Original Research Article

An Outcome Based Exploration of Pharmacotherapeutics in Chronic Mechanical Non-Specific Low Back Pain (CNLSBP) Patients in Tertiary Care Hospital

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Abstract

Background: Low back pain is a symptomatic condition with multifactorial causation. It is characterized by pain & muscle stiffness or tension. The aim of management of low back pain is to relieve the pain quickly, to improve functional ability & prevention of disability. A range of Non-Steroidal Anti-Inflammatory drugs (NSAIDs) are used for management which provides variable symptomatic relief.**Aims and objectives:** To evaluate the pattern and prescribing trends of therapy with different NSAIDS & to evaluate the efficacy of different pharmacotherapeutics in the management of chronic mechanical nonspecific low back pain by using visual analogue scale (VAS) score and Oswestry Disability Index (ODI) score.**Materials and methods:** This prospective, observational, and questionnaire-based study was conducted in the Department of Physical Medicine and Rehabilitation center (PMR) of RG Kar Medical College and Hospital, Kolkata. 130 newly diagnosed CNSLBP patients were selected after satisfying inclusion and exclusion criteria. NSAIDs involved in the study are Aceclofenac, Paracetamol, Ibuprofen, Etodolac, Etoricoxib, Naproxen, Piroxicam. Mean VAS score and ODI score were evaluated in all patients at 0, 4, 8 and 12 weeks to assess the efficacy of NSAIDs in reducing pain and functional disability. **Results:** Among 130 patients involved in the study, 84(65%) were female and 46(35%) were male patients and the mean age of female was 40.46 and that of male was 39.96 years. All the different NSAIDS involved in this study were effective in reducing pain and functional disability in CNSLBP patients as evaluated by VAS score and ODI score.

Keywords: Low back pain; visual analogue scale; Oswestry Disability Index; NSAIDS.

Introduction

Pain is the most prevalent symptom of a disease process and is concordant with the Biomedical Model of Illness which links pain to tissue damage.[1] Low back pain (LBP) is the most common pain symptoms reported in medical publications worldwide. At least eight out of ten human beings will suffer from back pain once in their lifetime. The population affected ranges from 60-80%. In India prevalence have been found to range from 6.2% - 92% and it increases with age and is more in females. LBP presents with muscle tension and soft tissue spasm or stiffness ranging from an area below the 12th costal margin till above the inferior gluteal fold. LBP is seen most in elderly patients. The reason of LBP may be due to lack of adequate physical activity or exercises and muscle stiffness. Peoples at higher risk are those involved in activity such as prolonged sitting, standing, or stooping position and also those who carry heavy loads.Pain persisting for more than 12 weeks is called chronic low back pain. Ninety percent patients do not have any demonstrable underlying pathology or apparent tissue damage relevant to the problem.Psychological factors such as anxiety, depression, mental stress, and obesity have also been found to be associated with LBP.[2]The vast majority of patients experiencing low back pain have non-specific back pain. This is also known as simple, common, or chronic mechanical non-specific low back pain (CNSLBP). Thus, a diagnosis of non-specific LBP is based on the absence of criteria for identifiable pathology. LBP badly affects Health- Related Quality of Life (HRQOL).[3] Unfortunately LBP was rarely a focus of public health. It is the leading cause of activity limitation and work absence throughout the world which in turn causes a great economic burden on individuals, communities and governments.[4] A patient's permanent disability is evaluated by the Oswestry Disability Index (ODI) by using Oswestry low back pain disability questionnaire which has 10 sections and each of the sections are scored separately from 0 to 5 points which are then added up. The 10 sections are pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, sexual life and travelling. This index is considered the 'gold standard' of all the tools used to evaluate low back functional outcome.[5] The treatment of CNSLBP needs multidisciplinary approach. The focus should be on proper rehabilitation which is considered end point of treatment. Patients of chronic LBP are managed by several non-pharmacological and many pharmacological means. Non-pharmacological means include patient education, posture care, lifestyle modification and physical modalities such as ultrasound therapy,infrared therapy,short wave diathermy, inter-ferential current therapy and therapeutic exercises such as flexion and extension exercises, spinal stabilization and core muscle strengthening exercises depending upon patients complain. Pharmacotherapy is the most frequently recommended interventions used for the treatment of CNSLBP.[6]Before initiation of pharmacotherapy red flag and yellow flag signs should be ruled out.

