

Original Article



Conservative Treatment Alone and With Diclofenac Sodium Phonophoresis on The Patients With Low Back Pain Due to Prolapsed Lumbar Intervertebral Disc

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Abstract

Background: Prolapsed lumbar intervertebral disc (PLID) one of the major causes of low back pain. The PLID has become an important and increasingly general health problem, both in Bangladesh and across the world. Phonophoresis has been used clinically since the early 1960s in attempts to drive these drugs transdermally into subcutaneous tissues. The efficacy of Phonophoresis has not been conclusively established in PLID linked low back pain.

Objective: To evaluate the effects of Diclofenac Sodium Phonophoresis on patients with low back pain due to PLID.

Materials and Methods: The comparative study was conducted on the 72 patients diagnosed as PLID after being confirmed by Magnetic Resonance Imaging (MRI) and, were randomly assigned to Group A (Control group) and Group B (Case group), 36 patients in each group. Visual analog scale (VAS), Straight leg-raising (SLR) test used to assess the effects on the last 3rd day of the consecutive week.

Results: There were significant differences of improvement in outcome measure between the two groups from pretreatment to week 4. After 4 weeks of treatment VAS score in Group A was 2.10 ± 0.5 and in Group B was 1.7 ± 0.5 , P-Value was 0.026. The significant improvement was observed in Group B patients, and according to Straight leg raising test of patients in Group A was 65.27 ± 7.36 and for group B it was 75.1 ± 6.9 . P-Value of 0.069 implies that it was not significant.

Conclusion: Effectively managed Diclofenac sodium Phonophoresis can reduce the pain consistency of PLID to a major extent.

Key words: Prolapsed lumbar intervertebral disc, Phonophoresis, Diclofenac sodium, Conservative treatment.

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Introduction

The low back pain is considered to include dorsal pain located anywhere between the 12th thoracic vertebrae and lower buttock up to the gluteal folds or anus.^{1,2} Prolapsed lumbar intervertebral disc (PLID) one of the major causes of low back pain. PLID refers to localized displacement of lumbar disc material beyond the normal margins of the intervertebral disc space.³ Low Back pain associated with herniated discs has become an important and increasingly general health problem, both in Bangladesh and across the world.

The lumbar region is the most common site involved in musculoskeletal pain. In developed countries, low-back pain ranks second after headaches among the other causes of pain. Of people living in industrialized countries, approximately 80%

suffer from low-back pain at a certain time in their lives.⁴ Low back pain often starts at a young age, and the prevalence is the highest in middle-aged population.¹ The majority of people presenting with low-back pain have problems with intervertebral discs. Intervertebral disc diseases, which are an important etiological cause of low-back pain, often occur in the lumbar region (61.94%).⁵

Prolapsed lumbar intervertebral disc (PLID) is a musculoskeletal disorder responsible for low back pain and sciatica and occurs due to rupture of the annulus fibrosus, following the displacement of the central mass of the intervertebral disc into the dorsal or dorso-lateral disc spaces.⁶ Considered a frequent reason for injury-related work leave.⁷ To date, optimal strategies

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for management of patients with PLID remain elusive. There are so many treatment options available for PLID. In the vast majority of the patients symptoms subside spontaneously within six weeks after presentation and these patients are best off treated conservatively.⁸ Moreover, the results of surgery are not always favorable in terms of outcome and recurrences.⁹ The preliminary evidence suggests that a multimodal treatment program consisting of therapeutic exercise, activities of daily living (ADL) advice, non-steroidal anti-inflammatory drug (NSAID), lumbar traction along with specific type of thermo therapeutic modalities like phonophoresis may result in positive outcome of the patients with low back pain due to PLID.^{10,11} There exists no therapy that can reverse the biochemical and pathological changes. However, through prudent use of medication and practical recommendation of therapeutic exercise and thermotherapy management of such case is possible.

Low back pain due to PLID is one of the most common musculoskeletal disorders around the world whether it is measured as a symptom in the general population, as a source of disability, as a reason for seeking health care, or as a cause of both short- and long-term work losses. Prolapsed disc is important in our community as most of the people earn their living through stressful works which predisposes them to spinal injuries and ultimately leading to disc prolapse.

