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ORIGINAL ARTICLE **OPEN ACCESS**

Single-Dose Intramuscular Ketorolac versus Diclofenac in Acute Moderate-to-Severe Low Back Pain: A Randomized Controlled Trial

M Salguna Sambhannan Vivek [1], Kantilal C. Chandaliya [2], Rajesh K. Ambulgekar [3], Girish Raparti [4]
Junior Resident [1], Professor and Head [2], Professor and Head [3], Associate Professor [4]
Department of Pharmacology [1,2,4], Department of Orthopaedics [3]
Dr. Shankarrao Chavan Government Medical College, Nanded, IND

ABSTRACT

Acute low back pain (LBP) is one of the leading causes of disability worldwide and represents a major clinical and socioeconomic burden due to its high prevalence, associated functional impairment, and healthcare utilization. Rapid and effective pain control is essential to improve mobility, reduce disability, and facilitate early return to daily activities. Intramuscular nonsteroidal anti-inflammatory drugs (NSAIDs) remain a cornerstone of pharmacological management in patients presenting with acute moderate-to-severe LBP. Although diclofenac is widely used in clinical practice, ketorolac possesses potent analgesic properties and has demonstrated efficacy in various acute pain conditions. However, direct comparative evidence between these agents in patients with acute moderate-to-severe LBP remains limited, particularly from well-designed randomized controlled trials. This study was therefore undertaken to compare the efficacy and safety of single-dose intramuscular ketorolac (30 mg) and diclofenac (75 mg) in the management of acute moderate-to-severe low back pain. A prospective, randomized, double-blind, parallel-group controlled trial was conducted in a tertiary care teaching hospital involving 52 adult patients who were randomly allocated to receive either intramuscular ketorolac or diclofenac (26 participants per group). Pain intensity, functional disability, and spinal mobility were assessed using the Visual Analogue Scale (VAS), Roland-Morris Disability Questionnaire (RMDQ), and Finger-to-Floor (FTF) distance at baseline and at 1, 2, and 3 hours following drug administration. Patients receiving ketorolac demonstrated significantly greater reductions in VAS pain scores at 1 hour ($p = 0.04$) and significantly greater improvement in FTF mobility ($p = 0.007$) compared with the diclofenac group. Although both groups showed improvement in RMDQ scores, the difference was not statistically significant ($p = 0.39$). No adverse events were reported in either treatment group, indicating comparable short-term tolerability. These findings demonstrate that single-dose intramuscular ketorolac provides faster and superior early analgesia and functional mobility compared with intramuscular diclofenac while maintaining a similar safety profile. The results support ketorolac as an effective first-line parenteral NSAID for the management of acute moderate-to-severe low back pain in emergency and outpatient settings. Larger multicenter studies with longer follow-up are warranted to confirm these findings and evaluate long-term clinical outcomes.

Keywords: *ketorolac, Visual Analogue Scale, diclofenac, Randomized Controlled Trial, low back pain*

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INTRODUCTION

Pain is defined by the International Association for the Study of Pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage [1].

Low back pain (LBP) is a highly prevalent condition worldwide, affecting approximately 38% of the population annually. It is the leading cause of years lived with disability globally and imposes a substantial burden on individuals, healthcare systems, and society [2].

In nearly 90% of cases, LBP is classified as non-specific, with no identifiable underlying pathology. Acute non-specific LBP may be triggered by physical factors such as lifting heavy weight and bending forward, as well as psychosocial factors including stress, anxiety, and fatigue. Patients commonly present with pain, muscle spasm, and reduced mobility. The spasm-pain-spasm cycle contributes to persistence and recurrence of symptoms [3]. The primary goals in managing acute LBP are to reduce pain and improve functional mobility.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line pharmacological therapy for acute LBP. However, available evidence suggests that their overall analgesic benefit may be modest, and

