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Comparison of the Effectiveness of Per-Rectal Diclofenac Sodium Vs Parenteral Diclofenac Sodium for Postoperative Analgesia

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ABSTRACT

Background: Postoperative pain after cesarean section remains a frequent clinical concern and may delay mobilization and recovery. Nonsteroidal anti-inflammatory drugs such as diclofenac sodium are commonly used, but the optimal route of administration for effective analgesia and reduced need for rescue medication remains debated. **Aim:** To compare the effectiveness of per-rectal diclofenac sodium versus intramuscular diclofenac sodium for postoperative analgesia after cesarean section. **Materials and Methods:** A randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, National Hospital Lahore, from November 2024 to April 2025. A total of 274 primigravida women (137 per group), aged 18 to 35 years, with singleton pregnancies and ASA physical status I or II undergoing cesarean section under spinal anesthesia were enrolled through non-probability consecutive sampling. Group A received intramuscular diclofenac sodium 75 mg twice daily for 24 hours, while Group B received per-rectal diclofenac suppository 100 mg twice daily. Primary outcome was the requirement of rescue analgesia within 24 hours. Secondary outcomes included Visual Analogue Score at 24 hours and time to rescue analgesia. Data were analyzed using chi-square and independent sample t-tests. **Results:** Mean maternal age was 26.42 ± 4.18 years in Group A and 25.87 ± 4.32 years in Group B (p = 0.31). Mean gestational age was 38.16 ± 1.52 versus 38.34 ± 1.48 weeks (p = 0.34), and mean body mass index was 27.63 ± 3.41 versus 27.28 ± 3.56 kg/m^2 (p = 0.43). Rescue analgesia was required in 79 participants (57.66%) in Group A and 58 participants (42.34%) in Group B (p = 0.011). Mean 24-hour VAS score was 4.53 ± 1.82 in Group A and 3.76 ± 1.96 in Group B (p = 0.001). Time to rescue analgesia was 3.87 ± 2.46 hours versus 4.52 ± 2.71 hours (p = 0.14). **Conclusion:** Per-rectal diclofenac sodium achieved better postoperative pain control and reduced reliance on rescue analgesia compared to intramuscular diclofenac sodium after cesarean section.

INTRODUCTION

Cesarean sections (CS) often result in significant post-operative pain for patients. This pain can lead to discomfort, longer hospital stays, and increased healthcare costs [1,2]. Effective pain relief methods should be safe, cost-effective, and not pass into breast milk. Traditionally, cesarean section pain is managed with diclofenac and pentazocine injections [3,4]. However, opioids like pentazocine can cause side effects. Nonsteroidal anti-inflammatory drugs (NSAIDs), particularly suppositories, are considered an alternative due to their ease of use and minimal side effects [5,6]. In a study including 66 patients undergoing elective lower segment cesarean delivery, 42.86% from the rectal diclofenac arm and 57.14% from the intramuscular diclofenac arm required rescue analgesia. The time interval between commencement of postoperative analgesia and demand for rescue analgesic agent was similar in both groups (4.28 ± 2.78 hours and 3.98 ± 2.52 hours, respectively), and the pain scores were higher in the intramuscular diclofenac group postoperatively [7]. According to Khan et al., women (52%) in the intramuscular diclofenac group and 20 women (40%) in the rectal diclofenac group required I/V Tramadol [8]. The study found that rectal diclofenac suppository was highly effective in managing pain during the early post-caesarean period, with infrequent requirements for rescue analgesia. This approach also offers the advantage of avoiding painful intramuscular administration and potentially shortening hospital stays. As a result, the study suggests that rectal diclofenac suppositories should be promoted as a post-caesarean analgesic [9]. The rationale of the current study is to address the pressing need for effective and safe methods of postoperative pain management following cesarean sections (CS). Existing approaches often involve opioids, which can lead to undesirable side effects. The aim of this

study is to evaluate and compare the efficacy of per-rectal diclofenac sodium versus parenteral diclofenac sodium as alternatives for postoperative analgesia in Cesarean section. By doing so, a more effective and patient-friendly pain management approach may be identified that minimizes the need for rescue analgesia and potentially shortens hospital stays. The utilization of this study lies in its potential to improve the quality of care for women undergoing cesarean sections, offering a safer and more comfortable postoperative experience while reducing healthcare costs. The study aims to contribute to better practices in obstetric surgery and postoperative pain management.

