

Comparative Study Between Shock Wave Therapy and Electromagnetic Waves on Pain and Function in Patients with Lumbar Disc Prolapse. A randomized controlled trial

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Abstract

Background: Low back pain has been reported to affect about 84% of adults at different points during their lives. Intervertebral disc degeneration is a common disease of the discs which connect each two adjoining vertebrae as structural damage causes degeneration of the disc and also the surrounding area.

Aim of the work: Comparing the effects of shock wave therapy (ESWT) and electromagnetic field on pain severity functional abilities on elderly patients with lumbar disc prolapse (LDP).

Subject and method: 48 elderly patients with lumbar disc of both sexes aging from 55 to 75 years contributed in this study. They were randomly assigned to three groups (one control group and two study groups). The control group A received conventional physical therapy only. Study group B received electromagnetic waves plus conventional physical therapy (Moist hot pack, transcutaneous nerve stimulation (TENS), exercises), study group C received shock wave plus conventional physical therapy. Primary outcome were pain assessment assessed by Visual analogue scale (VAS) and assessment of functional disability assessed by Oswestry disability index (ODI), all outcomes measures were assessed for each patient pre and post four weeks of treatment program in the three groups (3 sessions / week).

Results: There was no significant difference in all measured variables (VAS and ODI) between group I and III post four weeks of the treatment (p > 0.05). While there was a significant decrease in all measured variables in B in comparison with that of group A post treatment (p < 0.05) and in group B in comparison with that of group C post treatment (p < 0.05) regarding to pain variable only.

Conclusions: The results showed that both electromagnetic and shock wave have similar effect on functional disability in patients with lumbar discogenic lesion. While, electromagnetic is more effective to improve pain than shock wave.

Key words: Lumbar disc, Electromagnetic field, Shock wave therapy, Lumbar disc prolapse; Pain, Visual analogue scale, Oswestry disability index, Functional disability.

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Introduction

lumbar disc prolapse (LDP) is One of the common causes of Low back pain (LBP) that affects more than 80% of people in the developed countries and disable their lives [1] [2]. LDP can frequently causes lumbosacral radiculopathy due to a confined disc material displacement outside the boundaries of the intervertebral disc space [3]. LDP causing local or radiated symptoms which differ according to the degree of that displacement compressing the posterior or posterolateral part of the Lumbar spinal segments [4].

Lumbar intervertebral disc herniation (IDH) results in Sciatica which is considered the most common cause of radicular pain [5].

Extracorporeal shock wave therapy (ESWT) is considered one of the most hopeful physical approaches for the tratment of musculoskeletal disorders is [6].

Electromagnetic field is nowadays considered an important intervention recently used and has excellent results on painful conditions [7].

Few studies that were carried out to evaluate the effectiveness of electromagnetic field in conservative treatment of low back pain (LBP) and preliminary results showed promising outcomes relative to lumbar disc herniation with and without radicular symptoms [8,9]. Shock wave is a new non invasive therapeutic method which can promote revascularization that improves both muscle strength and manage pain [10].

Shock wave is reported to be used for the treatment of various musculoskeletal diseases. Recently shock wave is used in the management of musculoskeletal, bone disorders and also in the treatment and management of pain for chronic diabetic foot ulcers, ischemic heart disease, complex regional pain syndrome, knee osteoarthritis, and spinal fusions [11].





Shock wave therapy mechanism includes rapid oscillations of pressure waves that can travel through various mediums to induce high energy causes changes in the cell structure, cell membrane and cytoplasmic organelles, thus stimulating the nucleus [12,13].

Extracorporeal shockwaves are a shockwave is a non-linear pressure with a duration of 10 microseconds. There is a positive phase, characterized by high-pressure waves hitting a tissue interface that allow penetration or reflection. During the negative phase, the accelerated pressure causes the tissue layers to cavitate, inducing an air bubble formation and produces a second shock wave. The energy that Shock wave helps wound healing via collagen deposition and increase in neovascular formation within the first week after application with plateau around four weeks [12].

