Acupuncture for fibromyalgia—a systematic review of randomized clinical trials

E. Mayhew and E. Ernst

Objective. Acupuncture is often used and frequently advocated for the symptomatic treatment of fibromyalgia. A systematic review has previously demonstrated encouraging findings. As it is now outdated, we wanted to update it.

Methods. We searched seven electronic databases for relevant randomized clinical trials (RCTs). The data were extracted and validated independently by both authors. As no meta-analysis seemed possible, the results were evaluated in narrative form.

Results. Five RCTs met our inclusion criteria, all of which used acupuncture as an adjunct to conventional treatments. Their methodological quality was mixed and frequently low. Three RCTs suggested positive but mostly short-lived effects and two yielded negative results. There was no significant difference between the quality of the negative and the positive RCTs. All positive RCTs used electro-acupuncture.

Conclusion. The notion that acupuncture is an effective symptomatic treatment for fibromyalgia is not supported by the results from rigorous clinical trials. On the basis of this evidence, acupuncture cannot be recommended for fibromyalgia.

KEY WORDS: Acupuncture, Fibromyalgia, Effectiveness, Systematic review.

Introduction

Fibromyalgia is a syndrome characterized by widespread musculoskeletal pain with associated symptoms including stiffness, fatigue, sleep disturbance and functional impairment. The American College of Rheumatology’s classification criteria for fibromyalgia require an individual to have chronic widespread pain (defined as pain involving all four quadrants of the body and the axial skeleton) and the presence of at least 11 out of 18 tender points on examination [1]. Approximately 2% of the general population is affected by fibromyalgia with highest prevalence in women aged between 40 and 60 (5.8%) yrs [2]. There is no known curative treatment.

Complementary and alternative medicine (CAM) is commonly used by fibromyalgia patients. One survey found that 91% of fibromyalgia-sufferers had used CAM [3] and another reported that significantly more fibromyalgia patients used CAM than patients with other rheumatologic diseases [4]. One of the most commonly used form of CAM is acupuncture.

Acupuncture can be defined as the insertion of needles into specified points on the body for therapeutic purposes. Acupuncture points can also be stimulated by electricity, laser, heat, ultrasound or pressure. Acupuncture is believed to have originated in China and is a component of traditional Chinese medicine. In recent years, it has become a widely accepted curative treatment.

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A review of the evidence for acupuncture for fibromyalgia included three randomized clinical trials (RCTs) and four cohort studies (1999) [6]. It concluded that ‘the limited amount of high-quality evidence suggests that real acupuncture is more effective than sham acupuncture for improving symptoms of patients with fibromyalgia syndrome. However further high-quality randomized trials are needed to provide more robust data on effectiveness’ [6]. Since the publication of this article, several further studies have emerged.

This systematic review aims to update the evidence from RCTs for or against the effectiveness of acupuncture as a symptomatic treatment for fibromyalgia.

Methods

Electronic literature searches were conducted to locate all RCTs of acupuncture for fibromyalgia. The search [acupuncture] and [fibromyalgia] was carried out on databases: AMED, Cnahl, Embase, Medline, PsychInfo, Cochrane Database and Scopus, from inception to 2006. In Medline, the text words were exploded as MeSH terms and combined. No language restrictions were applied. Reference lists were also scanned.

Only acupuncture trials with a control group, reporting randomization, using patients diagnosed with fibromyalgia as defined by the American College of Rheumatology were included. Acupuncture was defined as any method of stimulating acupuncture points and any type of acupuncture was accepted. The control groups could be treated with sham acupuncture, non-acupuncture treatments or no treatment at all. Studies comparing one type of acupuncture with another were excluded and so were trials not reporting clinical endpoints or dual publications.

Copies of the RCTs thus found were obtained in full. Data were extracted and validated independently by both authors. Discrepancies were settled through discussions. A meta-analytic approach was considered but had to be abandoned due to clinical and statistical heterogeneity of the primary data. The methodological quality of all RCTs was evaluated using the Jadad score [7].

