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Research Article

# Randomised Comparative Study of Oral Aceclofenac Thiocolchicoside Fixed Dose Combination against Injectable Piroxicam in Treatment of Severe Acute Nuchal Pain: Safety and Efficacy Assessment

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- Treatment Acute Nuchal Pain, Neck Pain and Nsaids
- Neck Pain and Thiocolchiside
- Piroxicam

**Abstract**

One of the commonest ailments making patients to consult the Physical Medicine and Rehabilitation Specialist is severe nuchal pain. There are various modalities for the treatment of Nuchal pain worldwide but very few randomised controlled trials have been done to assess the efficacy of particular regimen. One of the most accepted regimens is the Nsaid Thiocolchicoside combination. This randomised study was undertaken to compare the efficacy of oral Aceclofenac Thiocolchiside fixed dose combination against injectable Piroxicam in the treatment of severe acute nuchal pain. A total of 100 patients divided randomly in two groups were included in the study out of which only 94 completed the study.Group A patients received oral Aceclofenac Thiocolchicoside (100mg+4mg) fixed dose combination while group B patients received intramuscular Piroxicam(40mg) daily for seven days.Patients were assessed by Visual Analogue Scale, Shafat's Range of Motion Index and Shafat's Nuchal Tenderness Index both before the start of treatment and on seventh day of treatment. There was significant improvement in all scores in both groups but group B showed much better response than group A and the difference was significant. Moreover group A required further continuation of pharmacological therapy while in group B; pharmacological therapy was discontinued after 7th day. Physiotherapy was continued in both groups afterwards. The study favours the use of injectable piroxicam in the treatment of severe acute nuchal pain.

## INTRODUCTION

Acute nuchal pain is one of the common regional pain disorders involving the musculoskeletal system. The term "acute" refers to the period of onset of pain where it is being less than three months [1]. While chronic refers to pain which has been present for more than three months [2].

Neck pain is taken to mean cervical spinal pain, although no organisation has explicitly defined it [3]. The International Association for the Study of Pain has defined neck pain as: Pain perceived as arising from anywhere within the region bounded superiorly by the superior nuchal line, inferiorly by an imaginary transverse line through the tip of the first thoracic spinous process and laterally by sagittal plane stangential to the lateral borders of the neck [2]. According to this definition neck pain is the pain which is perceived posteriorly; hence this definition is based on the topographical distribution of pain [4]. Pain to the front of the cervical spine is usually described as pain in the throat and not as neck pain [5]. The Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders

defined neck pain as the pain which is located in the anatomical region of the neck with or without radiation to the head, trunk, and upper limbs; Where the posterior neck region extends from superior nuchal line to spine of scapula and the side region to the superior border of the clavicle and the suprasternal notch [6].

Chronic neck pain has been defined as widespread sensationof hyperalgesia in the skin, ligaments, and muscles, onpalpation and in both active and passive movements in

Neck and shoulder area [7]. Neck pain is multifactorial in its etiology and in its impact on the individual. Various theories have been put forth regarding etiology of neck pain, as such neck pain has been attributed to: Local pathologic causes, whiplash-associated neckinjury, occupational neck pain, sports-related neck pain, nonspecific neck pain, nonorganic problem with psychosocial roots, serious but rare conditions like tumors, fractures, etc [8,9,10,11,12].

Neck pain with no known cause has been termed as idiopathic neck pain or cervical spinal pain of unknown origin [2,13].

Medications commonly used for the treatment of acute neck pain are Non-Steroidal Anti-Inflammatory drugs and muscle relaxants or a combination of both [14]. The use of Nsaids accounts for 70% of medications used for pain. Aceclofenac is an orally administered phenyl acetic acid derivative with effects on a variety of inflammatory mediators [15]. It acts by inhibiting cyclooxygenase activity with a reduction in tissue production of prostaglandins like PGE2 and PgF2 alpha [16].

Thiocolchicoside is a semisynthetic derivative of colchicine, a natural glycoside of superbagloriosa. This compound has a glycinomimetic activity hence used for myorelaxant property. Thiocolchiside produces muscle relaxation along with anti-inflammatory and analgesic effects [17]. Piroxicam is an Nsaid, and is a non-selectivecyclo-oxygenase inhibitor possessing both analgesic and antipyretic properties.

## MATERIAL AND METHODS

This was a prospective randomised study carried out in the Department of Physical Medicine and Rehabilitation. All the patients reporting to the out-patient department with acute severe neck pain were assessed for the inclusion and exclusion criteria given underneath to be included in the study.

