

## A Comparative Study on Indomethacin Suppositories with Physical Therapy and Conventional Treatment Modalities for Lumbago Sciatica

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### Abstract

**Introduction:** Most of the patients with Lumbago sciatica can be managed conservatively in a primary care setting with the expectation of a good outcome. It is one of the most common causes of pain and disability pertinent to lumbar spine. There are many alternative forms of treatment for this condition but the evidence of the efficacy of Indomethacin suppositories is yet to be established from clinical trials. Though several interventions are used in combination with physical therapy but indomethacin suppositories is commonly employed as a first line agent in the management of lumbago sciatica.

**Objective:** To ascertain whether a comparative effect of Indomethacin suppositories with other conventional treatment modalities produce a significant difference in the outcome.

**Materials and Methods:** This experimental clinical study was carried out at the Department of Physical Medicine, Combined Military Hospital (CMH), Dhaka and Department of Physical Medicine and Rehabilitation BSMMU, from 01 September 2015 to 28 February 2016. A total of 153 patients were randomly selected for trial and they were divided by lottery into 3 Groups. Group-"A" received Indomethacin suppositories with physical exercise and patients were 54 in number. 'Group-B' received NSAIDs (except indomethacin suppositories), SWD /MWD/IFT/TENS and patients were 47. In 'Group-C' there were 52 patients who received counseling with only physical exercises. Each Group received above-mentioned treatment modalities 5 days in a week for 6 weeks.

**Results:** The results were observed and noted with the help of visual analogue scale (VAS). The highest significant improvement was observed in 'Group-A' throughout the whole treatment period. The significant difference of improvement was found between groups finally in week 4 (W<sub>4</sub>) to week 6 (W<sub>6</sub>). The group received Indomethacin suppositories with physical exercise shows improvement of patients with lumbago sciatica.

**Conclusion:** The use of Indomethacin suppositories with physical therapy and the conventional modalities of treatment comparison help the physician to provide treatment facilities. The result was found better in groups those who received Indomethacin suppositories (Group-A) rather than those Groups who received other conventional treatment modalities.

**Key-words:** Lumbago sciatica, Visual Analogue Scale (VAS), Activities of daily livings (ADLs).

### Introduction

Lumbago sciatica is a symptom but not a disease or diagnosis<sup>1</sup>. The low back pain is considered to include dorsal pain located anywhere between the 12th thoracic vertebra and lower buttock up to gluteal folds or anus<sup>2</sup>. Back pain has been termed as "an illness in search of a disease"<sup>3</sup>. When the back pain radiates down to gluteal fold it is sciatica. When the pain is up to three months and with immediate onset, it is acute lumbago. Lumbago may be recurrent when it recurs after a pain-free interval. About 40% of people say that they have had low back pain within the last 6 months Eight percent of general populations are thought to suffer from back pain at some stage during their life time<sup>4</sup>. Nonspecific or mechanical back pain with severe pathology in vast majority falls into the category of back pain<sup>5</sup>. Studies have shown the lifetime prevalence as high as 84%. Inflammation of the joint creates pain signals which are implicated in 15-45% of patients with low back pain<sup>6</sup>. Most episodes resolve with or without treatment. Between 80% and 90% of the healthcare and social cost of back pain are for the 10% who develop chronic low back pain and disability. Just over 1% of adults in the USA are permanently disabled by back pain, and another 1% is temporarily disabled. The percentage of patients disabled by back pain, as well as the cost of low back pain, has steadily increased over the past 25 years<sup>7</sup>. It is estimated that 2 to 5 percent of industrial workers experience low back pain each year in western countries<sup>8</sup>. This study was conducted to find out the

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effect of Indomethacin suppositories with physical therapy and other conventional treatment modalities like deep heat modalities, ADLs (Activities of Daily livings), physical exercises and other oral NSAIDs on the patients with lumbago sciatica.