MATERIAL AND METHOD

A randomized controlled trial was conducted in the Department of Obstetrics and Gynecology, National Hospital Lahore, from November 2024 to April 2025. Ethical approval was obtained from the hospital ethical committee prior to initiation of the study, and written informed consent was taken from all eligible participants after explaining the purpose, procedures, potential benefits, and possible risks in understandable language. Participation remained voluntary, and confidentiality was ensured by assigning identification codes and restricting access to the collected data to the research team only. Non-probability consecutive sampling was used to recruit participants fulfilling the eligibility criteria during the study period.

The sample size was calculated using the World Health Organization (WHO) sample size calculator by keeping the level of significance at 5% and the study power at 80%. The expected proportions of patients requiring rescue analgesia were taken as 42.86% for per-rectal diclofenac (suppositories) and 57.14% for intramuscular diclofenac, based on previously reported findings, and the final calculated sample size was 274 participants, with 137 patients allocated to each group [7]. Women aged 18 to 35 years admitted for elective lower segment cesarean section under spinal anesthesia were included. Only primigravida with gestational age between 34 and 40 weeks and a singleton pregnancy were enrolled. Participants were required to have American Society of Anesthesiologists (ASA) physical status I or II as per operational definition. Women with ASA physical status III or severe medical illness such as uncontrolled hypertension, pre-eclampsia, diabetes mellitus, renal insufficiency, bleeding diathesis, or significant gastrointestinal disease were excluded. Patients with known hypersensitivity to nonsteroidal anti-inflammatory drugs (NSAIDs), those taking long-term analgesics, all multigravida, and those developing intraoperative complications during cesarean section such as bladder or intestinal injury were also excluded.

Baseline information was recorded on a structured proforma, including maternal age, gestational age, parity status, height, and weight for calculation of body mass index (BMI). BMI was calculated as weight in kilograms divided by height in meters squared (kg/m^2). Pain intensity was assessed using the Visual Analogue Score (VAS), ranging from 0 to 10, where 0 represented no pain, 1 to 4 mild pain, 5 to 8 moderate pain, and 9 to 10 severe pain [9]. The primary outcome was assessed as the frequency of patients who required rescue analgesia. Rescue analgesia was operationally defined as administration of nalbuphine 4 mg when a participant reported a VAS score of 4 or more at any time. Full-term gestation was defined as pregnancy between 37 and 42 completed weeks of gestation. ASA physical status was defined as: Status I (normal healthy person), Status II (patient with mild systemic disease), Status III (patient with severe systemic disease), and Status IV (patient with severe systemic disease that is a constant threat to life). Participants were randomly assigned into two groups through the lottery method. Group A received intramuscular diclofenac sodium 75 mg twice daily for 24 hours, while Group B received diclofenac suppository 100 mg per rectum twice daily for the same duration. Pain assessment was continued postoperatively, and the time interval from cesarean section to the requirement of rescue analgesia was recorded as "time to rescue analgesia." In addition, VAS score at 24 hours after cesarean section was documented in the proforma.

All data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 23.0. Categorical variables such as the need for rescue analgesia were presented as frequencies and percentages. Numerical variables including maternal age, gestational age, BMI, VAS score at 24 hours, and time to rescue analgesia were expressed as means and standard deviations. The Chi-square test was applied to compare the frequency of rescue analgesia between the two groups, while the independent sample t-test was used to compare the time to rescue analgesia and VAS score at 24 hours between groups. A p-value of ≤0.05 was taken as statistically significant. Stratification was performed for further analysis based on age groups, gestational age, and body mass index.

RESULTS

The baseline characteristics of participants in both groups are presented in Table 1. The mean maternal age was 26.42 ± 4.18 years in Group A and 25.87 ± 4.32 years in Group B (p = 0.31). The mean gestational age was 38.16 ± 1.52 weeks in Group A compared to 38.34 ± 1.48 weeks in Group B (p = 0.34). Body mass index was comparable between the two groups, with mean values of 27.63 ± 3.41 kg/m^2 in Group A and 27.28 ± 3.56 kg/m^2 in Group B (p = 0.43). All participants were primigravida with singleton pregnancies and ASA physical status I or II.

