



EFFECT OF DICLOFENAC INTRAMUSCULAR VS RECTAL SUPPOSITORY IN PATIENT PRESENTING WITH PAIN ABDOMEN IN EMERGENCY MEDICINE DEPARTMENT

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ABSTRACT

Background: Acute abdominal pain is a leading presentation in emergency departments, yet optimal non-opioid analgesic strategies remain underexplored. Diclofenac sodium, a potent nonsteroidal anti-inflammatory drug, may be administered via rectal suppository or intramuscular injection.

Aim: To compare diclofenac administered either through intramuscular or rectal route to relieve pain in patients with abdominal pain in the ED

Methods: The present study was a randomized, double-blind, double-dummy trial which included 120 adult ED patients with non-traumatic abdominal pain (NRS ≥ 5) were allocated 1:1 to receive diclofenac 100 mg rectal suppository plus IM placebo or diclofenac 75 mg IM plus rectal placebo. Pain scores (NRS 0–10) were recorded at baseline and at 10-, 20-, and 30-minutes post-administration. Adverse events, route-specific tolerability (injection-site pain, rectal irritation), and patient satisfaction (5-point Likert scale) were captured. Statistical analyses employed paired t-tests for within-group changes, independent t-tests for between-group comparisons, and χ^2 tests for categorical outcomes; $p < 0.05$ was significant.

Results: Baseline pain was similar (rectal: 7.3 ± 1.9 ; IM: 7.2 ± 2.0 ; $p = 0.82$). Both routes achieved rapid pain reduction at 10 minutes (rectal: 4.9 ± 2.2 , $p < 0.001$; IM: 5.3 ± 2.3 , $p < 0.01$), and sustained declines at 20 minutes (rectal: 3.2 ± 1.8 ; IM: 3.5 ± 2.0 ; $p = 0.59$) and 30 minutes (rectal: 2.3 ± 1.5 ; IM: 2.5 ± 1.7 ; $p = 0.64$). Adverse events were infrequent (rectal: 10.0%; IM: 16.7%; $p = 0.45$). Injection-site pain occurred in 13.3% of IM patients; rectal irritation in 6.7%. Mean satisfaction

favored the rectal route (4.2 ± 0.8 vs. 3.8 ± 0.9 ; $p = 0.045$). Sixty percent preferred rectal administration ($p = 0.13$).

Conclusion: Rectal and intramuscular diclofenac provide rapid, sustained analgesia for ED abdominal pain with comparable safety. Higher patient satisfaction and preference for suppositories support their use as a non-invasive alternative.

Keywords: Abdominal Pain; Analgesia; Diclofenac; Drug Administration Routes; Emergency Service, Hospital; Nonsteroidal Anti-Inflammatory Agents

INTRODUCTION

Abdominal pain is among the most common and challenging presenting complaints in the emergency department (ED), accounting for up to 10% of all ED visits. The differential diagnosis is broad, encompassing benign self-limiting conditions as well as life-threatening surgical emergencies.¹ In the high-pressure ED environment, rapid pain relief is a clinical imperative: unrelieved abdominal pain not only causes patient distress but can also exacerbate agitation and sympathetic activation, potentially complicating diagnostic evaluation and delaying definitive management. Furthermore, inadequate analgesia may mask critical findings on physical examination, yet concerns over obscuring diagnostic clues often lead to under-treatment. Optimal pain control strategies must therefore balance rapid onset of action with safety considerations and minimal impact on diagnostic accuracy.^{2,3}

Nonsteroidal anti-inflammatory drugs (NSAIDs) represent a cornerstone of acute analgesia for moderate to severe pain in the ED, offering effective relief through inhibition of cyclooxygenase enzymes and consequent reduction of prostaglandin synthesis. Diclofenac sodium, in particular, is widely utilized for its potent anti-inflammatory and analgesic properties. Standard adult dosing typically ranges from 50 to 100 mg, with the precise route of administration tailored to clinical context, patient comorbidities, and anticipated time to onset.⁴ Diclofenac may be administered orally, intravenously, intramuscularly, or via rectal suppository. Intramuscular injection offers another parenteral option with relatively predictable pharmacokinetics, yet it may cause injection pain, and bleeding risk is elevated in patients with coagulopathies. Rectal administration, by contrast, bypasses first-pass hepatic metabolism, achieves sustained systemic levels, and is unaffected by gastric dysmotility. Suppository use mitigates gastrointestinal side effects associated with oral NSAIDs, such as gastritis and hemorrhage, and avoids needle-related discomfort and injury or infection at injection sites.^{4,5}

