

A Comparative study of efficacy of Thiocolchicoside with Diclofenac vs Eperisone with Diclofenac in patients with back pain

Ambrish S¹, Nagesh Raju G², Dharmaraj B³, Nagendra Gowda M R⁴

¹Dr. Ambrish S, Department of Orthopedics, ²Dr. Nagesh Raju G, Department of Pharmacology, ³Dr. Dharmaraj B, Department of Pharmacology, ⁴Dr. Nagendra Gowda M R, Department of Community Medicine, all authors are affiliated with Basaveshwara Medical College & Hospital, Chitradurga, Karnataka 577502, India.

Address for Correspondence: Dr. Ambrish S, Email: nhimabindu2003@gmail.com

Abstract

Background: A number of drugs are available for the treatment of Low back pain (LBP) as per the available literature. This study was undertaken to compare the efficacy of Thiocolchicoside– diclofenac and Eperisone – diclofenac in patients with low back pain. **Materials and Methods:** A prospective, open labeled, randomized, comparative clinical study was conducted in order to establish the efficacy of Thiocolchicoside – diclofenac and Eperisone – diclofenac in patients with back pain. Thirty patients of either sex with back pain were randomly allocated to two groups to receive either Thiocolchicoside (4 mg)+Diclofenac (50mg) twice a day (Group A) or Eperisone (150 mg) Sustained Release+Diclofenac (100mg) preparation once a day (Group B). **Results:** The finger to floor distance was improved significantly after treatment with both the drugs for 7 days. There was a statistically significant difference in improvement of finger to floor distance of both the drugs and was marked in Group B. About 80% of the patients were normal after 7 days of treatment in Group B. The VAS scores and Global assessment scale had also shown the lower scores for group B compared to group A. **Conclusion:** The Eperisone with diclofenac was found to be more effective in terms of Finger floor distance and improvement in Lasegue’s sign, VAS score and global assessment scale than Thiocolchicoside with Diclofenac.

Key words: Low back pain, Thiocolchicoside, Eperisone

Introduction

Low back pain (LBP) is an important symptom in orthopedics with 60 – 80% of the world population experiencing pain at some time in their life [1]. Back pain is second most common reason to visit a physician and is most common chronic pain syndrome in individual countries [2]. The annual incidence of low back pain is 10 – 15% and a point prevalence of 15 – 30% in adult population [3]. Low back pain is a common musculoskeletal symptom that may be either acute or chronic. It may be caused by a variety of diseases & disorders that affect the lumbar spine. The most frustrating aspect in the treatment of back pain is that there are “no magic bullets”[4].

Muscle relaxants and non steroidal anti inflammatory drugs (NSAIDs) are shown to have a therapeutic utility in the management of painful spasms of low back pain [5]. But the muscle relaxants have the common side effect of sedation which limits their use which affects the daily activity and decreases the capacity of working [6]. The

inhibition of the neural activity and pain sensation results when the voltage gated sodium channels are blocked [7].

Eperisone is a centrally acting skeletal muscle relaxant that has been used in the treatment of muscle spasm & spasticity. It inhibits the mono and multi synaptic spinal reflexes and may also have a vasodilator action [4,8].

Thiocolchicoside is a semi synthetic derivative of the colchicoside which acts through GABA mediated mechanism which relaxes the spasm and relieves pain.

It is used in the symptomatic treatment of painful muscle spasm [6, 9].

The studies comparing the Thiocolchicoside– diclofenac and Eperisone – diclofenac in patients with back pain are scant in the world and in this part of the country.

Hence this study was undertaken with the aim of comparing the efficacy of Thiocolchicoside– diclofenac and Eperisone – diclofenac.

Materials and Methods

A prospective, open labeled, randomized, comparative clinical study was undertaken in the department of Orthopaedics, Basaveshwara Medical College & Hospital, Chitradurga among 60 in patients of back pain specially admitted for the purpose of the study. The study is in accordance with the principles of good clinical practice and declaration of Helsinki. An informed consent was obtained from all the patients enrolled for the study. Clearance from institutional ethical committee was obtained from the institutional ethics committee.

The study sample comprised of two groups each of 30 patients of either sex with back pain were randomly allocated to receive either Thiocolchicoside (4 mg) +Diclofenac (50mg) twice a day (Group A) or Eperisone (150 mg) Sustained Release +Diclofenac (100mg) preparation once a day (Group B) by using computer generated random numbers.

