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e-ISSN 2544-1620

Medical Science Pulse 2020 (14) 1

Reviews

Published online: 30 Mar 2020

DOI: 10.5604/01.3001.0013.9718

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) IN CHRONIC LOW BACK PAIN: A SYSTEMATIC REVIEW OF RANDOMIZED CLINICAL TRIALS

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A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Extracorporeal Shock Wave Therapy (ESWT) has become a popular tool to treat musculoskeletal disorders and chronic low back pain.

Aim of the study: To review the current scientific literature and assess the utility of ESWT in treating chronic low back pain.

Material and methods: This systematic review was conducted from November 2019 to January 2020. Its purpose was to determine what the effectiveness is of the various forms of ESWT for the treatment of chronic low back pain. The critical review of the literature on the use of ESWT in chronic low back was made using the scientifically recognized medical databases PubMed, MEDLINE, Physiotherapy Evidence Database (PEDro) and Web of Science Core Collection. There was no restriction by date. Exclusion criteria were experimental, in vitro, animal, review, case reports, non-randomized clinical trials or studies with healthy participants. All articles written in languages other than English have also been excluded.

Results: Six studies were included in the final analysis. According to the applied PEDro classification, the average scoring for the studies was 4.83, which indicates overall low quality of the presented reports. However, this result appeared closer to the moderate (acceptable) quality range (6-8 points) than to the unacceptable range (0-2 points).

Conclusions: Based on the findings in the analyzed articles, ESWT promises to be an efficient and useful procedure in chronic low back pain treatment. Unfortunately, the level of evidence is relatively weak because there are a limited number of published studies related to ESWT and the final score in the PEDro classification was low. Together, these results indicate the need for further high quality randomized clinical trials.

KEYWORDS: low back pain, ESWT, shock waves, treatment

Background

Extracorporeal Shock Wave Therapy (ESWT) has emerged as a popular tool for treatment of musculoskeletal disorders such as lateral epicondylitis [1–3], painful shoulder syndrome [4–6] and plantar fasciitis [7,8]. Additionally, it has been used to treat lymphedema [9,10], chronic unhealed wounds [11] and muscle spasticity [12–14]. Some reports also indicate there is significant utility and clinical efficacy in applying ESWT to cases of low back pain.

The two primary types of shock waves are the Focused Extracorporeal Shock Wave (fESW) and the Radial Extracorporeal Shock Wave (rESW). They differ in terms of the manner and extent of the acoustic energy propagation, the shape of the beam and its physical properties. The fESW was initially used in lithotripsy devices, which are devices used in interventional urology or abdominal surgery as a non-invasive procedure for crushing urinary or gallstones. The devices emitting this type of wave are usually generated from an electromagnetic, electrohydraulic or piezoelectric method. The wave physically manifests as pressure, which increases rapidly to 100-1000 bars (10-100 MPa) in less than 10 ns, which absorbs soft tissue at a depth of up to 12 cm. The standard wave beam is characterized by a focused propagation shape of the focal length, or the place with the highest energy density over a relatively small area, located 4-6 cm deep.

The rESW, in contrast to the fESW, is generated by the pneumatic (ballistic) technique. This wave is characterized by a slow increase in pressure, reaching 1–10 bars (0.1–1 MPa) in more than 5 μs; it absorbs at a depth of up to 3 cm with a typically diffused (unfocused) beam shape [15,16].

Aim of the study

The purpose of this paper was to assess the utility of ESWT for chronic lower back pain treatment by performing a thorough review of the current, relevant scientific literature.

Material and methods

This systematic review was conducted from November 2019 to January 2020. Its purpose was to determine how effective the various forms of ESWT are for the treatment of chronic low back pain. The study was conducted in accordance with the Preferred Reporting System Items for Systematic Reviews and Meta-analyses (PRISMA) statement.

Search strategy

The critical review of the literature on the use of ESWT in chronic low back was made using the following scientifically recognized medical databases: PubMed, MEDLINE, Physiotherapy Evidence Database (PEDro) and Web of Science Core Collection. The search criteria used were as follows: (efficacy OR management OR effectiveness) AND (low back OR lumbar changes OR coccydynia OR disc pathology OR pain) AND (ESWT OR shock wave OR extracorporeal). These keywords were identified after preliminary literature searches. There was no restriction by date. Exclusion criteria were experimental, in vitro, animal, review, case reports, non-randomized clinical trials or studies with healthy participants. All articles written in languages other than English have also been excluded.

