The effectiveness of Extracorporeal Shockwave Therapy in the treatment of chronic low back pain: A Systematic Review

Abstract

Introduction: Low back pain is the most prevalent chronic pain syndrome in clinical practice. Due to safer benefits, nonpharmacological, exercise-based treatments represent the first choice for chronic low back pain (CLBP). Recently, Extracorporeal Shockwave Therapy (ESWT) has been suggested as a new treatment option for CLBP. The aim was to provide an overview of the effectiveness of ESWT in combination with exercise versus exercise alone in pain and disability reduction in CLBP through a systematic review of published randomised control trials (RCTs).

Methods: Original RCTs related to the use of ESWT in CLBP were searched in PubMed, Cochrane’s library and the Physiotherapy Evidence Database back ten years from January 2023. The recommendations of the Preferred Reporting Items for Systematic Review and Meta-Analysis statement and The Prisma in Exercise, Rehabilitation, Sport Medicine and SporTs scientific guidance were followed. Data on study information, Population characteristics, Intervention treatment, Control or comparators, and Outcomes were extracted. Outcomes of primary interest were pain and disability, observed before and after treatments. The results are presented systematically and narratively.

Results and Discussion: Two eligible RCTs were included from the initial 30 identified. Despite the evident reduction in pain and disability in the ESWT groups, the significance of the outcome versus the control groups in the short and long-term periods is conflicting between studies.

Conclusion: In treating CLBP, ESWT combined with exercises is to some extent clinically superior to exercises alone; however, evidence should be used with caution due to the lack of studies and existing confrontations.

Keywords: chronic pain, extracorporeal shockwave therapy, low back pain, physical therapy modalities, systematic review

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Introduction

Low back pain (LBP) is clinical practice’s most prevalent chronic pain syndrome.1 Because of years spent with disabilities2 and reduced quality of life3 of adults in their otherwise productive age, low back pain represents both individual and societal burden.4 In treating and preventing the consequences of low back pain, it is essential to make treatment decisions based on evidence, safety and efficacy. For chronic low back pain (CLBP) management, strong recommendations are given for choosing nonpharmacologic treatments5 - exercises in the first line.6 Nonpharmacological interventions provide safer benefits than pharmacological or invasive interventions in treating CLBP.7

A widely propagated nonpharmacologic and noninvasive therapeutic modality in the treatment of numerous musculoskeletal disorders is Extracorporeal Shockwave Therapy (ESWT)8, and two types of technical principles usually included in it, focused ESWT (F-ESWT) and radial pressure waves (RPW).9 The physiologic effects of ESWT have been widely investigated, with observations that different energy forms affect the musculoskeletal system10 by augmenting pain relief, neovascularisation, protein biosynthesis, cell proliferation, neuro and chondroprotection, and destruction of calcium deposits in musculoskeletal structures.8 Increasing evidence suggests ESWT is a safe and effective treatment9, leading to tissue regeneration, significant alleviation of pain, and improved functional outcomes.8

To date, ESWT has shown great potential as a proper regenerative technique for treating numerous musculoskeletal disorders8, including soft and hard tissue11, with most evidence of effectiveness in chronic tendinopathies8 but also recently suggested as a new treatment option in CLBP.12 ESWT proved effective alone or combined treatment in augmenting pain relief and functional outcomes in patients with CLBP.13,14 However, only several studies investigated its effectiveness12, meaning further research is needed. The only two reviews, simultaneous meta-analyses, highlight the heterogeneity between studies due to clinically diverse aetiology, duration of pain, ESWT treatment features, various unimodal or multimodal comparators, and outcome measures observed.13,14 They also emphasise that randomised controlled studies (RCTs) of adequate quality should be conducted to produce high-quality evidence of ESWT effectiveness and safety in CLBP and promote the application of ESWT in clinical practice.