Patients aged between 20 – 60 years of age of either sex and with complaints of low back pain of acute onset due to muscle sprains and prolapsed disc were included in the study. Pregnant / lactating women, Pain associated with fractures, Head injury patients with back pain and patients with history of intake of opioid analgesics were excluded from the study.

Group A patients received Thiocolchicoside (4mg) + Diclofenac (50mg) twice a day for 7 days or Group B patients comprising of 30 patients with low back ache received Eperisone (150mg) Sustained Release +Diclofenac (100mg) preparation once a day.

The ward staff nurse was advised to ensure by observing the patient swallowing the tablet in order to assess the patient compliance. The patients admitted were not advised with any other modalities of treatment.

Results

Table-1:Socio demographic variables of the study.

	Group A	Group B	Test value	P value, Sig
Age (Mean ± SD)	48.9 ± 8.52	51.17 ± 8.15	T value= 1.053	0.297, NS
Males, n (%)	18 (60.0)	16 (53.3)	χ^2 value=0.271	0.602, NS
Females, n (%)	12 (40.0)	14 (46.7)		

The mean age of the Group A patients was 48.9 (\pm 8.52) years and group B was 51.17 (\pm 8.15) years. There was no statistically significant difference between the two groups ensuring the comparability between the two groups.

Most of the study subjects in both the group were males. The difference between the sex of both the groups was not statistically significant also ensuring the comparability.

The patients were assessed at the baseline and after 7 days of starting the drugs with Finger to floor distance in centimeters test in order to assess the spasm, Lasegue's Sign [lumbar pain or exacerbation of existing pain on passive movement of the legs during flexion of hip joint], the severity of Pain in lower limb was assessed using VAS Scale[10] and Global Assessment [11] of response to therapy.

The finger to floor distance test was applied according to the Magnusson et al. The patients were explained about the procedure and were asked to keep the knees completely extended and from then on, to flex the trunk towards the floor, with head and arms relaxed.

The final flexion position was indicated by a sensation of muscular tension that caused great HM discomfort and in this moment, pictures were taken. Fingertips distance from ground (in cm) was measured based on a known linear measure, placed on same visual filed from the individuals [12].

The patients were assessed at baseline and on day 7 to observe the side effects of therapy. Any other adverse effect reported by the patient was recorded in ADR reporting form. In addition to the follow up, the patients were instructed to report immediately in case of any side effect, as and when required.

The data thus obtained was analyzed by using Statistical Package for Social Services (SPSS vs 20).

The quantitative variables were analyzed using Mean and standard deviation. An independent sample T test was used to compare the mean difference between the two groups.

Table-2: Finger to floor distance of the study group.

	Group A	Group B	T value	P value, Sig
Day 1	24.3 ± 11.41	16.6 ± 13.454	2.402	0.02, Sig
Day 7	6.83 ± 3.63	2.67 ± 2.155	5.403	0.000, Sig
T value	9.916	20.421		
P value, Sig	0.000, Sig	0.000, Sig		

The mean finger to floor distance of group A patients on day 1 was 24.3 (± 11.41) cm and on day 7 was 6.83 (± 3.63) cm. This difference was statistically significant between day 1 and day 7. The mean finger to floor distance of Group B patients on day 1 was 16.6 (± 3.454) cm and day 7 was 2.67 (± 2.155) cm. This difference was also statistically significant between the day 1 and day 7. The difference in finger to floor distance was statistically significant on day 7 favoring Group B patients.

Table-3: Lasegues sign of the study group at day 1 & 7.

Laseague's sign	Day 1		Day 7	
	Group A n (%)	Group B n (%)	Group A n (%)	Group B n (%)
Normal	5 (16.7)	7 (23.3)	14 (46.7)	24 (80.0)
Mild hypertonia	5 (16.7)	14 (46.7)	13 (43.3)	6 (20.0)
Moderate hypertonia	14 (46.7)	6 (20.0)	3 (10.0)	0
Marked hypertonia	6 (20.0)	3 (10.0)	0	0
Total	30 (100)	30 (100)	30 (100)	30 (100)
χ^2 value=8.796 df=3 P value=0.032, Sig			χ^2 value=8.211 df=2 P value=0.016, Sig	

In group A on day 1, about 46.7% of the patients of group A had moderate hypertonia and 46.7% of the group B patients had mild hypertonia. There was a statistically significant difference between the lasegue's sign of the group A and group B on day 1. At the end of day 7, about 46.7% of the Group A patients and 80% of the Group B patients were normal by lasegue's sign. This difference in tone by Lasegue's sign was statistically significant between the two groups.

