International Journal of Medicine
pISSN 1468-3814 | eISSN 2667-7008
https://theinternationalmedicine.com/

Original Researcher Article *DOI: 10.61336/im/26-01-45*

Comparative Effectiveness and Safety of Tizanidine and Thiocolchicoside in Patients with Acute Low Back Pain: A Prospective Observational Study.

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Received: 12-12-2025
Revised: 28-12-2025
Accepted: 13-01-2026
Published: 30-01-2026

Abstract

Background: Acute low back pain is frequently accompanied by painful muscle spasm and short-term functional restriction. Centrally acting muscle relaxants are commonly prescribed, although direct real-world comparisons between tizanidine and thiocolchicoside remain limited.***Objectives:*** To compare the effectiveness and safety of tizanidine and thiocolchicoside in adults with acute low back pain.***Methods:*** This prospective observational study included 80 patients treated at a tertiary-care teaching hospital between January and May 2025. Forty patients received tizanidine and 40 received thiocolchicoside according to the treating physician's clinical decision. Pain was assessed using the Visual Analogue Scale at baseline and on days 3, 7, and 14. Functional disability was evaluated using the Roland-Morris Disability Questionnaire at baseline and on days 7 and 14. Clinical response, muscle-spasm relief, rescue-analgesic use, and adverse events were recorded.***Results:*** Baseline characteristics were comparable between groups. Mean pain scores declined from 7.26 ± 1.03 to 1.42 ± 0.78 with tizanidine and from 7.18 ± 1.08 to 1.30 ± 0.72 with thiocolchicoside by day 14; the between-group difference was not significant. Disability scores improved from 15.4 ± 3.1 to 4.6 ± 2.2 and from 15.1 ± 3.3 to 4.2 ± 2.0, respectively. A reduction of at least 50% in pain by day 7 occurred in 72.5% and 77.5% of patients. Any adverse event occurred in 32.5% and 17.5%, respectively. Drowsiness was more frequent with tizanidine. No serious adverse event occurred.***Conclusion:*** Both treatments produced substantial short-term improvements in pain, muscle spasm, and disability. Their effectiveness was comparable, while thiocolchicoside showed a more favourable tolerability profile, particularly regarding drowsiness

Keywords: Acute low back pain; tizanidine; thiocolchicoside; muscle relaxants; Visual Analogue Scale; Roland-Morris Disability Questionnaire; drug safety.

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INTRODUCTION

Low back pain is one of the most common musculoskeletal complaints and a major contributor to disability, healthcare use, and loss of productivity worldwide. Most patients presenting in primary or outpatient care have non-specific low back pain, in which a precise structural cause cannot be established. Acute episodes are generally defined by a symptom duration of less than six weeks and often include pain-related limitation, paraspinal muscle spasm, and difficulty with routine movement. Although the natural course is favourable for many patients, intense early symptoms can disrupt sleep, mobility, and occupational activity.1,2 In resource-constrained settings, early symptom control also has practical importance because repeated consultations and work absence increase indirect costs.

Current clinical guidance emphasises reassurance, maintenance of activity, superficial heat, and selected non-pharmacological measures. Pharmacotherapy is considered when symptoms remain troublesome, with non-steroidal anti-inflammatory drugs and skeletal muscle relaxants among the commonly used options.3,4 Muscle relaxants are generally prescribed for a short period to reduce painful spasm and facilitate activity. However, their clinical value is influenced by modest treatment effects, heterogeneity among individual drugs, and adverse events such as sedation, dizziness, and weakness. The choice of agent should therefore balance symptom relief with tolerability, particularly in patients who drive, operate machinery, or require rapid return to work.

Systematic reviews have reported that non-benzodiazepine antispasmodics can provide short-term pain reduction in acute low back pain, but the certainty of evidence remains limited and the average benefit is small.5-7 Differences in pharmacological action and adverse-effect profiles also prevent the available agents from being treated as a uniform class.

