A Single-Blind Randomized Controlled Trial Investigating Changes in Electrical Muscle Activity, Pain, and Function after Shockwave Therapy in Chronic Non-Specific Low Back Pain: Pilot Study

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SUMMARY

Background. To investigate the effect of adding r-ESWT to a standard exercise program of chronic non-specific LBP on electrical muscle activity (EMG), pain and function.

Materials and methods. Our single-blind randomized controlled trial enrolled 30 patients with chronic nonspecific LBP randomly allocated to an r-ESWT (n=15) group and a control group (n=15). All patients received a standard exercise program, while r-ESWT was additionally administered in the r-ESWT group. EMG activity, pain and function were assessed before and after 6 weeks of treatment.

Results. After treatment, all outcome measures were significantly different (p < 0.05). The addition of r-ESWT produced a significant increase in EMG activity (of all muscles tested) and a reduction in pain intensity and functional disability scores (p < 0.05) compared to the control group.

Conclusions. 1. A standard intervention offered either alone or with r-ESWT increased EMG activities, reduced pain, and enhanced function in patients with chronic non-specific LBP. 2. Adding r-ESWT to the standard intervention program might produce better results.

Key words: chronic pain, electromyography, muscle, extracorporeal shockwave therapy

BACKGROUND

Low back pain (LBP) is the commonest musculoskeletal problem. It is characterized by a high prevalence rate [1]. The non-specific type of LBP, which has no identifiable cause, represents the majority of the diagnoses with a percentage of up to 85% of all LBP patients [2]. Chronic LBP may decrease productivity, increase the rate of sick leaves, and places a huge burden on health systems [3].

The pathophysiology and mechanism of action that explain the onset of non-specific LBP and turning from acute to chronicity are still unclear. Several different mechanisms have been proposed. One of important explanation is a decline in muscular performance and activation patterns [4]. Other hypotheses have pointed to alterations in electromyographic activity of LBP patients with the most obvious changes occurring in the transverse abdominus and multifidus muscles [5, 6]. Moreover, deep trunk muscles showed a decreased rate of activation during trunk forward-leaning, as described by Hodges and colleagues [7], and reduced electromyographic activities especially in the multifidus, iliocostalis lumborum, gluteal muscles and abdominal muscles [8-10].

Such findings have been attributed to the increased influence of nervous system activity on the nearby muscles which could increase muscular stress and make the individual prone for developing trigger points. Trigger points are common features associated with chronic LBP and could be a causative factor [11]. It leads to localized and referred pain, stiffness of the affected muscle, disturbs sleep, and causes a decline in function [12].

Physical therapy is a gold standard treatment for such chronic cases; modalities such as soft tissue manipulation, exercise, manual therapy, electrotherapy and hydrotherapy can improve neural impulses and normalize muscle tone, reduce pain and enhance performance [13-16].

Recently, there has been interest in radial shock wave therapy (r-ESWT), which uses waves generated by a pneumatic pressure resulting from compressed air which moves a special bullet placed inside an applicator. This bullet transfers its energy through hitting the target tissue to produce a shock wave [17]. This type of shock wave therapy is characterized by a relatively low price, popularity and it has been used in many health care facilities [18].

As a new treatment modality, r-ESWT has been introduced to the field of physical therapy. This method of treatment has gained wide acceptance and produced favorable results in treating chronic musculoskeletal injuries resistant to traditional therapy. Moreover, shockwave demonstrated significant effectiveness in pain reduction and desensitization of active trigger points in a previous work [19]. These results were associated with improved performance and function. Yet the direct influence of this modality on electrical muscle activity has not been adequately studied [17]. Additionally, its effect on active trigger points has not been addressed in previous work. Moreover, according to Walewicz et al., the level of evidence regarding the use of r-ESWT on LBP is still limited due to the poor quality of the available literature [17].

Objectives

The purpose of this study was to investigate the effect of adding r-ESWT to a standard treatment on electromyographic activity of trunk muscles, pain intensity, and function in patients with chronic non-specific LBP.

MATERIAL AND METHODS

Design of the study

This was a randomized single-blind (patients) controlled trial with a 1:1 allocation ratio. This study was conducted at the Local University's outpatient clinic and Laboratory of Electromyography. The study was conducted between September 2019 and April 2020. The study protocol was approved by the local Research Ethical Committee, registered at Pan African Clinical Trial Registry (PACTR 201907878425407), and was reported according to the guidelines of the CONSORT statement guidelines [20].