Bangladesh is a poor country with huge population and very limited resources. So, it is quite difficult to manage such a huge number of patients with low back pain due to PLID with our existing resources and management system. As diagnostic approach and therapeutic options are diverse and often inconsistent, resulting in rising costs and variability in the management throughout the country, the research data are needed as to which of these options are cost-effective in the treatment of PLID. However, the efficacy of Phonophoresis has not been conclusively established in low back pain associated with PLID. To serve that purpose, the present study was aimed to evaluate the effect of Diclofenac Sodium Phonophoresis on the patients with PLID to make the treatment easy and cost effective and to make the disabled patients into working one.

Materials and Methods

This was a randomized clinical trial (RCT) as Controlled Comparative Study. This study was carried out in the Department of Physical Medicine and Rehabilitation at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka. This study was conducted from 01.03.2016 to 31.08.2016 for a period of six (6) months. All the patients attending at Physical Medicine and Rehabilitation department, at Bangabandhu Sheikh Mujib Medical University (BSMMU), by referring from different department and from general practitioners outside the hospital with low back pain due to PLID in an age between 20 and 70 years of both sexes included in the study. Inclusion criteria's were, Patients of both sexes, age of patients were ≥ 20 years and ≤ 70 years, patients with low back pain due to PLID, visual analog scale (VAS.0-10) for pain was >4 .

A total number of 72 patients presented with LBP due to PLID who were fulfilled the selection criteria were taken as study population. They were divided into two groups named as control group (Group A) and case group (Group B). Each group

was containing 36 patients. Patients were selected by randomized sampling method. Incorporation of the patients in the two groups was performed by lottery. The materials used were Visual analogue scale, Goniometer, Assessment sheets.

The main outcome variable were, Measurement of pain on a visual analogue scale (VAS), Straight leg-raising test (SLR). The patients with VAS score more than 4 and patients with SLR less than 60 degree were taken in this study. The Demographic variables were Age, Gender, Occupation, Risk factor and the Clinical Variables were Characteristics of pain, MRI findings. Grouping and treatment assignment was done like - Group A (Control group) got NSAID (Naproxen-250 mg; twice daily after meal for 15 days with proton pump inhibitor as Esomeprazole 20mg twice daily 20 minute before meal.), Therapeutic Exercise, Lumbar traction, ADL instructions and Group B (Case group) got NSAID (Naproxen-250 mg; twice daily after meal for 15 days with proton pump inhibitor as Esomeprazole 20mg twice daily 20 minute before meal.), Therapeutic Exercise, Lumbar traction, ADL instructions, Diclofenac Sodium Phonophoresis.

The patients were advised to come three times weekly for 4 weeks of initial treatment. The respondents of all groups were examined to see the effects of treatment, every week on the last third day of the consecutive week. The VAS, Straight leg-raising (SLR) test was used to assess the effects.

There was no physical, psychological and social risk to the study subject, both applicator and receiver used protective measures for better safety. Each patient enjoyed every right to participate or refuse or even withdraw from the study at any point of time. Data taken from the participants regarded as confidential and used only for this scientific study.

The patients were asked to take the provided medication, do the therapeutic exercises and follow the ADL advices on regular basis as prescribed. The importance of each was thoroughly explained to the patient. The common side effects of the drugs prescribed to the patient were explained in an understandable language and measures to overcome it was also explained, this was ensured that the patient did not stop taking the drug due to desired side effects of the drug. The patients were asked to take the drug regularly unless undesired side effects develop. The patients were advised to bring the used medication strip files on every follow up to ensure that patient had been compliant with the regular intake of medicines. Patients were suggested to follow a calendar as well as use alarm clocks available in their mobile phones to remind themselves to take the medication on time and on daily basis. Group B patients were directly observed who received phonophoresis with conservative treatment and over telephone. The Group A patients were monitored over telephone. The Data were collected using a structured questionnaire containing all the variables of interest. The questionnaire was finalized following pretesting. After the treatment of the patients as per schedule, the patients were followed up weekly for four weeks and the outcome recorded in the assessment data sheet. Before admission into the trial, the nature of the study was discussed with the patients and verbal consent of the patients was taken. History, clinical examination and relevant investigations were done. The Data was processed

and analyzed using computer software SPSS-20 (Statistical Package for Social Sciences). The test statistics used are descriptive statistics, Student's t Test and Chi-square (χ^2) Test. Level of significance was set at 0.05 and $p < 0.05$ considered significant.

Based on Visual Analogue Scale (VAS), Straight leg-raising (SLR) test pre-treatment and after treatment data was compared statistically. Prior to the commencement of this study, the research protocol was approved by the ethical committee (Local Ethical committee) of Bangladesh College of Physicians and Surgeons (BCPS).

