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Effect of Low Dose Intrathecal Pethidine on Incidence and Intensity of Shivering During Caesarean Section Under Spinal Anaesthesia: An Observational Study

Rahul Kumar Chaudhary[1]*, Ankit Agrawal[1] and Moda Nath Marhatta[2]

[1]Department of Anesthesiology and Critical Care, Birat Medical College Teaching Hospital, Morang, Nepal, India

[2]Nepal Medical College Teaching Hospital, Kathmandu, Nepal, India

ABSTRACT

Background

Shivering is a frequent and distressing complication during Cesarean Sections (CS) under spinal anesthesia, affecting over 40% of patients. It compromises maternal comfort, increases metabolic demand, and may lead to adverse hemodynamic effects, delayed recovery, and postoperative complications. While various interventions exist, their efficacy and safety remain inconsistent. Low-dose intrathecal pethidine, a synthetic opioid with anti-shivering properties via kappa and mu receptor modulation, offers a promising preventive approach. This study assessed its efficacy and safety in elective CS under spinal anesthesia.

Methods

A hospital-based interventional comparative study was conducted at Nepal Medical College Teaching Hospital, enrolling 100 ASA II parturients aged 18–40 years scheduled for elective CS. Participants were randomized into two groups: Group B (n=50) received intrathecal bupivacaine (10 mg), while Group P (n=50) received bupivacaine (10 mg) plus pethidine (10 mg). Hemodynamic parameters, shivering incidence (graded 0–4 using the Crossley and Mahajan scale), neonatal Apgar scores, and side effects were recorded.

Results

Results demonstrated a significant reduction in shivering with pethidine (0% in Group P vs. 44% in Group B, $p < 0.001$), with no severe shivering in Group P. Hemodynamic stability was maintained in both groups, with no clinically significant differences in blood pressure, heart rate, or oxygen saturation. Neonatal outcomes were comparable, with similar Apgar scores at 1 and 5 minutes. Side effects (hypotension, bradycardia, nausea, vomiting, pruritus) were minimal and manageable, with no major adverse events.

Conclusions

Low-dose intrathecal pethidine effectively prevents shivering without compromising maternal or neonatal safety. Its dual receptor action and favorable side effect profile make it a valuable adjunct in spinal anesthesia for CS, enhancing perioperative comfort. Further large-scale studies are warranted to confirm these findings and establish its role in obstetric anesthesia practice.

***Corresponding author**

Rahul Kumar Chaudhary, Department of Anesthesiology and Critical Care, Birat Medical College Teaching Hospital, Morang, Nepal, India.

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Abbreviations

APGAR: Appearance, Pulse, Grimace, Activity and Respiration
ASA: American Society of Anesthesiologists
BMI: Body Mass Index
CS: Cesarean Section
DBP: Diastolic Blood Pressure
SBP: Systolic Blood Pressure
ECG: Electrocardiography
NIBP: Non-Invasive Blood Pressure
SPO2: Oxygen Saturation
GA: General Anaesthesia
HR: Heart Rate
hr: hour
IRC: Institutional Review Committee
Inj: Injection
IV: Intravenous
kg: kilogram
LA: Local Anaesthetics
MAP: Mean Arterial Pressure
Mcg: Microgram
Mg: Milligram
Min: Minute
Ml: Milliliter
mmHg: Millimeter of Mercury
IT: Intrathecal
SAB: Sub Arachnoid Block
ICP: Intracranial Pressure

IOP: Intraocular Pressure

Introduction

Cesarean Section (CS) is a life-saving surgical procedure but carries risks for both mother and newborn when performed without clear indications. Globally, CS rates have risen sharply, from 7% in 1990 to 21% today, with projections reaching 29% by 2030, particularly in regions like Eastern Asia (63%) and Latin America (54%) [1]. In Nepal, disparities exist between urban (15%) and rural (3.5%) CS rates [2]. Spinal anesthesia (SAB) is preferred for CS due to its rapid onset, cost-effectiveness, and reduced fetal drug exposure compared to general anesthesia [3-5]. However, SAB is associated with complications, including hypotension, bradycardia, and shivering, which occurs in over 55% of cases [11].

Shivering during CS increases oxygen consumption, metabolic demand, and may impair monitoring, delay recovery, and worsen postoperative pain [12,17]. Its mechanisms include thermoregulatory vasodilation, heat redistribution, and altered spinal reflexes [11,13-15]. While non-pharmacological measures (warming blankets, fluid warming) help, pharmacological interventions like pethidine—a synthetic opioid with kappa and mu receptor activity—are more effective [16,21]. Pethidine lowers the shivering threshold more than vasoconstriction, making it superior to other opioids [13,28].