### Materials and Methods

This experimental clinical study was carried out at the Department of Physical Medicine CMH, Dhaka and Department of Physical Medicine and Rehabilitation, Bangabandhu Sheikh Mujib Medical University (BSMMU) from 01 September 2015 to 28 February 2016. The objectives of this study were to compare the effects of Indomethacin suppositories with the others conventional treatment modalities. According to the selection criteria, 153 patients were selected randomly for the study. The selected patients were divided into three Groups (Group-A, Group-B, and Group-C) by randomly. Patients in 'Group-A' were treated with Indomethacin suppositories and physical exercises with counseling and numbers of patients were 54. Patients in 'Group-B' were treated with oral NSAID (except indomethacin suppositories) with deep heat modalities and numbers of patients were 47. In 'Group-C' patients were treated with counseling and only physical exercises and number of patients was 52. Patients were observed weekly from week one to week six as  $W_0$ ,  $W_1$  to  $W_6$ .

The study was approved by ethical committee of Directorate General of Medical services (DGMS), Ministry of Defense. Before enrollment patient received detailed written and verbal information regarding the aim of the study. Patients completed the questionnaire during or before the treatment session.

The statistical analysis of the data was performed using SPSS version 15 (SPSS Inc. Chicago IL, USA). The results related to the continuous variables are presented as mean $\pm$ SD, median and interquartile range and those related to the quantitative or categorical data are shown as percentage and frequency. Statistical analyses were performed using paired t-test and repeated measuring test and  $p < 0.05$  was considered as statistically significant.

### Results

In this study, the female was found affected more with Lumbago sciatica than the male and the male-female ratio was 1: 1.6 (Table-I).

**Table-III:** Distribution of patients by sex (n=153)

Sex	No of patients	Percentage
Male	58	37.9
Female	95	62.1
Total	153	100

Minimum age of the patients was 30 and maximum 70 years irrespective of sex and mean age of both sexes was  $47.82 \pm 7.96$  years. Most of the patients 78(50.98%) belonged to age Group 40-49 years followed by 50-59 years 42(27.45%) (Table-II).

**Table-II:** Distribution of patients by age (n=153)

Age in years	Frequency	Percentage
30-39	17	11.11
40-49	78	50.98
50-59	42	27.45
60-70	16	10.46
Total	153	100

Table-III showed that the study patients had their occupation mostly as housewives 84(54.9%), Govt job employees were 42(27.2%) and labourer was least 11(7.1%).

**Table-III:** Distribution of patients by occupation (n=153)

Type of occupations	Frequency	Percentage
Housewives	84	54.9
Govt jobs	42	27.2
Business	16	10.8
Labourer	11	7.1
Total	153	100

It was observed from this study that out of 153 patients majority 90(58.81%) were due to prolonged sitting which aggravated the pain, next was due to prolonged standing which was found as another important aggravating factor of pain amongst 41(26.8%) patients. Due to prolonged walking 13 (8.49%) and leaning forward position was 9(5.9%) (Table-IV).

**Table-IV:** Distribution of patients by aaggravating factors of pain (n=153)

Aggravating factors	Frequency	Percentage
Prolong walking	13	8.49
Prolong standing	41	26.8
Leaning forward	9	5.9
prolong sitting	90	58.81
Total	153	100

Among 153 patients irrespective of sex it was observed that most of the patients 113(58.4%) were relieved of pain after lying flat, while 32(20.9%) after taking rest and 10(20.7%) with Indomethacin Suppositories (Table-V).

**Table-V:** Distribution of patients by relieving factors of pain (n=153)

Relieving factors	Frequency	%
Rest	32	20.9
Lying flat	113	58.4
Indomethacin suppositories	10	20.7
Total	153	100

Fifty four patients were included in 'Group-A' and all of them regularly took the treatments allocated to them. VAS for lumbago sciatica pre-treatment and post-treatment data was compared statistically. Pre-treatment vs post-treatment summation score was 63.60±4.18 vs 17.68±10.98. Combined treatment with Indomethacin suppositories exercise with counseling is effective for the improvement of the patients with Lumbago sciatica (Table-VI). Forty seven patients were included in 'Group-B' and all of them regularly took the treatments allocated to them. Pretreatment vs post-treatment summation score was 65.27±3.18 vs 20.15±3.66. Combined treatment with oral NSAIDs (except indomethacin suppositories) exercise with heating modalities was less effective than 'Group-A' (Table-VII). Fifty two patients were included in 'Group-C' and all of them regularly took the treatments allocated to them. Pre-treatment and post-treatment data were compared statistically. There was very less improvement at the end of treatment in 'Group-C' (Table-VIII).

