Original Research Article

Expert opinion on the use of analgesics for the management of cervical spondylosis and low back pain in real-world Indian settings

ABSTRACT

Objective: The present survey-based study aims to gather clinicians' opinions regarding the use of analgesics, for the management of cervical spondylosis (CS) and low back pain (LBP) in Indian settings, both as mono and combination therapies.

Methodology: The multiple-response questionnaire-based survey, comprising 23 questions, gathered feedback on current practices, clinical observations, and experiences related to the use of analgesics, both as mono and combination therapies, in routine settings. The survey respondents were specialists with expertise in managing CS and LBP.

Results: Out of 598 clinicians, 58% preferred the combination of aceclofenac and thiocolchicoside for managing LBP. Approximately 47% of clinicians prescribed this combination to patients aged 30 to 40 years for managing LBP. About 65% of clinicians indicated that the combination of aceclofenac and thiocolchicoside is typically prescribed for more than 5 days. Around 64% of clinicians expressed the opinion that this combination relieves pain within 24 to 48 hours. Notably, about 91% of clinicians reported that they consider both minimal sedation and efficacy as important factors when prescribing muscle relaxants to patients. The majority of clinicians (77.26%) preferred using a combination of aceclofenac and paracetamol to manage arthritic pain. Furthermore, approximately 92% of the respondents stated that aceclofenac is associated with fewer gastrointestinal (GI) side effects.

Conclusion: The survey results indicate a strong preference among clinicians for the combination of aceclofenac and thiocolchicoside for managing LBP. The survey underscores the importance of considering both sedation levels and efficacy when prescribing muscle relaxants and highlights aceclofenac and paracetamol as the preferred combination for managing arthritic pain. Additionally, the clinicians emphasize the lower incidence of gastrointestinal side effects associated with aceclofenac.

Keywords: Analgesics, Cervical spondylitis, Lower back pain, Aceclofenac, Thiocolchicoside, Paracetamol

1. INTRODUCTION

Cervical spondylosis (CS) affects approximately 75% of individuals worldwide who are over 50 years of age. In patients with CS, changes in the cervical spine, including the narrowing of intervertebral foramina, occur at the solitary disc space level in 15-40% of cases and at multiple levels in 60-85% of cases [1-3]. Neck pain, a common symptom of CS, is the fourth-ranked global cause of disability. In India, it affects about 10 million individuals every year, with an incidence rate of 25-50% per year in adults [2]. CS is more predominant in females,

and asymptomatic subjects between the ages of 60 and 65 have been reported to exhibit significant degenerative changes at one or more levels [3,4].

Low back pain (LBP) is also more common in the age group of 50-55 years, and the associated disability impact is predominant among the elderly. LBP affects around 619 million individuals globally, and it is projected to reach around 843 million by 2050 due to population growth and increased life expectancy [5]. Studies from India have shown an increased prevalence of LBP in females, individuals residing in rural areas, and elementary workers. LBP significantly impacts the quality of life, with approximately 8% of individuals in India experiencing LBP-related disability [6-8].

Analgesics are commonly employed for the conservative management of symptomatic CS and LBP [9,10]. DiPalma and DiGregorio reported that 90% of LBP can be managed successfully by the skillful and appropriate use of the major analgesic drugs [11]. Similarly, Wewege et al. reported that analgesics are the most prescribed interventions in the management of LBP [12].

It is essential to understand the severity of CS and LBP for better management and treatment processes. Studies have shown that combining analgesics with muscle relaxants is more effective in alleviating the pain associated with LBP therapy. When treating patients with acute LBP, the combination of aceclofenac with thiocolchicoside, a muscle relaxant, has proven to be more effective than using aceclofenac alone [13]. The mechanism of action of aceclofenac is mainly based on its selective inhibition of cyclooxygenase (COX-2), leading to the suppression of prostaglandin production (COX-2/COX-1 ratio 0.26) [14]. Aceclofenac is a preferential COX-2 inhibitor with analgesic and anti-inflammatory properties [15]. The objective of the present survey is to gather clinicians' perspectives on the clinical use of analgesics in managing CS and LBP in Indian settings, both as mono and combination therapies.