Results

Five RCTs met the inclusion criteria (Table 1). Three trials were of reasonably good methodological quality (Jadad score = 3), reporting the randomization process, detailing dropouts and blinding patients, data analysts and coordinators [1, 2, 8]. The maximum Jadad score for any acupuncture trial would be 4 (not 5) as therapist blinding is not an option.

Two of the high-quality trials evaluated the adequacy of blinding through patient questionnaires [9, 10]. The remaining two trials did not report details of the randomization process, failed to blind patients and provided no details about dropouts [11, 12].

A small but well-reported (Jadad score = 3) trial by Martin et al. [9] randomly assigned 50 patients to acupuncture (n = 25) or sham needling (n = 25) every 2–4 days for a total of six sessions [9]. The acupuncture treatment was standardized with electrical
<table>
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<th>Source</th>
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<td>Martin et al. [9]</td>
<td>Single-blind, placebo-controlled RCT</td>
<td>n = 50</td>
<td>Traditional Chinese acupuncture (with EA) n = 25 Six sessions (2–4 × week)</td>
<td>Sham needling n = 25</td>
<td>Baseline, after each treatment and at 1 and 7 months after end of treatment.</td>
<td>FIQ mean score improved in the acupuncture group compared with the control group during the study period (P = 0.01) and at 1 month after treatment (P = 0.007), but diminished after 7 months (P = 0.24).</td>
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<td>Assefi et al. [10]</td>
<td>Single-blind, placebo-controlled RCT</td>
<td>n = 100</td>
<td>Traditional Chinese acupuncture n = 25 24 sessions (2 × week)</td>
<td>(i) Traditional Chinese acupuncture for unrelated condition n = 25 (ii) Sham acupuncture points n = 25 (iii) Sham needling n = 25 24 sessions (2 × week)</td>
<td>Baseline and weeks 1, 4, 8 and 12 during treatment and 3 and 6 months after treatment. VAS for: pain, fatigue, sleep and overall well-being; SF-36 for physical and mental functioning.</td>
<td>No significant differences were detected between acupuncture and the pooled control group for any of the outcomes. The mean between-group difference was 0.5cm (95% CI, –0.3–1.2 cm) for pain (P &gt; 0.2).</td>
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<tr>
<td>Guo and Jia [11]</td>
<td>RCT n = 66</td>
<td></td>
<td>EA (A) n = 22 Dermal neurological electrical stimulation (B) n = 22 40 sessions (1 × day with 4 day break after 20 sessions)</td>
<td>Medical group (C) n = 22 Oryzanol (30 mg) 3 × daily VIt B (30 mg) 3 × daily Amitriptyline (10 mg increased to 30 mg) 1 × day 45 days</td>
<td>Baseline, 45 days, 6 months, 12 months and 24 months after end of treatment; VAS scale.</td>
<td>Percentage of patients experiencing at least some reduction in pain after 45 days. A = 100% B = 95.5% C = 68.2% (χ² = 18.03, 17.27, P &lt; 0.01)</td>
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<tr>
<td>Sprott [12]</td>
<td>RCT n = 30 ACR classification criteria 1</td>
<td></td>
<td>Traditional Chinese acupuncture Six sessions (2 × week) n = 10</td>
<td>(i) Sham laser acupuncture n = 10 Six sessions (2 × week) No treatment n = 10</td>
<td>Before and after each treatment and 2 months after end of treatment. Dolorimetry of tender and control points, VAS, pain score sheet and follow-up questionnaire.</td>
<td>Number of tender points decreased significantly after treatment in the acupuncture group compared with the control groups. No significant differences between groups in the 2 month follow-up.</td>
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<td>Delzue et al. [8]</td>
<td>Single-blind, placebo-controlled RCT</td>
<td>n = 70</td>
<td>EA n = 36 Six sessions (2 × week)</td>
<td>Sham EA n = 34</td>
<td>Before and after each treatment: pain threshold, number of analgesics used, regional pain score pain recorded on VAS, sleep quality, morning stiffness, and patient’s and evaluating physician’s appreciation.</td>
<td>Five out of eight parameters improved significantly in EA group as opposed to the control group including the main parameter, pain threshold which improved by 70% in the EA group and 4% in the sham EA group.</td>
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RCT, randomized clinical trial; EA, electro-acupuncture; VAS, visual analogue scale.