Comparative effectiveness data generated under routine clinical conditions are useful because prescribing decisions are shaped by comorbidity, expected sedation, concomitant analgesic use, cost, and local availability.

Tizanidine is a centrally acting alpha-2 adrenergic agonist that reduces excitatory input to spinal motor pathways. Earlier trials have demonstrated symptomatic improvement in acute low back pain, either alone or in combination with anti-inflammatory therapy, although drowsiness is a recurrent concern.8-11 Thiocolchicoside is a semi-synthetic muscle relaxant with glycinergic and gamma-aminobutyric acid-related activity. Placebo-controlled and comparative studies have shown improvement in pain and mobility, while recent evidence has highlighted the need for careful interpretation of both efficacy and safety.12-14 Direct prospective observational comparisons between these two drugs remain limited in Indian tertiary-care practice. Therefore, the present study aimed to compare tizanidine and thiocolchicoside for reduction of pain intensity and functional disability in adults with acute low back pain, and to evaluate muscle-spasm relief, rescue-analgesic requirement, overall clinical response, and treatment-emergent adverse events.

METHODOLOGY

Study design and setting

This prospective comparative observational study was conducted in the Orthopaedics outpatient services of Government Medical College/Government General Hospital, Bhadradri Kothagudem, Telangana, India, from January 2025 to May 2025. Patients were observed according to the treatment selected by the attending physician; no intervention was assigned by the investigators.

Participants and sampling

Adults aged 18-65 years with non-specific acute low back pain lasting less than two weeks, a baseline Visual Analogue Scale (VAS) score of at least 4, and paraspinal muscle spasm were screened consecutively. Patients were excluded when pain was related to major trauma, vertebral fracture, inflammatory spondyloarthropathy, malignancy, spinal infection, cauda equina syndrome, progressive neurological deficit, or chronic low back pain. Other exclusions were pregnancy or lactation, seizure disorder, significant hepatic or renal dysfunction, drug hypersensitivity, and recent use of another centrally acting muscle relaxant. Of 86 patients assessed, 80 were eligible, consented, completed follow-up, and formed two cohorts of 40 patients each. The target sample of 80 reflected the caseload and feasibility of serial follow-up during the study period.

Treatment exposure and follow-up

The tizanidine cohort included patients prescribed oral tizanidine, whereas the thiocolchicoside cohort included patients prescribed oral thiocolchicoside, as part of routine clinical care. Treatment choice, dose adjustment, and concomitant analgesic therapy remained at the treating physician's discretion. All participants received standard advice on activity, posture, avoidance of prolonged bed rest, and warning symptoms. Rescue-analgesic use and treatment adherence were documented at each contact. Follow-up evaluations were performed on days 3, 7, and 14.

Outcome assessment

Pain intensity was recorded on a 0-10 VAS at baseline and on days 3, 7, and 14. Functional disability was assessed with the Roland-Morris Disability Questionnaire (RMDQ) at baseline and on days 7 and 14, consistent with outcome domains used in prior comparative low back pain trials.9-11,13 The primary effectiveness outcome was change in VAS score from baseline to day 14. Secondary outcomes included serial VAS scores, change in RMDQ score, at least 50% pain reduction by day 7, relief of paraspinal muscle spasm, return to usual activity, rescue-analgesic requirement, and overall clinical response. At each visit, drowsiness, dizziness, weakness, dry mouth, gastrointestinal symptoms, discontinuation, and serious adverse events were recorded.

Statistical analysis

Continuous variables were summarised as mean and standard deviation and compared between groups using the independent-samples t-test. Within-group changes from baseline were evaluated using paired comparisons. Categorical variables were expressed as frequency and percentage and analysed using Pearson's chi-square test; Fisher's exact test was applied when expected cell counts were small. All tests were two-sided, and $p<0.05$ was considered statistically significant. Because treatment was not randomised, analyses were interpreted as comparative associations rather than causal treatment effects.

Ethical considerations

Necessary Permissions were obtained before starting the study. Written informed consent was obtained from every participant before enrolment. Confidentiality was maintained by using coded study records, and clinical care was not altered by participation.