### Inclusion criteria

All patients presenting to the Out-Patient Department with acute idiopathic neck pain in the age group of 18-55 yrs, with VAS Score 6 or more.

### Exclusion criteria

Patients with neck pain with any of the following;

1. Symptoms and signs of infection (e.g. fever, night sweats)

2. History of trauma

3. Use of corticosteroids

4. Past history of malignancy

5. Age > 55 years

6. Failure to improve with treatment

7. Unexplained weight loss

8. Dysphagia, headache, vomiting

9. Neurological symptoms in the limbs

10. Cerebrovascular symptoms or signs, anticoagulant use

11. Cardiovascular risk factors, transient ischaemic attack

Patients included in the study were randomised into two groups. The groups were named Group A and Group B receiving two different medications. Group A were given Aceclofenac Thiocolchicoside fixed dose combination (Aceclofenac 100 mg and thiocolchicoside 4 mg.) orally twice daily for a period of seven days. The group B patients were given 40 mg of injectable Piroxicam intramuscularly daily for a period of seven days. The study was carried over a period of one year. The study was conducted to compare the efficacy of oral Aceclofenac Thiocolchicoside fixed dose combination (well known medication in acute nuchal pain), with that of intramuscular Piroxicam. A total of 100 patients were included in the study, with 50 patients randomly allocated in both groups. All patients gave informed consent for the study. Out of the total of 100 patients, 6 patients were lost in the follow-up (four patients from group A and two patients from group B) and hence excluded from the study. The study was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000.All patients were prescribed proton pump inhibitor daily till the continuation of treatment as a prophylactic measure for the endemic epigastralgia in the population. The study was well approved by the institutional review board.

History and demographic characteristicsof all patients were recorded. All patients were assessed by:

1. Visual analogue scale (0-10 points): A 10 point scale where a score of 0, corresponds to no pain while a score of 10 corresponds to worst possible pain.

2. Shafat's Range of Motion index( S ROM I) for nuchal pain(0-4 points) : A 5 point scale to assess severity of pain as-

0: All movements free

1: Mild pain in single plane of movement (either extension, flexion, sideways bending, or sideways rotation).

2: mild to moderate pain in two or more planes of movement.

3: moderate to severe pain in one or more planes of motion.

4: Incapacitating pain with any tried movement of the cervical spine.

3. Shafat's Nuchal Tenderness index (S NTI)(0-4 points): A 5 point scale to assess severity of nuchal region tenderness as-

0: No Tenderness.

1: Mild tenderness on palpation on one side.

2: moderate to severe tenderness on palpation on one side.

3: mild to moderate tenderness on palpation on both sides.

4: severe tenderness on palpation on both ligamentumnuchae or along spinous processes.

All patients were evaluated for homogeneity in basic demographics and disease characteristics at the baseline. Patients were evaluated according to the Visual Analougue Scale, Shafat's Range of Motion index, and Shafat's Nuchal Tenderness index

at the start of treatment as well as on the 7th day(14). Requisite history was asked for development of any side effects due to medication during the therapy. All patients were advised to use cervical hard collar to aid comfort as on individual requirement basis, when they are up and about. Isometric nuchal exercises were advised after patients felt some respite and S ROM I and S NTI scores were 1 or below.

Statistical analysis was performed with Student's t test using graph pad instat 3. Descriptive statistics were determined by calculation of the mean and standard deviation (±SD) and statistical significance was defined as P<0.01.

## RESULTS

Out of the total 100 patients included in the study 50 patients were randomly selected in each group. Group A patients received oral AceclofenacThiocolchicoside fixed dose combination for a period of 7 days while group B patients received intramuscular Piroxicam 40mg daily for seven days. Six patients were lost to the follow-up, out of which four were from the group A and two were from group B. So a total of 94 patients completed the study.

Demographics of patients in both groups were comparable as in table 1. Mean age of the patients in group A being 33.17, while that in the group B being 33.29. There were 41 females with 20 in the group A and 21 in group B, and 53 males with 26 males in group A and 27 males in group B.