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Pharmacotherapy can treat symptoms of pain and muscle stiffness. Each class of drug has unique efficacy and side effects. Chief pharmacological agents include acetaminophen, NSAIDS, opioids, tramadol, skeletal muscle relaxants, tricyclic antidepressants and SSRI, anticonvulsants, calcium, vitamin D, steroids as well as some locally active agents. These agents are used in various permutations and combinations. NSAIDS are the backbone of pharmacotherapy. Till date there is no gold standard guidelines for management of CNSLBP. The primary focus of the study was on the prescribing pattern of NSAIDS. The effectiveness of various NSAIDS in ameliorating CNSLBP was also considered.

Materials and Methods

This prospective, observational, and questionnaire-based study was conducted in the outpatient Department of physical medicine and rehabilitation (PMR) and Department of Pharmacology of R G KAR Medical college and hospital, Kolkata. 130 newly diagnosed CNSLBP patients were selected after satisfying inclusion and exclusion criteria. Before initiation of the study due permission from institutional ethics committee was obtained. The patients were enrolled in the study after considering the exclusion and inclusion criteria and after obtaining written consent form. Newly diagnosed patients of both sexes in the age group of 18-55 years who were prescribed monotherapy with standard dose and those who were able to respond appropriately to the VAS and the Oswestry low back pain disability questionnaires were included in the study. Patients with deformities in the region of dorso-lumbar and lumbosacral spine, history of trauma, previous spinal surgery, patients with TB spine, immunocompromised patients or those with malignancy, pregnancy, patients with neurological disease, renal or hepatic dysfunction and any adverse drug reaction or contraindication to any drug involved in the study were excluded from the study.

This was a systemic structured study and an initial piloting with 10 patients for 1 month were done to ensure feasibility of VAS and Oswestry low back pain disability questionnaire and those patients were excluded from the study. The mode of interview was finalized after incorporating suggestion from the faculties. The main study was commenced after piloting. The mean reduction of pain score over a period of 12 weeks were noted from the VAS for the different analgesics that were prescribed. The mean reduction in the extent of disability were noted over a period of 12 weeks from the ODI score for all the different analgesics that were prescribed. Analgesics involved in the study prescribed from PMR OPD were Aceclofenac – 100 mg twice daily, paracetamol- 650 mg twice daily, ibuprofen - 400 mg thrice daily, etodolac- 400 mg thrice daily, etoricoxib- 90 mg once daily, naproxen- 250 mg twice daily, piroxicam- 20 mg once daily. The analgesic drugs used in the study were prescribed for the initial 2 weeks. This was followed by a period of 10 weeks where analgesic drugs were not administered. Non analgesic drugs such as calcium, vitamin D3, pregabalin, amitriptyline and PPIs along with physical modalities of therapy and exercises were prescribed for the entire 12 weeks of the study.

Statistical analysis: All data represented as suitable pie charts, bar diagrams and tabulations. All statistical analyses were performed by use of Statistical Package for Social Sciences (SPSS) Ver 13.0. Paired t test done to compare the Mean VAS score & mean Oswestry Disability Index (ODI) among different follow up visits. Comparative analysis based on Mean VAS score & mean Oswestry Disability Index (ODI) between the 3 most commonly prescribed drugs done by ANOVA. *P* value <0.05 taken as statistically significant result.

