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Research Article

Effectiveness and Safety of Aceclofenac–Paracetamol–Serratiopeptidase Combination in Pain Management: Real-World Retrospective Analysis

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ABSTRACT

Background: Effective pain management remains a key clinical priority across a wide range of acute conditions. The combination of aceclofenac, paracetamol, and serratiopeptidase is commonly prescribed for its synergistic analgesic and anti-inflammatory effects. However, real-world evidence supporting its effectiveness and safety is limited.
Objective: To evaluate the effectiveness and safety of aceclofenac in combination with paracetamol and serratiopeptidase in routine clinical practice.
Methods: This multicenter, retrospective, real-world study analyzed data from 2,543 patients treated for various painful conditions. Demographic details, indications, duration of illness, clinical outcomes, and adverse events were assessed. Pain intensity was evaluated in a subset of patients (n = 879) using categorical scales (mild, moderate, severe).
Results: The mean age of patients was 43.25 ± 12.18 years, with a male predominance (70.1%). The most common indication was injury/trauma (54.2%), followed by post-operative pain (31.1%), while other indications included dental pain (4.9%), generalized pain (4.6%), joint pain (3.4%) and low back pain (2.5%). The mean duration of illness prior to treatment was 7.2 ± 5.3 days. In the subset analysis, A marked improvement in pain intensity was observed, with the proportion of patients achieving complete pain resolution increasing to 79%, while moderate and severe pain decreased to 5% and 2%, respectively, indicating significant clinical effectiveness. A total of adverse events were infrequent and mild, with nausea (1.8%) being the most commonly reported, followed by abdominal pain (0.7%), gastritis (0.6%), and vomiting, heartburn, and diarrhea (0.4% each).
Conclusion: The combination of aceclofenac, paracetamol, and serratiopeptidase demonstrated effective pain relief with a favorable safety profile in real-world clinical settings. These findings support its use as a reliable therapeutic option for the management of acute pain conditions.

Keywords: *Aceclofenac, Paracetamol, Serratiopeptidase, Analgesics, Non-Steroidal, Acute Pain.*

INTRODUCTION

Pain is one of the most common reasons for seeking medical care and significantly impacts quality of life and functional ability. Acute pain conditions such as post-operative pain, musculoskeletal injuries, and dental pain require prompt and effective management to prevent complications and chronicity.[1,2] Nonsteroidal anti-inflammatory drugs (NSAIDs) remain the cornerstone of pharmacological therapy due to their analgesic and anti-inflammatory properties mediated through inhibition of cyclooxygenase (COX) enzymes.[3]

Aceclofenac, a phenylacetic acid derivative NSAID, is widely used in the management of pain and inflammation. Aceclofenac primarily exerts its action by inhibiting prostaglandin synthesis through selective inhibition of the COX-2 enzyme. It is known for its favorable gastrointestinal tolerability compared to traditional NSAIDs, while maintaining comparable efficacy.[4,5] Paracetamol (acetaminophen), a centrally acting analgesic and antipyretic agent, is often combined

with NSAIDs to enhance analgesic efficacy through complementary mechanisms of action.[6] Such combinations provide superior pain relief compared to monotherapy, particularly in acute pain settings.[7]

Serratiopeptidase, a proteolytic enzyme, has gained attention for its anti-inflammatory and anti-edematous properties. It is believed to facilitate the breakdown of inflammatory mediators and promote resolution of edema, thereby improving pain and tissue healing.[8,9] The combination of aceclofenac, paracetamol, and serratiopeptidase is commonly prescribed in clinical practice for a wide range of painful conditions, leveraging synergistic effects for enhanced therapeutic outcomes. Despite widespread use, there is limited real-world evidence evaluating the effectiveness and safety of this combination in diverse patient populations. Real-world studies are essential to complement randomized controlled trials by providing insights into routine clinical practice, including broader patient demographics and varying indications.

Therefore, this retrospective real-world study was conducted to evaluate the clinical outcomes and safety profile of the aceclofenac, paracetamol, and serratiopeptidase combination in the management of pain across multiple indications.

METHODOLOGY

Study Design and Setting:

This was a multicenter, retrospective, observational, real-world study conducted to evaluate the effectiveness and safety of the combination of aceclofenac, paracetamol, and serratiopeptidase in the management of pain across multiple clinical indications. Data were collected from routinely maintained medical records across participating clinical centers.