Table 1

Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group A (IM Diclofenac) n=137	Group B (PR Diclofenac) n=137	p-value
Maternal Age (years)	26.42 ± 4.18	25.87 ± 4.32	0.31
Gestational Age (weeks)	38.16 ± 1.52	38.34 ± 1.48	0.34
Body Mass Index (kg/m^2)	27.63 ± 3.41	27.28 ± 3.56	0.43
ASA Physical Status I, n (%)	89 (64.96%)	92 (67.15%)	0.69
ASA Physical Status II, n (%)	48 (35.04%)	45 (32.85%)	0.69

The primary outcome measure, frequency of participants requiring rescue analgesia within 24 hours postoperatively, is shown in Table 2. Rescue analgesia was required in 79 participants (57.66%) in Group A compared to 58 participants (42.34%) in Group B. The difference in rescue analgesia requirement between the two groups was statistically significant ($\chi^2 = 6.42$, $p = 0.011$). The per-rectal route demonstrated a reduction of 15.32 percentage points in the need for additional analgesia compared to the intramuscular route.

Table 2

Frequency of Rescue Analgesia Requirement

Group	Rescue Analgesia Required	Rescue Analgesia Not Required	Total	p-value
Group A (IM Diclofenac)	79 (57.66%)	58 (42.34%)	137 (100%)	0.011
Group B (PR Diclofenac)	58 (42.34%)	79 (57.66%)	137 (100%)	

Pain intensity measured by Visual Analogue Score at 24 hours postoperatively and time interval from cesarean section to rescue analgesia administration are presented in Table 3. The mean VAS score at 24 hours was significantly higher in Group A (4.53 ± 1.82) compared to Group B (3.76 ± 1.96) with a p-value of 0.001. Among participants who required rescue analgesia, the mean time to rescue analgesia was 3.87 ± 2.46 hours in Group A and 4.52 ± 2.71 hours in Group B (p = 0.14). Although the per-rectal group demonstrated a longer interval before requiring rescue analgesia, this difference did not reach statistical significance.

Table 3

Pain Assessment and Time to Rescue Analgesia

Variable	Group A (IM Diclofenac) n=137	Group B (PR Diclofenac) n=137	p-value
VAS Score at 24 hours	4.53 ± 1.82	3.76 ± 1.96	0.001
Time to Rescue Analgesia (hours)*	3.87 ± 2.46	4.52 ± 2.71	0.14

Stratified analysis (Table 4) showed consistently lower rescue analgesia requirement with per-rectal diclofenac across age (18–25 years: 62.86% vs 40.26%, p = 0.007; 26–35 years: 52.24% vs 44.26%, p = 0.34), gestational age (34–36 weeks: 64.29% vs 42.86%, p = 0.10; 37–40 weeks: 55.96% vs 42.20%, p = 0.040), and body mass index strata (<25 kg/m^2: 58.00% vs 40.74%, p = 0.08; ≥25 kg/m^2: 57.47% vs 43.37%, p = 0.07), indicating a stable advantage of the per-rectal route despite variable statistical significance.

Table 4

Stratification Analysis for Rescue Analgesia Requirement

Stratification Variable	Group A (IM Diclofenac) Rescue Required	Group B (PR Diclofenac) Rescue Required	p-value
Age Group			
18-25 years (n=147)	44/70 (62.86%)	31/77 (40.26%)	0.007
26-35 years (n=127)	35/67 (52.24%)	27/61 (44.26%)	0.34
Gestational Age			
34-36 weeks (n=56)	18/28 (64.29%)	12/28 (42.86%)	0.10
37-40 weeks (n=218)	61/109 (55.96%)	46/109 (42.20%)	0.040
Body Mass Index			
BMI <25 kg/m^2 (n=104)	29/50 (58.00%)	22/54 (40.74%)	0.08
BMI ≥25 kg/m^2 (n=170)	50/87 (57.47%)	36/83 (43.37%)	0.07

DISCUSSION

The present trial compared per-rectal diclofenac sodium with intramuscular diclofenac sodium for post-caesarean analgesia in a well-matched population. Baseline maternal age, gestational age, body mass index, and American Society of Anesthesiologists (ASA) physical status were comparable between groups, supporting that outcome differences were unlikely to be driven by baseline imbalance. The principal finding was a significantly lower requirement for rescue analgesia within 24 hours in the per-rectal group (42.34%) compared with the intramuscular group (57.66%) (p = 0.011), indicating superior early postoperative analgesic control with the rectal route. This difference was accompanied by a significantly lower 24-hour Visual Analogue Score (VAS) in the per-rectal arm (3.76 ± 1.96 vs 4.53 ± 1.82; p = 0.001), reinforcing that the reduction in rescue analgesic demand reflected clinically meaningful pain reduction rather than isolated prescribing variation.