Results

A total number of 72 patients with low back pain due to PLID were recruited for this study of which 36 patients were in control group (Group A) and the rest 36 patients were in the case group (Group B).

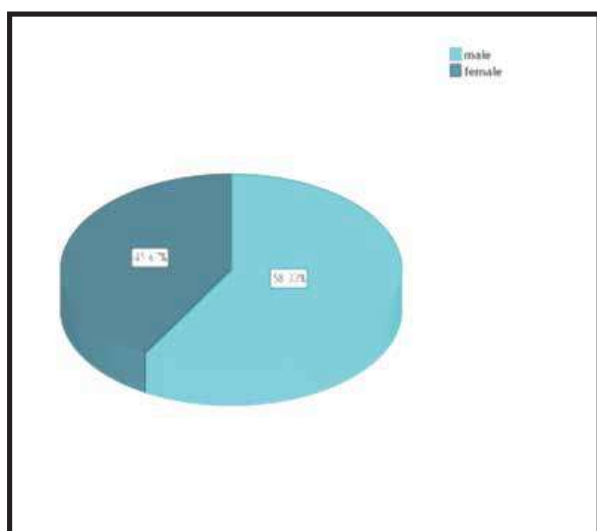


Figure 1: Distribution of the Study Population according to gender (n=72)

According to gender, in group A male was predominant than female which was 23 (63.9%) cases and 13 (36.1%) cases respectively. In group B male was also predominant than female which was 19 (52.8%) cases and 17 (47.2%) cases respectively. Among 72 patients percentage of male and female was 42 and 30 percent respectively. Male female ratio was 1.4:1 (Figure 1).

According to age, in group A, majority of the patients were in age group of 31 to 40 years which was 14 (38.8%) cases followed by 41 – 50 years age group, 20-30 years age group, 51-60 years age group and 61-70 years age group which were 10 (27.7%) cases, 6 (16.7) cases, 3 (8.3%) and 3 (8.3%) cases respectively. Similarly in group B, majority of the patients were in the age group of 31 – 40 years which was 16(44.4%) cases followed by 41 – 50 years age group, 20-30 years age group, 51-60 years age group and 61-70 years age group which were 8 (22.2%) cases, 5 (13.9%) cases, 5 (13.9%) cases and 2 (5.6%) cases respectively.

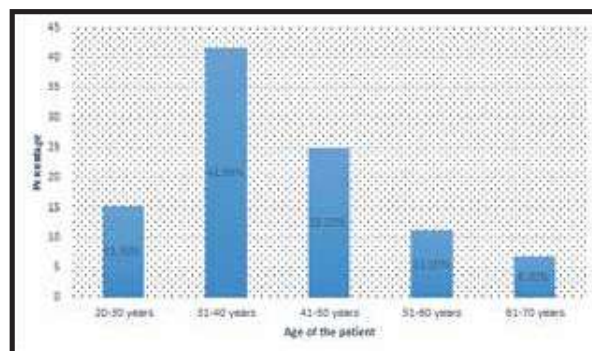


Figure 2: Distribution of the Study Population according to age (n=72)

Out of total 72 patients irrespective of sexes it was observed that most patients that were 30(41.6%) belonged to age group 31 to 40 years. The mean \pm SD age of the patients was 35.7 ± 7.8 and 34.8 ± 7.7 in group A and group B respectively. The difference of age between these two groups was not statistically significant ($p > 0.05$)(Figure 2).

By occupation, in group A, most of the patients were worker/labour which was 10 (27.7%) cases followed by service holder, driver, businessman, housewife, student and farmer which were 7(19.4%) cases,6(16.7%) cases, 6 (16.7%) cases, 3 (8.3%) cases, 3 (8.3%) cases and 1 (2.8%) cases respectively . Similarly in group B, most of the patients were worker / labour which was 11 (30.6%) cases followed by service holder, driver, businessman, house wife, student, farmer and hawkker which were 6 (16.7%) cases, 7 (19.4%) cases, 5(13.8%)cases, 5(13.8%)cases, 2 (5.6%)cases, 0 (0%) cases and 2 (5.6%) cases respectively . And in total highest in worker/ labour which was 21(29.1%) followed by service holder, driver, businessman, housewife, student and farmer which were 13(18.05%) cases, 13(18.05%) cases, 11(15.2%) cases, 8(11.1%) cases, 5 (6.9%) cases and 1 (1.3%) cases respectively.