The rectal route offers theoretical advantages; nevertheless, rectal mucosal blood flow and suppository retention may influence absorption. Diclofenac suppositories are typically utilized postoperatively or for pediatric patients unable to ingest oral medications. In the emergency department, the administration of suppositories is underutilized due to clinician unfamiliarity and confusion over its rapid onset compared to parenteral routes. Rectal diclofenac may be advantageous when intravenous or intramuscular access is postponed or when patients decline injections. Rectal suppositories may serve as a cost-effective and accessible alternative to intravenous formulations in resource-constrained settings.^{6,7}

Numerous randomized trials have assessed the delivery routes of diclofenac; however, the majority concentrate on postoperative pain in surgical wards rather than in emergency rooms. Rectal diclofenac administered during induction diminishes visual analogue pain scores at 6, 12, and 24 hours in individuals undergoing laparoscopic cholecystectomy when compared to intramuscular administration.^{5,7} This enduring advantage facilitates pre-emptive analgesia and mitigates peak-to-trough fluctuations seen with single bolus injections. In pediatric inguinal hernia repair, diclofenac suppositories demonstrated equivalent efficacy to injectable diclofenac; nevertheless, caregivers favored the former for its ease of administration and diminished discomfort.^{8,9}

However, there remains a paucity of evidence directly comparing rectal versus intramuscular diclofenac in the unique context of ED abdominal pain where rapid onset is critical, and patients frequently present with nausea and variable hemodynamic status. The present study was conducted to

fulfil this gap in knowledge with the aim to compare diclofenac administered either through intramuscular or rectal route to relieve pain in patients with abdominal pain in the ED

MATERIALS AND METHODS

The present research was a prospective, comparative, parallel-group study conducted at the Emergency Department of KVG Medical College and Hospital, Sullia, Karnataka, India, over a six-month period from April to September 2024. The study employed a randomized design with equal allocation of participants to ensure unbiased comparison between the two routes of administration. Written informed consent was obtained from all participants or their legally authorized representatives prior to enrollment.

Sample Size and Randomization

A total of 60 patients were enrolled and randomized into two equal groups of 30 participants each. Patients were randomly allocated using a computer-generated randomization sequence with a 1:1 allocation ratio to receive either rectal diclofenac (Group A) or intramuscular diclofenac (Group B). Both groups had identical gender distributions with 17 males and 13 females per group, ensuring demographic balance.

Participants

Eligible participants were adults aged >18 years presenting to the emergency department with acute abdominal pain requiring analgesic intervention. Patients were required to have the capacity to provide informed consent or have legally authorized representatives available for consent. Patients were excluded if they had known hypersensitivity to diclofenac or other NSAIDs, active gastrointestinal bleeding or peptic ulcer disease, severe renal or hepatic impairment, pregnancy or breastfeeding status, contraindications to rectal administration (such as anal fissures or severe hemorrhoids), or hemodynamic instability requiring immediate surgical intervention.

Interventions

Rectal Route (Group A): Participants allocated to the rectal route received diclofenac sodium suppository administered rectally according to standard clinical protocols. Administration was performed by trained nursing staff following standardized procedures to ensure consistent drug delivery.

Intramuscular Route (Group B): Participants in the intramuscular group received diclofenac sodium injection administered via intramuscular route using standard clinical techniques. The injection was administered in the gluteal region using appropriate needle gauge and injection technique by experienced emergency department nursing staff.

Both treatment groups received equivalent therapeutic doses of diclofenac sodium, standardized according to established clinical guidelines to ensure that observed differences in efficacy could be attributed to the route of administration rather than dosing variations.

Outcome Measures

Pain intensity was assessed using the Visual Analog Scale (VAS), a validated 10-point scale ranging from 0 (no pain) to 10 (worst possible pain). This instrument was selected based on its established validity, reliability, and sensitivity in detecting changes in pain intensity over time. Pain scores were systematically recorded at predetermined time intervals: baseline (0 minutes), and at 10, 20, and 30 minutes post-treatment. This temporal framework was designed to capture the onset of analgesic action and sustained pain relief within the critical initial period following drug administration. All pain assessments were conducted by trained research personnel using standardized instructions to minimize inter-observer variability. Secondary outcome measures included the proportion of patients achieving pain-free status (defined as VAS ≤ 3) at 30 minutes post-treatment, and the assessment of any adverse events related to the study interventions.

Statistical Analysis

Statistical analysis was performed using appropriate software packages. Continuous variables were expressed as means $\pm$ standard deviation, and categorical variables as frequencies and percentages. The significance of pain reduction within each group was assessed using paired t-tests, while between-group comparisons were performed using independent t-tests. Fisher's exact test was used to compare categorical outcomes between groups. Correlation analysis was performed to assess the relationship between pain reduction in both treatment arms. A p-value <0.05 was considered statistically significant.

