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Efficacy of low frequency pulsed subsensory threshold electrical stimulation vs placebo on pain and physical function in people with knee osteoarthritis: systematic review with meta-analysis

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SUMMARY

Objective: To determine if low frequency (≤100 Hz) pulsed subsensory threshold electrical stimulation produced either through pulsed electromagnetic field (PEMF) or pulsed electrical stimulation (PES) vs sham PEMF/PES intervention is effective in improving pain and physical function at treatment completion in adults with knee osteoarthritis (OA) blinded to treatment.

Method: The relevant studies were identified by searching eight electronic databases and hand search of the past systematic reviews on the same topic till April 5, 2012.

We included randomized controlled trials (RCTs) of people with knee OA comparing the outcomes of interest for those receiving PEMF/PES with those receiving sham PEMF/PES. Two reviewers independently selected studies, extracted relevant data and assessed quality. Pooled analyses were conducted using inverse-variance random effects models and standardized mean difference (SMD) for the primary outcomes.

Results: Seven small trials (459 participants/knees) were included. PEMF/PES improves physical function (SMD = 0.22, 95% confidence interval (CI) = 0.04, 0.41, $P = 0.02$, $I^2 = 0\%$), and does not reduce pain (SMD = 0.08, 95% CI = −0.17, 0.32, $P = 0.55$, $I^2 = 43\%$). The strength of the body of evidence was low for physical function and very low for pain.

Conclusion: Current evidence of low and very low quality suggests that low frequency (≤100 Hz) pulsed subsensory threshold electrical stimulation produced either through PEMF/PES vs sham PEMF/PES is effective in improving physical function but not pain intensity at treatment completion in adults with knee OA blinded to treatment. Methodologically rigorous and adequately powered RCTs are needed to confirm the findings of this review.

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Introduction

Osteoarthritis (OA) is a degenerative disorder of the articular cartilage associated with hypertrophic bone changes[1]. It is the most common chronic joint disease and the leading cause of pain and disability among older adults around the world[2]. Knee OA has an immense public health impact due to the need for healthcare services particularly if surgical replacement of the knee joint is required[3]. In 2000, 25 million people in North America had knee OA, and that number is expected to double by 2020 due to several factors including sedentary life style, increasing prevalence of obesity and population aging[4].

Effective, conservative interventions for relieving pain and improving physical function are needed for people with knee OA[5]. Pulsed electromagnetic field (PEMF) and pulsed electrical stimulation (PES) are emerging non-pharmacologic conservative treatments of knee OA. Both treatments produce pulsed electric potentials below the sensory threshold either through an electromagnetic coil system (PEMF) or surface electrodes (PES) applied around the knee joint[6–8]. These subsensory-threshold pulsed electric potentials stimulate intrinsic potentials[9], which alter the homoeostatic balance of cartilage matrix degradation and synthesis in favour of cartilage repair[10]. In cell culture and animal studies, electrical stimulation similar to that produced by PEMF/PES increases cartilage synthesis by down regulation of interleukin-1 (IL-1) and up regulation of transforming growth factor beta (TGFβ)

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which lead to increased aggrecan, type II collagen, and proteoglycan content in the cartilage matrix and enhanced chondrocyte proliferation[11]. In an animal model study, PES of less than 100 Hz has shown higher efficacy than frequencies of 150 Hz or more[12]. Moreover, higher frequencies have been associated with harmful changes in bone tissue[6].

Previous systematic reviews have addressed the question of efficacy of PEMF and PES for knee OA management and reached contradicting conclusions[13,14]. McCarthy *et al.* (2006) pooled data from five randomized controlled trials (RCTs) (276 participants/knees) and concluded that PEMF and PES are not effective for knee OA pain or physical function[13]; Vavken *et al.* (2009) pooled data for nine RCTs (483 participants/knees) and concluded that PEMF and PES might improve physical function but not pain in the knee OA population at treatment completion[14]. A systematic review conducted by We *et al.* searched literature published to December 2011 to determine the efficacy of PEMF pooling data from 14 studies (930 participants/knees) reporting knee OA pain and physical function outcomes at 4, 8, 12, and 16 weeks[15]. Similar to the conclusions reported by Vavken *et al.* (2009), We *et al.* reported that physical function was improved at 8 weeks with active PEMF (five trials, 304 participants/knees; all interventions completed at 6 weeks) and pain was not significantly improved at any time point (maximum of 11 trials, 762 participants/knees (at 4 weeks) in which the intervention period was 2, 3, 4, or 6 weeks). However, the inclusion of trials in which pulsed subsensory threshold electrical stimulation was applied at higher frequencies than that expected to be biologically beneficial to participants with and without knee OA who were not blinded and/or not randomized to treatment leaves the question of efficacy unresolved.