Table-4: Visual Analogue score of the study group.

	Group A	Group B	T value	P value, Sig
Day 1	6.37 ± 1.63	6.43 ± 1.79	0.151	0.881, NS
Day 7	2.17 ± 1.31	1.33 ± 1.63	2.183	0.033, Sig
T value	5.99	16.155		
P value, Sig	0.000, Sig	0.000, Sig		

The mean VAS score of Group A patients was 6.37 (± 1.63) which was reduced to 2.17 (± 1.31) which was statistically significant between day 1 to day 7. The mean VAS score of Group B patients on day 1 was 6.43 (± 1.79) which was reduced to 1.33 (± 1.63) on day 7. This difference was statistically significant. The VAS scores were statistically significant between the two groups on day 7.

Table-5: Distribution of the study group according to Global scale.

Lasegue's sign – Day 7	Group A n (%)	Group B n (%)
Poor	1 (3.3)	2 (6.7)
Average	10 (33.3)	1 (3.3)
Good	18 (60.0)	13 (43.3)
Excellent	1 (3.3)	14 (46.7)
Total	30 (100)	30 (100)

 χ^2 value=19.77

df=3

P value=0.000, Sig

The global assessment scale has indicated that about 33.3% of the patients in group A had the average grade and 60% had good grade among Group A patients. Among the Group B patients, 43.3% of the patients were graded as good and 46.7% were graded as excellent. This difference in grading of Global scale was statistically significant between group A and Group B.

Discussion

This study was conducted to compare the efficacy of Thiocolchicoside with diclofenac and Eperisone with diclofenac. The main goal of the pharmacological intervention in low back pain is not only relief from the pain but also to reduction of the muscle spasm and inflammation. Eperisone is a muscle relaxant which in addition to inhibition of mono and multi synaptic reflexes also regulates the blood supply to the skeletal muscles [13]. Thiocolchicoside being a spinal GABA agonist compound has been reported to exert inhibitory effect and result in muscle relaxation [14]. Unlike other muscle relaxants, these drugs have been reported to have less gastro intestinal side effects and sedative effects [15].

This study had shown that, the finger to floor distance was improved by 71.9% in Thiocolchicoside group and 83.9% in the Eperisone group which was statistically significant.

A study by Cabitza et al had shown to improve the FFD more in Eperisone group similar to the results of this study after 7 days of treatment [9]. Maaz et al [16] have also supported the results of Cabitza et al. In contrary to these results, Rao et al [17] and Soonawala et al reported Thiocolchicoside is a better drug of choice in comparison with Eperisone [18].

The lasague's sign was improved in both groups but it was marked in Eperisone group. About 46.7% of the patients in Thiocolchicoside group had the moderate hypertonia improved to normal in 46.7% of the patients after 7 days of treatment. In the Eperisone group, about 46.7% of the patients had mild hypertonia which improved to normal in 80% of the patients. There was a statistically significant between the two groups. Cabitza et al [9] and Maaz et al [16] have also reported that the VAS score of pain decreased significantly in patients receiving Thiocolchicoside and Eperisone. A study by Frandisco et al [19] and Soonawala et al [18] have also reported that both Eperisone and Thiocolchicoside decrease the muscle spasm.

The global assessment scale has indicated that 60% had good grade in Thiocolchicoside group and 46.7% were graded as excellent in the Eperisone group. This difference in grading of Global scale was statistically significant between the two groups. No studies have reported the findings of Global assessment and hence these study results were not compared with other studies.

The adverse effects in the study were negligible and hence were not reported. The usual gastro intestinal side effects due to diclofenac have been reported and treated appropriately by using proton pump inhibitors.

Conclusion

Although Thiocolchicoside with diclofenac and Eperisone with Diclofenac are found to effective drugs in relieving the Lower back pain, Eperisone with Diclofenac was found to be more effective in terms of Finger floor distance and improvement in Lasague's sign, VAS score and global assessment scale.

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