2. MATERIALS AND METHODS

We carried out a cross sectional, multiple-response questionnaire-based study involving clinicians with expertise in managing CS and LBP in the major Indian cities from June 2022 to December 2022.

2.1 Questionnaire

The questionnaire booklet named CORAL (Clinicians Opinion on management of aRthritis And Low back pain) study was sent to the clinicians who were interested to participate. The CORAL study questionnaire consisted of 23 items related to specialists' clinical observations, current feedback, and prescription practices concerning analgesics for managing CS and LBP, both as mono and combination therapies. The study was conducted after getting approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

2.2 Participants

An invitation was sent to leading clinicians in treating CS and LBP in the month of March 2022 for participation in this Indian survey. About 598 doctors from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provided necessary data. Participants were asked to complete the questionnaire without

discussing with their peers. A written informed consent was obtained from each physicians before initiation of the study.

2.3 Statistical Methods

Descriptive statistics were conducted for data analysis. Categorical variables were represented as percentages to depict their distribution. The frequency of each variable's occurrence and the corresponding percentage were used to visualize their distribution through bar charts, created using Microsoft Excel 2013 (version 16.0.13901.20400).

3. RESULTS

The study surveyed 598 clinicians, with 76% reporting that LBP was the most common presentation of pain in routine practice. According to 50% of the survey respondents, 20 to 40 patients visit with pain complaints per week in routine practice. Approximately 54% of clinicians stated that patients often complained of mild to moderate pain, while 38% stated the pain severity reported as moderate to severe. Around 44% of the participants noted problems with the spine as the most common source of low back pain, while 37% reported it as problems with muscles.

Majority (57.02%) of the clinicians stated that LBP is more prevalent in the 40 to 60 years' age group, with 38% reported it as common in the 20 to 40 years' age group. Approximately 50% of the participants reported that CS is common in patients aged 40 to 60 years, while 42% reported the predominant age group as 20 to 40 years. Nearly 60% of the clinicians stated that LBP is common in both genders, while 34% reported it as predominant in female patients. Around 59% of clinicians opined that CS is prevalent in both genders.

According to 51% of the respondents, the prevalence of LBP in routine practice is approximately 21-30%. More than half of the clinicians (57%) identified MRI as the best tool for diagnosing the cause of LBP. Nearly 40% of the clinicians noted the duration of pain in patients as 4 to 6 days, while 31% reported it as 2 to 4 days. According to 37% of clinicians, pain medication is the preferred treatment for LBP. More than half (58.19%) of the clinicians preferred the combination of aceclofenac and thiocolchicoside, while 30% favored the combination of aceclofenac, paracetamol, and chlorzoxazone for managing LBP (Table 1).

Table 1: Distribution of response on the preferred drug combinations for managing LBP

Drug combination	Response rate (n = 598)
Aceclofenac + thiocolchicoside	58.19%
Aceclofenac + paracetamol + chlorzoxazone	26.92%
Aceclofenac + paracetamol	13.21%
All the above	0.50%
Tramadol plus paracetamol and muscle relaxant	0.17%

Aceclofenac, paracetamol, etoricoxib, metaxalone	0.17%
Tramadol and paracetamol	0.17%
Paracetamol and tolperisone	0.17%
Depends on the severity of the pain	0.17%
Etoricoxib + thiocolchicoside	0.17%
Not attempted	0.17%

The combination of aceclofenac and thiocolchicoside is frequently prescribed to patients aged 30 to 40 years, as reported by 47% of clinicians (Table 2). Approximately 65% of clinicians stated that the combination of aceclofenac and thiocolchicoside is generally prescribed for more than 5 days, while 34% reported it as fewer than 5 days (Fig. 1).