Intrathecal pethidine, used in doses as low as 10 mg, has shown significant anti-shivering effects without major side effects [39-41]. Studies confirm its efficacy: Zabetian et al. reported an 85.7% shivering incidence in controls vs. 5.7% with pethidine, while Shami et al. found 50% shivering in placebo groups vs [39]. 4% with 10 mg pethidine [40]. However, higher doses (≥20 mg) increase nausea, vomiting, and pruritus [49,51]. Meta-analyses support low-dose pethidine (0.05–0.5 mg/kg), reducing shivering by 69% (RR 0.31) but slightly raising nausea/vomiting risks [52,53]. Neonatal outcomes (Apgar scores) remain unaffected [53].

This study evaluates low-dose (10 mg) intrathecal pethidine combined with bupivacaine for shivering prevention in elective CS, assessing incidence, severity, maternal hemodynamics, and neonatal safety. Prior research demonstrates efficacy, but optimal dosing and side-effect profiles in resource-limited settings require further validation.

Methods

This study aimed to evaluate the efficacy and safety of low-dose intrathecal pethidine in reducing the incidence and severity of shivering during CS performed under spinal anesthesia. The primary objective was to compare the occurrence of post-spinal shivering between two groups: one receiving standard bupivacaine alone and the other receiving a combination of bupivacaine with pethidine. Additionally, the study sought to assess differences in shivering intensity using a standardized grading scale. Secondary objectives included comparing adverse effects such as hypotension, bradycardia, nausea, vomiting, and pruritus between the groups, as well as evaluating neonatal outcomes through APGAR scores at 1 and 5 minutes post-delivery. By investigating these outcomes, the study aimed to determine whether prophylactic intrathecal pethidine could enhance maternal comfort without compromising hemodynamic stability or neonatal well-being.

Research Design

This hospital-based interventional comparative study was conducted at Nepal Medical College Teaching Hospital (NMCTH) from October 2022 to April 2024. The study population comprised ASA-PS II parturients scheduled for elective CS under spinal anesthesia.

Sample Size Calculation

Using a 95% confidence level (Z=1.96), an urban CS rate of 15% (p=0.15), and a 10% margin of error (d=0.1), the calculated sample size was 49 per group, totaling 98 participants after doubling for comparative analysis.

Inclusion & Exclusion Criteria

- **Included**
  Age 18–40 years, ASA II, singleton pregnancy, elective CS under spinal anesthesia.
- **Excluded**
  Patient refusal, severe preeclampsia/eclampsia, drug allergies, height <140 cm.

Ethical Considerations

Approval was obtained from Institutional Review Committee (ref: 10-079/080). Written informed consent was secured, ensuring participant autonomy, confidentiality, and the right to withdraw. Risks, benefits, and procedures were explained in comprehensible terms, with a witness present if needed.

Procedural Details

Preoperative Preparation

- Fasting for ≥6 hours; premedication with ranitidine (150 mg) and metoclopramide (10 mg).
- IV cannulation (18G) and preload with warmed Ringer's lactate (500 mL).
- Prophylactic ondansetron (4 mg IV) to mitigate opioid-related nausea/pruritus.

Spinal Anesthesia

- Group B (Control): 10 mg (2 mL) 0.5% hyperbaric bupivacaine + 0.2 mL saline.
- Group P (Intervention): 10 mg bupivacaine + 0.2 mL pethidine (10 mg).
- Administered via 25G pencil-point needle at L3-L4/L4-L5 in sitting position.
- Blinding: Anesthesiologist performing SAB was unaware of the drug mixture.

Intraoperative Management

- Monitoring: ECG, HR, NIBP, SpO_2, axillary temperature (every 5 mins).
- Shivering Assessment: Graded using the Crossley & Mahajan scale (0–4).
- Hypotension (↓MAP >20%): Treated with mephentermine (5–10 mg IV).
- Bradycardia (HR <50 bpm): Managed with atropine (0.6 mg IV).
- Shivering (Grade ≥2): IV pethidine (0.5 mg/kg) post-delivery.

Neonatal & Postoperative Outcomes

- APGAR scores at 1/5 minutes.
- Side effects (nausea/vomiting, pruritus) recorded and managed with ondansetron.