**Table-VI:** Treatment response in 'Group-A' (n=54) at week<sub>0</sub> to week<sub>6</sub>

Time points	Mean ± SD	95% CI	P-value
W <sub>0</sub> vs W <sub>1</sub>	63.60 ±4.18 vs 57.02 ±4.41	4.531 to 8.629	<0.001
W <sub>0</sub> vs W <sub>2</sub>	63.60 ±4.18 vs 44.08 ±5.10	17.296 to 21.744	<0.001
W <sub>0</sub> vs W <sub>3</sub>	63.60 ±4.18 vs 37.38 ±6.72	23.551 to 28.889	<0.001
W <sub>0</sub> vs W <sub>4</sub>	63.60 ±4.18 vs 30.32 ±8.20	30.176 to 36.384	<0.001
W <sub>0</sub> vs W <sub>5</sub>	63.60 ±4.18 vs 24.22 ±9.43	35.901 to 42.859	<0.001
W <sub>0</sub> vs W <sub>6</sub>	63.60 ±4.18 vs 17.68 ±10.98	41.957 to 49.883	<0.001

**Table-VII:** Treatment response in 'Group-B' (n=47) at week<sub>0</sub> to week<sub>6</sub>

Time points	Mean ± SD	95% CI	P-value
W <sub>0</sub> vs W <sub>1</sub>	65.27±3.68 vs 64.38±3.28	-1.862 to 0.082	0.073
W <sub>0</sub> vs W <sub>2</sub>	65.27±3.68 vs 65.23±3.37	-1.024 to 0.944	0.936
W <sub>0</sub> vs W <sub>3</sub>	65.27±3.68 vs 64.54±6.43	-2.191 to 0.731	0.325
W <sub>0</sub> vs W <sub>4</sub>	65.27±3.68 vs 65.38±3.48	-0.889 to 1.109	0.828
W <sub>0</sub> vs W <sub>5</sub>	65.27±3.68 vs 64.73±3.57	-1.551 to 0.471	0.293
W <sub>0</sub> vs W <sub>6</sub>	65.27±3.68 vs 64.75±3.66	-1.544 to 0.504	0.317

**Table-VIII:** Treatment response in 'Group-C' (n=52) at week<sub>0</sub> to week<sub>6</sub>

Time points	Mean ± SD	95% CI	P-value
W <sub>0</sub> vs W <sub>1</sub>	62.53±4.99 vs 61.29±5.26	-2.67 to 0.19	0.089
W <sub>0</sub> vs W <sub>2</sub>	62.53±4.99 vs 61.3 ±3.62	-2.5 to 0.06	0.062
W <sub>0</sub> vs W <sub>3</sub>	62.53±4.99 vs 62.51±4.20	-1.306 to 1.266	0.975
W <sub>0</sub> vs W <sub>4</sub>	62.53±4.99 vs 61.69±4.69	-2.19 to 0.51	0.221
W <sub>0</sub> vs W <sub>5</sub>	62.53±4.99 vs 61.47±5.22	-2.484 to 0.364	0.143
W <sub>0</sub> vs W <sub>6</sub>	62.53±4.99 vs 61.76±5.16	-2.188 to 0.646	0.285

**Table-IX:** Comparative improvements of symptoms between 'Group-A' and 'Group-B' in different weeks

Group	W <sub>0</sub>	W <sub>1</sub>	W <sub>2</sub>	W <sub>3</sub>	W <sub>4</sub>	W <sub>5</sub>	W <sub>6</sub>
'Group-A' (n=54)	62.60±4.18	57.02±4.405	44.08±5.102	37.38±6.722	30.32±8.198	24.22±9.429	17.68±10.979
'Group-B' (n=47)	65.27±3.18	59.38±3.279	47.23±3.372	40.00±3.209	33.38±3.480	36.73±3.565	30.15±3.661
P-value	<0.001*	0.017*	0.004*	0.036*	0.035*	<0.001*	<0.001*
95% CI	-0.174 to -3.513	0.429 to -4.290	0.993 to -5.307	0.175 to -5.064	0.221 to -0.5.899	-1.083 to 6.103	-1.661 to 6.602

\*Highly significant improvement was observed throughout the whole treatment period in 'Group-A'.