Participants

A total of 45 subjects were assessed for eligibility, of whom 30 met the inclusion criteria and agreed to join the study. The inclusion criteria were chronic LBP, age above 20 years, active trigger points in the low back muscles. Specific LBP, sciatica, discogenic lesion, spinal deformity, spondylolistheses, severe obesity (BMI >35), pregnant mothers, history of lumbar, abdominal, or pelvic surgery were the exclusion criteria.

Interventions

Radial extracorporeal shock wave therapy (r-ESWT)

An HC SWT (Elettronica Paganis Medical Devices, UK) device was used to conduct shock wave therapy sessions in the current study. 2000 shocks, 0.10 mj/mm² energy, 5 Hz frequency, using a 17 mm head were administered. Sessions were conducted twice a week for 6 weeks [21].



Fig. 1. Radial shock wave head applied to an active trigger point over gluteal area

After appropriate parameters were set, the patients were asked to assume the position that allows exposure of the targeted trigger points and a lubricant gel was applied to the head of the r-ESWT device. Active trigger points identified during the initial screening and assessment were treated using the r-ESWT parameters described above. The head of the r-ESWT device was kept perpendicular to the target trigger point and provided moderate tolerable pressure. A standard US gel was used as a coupling medium. Subjects who could not withstand continuous session were allowed to take 2- to 3-minute pauses. After each session, the treated areas were visually inspected for any signs of contusions, and subjects were advised to apply cold packs between sessions to eliminate pain and discomfort [22]. This intervention was administered to the experimental group (r-ESWTG) only.

Standard intervention

The standard program performed in the current study had been conducted previously by Hussien and colleagues [14]. Stretching exercises were performed for the hamstrings, iliopsoas, and back extensors. Each stretching position was maintained for 30 seconds and repeated 3 times per session. Additionally, progressive strengthening exercises were applied to the abdominal and back extensors from crock lying and prone positions, respectively. One set of 10 repetitions was the target in the first week. The exercises were progressed according to the patient's tolerance and limits of fatigue. Both r-SWTG and control groups received the standard intervention as two sessions per week for 6 weeks.

Outcome measures

Initial screening and demographic data

At the first meeting, the assessor screened the subjects against the inclusion and exclusion criteria. The demographic data of the eligible subjects was collected. All subjects signed a consent form before the start of the study. Baseline ratings of pain and functional levels were performed at the first meeting. In the current study, the main outcome measure was electromyography as indicated by the root mean square (RMS), and the secondary outcome measures were pain and functional level.

Electromyography (EMG)

Electromyography is the most objective and reliable technique for evaluating muscle function and efficiency by detecting their electrical potentials [23]. It makes it possible to assess the extent and duration of muscle activity [24]. Surface electromyography (Neuro-EMG-Micro, Neurosoft, Ivanovo, Russia) was used to record the EMG activities. Two-channel surface recording electrodes (bipolar silver-silver chloride disposable electrodes) with a diameter of 10 mm and inter-electrode distance of 20 mm were used for recoding muscle activity [25]. EMG data were obtained from both the r-ESWT group and the control group. The root mean square (RMS) parameter was used to indicate EMG amplitude. The muscles assessed were the rectus abdominus, external oblique, lumbar erector spinae, and lumbar multifidus muscle on both sides (except rectus abdominus). Skin hair was removed, and sweating was cleaned using an alcohol cotton swab.

The surface electrodes were placed over the L5 and aligned parallel to the line between the posterior superior iliac spine (PSIS) and the L1–L2 interspinous space to record the lumbar multifidus muscle [26]. For the lumbar erector spinae, the electrodes were placed 3 cm lateral to the midline, at the L2 spinous process level [27]. Electrodes used for recordings from the rectus abdominus muscle were placed 1 cm above the umbilicus and 2 cm lateral to the midline. For the external oblique muscle, electrodes were placed 15 cm lateral to and at the level of the umbilicus [26]. These placements were also in accordance with the SENIAM protocol for non-invasive assessment of muscle activity [28].