*American College of Rheumatology: 1990 classification criteria.
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stimulation applied to two points bilaterally. In the control group, identical points were used with a placebo needle that did not penetrate the skin and electrical stimulation without electrical current. The ability of patients to determine which group they had been assigned to was tested and was found not to exceed chance. Ten patients withdrew from the study although none due to adverse effects. Overall, the treatments were well-tolerated and no serious adverse events were recorded. Acupuncture treatment was associated with maximum benefit 1 month after treatment; the mean Fibromyalgia Impact Questionnaire total score increased by 7.4 points ($P = 0.007$) and Multidimensional Pain Inventory score decreased by 7.4 points ($P = 0.03$) compared with the control group. At follow up, the effect was smaller and the only statistically significant improvements were in fatigue and anxiety. The improvements were additive to the benefits obtained with the Fibromyalgia Treatment Programme (education, counseling and group discussion about symptom management) to which the patients of both the experimental and the control group had been referred.

Assefi et al. [10] conducted a high-quality trial (Jadad score = 3), randomizing 100 fibromyalgia patients to either acupuncture or one of three different sham acupuncture treatments [10]. Participants were adequately blinded as were the data collection staff and data analysts. Treatment sessions were twice weekly for 12 weeks. Acupuncture points were chosen according to the principles of traditional Chinese medicine and applied uniformly. No electrical stimulation was applied. The sham treatments included acupuncture at acupuncture points not suited for fibromyalgia, needle insertion at non-acupuncture points or non-penetrating simulated acupuncture. The primary outcome measure was subjective pain quantified with a visual analogue scale (VAS). Other outcome measures using VAS included: intensity of fatigue, sleep quality and overall well-being. Physical and mental functioning was assessed by the Medical Outcomes Study 36-item Short-Form Health Survey. The adequacy of the blinding was also evaluated. Fourteen patients dropped out, none were treatment-related and 86 patients completed the study. No significant differences were detected between the acupuncture and the pooled control group for any of the outcomes, including the blinding evaluation.

Delzue et al. [8] examined the efficacy of electro-acupuncture (EA) for patients with fibromyalgia (Jadad score = 3). Seventy subjects were randomly assigned to either EA ($n = 36$) or sham EA ($n = 34$). The participants were given six treatments over a 3-week period. The EA group received treatment at two peripheral acupuncture points and up to six others near painful sites with an intensity high enough to cause muscle contractions. The control group received just perceptible EA treatment 20 mm from points that would have been used. The patients and evaluating physicians were blinded, but the adequacy of this was not assessed. Outcome measures included evaluation questionnaires on pain threshold, number of analgesics used in the last week, regional pain score, pain recorded on VAS, sleep quality, morning stiffness, as well as patient- and physician-rated improvements. There was no follow-up period. The response in the EA group was significantly superior in five out of the eight outcome measures. Pain threshold, the primary endpoint, improved by 70% in the EA group compared with 4% in the control group. The other variables which showed significant inter-group differences in favour of acupuncture were pain measured on a VAS, morning stiffness, patient appreciation and physician appreciation. A total of 15 patients dropped out. Of that, 10 were due to an exacerbation of symptoms or the unpleasantness of the intervention (equally in the EA and control groups). The authors concluded that EA is effective in relieving the symptoms of fibromyalgia but the long-term benefits remained unknown.

