

## **A Study on Efficacy Of Aceclofenac Versus Aceclofenac Plus Pregabalin In Management Of Non Specific Chronic Low Back Pain**

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### **Abstract**

**Back Ground:** Chronic low back pain (CLBP) has been associated with neurochemical, structural, and functional cortical changes of several brain regions including the somatosensory cortex. Complex processes of peripheral and central sensitization may influence the evolution of acute to chronic pain. It is a common disorder involving the muscles, nerves, and bones of the back. Low back pain may be classified by duration as acute (pain lasting less than 6 weeks), sub-acute (6 to 12 weeks), or chronic (more than 12 weeks). In most episodes of low back pain, a specific underlying cause is not identified.

Aceclofenac is a Non-Steroidal Anti-Inflammatory Drug (NSAID). It works by blocking the release of certain chemical messengers that cause fever, pain and inflammation (redness and swelling). Pregabalin is an Anticonvulsant Drug Used For Neuropathic Pain, epilepsy and generalized anxiety disorder. It presents antihyperalgesic actions by binding to the  $\alpha 2\delta$  subunit of the voltage-dependent calcium channels without presenting antinociceptive actions.

**Aim:** To study the efficacy of Aceclofenac vs Aceclofenac plus Pregabalin in patients with chronic low back pain

**Objectives:** To compare and evaluate the therapeutic effectiveness of aceclofenac and aceclofenac plus pregabalin in relieving chronic low back pain To identify and apply strategies to prevent the increase of pain To provide patient counseling in the betterment of patients quality of life and provide awareness towards medication adherence.

**Materials And Methods:** In this study, aceclofenac as a single and aceclofenac with pregabalin as a combinational regimen were randomly received by 105 patients for 14 days. Patient's pain was assessed using VAS scale (visual analogue scale) on day 1,7,14.

**Results:** When patients were pooled according to VAS scale Aceclofenac and Aceclofenac plus Pregabalin were effective in reducing non specific chronic low back pain. The combination therapy showed more effectiveness when compared to single/ monotherapy when patients were taken according to VAS.

### **Conclusion**

- Aceclofenac plus Pregabalin combination is more effective than monotherapy with Aceclofenac for non specific chronic low back pain.
- Combination showed quicker relief of pain when compared to monotherapy.

**Keywords:** Non-Specific Chronic Low Back Pain, Aceclofenac, Pregabalin, Effectiveness, Visual Analogue Scale.

### **Introduction**

Low back pain (LBP) is the fifth most common reason for physician visits, which affects nearly 60-80% of people throughout their lifetime. Low back pain that has been present for longer than three months is considered chronic low back pain (CLBP).<sup>1</sup> Specific causes of LBP are uncommon, and in approximately 90% of patients, a specific generator cannot be identified with certainty.

Nearly a third of people seeking treatment for low back pain will have

### **Methodology**

**Study Site:** The study was conducted in the Outpatient Department of ORTHOPAEDICS at Malla Reddy Institute of Medical Sciences, which is a 625 bedded teaching hospital located at Suraram, Ranga Reddy District.

**Study Type And Design:** Observational and interventional study Questionnaires and direct patient interview were used along with VAS. Readings were noted on day 1, day 7 & day 14.

**Sample Size:** Approximately 100

**Study Period:** 6 months from January 2018 to June 2018

**Inclusion Criteria:** Both males and females.

Age 18 to 75 years.

Patients with low back pain more than 3 months.

Fibromyalgia.

**Exclusion Criteria:** History of surgery in recent past.

Patients with spinal metastasis having low back pain.

History of injury.

Pregnancy and lactation.

Age less than 18 and greater than 75.

Post Operative cases.

Infection related spine problems.

**Materials:** Data collection and questionnaire form : for interviewing patient's & collecting patient's medical history by asking few questions to the patient.

Visual analogue scale {VAS}: It is a standard scale for assessing the severity of pain.

➤ persistent moderate pain for one year after an acute episode. It is estimated that seven million adults in many countries have activity limitations as a result of chronic low back pain

➤ Chronic low back pain (CLBP) has been associated with neurochemical, structural, and functional cortical changes of several brain regions including the somatosensory cortex. Complex processes of peripheral and central sensitization may influence the evolution of acute to chronic pain.

➤ It is a common disorder involving the muscles, nerves, and bones of the back.<sup>2</sup> Low back pain may be classified by duration as acute (pain lasting less than 6 weeks), sub-acute (6 to 12 weeks), or chronic (more than 12 weeks).<sup>3</sup> In most episodes of low back pain, a specific underlying cause is not identified .

➤ Patient may have back stiffness, decreased movement of the lower back, and difficulty standing straight.