RESULTS

Participant flow and baseline characteristics

A total of 86 patients with acute low back pain were assessed for eligibility. Six were excluded: four did not meet the eligibility criteria and two declined participation. The remaining 80 patients were enrolled, completed the scheduled follow-up, and were included in the analysis. Forty received tizanidine and 40 received thiocolchicoside according to the treating physician's clinical decision. No participant was lost to follow-up.

The mean age of the study population was 41.2 ± 11.6 years (range, 20-65 years). There were 46 (57.5%) males and 34 (42.5%) females, and the mean duration of symptoms before presentation was 4.6 ± 2.1 days. Age, sex, body mass index, symptom duration, previous episodes, muscle spasm, baseline pain, and baseline disability were comparable between groups (Table 1).

Table 1. Baseline demographic and clinical characteristics of the study participants

Characteristic	Tizanidine group (n=40)	Thiocolchicoside group (n=40)	p-value
Age, years, mean ± SD	41.6 ± 11.8	40.8 ± 11.5	0.761
Sex, n (%)	Male: 24 (60.0) Female: 16 (40.0)	Male: 22 (55.0) Female: 18 (45.0)	0.651
Body mass index, kg/m², mean ± SD	25.7 ± 3.4	25.3 ± 3.7	0.617
Duration of symptoms, days, mean ± SD	4.7 ± 2.2	4.5 ± 2.0	0.672
Previous episode of low back pain, n (%)	13 (32.5)	15 (37.5)	0.639
Paraspinal muscle spasm, n (%)	34 (85.0)	35 (87.5)	0.745
Baseline VAS score, mean ± SD	7.26 ± 1.03	7.18 ± 1.08	0.735
Baseline RMDQ score, mean ± SD	15.4 ± 3.1	15.1 ± 3.3	0.676

RMDQ: Roland-Morris Disability Questionnaire; SD: standard deviation; VAS: Visual Analogue Scale. p-values were calculated using the independent-samples t-test or Pearson chi-square test, as appropriate.

Pain intensity

Pain intensity decreased progressively in both groups. In the tizanidine group, the mean VAS score declined from 7.26 ± 1.03 at baseline to 4.52 ± 1.12 on day 3, 2.58 ± 1.04 on day 7, and 1.42 ± 0.78 on day 14. The corresponding scores in the thiocolchicoside group were 7.18 ± 1.08, 4.31 ± 1.07, 2.34 ± 0.96, and 1.30 ± 0.72. Within-group reductions were statistically significant at each follow-up ($p<0.001$). Between-group differences were not significant at any assessment, and the mean reduction from baseline to day 14 was also comparable (Table 2). The proportional decline in mean VAS score by day 14 was approximately 80% in both groups.

Table 2. Comparison of pain intensity between the treatment groups

Assessment	Tizanidine, mean ± SD	Thiocolchicoside, mean ± SD	Mean difference	p-value
Baseline	7.26 ± 1.03	7.18 ± 1.08	0.08	0.735
Day 3	4.52 ± 1.12	4.31 ± 1.07	0.21	0.393
Day 7	2.58 ± 1.04	2.34 ± 0.96	0.24	0.286
Day 14	1.42 ± 0.78	1.30 ± 0.72	0.12	0.476
Reduction: baseline to day 14	5.84 ± 1.13	5.88 ± 1.16	-0.04	0.876

SD: standard deviation. Between-group p-values were calculated using the independent-samples t-test. Within-group reductions at each follow-up were significant at $p<0.001$.

Functional disability

Functional disability improved substantially in both cohorts. Mean RMDQ scores in the tizanidine group decreased from 15.4 ± 3.1 at baseline to 9.1 ± 2.8 on day 7 and 4.6 ± 2.2 on day 14. Scores in the thiocolchicoside group declined from 15.1 ± 3.3 to 8.5 ± 2.6 and 4.2 ± 2.0, respectively. The within-group improvements were significant ($p<0.001$), whereas no statistically significant difference was observed between groups at either follow-up or for the total reduction by day 14 (Table 3).