Table 2: Distribution of response on the preferred age groups commonly prescribed with the combination of aceclofenac and thiocolchicoside

Age group	Response rate (n = 598)
18 – 30 years	**12.54%**
30 – 40 years	**46.82%**
41 – 50 years	**30.1%**
51 – 60 years	**5.69%**
>61 years	**0.67%**
All the above	**4.01%**
Not attempted	**0.17%**

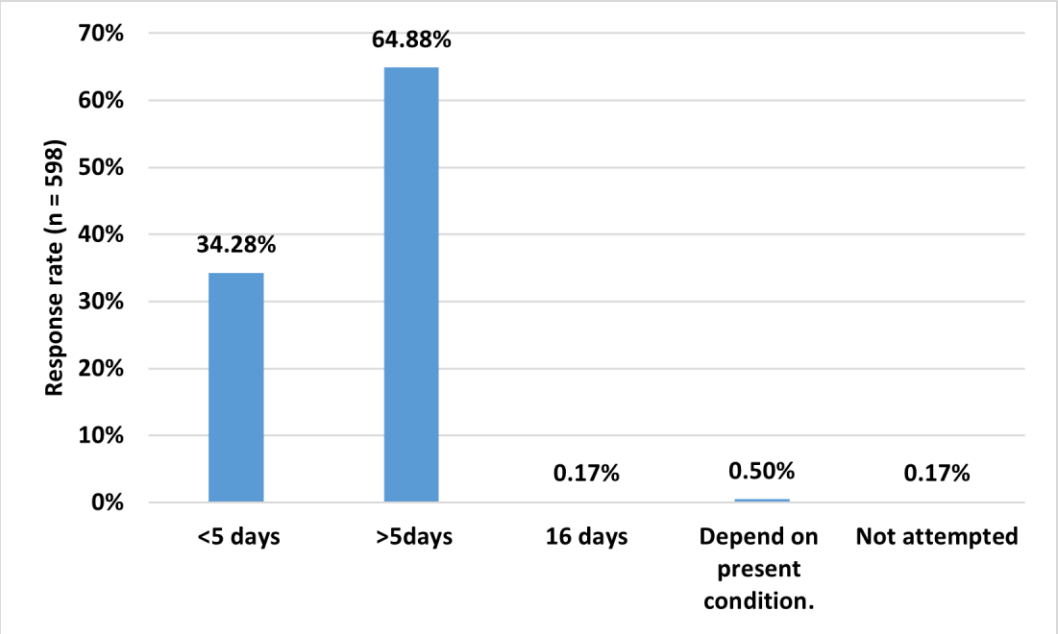

Fig. 1: Distribution of response on the preferred duration of use of aceclofenac and thiocolchicoside in patients with LBP

Around 64% of the clinicians opined that the combination of aceclofenac and thiocolchicoside relieves pain within 24 to 48 hours (Fig. 2). About 91% of clinicians reported considering least sedation along with efficacy as an important factor when prescribing muscle relaxants to patients. Majority of the clinicians (77.26%) preferred using a combination of aceclofenac and paracetamol to manage arthritic pain (Table 3). Approximately 92% of the respondents stated that aceclofenac causes fewer gastrointestinal (GI) side effects (Fig. 3).

