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The effectiveness of conservative, non-pharmacological treatment, of plantar heel pain: A systematic review with meta-analysis

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ABSTRACT

Plantar heel pain is one of the most common causes of pain and musculoskeletal pathologies of the foot. The aim of this systematic review was to identify the most effective, conservative and non-pharmacological treatments regarding pain in patients with plantar heel pain.

The authors searched 5 databases and included only randomized control trials which investigated the efficacy of a conservative non-pharmacological treatment compared to the placebo, for the outcome of pain.

Study selection, data collection and risk of bias assessment were conducted independently by two authors, and consensus was reached with a third author. Results were quantitatively summarized in meta-analyses, by separating homogeneous subgroups of trials by type of intervention.

A total of 20 studies that investigated the efficacy of 9 different types of interventions were included, with a total of 4 meta-analyses carried out. The interventions: shock waves, laser therapy, orthoses, pulsed radio-frequency, dry-needling, and calcaneal taping resulted in being effective treatments for the outcome pain in patients with plantar heel pain when compared to the placebo. However, considering that the improvements were very small, and the quality of evidence was mostly low or moderate for many of the interventions, it was not possible to give definitive conclusions for clinical practice.

1. Introduction

Plantar heel pain is one of the most common causes of pain and musculoskeletal pathologies of the foot [1,2]. The latest trials confirm that it affects 2 million American people, and that 10% of the American population has experienced plantar heel pain at least once in their lifetime [2]. The most commonly reported presentation is plantar heel pain, it can be intense and may radiate into and involve the entire plantar fascia. Up to 80% (that is 4/5 cases) of plantar heel pain resolve over the course of 12 months from the onset without any therapeutic intervention. There is a reported 90% resolution of heel pain (that is 9/10 cases) in those cases that undergo conservative treatments (non-surgical) [3], which include: articular mobilization [4], stretching [5], orthotic therapy [6], shock wave therapy [7], and laser therapy [8]. However there is a lack of overall evidence of the true effectiveness of these interventions. This omission is addressed by this systematic review and meta-analysis.

2. Methods

2.1. Registration

The review protocol was registered on the International Register of Systematic Reviews (PROSPERO) on 09/03/2017 code CRD42017058233, available here https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017058233.

2.2. Inclusion criteria

Population: Studies of adults (> 18 years) with a clinical or instrumental (ultrasound or magnetic resonance) diagnosis of plantar heel pain or plantar fasciitis, who were symptomatic at the time of enrolment.

Treatments: Studies that considered conservative, non-pharmacological treatments, compared to a placebo, no treatment or sham treatment.

Outcome: Studies that reported pain intensity, assessed by numerical or visual analogue scales.

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Study characteristics: Published randomized controlled trials (RCT) in English language, as the major journals available in medical databases are published in English.

2.3. Exclusion criteria

Population: Studies that reported patients with fascial plantar fibromatosis, tarsal tunnel syndrome, lesion of plantar nerve, Morton's syndrome, fracture, tumor, osteoarthritis, diabetic pathologies e.g. ulcers, rheumatic pathologies, neurological pathologies, acute or chronic infections.

Treatments: Studies that considered pharmacological treatments and surgery.

Outcome: Studies that reported outcome data required for the meta-analysis (i.e. mean difference and standard deviation) not available.

Study characteristics: Studies with abstract not available.

2.4. Search strategy and study selection

Two authors searched the following databases: Medline, PEDro, Cochrane Central Register of Controlled Trials, Cinahl, and Embase. The last search was made on 10th March, 2017. Search terms used were: plantar fasciitis, heel spur, heel pain, physical therapy modalities, acupuncture therapy, cryotherapy, laser therapy, placebos, diathermy, orthotic devices, extracorporeal shock wave therapy, and dry needling (Appendix A).

Further research was conducted by consulting the bibliographies of the included trials, other systematic reviews, protocol databases of RCT, and groups of interest. The study selection was carried out independently by the same two authors and consensus was reached with the third author, in a two-phase screening process: firstly by reading the title and abstract, and secondly by reading the full text by all parties.

2.5. Risk of bias of included studies

The risk of bias was assessed with the Cochrane's Risk of Bias Tool [9], specifically within the following domains: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias.