Aim of the work

Comparing the effects of shock wave therapy (ESWT) and electromagnetic field on pain severity functional abilities on elderly patients with lumbar disc prolapse (LDP).

Materials and Methods

Study design: This randomized controlled experimental trial was carried out at the outpatient clinic of faculty of physical therapy, Kafr El sheikh University from August 2021 to September 2022. The aims of the study and the study protocol were explained for each patient before participation in the study. All patients signed an approved informed consent form for participation in this study. Before starting the treatment program, a complete history and physical examination will be taken for all patients.





Ethical Approval as per university standard written ethical approval has been collected and preserved by the author (s).

This study was approved by the Ethics Committee of the Faculty of Physical Therapy, Kafr Elsheikh University (P.T / NEUR /22 /8 /2021).

Consent: Informed consent was signed by all participants in the study.

Inclusion criteria:

All participants with a past chronic history of lumbar disc prolapse at L5-S1 spine segment. Patient's ages from 55 to 75 years. They will be medically stable and did not suffer from any other diseases which may affect the trail results like cardiovascular diseases, neurological disorders and chest disease.

Participants sixty four patients with lumbar disc of both sexes were initially screened for eligibility criteria. Patients were diagnosed and referred from a neurologist or a neurosurgeon as having lumbar disc based on a careful clinical evaluation. This diagnosis was confirmed by X rays of the lumbar spine and lumbar MRI for diagnosis of disc herniation through sagittal T1-weighted images (WI), sagittal T2-WI and axial T2-WI.

Patients first underwent a comprehensive physical evaluation by a physical therapist to confirm the presence of dysfunction in the lumbar spine and exclude other causes of sciatica. After the screening process, 48 patients were eligible to participate and complete the study as shown in Figure (1). Patients were eligible to participate in this study if they had (i) age ranging from 55 to 75 years, (ii) concurrent back and leg pain for at least three months were described as related to lumbar position or movement. Patients were excluded if they had (i) pain and sciatica due to qauda equina syndrome; (ii) Lumbar myelopathy; (iii) Other causes of back and leg pain (iv) Other neurological disorders (eg, stroke, cerebellar disorders, multiple sclerosis, Parkinson's disease,); (v) Congenital anomalies involving the lumbar spine; (vi) Systemic disease such as diabetes mellitus; (vii) poor vision and hearing; (viii) Medications that cause dizziness; (ix) Recent lumbar fracture or dislocation (in the last 3 months), infection in lumbar spine, cancer,





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active inflammatory joint disease and pregnancy; (x) Psychiatric disease and (xi) previous surgery to the lumbar spine. (xii) Obesity (BMI \ge 35 kg/m²