To obtain accurate readings, the electrodes were placed in line with muscle fibers, 1000 Hz sampling frequency was used with 500 μ s sensitivity, and the subjects were asked to perform maximum isometric voluntary contraction (MIVC) effort against resistance. Meanwhile, the therapist was applying isometric resistance to the appropriate body part [29].

The subject was instructed to assume the prone position for recording RMS during MIVCs of the erector spinae and lumbar multifidus muscles while lying supine when rectus abdominus and external oblique activity was assessed.

An appropriate number of straps were used to fix the subject's legs and pelvis. Each MIVC was repeated three times and the patient was asked to gradually increase the force to reach an absolute maximum force, and then to hold for 10 seconds. A 30 second rest interval was allowed between each trial [25].

Pain intensity

A horizontal non-numeric visual analog scale (VAS) with a 100 mm (10 cm) horizontal line was used to rate pain intensity experienced by the subject. Subjects were asked to rate their pain by making a mark over the line at the point they feel represents the pain severity [1,30]. The distance from the 0 point to the mark made by the subject was measured by a ruler. The cutoff points for the VAS were 0-4 mm for no pain, 5-44 mm for mild pain, 45-74 mm for moderate pain, and 75-100 mm for severe pain. The VAS is considered valid and reliable in reporting musculo-skeletal pain [31,32].

Oswestry Disability Index (ODI)

The Oswestry Disability Index (ODI) is a functional level measuring scale. It is a 10-item questionnaire, with 6 responses to each item numbered from 0 to 5. These items include pain intensity, personal care, lifting, walking, sitting, sleeping, sex life (if applicable), and social life [33]. It has been used in many instances before [14,22,34]. A translated valid and reliable version of ODI was used where patients were asked to choose the statement that represented their functional status [35]. The raw data of ODI was used in all statistical analyses. Using raw data could increase the sensitivity of ODI to reflect the small amount of change in the functional level scores compared with using the final score in the percentage form [14].

Sample Size

The size of the sample was determined using G*Power version 3.1.9.2 (Franz Faul, Uni Kiel, Germany). This calculation was based on the F test. The type I error was 5%, alpha-level was 0.05, power 80%, and medium effect size (0.33). 15 subjects per group were the appropriate number.

Randomization and concealment

Patients were allocated randomly into two groups. To ensure an equal sample size in each group, blocks of different sizes (4,6) were used. The process of allocation was concealed to all researchers and patients, while patients only were blind to the intervention arms throughout the study.

Statistical analysis

Descriptive statistics (mean \pm SD) were used to express all data. Unpaired t-tests were conducted to compare both groups' demographic data. The normal distribution of data was checked using the Shapiro-Wilk test. Homogeneity was tested using Levene's test. Mixed design MANOVA was performed to determine the main effects while post-hoc tests, with Bonferroni corrections, were used for the subsequent multiple comparisons. The level of significance for all statistical tests was set at p < 0.05. statistical analysis was conducted using the Statistical Package for Social Studies (SPSS) version 25 for Windows (IBM SPSS, Chicago, IL, USA).

RESULTS

A total of 30 subjects participated in this study and completed the six-week rehabilitation program as well as the follow-up assessment. No adverse effects were reported except minor soreness at the sites of application of r-ESWT, which was expected and usually resolved within 48 hours. The sampling process is summarized in Figure 2.

Both groups were similar at baseline regarding demographic data and outcome measures (Tab. 1). The distribution of gender between both groups was not statistically significant (p = 0.31).

	Mean \pm SD		MD		
	r-ESWG	CG	IVID	р	
Age (year)	32.73 ± 6.73	33.26 ± 5.48	0.53	0.81	
Weight (Kg)	74.26 ± 5.7	76.46 ± 5.02	2.2	0.27	
Height (cm)	172.6 ± 5	173 ± 6.55	0.4	0.85	
BMI	24.93 ± 1.72	25.56 ± 1.27	0.63	0.27	

Tab. 1. Demographic data of both groups

SD, standard deviation; MD, mean difference; P, significance; ESWG, extracorporeal shock wave group; CG, control group