The risk of bias

The articles were analyzed using the Physiotherapy Evidence Database (PEDro) Scale checklist for randomized clinical trials (Tab. 1). Using the criteria in the PEDro checklist, each paper was scored as "high quality, low risk of bias", "acceptable quality, moderate risk of bias", "low quality, high risk of bias", or "unacceptable quality" which resulted in rejection. For each criterion on the checklist, a value of 0 or 1 was assigned for each "no" or "yes" response, respectively. The checklist was comprised of ten items and final quality scores were assigned as follows: high quality, low risk of bias, 9-10; acceptable quality, moderate risk of bias, 6-8; low quality, high risk of bias, 3-5; unacceptable (reject), 0-2.

Table 1. The PEDro scale.

Items	Score: Yes (1 point), No (0 points)
1. Eligibility criteria* 2. Random allocation 3. Concealed allocation 4. Baseline comparability 5. Blind subjects 6. Blind therapists 7. Blind assessors 8. Adequate follow-up 9. Intention-to-treat analysis 10. Between-group comparisons 11. Point estimates and variability	

* Does not contribute to total score.

Data extraction

The data resulting from the collected articles were analyzed by only one researcher and focused on the characteristics of the material and methods, main outcomes and final conclusions. The primary parameters were pain scales and questionnaires, range of motion measurements and quality of life aspects.

Results

The flowchart of randomized clinical trials at all stages of the systematic review is shown in Fig. 1. In total, six studies were included in the final analysis. The characteristics of the included articles are outlined in Tab. 2 and 3. The average quality score for the studies was 4.83, which indicates a general low quality. However, this result was closer to the moderate (acceptable) quality range (6-8 points) than to the unacceptable range (0-2 points).

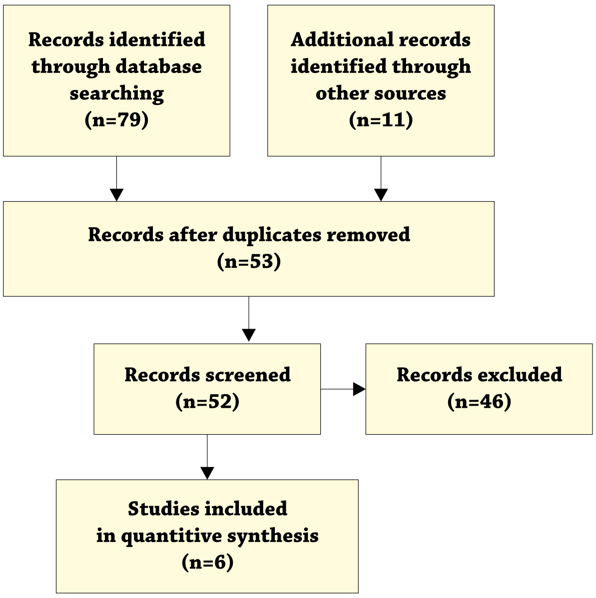

Figure 1. The Prisma flowchart.

Discussion

The following studies show that ESWT may be an effective tool in managing chronic low back pain. Additionally, the literature review illustrates the potential therapeutic mechanisms of ESWT. Basic science studies have well-documented in vitro and animal experiments that demonstrate the pro-angiogenic and anti-inflam-

Table 2. Characteristics of included articles.