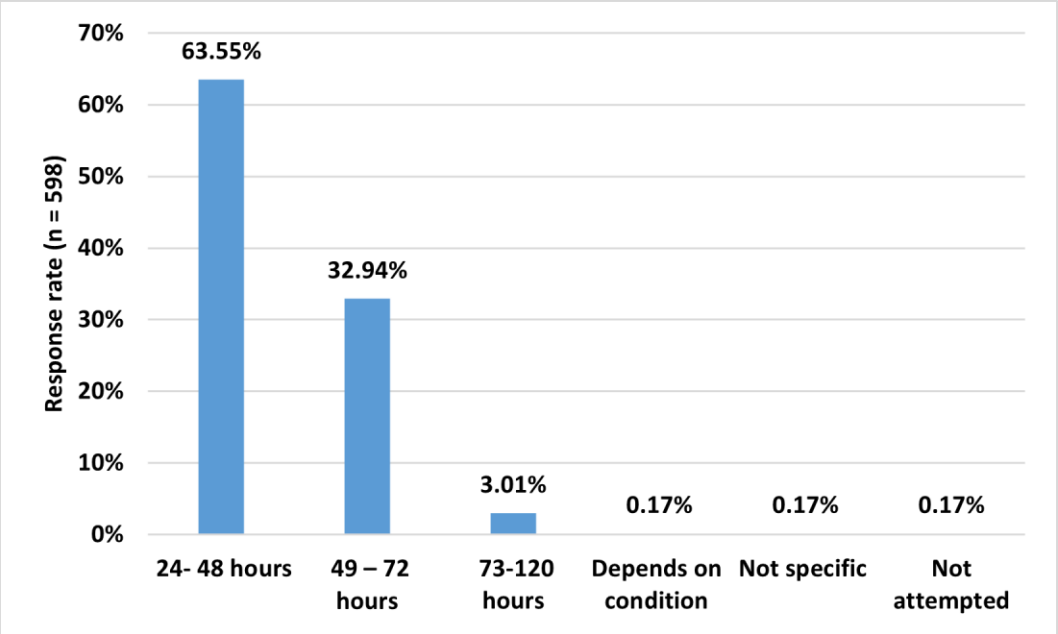

Fig. 2: Distribution of response on time for pain relief after using a combination of aceclofenac and thiocolchicoside

Table 3: Distribution of response on the preferred drug combination for managing arthritic pain

Combination of drugs	Response rate (n = 598)
Aceclofenac + paracetamol	77.26%
Diclofenac + paracetamol	5.35%
Tramadol + paracetamol	16.05%
Piroxicam	0.17%
Paracetamol and tolperisone	0.17%
Etoricoxib	0.17%
Aceclofenac +paracetamol +tramadol	0.17%
Depends on conditions	0.33%

Not attempted	**0.33%**

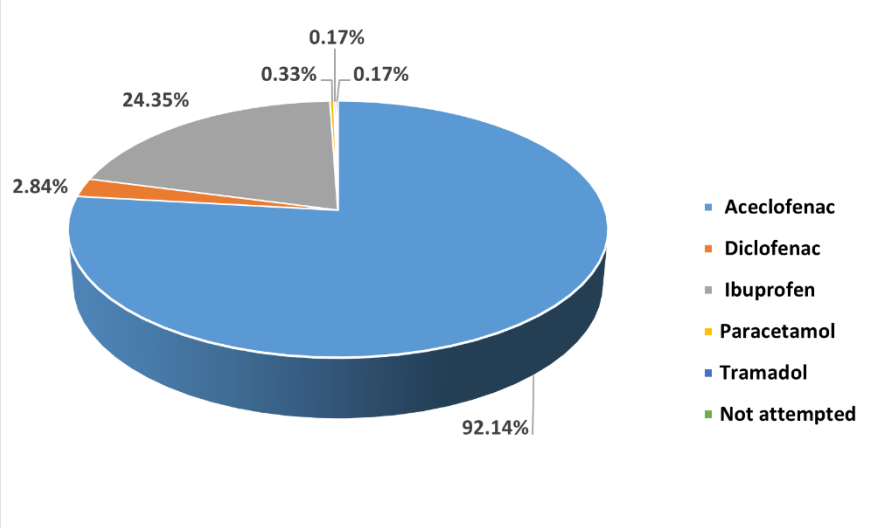

Fig 3: Distribution of response on the common GI side effects of analgesics

Around 51% of the clinicians reported 2-4 weeks as the commonly preferred duration for non-steroidal anti-inflammatory drug (NSAIDs) use for arthritic pain management. Approximately 47% of the clinicians reported that 2-5% of patients would require surgery for a herniated disk in patients with LBP. Around 47% of the participants stated that inflammatory back pain is the most common symptom noted in patients with ankylosing spondylitis (AS), while 40% reported it as neck pain with visible swelling. Majority of the respondents (76%) opined NSAIDs as the first-line treatment indicated for the management of AS.

4. DISCUSSION

The survey emphasizes the significant preference of analgesic combinations for managing CS and LBP. The findings highlight the potential benefits of combining different analgesics to effectively manage symptoms and alleviate pain in these patient populations.

