongation.

Adverse effects were mild and clinically acceptable. Pruritus occurred in 8.2% of patients receiving nalbuphine (p=0.04), consistent with opioid receptor-mediated effects reported in earlier studies by Nirala et al., and Ferrea et al.[28,29] Importantly, no respiratory depression was observed, supporting nalbuphine's safety profile due to its ceiling effect on respiratory suppression. Sedation was more frequent in the nalbuphine group but not statistically significant. Neonatal Apgar scores at 1 and 5 minutes were comparable, corroborating previous obstetric studies Subramani et al., Shrivastava et al., and Ferrea et al., demonstrating that low-dose intrathecal opioids do not adversely affect neonatal outcomes.[13,14,29]

Limitations

This study was conducted at a single tertiary care center with a relatively modest sample size, which may limit generalizability. Core temperature was measured using axillary recordings rather than invasive thermometry, potentially underestimating subtle temperature variations. Additionally, long-term maternal and neonatal outcomes were not assessed. Dose-response relationships for both intrathecal nalbuphine and magnesium sulphate were not explored, which may influence comparative efficacy.

CONCLUSION

In this prospective randomized study of parturients undergoing caesarean section under spinal anaesthesia, intrathecal nalbuphine demonstrated superior efficacy in reducing the overall incidence of shivering compared to intrathecal magnesium sulphate, while maintaining comparable hemodynamic stability and neonatal outcomes. Although magnesium sulphate showed a modest anti-shivering effect, it was associated with delayed onset of sensory block. Both agents were well tolerated, with minimal adverse effects and no respiratory depression. Based on these findings, intrathecal nalbuphine appears to be a more effective and clinically reliable adjuvant for the prevention of post-spinal shivering in obstetric patients.

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