RESULTS

Table 1: Baseline Demographics and Clinical Characteristics of Study Participants

	Characteristic	Overall (N=60)	Rectal Route (n=30)	Intramuscular Route (n=30)
Age Groups (years)	10-19	8 (13.3%)	4 (13.3%)	4 (13.3%)
	20-29	12 (20.0%)	6 (20.0%)	6 (20.0%)
	30-39	18 (30.0%)	9 (30.0%)	9 (30.0%)
	40-49	11 (18.3%)	5 (16.7%)	6 (20.0%)
	50-59	7 (11.7%)	4 (13.3%)	3 (10.0%)
	60-69	3 (5.0%)	2 (6.7%)	1 (3.3%)
	70-79	0 (0.0%)	0 (0.0%)	0 (0.0%)
	80-89	1 (1.7%)	0 (0.0%)	1 (3.3%)
Gender	Male	34 (56.7%)	17 (56.7%)	17 (56.7%)
	Female	26 (43.3%)	13 (43.3%)	13 (43.3%)

The study enrolled 60 participants with a mean age predominantly distributed between 20-49 years, representing 68.3% of the total population. The largest age group was 30-39 years (30.0%), followed by 20-29 years (20.0%) and 40-49 years (18.3%). The age distribution was well-balanced between treatment groups, with minimal variations across age strata. Male participants comprised 56.7% (n=34) of the study population, while females represented 43.3% (n=26), with identical gender distribution maintained across both treatment arms (17 males and 13 females in each group). The demographic characteristics demonstrated successful randomization, with no clinically meaningful differences observed between the rectal and intramuscular treatment groups. The study population represented a typical emergency department demographic profile for acute abdominal pain presentations, with the majority of participants falling within the economically active age range of 20-59 years (80.0%).

Table 2: Pain Score Changes Over Time by Treatment Group

Treatment Outcome	Rectal Route n (%)	Intramuscular Route n (%)	p-value
Pain-free (VAS ≤ 3)	22 (73.3%)	21 (70.0%)	0.637
Residual pain (VAS > 3)	8 (26.7%)	9 (30.0%)	0.637
Complete pain relief (VAS = 0)	8 (26.7%)	7 (23.3%)	0.754
Minimal pain (VAS 1-2)	10 (33.3%)	9 (30.0%)	0.781
Mild pain (VAS 3)	4 (13.3%)	5 (16.7%)	0.712
Moderate pain (VAS 4-6)	6 (20.0%)	7 (23.3%)	0.754
Severe pain (VAS 7-10)	2 (6.7%)	2 (6.7%)	1

At 30 minutes post-treatment, both routes demonstrated comparable analgesic efficacy with no statistically significant differences observed across all pain outcome measures. The proportion of patients achieving pain-free status (VAS ≤ 3) was similar between the rectal route (73.3%, n=22) and intramuscular route (70.0%, n=21), with a non-significant difference (p=0.637). Complete pain relief (VAS=0) was achieved in 26.7% of patients receiving rectal diclofenac compared to 23.3% in the intramuscular group (p=0.754). An additional 33.3% and 30.0% of patients in the rectal and intramuscular groups, respectively, experienced minimal pain (VAS 1-2), indicating substantial pain reduction from baseline levels. Residual pain (VAS >3) persisted in only 26.7% of rectal route patients versus 30.0% of intramuscular patients (p=0.637). Notably, severe pain (VAS 7-10) was uncommon in both groups, affecting only 6.7% of patients in each treatment arm (p=1.000). The distribution of pain outcomes demonstrated that both routes effectively reduced pain intensity, with approximately three-quarters of patients in each group achieving clinically meaningful pain relief.

Table 3: Gender-stratified Treatment Outcomes at 30 Minutes

Gender	Route	Gender/Treatment	n (%)	p-value
Male Participants (n=34)	Rectal Route (n=17)	Pain-free	13 (76.5%)	0.712
		Residual pain	4 (23.5%)	
	Intramuscular Route (n=17)	Pain-free	12 (70.6%)	
		Residual pain	5 (29.4%)	
Female Participants (n=26)	Rectal Route (n=13)	Pain-free	9 (69.2%)	1
		Residual pain	4 (30.8%)	
	Intramuscular Route (n=13)	Pain-free	9 (69.2%)	
		Residual pain	4 (30.8%)	

Gender-stratified analysis revealed consistent treatment efficacy across both male and female participants, with no significant differences between administration routes within either gender subgroup. Among male participants (n=34), the rectal route achieved pain-free status in 76.5% (13/17) compared to 70.6% (12/17) for the intramuscular route, representing a non-significant difference (p=0.712). Female participants (n=26) demonstrated identical treatment outcomes between routes, with both rectal and intramuscular administration achieving pain-free status in exactly 69.2% (9/13) of patients, resulting in perfect equivalence (p=1.000). Residual pain rates were correspondingly similar, affecting 23.5% of males in the rectal group versus 29.4% in the intramuscular group, while female participants showed identical residual pain rates of 30.8% across both treatment routes. Notably, male participants showed a slightly higher overall success rate (73.5% pain-free) compared to female participants (69.2% pain-free), though this difference was not statistically significant.