**Table-X:** Comparative improvements in 'Group-B' and 'Group-C' in different weeks

Group	W <sub>0</sub>	W <sub>1</sub>	W <sub>2</sub>	W <sub>3</sub>	W <sub>4</sub>	W <sub>5</sub>	W <sub>6</sub>
'Group-B' (n=47)	65.27±3.181	59.38±4.62	47.23±3.372	40.00±3.209	33.38±3.480	31.73±3.565	30.15±3.661
'Group-C' (n=52)	64.53±2.987	56.29±4.26	47.31±3.615	40.51±4.203	33.69±4.686	32.47±5.221	30.76±5.157
P-value	0.092	0.084	0.927	0.587	0.764	0.511	0.587
95% CI	-1.601 to 0.120	-2.329 to 0.149	-1.657 to 1.817	-1.357 to 0.546	-1.752 to 2.372	-1.497 to 2.977	-1.627 to 2.847

The unremarkable improvement observed between 'Group-B' and 'Group-C'.

**Table-XI:** Comparative improvements of symptoms in between 'Group-A' and 'Group-C' in weeks

Group	W <sub>0</sub>	W <sub>1</sub>	W <sub>2</sub>	W <sub>3</sub>	W <sub>4</sub>	W <sub>5</sub>	W <sub>6</sub>
'Group-A' (n=54)	59.60±4.175	55.02±4.40	44.08±5.10	37.38±6.72	30.32±8.19	24.22±9.42	17.68±10.97
'Group-C' (n=52)	62.53±2.987	56.29±3.02	47.31±3.61	40.51±4.20	33.69±4.68	32.47±5.22	30.76±5.157
P-value	<0.001*	0.018*	0.003*	0.023*	0.041*	0.034*	0.042*
95% CI	-2.818 to 0.678	-2.551 to 1.091	1.099 to -5.360	0.426 to 5.833	0.149 to -0.6.591	0.240 to -6.259	-1.062 to 7.222

Significant improvement was observed in 'Group-A' than 'Group-C' throughout the study period.

## Discussion

The male-female ratio in this study is 1:1.64 and females were more affected. O'Neill et al<sup>9</sup> explored in UK adult population over age 50 years, finding 74% of men and 84% of women at 1:1.35 ratio to demonstrate back pain with increased incidence among individuals with more physical activity. Shakoor MA et al<sup>10</sup> in a study conducted with 102 patients of chronic low back pain in BSMMU from April 2006 to March 2007 found that male-female ratio was 1:1.43. These findings are consistent with this study.

The mean age of the patients in this study is 47.82±7.97 years, ranging from 30 to 70 years, and the majority of the patients 78(50.98%) belong to age Group of (40-49) years. This finding was consistent with the study Shakoor M et al<sup>10</sup> where the mean age was found 44.50±8.94. In Rothschild BM<sup>11</sup>, it was found that Lumbar spondylosis, while affecting 80% of patients older than 40 years, nevertheless was found in 3% of individuals aged 20–29 years in one study. This study supports the well-known phenomena that lumbago sciatica is a disease of middle age and elderly<sup>11</sup>.

In this study as occupation, the majority was housewives/ female 84(54.9%) and Govt or private employees were 27.2%. Moyeenuzzaman M et al<sup>2</sup> found 24% housewives, 15% students, 19% service holders, 13% farmers, 11% workers. Ahmed MS et al<sup>12</sup> found 28.9 % housewives/women in their study. Shakoor MA et al<sup>13</sup> in a study conducted with 102 patients in BSMMU found that most of the patients were housewives (58.8%). The reason of females affected more may be, in Bangladesh the housewives perform repetitive lifting and bending activities in furnishing their households. Example are washing, mopping floors, cooking and cutting things in an uncomfortable position. To the contrary, females after attaining adulthood they get hardly scope for regular physical exercises or walking or running. So those household activities may lead to recurrent rotational strain and minor compression injury causing an early degenerative process in the spine and also precipitates asymptomatic lumbago sciatica to a symptomatic one.