Results

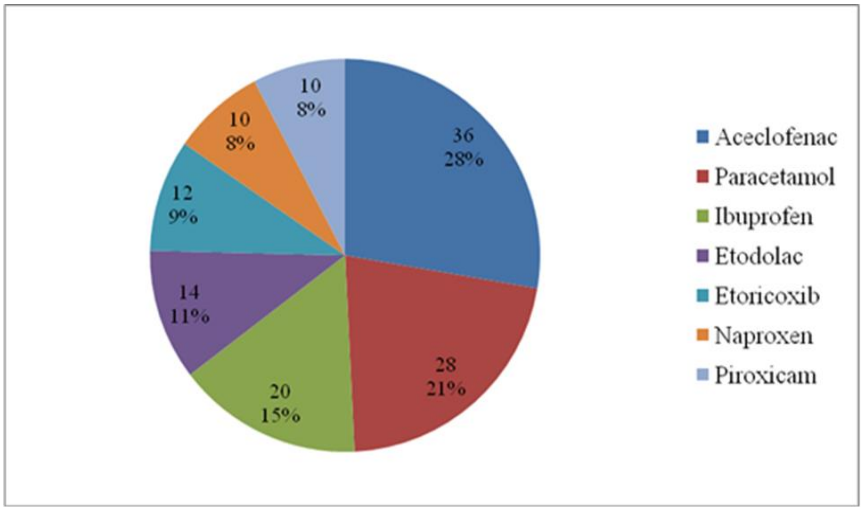

Fig 1: Pie chart showing distribution of different drugs prescribed in the study population for CNSLBP (n=130)

A total of 130 patients were included in the study. In the study population 46 (35%) were male and 84 (65%) were female. The mean age of the female study population was 40.46 years with ± 7.17 standard deviation and that of male population was 39.96 with ±7.703 standard deviation. Out of 130 patients 56(43.07%) belong to age group of 41-50 years, 49(37.69%) in the age group of 31-40 years, 13(10%) in less than 31 years of age group, 12(9.24%) in age group of more than 50 years. The distribution of the study population according to BMI was 12(9%) patients were below 18.5 kg/m^2, 53(41%) patients were between 18.5- 24.99 kg/m^2, 37(28%) patients were between 25- 29.99 kg/m^2 and 28(22%) patients were more than 30 kg/m^2. The mean BMI of males was 26.38 kg/m^2 and that of females was 25.35 kg/ m^2. The distribution of study population according to the drugs prescribed were 36(28%) patients received Aceclofenac,28(21%) patients received Paracetamol, 20(15%) received Ibuprofen,14(11%) patients received Etodolac, 12(9%) patients received Etoricoxib,10(8%) patients received Naproxen, 10(8%) patients received Piroxicam.

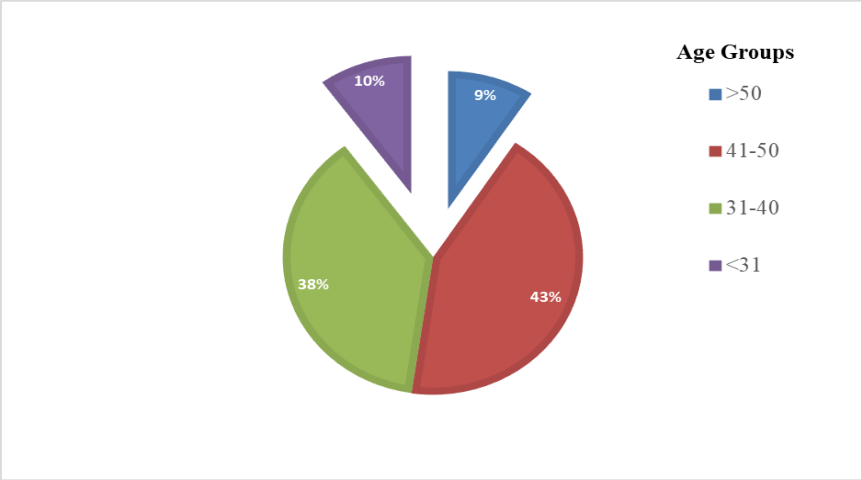

Fig 2: Pie chart showing distribution of age group in the study population (n=130)