Table 3. Comparison of functional disability between the treatment groups

RMDQ assessment	Tizanidine, mean ± SD	Thiocolchicoside, mean ± SD	p-value
Baseline	15.4 ± 3.1	15.1 ± 3.3	0.676
Day 7	9.1 ± 2.8	8.5 ± 2.6	0.324
Day 14	4.6 ± 2.2	4.2 ± 2.0	0.398
Reduction: baseline to day 14	10.8 ± 3.0	10.9 ± 3.1	0.884

RMDQ: Roland-Morris Disability Questionnaire; SD: standard deviation. Between-group p-values were calculated using the independent-samples t-test. Within-group reductions were significant at p<0.001.

Clinical response and muscle-spasm relief

A clinically meaningful response, defined as at least 50% reduction in baseline VAS score by day 7, occurred in 29 (72.5%) patients receiving tizanidine and 31 (77.5%) receiving thiocolchicoside (p=0.606). By day 14, absent or minimal paraspinal muscle spasm was recorded in 33 (82.5%) and 35 (87.5%) patients, respectively. Return to usual activities by day 7, rescue-analgesic requirement, and excellent or good overall response did not differ significantly between the groups (Table 4). Rescue analgesics were used by 11 (27.5%) patients in the tizanidine cohort and 8 (20.0%) in the thiocolchicoside cohort (p=0.431).

Table 4. Comparison of clinical treatment outcomes

Clinical outcome	Tizanidine group (n=40)	Thiocolchicoside group (n=40)	p-value
≥50% reduction in VAS by day 7, n (%)	29 (72.5)	31 (77.5)	0.606
Absent/minimal muscle spasm on day 14, n (%)	33 (82.5)	35 (87.5)	0.531
Return to usual activities by day 7, n (%)	27 (67.5)	30 (75.0)	0.459
Rescue analgesic required, n (%)	11 (27.5)	8 (20.0)	0.431
Excellent/good overall response, n (%)	34 (85.0)	36 (90.0)	0.499

VAS: Visual Analogue Scale. p-values were calculated using Pearson chi-square tests.

Safety and tolerability

At least one treatment-emergent adverse event was reported by 13 (32.5%) patients in the tizanidine group and 7 (17.5%) in the thiocolchicoside group; the overall difference was not statistically significant (p=0.121). Drowsiness was more frequent with tizanidine than with thiocolchicoside (20.0% versus 5.0%; p=0.043). Differences in dizziness, weakness, dry mouth, gastrointestinal symptoms, and treatment discontinuation were not significant (Table 5). One patient discontinued tizanidine because of excessive drowsiness and dizziness. No serious adverse event, clinically significant hypotension, neurological deterioration, hospitalisation, or death was recorded.

Table 5. Treatment-emergent adverse events

Adverse event	Tizanidine group (n=40)	Thiocolchicoside group (n=40)	p-value
Any adverse event, n (%)	13 (32.5)	7 (17.5)	0.121
Drowsiness, n (%)	8 (20.0)	2 (5.0)	**0.043***
Dizziness, n (%)	5 (12.5)	2 (5.0)	0.432
Generalised weakness, n (%)	3 (7.5)	1 (2.5)	0.615
Dry mouth, n (%)	3 (7.5)	1 (2.5)	0.615
Nausea/abdominal discomfort, n (%)	1 (2.5)	3 (7.5)	0.615
Discontinuation due to adverse events, n (%)	1 (2.5)	0 (0.0)	1.000

*Statistically significant. Pearson chi-square tests were used for overall adverse events and drowsiness; Fisher exact tests were used for sparse categorical comparisons.

Overall, both exposure groups showed marked short-term improvement in pain, functional limitation, and muscle spasm. Thiocolchicoside demonstrated numerically higher response rates and lower rescue-analgesic use, but these differences were not statistically significant. The principal safety distinction was the higher frequency of drowsiness among patients receiving tizanidine.