The risk factors of the patients were Trauma (8.3%), repetitive/ heavy weight lifting (27.7%), obesity (19.4%), smoking (16.7%), diabetes mellitus (22.2%) and positive family history(5.6%) were the risk factors in group A. Trauma(2.8%), repetitive/ heavy weight lifting (30.5%), obesity (25.0%), smoking (13.8%), diabetes mellitus (19.4%) and positive family history(8.3%) were the risk factors in group B.

The characteristics of pain among studied patients showed tingling in the most of the cases in both groups which were 20(55.6%) cases and 19 (52.8%) cases in group A and group B respectively; the difference between these two groups was not statistically significant.

The aggravating factors of the patients were Prolonged sitting(63.9%),prolonged standing (66.7%) and prolonged working (33.3%) were the main aggravating factors in group A, prolonged sitting (38.9%), similarly prolonged standing (52.8%), and prolonged working (38.9%) were the main aggravating factors in group B. The patients got relieved while taking rest were 10 (27.7%) in group A and 14 (38.9%) in group B; the difference between these two groups was not statistically significant.

The patients got relieved while taking NSAID were 26 (72.2%) in group A and 22 (61.1%) in group B; the difference between these two groups was not statistically significant.

Table I: Distribution of the patients according to levels of prolapsed intervertebral disc on MRI.

Level of Disc Prolapse	Group A (n=36)		Group B (n=36)		Total (n=72)	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
L5/S1	11	30.5%	13	36.1%	24	33.3%
L4/L5	10	27.7%	8	22.2%	18	25.0%
L3/L4	3	8.3%	2	5.6%	5	6.9%
L2/L3	0	0.0%	1	2.8%	1	1.38%
L5/S1, L4/L5	6	16.7%	9	25.0%	15	20.9%
L3/L4, L4/L5	3	8.3%	1	2.8%	4	5.6%
L5/S1, L4/L5, L3/L4	3	8.3%	2	5.6%	5	6.9%

Table I displayed the level of MRI findings of the patients. It was 30.5% at L5/S1 level, 27.7% at L4/L5 level, 8.3% at L3/L4 level, 0.0% at L2/L3 level, 16.7% at L5/S1, L4/L5 level, 8.3% at L3/L4, L4/L5 level and 8.3% at L5/S1, L4/L5, L3/L4 level in group A, and in Group B it was L5/S1 (36.1%), L4/L5 (22.2%), L3/L4 (5.6%), L2/L3 (2.8%), L5/S1, L4/L5 (25.0%), L3/L4, L4/L5 (2.8%), L5/S1, L4/L5, L3/L4 (5.6%). So, the most of the patients were having PLID at the L5/S1 level which was about 33.3% of all cases.

Table II: Outcome of the patients according to Straight leg raising test (SLR) (n=72)

Straight leg raising test (SLR)	Group A (Mean ± SD)	Group B (Mean ± SD)	P value
Pre treatment	32.9 ± 9.6	33.7 ± 8.7	0.060
1 week after treatment	44.1 ± 7.9	50.9 ± 8.09	0.011
2 weeks after treatment	50.8 ± 9.1	56.5 ± 8.7	0.027
3 weeks after treatment	63.4 ± 7.05	68.1 ± 7.08	0.042
4 weeks after treatment	65.27 ± 7.36	75.1 ± 6.9	0.069

Student t-test was done to measure the level of significance

Table II showed disability of the patient assessed by SLR. The mean score of SLR before treatment were 32.9 ± 9.6 and 33.7 ± 8.7 in group A and group B respectively; the difference between these two groups was not statistically significant (p>0.05). The mean score of SLR after 1 week of treatment were 44.1 ± 7.9 and 50.9 ± 8.09 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The mean SLR after 2 weeks of treatment were 50.8 ± 9.1 and 56.5 ± 8.7 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The mean SLR after 3 weeks of treatment were 63.44 ± 7.05 and 68.1 ± 7.08 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The mean SLR after 4 weeks of treatment were 65.27 ± 7.36 and 75.1 ± 6.9 in group A and group B respectively; the difference between these two groups was not statistically significant (p>0.05). SLR was increased gradually in both groups.