Data Collection & Statistical Analysis

- **Variables:** Demographics, hemodynamics, shivering incidence/severity, adverse effects, neonatal APGAR scores.

Statistical Tests

- Independent t-test: Continuous variables (age, BMI, mephentermine dose).
- Chi-square test: Categorical data (shivering incidence, side effects).
- Ordinal logistic regression: Shivering intensity (ordinal scale).
- Significance threshold: $p < 0.05$. Data analyzed using SPSS v16.0.

Rationale

Shivering during CS under spinal anesthesia remains undertreated, risking increased O_2 demand, lactic acidosis, and discomfort. While IV pethidine is the gold standard for treatment, prophylactic intrathecal pethidine may prevent shivering and its complications. This study evaluates its efficacy and safety, potentially improving perioperative care for parturients.

Results

The study included 100 participants equally distributed between Group B (bupivacaine alone) and Group P (bupivacaine with pethidine). Baseline characteristics showed no significant differences between groups in age (28.54±4.12 vs 28.44±4.62 years, p=0.733), weight (69.28±3.24 vs 69.34±3.34 kg, p=0.932), or BMI (30.36±2.02 vs 30.38±1.98 kg/m², p=0.964) (Table 1).

Table 1: Age, Weight, BMI Distribution of Enrolled Cases

Variables	Group B	Group P	p- value
Age (years)	28.54 ± 4.117	28.44 ± 4.622	0.733
Weight (kg)	69.28 ± 3.24	69.34 ± 3.34	0.932
Height (cm)	151.14 ± 2.34	151.16 ± 2.24	0.948
BMI (kg/m^2)	30.36 ± 2.02	30.38 ± 1.98	0.964

