Pulsed signal therapy and the treatment of osteoarthritis

Authors' objectives
To assess the efficacy of pulsed signal therapy (PST) in the treatment of osteoarthritis.

Searching
MEDLINE and the Cochrane Controlled Trials Register were searched (the dates were not specified) using the keywords 'pulsed signal therapy', 'pulsed electromagnetic fields' and 'electromagnetic fields' in combination with 'osteoarthritis'. Articles in English, French, German, Spanish and Italian were included. In addition, the bibliographies of identified articles and publication lists from the International Network of Agencies for Health Technology Assessment were examined. Lists of articles from manufacturers were used to identify unpublished studies, web searches were carried out, and some authors were contacted.

Study selection
Study designs of evaluations included in the review
The inclusion criteria for study design were not explicitly stated. The included study designs were placebo comparison randomised controlled trials (RCTs), a longitudinal cohort comparison, and a longitudinal cohort study with no comparison group.

Specific interventions included in the review
Studies of PST were eligible for inclusion. The frequencies used in the included studies were 50 Hz (1 study), 2 to 60 Hz (1 study), 1 to 30 Hz (1 study) and 5 to 12 Hz applied stepwise (1 study). In two studies the patients received nine 1-hour treatment sessions (during 9 consecutive days in one study, and daily with a maximum of 48 hours between treatments in the other study); in one study there were 18 30-minute treatment sessions over a 1-month period; and in one there were daily sessions of 30 minutes/day for 4 weeks in the open phase of the trial and for 3 weeks for a subgroup of patients. Placebo involved simulation of the treatment using the same type of device in the inactive mode.

Participants included in the review
Patients with osteoarthritis were eligible for inclusion. Participants in two of the included studies had osteoarthritis of the knee; in one study patients with osteoarthritis of the cervical spine were included; and in another, patients with cervical and lumbar spondylosis were included. One study was excluded partly because it included patients in the treatment group with different affected joints to those in the control group.

Outcomes assessed in the review
The inclusion criteria for outcomes were not explicitly specified. The included studies used a range of outcome measures including spontaneous pain, pain at rest, pain on motion, and global assessment by patient and physician.

How were decisions on the relevance of primary studies made?
The author does not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The author does not state that they assessed quality. However, the included studies were assigned a level of evidence according to study design and some aspects of study quality (e.g. sample size and loss to follow-up) were discussed.

Data extraction
The author does not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.
Methods of synthesis
How were the studies combined?
A narrative synthesis of the studies was undertaken.

How were differences between studies investigated?
The table provided shows differences between the studies in terms of design, equipment used, treatment, study population, loss to follow-up, inclusion/exclusion criteria, outcomes and results.

Results of the review
Four studies (n=474) were included: 2 RCTs (n=207) and 2 cohort studies (n=267).

Two of the studies were classified as level 2 strength of evidence (randomised, double-blind, comparative trials with a placebo group). Two studies were classified at the lowest level of evidence, level 6 (descriptive studies). In one RCT, at the end of treatment and at the one-month follow-up, patients in the treatment group with osteoarthritis of the knee (n=42) showed a significant improvement from baseline in comparison with the placebo group (n=44) for pain (as assessed by a visual analogue scale, VAS), activities of daily living, tenderness, and global assessment by patient and physician. In the same trial, for patients with osteoarthritis of cervical spine, the treatment group (n=42) showed a significant improvement compared with the placebo group (n=39) for pain (using a VAS) and pain on passive motion. However, the placebo group also experienced improvement on most of the variables. The other RCT (n=40) found a significant difference between the treatment and placebo for pain on motion (using a VAS) at the end of treatment and at the 3-month follow-up, and for spontaneous pain at rest and on motion (assessed using the Lequesne algofunctional index) at the 3-month follow-up.

One cohort study (n=233) reported an improvement in pain and joint function, compared to baseline, at the end of treatment and at the 3- and 6-month follow-ups in patients with cervical or lumbar spondylosis. In the other cohort study (n=34) which had no control group, on average, the pain index decreased from 7.12 to 2.38 from baseline to the one-year follow-up in patients with osteoarthritis of the knee; pain on motion decreased from 7.15 to 1.47 for the same time period.

Authors’ conclusions
The results strongly suggest that PST has an analgesic effect and improves joint function in patients with osteoarthritis. However, the author points out that the results need to be confirmed by large rigorous trials.

CRD commentary
The review question was clear in terms of the intervention and participants of interest. The inclusion criteria for study design and outcomes were not stated. One RCT was excluded on the basis of sample size, the extent of loss to follow-up, and the clinical heterogeneity of the experimental and control groups. Two relevant electronic databases were searched and the subject headings used in the search strategy were given. Attempts were made to identify unpublished data and one of the included studies was unpublished. Although language restrictions were applied, studies in five languages were eligible and three of the four included studies were non-English. Details of the review process were not provided; therefore, it is not possible to assess whether appropriate strategies were employed to minimise error and bias. A quality assessment was not carried out, though the author discussed the findings in the context of aspects of study quality. Relevant details about the included studies were provided. Given the differences in study populations, outcomes measures and devices used, it was appropriate to combine the studies in a narrative synthesis. The author showed that all the studies were methodologically flawed and, therefore, the conclusions may be overconfident. That the findings need to be confirmed by larger well-designed studies is supported by the evidence presented.

Implications of the review for practice and research
Practice: The author states that until more conclusive research has been carried out, PST cannot be put into more general use.
Research: The author states that large well-designed trials are required to assess the effectiveness of PST in the treatment of osteoarthritis. Trials are also required to compare the efficacy and cost-effectiveness of PST with current standard osteoarthritis treatments, such as non-steroidal anti-inflammatory drugs and intra-articular treatments.

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