Table III: Outcome of the patients according to VAS (N=72)

Assessment by Visual analogue scale (VAS)	Group A (Mean ± SD)	Group B (Mean ± SD)	P value
Pre treatment	6.5 ± 0.8	6.6 ± 0.9	0.068
1 weeks after treatment	5.3 ± 0.8	4.9 ± 0.7	0.028
2 weeks after treatment	4.2 ± 0.7	3.8 ± 0.6	0.016
3 weeks after treatment	2.9 ± 0.6	2.6 ± 0.6	0.038
4 weeks after treatment	2.1 ± 0.5	1.7 ± 0.5	0.026

Student t-test was done to measure the level of significance

Table III showed the pain of the patient assessed by VAS. The mean score of VAS before treatment were 6.5 ± 0.8 and 6.6 ± 0.9 in group A and group B respectively; the difference between these two groups was not statistically significant (p>0.05). The mean score of VAS 1 week after treatment were 5.3 ± 0.8 and 4.9 ± 0.7 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The mean score of VAS 2 weeks after treatment were 4.2 ± 0.7 and 3.8 ± 0.6 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The mean score of VAS 3 weeks after treatment were 2.9 ± 0.6 and 2.6 ± 0.6 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The mean score of VAS 4 weeks after treatment were 2.1 ± 0.5 and 1.7 ± 0.5 in group A and group B respectively; the difference between these two groups was statistically significant (p<0.05). The VAS was decreased gradually in both groups.

Discussion

Low back Pain due to a PLID is an important medical and socio-economic problem. Pain and reduced mobility severely

compromise quality of life and are particularly disruptive to the working individual. The aim of any therapy should be achievement of normal lifestyle as soon as possible.

There are so many treatment strategies available for PLID. Ultrasound (US) is a physical modality which has been used for over 50 years in the treatment of various soft tissue injuries. Phonophoresis refers to a specific type of US application in which pharmacological agents such as corticosteroids, local anesthetics and salicylates etc. are introduced. This implies the movement of drugs through skin only very slowly, using ultrasound.¹² Phonophoresis has been used clinically since the early 1960s in attempts to drive these drugs transdermally into subcutaneous tissues. Conditions treated by Phonophoresis included epicondylitis, tendinitis, tenosynovitis, bursitis, and osteoarthritis.

Electrophysical modalities like Shortwave diathermy, Microwave diathermy, Ultrasound therapy, Transcutaneous electrical nerve stimulation (TENS), Interferential current therapy, Light amplification by stimulated emission of radiation (LASER) therapy, orthoses are commonly used in addition to the prescription of exercises, activities of daily living (ADL) advices are commonly applied for the treatment of non-specific LBP. There are many published studies regarding efficacy of these modalities for patients with low back pain due to PLID. Here we have tried to study the efficacy of Diclofenac Sodium Phonophoresis on patients with low back pain due to PLID.

In this study, total of 72 patients with low back pain due to PLID was selected to find out the effects of Diclofenac Sodium Phonophoresis. The findings of the study obtained from data analysis are presented below.

Age ranged 20-70 years with highest frequency was at the age group of 31-40 years.

In United States, the most commonly affected age group is 25-45 years.¹³ Ming from TCM Medical center, China, states that prolapsed lumbar intervertebral disc occurred often in youth and middle aged of 20-40.¹⁴

The majority (58.3%) patient was male and 41.7% was female, giving a male – female ratio of 1.4:1. Junaid et al analysis of 1058 lumbar prolapsed intervertebral disc found out of 1098 patients, male were 708 (66.9%) and female were 350(33.1%).- Sex ratio 2.02:1.¹⁵ For this reason, it can be clarified that gender distribution of this study is consistent and relevant with the above study. Dr. Ming from TCM Medical Centre, China, also states that in PLID males surpasses the female in number.¹⁴

The predominant occupations of the patients were manual labor(29.1%) and driver and service holder both were (18.05%). Other occupants were businessman (15.2%),housewife(11.1%), student(6.9%), and farmer (1.3%). In one study, Ansari et al showed predominant occupation was manual labour (42%).¹⁶ Similarly, in present study most of the patients were worker/ labour 29.1%. Because the physical labor they perform requires working most of the time in bending position that particularly burdens the lower spine, they have increased lifetime risk of lumbar disc herniation. In a sample of 1001

examinees Croatian island populations, where they identified all subjects who underwent surgery of the lower spine due to lumbar disc herniation L/4L5 or L5/S1. Comparison of 67 identified cases with 268 controls revealed the intensity of physical labour at work defined as “hard”(OR2.77,95%).¹⁷ Compared with changes seen in normal population (non athletes) disc degeneration defined to be significantly more severe in Olympic athletes who had disc height reduction at a single level is 68%.¹⁸ Because of the human sedentary nonmoving lifestyle, disc degeneration is progressive.