Ethical Considerations:

The study protocol was reviewed and approved by the Lifepoint Research Ethics Committee, Pune, prior to commencement. As this was a retrospective analysis of anonymized patient data, the requirement for informed consent was waived in accordance with applicable ethical guidelines.

Study Population:

A total of 2,543 patients who received the combination therapy for pain management were included in the analysis. Patients of either gender and all adult age groups with documented clinical data were considered eligible. Patients prescribed aceclofenac, paracetamol, and serratiopeptidase combination with complete clinical records were included, while those with incomplete or missing data were excluded.

Data Collection:

Data extracted from medical records included demographic details (age, gender), clinical indications, duration of illness, treatment outcomes, and reported adverse events. Pain intensity was assessed in a subset of patients using categorical classification (mild, moderate, severe) at baseline and at the end of treatment.

Outcome Measures:

The primary outcome was the proportion of patients achieving complete resolution of symptoms. Secondary outcomes included change in pain intensity and incidence of adverse events.

Statistical Analysis:

Descriptive statistics were used to summarize the data. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Changes in pain intensity were evaluated descriptively.

RESULTS

A total of 2,543 patients were included in this retrospective real-world analysis. The mean age of the study population was 43.25 ± 12.18 years, with a predominance of males (1,782; 70.1%) compared to females (761; 29.9%). The mean duration of illness prior to treatment initiation was 7.2 ± 5.3 days.

The most common indication for treatment was injury/trauma (54.2%), followed by post-operative pain (31.1%), with other indications contributing to a smaller proportion of cases (Table 1).

Table 1: Indication-wise Distribution (n = 2,543)

Indication	n (%)
Injury/trauma	1,378 (54.2%)
Post-operative pain	791 (31.1%)
Dental pain	125 (4.9%)
Joint pain	86 (3.4%)
Low back pain	63 (2.5%)
Generalized pain	31 (1.2%)
Muscle pain	30 (1.2%)

Soft tissue injury	24 (0.9%)
Others (Neck pain, Tendinitis, Headache etc)	15 (0.6%)

In a subset of patients with documented pain intensity scores (n =879), a marked improvement in pain severity was observed. A substantial improvement in pain intensity was observed following treatment. At baseline, the majority of patients had moderate (35.3%) to severe pain (40.3%). After treatment, 79% of patients achieved complete pain resolution, while the proportion of patients with moderate and severe pain decreased to 5% and 2%, respectively, indicating a marked shift toward lower pain severity (Table 2).

Table 2: Change in Pain Intensity (n = 879)

Pain Intensity	Before Treatment n (%)	After Treatment n (%)
Mild	215 (24.5%)	123 (14%)
Moderate	310 (35.3%)	44 (5%)
Severe	354 (40.3%)	18 (2%)
No pain (resolved)	0 (0%)	694 (79%)

Regarding safety, adverse events were infrequent and mild, with gastrointestinal events being the most commonly reported. The overall incidence of adverse events was low relative to the total study population (Table 3).

Table 3: Adverse Events Summary (n = 2,543)

Adverse Event	n (%)
Nausea	45 (1.8%)
Vomiting	9 (0.4%)
Abdominal pain	19 (0.7%)
Gastritis	14 (0.6%)
Heartburn	9 (0.4%)
Diarrhea	9 (0.4%)

DISCUSSION

This retrospective real-world study demonstrates that the combination of aceclofenac, paracetamol, and serratiopeptidase provides effective pain relief with a favorable safety profile across a broad range of acute pain conditions. In subset analysis, high proportion of patients (79%) achieved complete resolution of symptoms, along with a marked reduction in pain intensity, indicating robust clinical effectiveness in routine practice.

The findings of the present study are consistent with previous evidence supporting the efficacy of aceclofenac-based therapies. In a study by Pareek et al.5, aceclofenac demonstrated comparable or superior analgesic efficacy with better gastrointestinal tolerability than traditional NSAIDs such as diclofenac, supporting its role as a preferred NSAID in pain management. Similarly, the significant reduction in moderate and severe pain observed in our study aligns with findings from Ong et al.7, who reported that combination analgesic therapy offers superior pain relief compared to monotherapy due to synergistic mechanisms of action.