The improvement of symptoms within the three Groups began after one week of treatment. The trend of improvement continued throughout the whole period of six weeks in 'Group-A'. At the end of 6th-week significant improvements of symptoms were found in 'Group-A'. All these tested therapeutic modalities and exercise with Indomethacin suppositories were helpful for the patients with chronic lumbago. It may be noted that all Group got some improvement. But there is a significant difference between them in comparison to their effectiveness in 'Group-A' which was more effective than the 'Group-B' and 'Group-C'.

Rahman M found in their study that 77.4% patients improved after treatment with SWD<sup>14</sup>. In Shakoor MA it is stated that physical therapy was used as an adjunct to NSAID therapy<sup>10</sup>. But in this study, it was found that Indomethacin suppositories were effective in improving pain with physical therapy and counseling. In Jacobs JH in their study showed that indomethacin in the dose used was ineffective in the treatment of uncomplicated low back pain but that there was a significant preference for indomethacin over placebo in the group of patients with low back pain associated with radicular involvement<sup>15</sup>.

## Conclusion

To address Lumbago sciatica, an adequate management system in multiple approaches is needed. Lumbago sciatica is a pain bearing state of a patient. It needs immediate attention to relief pain. In this study, Indomethacin suppositories were found effective in improving pain with physical therapy and counseling. Considering the information gathered from this study, it can be concluded that the uses of Indomethacin suppositories with physical therapy seemed to improve the patients with lumbago sciatica more than other oral NSAIDs with conventional treatment modalities. An elaborate study may be recommended for future guideline for the management of the patient. Study with longer duration can be carried out with large number of subjects and multicentre study at different region of the country could be carried out.

## References

1. Back pain over view, Para 1, Page 26: Key topic in sports medicine. AA Narvani, P Thomas and B Lynn, 1st Ed, 2006, Roudledge.
2. Moyeenuzzaman M et al. A study on the patients with low back pain attending physical medicine department of IPGMR, 1992 (Dissertation).
3. Williams ME, Hadler NM. Sounding Board. The illness as the focus of geriatric medicine. N Engl J Med 1983; 308(22):1357-60.
4. Back pain over view page 25, para 25: Key topic in sports medicine by AA Nariani, P Thomas and B Lynn; 1st Ed, 2006, Roudlwdge.
5. Doherty M, Lanyon P, Raloston SH et al. Editors. Davidsons Principles and Practice of Medicine. Edinburg. Churchill livingstone 2002; 20:957-1047.
6. Middleton K and Fish DE. Lumbar spondylosis: Clinical presentation and treatment approaches. Curr Rev Musculoskelet Med 2009; 2(2):94–104.
7. Braddom RL, Buschbacher RM, Chan L, Kowalske KJ, Laskwski ER, Matthews DJ, Ragnarsson KT. Editors: Randall L, Braddom MD. Physical Medicine & Rehabilitation, 2nd ed. Philadelphia-London. WB Saunders 2007; 23:871-4.

8. Solomon L, Warwick DJ, Nayagam S. Back pain. In: Apley's system of orthopedics and fractures. New York, Oxford University Press 2001; 18:371-404.
9. O'Neill TW, McCloskey EV, Kanis JA et al. The distribution, determinants and clinical correlates of vertebral osteophytosis: A population based survey. The Journal of Rheumatology 1999; 26(4):842-8.
10. Shakoor MA, Rahman MS, Moyeenuzzaman M. Effects of deep heat therapy on the patients with chronic low back pain. Mymensingh Med J 2008 Jul; 17(2 Suppl):S32-8.
11. Rothschild BM. Lumbar spondylosis. Inmedicine publication 2008. Available via WebMD. <http://emedicine.medscape.com/article/249036-overview>.
12. Ahmed MS et al. A study of patients with Low Back Pain a Physiatric perspective 2002 (Dissertation).
13. Shakoor MA, Rahman MS, Moyeenuzzaman M. Effect of deep heat therapy on the patients with chronic low back pain. Mymensingh Med J 2008; 117:32-38.2001; 26(5):E93113.
14. Rahman MM. Low back pain: Clinical analysis of 342 cases. Bangladesh Med Col J 1999; 4(2):67- 71.
15. Jacobs JH, Grayson MF. Trial of an Anti-inflammatory Agent (Indomethacin) in Low Back Pain with and without Radicular Involvement Brit Med J 1968; 3:158-160.