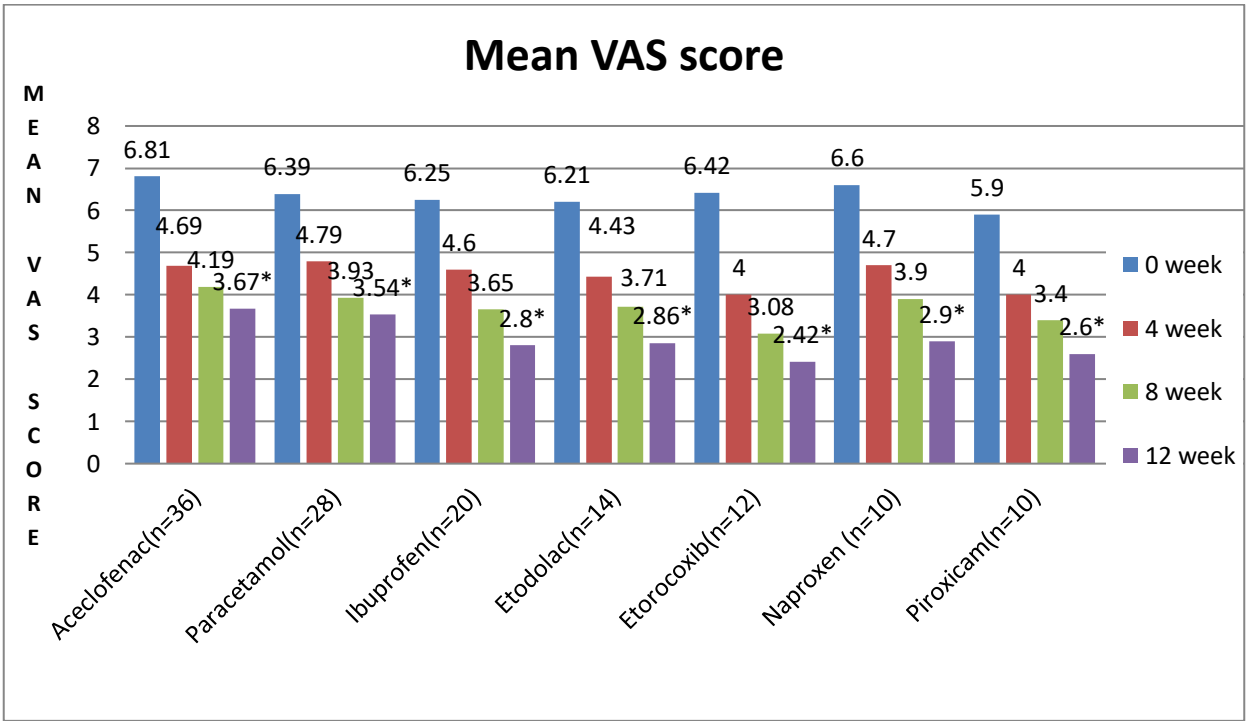

Fig 3: Mean VAS score changes over a period of 12 weeks after receiving different drugs

*** *P* value <0.0001 comparing Mean VAS score between 1st visit (0 weeks) & 4th visit (12 weeks) by Paired T test**

The mean VAS score in the Aceclofenac, Paracetamol, Ibuprofen, Etodolac, Etoricoxib, Naproxen, Piroxicam study group at 0 week was 6.81, 6.39, 6.25, 6.21, 6.42, 6.60, 5.90 at 4 week was 4.69, 4.79, 4.60,4.43, 4.00, 4.7, 4.00 at 8 week was 4.19, 3.93, 3.65, 3.71, 3.08, 3.90, 3.40 and at 12 week was 3.67,3.54, 2.80, 2.86, 2.42, 2.90, 2.60. A significant p-value of <0.0001 was revealed when compared between baseline (0 week) and fourth visit (12 weeks) in all the study groups as showed in figure 3.