	Methods	Results	Conclusions
Han et al. [17]	30 chronic low back pain patients were divided into an extracorporeal shock wave therapy group (ESWTG, n=15) and a conservative physical therapy group (CPTG, n=15). The ESWTG received extracorporeal shock wave therapy (1000 shock waves-7 times per sec were applied at 2.5 Hz at low energy flux densities of 0.01–0.16 mJ/mm2 using a 17 mm head) and the CPTG received general conservative physical therapy two times per week for six weeks. Pain was measured using a visual analog scale (VAS), the degree of disability of the patients was assessed using the Oswestry Disability Index (ODI), and their degree of depression was measured using the Beck depression index (BDI).	In intra-group comparisons, ESWTG and CPTG showed significant decreases in VAS, ODI, and BDI scores. Intergroup comparisons revealed that these decreases in VAS, ODI, and BDI scores were significantly larger in ESWTG than in CPTG.	Extracorporeal shock wave therapy is an effective intervention for the treatment of pain, disability, and depression in chronic low back pain patients.
Schneider [18]	Eligible patients were adults seeking physiotherapeutic treatment. They were randomly allocated to either six treatments of MT (myofascial training) or to six treatments of combined MT and vibro treatment with ESWT. Outcome parameters were pain intensity, pain days, pain duration, and quality of life.	The pain relieving effects of the combined treatment were very large (d=1.6). It clearly outperformed MT and considerably improved patients' health related quality of life.	Combining MT with ESWT enhances the physiotherapeutic effectiveness of treating chronic back pain.
Moon et al. [19]	30 patients with low back pain were assigned randomly to ESWT (n=15) and sham control (n=15) groups. The ESWT group received 2000 shockwaves with energy set to the maximum level tolerable by the patient (energy density=0.09 to 0.25 mJ/mm2). The probe was oriented perpendicular to the posterior lumbar line and moved up and down along the joint line. The sham control group received 2000 shockwaves with the probe oriented parallel to the posterior lumbar line. A 10-cm numeric rating scale (NRS) and the Oswestry Disability Index (ODI) scores were assessed before the intervention, and 1- and 4-weeks post intervention.	In the ESWT group, NRS decreased significantly at post-treatment week 4 (3.64 (95% confidence interval 2.29 to 4.99)) compared to baseline (6.42 (5.19 to 7.66); $p < 0.05$). ODI improved at 1 and 4 weeks compared to baseline, but not significantly. In the sham group, NRS and ODI did not differ at any post-treatment time point. There was a significant group difference in NRS at week 4 post-treatment (3.64 (2.29 to 4.99) in the ESWT group versus 6.18 (5.34 to 7.02) in the sham control group; $p<0.05$), but this was not the case for ODI.	ESWT represents a potential therapeutic option for decreasing chronic low back pain.
Notarnicola et al. [20]	30 patients affected by low back pain were treated with ESWT (shockwave group) or a standard protocol characterized by rehabilitative exercises (control group).	At one and three months, the patients treated with shockwave therapy showed clinical improvement measured by VAS scales (p=0.002; p=0.02), and disability evaluated with Roland scales (p=0.002; p=0.002) and Oswestry (p=0.002; p=0.002). At three months, the patients treated with shock waves showed a significant improvement in terms of values of amplitude of the sensory nerve conduction velocity (SNCV) of the plantar medialis nerve (left: p=0.007; right: p=0.04), the motor nerve muscular conduction (MNCV) of the deep peroneal nerve (left: p=0.28; right: p=0.01) and recruitment of motor units of finger brevis extensor (left: p=0.02; right: p=0.006). In the control group, there was a trend to increase the clinical and electromyographic results without statistical significance.	The results suggest a good applicability of shockwave therapy in the treatment of low back pain, in accordance with the anti-inflammatory, antalgic, decontracting effects and remodeling of the nerve fiber damage verified in previous studies conducted on other pathological models.
Lee et al. [21]	28 patients with chronic low back were divided into an extracorporeal shockwave therapy group (ESWTG – 2000 shocks, 7 times per sec shockwave impulses 5 Hz at an energy flux density of 0.10 mJ/mm2 were delivered using a 17-mm head; n=13) and a conservative physical therapy group (CPTG; n=15). An exercise program that included Williams' exercises and McKenzie's exercises was performed by both groups. The program was implemented twice a week for six weeks. The visual analog scale (VAS) was used to measure the chronic low back pain of the patients. Their dynamic balance ability was measured with BioRescue.	The within-group comparison of the VAS of the ESWTG and the CPTG showed significant improvements after the intervention. In the VAS comparison between the groups after the treatment, the ESWTG showed a significantly larger improvement. In the within-group comparison of dynamic balance ability, the ESWTG showed significant improvements after the intervention in balance control.	The exercise program combined with the ESWT relieved chronic back pain more than the exercise program combined with the CPT.
Walewicz et al. [22]	40 patients with low back pain were randomized into group A (n=20) treated with ESWT (2000 pulses; 2.5 bars; 5 Hz, 7 mins) performed twice a week for five weeks (10 sessions) and stabilization training, as well as group B (n=20) treated with sham ESWT and stabilization training. To analyze the therapeutic progress, the following tests were performed (before and after therapy; 1- and 3-months follow-up) to assess pain and functional efficiency: (1) Visual Analog Scale (VAS), (2) Laitinen Pain Scale (LPS), and (3) Oswestry Disability Index (ODI).	The control group had a statistically significant advantage over the ESWT group (4.4 vs. 3.1 points on the VAS; p=0.039). However, in long-term observations, group A gradually experienced more pain relief than group B (2.7 vs. 3.5 points, $p>0.05$, at one month and 2.0 vs. 4.4 points at three months after treatment; $p<0.0001$). Similar findings can be seen in the analysis of changes in pain sensations measured with the LPS. The functional state (ODI) was better in ESWT group, especially in follow-up observation (9.3 vs. 14.6 points, p=0.033, at one month and 9.3 vs. 17.8 points, p=0.004, at three months after treatment).	The ESWT combined with stabilization training is particularly effective in the long-term and achieves a stable beneficial effect for patients with LBP. The use of ESWT has a significant long-term influence on the reduction of pain and the improvement of the general functional state in relation to the conventional motor improvement program.

Table 3. Quality of included articles.