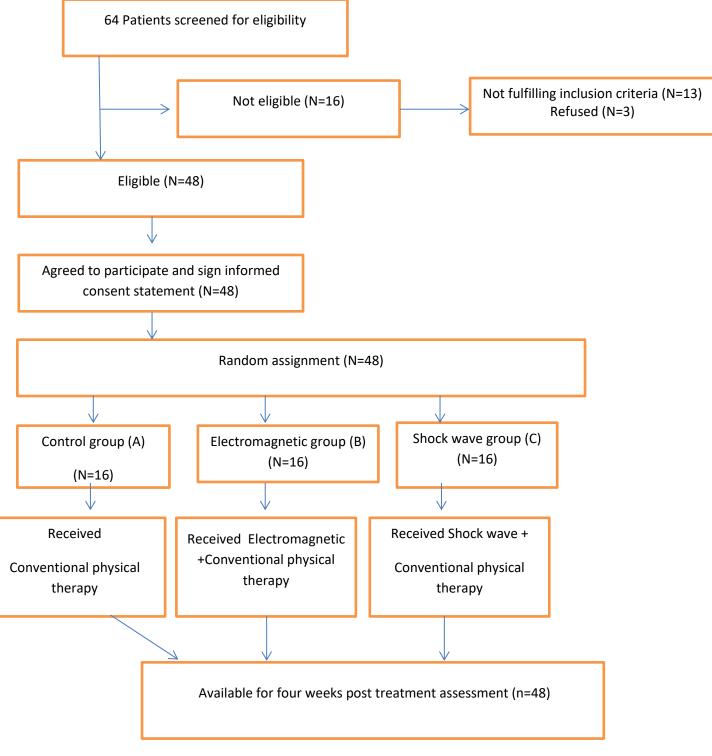
After the screening process, 13 patients were excluded as they did not fulfill the inclusion criteria and three patients were excluded as they refused to participate in the study. A randomization process was performed for 46 patients; the allocation was performed using a computer generated randomized table. Patient allocation was concealed using a random numerical sequence in sealed opaque envelopes. As each patient formally entered the trial, the researcher opened the next envelope in the sequence in the presence of the patient. A diagram of patient's retention and randomization throughout the study is shown in figure 1. Patients were randomly assigned to one of the following three groups (1:1:1).: control group which included 18 patients (5 males and 9 females) and electromagnetic group which included 18 patients (6 males and 10 females). All patients signed an informed consent form for participation in the present study.

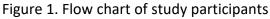
Patients were randomly divided to three equal groups. The patients in group A received only the conventional physical therapy program. The patients in group B received electromagnetic in addition to the conventional physical therapy program while patients in group C received shock wave therapy (ESWT) in addition to conventional physical therapy program. The conventional physical therapy program for both groups consisted of electrotherapy using TENS (20 minutes), Moist hot pack (15 minutes) and exercise program. All patients in the three. groups were assessed through Visual analogue scale (VAS) for pain assessment and Oswestry disability index (ODI) for functional disability assessment.



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Assessment of low back pain

A visual analogue scale (VAS) was employed to measure pain levels before and after treatment. The Visual analogue scale (VAS: 0–10) was used to assess the severity of LBP with 0 (no pain) to 10 (worst pain ever) [14].

Patients were asked to rate their pain radiation on VAS. Patients selected the level of their pain via putting a sign on a line (10cm), with 0 (no pain) and 10 (worst pain possible) at the endpoints of the VAS line. VAS is considered a valid and accurate measure for chronic pain assessment [15].

Assessment of disability

The Modified Oswestry Low Back Pain Disability Questionnaire (OSW) was used to assess patients with LBP by determining impact on activities of daily living before and after application in the three groups [16].

Treatment Procedure

Treatment Procedure All patients in the three groups received the same conventional physical therapy treatment including [Moist hot pack, Transcutaneous nerve stimulation (TENS)]. Each patient was instructed to be prone, Hot packs were placed on lumbar region for 15 minutes. Then, TENS was administered at a frequency of 80 Hz with 1030 mA intensity for 20 minutes using four surface electrodes, 5x5 cm each, were placed over the painful lumbar area. After that, exercise was done to each patient. This conventional physical therapy treatment was repeated 3 times a week for 4 weeks. The patients in the control group (group A) received this conventional treatment only.

For the study group B only, all patients were subjected to a rehabilitation program in the form of electromagnetic field, that was applied for 20 min for four weeks successively; the field strengths ranged from 5 to 15 Gauss (G) and the frequency ranged from 7 Hz to 4 kHz [14].

For the study group C only, all patients were subjected to a rehabilitation program in the form of shock wave treatment with parameters as follows:





Treatment intensity: 4-7, Treatment frequency: 150 shocks/min.; the total number of shock waves: 1000-5000 [17].