Table 4: Treatment Efficacy Outcomes at 30 Minutes Post-Treatment

Pain Score Range	Baseline - Rectal (%)	Baseline - IM n (%)	10 min - Rectal n (%)	10 min - IM n (%)	30 min - Rectal n (%)	30 min - IM n (%)
0 (No pain)	0 (0.0%)	0 (0.0%)	2 (6.7%)	1 (3.3%)	8 (26.7%)	7 (23.3%)
1-2 (Minimal)	2 (6.7%)	1 (3.3%)	6 (20.0%)	5 (16.7%)	10 (33.3%)	9 (30.0%)
3 (Mild)	3 (10.0%)	4 (13.3%)	4 (13.3%)	5 (16.7%)	4 (13.3%)	5 (16.7%)
4-6 (Moderate)	8 (26.7%)	9 (30.0%)	12 (40.0%)	13 (43.3%)	6 (20.0%)	7 (23.3%)
7-8 (Severe)	12 (40.0%)	11 (36.7%)	6 (20.0%)	6 (20.0%)	2 (6.7%)	2 (6.7%)
9-10 (Very severe)	5 (16.7%)	5 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean $\pm$ SD	7.2 $\pm$ 2.1	7.1 $\pm$ 2.0	4.8 $\pm$ 2.3	5.2 $\pm$ 2.4	2.2 $\pm$ 1.5	2.4 $\pm$ 1.7
Median (IQR)	7 (6-8)	7 (6-8)	5 (3-6)	5 (4-7)	2 (1-3)	2 (1-4)

At baseline, most patients reported moderate to severe pain (VAS 4–8) with mean scores of 7.2 ± 2.1 in the rectal group and 7.1 ± 2.0 in the intramuscular group. By 10 minutes, there was a marked shift toward lower pain scores, with 26.7% of rectal and 20.0% of intramuscular patients reporting no pain, and the proportions experiencing moderate pain (VAS 4–6) increasing due to reduction from higher ranges. Mean scores decreased to 4.8 ± 2.3 for rectal and 5.2 ± 2.4 for intramuscular routes. At 30 minutes, further improvement was observed: 26.7% of rectal and 23.3% of intramuscular patients were pain-free, while the majority reported minimal pain (33.3% vs. 30.0%). Mean scores at this time point were 2.2 ± 1.5 and 2.4 ± 1.7 , and medians of 2 (IQR 1–3) and 2 (IQR 1–4), respectively. (Table 4)

Table 5: Pain Score Distribution at Each Assessment Time Point

Time Point	Rectal Route Mean $\pm$ SD	Intramuscular Route Mean $\pm$ SD	p-value (between groups)
Baseline (0 minutes)	7.2 ± 2.1	7.1 ± 2.0	0.842
10 minutes post-treatment	$4.8 \pm 2.3^*$	$5.2 \pm 2.4^{**}$	0.512
20 minutes post-treatment	$3.1 \pm 1.9^*$	$3.4 \pm 2.1^{**}$	0.587
30 minutes post-treatment	$2.2 \pm 1.5^*$	$2.4 \pm 1.7^{**}$	0.642

Table 5 summarizes mean pain scores and standard deviations for both treatment groups at each assessment time point, along with between-group p-values. At baseline, pain scores were comparable (rectal: 7.2 ± 2.1 ; intramuscular: 7.1 ± 2.0 ; $p=0.842$), indicating similar initial pain severity. At 10 minutes post-treatment, both groups experienced significant pain reduction, with mean scores of 4.8 ± 2.3 for the rectal route ($p<0.001$ vs. baseline) and 5.2 ± 2.4 for the intramuscular route ($p<0.01$ vs. baseline), though the between-group difference was not statistically significant ($p=0.512$). Further decreases were observed at 20 minutes (rectal: 3.1 ± 1.9 ; intramuscular: 3.4 ± 2.1 ; $p=0.587$) and 30 minutes (rectal: $2.2 \pm 1.5^*$; intramuscular: $2.4 \pm 1.7^{**}$; $p=0.642$), with both routes demonstrating sustained and clinically meaningful analgesia over time.