DISCUSSION

This prospective observational study found substantial improvement in pain intensity, functional disability, and paraspinal muscle spasm with both tizanidine and thiocolchicoside over 14 days. Mean VAS scores fell by approximately 80%, and RMDQ scores improved by about 11 points in each group. None of the between-group effectiveness comparisons reached statistical significance. Thus, the two treatments had broadly comparable short-term clinical effectiveness in the observed population. The clearest difference concerned tolerability: drowsiness occurred significantly more often with tizanidine, while overall adverse-event rates showed a non-significant numerical advantage for thiocolchicoside.

The pain and functional improvement recorded with tizanidine is consistent with earlier clinical research. Berry and Hutchinson reported benefit in acute low back pain and identified drowsiness as a common treatment effect.8 Pareek et al. observed that an aceclofenac-tizanidine combination improved acute low back pain more than aceclofenac alone, supporting the value of muscle-relaxant therapy in selected patients.9 In contrast, Friedman et al. found no additional one-week functional benefit when tizanidine was added to ibuprofen in emergency-department patients, and a 2024 multicentre

trial reported that adding tizanidine to diclofenac did not improve RMDQ outcomes compared with diclofenac alone.10,11 These differences illustrate how background analgesic treatment, case selection, baseline severity, and outcome timing influence observed effectiveness.

Thiocolchicoside was associated with similar pain reduction and a numerically lower adverse-event burden in the present study. A placebo-controlled trial by Tuzun et al. demonstrated improvement in acute low back pain, while Ketenci et al. directly compared thiocolchicoside and tizanidine and reported clinical efficacy with differing psychomotor effects.12,13 A recent meta-analysis confirmed statistically detectable pain reduction with thiocolchicoside but concluded that the average benefit was small and the certainty of evidence was very low.14 The large improvement seen in both cohorts in our study therefore reflects a combined effect of medication, routine advice, concomitant care, and the favourable natural history of many acute episodes rather than a drug effect alone.

The higher occurrence of drowsiness with tizanidine has direct clinical relevance. Sedation can interfere with driving, skilled work, and adherence, even when pain relief is satisfactory. Thiocolchicoside produced more gastrointestinal complaints numerically, but the numbers were small and the difference was not significant. Broader reviews of muscle relaxants similarly show that short-term benefit must be weighed against adverse events and uncertain comparative superiority.5-7 Drug selection should therefore be individualised according to occupational demands, comorbidities, concurrent medicines, and patient preference.

The study adds routine-care comparative evidence from an Indian tertiary-care setting and incorporated serial pain assessment, disability measurement, clinical recovery, rescue medication, and safety outcomes. Balanced group sizes and complete 14-day follow-up strengthened the descriptive comparison. Nevertheless, the observational allocation prevents causal inference, and the findings should be interpreted as associations that can inform, rather than replace, adequately powered randomised comparative trials.

Limitations

This study was conducted at a single centre with a modest sample size and a 14-day follow-up. Treatment allocation depended on the treating physician, creating potential confounding by indication despite comparable baseline characteristics. Concomitant analgesic exposure was not standardised, adherence relied partly on patient reporting, and outcomes were not assessed by blinded investigators. Rare adverse events and recurrence beyond the observation period could not be evaluated.

CONCLUSION

Tizanidine and thiocolchicoside produced significant short-term reductions in pain intensity, paraspinal muscle spasm, and functional disability among adults with acute low back pain. Their effectiveness was comparable across the 14-day observation period, with no significant differences in pain reduction, functional recovery, clinical response, return to activity, or rescue-analgesic use. Thiocolchicoside showed a more favourable tolerability pattern, chiefly because drowsiness occurred more frequently with tizanidine. These findings support careful, patient-specific selection of a short-course muscle relaxant, considering occupational needs, concurrent medication, and susceptibility to sedation. Close follow-up remains essential when symptoms persist, recur, or suggest an alternative diagnosis. Future multicentre studies with random allocation and longer follow-up should confirm these comparative safety findings.

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