The trial by Guo and Jia [11] was not blinded nor placebo-controlled. Sixty-six fibromyalgia patients were randomly assigned to receive either EA ($n = 22$) or dermal–neurological electric stimulation (DE) (applied to acupuncture points) ($n = 22$) or oryzanol, vitamin B1 and amitriptyline ($n = 22$) daily for 45 days. A VAS was used to evaluate pain, other symptoms and social adaptability before and after each treatment and at 45 days post treatment. There was little difference between the EA and DE groups, but when compared with the third group, there was a significant difference ($P < 0.01$). There were no dropouts. At 24 months, the recurrence rates of the EA and DE groups were lower than those of the third group. It should, however, be noted that the recurrence rate is not an accepted outcome measure for fibromyalgia.

Sprott [12] tested the effectiveness of acupuncture in patients with fibromyalgia by randomly dividing 30 patients into three groups receiving either: acupuncture, placebo treatment (with a disconnected laser) for six sessions, or no treatment. A significant difference between acupuncture and the placebo was not established. The author concluded, ‘the clinician is cautioned not to use acupuncture as the only remedy [12].’

Discussion

Overall, the evidence for acupuncture in the treatment of fibromyalgia is mixed. Three RCTs are positive, i.e. implying acupuncture is effective [8, 9, 11] including two that are amongst the more rigorous studies [8, 9]. The effects were, however, mostly short-lived, small and therefore of debatable value to patients. Two RCTs are negative, i.e. they fail to show effectiveness [10, 12]. One negative trial [10] was large and well-designed, addressing some of the deficiencies in the previous trial by Delzue et al. [8] (in particular, potentially inadequate blinding). There was no significant difference in average Jadad score between the positive and the negative RCTs. The three positive trials all used EA either exclusively [8, 11] or in combination with manual stimulation [9]. The two negative trials [8, 9] used only manual acupuncture.

The outcome measures varied between RCTs with some debate as to the most sensitive. Martin et al. [9] argued that the Fibromyalgia Impact Questionnaire, as a disease-specific tool, was the most appropriate but it was not used in any of the other trials. Deluze et al. [8] employed pain threshold as the main outcome measure, arguably a parameter of little relevance to patients.

Martin et al. [9] and Assefi et al. [10] standardized the points for all patients. The other RCTs used individualized points. Electro-acupuncture was used in at least three trials [8, 9, 11] and exclusively in two [8, 11]. All RCTs provided acupuncture on a regular basis, at least once a week but the treatment length varied between 6 and 40 sessions. Outcome did not seem to be related to treatment length. None of the RCTs excluded concomitant treatments, and in two RCTs, patients were receiving treatment or had just completed treatment as part of a fibromyalgia programme [9, 12]. Therefore, acupuncture was evaluated as an adjunctive fibromyalgia treatment only, and no RCT has so far tested its value as a sole intervention for fibromyalgia. Four RCTs had follow-up assessments ranging from 2 months to 2 yrs [9–12]. Only the low-quality trial by Guo and Jia [11] found sustained results.

The RCTs included in this review fail to fully control for possible placebo effects. It is therefore impossible to tell to what extent the therapeutic effect (if any) is due to specific or non-specific mechanisms. Recently non-penetrating sham devices have become available, which control optimally for placebo effect in acupuncture trials. A summary of all 11 RCTs available to date employing such devices suggested that the therapeutic effects of acupuncture are mostly, if not exclusively, due to placebo [13].

Our review has a number of important limitations. Even though our searches were thorough, we cannot be absolutely sure to have found all relevant RCTs. Moreover, publication bias can be a problem in CAM [14]. Thus the primary data may be incomplete or distorted, or both. In any case, it is scarce and methodologically...
weak. Recently, it has been argued that ‘systematic reviews of acupuncture have overstated effectiveness by including studies likely to be biased’ [15]. Some of the RCTs included in the present review were not successful in minimizing bias. These facts prohibit us to make definite judgments about the effectiveness of acupuncture.

In conclusion, the notion that acupuncture is an effective adjunctive, symptomatic treatment for fibromyalgia is not supported by unanimous results from RCTs. The existing evidence is mixed and further rigorous studies seem warranted.

The authors have declared no conflicts of interest.

References