Additional areas for improvement in the existing body of knowledge, and of particular importance for physiotherapy, is the effectiveness of the application of ESWT in combination with exercise compared to the application of exercise alone. Defining such a research problem by extracting exercises from the pool of physiotherapy interventions is based on the fact that exercise alone is the first line of treatment for CLBP, and ESWT can potentially augment patient outcomes. In addition to the knowledge of EWSST effectiveness concerning patient outcomes, this effect must be investigated and visible in pain, disability, and quality of life – core outcomes in patients with CLBP.15

Considering the existing body of knowledge, the aim is to provide an overview of the effectiveness of ESWT in combination with exercise in comparison to exercise alone on CLBP patient outcomes of pain and disability through a systematic review of published RTCs. This systematic review will have a scientific and practical contribution, given that it will provide insight into the current evidence and, therefore, the justification to some extent for applying ESWT in physiotherapy in patients with CLBP.

Methods

In developing this review, an effort was made to follow the recommendations of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement16 and The Prisma in Exercise, Rehabilitation, Sport Medicine and Sports Science (PERSiST) guidance.17

Information sources and search strategy

Original RCTs related to the ESWT in CLBP were sought in PubMed, Cochrane’s Library and Physiotherapy Evidence Database (PEDro). Grey literature, secondary sources or popular articles were not of search interest. PubMed database search consisted of Mesh terms “Extracorporeal Shockwave Therapy” AND “Low Back Pain”, with publication date filters January 2013-2023 and RCTs only. Since all studies were in English, no language filter was used.
The search of the Cochrane Register of Trials consisted of the terms “Extracorporeal Shockwave Therapy”, “Low Back Pain”, and “Randomised Controlled Trial” in the keywords, title and abstract search engine with publication date filters 2013-2023, with no language filter since all studies were on English.

In the PEDro database, the search consisted of the terms “Extracorporeal Shockwave Therapy” AND “Low Back Pain” in the title and abstract with publication date filters 2013-2023 and clinical trials only.

**Eligibility criteria**

The eligibility criteria were set according to the Patient Intervention Comparison Outcome (PICO) framework. The PICO research question was: “In chronic low back pain (P), is there a difference between extracorporeal shock wave therapy in combination with exercise (I) and exercise alone (C) in reducing pain and disability (O)?”.

RCTs were considered eligible if they examined the PICO elements of interest. RCTs conducted outside the clinical or laboratory setting were deemed ineligible. Studies in which participants were <18 years old and had acute low back pain or comorbidities other than CLBP were considered ineligible. Intervention and comparator treatment combined with any other treatment (i.e., manual therapy, electrotherapy, analgesics or anti-inflammatory drug use, surgery and similar) was considered ineligible, except sham ESWT in the control group. Regarding the outcome measures, studies were not considered eligible if they did not address both outcome measures, the outcome of pain and disability, regarding the biopsychosocial interaction of pain and the disability rate of over 80% in CLBP.

**Selection process**

The selection of studies was a several-step process, and the reviewer evaluated identified sources manually and by reading without a computer program. After records had been identified from databases, evaluated duplicate titles were removed. By scanning individual titles and associated abstracts, articles irrelevant or ineligible to the research question were removed. The full text was searched for relevant titles and abstracts, which included a search of various sources emphasising their scientific and academic integrity. Titles for which the full text was not found were excluded. After reviewing and evaluating the content of the complete texts, eligible studies were defined for inclusion in the report.

**Data extraction and qualitative analysis**

Data on study information, Population characteristics, Intervention treatment, control or comparators, and Outcomes (PICO) were extracted. Outcome measures of primary interest were pain and disability and, optionally, quality of life observed before and after the intervention/comparison treatment and in follow-up. The mean values, standard deviations and the significance of the difference between the ESWT and the control group were observed, analysed, and presented narratively and with studies quantitative data.

**Quality Assessment**

A possible already-existing assessment of the methodological quality of the works included in the review was investigated in the PEDro database. The PEDro scale assessment was intended for the absence of an existing evaluation of methodological quality.

