A COMPARATIVE STUDY OF COMBINED USE OF ACECLOFENAC ALONG WITH THIOCOLCHICOSIDE AND ACECLOFENAC ALONE IN PATIENTS DIAGNOSED OF LOW BACK PAIN

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ABSTRACT
The present study was undertaken with the aim of comparing the efficacy of Aceclofenac along with Thiocolchicoside and Aceclofenac alone administered in patients diagnosed of low back pain. Forty patients of either sex in the age range of 18 to 55 years diagnosed of low back pain were randomly divided into 2 groups of 20 each. One group was prescribed aceclofenac 100 mg along with thiocolchicoside 4mg (T+A), while the other group was prescribed aceclofenac 100 mg alone (A) twice a day for 7 days. Severity of pain at rest was recorded using Visual Analogue Scale (VAS), while severity of pain on movement, restriction of movement and straight leg raising were recorded using scoring pattern at baseline and on day 2 and day 7 after start of treatment. On day 2 and day 7 after start of treatment there was a significant decrease in score of pain at rest assessed by VAS. Also scores of severity of pain on movement, restriction of movement and straight leg raising were significantly decreased as compared to baseline scores within both the groups. The decrease in score of pain was more pronounced with group T+A as compared to group A. Thus Thiocolchicoside is a useful adjunct to aceclofenac in the treatment of acute low back pain in clinical practice.

Keywords: muscle spasm, NSAIDS, muscle relaxants, Visual Analogue Scale, Pain scoring pattern

INTRODUCTION

Low Back Pain (LBP) is a ‘human condition’ with 60-80% of the world population experiencing pain at some time in their life[1]. Back pain is second only to the common cold as the most frequent reason for visiting a physician and is the most common chronic pain syndrome in individual countries[2]. It is mostly a self limited
illness i.e. many attacks of low back pain resolve quickly, but some patients go on to develop severe, long term disability\(^3\).

Low back pain accounts for 30-50\% of rheumatic complaints encountered by general practitioners. The highest prevalence is in person’s aged 45–65 years\(^2\), although LBP is reported in adolescents also. In 85\% of low back pain cases, a presence of muscle spasm has been noted\(^3\), causing the condition to be more painful and produce functional impairment\(^4\). The course of treatment for low back pain will usually be dictated by the clinical diagnosis of the cause of pain\(^5\).

Non-Surgical treatment for low back pain is multiple and varied: eg. counseling and education, rest, medication, braces, passive modalities, spinal manipulation, injections, exercise and stretching, proper lifting technique\(^6\).

Surgical treatment for low back pain includes Spinal fusion and Disc replacement which are used when non- surgical treatment fails\(^6\).

Medications commonly used for the treatment of acute LBP include acetaminophen, methimazole and other non steroidal anti-inflammatory drugs and muscle relaxants\(^7\).

Aceclofenac is an orally administered phenyl acetic acid derivative with effects on a variety of inflammatory mediators. It is related to diclofenac. Through its analgesics and anti-inflammatory properties aceclofenac provides symptomatic relief in a variety of painful conditions\(^8\).

Most commonly used muscle relaxants are central nervous system depressants\(^9\). Although these groups of drugs usually help to reduce spasticity, but decrease in muscle tone elsewhere, may lead to a decrease in the mobility of the patient. Also the development of sedation, is found to be a major limiting factor in the use of muscle relaxants for the treatment of acute LBP, as they can affect daily activities and decrease working capabilities\(^9,10\). Hence, these limiting factors in the use of muscle relaxants raised a need for an ideal muscle relaxant devoid of effects on psychomotor performance, free of sedation and higher tolerability.

Thiocolchicoside is a semi-synthetic derivative of colchicine, a natural glycoside of Superba gloriosa. It’s in - vitro profile shows affinity for the inhibitory glycine and \(\text{GABA}_A\) receptors\(^{11}\) and therefore the compound is endowed with glycinomimetic
activity and is being used in rheumatology and orthopaedic field for its myorelaxant property\textsuperscript{[12]}. It has been reported that thiocolchicoside produces muscle relaxation without any subjective or objective sedative side effects\textsuperscript{[11]} as well as anti-inflammatory and analgesic effects\textsuperscript{[13]}. It is indicated for the adjunctive treatment of muscle spasm in acute low back pain\textsuperscript{[14]}.

Hence the present study was undertaken to compare the efficacy of aceclofenac in adjunction with thiocolchicoside and aceclofenac alone in patients diagnosed of low back pain.

**EXPERIMENTAL WORK**

**Subject Recruitment Procedure**

The approval for the conduct of the study was obtained from HREC of Shri Krishna Hospital and Pramukh Swami Medical College Karamsad.

