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Non-Opioid Rectal Suppositories in Post Cesarean Delivery Pain Management

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Abstract **Original Research Article**

Background: Post-cesarean pain management remains challenging, balancing effective analgesia with minimizing adverse effects on maternal-newborn bonding and breastfeeding. This study compared the efficacy of combined non-opioid rectal suppositories versus traditional intramuscular pethidine for post-cesarean pain management. ***Methods:*** In this prospective, randomized, single-blind study, 100 patients undergoing cesarean section were allocated into two groups of 50 each. The suppositories group received diclofenac (50 mg) and paracetamol (1000 mg) suppositories every eight hours, while the pethidine group received intramuscular pethidine (75 mg) every eight hours for 24 hours. Primary outcomes included visual analog scale (VAS) pain scores and patient satisfaction. Secondary outcomes included time to first ambulation, rescue analgesic requirements, adverse effects, and breastfeeding success. ***Results:*** The suppositories group demonstrated comparable or lower pain scores, particularly after 8 hours (24-hour VAS at rest: 2.4 ± 0.9 vs 3.2 ± 1.1, p=0.001). Time to first ambulation was significantly shorter in the suppositories group (12.4 ± 2.8 vs 15.6 ± 3.2 hours, p=0.001). The suppositories group showed significantly lower incidence of adverse effects including nausea (16% vs 44%, p=0.002), vomiting (8% vs 30%, p=0.005), and sedation (4% vs 36%, p=0.001). Breastfeeding success rates were higher in the suppositories group (92% vs 76%, p=0.028), with higher patient satisfaction scores (median 4 vs 3, p=0.001). ***Conclusion:*** The combination of diclofenac and paracetamol suppositories provides effective post-cesarean analgesia with significant advantages over intramuscular pethidine, including fewer adverse effects, earlier mobilization, and improved breastfeeding success. This non-opioid regimen represents a viable first-line option for post-cesarean pain management.

Keywords: Post-cesarean analgesia, Non-opioid analgesia, Diclofenac, Paracetamol, Suppositories, Pethidine, Pain management.

INTRODUCTION

Cesarean section rates have risen significantly worldwide over the past decades, with current rates ranging from 20-30% in many countries [1]. Effective post-cesarean pain management is crucial for optimal maternal recovery, early mobilization, and successful initiation of breastfeeding [2]. While opioids have traditionally been the cornerstone of post-cesarean analgesia, there is growing concern about their side effects and the potential risk of dependency [3,4].

Intramuscular pethidine, a commonly used opioid analgesic, can cause significant maternal side effects including sedation, nausea, and respiratory depression, which may interfere with early mother-infant bonding and breastfeeding initiation [5]. Additionally, opioids can transfer through breast milk, potentially affecting the newborn [6]. These concerns have led to increased interest in alternative pain management strategies that can provide effective analgesia while minimizing adverse effects.

Non-opioid analgesics, particularly the combination of diclofenac and paracetamol, have shown promising results in various post-operative settings [7]. The rectal route of administration offers several advantages, including bypass of first-pass metabolism, reliable absorption, and suitability for patients who cannot tolerate oral medications in the immediate post-operative period [8]. Furthermore, rectal suppositories can be particularly advantageous in the post-cesarean

setting as they avoid the need for repeated intramuscular injections [9].

Despite these potential benefits, there is limited research directly comparing the efficacy of non-opioid rectal suppository regimens with traditional intramuscular opioid protocols in post-cesarean pain management [10]. This study aims to evaluate the effectiveness of a combined diclofenac and paracetamol suppository regimen compared to intramuscular pethidine for post-cesarean analgesia, using visual pain scores and patient satisfaction as primary outcome measures.

Objectives

The primary objective of this study was to compare the efficacy of a combined non-opioid rectal suppository regimen (diclofenac 50 mg and paracetamol 1000 mg) with conventional intramuscular pethidine (75 mg) for post-cesarean delivery pain management over the first 24 hours. The study aimed to evaluate the effectiveness of these analgesic regimens through assessment of visual analog pain scores and patient satisfaction scores, while also comparing their side effect profiles and impact on early postoperative recovery in patients undergoing both elective and emergency cesarean sections.