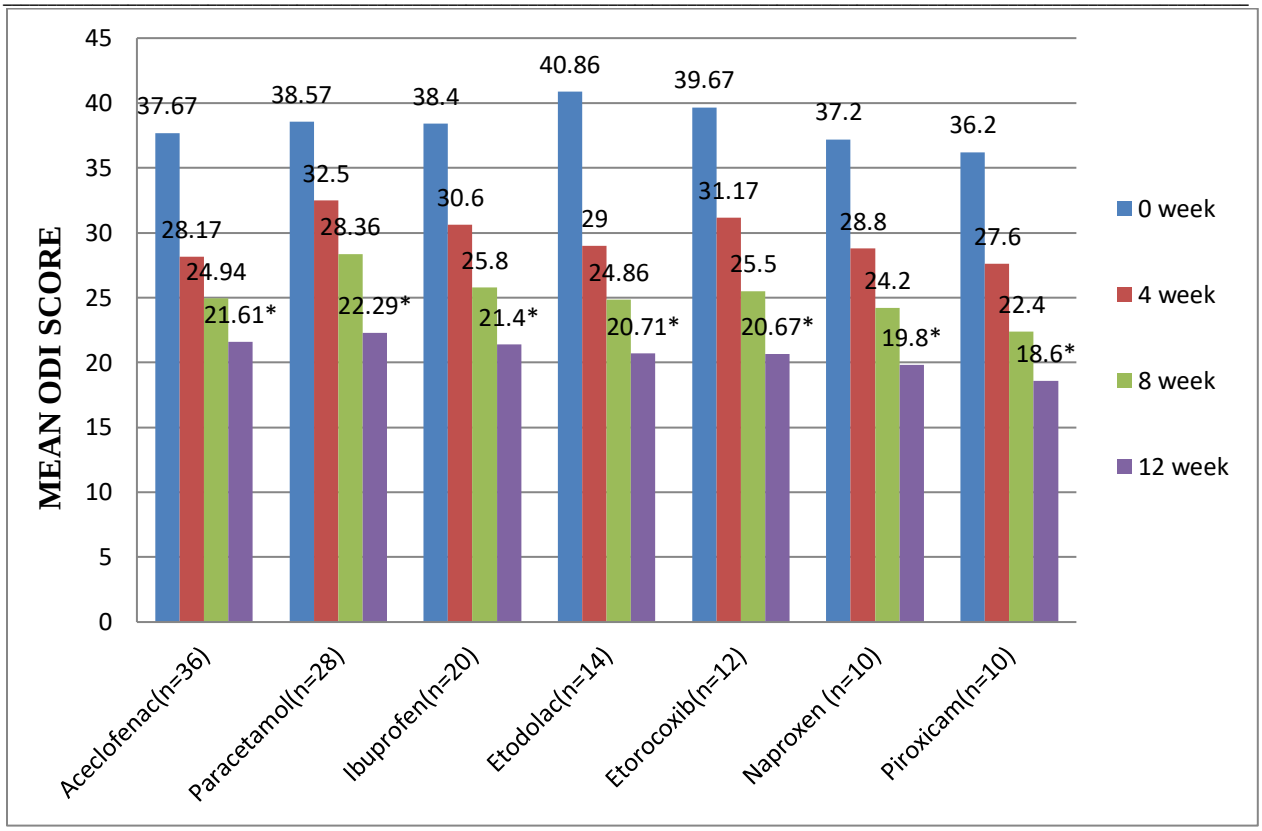

Fig 4: Mean ODI score changes over a period of 12 weeks after receiving different drugs

***P* value <0.05 comparing Mean VAS score between 1st visit (0 weeks) & 4th visit (12 weeks) by Paired T test**

The mean ODI score in Aceclofenac, Paracetamol, Ibuprofen, Etodolac, Etoricoxib, Naproxen, Piroxicam study group at 0 week was 37.67, 38.57, 38.40, 40.86, 39.67, 37.20, 36.20 at 4 week was 28.17, 32.50, 30.60, 29.00, 31.17, 28.80, 27.60 at 8 week was 24.94, 28.36, 25.80, 24.86, 25.50, 24.20, 22.40 and at 12 week was 21.61, 22.29, 21.40, 20.71, 20.67, 19.80, 18.60 as showed in figure 4. A significant p-value of <0.05 was revealed when compared between baseline (0 week) and fourth visit (12 weeks) in all the study groups.

Comparative analysis of the three most prescribed analgesics involved in the study such as Aceclofenac, Paracetamol, Ibuprofen using VAS score showed statistically significant differences in the 4th and 12th weeks of follow up (p value at 4th week and 12 week was 0.040 and 0.005), but no statistically significant difference was found at 8th weeks of follow up (0.509) as showed in the table 1.

Table 1: Comparative analysis of the most frequently prescribed analgesics in the study population (Aceclofenac, Paracetamol and Ibuprofen) using the ODI score

Drugs	Reduction at 4 weeks (Mean ± SD, %)	Reduction at 8 weeks (Mean ± SD, %)	Reduction at 12 weeks (Mean ± SD, %)
Aceclofenac(n=36)	31.2 ± 11.1	38.5 ± 9.7	46.5 ± 11.9
Paracetamol(n=28)	25.14 ± 7.5	38.78 ± 12.0	44.94 ± 8.1
Ibuprofen(n= 20)	26.6 ± 9.8	41.7 ± 9.0	54.8 ± 11.0
P-value	0.040	0.509	0.005

Comparison done between different drugs at each visit using ANOVA.