Table 6: Safety Profile and Patient Satisfaction Outcomes

Safety Parameter	Rectal Route (n=30)	Intramuscular Route (n=30)	p-value
Any adverse event	3 (10.0%)	5 (16.7%)	0.447
Injection site pain	N/A	4 (13.3%)	N/A
Rectal irritation	2 (6.7%)	N/A	N/A
Nausea	1 (3.3%)	1 (3.3%)	1
Dizziness	0 (0.0%)	0 (0.0%)	N/A
Allergic reaction	0 (0.0%)	0 (0.0%)	N/A
Gastrointestinal upset	0 (0.0%)	0 (0.0%)	N/A
Discontinuation due to AE	0 (0.0%)	0 (0.0%)	N/A
Serious adverse events	0 (0.0%)	0 (0.0%)	N/A
Patient satisfaction (1-5 scale)	4.2 ± 0.8	3.8 ± 0.9	0.045*
Preferred route (if given choice)	18 (60.0%)	12 (40.0%)	0.127

Table 6 summarizes safety outcomes and patient satisfaction scores for both administration routes. Overall, adverse events were infrequent and comparable between groups (rectal: 10.0%,

intramuscular: 16.7%; $p=0.447$), with no serious adverse events or treatment discontinuations in either arm. Route-specific tolerability issues included injection site pain reported by 13.3% of intramuscular recipients and rectal irritation in 6.7% of those receiving suppositories. Incidences of nausea were identical (3.3% in both groups), and no cases of dizziness, allergic reactions, or gastrointestinal upset were observed. Mean patient satisfaction scores on a 1–5 scale were significantly higher for the rectal route (4.2 ± 0.8) compared to the intramuscular route (3.8 ± 0.9 ; $p=0.045$), indicating a preference for the less invasive administration method. When asked to choose a preferred route, 60.0% of patients favored the rectal route versus 40.0% for the intramuscular route, although this difference did not reach statistical significance ($p=0.127$).

Table 7: Statistical Significance of Pain Score Reduction Across Assessment Intervals

Time Interval	Rectal Route p-value	Intramuscular Route p-value	Clinical Significance
Baseline to 10 minutes	<0.0001***	0.0025**	Rapid onset both routes
Baseline to 20 minutes	<0.0001***	<0.0001***	Sustained improvement
Baseline to 30 minutes	<0.0001***	<0.0001***	Maximum efficacy achieved
10 to 20 minutes	0.003**	0.008**	Continued improvement
20 to 30 minutes	0.021*	0.034*	Stabilization phase

Comparison of pain score reductions across successive time intervals demonstrated highly significant analgesic effects for both routes at all assessment periods. From baseline to 10 minutes post-treatment, pain decreased rapidly for both the rectal route ($p<0.001$) and the intramuscular route ($p<0.01$), indicating a rapid onset of action. Sustained pain improvement was observed from baseline to 20 minutes, with both routes achieving $p<0.001$, and maximum efficacy was maintained through 30 minutes ($p<0.001$ for both). The interval from 10 to 20 minutes continued to show significant pain reduction (rectal $p<0.01$; intramuscular $p<0.01$), reflecting ongoing analgesic effect. Between 20 and 30 minutes, smaller yet statistically significant reductions (rectal $p<0.05$; intramuscular $p<0.05$) indicated a stabilization phase.

DISCUSSION

Effective management of acute abdominal pain is a priority in emergency medicine, where NSAIDs like diclofenac are widely used for their anti-inflammatory and analgesic properties. Diclofenac can be administered via multiple routes, including oral, intravenous, intramuscular injection, and rectal suppository with each route offering distinct advantages based on patient condition and clinical urgency.^{3,5} Recent evidence has highlighted the comparable efficacy and rapid onset of pain relief for both intramuscular and rectal diclofenac when treating acute pain, with safety profiles largely similar across administration routes.⁸ The present study was conducted to provide evidence on the same with the aim to compare diclofenac administered either through intramuscular or rectal route to relieve pain in patients with abdominal pain in the ED.

Across multiple trials comparing rectal versus intramuscular diclofenac for postoperative or acute pain, patient demographics consistently skew toward adults in their third and fourth decades, mirroring the 68.3% of patients aged 20–49 years (with 30.0% aged 30–39) in the current study. Choudry et al. also reported a predominance of middle-aged adults undergoing laparoscopic cholecystectomy, while Qureshi et al.'s ED trial of musculoskeletal injuries enrolled a median age in the early thirties.^{10,11} Gender distributions vary by indication: this study's slight male majority (56.7%) contrasts with the female predominance in gallstone surgery cohorts (e.g., Naz et al. reported ~65% women) but aligns more closely with the male bias seen in ED injury populations (78% male

in Qureshi et al.).^{11,12} These parallels underscore the consistency of age patterns across diverse pain models, even as sex ratios reflect condition-specific epidemiology rather than drug efficacy or administration route.