Data analysis:

Sample Size and Statistical Analysis

Statistical package for social studies (SPSS) version 25 for Windows (IBM SPSS, Chicago, IL, USA) was used for analyzing data of this study. Mean standard deviation and frequencies were calculated for descriptive statistics. Statistical significance was defined as P < 0.05. Age, weight and duration of illness were compared among the three groups using ANOVA and sex distribution was compared among the three groups using Chi squared test.

Before data analysis, Shapiro Wilk test was used for checking the normality of data. Within group comparison pre and post treatment was carried using paired t test. Between groups comparison was carried out using ANOVA. Post hoc tests using the Bonferroni correction were performed for subsequent multiple comparisons.

Results

Base line patient's characteristics Demographic and clinical data of patients were shown in table 1. No statistically significant differences regarding age, weight, and sex distribution (p > 0.05) were observed among three groups (p > 0.05). There was significant difference regarding duration of illness (p > 0.05) were observed among three groups (p < 0.05), as shown in table 2

Table 1. Comparison of	of subject characteristics be	etween control and study groups.
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variable	Control group	electromagnetic	Shock wave	P value
Age (years)	61±5.899	60.81±7.54	61.94±4.97	.861
Weight (kg)	73.06 ± 13.25	71.88 ±9.76	79.12 ± 7.83	.124
Height (cm)	164.62±6.06	166.38 ± 5.62	165.88 ± 6.99	.975
Duration of illness (months)	11.69 ± 4.45	10.93 ± 5.54	14.93 ± 3.17	.036
Sex (male/female)	7/9	5/11	6/10	.766



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Table 2. Bonferroni correction of post hoc tests for duration of illness among three groups

	Duration of illness
Group A vs group B	1.000
Group A vs group C	.140
Group B vs group C	.046

Within group comparison The results revealed that a statistically significant decrease in the mean scores of VAS and ODI, after treatment in comparison with that before treatment in the three groups (p < 0.05) as shown in table 3.

Table 3. Comparison between pre and post treatment mean scores of VAS and ODI in the three groups

variable	Control gro	up	P value	Electromagne	etic	P value	Shock wave		P value
	Pre	post		Pre	post		Pre	post	
VAS	8.3± 1.78	5.81±1.83	.000	7.94 ± 1.65	4.13 ±1.54	.000	$8.56 \pm .89$	$5.56 \pm .81$.000
ODI	76.3 ±18.69	67.54 ±22.93	.001	82.50± 2.19	47.38 ±16.19	.000	78.80 ± 9.54	59.85±15.07	.000

Between group comparisons at baseline, no statistically significant differences were observed among the three groups in all measured variables (p > 0.05), as shown in table 4

Table 4. Comparison of pre treatment mean scores of VAS and ODI among three groups

	VAS	ODI
Group A vs group B	1.000	.565
Group A vs group C	1.000	1.000
Group B vs group C	.728	1.000

Post treatment, there was no statistically significant difference in the mean scores of VAS and ODI between group A and C (p > 0.05). While, there was a significant decrease in the mean scores of VAS and ODI of group B in comparison with that of group A after treatment (p < 0.05). While, there was no significant reduction in the mean scores VAS and ODI of group C in comparison with that of group A after treatment (p > 0.05). There was a significant decrease in the mean scores of VAS group B in comparison with that of group C after treatment (p < 0.05) with no significant reduction regarding ODI (p > 0.05) as showed in table 5.





	VAS	ODI
Group A vs group B	.006	.010
Group A vs group C	1.000	.730
Group B vs group C	.024	.184

Table 5. Bonferroni correction of post-hoc tests for VAS and ODI among three groups

Discussion

The present study is A Randomized Clinical Trial carried out with the purpose of assessment and comparison of the effect of shock wave therapy and electromagnetic on pain severity functional abilities on elderly patients with lumbar disc prolapse (LDP).

The disc degeneration is considered a normal result of aging, but other factors are precipitated to accelerate the disc degeneration [18].