The current survey respondents indicated a preference for the combination of aceclofenac and thiocolchicoside in managing pain for patients with LBP. Kumar et al., in their comparative study, also found that the combination of aceclofenac with thiocolchicoside significantly reduced pain intensity and improved mobility without causing side effects in the treatment of LBP within seven days among patients aged 18 to 55 years [16]. The current respondents also favored the drug combination for the 30 to 40 years' age group. Desai et al., in a comparable study, reported that this combination is effective in reducing the intensity of low back pain in the age group of 18 to 55 years [17]. A prospective study by Nellika et al. observed a significant decrease in pain intensity, from 8.1 on the first day to 2.5 on the seventh day, with the combination of aceclofenac and thiocolchicoside therapy in patients with LBP [18].

The present survey participants indicated that the combination is effective in less than three days of use for managing LBP. Consistent with this finding, a comparative study on the efficacy of the combination of aceclofenac and thiocolchicoside by Kumar et al. reported a significant reduction in pain intensity within three days from the baseline (P <0.001) [16].

The current survey participants also emphasized the effectiveness of aceclofenac with paracetamol combination in managing arthritic pain. Similarly, in a randomized, multicentric, comparative evaluation, Pareek et al. found that this combination was superior in reducing pain intensity (P = 0.005) [19]. In another study by Subramanian et al., the combination of aceclofenac and paracetamol resulted in a significant reduction in all three subscales of the Western Ontario and McMaster University Arthritis index scale (WOMAC) score during the follow-up visit compared to the initial visit (P <0.0001) [20].

The present study reported the use of aceclofenac has fewer GI effects on the patients. Similarly, in a meta-analysis of randomized control trials, Patel et al. found that aceclofenac had better tolerability and a 31% lower relative risk of GI compared to diclofenac and piroxicam [21]. In another comparative study by Pareek and Chandurkar reported the side effects of GI are significantly less than diclofenac [22]. Lolascon et al. in their study have reported that the effect of aceclofenac in GI is significantly lesser [14]. In another study by Castellsague et al. aceclofenac was associated with the lowest relative risks of upper GI complications among the other NSAIDs [23].

One of the major strengths of the present survey lies in the meticulous design and validation of the questionnaire used to gather expert data. However, it is important to acknowledge that personal perspectives and preferences could have introduced potential bias, thereby limiting the generalization of the study findings. Further research is warranted to corroborate and extend the current survey findings.

5. CONCLUSION

The survey findings underscore the tolerability and overall effectiveness of analgesic combination therapies for treating LBP and CS. Notably, the results reveal a strong preference among clinicians for the combination of aceclofenac and thiocolchicoside in managing LBP. Furthermore, clinicians favor the combination of aceclofenac and paracetamol for managing arthritic pain, while also emphasizing the lower incidence of gastrointestinal side effects associated with aceclofenac.

REFERENCES

1. Kuo DT, Tadi P. Cervical Spondylosis. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2023 Oct 12].
2. Kumar S. CERVICAL SPONDYLOSIS: A Rising Trend Worldwide. IJAR. 2017; 7(6):338.
3. Lv Y, Tian W, Chen D, Liu Y, Wang L, Duan F. The prevalence and associated factors of symptomatic cervical Spondylosis in Chinese adults: a community-based cross-sectional study. BMC Musculoskelet Disord. 2018 Sep 11;19:325.
4. Kelly JC, Groarke PJ, Butler JS, Poynton AR, O'Byrne JM. The Natural History and Clinical Syndromes of Degenerative Cervical Spondylosis. Advances in Orthopedics. 2011 Nov 28;2012: e393642.
5. Low back pain [Internet]. [cited 2023 Oct 12]. Available from: https://www.who.int/news-room/fact-sheets/detail/low-back-pain