no specific NSAID has demonstrated clear superiority over others. Consequently, the choice of NSAID is often based on clinical experience rather than strong comparative evidence [4].
Diclofenac is a widely used NSAID with rapid onset of action when administered intramuscularly, making it suitable for acute pain management [5]. Ketorolac is a potent NSAID with significant analgesic efficacy and is commonly used in acute pain settings. When administered intramuscularly, it provides rapid and effective analgesia comparable to opioid analgesics [6].
Previous studies evaluating ketorolac in acute musculoskeletal pain have limitations, including exclusion of patients with low back pain, imbalance in treatment allocation, or omission of patients with severe pain [7]. These limitations restrict the applicability of their findings to acute moderate-to-severe LBP.
Despite its widespread availability, the use of ketorolac in acute LBP remains limited due to concerns regarding safety. However, emerging evidence suggests that short-term use of ketorolac is comparable in safety to other NSAIDs [8]. There remains a lack of well-designed randomized controlled trials directly comparing intramuscular ketorolac and diclofenac in acute moderate-to-severe low back pain.
Therefore, this study was conducted to compare the safety and efficacy of single-dose intramuscular ketorolac (30 mg) versus diclofenac (75 mg) in patients with acute moderate-to-severe low back pain.

MATERIAL AND METHODS

Study Design and Setting

This prospective, randomized, double-blind, parallel-group controlled trial was conducted in the Department of Pharmacology in collaboration with the Department of Orthopaedics at Dr. Shankarrao Chavan Government Medical College and Hospital, Nanded, Maharashtra, India. The study was designed in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. Ethical approval was obtained from the Institutional Ethics Committee (Approval No. 034125), and written informed consent was obtained from all participants before enrolment.
The primary objective was to compare the efficacy and safety of a single intramuscular dose of ketorolac (30 mg) with diclofenac (75 mg) in adults presenting with acute moderate-to-severe low back pain.

Study Participants and Sampling

Adult patients aged 18 years or older presenting to the Orthopaedic outpatient department or emergency department with acute non-specific low back pain of less than six weeks' duration were screened for eligibility.
A total of 52 eligible patients were enrolled and randomly allocated in a 1:1 ratio into two treatment groups, with 26 participants assigned to each group. The study was conducted as a prospective randomized controlled clinical trial to evaluate comparative efficacy and safety under controlled conditions.

Inclusion Criteria

Participants were eligible if they fulfilled all of the following criteria:

- Age ≥18 years.
- Acute non-specific low back pain with symptom duration of less than six weeks.
- Moderate-to-severe pain, defined as a baseline Visual Analogue Scale (VAS) score ≥40 mm on a 100-mm scale.
- Clinical diagnosis confirmed by an orthopaedic specialist.
- Ability to understand study procedures and provide written informed consent.

Exclusion Criteria

Patients were excluded if they had:

- Hypersensitivity to ketorolac, diclofenac, aspirin, or other NSAIDs.
- Active peptic ulcer disease or history of gastrointestinal bleeding.
- Moderate or severe renal impairment.
- Significant hepatic dysfunction.
- Pregnancy or lactation.
- Analgesic use within eight hours before enrolment.
- Low back pain secondary to trauma, spinal infection, malignancy, inflammatory disorders, neurological deficits, or other specific pathological causes.
- Any medical condition that, in the investigator's opinion, could interfere with study participation or outcome assessment.

Randomization and Blinding

Participants were randomized using a computer-generated block randomization sequence prepared before study initiation. Allocation concealment was achieved using sequentially numbered, sealed, opaque envelopes that were opened only after patient enrolment.

This was a double-blind study. Neither the participants nor the investigators responsible for clinical assessment and outcome evaluation were aware of treatment allocation. Study medications were prepared in identical syringes by a healthcare professional who was not involved in patient recruitment, treatment administration, or outcome assessment, thereby maintaining blinding throughout the study.

Intervention

Following randomization, participants received a single intramuscular injection under aseptic precautions:

Group A: Ketorolac tromethamine 30 mg IM

Group B: Diclofenac sodium 75 mg IM

Both medications were administered as a single-dose intervention. No additional analgesics were permitted during the three-hour observation period.

Outcome Measures

Primary Outcome

The primary efficacy endpoint was the change in pain intensity measured using the 100-mm Visual Analogue Scale (VAS). Patients indicated their pain intensity on a horizontal line where 0 represented "no pain" and 100 represented the "worst imaginable pain" [9].

Secondary Outcomes

Secondary efficacy outcomes included:

Finger-to-Floor (FTF) Test

Lumbar spinal mobility was assessed by measuring the distance between the fingertips and the floor during maximal forward flexion with knees fully extended. Lower values indicated better spinal mobility [10].

