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TREATMENT OF ACUTE LUMBAGO; LOW DOSE DICLOFENAC SODIUM WITH VITAMIN-B COMPLEX COMPARED WITH DICLOFENAC ALONE

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ABSTRACT... Objective: To determine whether concomitant use of vitamins B1, B6, B12 along with low dose of diclofenac sodium causes quicker pain relief in patients of acute lumbago compared with diclofenac sodium alone. **Design:** A randomized clinical trial. **Setting:** Surgical Department of C M H Attock. **Period:** From September 2004 to August 2005 **Patients & Methods:** A total of 50 patients were selected for the study. The patients complaints were of acute lumbago of less than 3 days duration with severe impairments of movements. The age group of patients was between 20 and 65 years. The patients were randomly assigned into two groups. Group I was prescribed tablet diclofenac sodium 25mg along with vitamin B-complex containing combination of 100mg thiamine nitrate (B1), 100mg pyridoxine hydrochloride (B6), and 200mcg cyanocobalmine (B12) three times a day. Group II patients were prescribed 25mg of tablet diclofenac sodium alone. Improvement in the intensity of pain at rest and during movements (as assessed by the patients) was noted in accordance to visual analogue scale 1 to 10. The effectiveness of diclofenac sodium in combination with vitamin-B complex with diclofenac sodium alone was judged on the basis of extent of pain relief after 7 days of treatment. **Results:** A total of 25 patients were treated with combination of diclofenac sodium & vitamin-B complex (Group I) and 25 were treated with diclofenac sodium alone (Group II). As far as the extent of pain relief in first 7 days is considered, 22 patients (88%) belonging to group I and 10 patients (12%) belonging to group II had an excellent pain relief and were able to carry on with their normal routine activities. Remaining 3 patients in group I were completely relieved of pain in next 3 days while 15 patients in group II had to complete another 10 days for complete cure. To test the statistical significance of the result chi-square test was applied and the result showed that patients of Group I responded significantly well to the treatment as compared to those in Group II. **Conclusion:** Using the parameters of pain relief and movements of vertebral column, the combination of diclofenac sodium & vitamin-B complex was found to be more effective mode of treatment as the duration of treatment and the dosage of diclofenac sodium was less and also relief of pain was more rapid.

Key words: Acute lumbago, Vitamin-B complex, Diclofenac.

INTRODUCTION

Acute lumbar pain is one of the commonest illness which presents to the surgeons. It frequently results from a bad

posture leading to serve muscle spasm involving the back muscles. Predisposing factors include lack of spinal muscular exercise and obesity. Elimination of pain is the

prime target in such patients. Non-steroidal anti-inflammatory drugs are the mainstay of treatment¹, but administration of non-steroidal anti-inflammatory drugs (NSAIDs) is frequently associated with undesirable side effects of gastro-intestinal intolerance².

An effective treatment with reduced NSAID dosage for shorter duration with early pain relief is the need of the day. Vitamin-B complex has been reported to be clinically useful either alone or in combination with NSAIDs in a variety of painful vertebral syndrome³. This study proves the fact that a combination of vitamin-B complex with diclofenac sodium is far superior to than use of diclofenac sodium alone in patients of acute lumbago. The easy availability and affordable price with minimum side effects make vitamin-B complex an ideal drug to be used concomitantly with NSAIDs in patients of acute lumbago.

PATIENTS & METHODS

The study was a randomized clinical trial. The objective of study was to compare the effectiveness of a combination of diclofenac sodium and vitamin-B complex with diclofenac sodium alone in treatment of patients of acute lumbago. This clinical trial was carried out to answer the following hypothetical questions:

1. Whether pain relief can be achieved with reduced dose of diclofenac sodium if it is used in combination with vitamin-B complex?
2. Does the concomitant use of vitamin B1, B6, B12 along with diclofenac sodium reduce the length of treatment?

The study included adult patients (more than 20 years) of both sexes who presented with acute lumbago of less than 3 days duration with severe impairment resulting in inability to work in surgical out patient department of Combined Military Hospital, Attock from September 2004

to August 2005. The patients included both male and females. There should not be any marked degenerative changes / bony abnormalities in X-ray lumbo-sacral spine.

The exclusion criteria included patients of less than 20 years of age, those having history of trauma, complaints of chronic backache, bony lesions in X-ray lumbo-sacral spine or history suggestive of acute slip disc. Patients who have known hypersensitivity to NSAIDs or having history of acid-peptic disease were also excluded from study. The study included a total of 50 patients who were treated on out-door basis.

Patients were randomly divided into two groups. The two groups compared well in terms of age, sex and duration of illness. Patients in Group I were given 25mg diclofenac sodium with tablet B-complex containing 100mg thiamine nitrate (B1), 100mg pyridoxine hydrochloride (B6) and 200mcg cyanocobalmine (B12), three times a day. Patients in Group II received only tablet diclofenac sodium 25mg three times a day. In this trial the total dosage of diclofenac sodium used per day was 75mg against the usual dosage of 100-150mg per day which is used to treat such patients.