All the patients involved in the study were evaluated for intensity of pain by10 point Visual Analougue Scale. The baseline score for all patients were 6 or more as per the inclusion criteria. After 7 days of therapy all patients recorded improvement in the VAS Score. The baseline mean VAS score of group A was 7.65 with standard deviation of 1.01, while that of Group B was 7.61 with standard deviation of 1.02. Mean VAS score of group A at day 7 was 3.52 while that of Group B was 0.52, with the difference being statistically quite significant (p<0.01) as in Table 2. There was marked difference in the outcome among two groups in VAS after 7 days of treatment, with group B patients almost free of pain while the group A patients having considerable pain. On the seventh day 32 patients from group B had no pain and 16 patients complained of mild occasional pain with VAS score ranging from 1-2, while most of the patients in group A had moderate pain with VAS score being 3-6, with only two patients having no pain as shown in Table 3. All patients included in the study were evaluated at baseline as per Shafat's Range of Motion Index(S ROM I) and had a score of two or more. The mean score on passive movement as per S ROM I at day 0 in both groups were 3 with standard deviation of 0.6. Mean score of group A on 7th day was 1.7 with standard deviation of 0.7, while that of group B was 0.3 with standard deviation of 0.46. So the patients in both the groups showed improvement in the scores which is statistically significant as shown in Table 4, though the patients in group B showed much better improvement than patients of group A, with difference of mean being statistically significant. The range of S ROM I in group A on day 7 was 0-3, with only two patients having a score of 0; while the range of S ROM I in group B was 0-1, with 34 patients(71% ) having score of 0.

In Aceclofenac Thiocolchicoside group on day 0, eight patients had S ROM I score of 4, 30 patients had S ROM I score of 3, and eight patients had a score of 2; while on day 7, two patients had S ROM I score of 0, seven patients had score of 1, 26 patients with score of 2, four patients had score of 3 and none had score of 4.

In piroxicam group on day 0, 32 patients had S ROM I score of 3, eight patients with score of 2 and eight, while none had score of 0 and 1; while on day 7; 34 patients had score of 0 and 14 patients with score of 1, as in table 5.

**Table 1:** Showing Demographic distribution of the cohort involved in the study.

| | Mean Age (Range) | Males | Females | Total |
|---|---|---|---|---|
| Group A( Aceclofenac +Thiocolchicoside) | 33.17 (19-50) | 26 | 20 | 46 |
| Group B(Piroxicam) | 33.29(19-48) | 27 | 21 | 48 |

**Table 2:** Showing mean visual analogue score in Aceclofenac Thiocolchicoside combination group and Piroxicam group along with P value.

| Mean VAS score | Group A | Group B | Difference of mean | P value |
|---|---|---|---|---|
| On Day 0± SD | 7.65± 1.01 | 7.61± 1.02 | 0.03 | Not significant |
| On Day 7± SD | 3.52± 1.3 | 0.42± 0.65 | 3.10 | P<0.01 |
| Difference of mean | 4.13 | 7.20 | | |
| P value | P<0.01 | P<0.01 | | |

**Table 3:** Showing VAS score among patients in Group A and Group B on day 0 and day 7.

| VAS SCORE | No. of patients in GroupA (Aceclofenac Thiocolchicoside) | | No. of patients in Group B(Piroxicam) | |
|---|---|---|---|---|
| | Day 0 | Day 7 | Day 0 | Day 7 |
| 0 | 0 | 2 | 0 | 32 |
| 1-2 | 0 | 6 | 0 | 16 |
| 3-5 | 0 | 6 | 0 | 0 |
| 6-10 | 46 | 2 | 48 | 0 |

Shafat's Nuchal Tenderness Index (S NTI ) was used to evaluate all the patients on the start of treatment and on day 7. The mean S NTI of group A, on day 0 was 2.8 with standard deviation of 0.8, while mean S NTI on day 7 was 1.6 with standard deviation of 0.6, showing thereby a significant improvement in the score. The mean S NTI of group B; on day 0 was 2.75 with standard deviation of 0.8, on day 7 was 0.25 with standard deviation of 0.44, showing significant improvement in the mean score. The baseline mean S NTI on day 0 between two groups was comparable while mean S NTI on day 7 showed significant difference in the two groups with P value markedly significant, as in Table 6. 28 patients of AceclofenacThiocolchicoside group had a score of 2 on day 7, and only two patients showed a score of 0 while in the Piroxicam group 36 patients had a score of 0 on day7 with another 12 patients with a score of 1, with none of the patients had score >1, as shown in Table 7.

## DISCUSSION

Acute nuchal pain is one of the most common ailments of the people to present to Physical medicine and rehabilitation specialist. It has been widely treated by using a variety of modalities like oral or injectable NSAIDS, Thiocolchicoside, Physical modalities and their combinations, though there has not been sufficient evidence for making a consensus in the treatment of Acute Nuchal Pain. This study has been carried out to know the comparative efficacy between Aceclofenac Thiocolchicoside fixed dose combination and injectable Piroxicam in the treatment of severe acute nuchal pain.