Roland-Morris Disability Questionnaire (RMDQ)

Functional disability associated with low back pain was evaluated using the validated Roland-Morris Disability Questionnaire. Although RMDQ is generally intended for longer follow-up periods, it was included to explore early functional changes following treatment [11].

Safety Assessment

All participants were monitored throughout the observation period for adverse events including:

- Gastrointestinal symptoms
- Hypersensitivity reactions
- Injection-site reactions
- Dizziness
- Any unexpected clinical event

Study Procedure

Baseline assessment included demographic characteristics, medical history, physical examination, and baseline measurements of VAS, FTF distance, and RMDQ score.

Following administration of the allocated study medication, outcome assessments were performed at:

- Baseline (pre-injection)
- 1 hour
- 2 hours
- 3 hours post-injection

These time points were selected to evaluate the onset and early duration of analgesic response after intramuscular NSAID administration.

Statistical Analysis

Statistical analysis was performed using Microsoft Excel. Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were summarized as frequencies and percentages. Baseline characteristics between treatment groups were compared to ensure comparability. Between-group comparisons were performed using the independent Student's t-test, whereas within-group changes from baseline were analysed using the paired Student's t-test.

All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant.

RESULTS

Table 1: Baseline Demographic Homogeneity

Parameter	Group A (Ketorolac, n=26)	Group B (Diclofenac, n=26)	p-value
Age (years), Mean SD	45.07 ±15.16	40.8 ±14.68	0.31
BMI (kg/m^2), Mean SD	25.7 ± 2.77	26.06 ± 2.78	0.63

Table 2: Primary Efficacy Comparison Post-Injection

Outcome Measure	Group A (Ketorolac)	Group B (Diclofenac)	p-value
VAS Score (Mean difference at 1 hr)	Higher Improvement	Lower Improvement	0.04*
FTF Mobility (Significant Improvement)	73.07%	61.54%	0.007*
RMDQ Score (Average Improvement)	4.62	3.96	0.39
p < 0.05 denotes statistical significance.			

A total of 52 patients with acute moderate-to-severe low back pain were enrolled and randomized equally into two groups: Group A received intramuscular ketorolac 30 mg (n=26) and Group B received intramuscular diclofenac 75 mg (n=26).

The baseline demographic characteristics were comparable between the two groups, indicating successful randomization. The mean age of patients in the ketorolac group was 45.07 ± 15.16 years compared to 40.80 ± 14.68 years in the diclofenac group (p=0.31). Similarly, the mean body mass index (BMI) was 25.7 ± 2.77 kg/m^2 in Group A and 26.06 ± 2.78 kg/m^2 in Group B (p=0.63). No statistically significant differences were observed in baseline demographic parameters between the groups (Table 1).

Regarding efficacy outcomes, patients receiving ketorolac demonstrated significantly greater pain reduction at 1 hour post-injection as measured by the Visual Analogue Scale (VAS) compared to the diclofenac group (p=0.04). Functional mobility, assessed using the Finger-to-Floor (FTF) test, also improved significantly in the ketorolac group, with 73.07% of patients showing improvement compared with 61.54% in the diclofenac group (p=0.007).

Although improvement in Roland-Morris Disability Questionnaire (RMDQ) scores was numerically greater in the ketorolac group (4.62 versus 3.96), the difference did not reach statistical significance (p=0.39). These findings suggest that ketorolac provided faster analgesia and superior early improvement in mobility compared with diclofenac, while short-term disability outcomes were comparable between the two treatment groups (Table 2).

DISCUSSION

The present randomized controlled trial demonstrated that a single intramuscular dose of ketorolac produced significantly faster pain relief and greater early improvement in spinal mobility than intramuscular diclofenac in patients with acute moderate-to-severe low back pain. Although both treatment groups experienced clinically meaningful improvement, ketorolac showed superior analgesic efficacy during the early post-treatment period while maintaining an equivalent short-term safety profile. Rapid pain control is particularly important in the management of acute low back pain because it facilitates early mobilization, reduces functional limitation, and improves patient satisfaction. In the present study, patients receiving ketorolac experienced significantly greater reductions in VAS pain scores within one hour of administration, suggesting a faster onset of analgesic action than diclofenac. These findings are consistent with previous studies, including that of Plapler et al., which reported faster analgesic effects of ketorolac compared to other NSAIDs in acute pain conditions [7].