Degenerative disc disease is the most common etiological risk factor of chronic low back pain (LBP) [19]. Degenerative disc disease was treated by many available pharmacological treatment options to manage pain but with the recent occurrence of side effects and contraindications, a number of nonpharmacological therapies for LBP have been recently applied [20, 21].

Sciatica is associated with lumbar intervertebral disc herniation (IDH) and is considered the most common cause of radicular pain. Most patients with lumbar disc herniation are treated with minor cases undergo discectomy. Patients are widely varied in their responses after treatment with either spine surgery [5] or non-surgical approaches [22].

The findings of this research revealed a significant improvement regarding pain and functional disability in electromagnetic group in comparison with control group post treatment.

The findings revealed a significant improvement regarding pain in electromagnetic group in comparison with shock wave group post treatment.





The present study results agree with Omar et al., 2012 who reported that electromagnetic field therapy is an effective modality for conservative treatment of lumbar radiculopathy caused by lumbar disc prolapse, with significant reduction in pain severity as well as significant improvement in total modified Oswestry score in response to therapy.

Also Markov. 2014 and Bjordal et al., 2007 reported that electromagnetic field therapy (EMF) is now used as an alternative, safe treatment option with effective results for chronic pain in different clinical settings [16, 23].

The results of the present study agree with the permission of the American Food and Drug Administration (FDA) about the use of Electromagnetic fields for pain and edema management [24].

Electromagnetic fields (EMF) are now reported as a real physical modality that promotes healing of many health problems, even after conventional medicine has failed. Today magnetotherapy provides a noninvasive, safe and easy method to directly treat the site of injury, the source of pain, inflammation and other types of diseases and pathologies [7].

Electromagnetic fields has been reported to enhance the synthesis of extracellular matrix proteins with a direct effect on the proteins production that regulate gene transcription and also affect several membrane receptors, osteoblasts stimulation to secrete different growth factors such as transforming growth factor (TGF)-beta, bone morphogenic proteins 2 and 4 and [25].

Electromagnetic fields are a computer controlled therapy systems have been found to have excellent results for painful conditions with little risks of toxicity, addiction and complications of medications [7].

Few studies that were performed to evaluate the effectiveness of Electromagnetic fields as a conservative treatment of low back pain (LBP) and the





results showed good outcomes relative to lumbar disc herniation with or without radicular symptoms[9,26].

Shock wave therapy has been targeted towards treating pain in patients with spinal cord injury (SCI) [27].

Shock wave therapy was demonstrated to be an effective treatment that achieve pain reduction, improve ROM, and lower neck disability index scores in patients with cervical spondylosis and nuchal ligament calcification [28].

The present study results disagree with Akopyan et al., 2005 who observed remarkable improvement in both pain intensity and everyday function and reported the safe and effective use of shock wave therapy with no adverse effects for treatment of back pain [17].

There was a significant decrease in the mean scores of VAS group B in comparison with that of group C after treatment (p < 0.05) with no significant reduction regarding ODI (p > 0.05) as showed in table 5 which can be explained by the significant difference reported regarding the duration of illness (p > 0.05) between the two groups (p < 0.05), as shown in table 2

Conclusions

The present study results indicated that both Electromagnetic fields and Shock wave therapy lead to similar improvement functional disability measured in elderly patients with lumbar disc herniation. While Electromagnetic fields was more effective than Shock wave therapy in improving pain. Hence, adding Electromagnetic fields to the conventional physical therapy is useful for elderly patients with lumbar disc herniation suffering from concurrent back pain and functional disability.

Our results are recommend for more research works that should include larger numbers of elderly patients with lumbar disc lesions with longer follow-up





periods to recommend these unique modalities as a routine conservative methods of treatment in that domain.

Limitations

There was no follow-up, and the findings were in the short-term.

Disclaimer

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Data availability

The data used and analysed during the current study available from the corresponding author up on reasonable request.

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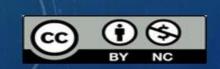
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