	Score	Limitations
Han et al. [17]	3/10	no sham therapy, no placebo, no blinded participants, therapists and assessors, no follow-up, no intention to treat
Schneider [18]	6/10	no blinded therapists and assessors
Moon et al. [19]	7/10	no blinded assessors, no intention to treat
Notarnicola et al. [20]	3/10	no sham therapy, no placebo, no blinded participants, therapists and assessors, no follow-up, no intention to treat
Lee et al. [21]	3/10	no sham therapy, no placebo, no blinded participants, therapists and assessors, no concealed allocation, no intention to treat
Walewicz et al. [22]	7/10	no blinded assessors, no intention to treat

matory effects of ESWT. Hatanaka et al. [23] performed in vitro single exposure experiments with a low energy wave (800 beats, frequency 1 Hz, dose 0.03 mJ/mm^2) on cultured human vascular endothelial cells. They measured a significant increase in mRNA expression and activity of Vascular Endothelial Growth Factor (VEGF) and of nitric oxide synthase. In addition, the researchers observed enhanced cellular signal transduction due to increased caveolin 1 and integrin β1 activity. These phenomena are hallmarks of blood vessel reconstruction.

Yahata et al. [24] used low-energy ESWT three times a week for three consecutive weeks in Sprague-Dawley rats with damaged spinal cords. The authors noted increased cellular VEGF as well as initiation of nerve regeneration and angiogenesis at the site of injury.

Kang et al. [25] also conducted an interesting rESWT experiment in Sprague-Dawley rats. They induced brain ischemia in 105 rats and randomly assigned them to three comparative groups. For the first group (n=45), rESWT was applied (200 beats, frequency 10 Hz, dose 1 bar). The second group (n=15) received an additional treatment compared to group 1 using the same parameters (200 beats, frequency 10 Hz, dose 2 bars). Finally, the third group (n=45) was not subjected to any physical treatment and served as the control. After a single exposure to the shockwave, a significant improvement in blood flow was observed in cerebral vessels compared to the control group irrespective of dose. In addition, enhanced VEGF activity and stimulation of the neovascularization process were detected in rats from the groups exposed to rESWT.

In another experiment, Kisch et al. [26] assigned 18 Sprague-Dawley rats into two groups that were either stimulated with a series of eight high-energy ESWT (1000 pulses, 10 J output energy) or were subjected to eight quasi-ESWT (sham therapy). Procedures were applied to the dorsal side of the hind limbs. Ten minutes after the end of each procedure, laser Doppler flowmetry measurements were taken within the skin capillaries both on the limb subjected to physical treatments and on the opposite side. Cutaneous blood flow increased by 152.8% in the first group compared to the placebo group (p=0.01), and the average oxygen pressure was 12.7% higher than in the control group (p=0.02).

There are reports promoting the theory that ESWT increases nerve fiber regeneration and prevents muscular atrophy. Lee and Cho [27] studied the effectiveness of low-energy waves (300 impulses, frequency 3 Hz, dose 0.09 mJ/mm^2) in mice in relation to a single-blind placebo group. A one-time application of low-energy waves was applied to the sciatic nerve of mice damaged by induced mechanical ischemia Therapeutic progress was evaluated by measuring the change in weight of the gastrocnemius and soleus calf muscles before and 14 days after the injury and analyzed using the Sciatic Functional Index (SFI). In all measured parameters, the ESWT group showed a statistically significant difference compared to the placebo-treated group.

Many researchers additionally emphasize that ESWT can be applied to stimulation of osteogenesis. Schnurrer-Luke-Vrbanić et al. [28] measured the rate of bone tissue regeneration in response to ESWT in Wistar rats. Forty-eight animals were randomly divided into two groups. In the first group (n=36), a radial wave (0.15 mJ/mm^2, 300 pulses) was used. The second group (n=12) served as the control and received no therapeutic intervention. After three weeks, a biopsy was performed, and they measured cross-sectional areas of bone beams from 0.04 mm^2 in the cartilage to 1.7 mm^2 in the bone trabeculae. Overall, the bone tissue was significantly greater in the ESWT-treated group compared to the control group.

Conclusions

Based on the findings in the analyzed articles, ESWT promises to be an efficient and useful procedure in chronic low back pain treatment. Unfortunately, the level of evidence is relatively weak because there are a limited number of published studies related to ESWT and the final score in the PEDro classification was low. Together, these results indicate the need for further high quality randomized clinical trials.

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Word count: 2659 • Tables: 3 • Figures: 1 • References: 28

Sources of funding:
The research was funded by the author.

Conflicts of interests:
The author reports that there were no conflicts of interest.

Cite this article as:
Walewicz K.
Extracorporeal Shock Wave Therapy (ESWT) in chronic low back pain:
a systematic review of randomized clinical trials.
MSP 2020; 14, 1: 51–56. Published online: 30 Mar 2020.

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Received: 29.01.2020
Reviewed: 2.03.2020
Accepted: 9.03.2020