Objective

The objective of this systematic review was to determine if low frequency ($\leq$100 Hz) pulsed subsensory threshold electrical stimulation produced either through PEMF/PES vs sham PEMF/PES intervention is effective in improving pain and physical function at treatment completion in adults with knee OA blinded to treatment. Adverse events were the primary safety outcome. Secondary outcomes included patient global assessment, imaging-based knee joint status, health-related quality of life and physician global assessment.

Methods

The Cochrane Collaboration methodology was followed[20] in the conduct of this review and PRISMA guidelines were followed for reporting the methods and results of this systematic review and meta-analysis[21].

Eligibility criteria and search strategy

Studies were included if: (1) participants with clinically and/or radiological confirmed knee OA; (2) PEMF/PES frequency was $\leq$100 Hz; (3) Comparator is sham PEMF/PES; (4) primary outcome was pain and/or physical function; (5) the study design is RCT with blinded participants; (6) data for knee OA participants were reported independently pre- and post-treatment; and (7) participants were over 30 years of age. Studies were excluded if: (1) results were reported in another trial; (2) published data were insufficient for meta-analysis and corresponding authors did not respond to requests for further information; (3) co-interventions were applied to only one group; and (4) the trial was written in a language other than English.

The relevant studies were identified by searching five electronic databases: MEDLINE, CINAHL, EMBASE, CENTRAL and AMED. The search strategy combined medical subject headings (MeSH) and text terms describing knee OA with terms describing PEMF/PES. The search was limited to English language, human, adult, and RCT. The keywords and MeSH used for each of the databases and the search results are shown in Appendix A. We searched three clinical trial registries to identify ongoing trials: Clinical Trials Registry, Current Controlled Trials and the World Health Organisation International Clinical Trials Registry Platform. Hand search of the past systematic reviews on the same topic was performed. The last search was run on April 5, 2012.

Study selection

The eligibility assessment of title and abstract of citations obtained from the search was performed by two independent reviewers (AN, AL) unblinded to author, journal and country. Any disagreement was resolved through consensus. After title and abstract screening for potentially eligible studies, two reviewers (AN, NM) checked the full text articles for eligibility independently and any disagreements were resolved through consensus. The agreement between the two reviewers was assessed by examining raw agreement and unweighted kappa (κ).

Data extraction and management

A data extraction form was developed for this review and pilot-tested independently on three randomly-selected studies by two reviewers (AN, NM) to ensure consistency in extraction. The extraction form was refined accordingly and data were extracted in duplicate. Six authors were contacted for further information, two authors responded and one provided numerical data that were presented graphically in the published paper[18]. The extracted information included the characteristics of participants (age, gender, knee OA severity and method of diagnosis), PEMF/PES (the device, application and treatment protocol), and the type of outcome measures, baseline data, post-treatment data, and change means and standard deviations (SDs) or the information from which SD could be derived, such as standard error or confidence interval (CI). When a trial presented outcomes at more than one time point, data for all time points were extracted; however, only data acquired immediately post-treatment were used in the meta-analysis.

Assessment of risk of bias for included studies

Two reviewers (AN, NM) independently assessed risk of bias for each study according to the Cochrane Handbook (chapter 8) for eight domains: sequence generation, allocation concealment, blinding of participants and care givers, blinding of outcome assessors, completeness of outcome data, completeness of outcome reporting and the potential for other threats to the validity of the study[21]. Any disagreement regarding risk of bias was resolved by consensus. Risk of publication bias was examined using a funnel plot of each study's effect estimates for the primary outcomes against their standard error; no statistical test was performed.

Data synthesis

The outcomes in the included studies reported continuous data (mean and SD) and used different outcome measures for each outcome with the exception of patient and physician global assessments, therefore, standardized mean differences (SMDs) were used to estimate the treatment effect to facilitate comparisons across all outcomes. Change means and SDs were pooled to adjust for the baseline differences between groups in each study. Three studies[22–24] reported post-treatment means and SDs. Therefore,

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