Original Article

Comparative Efficacy of Diclofenac Sodium Alone and in Combination with Thiocolchicoside in Patients with Low Back Pain

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ABSTRACT

Objective: This study was conducted to determine that combination of a Diclofenac sodium (NSAID) and thiocolchicoside is more effective than Diclofenac Sodium alone or not.

Study Design: Observational / prospective study

Place and Duration of Study: This study was conducted at the Orthopedics Out-Patient Department, Aziz Bhatti Shaheed Hospital, Gujrat from August 2016 to August 2017.

Materials and Methods: Adult patients with acute and sub-acute low back pain was recruited for study and was randomized in group A and group B. A sample of 288 patients, 144 patients in each treatment group was collected by purposive sampling technique.

Results: Group A received Diclofenac sodium 75mg two times a day for 7 days and group B received Diclofenac sodium 75mg twice daily plus Thiocolchicoside 4mg twice daily for 7 days. On the day 0 then on the day 3 and day 7, the patients were evaluated for low back pain with a visual analogue scale (VAS) and second outcome measured was hand to floor distance. Descriptive techniques with mean, standard error of mean and graphs were used whereas for inferential statistics, repeated measure ANOVA was used to compare results of day 0, day 3 and day 7. The mean VAS and head to floor distance was equivalent at inclusion. At day 7 pain scores and hand to foot distance was decreased in both groups compared to on day 0 at inclusion. But patients group B receiving combination therapy of NSAID and Thiocolchicoside had significantly less pain and head to floor distance (disability) than group A.

Conclusion: Combination of thiocolchicoside and Diclofenac sodium was proved to be more effective than Diclofenac sodium alone for the symptomatic treatment of low back pain, and the combinations was also well tolerated.

Key Words: Diclofenac Sodium, Thiocolchicoside, Muscle Relaxant, Low Back Pain

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INTRODUCTION

Low back pain is one of the most common health problem with a prevalence of 8% to 37%.[1] This prevalence increases between age of 45-60 years. It is a common reason for absenteeism fro job also responsible of huge national health expenditure. Recent studies conducted showed that more than 60% of the population suffers from low back pain in their life till the age of 60 years.

Majority of cases low back pain is non-specific, it may originate from age related degenerative process and also due to musculo-ligamentous injuries.

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One of the features of low back pain is muscle spasm which occurs due to irritations of muscles; inter vertical disc or ligaments. Muscle spasm reduced mobility due to which daily function and physical activity disturbed very badly.[2]

The causes of low back pain can be trauma, infection, osteoporosis, strains, prolapsed disc and mechanical low back pain.[3] mostly these pains are self limiting and recover in less than a month.

Many clinical guidelines have been issued in various countries to rationalize the treatment of low back pain,[3] Consistent and common features of which are the early mobilization of the patients, gradual activation and discouragement of bed rest Recognition of psychosocial factors are also very important as the risk factors of chronicity.[4-7]

To allow the patients to return to work as soon as possible it is very important to reduce the pain and muscle spasm the main cause of disability. This can only be achieved by the use of Muscle relaxants But there are many differences and discrepancies regarding the recommendations and use of the muscle

relaxants.[8-12] According to one school of thought muscle spasm is protective mechanism so muscle relaxants should not be used according to other school of thought muscle spasm leads to ischemia which leads to pain and further spasms and this vicious circle should be broken by use of muscle relaxants. Sedation and other adverse affects are also important reason of reluctance to use of muscle relaxants commonly.[13-14]

Thiocolchicoside (TCC) is a non–curare muscle relaxant, a semi-synthetic derivative of colchicoside derived from a naturally occurring glycoside present in the plant Gloriosa superba. It has strong affinity for the inhibitory GABA A and strychnine sensitive glycine receptor and it produces very effective muscle relaxation without any subjective or objective sedation.[5,15-16]

It possess anti inflammatory and analgesic properties. In double blind placebo control trials its safety and efficacy as a monotherapy for the treatment of low back pain has been well proved, also it is devoid of any sedation unlike the most other muscle relaxants. Thus during working and in situations where attention is required it can be use safely.[7]

It is not reported that Muscle relaxants are better than the more frequently prescribed analgesics and NSAIDS for the treatment of low back pain. However many physicians routinely prescribed muscle relaxant along with NSAIDS. But there is no clear evidence that the combination of muscle relaxant with NSAIDS or analgesics which is commonly prescribed for the treatment of low back pain has any advantage over NSAIDS or Analgesics prescribed alone. That is why this study was conducted to determine that is the combination of Thiocolchicoside with Diclofenac Sodium more effective for the treatment of non specific low back pain than when Diclofenac sodium used alone or not , and how is the tolerance of this combination in our patients.