MATERIALS AND METHODS

Study Design and Setting: This prospective, randomized, single-blind study was conducted between July 2022 and December 2022 at Department of Anesthesiology, Shahid M. Monsur Ali Medical College, Sirajgonj, Bangladesh. The study protocol was approved by the institutional ethics committee and written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki [11].

Patient Selection and Sample Size One hundred patients aged 20-40 years, with American Society of Anesthesiologists (ASA) physical status I-II, scheduled for either elective or emergency cesarean section under spinal anesthesia, were enrolled in the study. Exclusion criteria included contraindications to any study medications, history of substance abuse, chronic pain conditions, allergies to NSAIDs or paracetamol, coagulopathy, and significant hepatic or renal dysfunction [12]. Sample size was calculated using G*Power software (version 3.1), assuming an α error of 0.05 and power of 80% [13].

Randomization and Blinding Patients were randomly allocated into two groups of 50 each using computer-generated random numbers. Group allocation was concealed using sequentially numbered, opaque, sealed envelopes. While complete blinding was not feasible due to different routes of administration, the personnel collecting pain and satisfaction scores were blinded to group allocation [14].

Anesthetic Protocol All patients received standardized spinal anesthesia with 2.2 mL of 0.5% hyperbaric bupivacaine and 25 µg fentanyl at L3-L4 or L4-L5 interspace using a 25G Quincke needle [15]. Standard monitoring included continuous ECG, non-invasive blood pressure, and pulse oximetry.

Intervention Protocol Group 1 (Suppositories group, n=50): Patients received diclofenac (50 mg) and paracetamol (1000 mg) suppositories every eight hours for 24 hours, with the first dose administered immediately after surgery in the post-operative word.

Group 2 (Pethidine group, n=50): Patients received intramuscular pethidine (75 mg) every eight hours for 24 hours, with the first dose administered in the post-operative word.

Rescue analgesia (intramuscular tramadol 50 mg) was available for both groups if the visual analog scale (VAS) score exceeded 7 or upon patient request [16].

Outcome Measurements Primary outcomes included:

- Pain intensity assessed using a 10-point VAS (0 = no pain, 10 = worst imaginable pain) at rest and during movement at 0, 2, 4, 8, 16 and 24 hours post-surgery [17].
- Patient satisfaction measured using a 5-point Likert scale (1 = very dissatisfied, 5 = very satisfied) at 24 hours.

Secondary outcomes included:

- Time to first rescue analgesic requirement
- Total rescue analgesic consumption
- Side effects (nausea, vomiting, sedation, pruritus)
- Time to first ambulation
- Time to first bowel movement
- Maternal satisfaction with breastfeeding initiation

Assessment of sedation was performed using the Ramsay Sedation Scale [18]. All adverse events were recorded and managed according to institutional protocols.

Statistical Analysis Data analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Normality of data distribution was assessed using the Shapiro-Wilk test. Continuous variables were presented as mean ± standard deviation or median (interquartile range) as appropriate. Categorical variables were presented as frequencies and percentages. Between-group comparisons were performed using Student's t-test or Mann-Whitney U test for continuous

variables and Chi-square or Fisher's exact test for categorical variables. A p-value <0.05 was considered statistically significant [19].

RESULTS

Demographic and Baseline Characteristics A total of 100 patients completed the study, with 50 patients in each group. There were no significant differences between the groups regarding demographic characteristics, type of cesarean section (emergency vs. elective), or duration of surgery (Table 1).

Table 1: Demographic and Baseline Characteristics

Characteristic	Suppositories Group (n=50)	Pethidine Group (n=50)	P-value
Age (years)*	28.6 ± 5.2	29.1 ± 4.8	0.624
BMI (kg/m²)*	27.4 ± 3.8	26.9 ± 4.1	0.516
ASA Status (I/II)†	32/18	35/15	0.667
Emergency/Elective CS†	28/22	26/24	0.841
Duration of surgery (min)*	52.8 ± 8.4	54.2 ± 7.9	0.398
*Data presented as mean ± SD; †Data presented as numbers			
CS: Cesarean Section			

Pain Scores Patients in the suppositories group demonstrated comparable or lower pain scores at most time points compared to the pethidine group (Table 2).