Functional recovery represents an equally important therapeutic goal. Improvement in Finger-to-Floor distance was significantly greater among patients receiving ketorolac, indicating superior restoration of spinal mobility during the early phase of treatment. Early improvement in mobility may reduce patient discomfort, facilitate ambulation, and potentially shorten emergency department observation time. These benefits are clinically meaningful because restoration of movement is often as important as pain reduction in patients presenting with acute low back pain.

Although both treatment groups demonstrated improvement in Roland-Morris Disability Questionnaire scores, no statistically significant difference was observed between the groups. This finding should be interpreted cautiously because disability questionnaires generally reflect changes occurring over several days rather than within a few hours. Consequently, the three-hour follow-up period in the present study may have been insufficient to detect meaningful differences in functional disability.

Importantly, neither treatment group experienced adverse events during the observation period. These findings are in agreement with existing literature suggesting that short-term use of ketorolac has a safety profile comparable to other NSAIDs [12]. This observation is particularly relevant because concerns regarding ketorolac toxicity have often limited its clinical use despite evidence supporting its safety during brief therapeutic exposure.

The present study has several strengths. It employed a prospective randomized double-blind design, minimized allocation bias through concealed randomization, and assessed both subjective and objective measures of treatment response using validated outcome instruments. Furthermore, this study specifically evaluated patients with acute moderate-to-severe low back pain, a population that has been underrepresented in previous comparative studies.

However, certain limitations should be acknowledged. The relatively small sample size and short follow-up period restrict assessment of sustained analgesic efficacy, recurrence of symptoms, and delayed adverse events. Additionally, the study was conducted at a single tertiary care center, which may limit generalizability to other healthcare settings. Future multicenter randomized controlled trials with larger sample sizes and extended follow-up are warranted to validate these findings and determine long-term clinical outcomes.

ETHICAL CONSIDERATIONS

The study protocol received approval from the Institutional Ethics Committee of Dr. Shankarrao Chavan Government Medical College, Nanded (Approval No. 034125). Written informed consent was obtained from every participant before enrolment. Participant confidentiality was maintained throughout the study, and all procedures were conducted according to the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice guidelines.

LIMITATIONS OF THE STUDY

Although this randomized controlled trial provides valuable evidence regarding the comparative efficacy and safety of intramuscular ketorolac and diclofenac in patients with acute moderate-to-severe low back pain, several limitations should be acknowledged.

First, the study was conducted at a single tertiary care teaching hospital with a relatively small sample size of 52 participants. Although randomization and double blinding minimized selection and observer bias, the limited sample size may reduce the generalizability of the findings to broader and more diverse patient populations.

Second, the follow-up period was limited to three hours after drug administration. While this allowed assessment of the onset and early analgesic efficacy of the study medications, it did not permit evaluation of sustained pain relief, functional recovery, recurrence of symptoms, or delayed adverse events. Consequently, the long-term comparative effectiveness and safety of the two interventions could not be determined.

Third, the study evaluated only a single intramuscular dose of ketorolac and diclofenac. Therefore, the findings cannot be extrapolated to repeated-dose regimens or prolonged treatment commonly encountered in routine clinical practice.

Finally, although the Roland-Morris Disability Questionnaire (RMDQ) was included as a measure of functional disability, it is primarily designed to detect changes over longer follow-up periods. Its sensitivity to capture meaningful functional improvement within the three-hour observation period is inherently limited, which may explain the absence of statistically significant differences between the treatment groups.

Despite these limitations, the study employed a prospective randomized double-blind design with validated outcome measures, providing robust evidence that intramuscular ketorolac offers faster early pain relief and greater improvement in functional mobility than intramuscular diclofenac in patients with acute moderate-to-severe low back pain. Larger multicenter trials with longer follow-up are warranted to confirm these findings and establish their applicability in routine clinical practice.

CONCLUSION

This randomized double-blind controlled trial demonstrates that a single intramuscular dose of ketorolac provides faster and more effective early pain relief and significantly greater improvement in functional mobility than intramuscular diclofenac in adults with acute moderate-to-severe low back pain. Both treatments were well tolerated, with no adverse events observed during the study period, indicating comparable short-term safety.