MATERIALS AND METHODS

This prospective, randomized, single center observational study was conducted from August 2016 to August 2017 on patients with low back pain of Out-Patient Department of Aziz Bhatti Shaheed Hospital, Gujrat, fulfilling inclusion criteria. A total 288 patient were selected, two groups of 144 each, one group A (D) treated with Diclofenac 75 mg two times a day for 7 days alone and other group B(D+T)treated with Diclofenac 75 mg twice daily plus Thiocolchicoside 4mg two time a day for 7 days. Patients were included in this study from 18-70 years of age, low back pain associated with muscle spasm, signs and symptoms of muscle spasm of the lumbar region and existence of low back pain equal to or greater than 5mm on VAS. Patients were excluded from the study like pregnant and nursing women, presence of any psychiatric or mental disorder, severe gastrointestinal disorders, received a muscle relaxant during preceding 10 days, symptomatic low back pain with some obvious pathology like visceral or un-common low back pain, pelvis spondylitis, spondilodiskitis, spinal tumors, paget disease, osteoprotic compress, neuropathy, surgical intervention in last 6 month, hypersensitivity to NSAID or Thiocolchicosid and diagnosed case of sever diabetes, heart failure, CLD, renal failure, AIDS, psychosis, dementia, Alcoholism. All the patients were recruited between the age of 18-70 years with low back pain with muscles spasm and low back pain greater than 5cm on visual analog score. Evaluation was done and recorded on day 0.

Treatment Protocol: Patients were placed in two groups randomly. Patients in group A were administered with Diclofenac 75mg twice daily alone for a period of 7 days. In second group B, a combination therapy of Thiocolchicoside and Diclofenac was given in a dose 4mg and 75mg respectively twice daily for 7 days. Patients were followed at out-patient department.

Outcome Measures: Patients were examined on three different follow ups; at base line, on day 3 and day 7. The pain management was measured on degree of improvement in the intensity of low back pain on three follow ups by primary outcome measure of visual analogue score (VAS), second out measure for hand to floor distance.

VAS: On VAS pain is scaled from 0-10 cm, from no pain at zero to un-bearable pain at 10cm.

Hand to Floor Distance: In this patient is assessed on mobility by asking him to bend forward and touch his hand to the ground with flexing his knees, the remaining distance between his hand and ground is measured in centimeters.

RESULTS

The percentage of patients examined in Out-patient Department of Orthopedics as: 43.8% patients were 18-30 years of age, 27.1% patients were 31-49 years, 18.8% were 50-69 and only 10.4% were above 70 years. Male patients were 47% and female patients were 53%. Complaint of sedation none. Complaint nausea vomiting abdominal discomfort few patient in both group. Diarrhea reported by 6 patients in group B.

The severity of pain was assessed by VAS, F-test value for Diclofenac (D) is 290.17 with p-value 0.000 which is less than alpha value 0.05, which means results of Diclofenac (D) were statistically significant in all days. VAS score at day zero in treatment Diclofenac is 7.31, after 3 days 4.10 and at day 7 it reduced to 1.35. This shows a significant reduction in pain from day zero to day 7 by using Diclofenac. Similar results were shown for Diclofenac + Thiocolchicoside (D+T); however,

score of VAS is least at day 7 which was much less than Diclofenac (Table 1).

The severity of pain was assessed by VAS, F-test value for Diclofenac (D) is 1335.45 with p-value 0.000 which is less than alpha value 0.05, which means results of Diclofenac (D) were statistically significant in all days. Hand to floor distance score at day zero in treatment Diclofenac is 28.79, after 3 days 18.62 and at day 7 it reduced to 12.12. This shows a significant reduction in pain from day zero to day 7 by using Diclofenac. Similar results was shown for Diclofenac + Thiocolchicoside (D+T); however, score of hand to floor distance is least at day 7 which was much less than Diclofenac

At day 7 Patients with in both groups were improved but patients receiving Thiocolchicoside and NSAID had significantly less pain ($p<0.003$) and disability (foot ankle distance ($p=0.0005$) than patients taking NSAID alone.