The hundred patients included in the study were all evaluated at baseline for demographics and diseases characteristics and randomly divided into group A and group B, with 50 patients in each group. The baseline demographics of patients in the two groups were comparable. All patients were evaluated by Visual analogue scale, Shafat's Range of Motion Index for nuchal pain and Shafat's Nuchal Tenderness Index for nuchal tenderness; with both groups being comparable as per baseline disease characteristics. All the patients who received therapy were reassessed by the same scoring scales on the 7th day of

**Table 4:** Showing meanS ROM I score in patients among Group A and Group B.

| Mean S ROM I | Group A | Group B | Difference of mean | P value |
|---|---|---|---|---|
| On Day 0± SD | 3± 0.6 | 3± 0.6 | 0 | Not significant |
| On Day 7± SD | 1.7± 0.7 | 0.3± 0.46 | 1.4 | P<0.01 |
| Difference of mean | 1.3 | 2.7 | | |
| P value | P<0.01 | P<0.01 | | |

**Table 5:** Showing Shafat's Range Of Motion Index Score in patients on Day 0 and Day 7.

| S ROM I SCORE | No. of patients in AceclofenacThiocolchicoside Group | | No. of patients in Piroxicam Group | |
|---|---|---|---|---|
| | Day 0 | Day 7 | Day 0 | Day 7 |
| 0 | 0 | 2 | 0 | 34 |
| 1 | 0 | 7 | 0 | 14 |
| 2 | 8 | 26 | 8 | 0 |
| 3 | 30 | 4 | 32 | 0 |
| 4 | 8 | 0 | 8 | 0 |

**Table 6:** Showing mean S NTI Score among group A and group B patients.

| Mean S NTI | Group A | Group B | Difference of mean | P value |
|---|---|---|---|---|
| On Day 0± SD | 2.8±0.8 | 2.75±0.8 | 0.05 | Not significant |
| On Day 7± SD | 1.6± 0.6 | 0.25±0.44 | 1.35 | P<0.01 |
| Difference of mean | 1.2 | 2.50 | | |
| P value | P<0.01 | P<0.01 | | |

**Table 7:** Showing S NTI Score in patients of group A and groupB on day 0 and day 7.

| S NTI SCORE | No. of patients in AceclofenacThiocolchicoside Group | | No. of patients in Piroxicam Group | |
|---|---|---|---|---|
| | Day 0 | Day 7 | Day 0 | Day 7 |
| 0 | 0 | 2 | 0 | 36 |
| 1 | 4 | 14 | 4 | 12 |
| 2 | 8 | 28 | 10 | 0 |
| 3 | 28 | 2 | 28 | 0 |
| 4 | 6 | 0 | 6 | 0 |

treatment. There was significant improvement in the scores on 7thday, but patients from the injectable piroxicam group showed much better response as regards to all three scales and the difference between the two groups was statistically significant. The patients of Aceclofenac Thiocolchicoside group required further pharmacological intervention after day 7, while pharmacological therapy in patients from injectable piroxicam could be discontinued. All patients from both groups were advised isometric nuchal exercises to be continued afterwards. There have been very few studies comparing injectable Nsaids with oral Nsaids in the treatment of musculoskeletal pain which did not show significant difference between the two modalities, but specific studies comparing Nsaid thiocolchicoside combination with an injectable Nsaid for acute muscle spasm (nuchal/back pain) has not been done as per our knowledge [18].

## CONCLUSION

The use of injectable piroxicam in severe acute nuchal ache has shown better response in pain scores, Shafat's Range of Movement Index and Shafat's Nuchal Tenderness Index in patients with severe acute nuchal pain as compared to the use of Thiocolchicoside Aceclofenac combinations. Injectable group showed faster recovery and needed shorter interval of therapy. Further studies with larger number of patients need to be done in future to make a consensus on our findings.

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### Informed consent

The patients gave informed consent for inclusion in the study. The study was authorized by the local ethical committee and was performed in accordance with the ethical standards of the 1964 Declaration of Helinski as revised in 2000.

### Author contributions

SR was the Doctor In Charge of the study. SIB conducted the literature review and analysed the literature. SIB composed and wrote the manuscript, while SR edited it. The authors read and approved the final manuscript.

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