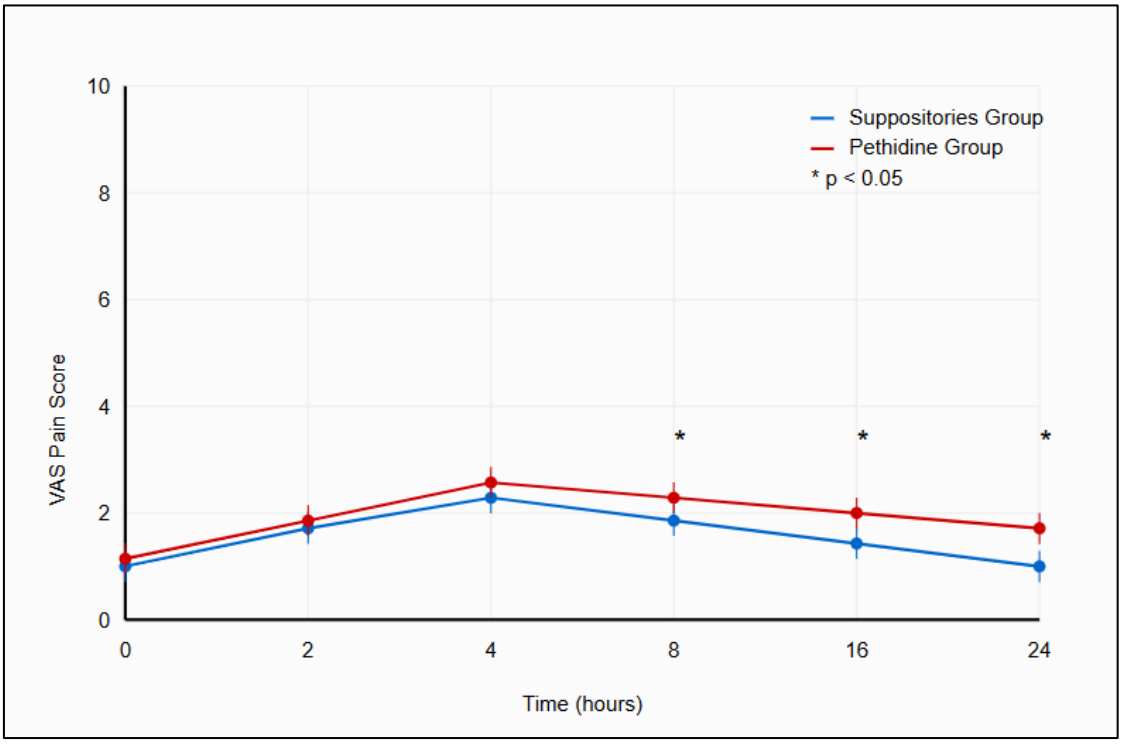

Fig 1: Mean VAS Pain Scores During Movement Over Time

Table 2: Visual Analog Scale Pain Scores at Rest and Movement

Time Point	Suppositories Group (n=50)	Pethidine Group (n=50)	P-value
At Rest			
0 hr	2.1 ± 0.8	2.3 ± 0.9	0.245
2 hr	3.2 ± 1.1	3.4 ± 1.2	0.384
4 hr	3.8 ± 1.3	4.2 ± 1.4	0.126
8 hr	3.4 ± 1.2	3.9 ± 1.3	0.048*
16 hr	2.9 ± 1.0	3.6 ± 1.2	0.002*
24 hr	2.4 ± 0.9	3.2 ± 1.1	0.001*

On Movement			
0 hr	3.2 ± 1.1	3.4 ± 1.2	0.384
2 hr	4.6 ± 1.4	4.8 ± 1.5	0.492
4 hr	5.2 ± 1.6	5.6 ± 1.7	0.224
8 hr	4.8 ± 1.5	5.4 ± 1.6	0.046*
16 hr	4.2 ± 1.3	4.9 ± 1.5	0.012*
24 hr	3.8 ± 1.2	4.5 ± 1.4	0.008*
Data presented as mean ± SD; *Statistically significant (p<0.05)			

Secondary Outcomes The suppositories group showed significant advantages in several secondary outcomes (Table 3).