Table No.1: Comparison of Treatment with ANOVA for VAS

Treatment	Time	Mean SEM	F-Test (P-value)
Diclofenac (D)	Day 0	7.31±0.273	290.17 (0.000)
	Day 3	4.1±0.166	
	Day 7	1.35±0.096	
Diclofenac + Thiocolchicoside (D+T)	Day 0	7.27±0.263	292.03 (0.000)
	Day 3	3.67±0.15	
	Day 7	0.94±0.096	

Table No.2: Comparison of Treatment with ANOVA for Hand to Floor Distance

Treatment	Time	Mean SEM	F-Test (P-value)
Diclofenac (D)	Day 0	28.79±0.305	1335.45 (0.000)
	Day 3	18.62±0.260	
	Day 7	12.12±0.175	
Diclofenac + Thiocolchicoside (D+T)	Day 0	28.70±0.277	3296.36 (0.000)
	Day 3	16.93±0.116	
	Day 7	10.54±0.072	

DISCUSSION

The important goal in the treatment of patients with low back pain is to relieve the pain and accompanying muscle spasm, and enable patient to resume its routine daily activities as early as possible and allowing the patients to return to their work as soon as possible.[9,17]

Non-steroid anti inflammatory drugs are most frequently used drugs for the treatment of low back pain.[13] Among NSAIDS mostly prescribed is Diclofenac. Elsy et al showed that Diclofenac is most commonly administrated analgesics above 72% and Acetaminphen being 14% and Aceclofenac 8%.[4,14,18] There are conflicting level 3 evidence that NSAIDS are better than acetaminophen for low back pain when administered with muscle relaxant.

Muscle relaxants are commonly used in orthopaedics, mostly the drugs used are central nervous system depressants. These drugs reduce the muscle spasm but they also reduce the muscle tone as well which leads to sense of weakness and decreased mobility. Sedation is other major factor which limit their use because it reduces the working capacity of the patients. Hence due to these limiting factors the need for ideal muscle relaxant was raised which should be devoid of effects on psychomotor performance and free of sedation. thiocolchicoside produces muscle relaxation without sedation, it also has antiinflamatory and analgesic effects.[19]

The American Pain Society recommend the use of NSAIDS as first line treatment for acute pain, and in acute low back pain use of muscle relaxants along with NSAIDS have better results.[3]

In our study the decrease in severity of pain was more in group receiving combination therapy (Diclofenac sodium plus Thiocolchicoside) as compared to patients receiving Diclofenac sodium alone and the difference between two groups was significant. Our results are similar to the studies conducted by Raut et al[10] and Pareek et al[16] using acelofenac–tizanidine combination in the treatment of acute low back pain.

Desai et al[18] also shows reduction in severity of low back pain especially at rest is more in group receiving combination of Aceclofenac and Thiocolchicoside than the Aceclofenac alone, although they found differences between these two groups was not statistically significant.

Our study reported a statistically significant improvement in hand to floor distance on 7th day in both groups however the decrease in hand to floor distance was more pronounced with group B (combination therapy) as compared to group A. similar results were also reported by Lahoti et al and Kumar et al.[19,20] None of patient complaint of sedation in our study a few patients complain of diarrhea and some complaint nausea and vomiting not statistically significant.

CONCLUSION

The results of our study are very much relevant to state that combination therapy of Diclofenac sodium and Thiocolchicoside had superior efficacy than Diclofenac sodium alone for the management of nonspecific low back pain and the combination was well tolerated.

Author's Contribution:

Concept & Design of Study:	Nauman Akhter
Drafting:	Muhammad Zahid Siddiq
Data Analysis:	Nauman Akhter
Revisiting Critically:	Muhammad Zahid

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Final Approval of version:	Nauman Akhter

Conflict of Interest: The study has no conflict of interest to declare by any author.

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