Forty patients diagnosed of low back pain, were randomly selected from Abhishek Orthopaedic Hospital Vadodara, on OPD basis under the supervision of Dr. Malhar Dave, MS (ortho). The written consent of patients was taken on inform consent form in the local language.

**Inclusion Criteria**

Patients of either sex in the age range of 18 to 55 years, suffering from low back pain.

**Exclusion Criteria**

1- Patients with back pain due to malignancy, infection, abnormal metabolism, osteoarthritis of hip or other disease.
2- Back pain referred from other organs.
3- Patients with a history of presence of peptic ulceration or gastrointestinal bleeding or severe dyspepsia.
4- Patients allergic to NSAID’S and skeletal muscle relaxants.
5- Patients treated with NSAID’S or skeletal muscle relaxants for 3 days preceding the study.
6- Patients with severe concurrent systemic disease including bleeding diathesis.
7- Patients on Anticoagulation therapy.
8- Pregnant and lactating women.
9- Patients suffering from hepatic or renal impairment.
10- Patients suffering from asthma or other allergic disorders.

**Study Design**

Visit I (Day 0)

- Demographic data and relevant medical history was obtained from all patients prior to initiation of therapy.

- Twenty patients attending OPD on Monday, Wednesday and Friday were randomly selected and were prescribed with Aceclofenac100mg along with Thiocolchicoside 4mg twice a day for 7 days.

- Twenty patients attending OPD on Tuesday, Thursday and Saturday were randomly selected and were prescribed with Aceclofenac alone in a dose of 100 mg twice a day for 7 days.

- On Day 0 baseline data of all investigations done with the help of scoring pattern and Visual Analogue Scale were recorded.

- Severity of pain at rest ranging from ‘no pain’ to ‘incapacitating pain’ was assessed by Visual Analogue Scale.

Severity of pain on movement was assessed on a 5 point scale as-

- 0: No pain with free movement.
- 1: Mild pain with movement possible.
- 2: Moderate pain with limited movement.
- 3: Severe pain with difficult movement.
- 4: Incapacitating pain.

Restriction of movement was assessed on a 5 point scale as-

- 0: Easy movement possible.
- 1: Movement causes mild discomfort.
- 2: Movement is moderately difficult.
- 3: Movement possible but difficult or painful.
- 4: No movement possible at baseline.

Straight Leg Raising (SLR) was assessed -
0: Both negative.
1: One leg positive for SLR.
2: Both legs positive for SLR at baseline

On visit II (Day 2, 48 hrs after visit I) and on visit III (Day 7, 5 days after visit II) detailed history of patients was taken with reference to drug allergy and investigations were carried out as mentioned above.

**Statistical Analysis**

Collected data were analyzed statistically for earlier stated objective using Independent T-test and Paired sample T-test and the results were expressed as mean difference in score of pain before and after drug treatment. P value<0.05 was considered to be statistically significant.

**RESULTS**

1- **Gender wise distribution of demographic data of patients and base line severity of pain** - Mean of demographic data like age, weight and BMI of male and female patients are depicted in Fig. 1. Also the difference in baseline severity of pain at rest based on VAS between male and female patients was assessed and is shown in Fig. 1.

![Figure 1](image)

**Figure 1**

Difference between genders with regard to mean weight, age, BMI and severity of pain.

2- **Frequency distribution of severity of pain based on VAS at baseline** - Severity of pain at rest was assessed by VAS at baseline and categorized as mild, moderate, severe and incapacitating. Its frequency distribution is depicted in figure 2.
3- **Correlation of BMI with severity of pain based on sex of patients**- Much difference was not observed in severity of pain in patients with normal BMI and obese patients of either sex. (Table 1)

**TABLE 1: BMI AND SEVERITY OF PAIN ASSESSED BY VAS AT BASELINE**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Severity of pain based on VAS</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Overweight</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Overweight</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>6</td>
</tr>
</tbody>
</table>

P = 0.179

4- **Comparison of severity of pain at rest assessed by VAS**- Score of pain at rest assessed by VAS on day 7 decreased significantly (P=0.000*) as compared to baseline score within both groups i.e., group of patients receiving T+A and patients receiving A. However, the decrease in severity of pain at rest assessed by VAS on day 7 was more pronounced within patients receiving T+A as compared to patients receiving A. (Table 2)
TABLE 2: MEAN DIFFERENCE IN SCORE OF PAIN AT REST ASSESSED BY VAS BETWEEN PATIENTS RECEIVING TWO GROUPS OF DRUG