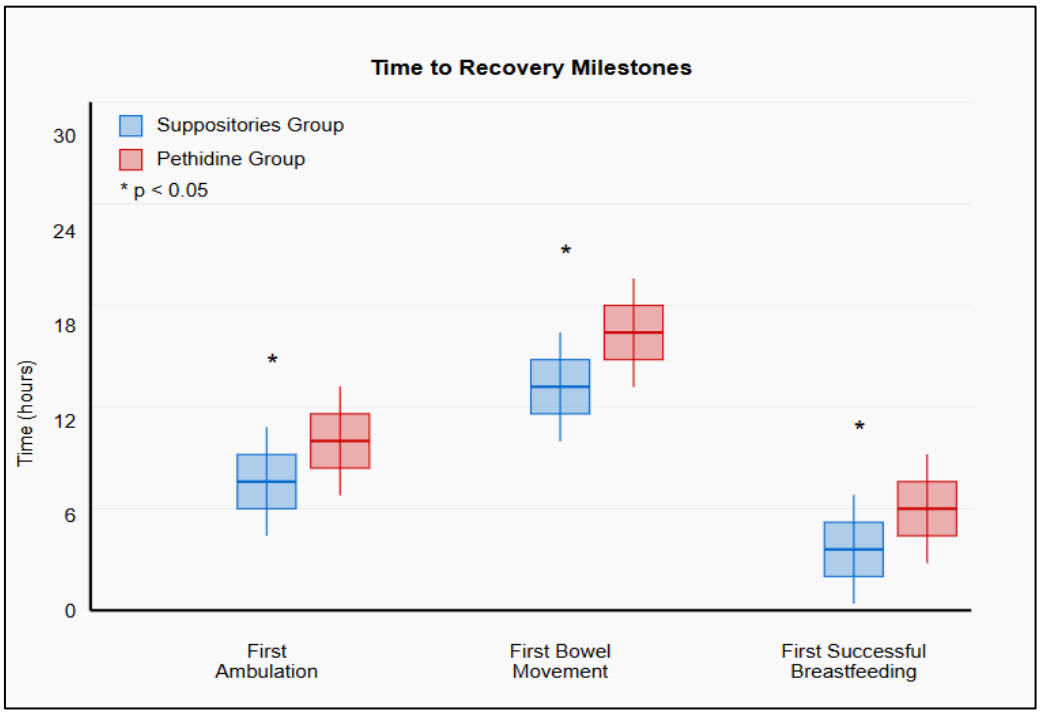

Fig 2: Time to Recovery Milestones - Box and Whisker Plot

Table 3: Secondary Outcome Measures

Outcome	Suppositories Group (n=50)	Pethidine Group (n=50)	P-value
Time to first rescue analgesic (hr)*	8.4 ± 2.2	6.2 ± 1.8	0.001†
Number of rescue doses required†	1 (0-2)	2 (1-3)	0.003†
Time to first ambulation (hr)*	12.4 ± 2.8	15.6 ± 3.2	0.001†
Time to first bowel movement (hr)*	18.6 ± 4.2	22.8 ± 4.6	0.001†
*Data presented as mean ± SD; †Data presented as median (IQR); †Statistically significant (p<0.05)			

Adverse Effects and Patient Satisfaction The incidence of adverse effects was significantly lower in the suppositories group (Table 4).

Table 4: Adverse Effects and Patient Satisfaction

Parameter	Suppositories Group (n=50)	Pethidine Group (n=50)	P-value
Nausea†	8 (16%)	22 (44%)	0.002*
Vomiting†	4 (8%)	15 (30%)	0.005*
Sedation†	2 (4%)	18 (36%)	0.001*
Pruritus†	1 (2%)	12 (24%)	0.001*
Patient Satisfaction Score‡	4 (3-5)	3 (2-4)	0.001*
†Data presented as n (%); ‡Data presented as median (IQR); *Statistically significant (p<0.05)			

Breastfeeding Success A significantly higher proportion of mothers in the suppositories group reported successful breastfeeding initiation within the first 24 hours (92% vs 76%, p=0.028).

DISCUSSION

This prospective randomized study demonstrated that a combination of diclofenac and paracetamol suppositories provides effective post-cesarean analgesia comparable to, and in some aspects superior to, traditional intramuscular pethidine. The findings have several important clinical implications for post-cesarean pain management protocols.

Pain Control and Analgesic Efficacy The combination of diclofenac and paracetamol suppositories demonstrated equivalent or superior pain control compared to intramuscular pethidine, particularly after the 8-hour mark. This finding aligns with previous studies showing the synergistic effect of combining NSAIDs with paracetamol [20]. The enhanced pain control in the later hours may be attributed to the sustained release properties of rectal suppositories and the complementary mechanisms of action of the two agents [21]. The lower requirement for rescue analgesia in the suppositories group further supports the efficacy of this multimodal approach, consistent with current evidence promoting opioid-sparing strategies in post-operative pain management [22].