Table 2: Comparative analysis of the three most prescribed analgesics in the study (Aceclofenac, Paracetamol and Ibuprofen) using the ODI score

Drugs	Reduction at 4 weeks (Mean ± SD, %)	Reduction at 8 weeks (Mean ± SD, %)	Reduction at 12 weeks (Mean ± SD, %)
Aceclofenac(n=36)	25.4 ± 10.7	33.8 ± 11.3	42.6 ± 14.8
Paracetamol (n=28)	15.79 ± 4.8	26.76 ± 9.0	42.42 ± 8.0
Ibuprofen(n= 20)	20.6 ± 5.3	33.3 ± 7.8	44.6 ± 6.7
P-value	0.0001	0.014	0.773

Comparison done between different drugs at each visit using ANOVA.

Statistically significant difference with the three commonly prescribed analgesics i.e., Aceclofenac, Paracetamol, Ibuprofen using ODI score showed were seen in the 4th and 8th week of follow up (p value at 4th and 8th week was 0.0001 and 0.014), but no statistically significant difference was found at 12th weeks of follow up (0.773) as showed in table 2.

Discussion

The present study focused on the distribution of age pattern in the study subjects. Out of 130 participants maximum, i.e., 56 (43.07%) belong to age group of 41-50 years. There was female preponderance in study subjects diagnosed with CNSLBP. The mean BMI for both male (26.38 kg/m^2) and female (25.35 kg/m^2) study subjects were in the overweight category (25-29.99 kg/m^2). Aceclofenac was the most prescribed drug, followed by Paracetamol, Ibuprofen, Etodolac, Etoricoxib, Naproxen and Piroxicam.There was significant reduction in mean VAS Score and mean ODI Score for all the different analgesics. Paired T test revealed p-value < 0.05, when compared when compared between baseline visit at 0 week and second visit at 4th week; between baseline visit at 0 week and fourth visit at 12 weeks. A significant difference was noted in the response between Aceclofenac, Paracetamol and Ibuprofen from the mean VAS score at first follow up (4th week) and third follow up (12th week). ANOVA test was done. A significant difference was noted in the response between the three most prescribed drugs from the ODI score at first follow up at 4 weeks and secondfollow up at 8 weeks from the baseline. ANOVA test was done. All the different NSAIDs were effective in reducing pain as noted from the VAS scale. All of them were effective in reducing disability as evident from the ODI.

The studies at JNM Hospital & COM [7]and Ayaan Institute of Medical Sciences, Teaching Hospital and Research Centre [8] observed female preponderance and similar age distribution like the present study. The mean BMI of females and males were in the overweight category. Positive associations between overweight and LBP have been observed in many studies. [9,10] The association between obesity and LBP has been reported to be stronger among women than men. [11,12] The study at JNM Hospital & COM revealed that Paracetamol was the most commonly prescribed drug whereas it was the second most commonly prescribed in present study. A study conducted at Kempegowda Institute of Medical Sciences; Bangalore revealed that Aceclofenac was the most commonly prescribed drug similar to the present one.[13] This could be due to similar socio-economic status of the study population. A meta- analysis of four trials [14]compared the efficacy of NSAIDS with that of placebo and the pooled results indicated a statistically significant decrease in pain intensity in the VAS score in patients with chronic LBP. A statistically significant reduction in disability by ODI was observed at Kasturba Medical College, Bangalore.[15] The present study also observed a significant reduction in ODI score and VAS score for all the analgesics used.

Conclusion

There was female preponderance in study subjects diagnosed with CNSLBP. The mean BMI for both male and female study subjects were in the overweight category. There was significant reduction in mean VAS Score and mean ODI Score for all the different analgesics. For all the seven different analgesics prescribed for the study population, significant reduction was observed in mean VAS score and mean ODI score, when compared between initiation of therapy (0 week) and 2nd follow up at 4 week and also between initiation of therapy (0 week) and final follow up at 12 weeks. When comparison was done between the three commonly prescribed drugs i.e., aceclofenac, paracetamol and ibuprofen by ANOVA test, significant reduction in ability to reduce CNSLBP by mean VAS score was noted during follow up at 4 weeks and 12 weeks, whereas significant reduction in the ability to reduce functional disability by ODI score was noted during follow up at 4 weeks and 8 weeks.Present study was conducted with few subjects and is a small effort to overview this huge burden in the society. A randomized, blinded, clinical trial may be initiated in future for better management of CNSLBP.

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