

Evaluation of the Effects of Lumbosacral Corset on the Patients with Chronic Non-specific Low Back Pain

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Abstract

A randomised clinical trial was conducted in the Department of Physical Medicine & Rehabilitation (PMR), Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh. A total of 81 patients having chronic LBP were included according to the selection criteria. Out of them, 31 (38.3%) were male and 50 (61.7 %) were female in a ratio of 1: 1.61. The mean age of the patients in study was 41.65 ± 8.41 years. Female persons were affected in their earlier ages (between 30 and 45 years) than male. Most of the patients were housewives (54.3%). The patients were divided randomly into two groups by the way of lottery for the clinical trial. Group-A patients were treated with NSAIDs, activities of daily living instructions (ADLs) and lumbosacral corset and group-B patients were treated with NSAIDs and ADLs. The patients were followed up weekly for five weeks and significant improvement was recorded after the treatment in both the groups ($p=0.001$). In comparison between two groups, it was found that there was no significant improvement in pre-treatment, after 1st week and after 3rd week. A little bit improvement was found in group-A patients than group-B after 4th week ($p=0.06$). But finally, there was significant improvement in group-A than group-B patients after 5th week ($p=0.005$). So, it may be concluded that both the treatment is effective for the patients with chronic non-specific LBP. But the patient may be more benefited if lumbosacral corset is used as an adjunct to NSAIDs.

Key words: Low back pain, lumbosacral corset.

Introduction:

Low back pain (LBP) is most common, experienced at some time by up to 80 % of the population¹. Pain in the area between the lower rib case and gluteal folds is called low back pain². LBP is the most common medical cause of inability to work in the western

countries³ and the leading cause of disability in people under the age of 45 years^{4,5} specially most prevalent medical disorders in industrialised societies⁶. Disability related to back pain has increased exponentially over the past 20 years due, at least in part, to psychological and social factors that influence adaptation to back pain early in the process⁷. Defining LBP is difficult, but it refers to a symptom complex in which pain is localised to the lumbar spine or referred to the leg or foot and majority of cases of the backache is associated with some abnormality of the intervertebral discs at the lowest two levels of the spine⁸⁻⁹. Abnormalities in the lumbar spine are common and degenerative changes virtually be found in all older people¹⁰. Despite its high prevalence, LBP remains poorly understood and inadequately treated. This is due to the heterogeneity of the patients' population, and the lack of a simple and easy to apply, clinically useful system for characterisation of patients¹¹. Non-specific LBP of mechanical origin is second only to the common cold as a cause of self-limiting symptoms and disability in the community¹², 70% of patients with an episode of LBP recover within one month, and 90% within 3 months. Only 4% patients will have symptoms larger than 6 months. This

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relatively small number of patients' account for 85% to 90% of funds spent on the treatment and compensation for LBP. Only 50% of these chronically symptomatic patients return to work, according to one study⁶. LBP affects 60%-80% of US adults at some times during their lives, up to 50% have pain within a given year, in 5%-10% of patients with LBP become chronic¹³. Another study¹⁴ in the USA it is found that LBP is the most common single musculoskeletal complaint and a major cause for being out of work, resulting in billions of dollars in lost wages and compensations payment annually. It was estimated in 1997 that the financial cost of LBP accounting for medical bills compensation and forfeited productivity, was somewhere between \$38 billion and \$ 50 billion in the United States¹⁵. The treatment and management of LBP is not simple. There are many divergent ways of management of LBP. Chronic LBP is resistant to treatment, and patients are often referred for multidisciplinary treatment. Current multidisciplinary bio-psychosocial rehabilitation regards disabling chronic pain as the result of multiple interrelating physical, psychological, and social or occupational factors¹⁶. Bangladesh is a developing and densely populated country with very limited resources and poor management. So, for various reasons we cannot manage a huge number of disabled patients with low back pain with our present resources and management system. Lumbar corset is used to support the lumbar spine as a physical modality which is used to fix the lower back and abdomen. Fixation of the lower back reduces LBP by 3 actions: (1) limiting the movement of painful muscles, intervertebral joints, intervertebral discs, and fractured vertebral bodies, (2) maintaining good posture and (3) reducing the mechanical load on the lower lumbar spine¹⁷.