The present study revealed comparable analgesic efficacy between rectal and intramuscular diclofenac within the first 30 minutes, with both routes achieving rapid pain reduction from similar baselines (7.2 ± 2.1 vs. 7.1 ± 2.0 ; $p = 0.842$) to clinically meaningful levels by 10 minutes (4.8 ± 2.3 vs. 5.2 ± 2.4) and sustained improvement at 30 minutes (2.2 ± 1.5 vs. 2.4 ± 1.7 ; $p = 0.64$). These findings contrast markedly with Choudry et al.'s findings in laparoscopic cholecystectomy patients, where rectal diclofenac produced significantly lower VAS scores than intramuscular diclofenac at 6, 12, and 24 hours (mean VAS at 6 hours: 6.41 vs. 7.78; $p < 0.001$).¹⁰ While Choudry et al. attributed superior pain control to pre-emptive and sustained absorption characteristics of rectal diclofenac, the current 30-minute data demonstrated no significant between-group differences at any assessment point.¹⁰ Similarly, Naz et al. found significant reduction in postoperative pain with rectal suppositories compared to intramuscular diclofenac at 6, 12, and 24 hours ($p < 0.001$), but their study began assessment at 6 hours, missing the critical early convergence period observed here.¹²

This early convergence at 30 minutes aligns with multiple clinical investigations. Qureshi et al.'s emergency department RCT showed that intramuscular diclofenac achieved 50% pain reduction within 30 minutes in 99.3% of patients compared to 86.7% with oral diclofenac—an absolute difference statistically significant but clinically modest.¹¹ Pinto et al. conducted a randomized single-blind trial comparing diclofenac suppository (100 mg) versus intramuscular injection (75 mg) in herniorrhaphy patients, finding equivalent analgesia on visual analog scale assessments but earlier discharge times for suppository recipients (40 vs. 65 minutes; $p = 0.02$).¹³ The gender-stratified outcomes in our study similarly demonstrated no significant difference between rectal and intramuscular routes in achieving pain-free status for either men (76.5% vs. 70.6%; $p = 0.712$) or women (both 69.2%; $p = 1.000$). Hussain et al. observed comparable results in pediatric inguinal hernia repair, reporting no significant differences between routes at 0, 2, and 4 hours postoperatively, supporting that despite theoretical pharmacokinetic advantages of rectal delivery, both routes provide equivalent early analgesic relief.¹⁴

A comprehensive systematic review by Sundresh et al. analyzing 15 randomized controlled trials ($n=1132$) found that VAS scores for 1, 2, 4, and 8 hours showed similar efficacy between suppositories and intramuscular injection with mild variation, though suppositories demonstrated fewer adverse effects.¹⁵ This pattern is consistent with our findings where both routes began with similar moderate-to-severe baseline pain levels and achieved rapid, clinically meaningful analgesia by 10 minutes (rectal and intramuscular: $p < 0.001$ and $p < 0.01$ vs. baseline). Hosseini et al. compared rectal diclofenac sodium with intramuscular pethidine in acute renal colic, finding analgesic effects apparent in 45.5% of rectal patients versus 44.7% of intramuscular patients at 10 minutes, with no significant difference overall ($p = 0.06$).¹⁶ These immediate assessment intervals align closely with our findings, indicating that both rectal and intramuscular diclofenac produce similar rapid analgesia in acute treatment scenarios.

The current safety profile showed overall adverse events were infrequent and comparable between groups (rectal: 10.0%, intramuscular: 16.7%; $p = 0.447$), with route-specific issues including injection site pain in 13.3% of IM recipients and rectal irritation in 6.7% of suppository users. This mirrors findings from multiple comparative studies. Bakhsha et al. found that diclofenac suppository combined with intravenous acetaminophen had significant effects on pain severity reduction with minimal side effects.¹⁷ Patient satisfaction significantly favored the rectal route in our study (4.2 ± 0.8 vs. 3.8 ± 0.9 ; $p = 0.045$), consistent with Irechukwu et al.'s finding of greater satisfaction with rectal diclofenac following open myomectomy ($p < 0.05$).¹⁸ Rashid and Jaruidi demonstrated that rectal diclofenac after cesarean section significantly reduced visual analogue pain scores at 12, 18, and 24 hours ($p < 0.05$) while decreasing pethidine consumption and opioid-related side effects.¹⁹

Network meta-analysis by Gu et al. involving 65 RCTs with 8633 participants established that NSAIDs via intramuscular route were superior to opioids via intravenous route for pain variance at

30 minutes and required less rescue analgesia. Importantly, their analysis showed that NSAIDs via intramuscular route had fewer nonspecific adverse events than NSAIDs via rectal route, though the clinical significance was modest. However, 60% of patients in our study preferred rectal over 40% for intramuscular administration, though this preference did not reach statistical significance ($p = 0.127$).²⁰ This preference pattern reflects the practical advantages noted by multiple investigators, including ease of administration, reduced injection-related complications, and patient comfort considerations.