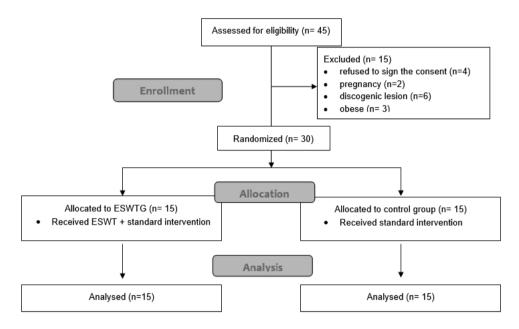


Fig. 2. Experiment flow chart

Tab. 2. Results of within-group comparisons

Outcomes	Group	Pre-treatment	Post treatment	MD	Р
VAS	r-ESWG	7.46 ± 1.88	0.93 ± 0.59	6.53	0.001
	CG	7.2 ± 2.04	1.8 ± 0.67	5.4	0.001
ODI -	r-ESWG	52.55 ± 18.79	13.12 ± 5.4	39.43	0.02
	CG	47.23 ± 19.75	21.69 ± 8.17	25.54	0.04
RMS					
RA –	r-ESWG	525.7 ± 101.75	1169.6 ± 197.66	-643.9	0.01
	CG	518.53 ± 81.9	801.4 ± 173.33	-282.87	0.03
Right EO –	r-ESWG	435.79 ± 106.46	991.1 ± 125.18	-555.21	0.001
	CG	423.37 ± 77.27	690.86 ± 109.45	-267.49	0.021
Left EO	r-ESWG	489.68 ± 110.97	1003.86 ± 121.49	-514.18	0.005
	CG	447.93 ± 132.1	778 ± 120.45	-330.07	0.022
Right LES –	r-ESWG	479.29 ± 64.07	1108.4 ± 86.84	-629.11	0.001
	CG	467.73 ± 61.1	625.21 ± 74.36	-157.47	0.001
Left LES -	r-ESWG	459.19 ± 66.57	1073.13 ± 90.45	-613.94	0.001
	CG	453.62 ± 78.14	647.66 ± 88.75	-194.06	0.001
Right LM	r-ESWG	453.45 ± 88	1075.61 ± 101.01	622.15	0.001
	CG	422.86 ± 70	597.41 ± 103.13	-174.54	0.001
Left LM	r-ESWG	430.31 ± 75.94	993.22 ± 78.71	-563.22	0.001
	CG	411.14 ± 59.72	578.46 ± 69.41	-167.46	0.001

SD, standard deviation; MD, mean difference; P, significance; r-ESWG, radial extracorporeal shock wave group; CG, control group; VAS, visual analog scale; ODI, Oswestry disability index; RMS, root mean square; RA, rectus abdominus; EO, external oblique; LES, lumbar erector spinae; LM, lumbar multifidus

Outcomes	Timing of Assessment	r-ESWG	CG	MD	Р
VAS	Pre-treatment	7.46 ± 1.88	7.2 ± 2.04	0.26	0.71
	Post treatment	0.93 ± 0.59	1.8 ± 0.67	0.87	0.001
DOI	Pre-treatment	52.55 ± 18.79	47.23 ± 19.75	5.32	0.45
	Post treatment	13.12 ± 5.4	21.69 ± 8.17	-8.57	0.002
RMS					
RA	Pre-treatment	525.7 ± 101.75	518.53 ± 81.9	7.17	0.83
	Post treatment	1169.6 ± 197.66	801.4 ± 173.33	368.2	0.01
Right EO	Pre-treatment	435.79 ± 106.46	423.37 ± 77.27	12.42	0.71
	Post treatment	991.1 ± 125.18	690.86 ± 109.45	300.14	0.003
Left EO	Pre-treatment	489.68 ± 110.97	447.93 ± 132.1	41.75	0.35
	Post treatment	1003.86 ± 121.49	778 ± 120.45	225.86	0.0001
Right LES	Pre-treatment	479.29 ± 64.07	467.73 ± 61.1	11.56	0.61
	Post treatment	1108.4 ± 86.84	625.21 ± 74.36	483.2	0.0001
Left LES	Pre-treatment	459.19 ± 66.57	453.6 ± 78.14	5.59	0.83
	Post treatment	1073.13 ± 90.45	647.66 ± 88.75	425.47	0.0001
Right LM	Pre-treatment	453.45 ± 88	422.86 ± 70	30.59	0.31
	Post treatment	1075.6 ± 101.01	597.4 ± 103.13	478.2	0.0001
Left LM	Pre-treatment	430.31 ± 75.94	411.14 ± 59.72	19.1	0.45
	Post treatment	993.22 ± 78.71	578.46 ± 69.41	414.76	0.0001

Between-groups	

SD, standard deviation; MD, mean difference; P, significance; r-ESWG, radial extracorporeal shock wave group; CG, control group; VAS, visual analog scale; ODI, Oswestry disability index; RMS, root mean square; RA, rectus abdominus; EO, external oblique; LES, lumbar erector spinae; LM, lumbar multifidus

Regarding all outcome measures, the main effect of treatment (F= 22.28), the main effect of time (F= 331.57), and the main interaction effect (F= 70. 97) were all statistically significant (p < 0.05).