The addition of serratiopeptidase in the present combination may further enhance therapeutic outcomes by reducing inflammation and edema. This is supported by findings from Mazzone et al.8 , who demonstrated that serratiopeptidase has significant anti-inflammatory and anti-edematous effects, contributing to improved pain relief and faster recovery in inflammatory conditions. The high rate of symptom resolution observed in our study may, therefore, be attributed to the combined analgesic and anti-inflammatory actions of all three components.

In terms of safety, the incidence of adverse events in this study was low (~4%), with predominantly mild gastrointestinal events such as nausea and abdominal discomfort. These findings are consistent with earlier studies indicating that aceclofenac has a relatively favorable gastrointestinal safety profile compared to other NSAIDs. No serious adverse events were reported, further supporting the tolerability of this combination in real-world settings.

Importantly, this study provides valuable real-world evidence across a large and diverse patient population, encompassing multiple indications such as injury, post-operative pain, joint pain and dental pain. Unlike randomized controlled trials, real-world studies better reflect routine clinical practice and enhance the generalizability of findings.

However, certain limitations should be acknowledged, including the retrospective design, lack of a comparator group, and limited availability of pain score data in all patients. Despite these limitations, the large sample size and consistent findings strengthen the reliability of the results.

Overall, the present study reinforces existing evidence that the combination of aceclofenac, paracetamol, and serratiopeptidase is an effective and well-tolerated option for the management of acute pain in real-world clinical practice.

CONCLUSION

The combination of aceclofenac, paracetamol, and serratiopeptidase demonstrated effective pain relief with a high rate of symptom resolution and a favorable safety profile in real-world clinical practice. The significant reduction in pain intensity and low incidence of mild adverse events support its use as a reliable and well-tolerated therapeutic option for the management of acute pain across diverse clinical conditions.

Conflict of interest

Authors NM, KS, and AS are full-time employees of the Medical Affairs Department, Alkem Laboratories Ltd., Mumbai, India.

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Ethical Clearance: The study protocol was reviewed and approved by the **Lifepoint Research Ethics Committee, Pune.**

REFERENCES

1. Goldberg DS, McGee SJ. Pain as a global public health priority. BMC public health. 2011 Oct 6;11(1):770.
2. Apfelbaum JL, Chen C, Mehta SS, Gan TJ. Postoperative pain experience: results from a national survey suggest postoperative pain continues to be undermanaged. Anesthesia & Analgesia. 2003 Aug 1;97(2):534-40.
3. Vane JR, Botting RM. Mechanism of action of nonsteroidal anti-inflammatory drugs. The American journal of medicine. 1998 Mar 30;104(3S1):2S-8S.
4. Hinz B, Rau T, Auge D, Werner U, Ramer R, Rietbrock S, Brune K. Aceclofenac spares cyclooxygenase 1 as a result of limited but sustained biotransformation to diclofenac. Clinical Pharmacology & Therapeutics. 2003 Sep;74(3):222-35.
5. Pareek A, Chandanwale AS, Oak J, Jain UK, Kapoor S. Efficacy and safety of aceclofenac in the treatment of osteoarthritis: a randomized double-blind comparative clinical trial versus diclofenac–an Indian experience. Current medical research and opinion. 2006 May 1;22(5):977-88.
6. Graham GG, Scott KF. Mechanism of action of paracetamol. American journal of therapeutics. 2005 Jan 1;12(1):46-55.
7. Ong CK, Seymour RA, Lirk P, Merry AF. Combining paracetamol (acetaminophen) with nonsteroidal antiinflammatory drugs: a qualitative systematic review of analgesic efficacy for acute postoperative pain. Anesthesia & Analgesia. 2010 Apr 1;110(4):1170-9.
8. Mazzone A, Catalani M, Costanzo M, Drusian A, Mandoli A, Russo S, Guarini E, Vesperini G. Evaluation of Serratia peptidase in acute or chronic inflammation of otorhinolaryngology pathology: a multicentre, double-blind, randomized trial versus placebo. Journal of International Medical Research. 1990 Sep;18(5):379-88.
9. Tiwari M. The role of serratiopeptidase in the resolution of inflammation. Asian journal of pharmaceutical sciences. 2017 May 1;12(3):209-15.