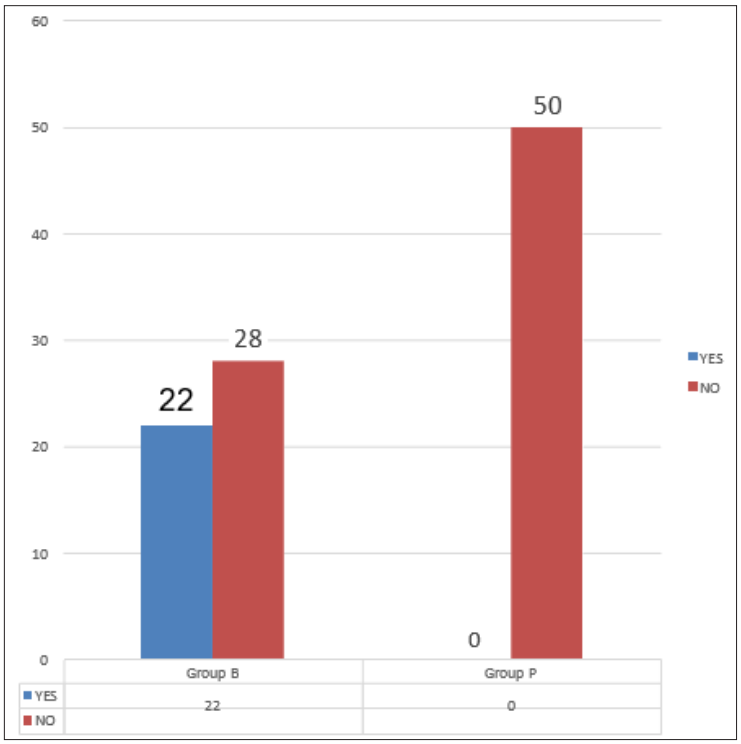

Figure 1: Bar Diagram Showing Incidence of Shivering

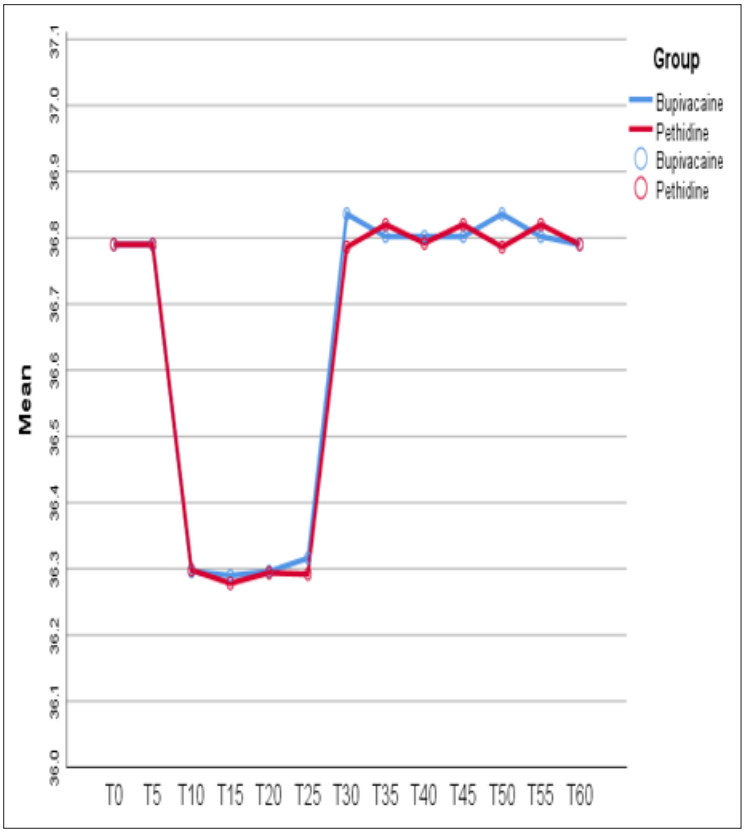

Figure 2: Line Diagram Showing Mean of Temparatures Between Two Groups at 5Minute Intervals. (Note – T0 Denotes Baseline Temperature with 5Minute Increament Like T5, T10 and So on and Mean Temperature at X-axis.)

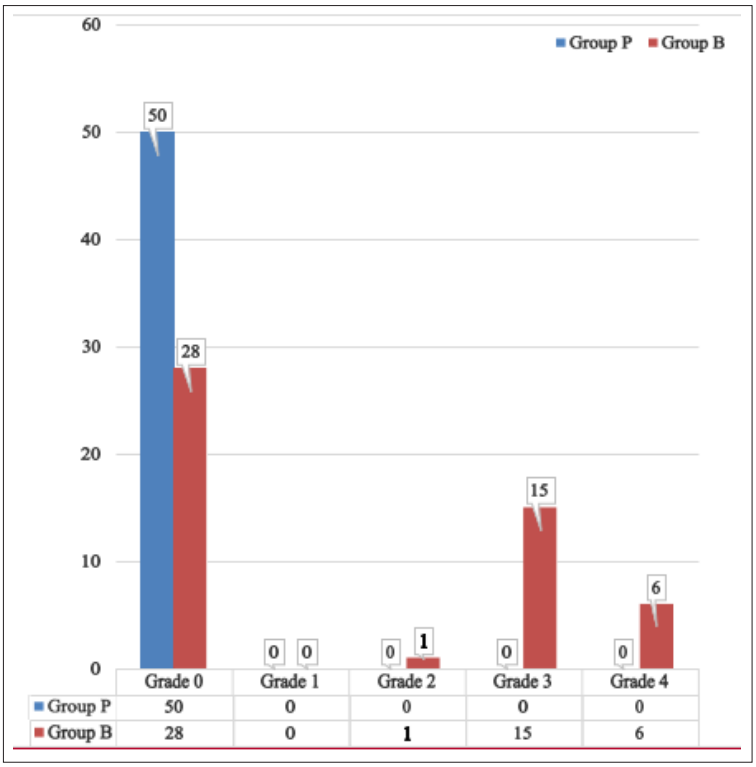

Figure 3: Bar Diagram Showing Intensity of Shivering

Hemodynamic outcomes showed similar hypotension rates (Group B: 72% vs Group P: 74%, p=0.822), though Group P required marginally higher mephentermine doses (11.2±7.32 mg vs 8.5±6.80 mg, p=0.059) (Table 6, Figure 4). Bradycardia incidence was minimal (Group P: 2% vs Group B: 0%, p=0.315) (Table 2). Adverse effects were rare, with single cases of nausea/vomiting (2%) and pruritus (2%) occurring only in Group P (p=0.315 for both) (Tables 3-4).