The risk factors that induce pain in PLID, 29.1% of the patients informed that their pains were aggravated by repetitive/ heavy weight lifting, 22.2% were obese, 19.4% were diabetic, 5.2% were smoker, 8.3% had positive family history and 5.6% had history of trauma. So, It can be said that lifestyle modification by proper therapeutic exercises and ADL advices and by control of other risk factors like diabetes mellitus, obesity, smoking can have a major role on preventing the development of PLID and reduction of pain induced by PLID.

The Pain was tingling in character in most of the cases 54.1% then sharp in 29.1% cases and dull in 16.7% cases. Out of 72 patients 51.4% told that pain was aggravated by prolonged sitting, while 59.7% said on prolonged standing and 36.1% by prolonged working. In most cases pain got partially relieved for few hours while taking NSAID which was 66.7% and after taking rest in 33.3% patients.

When the level of MRI presentation was taken into consideration most commonly affected disc spaces were at L5/S1 level (33.3%), L4/L5 level(25.0%) and (20.9%) of patients had disc involvement at 2 levels of L5/S1 and L4/L5. In Pakistani study by Junaid Metal, disc prolapse was seen to be most common at the level of L5/S1 (34.6%), which was then followed by the disc prolapse at L4/L5 level (33.4%).

Disability of patients was assessed by Straight leg raising test (SLR). The result of this study showed that there was a significant difference in improvement between the pre and post treatment SLR value in participants treated with conservative treatment alone and with Diclofenac Sodium Phonophoresis. As described before, the SLR test causes gliding of lumbar nerve roots which get compressed by the herniated disc proximal to neural foramina leading to radiation of pain down the leg in nerve root distribution.¹⁹ So, this improvement in SLR indicating that, nerve root compression by herniated disc and total inflammatory condition was reduced by the effect of phonophoresis. This was because effect of phonophoresis helps in dialating points of drug entry (e.g., hair follicles, sweat glands), increasing local circulation and increasing cell membrane permeability.

The pain of patient was assessed by visual analogue scale (VAS). Boyraz I et al showed the effect of High Intensity Laser Therapy (HILT) and Ultrasound therapy (UST) on patients with lumbar disc herniation. In case of HILT, pretreatment VAS was 7.55 and after 10 days treatment it became 4.00 and after 3 month 3.25 and p value was 0.983. In case of Ultrasound therapy VAS was 7.52 and after 10 days treatment it became 3.40 and after 3 month 2.96 and p value was 0.169.5 In another study Klaiman MD et al showed comparative effect of Phono

phoresis (PH) and ultrasound in the treatment of common musculoskeletal conditions like lateral epicondylitis, supraspinatus tendinitis, DeQuervain's tenosynovitis, Achilles tendinitis, plantar fasciitis.²⁰ They showed at the end of treatment significant decrease in pain level in both groups. From the onset of the treatment to the end of week 3 (VAS: US 5.5-1.9; PH 5.0-2.0). At last they concluded that PH with fluocinonide did not augment the benefits of US used alone.

In this study the mean (SD) score of VAS before treatment were 6.5 ± 0.8 and 6.6 ± 0.9 in group A and group B respectively; the difference between these two groups was not statistically significant ($p > 0.05$). The mean (SD) score of VAS 4 weeks after treatment were 2.1 ± 0.5 and 1.7 ± 0.5 in group A and group B respectively; the difference between these two groups was statistically significant ($p < 0.05$). The VAS was decreased gradually in both groups. In both group pain was decreased gradually but the improvement was better in group B patients than group A patients. So, it can be said that the effect of Phonophoresis and HILT and Ultrasound therapy in treating PLID almost similar and it can be used successfully as a useful thermo therapeutic agent for the treatment of low back pain due to PLID like other common musculoskeletal conditions.

Although the results of this study support the hypothesis, there are some facts to be considered which might affect results. This was a single centered study and because of time limitation and financial constraints the study was conducted with small sample size. So, it may not be adequate to represent the whole population.

Conclusion

For the effective reduction of sciatic pain and possible improvement in SLR, Diclofenac Sodium Phonophoresis should be combined with conservative treatment for the management of low back pain due to PLID.

Further prospective studies with larger sample size should be carried out from primary to tertiary level hospitals in Bangladesh for better understanding to the effect of Diclofenac Sodium Phonophoresis on patients with low back pain due to PLID.

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