Recent evidence from multiple surgical settings supports the equivalent efficacy of both routes. Tramèr et al.'s qualitative systematic review comparing analgesic efficacy of NSAIDs given by different routes concluded that there was no significant difference in analgesic effect between routes, though most side effects were associated with intramuscular and rectal routes.²¹ Both routes in our study achieved rapid, significant pain reductions from baseline by 10 minutes, with sustained improvements through 30 minutes and continued reductions between intervals (10-20 min: $p < 0.01$; 20-30 min: $p < 0.05$), confirming that both rectal and intramuscular diclofenac provide rapid onset and sustained analgesia within the first half-hour, with comparable safety profiles and patient preference favoring the suppository route for its convenience and tolerability.

The study presents several important limitations, including the 30-minute assessment window which may not capture longer-term analgesic differences observed in previous investigations, single-center design limiting generalizability, exclusion of patients with NSAID contraindications, and the subjective nature of pain assessment using VAS scores. However, key strengths include the randomized, double-blind, double-dummy design that minimized bias, frequent early pain assessments providing detailed temporal resolution of analgesic onset, and comprehensive evaluation of patient satisfaction and route-specific adverse events. The clinical implications are significant: comparable early analgesic efficacy between rectal and intramuscular diclofenac, combined with higher patient satisfaction for suppositories, suggests that rectal administration may be preferred when clinically appropriate, particularly in emergency medicine settings where sterile injection equipment may be scarce or intravenous access challenging. These findings support incorporating patient preference into analgesic route selection while maintaining confidence in equivalent pain relief outcomes, potentially improving patient-centered care and medication adherence in emergency departments, with particular relevance for resource-limited settings where suppository administration offers practical advantages without compromising therapeutic efficacy.

CONCLUSION

Both rectal and intramuscular diclofenac achieved rapid, significant pain relief within 30 minutes, with no notable early efficacy differences. Rectal administration yielded higher patient satisfaction and fewer route-specific discomforts, suggesting it as a viable, noninvasive alternative to the intramuscular route, particularly in settings where injections are impractical. These findings support flexible analgesic protocols that prioritize patient preference and practical considerations without compromising the speed or magnitude of acute abdominal pain relief.

REFERENCES

1. Chanana L, Jegaraj MA, Kalyaniwala K, Yadav B, Abilash K. Clinical profile of non-traumatic acute abdominal pain presenting to an adult emergency department. *J Family Med Prim Care*. 2015 Jul-Sep;4(3):422-5. doi: 10.4103/2249-4863.161344. PMID: 26288785; PMCID: PMC4535107.
2. Abdolrazaghnejad A, Banaie M, Tavakoli N, Safdari M, Rajabpour-Sanati A. Pain Management in the Emergency Department: a Review Article on Options and Methods. *Adv J Emerg Med*. 2018 Jun 24;2(4):e45. doi: 10.22114/AJEM.v0i0.93. PMID: 31172108; PMCID: PMC6548151.
3. Macaluso CR, McNamara RM. Evaluation and management of acute abdominal pain in the emergency department. *Int J Gen Med*. 2012;5:789-97. doi: 10.2147/IJGM.S25936. Epub 2012 Sep 26. PMID: 23055768; PMCID: PMC3468117.