Table 2: Incidence of Bradycardia

Bradycardia			
	Yes	**No**	**p-value**
Group B	0	50	0.315
Group P	1	49	

Table 3: Incidence of Nausea/Vomiting

Nausea/Vomiting			
	Yes	**No**	**p-value**
Group B	0	50	0.315
Group P	1	49	

Table 4: Incidence of Pruritus

Pruritus			
	Yes	**No**	**p-value**
Group B	0	50	0.315
Group P	1	49	

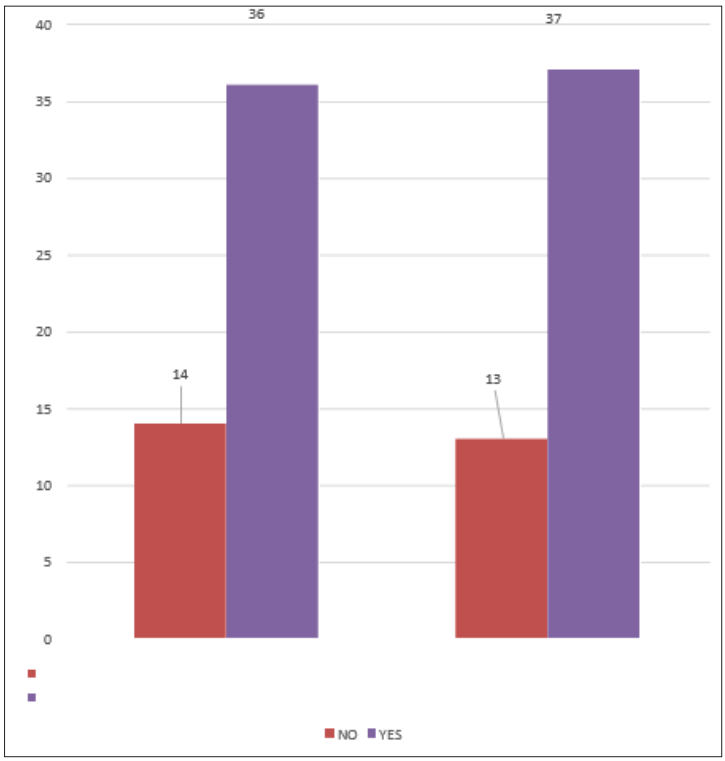

Figure 4: Bar Diagram Showing Incidence of Hypotension

Neonatal outcomes were excellent in both groups, with all infants achieving APGAR scores of 8 and 9 at 1 and 5 minutes respectively (p=1.0) (Table 5). Rescue pethidine requirements differed significantly - 34% of Group B required one dose (0.5mg/kg) and 10% needed two doses, while Group P required none (p<0.001) (Figure 5, Table 7). The mean rescue pethidine dose in Group B was 0.54±0.68 mg/kg (Table 7).

Table 5: Mean APGAR Score

Mean APGAR score			
	1 minute	5 minutes	p-value
Group B	8	9	1
Group P	8	9	

Table 6: Mean dose of Mephentermine

Mean dose of Mephentermine in mg (Mean ± SD)		
Group B	8.5 ± 6.795	0.059
Group P	11.2± 7.323	

Table 7: Mean dose of Pethidine

Mean dose of Pethidine in mg/kg (Mean ± SD)		
Group B	0.54 ± 0.676	0.000
Group P	0	

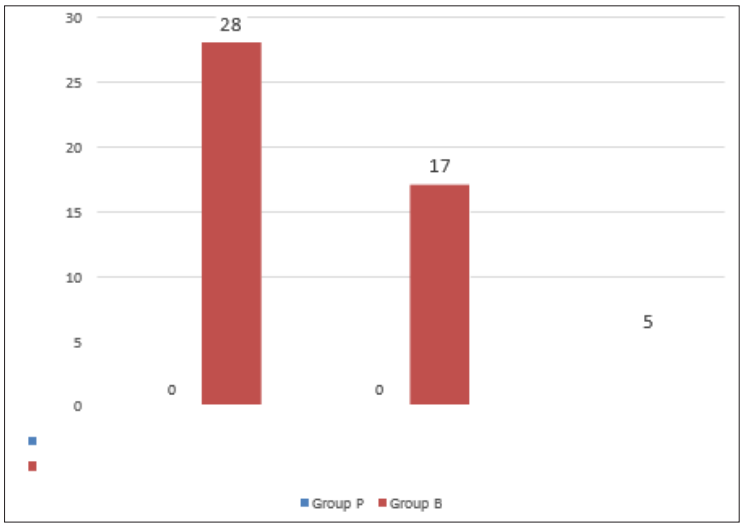

Figure 5: Bar Diagram Showing Number of IV Pethidine Doses to Control Shivering

Discussion

Our study demonstrates that low-dose (10 mg) intrathecal pethidine effectively prevents shivering during cesarean sections under spinal anesthesia, with complete elimination (0% incidence) compared to 44% in the bupivacaine-only group (p<0.001). These findings align with previous research showing pethidine's superior anti-shivering properties through kappa-opioid receptor modulation (11,13,28). The 44% shivering incidence in our control group matches Crowley and Buggy's reported median of 55% (11), while our pethidine group's 0% incidence surpasses Zabetian et al.'s 5.7% and Shami et al.'s 4%, likely due to our standardized warming protocols [39,40].