Maternal Recovery and Mobility The significantly earlier ambulation time observed in the suppositories group (12.4 ± 2.8 vs 15.6 ± 3.2 hours, p=0.001) represents a crucial advantage in post-cesarean recovery. Early mobilization is associated with reduced risk of thromboembolism and faster overall recovery [23]. The earlier return of bowel function in the suppositories group may be attributed to both the reduced opioid use and earlier mobilization, factors well-documented to influence post-operative ileus [24].

Adverse Effects Profile The marked reduction in adverse effects in the suppositories group, particularly regarding nausea, vomiting, and sedation, represents a significant clinical advantage. These findings support previous research highlighting the burden of opioid-related side effects in post-operative patients [25]. The lower incidence of sedation (4% vs 36%, p=0.001) is particularly relevant in the context of post-cesarean care, where maternal alertness is crucial for early bonding and newborn care [26].

Breastfeeding Success The higher rate of successful breastfeeding initiation in the suppositories group (92% vs 76%, p=0.028) is a noteworthy finding that may be attributed to several factors. Reduced maternal sedation, better pain control, and earlier mobilization likely contributed to more effective early breastfeeding attempts [27]. This outcome aligns with WHO recommendations for minimizing medications that may interfere with early breastfeeding initiation [28].

Patient Satisfaction The higher satisfaction scores in the suppositories group likely reflect the combination of effective pain control and fewer side effects. This finding is consistent with studies showing that patient satisfaction in post-operative pain management is influenced not only by pain control but also by the absence of side effects and the ability to participate in recovery activities.

Cost and Resource Implications While not directly measured in this study, the suppository regimen potentially offers economic advantages through reduced nursing workload (fewer injections), lower requirement for rescue analgesia, and potentially shorter hospital stays due to faster recovery. Future studies should include formal cost-effectiveness analyses.

Study Limitations Several limitations should be considered when interpreting our results. First, complete blinding was not possible due to different routes of administration. Second, pain assessment during movement was limited to standardized activities and may not reflect all post-operative scenarios. Third, the study was conducted at a single center, potentially limiting its generalizability. Finally, the follow-up period was limited to 24 hours, and longer-term outcomes were not assessed.

Clinical Implications and Future Directions Our findings support the implementation of non-opioid analgesic protocols in post-cesarean pain management. Future research should focus on:

1. Long-term follow-up to assess chronic pain development
2. Cost-effectiveness analyses including both direct and indirect costs
3. Investigation of optimal timing and dosing schedules
4. Impact on longer-term breastfeeding success rates
5. Potential benefits in high-risk populations

The promising results with this non-opioid regimen also align with current global efforts to reduce opioid use in post-operative pain management while maintaining effective analgesia. The findings suggest that this approach could be particularly valuable in settings where opioid monitoring is challenging or resources are limited.

CONCLUSION

This prospective randomized study demonstrates that the combination of diclofenac and paracetamol suppositories is an effective alternative to

traditional intramuscular pethidine for post-cesarean pain management. The suppository regimen showed several significant advantages: comparable or superior pain control, reduced need for rescue analgesia, fewer adverse effects, earlier mobilization, and improved breastfeeding success rates. The marked reduction in opioid-related side effects, particularly sedation and nausea, coupled with high patient satisfaction scores, suggests that this protocol could be adopted as a standard part of enhanced recovery after cesarean delivery programs.

The findings support a paradigm shift towards opioid-sparing analgesic strategies in post-cesarean care, offering a safe, effective, and patient-friendly approach to pain management. This non-opioid regimen may be particularly valuable in settings where regular patient monitoring is challenging or where there are concerns about opioid availability and dependence. Future research focusing on long-term outcomes and cost-effectiveness analyses would further strengthen the evidence base for this approach.

These results suggest that the combination of diclofenac and paracetamol suppositories should be considered as a first-line analgesic option for post-cesarean pain management, potentially reserving opioids for breakthrough pain only. The implementation of this protocol could contribute to improved maternal recovery, enhanced mother-infant bonding, and better overall post-cesarean outcomes.

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