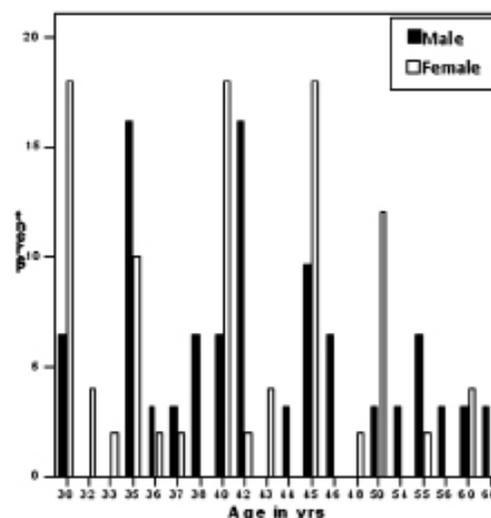
Several studies of pain and instability of the lower extremities indicated that the wearing of elastic lumbar orthoses improved the patients' feeling of joint stability and improved the subject's joint position sense by increasing afferent proprioceptive input *via* the mechanoreceptors of the skin and it can affect LBP and instability or can improve restricted proprioception¹⁸. But still the efficacy is not been established in case of chronic non-specific LBP. So, the aims of this study is to find out the effects of lumbosacral corset on the patients with chronic non-specific LBP.

Materials and Methods:

This randomised clinical trial was conducted in the Department of Physical Medicine & Rehabilitation (PMR), Bangabandhu Sheikh Mujib Medical

University (BSMMU), Dhaka, from April 2008 to March 2009. Patients having chronic non-specific LBP were selected according to the following clinical criteria: patients of both sexes, age ≥ 30 years and ≤ 70 years, having complaints of LBP for more than three months excluding any specific chronic cause, having no evidence or history of nephropathy or peptic ulcer diseases. Before starting the study ethical clearance was given by the institute and informed consent was taken from the patients properly. A total of 100 patients were selected for the study according to the selection criteria. Selection was done randomly by the way of lottery and divided into two groups. Group-A (n=50) patients were treated with NSAIDs, ADLs and lumbosacral corset and group-B (n=50) patients were treated with NSAIDs and ADLs. Naproxen (250mg) twice daily orally was prescribed in both the groups with capsule omeprazole (20mg) twice daily. All the drugs were given from the same company to avoid any discrepancy of efficacy. Activities of daily living (ADL) instructions were given to protect the back from pain in both the groups. Lumbosacral corset was given to the group-A only and advices were given to these patients to use corset during journey and activity and not to use it during sleeping. The patients were followed up weekly for five weeks and the outcome were recorded accordingly. Assessment of pain intensity, disability, and physical impairment were done by using visual analogue scale, Schober's test, Oswastry Disability Index and Modified Zung Index. The numerical data were analysed statistically by using the SPSS-package program (version-18) for Windows. Student's 't' test was done to see the level of significance.

Fig I: Distribution of Sex in Relation to Age of the Study Subjects (n= 81)



Results:

A total of 100 patients were included but 19 patients were dropped out from the study because they cannot follow the instructions of daily living properly. So, 81 patients followed the treatment allocated for them properly. Out of them, 31 (38.3 %) were male and 50 (61.7%) were female and male: female ratio was 1: 1.61. The mean age of the patients was 41.65 ± 8.41 years. Female persons were affected in their earlier ages ie, between 30 and 45 years, (Fig1) than male. Before admission into the clinical trial, baseline characteristics of the patients of the two groups were compared and found identical (Table 1). All patients are married except one

who was unmarried, maximum patients gave the history of gradual onset of the pain (80.2 %), some had history of sudden onset (13.6%) and a few gave the history of pain after trauma (6.2 %). Pain of most of the patients relieved by rest (56.8 %) and lying flat (43.2 %) and aggravated by activity. Maximum patients had the pain intermittent in character (84 %) but 16% patients had the pain of constant in character. There was significant improvement after treatment in group-A. In respect to time point improvement, marked improvement was started to occur after one week (p = 0.001, 95% CI = 2.89 to 5.77, Table 2). Improvement gradually increased day by day and after the end of treatment, highly