**Results**

**Study inclusion**

A total of 30 studies were identified through the initial search. After removing duplicates, 20 records were placed, 16 of which were excluded for being irrelevant or ineligible to the PICO research question or criteria. Of the following 4, full texts were found for only two studies corresponding to our PICO question. The remaining two were included in the review and qualitatively analysed due to their full eligibility. The PRISMA flow diagram of the study selection procedure is shown in Figure 1.

**Characteristics of the included studies**

The included two RCTs in the review were of recent date representing Poland and the same research setting, and were prospectively registered. Radial and focused types of ESWT were used in the studies. Extracted data on study information, Population characteristics, Intervention treatment, control or comparators, and Outcomes (PICO) are contained in Table 1. Below is a brief overview of the studies’ key and summarised features.
related quality of life was not measured in either of these two studies.

Both studies included stabilisation training in intervention and comparison groups (45 mins, once daily, five days a week). In the intervention groups, real ESWT was applied on lumbosacral soft tissue twice a week, a total of 10 treatments with an average flux density of 0.125 mJ/mm², 1500 pulses and 4.5 Hz frequency. The control group received sham ESWT. Subjects were blinded to the form of ESWT they were receiving.
### Table 1. Summary and characteristics of RCTs included in the review

Study information, Population characteristics, Intervention treatment, control or comparators, and Outcomes (PICO)

<table>
<thead>
<tr>
<th>Study information, Population characteristics, Intervention treatment, control or comparators, and Outcomes (PICO)</th>
<th>Patients</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcomes</th>
<th>Authors’ Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ESWT vs control:</strong></td>
<td><strong>Inclusion:</strong> age &gt;18 years; CLBP of L5-S1 discopathy; CLBP history &gt; 3 months</td>
<td><strong>Eligibility criteria</strong></td>
<td><strong>VAS</strong></td>
<td><strong>ODI</strong></td>
<td><strong>Conclusion</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Exclusion:</strong> acute spinal pain; different level spine discopathy; no pain; reduced mobility in the lumbosacral segment; specific spinal diseases; pregnancy; pacemaker; cardiovascular diseases; blood coagulation disorders; metal implants; mental disorders; cancer; skin lesions; infections; spinal surgery; drug use</td>
<td><strong>ESWT vs control:</strong> Disability</td>
<td><strong>VAS</strong></td>
<td><strong>Baseline:</strong> 4.7 ± 1.4 vs 3.1 ± 1.4 (p=0.039) 1-month FU: 2.7 ± 1.7 vs 3.5 ± 1.1 (p&gt;0.05) 3-month FU: 2.0 ± 2.0 vs 4.4 ± 1.2 (p&gt;0.0001)</td>
<td><strong>ESWT is effective both in short and long-term, substantially influencing pain reduction and improving functional state versus conventional exercise program</strong></td>
</tr>
<tr>
<td><strong>Device:</strong> Radial, Cosmogamma, Indonesia Parameters: 2.5 bars; 5 Hz; 2000 pulses; 0.1 mJ/mm²; 7 min Sessions: twice a week for five-week training: in the form of stabilization and functional exercises, relaxation and proper breathing: 45 min, once a day, five days a week</td>
<td><strong>Sham ESWT:</strong> polyethylene applicator cap that prevents the actual procedure to have a therapeutic effect Training: in the form of stabilization and functional exercises, relaxation and proper breathing: 45 min, once a day, five days a week</td>
<td><strong>LPS</strong></td>
<td><strong>Baseline:</strong> 6.3 ± 2.0 vs 6.2 ± 2.8 (p&lt;0.05) 1-month FU: 3.9 ± 1.8 vs 5.2 ± 2.2 (p&lt;0.043) 3-month FU: 2.2 ± 2 vs 6.4 ± 2.6 (p=0.0001)</td>
<td></td>
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<tr>
<td><strong>Author and Year</strong></td>
<td><strong>Author and Year</strong></td>
<td><strong>N:</strong> 20 (20) vs 20 (17)</td>
<td><strong>N:</strong> 20 (19) vs 20 (18)</td>
<td><strong>Age:</strong> 42.3 ± 13.1 vs 45.4 ± 14.0</td>
<td><strong>Age:</strong> 43.2 ± 13.1 ± 13.3</td>
</tr>
<tr>
<td><strong>Walewicz et al., 2019</strong></td>
<td><strong>Rajfur et al., 2022</strong></td>
<td><strong>Gender:</strong> female/male; 14/6 vs 15/5</td>
<td><strong>Gender:</strong> female/male; 10/10 vs 10/10</td>
<td><strong>Disease duration:</strong> 117.6 ± 61.2 vs 108.0 ± 49.2</td>
<td><strong>Disease duration:</strong> 57.5 ± 50.9 vs 61.8 ± 53.1</td>
</tr>
</tbody>
</table>
In both studies, a smaller number of dropouts was recorded, but considering that it is within the permitted percentage calculated in the initial number of randomised, it is considered insignificant. Outcomes were measured before, after, and in follow-ups and for all comparisons made, a significance level of $\alpha=0.05$ was used.