These findings suggest that ketorolac may represent a preferable first-line parenteral NSAID for patients requiring rapid analgesia in emergency departments and outpatient settings. By providing earlier pain control and improved mobility, ketorolac has the potential to enhance patient comfort and facilitate earlier functional recovery. Although the results are encouraging, larger multicenter randomized controlled trials with longer follow-up are required to confirm these findings, evaluate long-term outcomes, and establish the role of ketorolac within evidence-based treatment guidelines for acute low back pain.

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CONFLICT OF INTEREST
The author declares no conflict of interest related to this study.

REFERENCES
1. Cohen M, Quintner J, van Rysewyk S. (2018). Reconsidering the International Association for the Study of Pain definition of pain. *Pain Rep*. 3(2):e634. Published 2018 Mar 5. doi:10.1097/PR9.0000000000000634
2. Meucci RD, Fassa AG, Faria NM. (2015). Prevalence of chronic low back pain: systematic review. *Rev Saude Publica*. ;49:1. doi:10.1590/S0034-8910.2015049005874
3. Pincus T, Burton AK, Vogel S, Field AP. (2002). A systematic review of psychological factors as predictors of chronicity/disability in prospective cohorts of low back pain. *Spine (Phila Pa 1976)*. 27(5):E109-E120. doi:10.1097/00007632-200203010-00017.
4. Cashin AG, Wand BM, O'Connell NE, et al. (2023). Pharmacological treatments for low back pain in adults: an overview of Cochrane Reviews. *Cochrane Database Syst Rev*.;4(4):CD013815. Published 2023 Apr 4. doi:10.1002/14651858.CD013815.pub2
5. Sproviero E, Albamonte E, Costantino C, et al. (2018). Efficacy and safety of a fixed combination of intramuscular diclofenac 75 mg + thiocolchicoside 4 mg in the treatment of acute low back pain: a phase III, randomized, double blind, controlled trial. *Eur J Phys Rehabil Med*.54(5):654-662. doi:10.23736/S1973-9087.17.04923-1
6. Veenema KR, Leahey N, Schneider S. (2000). Ketorolac versus meperidine: ED treatment of severe musculoskeletal low back pain. *Am J Emerg Med*. 18(4):404-407. doi:10.1053/ajem.2000.7314
7. Plapler PG, Scheinberg MA, Ecclissato Cda C, Bocchi de Oliveira MF, Amazonas RB. (2016). Double-blind, randomized, double-dummy clinical trial comparing the efficacy of ketorolac trometamol and naproxen for acute low back pain. *Drug Des Devel Ther*. 10:1987-1993. Published 2016 Jun 17. doi:10.2147/DDDT.S97756
8. Patil S, Nadaf N, Gupta S, et al. (2024). A Comparative Analysis of the Efficacy and Safety of Nimesulide/Paracetamol Fixed-Dose Combination With Other NSAIDs in Acute Pain Management: A Randomized, Prospective, Multicenter, Active-Controlled Study (the SAFE-2 Study). Cureus. 16(4):e58859. Published 2024 Apr 23. doi:10.7759/cureus.58859
9. Fontana Carvalho AP, Dufresne SS, Rogerio de Oliveira M, et al. (2020). Effects of lumbar stabilization and muscular stretching on pain, disabilities, postural control and muscle activation in pregnant woman with low back pain. *Eur J Phys Rehabil Med*. 56(3):297-306. doi:10.23736/S1973-9087.20.06086-4
10. Taşpınar G, Angın E, Oksüz S. (2023). The effects of Pilates on pain, functionality, quality of life, flexibility and endurance in lumbar disc herniation. *J Comp Eff Res*. 12(1):e220144. doi:10.2217/cer-2022-0144
11. Danazumi MS, Bello B, Yakasai AM, Kaka B. (2021). Two manual therapy techniques for management of lumbar radiculopathy: a randomized clinical trial. *J Osteopath Med*. 121(4):391-400. 26. doi:10.1515/jom-2020-0261
12. Strom BL, Berlin JA, Kinman JL, et al. (1996). Parenteral Ketorolac and Risk of Gastrointestinal and Operative Site Bleeding: A Postmarketing Surveillance Study. *JAMA.* 275(5):376–382. doi:10.1001/jama. 1996.03530290046036

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