Severity of pain based on VAS

<table>
<thead>
<tr>
<th>T+A group</th>
<th>A group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean score of pain at rest of 20 patients</td>
<td>Difference in mean score of pain at rest between 2 visits</td>
</tr>
<tr>
<td>Day 0</td>
<td>Day 7</td>
</tr>
<tr>
<td>77.55</td>
<td>9.85</td>
</tr>
<tr>
<td>67.65</td>
<td>11.10</td>
</tr>
</tbody>
</table>

5- Comparison of severity of pain on movement and restriction of movement by scoring pattern

Score of pain on movement and restriction of movements assessed by scoring pattern on day 7 decreased significantly (P=0.000*) as compared to baseline score within both the groups i.e., group of patients receiving T+A and patients receiving A. However, the decrease in mean score of severity of pain on movement and restriction of movements assessed by scoring pattern on day 7 was more pronounced in patients receiving T+A as compared to patients receiving A. (Table 3, Table 4)

TABLE 3: MEAN DIFFERENCE IN SCORE OF PAIN ON MOVEMENT ASSESSED BY SCORING PATTERN BETWEEN PATIENTS RECEIVING TWO GROUPS OF DRUG.

Severity of pain on movement assessed by scoring pattern

<table>
<thead>
<tr>
<th>T+A group</th>
<th>A group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean score of pain on movement of 20 patients</td>
<td>Difference in mean score of pain on movement between 2 visits</td>
</tr>
<tr>
<td>Day 0</td>
<td>Day 7</td>
</tr>
<tr>
<td>3.00</td>
<td>0.65</td>
</tr>
<tr>
<td>2.50</td>
<td>0.75</td>
</tr>
</tbody>
</table>
###TABLE 4: MEAN DIFFERENCE IN SCORE OF RESTRICTION OF MOVEMENT ASSESSED BY SCORING PATTERN BETWEEN PATIENTS RECEIVING TWO GROUPS OF DRUG

<table>
<thead>
<tr>
<th>Restriction of movement assessed by scoring pattern</th>
<th>T+A group</th>
<th>A group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean score of restriction of movement of 20 patients</td>
<td>Difference in mean score of restriction of movement between 2 visits</td>
<td>P value</td>
</tr>
<tr>
<td>Day 0</td>
<td>Day 7</td>
<td>2.500</td>
</tr>
<tr>
<td>2.90</td>
<td>0.40</td>
<td>2.50</td>
</tr>
</tbody>
</table>

6- Comparison of Straight Leg Raising (SLR) by scoring pattern:–

Straight Leg Raising (SLR) assessed by scoring pattern was coded as:

0=both negative, 1=one leg positive for SLR and 2=both legs positive for SLR.

There was no significant decline in SLR between baseline score and score of SLR on day 2, but there was statistically significant decline in the SLR sign at the end of the treatment (Day 7) in patients receiving T+A (P=0.004*) and patients receiving A (P=0.015*). The decline in SLR score in patients receiving T+A was found to be more consistent and with less error as compared to patients receiving A. (Table 5)

**DISCUSSION**

In the present study severity of pain at rest was assessed using VAS between two groups of drugs. Score of pain at rest on day 7 assessed using VAS, decreased significantly as compared to baseline score within the two groups of patients. However the decrease in severity of pain at rest was more pronounced within group of patients receiving T+A as compared to patients receiving A, though the difference between the two groups was not found to be statistically significant. This result is in accordance with
the result reported in European Spine Journal\cite{15}, which states that combination of aceclofenac with muscle relaxants gives significantly better improvement in pain at rest.

Score of severity of pain on movement and restriction of movement assessed by scoring pattern on 7th day decreased significantly as compared to baseline score within both the groups.

However, the decrease in score of severity of pain on movement was more pronounced in patients receiving T+A as compared to patients receiving A, though the data shows no statistical significance. This result is in accordance with the result reported in European Spine Journal\cite{15}, which states that pain on movement was significantly reduced in patients treated with aceclofenac and muscle relaxants.

A statistically significant decline in SLR score was observed at the end of the treatment within both the groups. However, the therapy with group T+A was more effective in improving the straight leg raising sign as compared to group A, though; the difference was not statistically significant.

CONCLUSION

The results of our study suggest that thiocolchicoside is a useful adjunct to aceclofenac in the treatment of acute low back pain in clinical practice. In terms of efficacy the combination of aceclofenac and thiocolchicoside was found to be superior to aceclofenac alone. Comparing the effectiveness in reducing pain within the group statistically significant results were obtained in both the groups.

However, when the two groups are compared in their ability to reduce pain, more decrease in pain was observed among patients receiving T+A though the results were not found to be statistically significant.

This may probably be due to less number of subjects recruited in the study.

REFERENCES


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