➤ Aceclofenac is a non-steroidal anti-inflammatory drug (NSAID). It works by blocking the release of certain chemical messengers that cause fever, pain and inflammation (redness and swelling). Aceclofenac is used in fever, headache, arthralgia, muscle pain, dental pain, post-operative pain, pain during menstruation, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis , gout etc

Aceclofenac has marked anti-inflammatory and analgesic properties. It is reported to have a higher anti-inflammatory action or at least effects comparable to other NSAIDs in double-blind studies.

Aceclofenac potently inhibits the cyclo-oxygenase enzyme (COX) that is involved in the synthesis of prostaglandins, which are inflammatory mediators that cause pain, swelling, inflammation, and fever. It is orally administered for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

Aceclofenac belongs to BCS Class II, as it possesses poor aqueous solubility. It displays high permeability to penetrate into synovial joints where in patients with osteoarthritis and related conditions, the loss of articular cartilage in the area causes joint pain, tenderness, stiffness, crepitus, and local inflammation.

Aceclofenac is also reported to be effective in other painful conditions such as dental and gynaecological conditions.

Drug	Effective	Non Effective
<b>Aceclofenac+ Pregabalin</b>	46 (44%)	8 (7%)
<b>Aceclofenac</b>	31(30%)	20 (19%)

Pregabalin is an anticonvulsant drug used for neuropathic pain, epilepsy and generalized anxiety disorder. It presents anti hyperalgesic actions by binding to the  $\alpha 2\delta$  subunit of the voltage-dependent calcium channels without presenting antinociceptive actions. It is considered to have a dependence

**Study Procedure**

1. The study was conducted after the approval of IEC.
2. Subjects were selected based on inclusion and exclusion criteria.
3. Subjects were divided into 2 groups:
  - The 1st group - Group - A was treated with Aceclofenac 100mg BD for 7 days
  - The 2nd group - Group - B was treated with Aceclofenac 100mg+Pregabalin 75mg Bd Combination for 7 days.

**Every Alternate Patient Was Assigned To Group A Or Group B**

Data Collection Form such as the VAS and the Questionnaires were used as the study tools for studying patient’s demographic details and severities of pain respectively.

Severity of pain ranging from mild to incapacitating pain was assessed by VAS-scale and interviewing them at 2 levels:

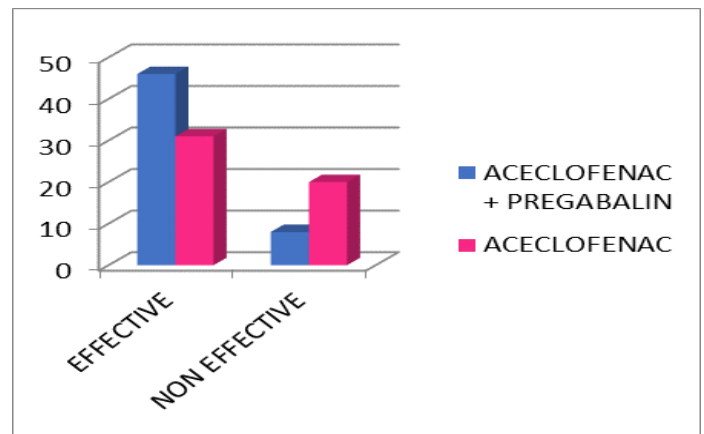
- before initiation of the treatment
- at the end of the treatment (i.e follow up)

6. Reports of the 2 groups of the subjects were compared in order to evaluate the efficacy of aceclofenac and aceclofenac plus pregabalin.

**Tables**

were analyzed and reported but I am enclosing 1 main table while the rest tables will be enclosed in the final copy of the paper publication after your acceptance. )

**Comparison of Effectiveness Of Combination And Single Therapy:**



**References**

1. Balagué F1, Mannion Af, Pellisé F, Cedraschi C. Non-Specific Low Back Pain. Lancet. 2012 Feb 4;379(9814):482-91.
2. "Low Back Pain Fact Sheet". National Institute Of Neurological Disorders And Stroke. 3 November

2015. Archived From The Original On 4 March 2016.

Retrieved 5 March 2016

3. Koes Bw, Van Tulder M, Lin Cw, Macedo Lg, Mcauley J, Maher C "An Updated Overview Of Clinical Guidelines For The Management Of Non-Specific Low Back Pain In Primary Care". *European Spine Journal*. **19** (12): 2075–94. (December 2010).
4. Manusov Eg "Evaluation And Diagnosis Of Low Back Pain". *Primary Care*. **39** (3): 471–9. (September 2012).
5. Deyo Ra, Phillips Wr. Low Back Pain: A Primary Care Challenge. *Spine*. 1996;21:2826–2832.
6. Spitzer Wo, Leblanc Fe: Scientific Approach To The Assessment And Management Of Activity-Related Spinal Disorders, Report Of The Quebec Task Force On Spinal Disorders. *Spine*. 1987;12(7 Suppl):S1–59.