Table 1- Baseline Clinical and Investigation Criteria of the Patients with LBP

Group	Age in years	Height in cm	Weight in kg	Pulse/minute	SBP in mm Hg	DBP in mmHg	ESR after 1st hour (mm)	Blood sugar (2HP-PBS in mmol/l)	Serun. uric acid
A (n=42)	42.81 ± 9.05	155.91 ± 8.92	57.90 ±10.01	80.88 ±5.49	122.57±14.28	76.98 ±7.77	23.90 ± 13.04	6.47 ± 2.16	4.36 ± 1.13
B (n=39)	40.41 ± 7.59	160.07 ±4.53	55.61 ±5.97	79.44 ±563	123.85±12.95	75.64 ±10.46	22.15 ± 16.27	6.76	4.22 ± 0.94
p-value	0.19	0.01	0.21	0.24	0.67	0.51	0.59	0.51	0.55
95% CI	-1.28 to 6.08	-7.27 to -1.05	-1.33 to 5.91	1.23to -1.02	-7.29 to 4.74	-2.77 to 5.44	- 4.81 to 8.31	-1.17 to 0.59	-0.32 to 0.60

The results are expressed in mean ± standard deviation (SD). n = Number of the patients participated in the clinical trial, SBP-Systolic BP, DBP-Diastolic BP.

Table 2- Treatment Responses on Different Time Points in Group-A (n = 42)

Time-point score	Mean ± SD	P-value	95% CI
Pre-treatment Vs W1	30.71 ±7.19 Vs 26.38	0.001	2.89 to 5.77
Pre-treatment Vs W2	30.71 ± 7.19 Vs 23.84 ± 4.96	0.001	5.46 to 9.01
Pre-treatment Vs W3	30.71 ± 7.19 Vs 20.69 ± 4.67	0.001	7.72 to 12.31
Pre-treatment Vs W4	30.71 ± 7.19 Vs 18.19 ± 5.18	0.001	10.08 to 14.96
Pre-treatment Vs Post-treatment	30.71 ± 7.19 Vs 14.88 ± 4.73	0.001	13.41 to 18.25

The results are expressed in mean ± standard deviation (SD). n = Number of the patients participated in the clinical trial. W= weak.

Table 3 - Time-point Treatment Response in Group-B (n = 39)

Time-point	Score in mean ± SD	p-value	95 % CI
Pre-treatment Vs W1	30.41± 7.35 Vs 27.74 ± 7.95	0.001	1.17 to 4.17
Pre-treatment Vs W2	30.41± 7.35 Vs 24.62 ± 7.64	0.001	4.04 to 7.54
Pre-treatment Vs W3	30.41± 7.35 Vs 22.67 ± 7.19	0.001	5.85 to 9.63
Pre-treatment Vs W4	30.41 ± 7.35 Vs 20.62 ± 6.16	0.001	7.55 to 12.03
Pre-treatment Vs Post-treatment	30.41± 7.35 Vs 18.44 ±6.03	0.001	9.88 to 14.06

The results are expressed in mean ± standard deviation (SD). n = Number of the patients participated in the clinical trial. W=weak

significance improvement was found ($p=0.001$, 95% CI = 13.41 to 18.25, Table 3). Significant improvement also found after treatment in group-B. In respect to time point improvement, marked improvement was started to occur after one week ($p = 0.001$, 95 % CI = 1.17 to 4.17, Table 3). Improvement gradually increased day by day and after the end of treatment, there was highly significance of improvement ($p= 0.001$, 95 % CI= 9.88 to 14.06, Table 3). In comparison between two groups,

it was found that there was no significant difference in improvement up to third week. But more improvement was found in group-A than group-B after 4th week ($p= 0.06$). Finally, there was more improvement in group-A than group-B after 5th week ($p= 0.005$, Table 4). This indicates that NSAIDs are effective for the improvement of the patients with chronic LBP but when lumbar corset is used as an adjunct to NSAIDs, more improvement was found than only NSAIDs receiving group.