6. Shetty GM, Jain S, Thakur H, Khanna K. Prevalence of low back pain in India: A systematic review and meta-analysis. Work. 2022;73(2):429–52.
7. Volinn E. The epidemiology of low back pain in the rest of the world. A review of surveys in low- and middle-income countries. Spine (Phila Pa 1976). 1997 Aug 1;22(15):1747–54.
8. Bhattarai S. A Study on Factors Affecting Low Back Pain and Safety and Efficacy of NSAIDs in Acute Low Back Pain in a Tertiary Care Hospital of Western Nepal. J Clin Diagn Res. 2013 Dec;7(12):2752-8.
9. Jackson JA, Liv P, Sayed-Noor AS, Punnett L, Wahlström J. Risk factors for surgically treated cervical spondylosis in male construction workers: a 20-year prospective study. The Spine Journal. 2023 Jan;23(1):136–45.
10. Saragiotto BT, Machado GC, Ferreira ML, Pinheiro MB, Abdel Shaheed C, Maher CG. Paracetamol for low back pain. Cochrane Database Syst Rev. 2016 Jun 6;2016(6):CD012230.
11. DiPalma JR, DiGregorio GJ. Management of low back pain by analgesics and adjuvant drugs. Mt Sinai J Med. 1991 Mar;58(2):101–8.
12. Wewege MA, Bagg MK, Jones MD, McAuley JH, Cashin AG, Day RO, et al. Analgesic medicines for adults with low back pain: protocol for a systematic review and network meta-analysis. Systematic Reviews. 2020 Nov 4;9(1):255.
13. Nellika AM, Mothalampet A, Rajagopal S. A prospective study comparing the safety and efficacy of combination of aceclofenac and thiocolchicoside against aceclofenac alone in low back pain. International Journal of Basic & Clinical Pharmacology. 2018 Jan 23;7(2):333–6.
14. Iolascon G, Giménez S, Mogyorósi D. A Review of Aceclofenac: Analgesic and Anti-Inflammatory Effects on Musculoskeletal Disorders. J Pain Res. 2021 Nov 30;14:3651–63.
15. Shah D, Pal AK, Bedi G, Grover A, Purkait I, Jawdekar A, et al. Aceclofenac in Osteoarthritis - NSAID with Novel Mechanism of Action. Acta Scientific Orthopaedics. 2020; 3(12): 02-13.
16. Kumar S, Rani S, Siwach R, Verma P. To compare the efficacy and safety of the fixed-dose combination of thiocolchicoside and aceclofenac versus chlorzoxazone, aceclofenac, and paracetamol in patients with acute lower backaches associated with muscle spasm. Int J Appl Basic Med Res. 2014;4(2):101–5.
17. Desai AA, Sachdeva PD, Arora BD. A comparative study of the combined use of aceclofenac along with thiocolchicoside and aceclofenac alone in patients diagnosed of low back pain. PSM. 2011; 2(2): 141-151.
18. P A, Geetha P, Shanmugasundaram P. Comparison of Aceclofenac and combination (Aceclofenac + Thiocolchicoside) therapy in acute low back pain patients. Research Journal of Pharmacy and Technology. 2016 Nov 28;9(11):1927–9.
19. Pareek A, Chandurkar N, Sharma VD, Desai M, Kini S, Bartakke G. A randomized, multicentric, comparative evaluation of aceclofenac-paracetamol combination with aceclofenac alone in Indian patients with osteoarthritis flare-up. Expert Opin Pharmacother. 2009 Apr;10(5):727–35.

20. Subramanian A, Adhimoolam M, Gnanasegaran S, Mohammed MAR. Study to Assess the Prescription Pattern and Quality of Life in Osteoarthritis Patients at a Tertiary Care Hospital. JCDR. 2020 Dec;14(12):FC01-FC05.
21. Patel PB, Patel TK. Efficacy, and safety of aceclofenac in osteoarthritis: A meta-analysis of randomized controlled trials. Eur J Rheumatol. 2017 Mar;4(1):11–8.
22. Pareek A, Chandurkar N. Comparison of gastrointestinal safety and tolerability of aceclofenac with diclofenac: a multicenter, randomized, double-blind study in patients with knee osteoarthritis. Curr Med Res Opin. 2013 Jul;29(7):849–59.
23. Castellsague J, Riera-Guardia N, Calingaert B, Varas-Lorenzo C, Fourrier-Reglat A, Nicotra F, et al. Individual NSAIDs and Upper Gastrointestinal Complications. Drug Saf. 2012;35(12):1127–46.