Post-treatment, both groups demonstrated a significant increase in RMS of all muscles assessed (p < 0.05). These findings were reported in both groups. Additionally, pain scores on VAS (p=0.001) and functional disability level on ODI (p < 0.05) were significantly lower in both groups post-intervention (Tab. 2).

At baseline assessment, all outcome measures were similar in both groups (p > 0.05). On the other hand, post-treatment results were significantly different in favor of r-ESWTG regarding RMS values of all muscles (p < 0.05), pain intensity (p = 0.001), and functional disability (p = 0.002) as shown in Tab. 3.

DISCUSSION

This study investigated the effect of r-SWT to the active trigger points in addition to standard treatment on electrical muscle activity, represented as RMS, of selected abdominal and back muscles, pain, and function in patients with chronic non-specific LBP. The standard treatment both alone and with r-ESWT yielded significant improvement in all outcome measures. However, the addition of r-ESWT to standard treatment made the intervention more effective.

While different outcomes such as pain, disability, quality of life, depression, dynamic balance were assessed after application of r-ESWT, few studies have assessed muscle electrical activity [17,21,22,34,36].

Interestingly, most of the outcomes examined in previous research demonstrated significant improvement. In a recent study by Celik and colleagues, pain, disability in addition to anxiety, and quality of life improved after 6 weeks of r-ESWT as compared to sham treatment [34]. Similar improvements in pain and function were reported when r-ESWT was compared to a motor improvement program [17]. These findings were supported by the results of the current study as well as other trials [21,22,36,37].

However, there were considerable differences in the r-ESWT parameters. For example; many studies, as well as the current one, applied 2000 shocks, while others used 1000 and 1500 shocks [17,21,22,34,36, 37]. Variations were also evident regarding energy flux density and the number and frequency of sessions. Energy flux density, number and frequency of sessions in the current study were similar to those performed previously by Lee et al. and Walewicz et al. [17,21].

Regarding the site of application, there was no consensus in the literature. Han and colleagues applied shock waves to the quadratus lumborum and sacroiliac joints, while others have treated the quadratus lumborum, gluteal muscles, and piriformis [21,22, 36]. Walewicz et al. treated the most painful areas [17]. In a few studies, the site of application was not precisely specified [34,37].

The literature lacks evidence regarding the effect of r-ESWT on low back muscle electrical activity. Only a single study found that the back extensor muscles demonstrated a significant increase in EMG activity after 6 weeks of r-ESWT in addition to an exercise program [29].

The improvement demonstrated by r-ESWG could be attributed to the unique mode of application over active trigger points. In the current study, the authors aimed at trigger points found in the quadratus lumborum, gluteal muscles, and piriformis, which might have deactivated the points and reduced localized and referred pain, so that the muscles worked in a pain-free manner, as indicated by increased electrical activity [19, 38].

The successful release of trigger points-related pain and the increase in the activity of the trunk muscles could improve the role of muscles in controlling and initiating movement and consequently improve function as seen in the current study.

Despite being relatively expensive, r-ESWT could improve the efficiency of exercise programs designed for chronic LBP patients. Accordingly, health care practitioners should incorporate this modality in their options for treatment.

The small sample size represents the main limitation of the current study. Yet the authors performed a power test to determine the least appropriate number of patients. The second limitation is the lack of accurate clinical interpretation of EMG in LBP. The changes in EMG values could not be represented accurately in clinical settings. Further studies should consider a larger sample size and address the minimal clinical significance of EMG.

CONCLUSION

- 1. Standard exercises alone or with r-ESWT could improve EMG activities, reduce pain, and enhance function in patients with chronic non-specific LBP.
- 2. Adding r-ESWT to a standard exercise program could be superior to exercise alone.

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