Following findings were recorded as a measure of mobility and functional capacity of lumbar spine:

1. Lasegue sign.
2. Inclined finger to floor distance.
3. Lateral inclination of spine from right to left.

Improvement in the intensity of pain at rest and during movements (as assessed by the patients as well as doctor) was noted in accordance with visual analogue scale 1 to 10 and it was graded as follows:

1. Mild (scale 1-2)
2. Moderate (scale 3-5)

3. Severe (scale 6-8)
4. Intolerable (scale 9-10)

The effectiveness of diclofenac sodium in combination with vitamin-B complex compared with diclofenac sodium alone was judged on the basis of the extent of pain relief after 7 days of treatment. The time taken for complete cure in all the patients of each group was also noted, but it was not considered in assessing the efficacy of the two modalities of treatment. Clinical assessment of therapeutic success at the end of trial was carried out using the following score system:

Excellent:	Absence of complaints within 7 days of start of the treatment
Good:	Improvement but with persisting symptoms after 7 days of treatment
Fair:	Only marginal improvement

RESULTS

Among the 50 patients who were included in the clinical trial, the age group of patient was between 20 to 65 years (mean age 32.34). There were 37 males and 13 females. The patients were randomly assigned the two groups. Among the patients included, 17(34%) were suffering from intractable pain and all the tests for the functional mobility of lumbar spine were grossly deranged. Twenty four patients (48%) complained of severe pain at rest, 9 patients (18%) had moderate intensity of pain.

As far as the extent of pain relief in first 7 days is considered 22 patients (88%) belonging to group I and 10 patients (40%) belonging to group II had an excellent pain relief and were able to carry on with routine activities. Remaining 3 patients in group I were completely relieved of pain in next 3 days (total duration of treatment was 10 days) while 15 patients in group II had to complete another 10 days (duration of treatment 15 days) for complete cure. To test the statistical

significance of the results chi-square test was applied at the results of the two groups after 7 days of treatment and the result show $p < 0.05$. This show that the patients of Group I responded significantly well to the treatment as compared to those in group II.

As regard to the duration of pain relief, 88%(n=22) of the patients of group I were free of pain after 7 days and 12%(n=3) after 10 days of treatment. On the contrary 40%(n=10) of the patients of group II were free of pain after 7 days and 60%(n=15) after 15 days (Table I).

Duration of treatment	Number of patients (%age) in Group I (n=25)	Number of patients (%age) in Group II (n=25)
7 days	22 (88%)	10 (40%)
10 days	3 (12%)	8 (32%)
15 days	-	7 (28%)

Severe heartburn after 3 days was noted in 3 patients belonging to group I and 4 patients belonging to group II. The complaint was relieved by dietary modifications, no antacids or H₂ blockers were given.

DISCUSSION

Low back pain contributes substantially to the workload of general practice. During a year, 7% of adult population will consult doctor with this problem⁴. However it is generally believed that these episode will be short lived and 80-90% of attacks of low back pain recover in about six weeks irrespective of treatment⁵.

The treatment options available for cases of acute lumbago include:

1. Drug treatment: NSAIDs, opiates, muscle relaxants
2. Trans cutaneous electrical nerve stimulation

3. Exercise programmes
4. Spinal manipulation therapy
5. Spinal steroid injection
6. Epidural anaesthesia

Non-steroidal anti-inflammatory drugs are the first line drugs available for the treatment of lumbar syndromes⁶. Their main role is elimination of pain. However the administration of NSAIDs is frequently associated with undesirable gastro-intestinal side effects which is expected in 25% of all patients treated with NSAIDs⁷. Vitamin B have been reported to be clinically useful alone or in combination with non-steroidal anti-inflammatory drugs in painful spinal disorders like acute lumbago, polyneuropathy, neuritis, lumbago-ischalgia, painful vertebral syndrome or rheumatic disease⁸.

In animal experiments vitamin B1 (thiamine), vitamin B6 (pyridoxine) and vitamin B12 (cyanocobalmine) in combination were shown to possess anti-nociceptive activity against chemical and heat induced pain⁹. Stanislavchuk et al¹⁰ reported that thiamine dipropionate potentiated both the anti-inflammatory and anti-nociceptive activity of diclofenac sodium in rats with chronic adjuvant arthritis. Their involvement in dorsal horn mediated nociception has also been demonstrated.

The importance of vitamin B1, B6 and B12 in the metabolism of central nervous system is established beyond doubt. Vitamin B deficiency syndrome can lead to disintegration of myelin sheath in central as well as peripheral nervous system. In a study carried out on rabbits nerve injury was applied using extreme cold, and regeneration was accentuated by the addition of vitamin B supplements¹¹. In addition vitamin B6 [pyridoxine] has been found to be beneficial in preventing diabetic neuropathy and retinopathy¹².

In our study the results clearly show that the concomitant

use of vitamin B complex with diclofenac sodium reduces the dosage of diclofenac sodium as well as duration of treatment. Patients of group I were able to terminate treatment early owing to absence of pain and improvement in functional parameters.

The results of this clinical trial reconfirms the fact that the combination of diclofenac sodium and vitamin B1,6,12 is more effective in obtaining analgesia with reduced diclofenac sodium dose and also in a shorter duration in patients of acute lumbago.

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**Everyone thinks of changing
the world, but no one thinks
of changing himself**

Leo Tolstol