Table 4 - Comparative Improvement of Symptoms between Group-A and Group-B in Different Time Points

Group	Score at W0	Score at W1	Score at W2	Score at W3	Score at W4	Score at W5
A (n=42)	30.71±7.19	26.38 ± 5.45	23.48 ± 4.96	20.69 ± 4.67	18.19 ± 5.16	14.88 ±4.73
B (n=39)	30.41±7.35	27.74 ± 7.95	24.62 ± 7.64	22.67 ± 7.19	20.62 ± 6.16	18.44 ±6.03
95 % CI	-2.91 to-3.52	-4.41 to 1.68	-4.02 to 1.74	-4.69 to-0.73	-4.95 to 0.10	-5.97to -1.13
p-value	0.85	0.37	0.43	0.15	0.06	0.005

The results are expressed in mean ± standard deviation (SD), n = Number of the patients participated in the clinical trial. W=week

Discussion:

In this study, significant improvement of symptoms in both the groups began to appear at the end of first week ($p= 0.001$) and it was increasing day by day and finally there was highly significant improvement found ($p= 0.001$). But, in comparison between groups no significant difference of improvement was found at up to third week. After 4th week, more improvement was found in group-A than group-B ($p= 0.06$). In group-A, we prescribed lumbosacral corset and found more improvement, but in group=B, we prescribed NSAIDs without lumbosacral corset. At the end of treatment, there was more significant improvement in group-A than group-B patients after 5th week ($p= 0.005$). This indicates that NSAIDs are effective for the improvement of the patients with chronic LBP but when lumbar corset is used to protect the back with NSAID, more improvement was found than the patient receiving only NSAID. Chard and Dieppe¹⁹ reported in a review that aids and bracing is moderately effective in osteo-arthritis. This is in favour of this study. In our study, patients were also advised to protect the back by maintaining activities of daily living (ADLs). In some other studies^{20,21} it was also found that ADL has beneficial effects on chronic LBP. These all findings support the results of the present series, although lumbar orthosis has shown biomechanical effects on trunk performance, including stiffening of the torso. First, wearing a corset can restrict the hyperextension of the lumbar spine,

which may be a pain generating manoeuvre associated with spondylosis or facet syndrome. Second, wearing an hard corset can reduce the magnitude of lumbar rotation and increase hip rotation, changes that may benefit patients with conditions of lumbar disc degeneration²². A study²³ over 102 patients showed 64 were females (62.7%) and 76 (74.5%) patients had worn the lumbar corset for more than 1 year of duration where ninety (88%) patients normally wore the corset all day or most part of the day and there was more improvement in lumbar corset user group. This also suggests that wearing lumbar corset is useful to reduce chronic LBP.

Actually, lumbar support in the form of lumbar corset is used as an adjunct to NSAIDs therapy for pain management and in the maximum study, there is better tolerability and better improvement is found. In some another reviews, it was found that exercise is as effective intervention¹⁹ and some reported that exercise is as effective as NSAIDs²⁴. In a review²⁵ it was reported that exercises seemed not to be better than bed rest and other conservative treatments like traction, manipulation, hot packs, or corsets. So it may be said that conservative treatment like lumbosacral corset is as effective as exercise.

Conclusions:

It may be concluded that both the treatment (NSAID and lumbosacral corset) is effective for the treatment of chronic non-specific LBP. But the patient may be more

benefited if lumbar support in the form of lumbosacral corset is used as an adjunct to NSAIDs.

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