**Reduction in disability**

Despite the evident improvement in functional status in the ESWT groups, the significance of the outcome versus the control groups in the short and long-term periods is conflicting between studies. In both studies, the compared groups were homogeneous in terms of disability. One study reported no differences between the compared groups after treatment ($13.6 \pm 5.6$ vs $12.3 \pm 8.4$ on the ODI; $p>0.05$) but noticed a significant difference in favour of ESWT versus control in one month ($9.3 \pm 7.1$ vs $14.6 \pm 7.3$ on the ODI; $p=0.033$) and at a three-month follow-up ($9.3 \pm 8.7$ vs $17.8 \pm 7.2$; $p=0.004$). The other reported no significant difference between compared groups after ($18.3 \pm 7.5$ vs $19.5 \pm 6.5$ on the ODI; $p=0.664$), in one month ($17.3 \pm 7.1$ vs $18.7 \pm 6.6$ on the ODI; $p=0.480$) nor at a three-month follow-up ($18.3 \pm 6.8$ vs $19.9 \pm 7.4$ on the ODI; $p=0.578$) after treatment cessation.

**Methodological Quality**

Table 2 shows the methodological quality of the studies included in the review. Methodological quality assessment was found for both studies in the PEDro database.

**Discussion**

**Summary of evidence**

The reviewed studies included 80 subjects with CLBP, a middle age group generally associated with a higher incidence of musculoskeletal disorders. Most of the respondents were women. In addition to female dominance, research on CLBP indicates that prevalence and degree of disability are more significant in females, apropos their biopsychosocial characteristics. The chronic pain among the subjects is considered moderate, and the disability moderate to severe. For comparison, one group of subjects were treated with ESWT twice a week, a total of ten treatments combined with stabilisation exercises. The other had only stabilisation exercises, considering that sham ESWT was used.

The RCTs included in this review are considered “good” and provide level-1 evidence, although minor im-
provements in them would ensure their excellence. Although methodologically correct and similar, the results of these studies are different. Despite the evident reduction in pain intensity, interference, and disability in the ESWT groups, the significance of the outcome versus the control groups in the short and long-term periods is conflicting between studies.