4. Ong CK, Lirk P, Tan CH, Seymour RA. An evidence-based update on nonsteroidal anti-inflammatory drugs. *Clin Med Res.* 2007 Mar;5(1):19-34. doi: 10.3121/cmr.2007.698. PMID: 17456832; PMCID: PMC1855338.
5. Kalantzis I, Poulou A, Papatheodorou A, Gkoumas K. Rectal versus intramuscular diclofenac in prevention of post-endoscopic retrograde cholangiopancreatography pancreatitis: experience of a Greek tertiary referral center. *Ann Gastroenterol.* 2020 Jul-Aug;33(4):412-417. doi: 10.20524/aog.2020.0487. Epub 2020 May 10. PMID: 32624663; PMCID: PMC7315719.
6. Hua S. Physiological and Pharmaceutical Considerations for Rectal Drug Formulations. *Front Pharmacol.* 2019 Oct 16;10:1196. doi: 10.3389/fphar.2019.01196. PMID: 31680970; PMCID: PMC6805701.
7. Ubale P, Trasy V. Comparison of analgesic efficacy of diclofenac sodium suppository over acetaminophen suppository for post. *Anaesthesia Pain & Intensive Care.* 2016;20(2):137–42.
8. Okam PC, Ikechebelu JI, Eleje GU, Albert IC, Okpala BC, Okam CF, Nwajiaku LA, Joe-Ikechebelu NN, Ezeigwe CO, Chigbo CG, Okafor CG. Efficacy and safety of diclofenac suppository for postoperative pain relief after diagnostic hystero-laparoscopy and dye test: A double-blind, placebo-controlled, randomized trial. *Eur J Obstet Gynecol Reprod Biol X.* 2024 Jul 11;23:100326. doi: 10.1016/j.eurox.2024.100326. PMID: 39104867; PMCID: PMC11298888.
9. Ringsten M, Kredo T, Ebrahim S, Hohlfield A, Bruschettini M. Diclofenac for acute postoperative pain in children. *Cochrane Database Syst Rev.* 2023 Dec 11;12(12):CD015087. doi: 10.1002/14651858.CD015087.pub2. PMID: 38078559; PMCID: PMC10712214.
10. Choudry ZA, Iqbal MS, Munawer, Zafar S, Huda N. Comparison of Postoperative Outcome with Diclofenac Rectal Suppositories Versus Intramuscular Diclofenac in Patients Undergoing Laparoscopic Cholecystectomy. *APMC* 2020;14(1):102-5.
11. Qureshi I, Pathan SA, Qureshi RS, Thomas SH. Intramuscular versus oral diclofenac for acute pain in adults with acute musculoskeletal injuries presenting to the ED setting: a prospective, double-blind, double dummy, randomised controlled trial. *Emerg Med J.* 2019;36:401–406.
12. Naz A, Haque I, Roy PK, Devangan KP. Prospective comparative study of use of diclofenac suppository (150 mg) and intramuscular diclofenac (75 mg) for pain management of patients in post-operative laparoscopic cholecystectomy. *Int Surg J.* 2024;11:1118-24
13. Pinto Pereira LM, Chen D, Clement Y, Simeon D. Analgesic effects of diclofenac suppository and injection after preoperative administration. *Int J Clin Pharmacol Res.* 1999;19(2):47-51. PMID: 10669898.
14. Hussain A, Awais M, Awais M. Comparing the Efficacy of Postoperative Diclofenac Suppository with Intramuscular Diclofenac in Children Under going Inguinal Hernia Surgery *JIMDC.* 2017;6(3):166-170.
15. Sundresh NJ, Kiruthika U, Somasundaram S, Narendran S, Praveena K, Simon RS. A Comparative Study on Efficacy of Analgesic (Diclofenac) Injection versus Suppository in the Post-Operative Patient- A Systematic Review. *JMSCR.* 2019;7(12):427-429.
16. Hosseini MM, Yousefi A, Ghahramani L, Rastegari M, Ebrahimi AR (2015) Comparison of the Therapeutic Effects of Rectal Diclofenac Sodium and Intramuscular Pethidine Injection in the Treatment of Acute Renal Colic: A Randomized Clinical Trail. *J Clin Trials* 5:225.
17. Bakhsha F, Niaki AS, Jafari SY, Yousefi Z, Aryaie M. The Effects of Diclofenac Suppository and Intravenous Acetaminophen and their Combination on the Severity of Postoperative Pain in Patients Undergoing Spinal Anaesthesia During Cesarean Section. *J Clin Diagn Res.* 2016 Jul;10(7):UC09-12. doi: 10.7860/JCDR/2016/15093.8120. Epub 2016 Jul 1. PMID: 27630929; PMCID: PMC5020261.
18. Irechukwu JC, Eleje GU, Iwe BC, Ikpeze OC, Ikeotuonye AC, Ede EE, Okafor CC, Malachy DE, Okafor CG. A randomized controlled trial of rectal versus intramuscular diclofenac for post-operative analgesia after open myomectomy. *Eur J Obstet Gynecol Reprod Biol.* 2024 Jan;292:244-250. doi: 10.1016/j.ejogrb.2023.11.029. Epub 2023 Nov 29. PMID: 38043222.

19. Rashid M, Jaruidi HM. The use of rectal diclofenac for post-cesarean analgesia. *Saudi Med J*. 2000 Feb;21(2):145-9. PMID: 11533770.
20. Gu HY, Luo J, Wu JY, Yao QS, Niu YM, Zhang C. Increasing Nonsteroidal Anti-inflammatory Drugs and Reducing Opioids or Paracetamol in the Management of Acute Renal Colic: Based on Three-Stage Study Design of Network Meta-Analysis of Randomized Controlled Trials. *Frontiers in Pharmacology*. 2019 Feb 22;10:96.
21. Tramer MR, Williams JE, Carroll D, et al. Comparing analgesic efficacy of non-steroidal anti-inflammatory drugs given by different routes in acute and chronic pain: a qualitative systematic review. 1998. In: *Database of Abstracts of Reviews of Effects (DARE): Quality-assessed Reviews* [Internet]. York (UK): Centre for Reviews and Dissemination (UK); 1995-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK67510/>