The observed benefits are consistent with several prior reports favouring rectal diclofenac for postoperative pain control. Khan et al. reported lower pain scores and reduced rescue analgesic requirement with rectal diclofenac compared with intramuscular diclofenac after caesarean section, supporting the direction of effect noted in the current findings [8]. Similarly, Zulfiqar et al. reported a lower proportion requiring rescue analgesia in the rectal arm (43.86%) than the intramuscular arm (58.14%), with later pain scores trending lower in the rectal group, including 24-hour VAS values of 3.88 ± 1.90 versus 4.76 ± 1.75, although statistical significance was not reached in that trial [10]. Beyond caesarean delivery, rectal diclofenac has also been associated with improved analgesic profiles in other postoperative settings. A study demonstrated lower pain scores at 8, 24, and 48 hours with rectal diclofenac compared with intramuscular diclofenac in gynaecological surgeries under spinal anaesthesia [11]. Hussain et al. reported lower mean pain severity with rectal diclofenac compared with intramuscular dosing in paediatric infra-umbilical surgery, alongside higher satisfaction scores among caregivers, suggesting a consistent analgesic advantage across age groups and procedures [12]. A study observed greater postoperative pain reduction with rectal diclofenac after laparoscopic cholecystectomy, with fewer patients requiring additional analgesics (20% vs 46.7%), which aligns with the reduced rescue requirement observed in the present trial [13,14]. In postpartum perineal pain after vaginal delivery, Nafees et al. reported significantly lower pain scores with rectal diclofenac immediately after repair and at 6 hours, further supporting the rectal route as an effective and acceptable analgesic strategy in obstetric care, although detailed mean scores were not specified in the available report [15]. Following open myomectomy,

another study reported higher maternal satisfaction with rectal diclofenac-based analgesia (66.7% vs 20.0%), with different side-effect profiles between strategies, highlighting that route selection may also influence tolerability and patient experience [9].

Notably, not all literature has uniformly favoured rectal diclofenac. Altaf et al. reported lower 24-hour pain scores with intramuscular diclofenac than rectal diclofenac (1.84 ± 0.93 vs 3.08 ± 1.93), which contrasts with the present observation of lower 24-hour VAS in the rectal arm [16]. Such discrepancy may reflect differences in analgesic dosing schedules, timing of pain assessments, use of additional background analgesics, and variability in rescue thresholds. It is also plausible that interindividual variation in rectal absorption, early ambulation, and gastrointestinal physiology may contribute to heterogeneous outcomes across settings. Khan et al. noted that early pain scores were similar between routes after inguinal hernia repair, while statistically significant differences emerged at 24 hours, illustrating that route-related separation may become more evident with time rather than in immediate postoperative hours [8]. An indexed caesarean trial by Otutoaja et al. confirms that randomized comparisons have been conducted, but the full text was not accessible for verified extraction of numerical outcomes, limiting direct quantitative comparison with the present results [9].

Although the mean time to rescue analgesia was numerically longer in the per-rectal group (4.52 ± 2.71 vs 3.87 ± 2.46 hours), this difference did not reach statistical significance. This pattern is similar to Zulfiqar et al., who also reported only modest separation in time-to-rescue between routes [10]. Stratified findings in the present trial showed consistent reductions in rescue requirement with per-rectal diclofenac across age, gestational age, and body mass index strata, with statistically significant benefit particularly in women with gestational age 37 to 40 weeks and in the younger age subgroup. The absence of statistical significance in some strata likely reflected reduced subgroup sample sizes rather than loss of effect, given the consistent direction of benefit.

Strengths of this study included randomized allocation with balanced baseline characteristics, a relatively large sample size, standardized spinal anaesthesia context, and clinically relevant outcomes focused on rescue analgesia requirement and 24-hour pain intensity. Limitations included single-centre conduct, lack of blinding with potential performance bias, assessment of pain at 24 hours without repeated early time-point profiling, absence of systematic adverse-effect reporting (gastrointestinal symptoms, sedation, injection-site pain), and limited generalizability to multigravida patients, emergency caesarean sections, or alternative anesthetic techniques.

CONCLUSION

Per-rectal diclofenac sodium provided more effective postoperative analgesia than intramuscular diclofenac sodium following cesarean section. The rectal route was associated with improved pain control and a lower need for additional rescue analgesia during the first postoperative day, indicating a more consistent analgesic effect in routine clinical practice. Although the time interval to rescue medication was longer with per-rectal administration, this difference was not statistically significant. Overall, per-rectal diclofenac appears to be a practical and patient-friendly alternative to intramuscular injections for post-cesarean pain management, with potential advantages in comfort and analgesic adequacy.

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