In short-term pain intensity reduction, measured with VAS, Walewicz et al.\textsuperscript{22} reported a statistically significant advantage of control over the ESWT group. In contrast, Rajfur et al.\textsuperscript{23} reported no significant reduction in pain, while Rajfur et al.\textsuperscript{23} reported significant pain reduction and superiority of ESWT over control in one month. At three months of follow up, the studies reported either significant pain reduction\textsuperscript{22} or maintenance of the achieved improvement and in favor of ESWT\textsuperscript{23}. Particular findings were also seen in changes in pain interference measured with the LPS. In addition to short-term changes, Walewicz et al.\textsuperscript{22} reported higher pain interference in the ESWT group compared to the control. In contrast, Rajfur et al.\textsuperscript{23} reported the contrary and favoured ESWT. In the study that reported greater short-term efficacy in favour of control, the situation changed in favour of ESWT at both follow-ups.\textsuperscript{22} In the other study, despite the advantage of ESWT being maintained, it was not reported as statistically significant compared to the control in none of the follow-ups.\textsuperscript{23} The findings of previous meta-analyses have shown that ESWT led to a significantly more reduction in pain in the first month\textsuperscript{13,14} compared with comparator therapies. However, pooled results at the third-month follow-up were different; there was a significant reduction in pain intensity after ESWT compared to control\textsuperscript{14} and no statistically significant difference between ESWT and control groups.\textsuperscript{13} Here, observing certain discrepancies in the findings is also possible. However, it is necessary also to emphasise that both studies mentioned above included different unimodal or multimodal comparator therapies. In contrast, we extracted and reviewed studies that only had ESWT in combination with exercise as a comparator to exercises (and sham ESWT) alone.

Regarding disability reduction, that is, functional status augmentation, Walewicz et al.\textsuperscript{22} reported no differences between the compared groups immediately after treatment. However, they did note a significant difference in favour of ESWT versus control in one and three-month
Conclusion

Considering the outcomes of this review, the need for a new and more significant number of RCTs and their open access is evident. Despite more serious reviews with meta-analyses, this review has its additional value, considering that it is the first, by the objective, to address the problem of the effectiveness of ESWT in combination with exercises versus exercises alone as a primary nonpharmacological treatment of CLBP. It can be concluded that ESWT, in combination with exercises, is, to a certain extent, clinically superior to exercises alone. However, although ESWT has been recommended as a new treatment option in CLBP, its clinical application must be fully justified. Findings should be used cautiously due to the need for studies and confrontations between current evidence.

Limitations

Although the studies used in this review were of good quality, the number of studies in future reviews must be increased to reach firmer conclusions. It is a fact that the availability of full texts is limited. As a potential solution for increasing the number of studies, it is possible to use secondary sources, for example, research from existing and discussed meta-analyses. Still, this was not applied since this review condition was the availability of the full text of primary sources for a detailed review. As an addition to possible weaknesses, we note the fact of only one reviewer. However, given that the guidelines were followed and the studies used are verifiable, this deficiency could be considered a partial limitation.
References


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UČINKOVITOST IZVANTJELESNE TERAPIJE UDARNIM VALOM U LIJEČENJU KRONIČNE KRIŽOBOLJE: SUSTAVNI PREGLED LITERATURE

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Sažetak

Uvod: Bol u donjem dijelu leđa najčešći je sindrom kronične boli u kliničkoj praksi. Zbog veće sigurnosti, nefarmakološki tretmani temeljeni na vježbanju predstavljaju prvi izbor u liječenju kronične boli u donjem dijelu leđa (engl. chronic low back pain, CLBP). Nedavno je izvantjelesna terapija udarnim valom (engl. extracorporeal shockwave therapy, ESWT) predložena kao nova opcija liječenja kronične boli u donjem dijelu leđa. Cilj je rada pružiti pregled učinkovitosti izvantjelesne terapije udarnim valom u kombinaciji s vježbanjem u odnosu na samo vježbanje u smanjenju boli i invaliditeta kod kronične boli u donjem dijelu leđa kroz sustavni pregled objavljenih randomiziranih kontrolnih ispitivanja.

Metode: Izvorna ispitivanja koja se odnose na upotrebu izvantjelesne terapije udarnim valom kod kronične boli u donjem dijelu leđa pretražena su na platformi PubMed, u Cochraneovoj knjižnici i bazi podataka Physiotherapy Evidence Database u posljednjih deset godina do siječnja 2023. Autor se u radu pridržava smjernica za izvještavanje u preglednim radovima i metaanalizama PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis statement) i znanstvenih smjernica za tjelovježbu, rehabilitaciju, sport-

Ključne riječi: kronična bol, izvantjelesna terapija udarnim valom, bol u donjem dijelu leđa, modaliteti fizikalne terapije, sustavni pregled