The same two authors independently conducted the assessment, and if consensus was not met, disagreements were resolved by the third author so that every Risk of Bias judgement was given on the basis of a minimum of a 2/3 consensus.

2.6. Data extraction, primary outcome and synthesis of results

Data extraction was conducted by using a pre-piloted form, in which the following elements were collected: study design, country of the study, condition, treatment type and characteristics, control, outcome measure, follow-up considered in meta-analysis, sample size, number of drop-outs, and study results.

Data extraction was conducted independently by the two authors, and disagreements were resolved with the third author. The primary outcome considered in this review was pain intensity, assessed with numerical and visual-analogue scales, and considered the mean difference and standard deviation as a statistical index.

Results were reported quantitatively in the meta-analyses, using the variance inverse method with the fixed effect in case of absence of heterogeneity, and with the random effect in case of presence of heterogeneity, collecting the included studies in homogeneous subgroups of the same intervention. For the estimate effect, the mean difference was used when the meta-analysis included outcome measure scales that were the same and the standardized mean difference was used when the measure scales were different. Heterogeneity was assessed using the I^2 and chi-squared test (X^2, Chi^2), where P-value lower than 0.05 indicates significant heterogeneity. Meta-analyses were conducted using Review Manager Software (RevMan, version 5.3.5 for Windows). The results were interpreted with the help of some experienced physiotherapists, with at least 10 years of clinical experience, and academics in field of rehabilitation of musculoskeletal disorders. These were not considered as co-authors as they did not participated actively and significantly at the research, but only gave recommendations for results interpretation.

Quality of evidence was assessed using the GRADE approach, as reported in the Cochrane Handbook for Systematic Reviews of Interventions, by four grading levels from High to Very Low [9]. The grading was given on the basis of the methodological quality of the single studies, statistical heterogeneity, directness, precision of the estimate effect, and the presence of publication bias.

3. Results

3.1. Study selection

537 articles were screened for eligibility. After the removal of the duplicate trials, only 244 remained. 133 were excluded after screening by title and abstract, 13 because the abstract was not available, 1 did not report the authors, 68 did not concern plantar heel pain, 9 were not in English, and 6 were not RCT. Of the remaining 111 studies, 23 were excluded as the full text was not available in the databases and the paper's authors did not give any answer when asked for the full texts, 4 were not randomized, 16 used pharmacological treatments, 4 did not meet inclusion criteria, 3 did not include outcomes of interest, and 41 did not report the necessary data for meta-analysis. Ultimately, 20 articles were determined to have met all inclusion criteria and were eligible to be included in the review; 16 of these could be included in the meta-analysis. 4 studies were not suitable to be included in the meta-analysis as each one of them considered a different type of intervention (Fig. 1).

3.2. Study characteristics

The sample size in each study ranged from a minimum of 10 participants to a maximum of 285 [10,11], giving an aggregate total of 6656 participants, which included the totality of treated and not-treated subjects. Every study compared an active intervention with a sham or no-intervention. The eligibility criteria used in the majority of the studies are summarized in Table 1. The interventions analyzed in the included studies were: shock waves [11–20], laser therapy [8,21], orthoses [6,22], stretching [10,23], ultrasound-guided pulsed radiofrequency (USGPRF) [24], pulsed radiofrequency electromagnetic fields (PRFE) [25], dry-needling [26], low-dye taping [27], and calcaneal taping [10]. All of these interventions were compared to the placebo. Data collected from the studies are reported in Tables 2 and 3, organized firstly by the type of intervention and secondly by author in alphabetical order (Tables 2 & 3).

3.3. Risk of bias among studies

All of the included studies confirmed randomization, despite one not reporting the mode used [14]. 10 studies did not report information regarding concealed allocation [8,10–12,14,16,18–20,22,24], leading to a moderate risk of selection bias. There is a high risk of performance bias because 7 of these studies did not have blinding of personnel and 3 did not report it [6,10,14,18–20,22,23,26,27], and 1 did not report blinding of participants [17]. Since the outcome of interest of the review (pain intensity) was assessed by a subjective scale, blinding of patients corresponded to blinding of outcome assessment, with only one study not reporting information about assessor blinding [17]. There is a high risk of attrition bias between the studies, as 7 studies reported a high number of drop-outs, and 3 did not declare them [8,12–15,17–19,21,24]. Finally, there is high presence of other bias, as