The severity reduction was particularly striking, with 42% of controls experiencing severe shivering (Grades 3-4) versus none in the pethidine group [51]. This aligns with Mohammad et al.'s meta-analysis showing ORs of 0.25 for severe shivering with low-dose pethidine, and Lin et al.'s demonstration of 66% relative risk reduction [52]. Our results confirm that even 10 mg doses effectively prevent severe shivering, as seen in Nasseri et al.'s study (mean intensity 0.13±0.5 vs 1.47±1.07 in controls) [47].

Hemodynamic stability was maintained, with comparable hypotension rates (72% vs 74%, p=0.822) between groups, though pethidine required slightly higher mephentermine doses (11.2±7.32mg vs 8.5±6.80mg, p=0.059) [39]. This contrasts with Zabetian et al.'s findings but may reflect our stricter 20% MAP reduction threshold. Adverse events were minimal (2% nausea/vomiting and pruritus in pethidine group), significantly lower than in, likely due to our prophylactic ondansetron administration [40-44].

Neonatal outcomes remained excellent (Apgar 8/9 at 1/5 minutes in all cases), corroborating multiple studies [39,41,43,45,50-53]. This safety profile supports pethidine's use in obstetric anesthesia, particularly given its dual mechanism of action on both kappa and mu receptors compared to morphine's mu-specific effects [45]. While higher doses (>20mg) show greater efficacy in some studies our 10mg dose achieved complete shivering prevention without dose-dependent side effects like nausea/vomiting (OR 3.04 for low doses in

or pruritus (48.72% in Anaraki's 0.4mg/kg group [49,51,53]. This suggests 10mg represents an optimal balance between efficacy and safety, especially with antiemetic prophylaxis.

Our findings reinforce pethidine's role as the most effective pharmacological option for shivering prevention, outperforming alternatives like sufentanil and ondansetron [46]. The clinical implications are significant, as shivering increases oxygen consumption by 200-300% (17) and may delay recovery. By preventing rather than treating shivering, intrathecal pethidine addresses these risks proactively.

Limitations

This single-center study had several limitations: (1) restricted generalizability due to its setting; (2) moderate sample size, potentially underpowered for rare side effects; (3) exclusion of high-risk (ASA III+) and emergency cases; (4) fixed 10 mg pethidine dose without weight-based adjustments; (5) short-term adverse effect monitoring without neonatal follow-up; (6) lack of comparison with alternative anti-shivering interventions; and (7) reliance on axillary temperature measurements, which may lack precision. These factors highlight opportunities for future multicenter trials with expanded protocols.

Conclusion

This study demonstrates that low-dose (10 mg) intrathecal pethidine effectively eliminates shivering during cesarean sections under spinal anesthesia, with no cases observed compared to 44% in the bupivacaine-only group. Importantly, it reduces severe shivering (Grades 3-4) without increasing adverse effects such as hypotension, nausea, or pruritus beyond baseline rates. Neonatal outcomes remained excellent (Apgar 8/9 at 1/5 minutes), confirming its safety. Given its dual kappa/mu-opioid action, prophylactic pethidine offers a superior alternative to reactive treatments, improving maternal comfort while maintaining hemodynamic stability. These findings support its routine use in spinal anesthesia for cesarean delivery, particularly where active warming is unavailable. Future studies could explore optimal dosing and long-term neonatal effects.

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Author contributions

Conceptualization

Rahul Kumar Chaudhary, Ankit Agrawal, Moda Nath Marhatta.

Data curation

Rahul Kumar Chaudhary, Ankit Agrawal.

Formal analysis

Rahul Kumar Chaudhary, Ankit Agrawal

Methodology

Rahul Kumar Chaudhary.

Supervision

Rahul Kumar Chaudhary, Moda Nath Marhatta.

Writing-Original Draft

Rahul Kumar Chaudhary.

Writing-Review & Editing

Rahul Kumar Chaudhary.

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