Is Acupuncture Effective in the Treatment of Fibromyalgia?

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BACKGROUND. We conducted this study to assess the effectiveness of acupuncture in the treatment of fibromyalgia syndrome (FMS), report any adverse effects, and generate hypotheses for future investigation.

METHODS. We searched MEDLINE, EMBASE, Manual Therapy Information System, the Cochrane registry, the University of Maryland Complementary and Alternative Medicine in Pain, the Centralized Information Service for Complementary Medicine, and the National Institutes of Health Office of Alternative Medicine databases for the key words "acupuncture" and "fibromyalgia." Conference abstracts, citation lists, and letters supplemented the search. We selected all randomized or quasi-randomized controlled trials, or cohort studies of patients with FMS who were treated with acupuncture. Methodologic quality, sample characteristics, type of acupuncture treatment, and outcomes were extracted. Statistical pooling was not performed because of the differences in control groups.

RESULTS. Seven studies (3 randomized controlled trials and 4 cohort studies) were included; only one was of high methodologic quality. The high-quality study suggests that real acupuncture is more effective than sham acupuncture for relieving pain, increasing pain thresholds, improving global ratings, and reducing morning stiffness of FMS, but the duration of benefit following the acupuncture treatment series is not known. Some patients report no benefit, and a few report an exacerbation of FMS-related pain. Lower-quality studies were consistent with these findings. Booster doses of acupuncture to maintain benefit once regular treatments have stopped have been described anecdotally but not investigated in controlled trials.

CONCLUSIONS. The limited amount of high-quality evidence suggests that real acupuncture is more effective than sham acupuncture for improving symptoms of patients with FMS. However, because this conclusion is based on a single high-quality study, further high-quality randomized trials are needed to provide more robust data on effectiveness.

KEY WORDS. Acupuncture; fibromyalgia; pain; trigger points; systematic review. *(J Fam Pract 1999; 48:213-218)*

CLINICAL QUESTION Is acupuncture effective in the treatment of fibromyalgia?

The family physician is often the first medical practitioner to whom a patient with fibromyalgia syndrome (FMS) turns for help.[1] Clinic-based surveys[2,3] suggest that as many as 66% to 90% of patients with FMS are using at least one complementary therapy, such as herbal supplements, mind-body practices, or acupuncture concurrent with conventional treatment. As the first point of contact with the medical system, family physicians are increasingly expected to develop treatment plans that consider both pharmacologic and nonpharmacologic options. Antidepressants or analgesics are generally the first and most widely used pharmacologic options for treating FMS.[4] These are of variable effectiveness, and frequently the patient and physician find themselves in the position of weighing the benefits against the side effects. These side effects can include sedation or gastrointestinal problems.[4]

Acupuncture, a popular complementary therapy, is used by approximately 1 million Americans annually,[5] primarily for pain relief.[6] One meta-analysis on acupuncture for rheumatologic conditions has been published[7]; however, only inflammatory rheumatologic conditions were included, so FMS was not addressed. Two reviews have been published examining the nonpharmacologic options for FMS.[8,9] However, the first one[8] was published before the publication of any randomized controlled trials (RCTs) on acupuncture, and the other[9] discussed the results of only one acupuncture study. More recently, the Cochrane Collaboration has provided guidelines for minimizing bias in reviews,[10] making it important to examine the topics of earlier reviews using these guidelines. Therefore, the purposes of our clinical review are to assess the strength of evidence of the effectiveness of acupuncture in the treatment of FMS, report adverse effects, and summarize the important questions generated from this review to guide future investigation.

METHODS

To identify published studies, we searched EMBASE, Manual Therapy Information System (Mantis) and MEDLINE (1966-1997) on the key words "acupuncture" and

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"fibromyalgia." On MEDLINE, these terms were also searched as text words and exploded as MeSH terms, and sets were combined. The search was limited to human subjects, and all languages and experimental designs were included. We also searched our specialized composite complementary medicine databases (comprised of relevant citations from other databases) on the same key words. These specialized databases are the Cochrane Complementary Medicine Field trials registry, the University of Maryland Complementary and Alternative Medicine in Pain (CAMPAIN), Centralized Information Service for Complementary Medicine (CISCOM), and the National Institutes of Health Office of Alternative Medicine (NIH-OAM). The following databases were not searched because the relevant trials had already been incorporated into one of the composite databases: Acupuncture Database, Acupuncture Literature Analysis and Retrieval System, Current Awareness Topics/Alternative and Allied Medicine Database, and Dissertation Abstracts. Bibliographies from articles supplemented the search.

To identify abstracts of studies that had not been published as full articles (ie, gray literature), we handsearched 52 conference proceedings and abstracts with "acupuncture," "fibromyalgia," "rheumatology," or "arthritis" in the title. To identify unpublished studies, we sent an inquiry letter to 98 institutions or individuals in 15 countries who perform acupuncture-related research, education, or clinical care.* The decision to include both RCTs and cohort designs is in accordance with evidence-based medicine guidelines that suggest that when RCTs are lacking, the best available evidence should be reviewed.[11] Although only RCTs can be used for hypothesis testing, nonrandomized designs, such as cohort designs, are valuable for generating hypotheses.

The methodologic quality of the RCTs was scored using a validated instrument[11] that determines if randomization was stated, concealment was adequate, double-blinding was reported, double-blinding was likely to have been achieved, and dropouts were reported. The methodologic quality of cohort studies was scored using Cochrane Collaboration guidelines for assessing nonexperimental designs[12] that determine if the study controlled for confounders, outcomes assessors were blinded, and dropouts were reported. If study results were based only on subjects who completed the study, then when available data permitted, an intention-to-treat analysis[13] was performed to preserve randomization.

RESULTS

Sixty-seven citations were identified from electronic databases; 1 abstract was identified from handsearching conference poster sessions, 1 from a citation list, and 1 from a letter of inquiry. Of the 67 electronic citations, 28 were immediately excluded because they were letters, surveys, historical essays, or other manuscripts that did not present the results of a population of patients with FMS. The remaining citations were retrieved and read. Translations were obtained when necessary. Eight trials met inclusion criteria.[14-21] The sources of studies varied: MEDLINE or EMBASE, 3[15,19,20]; CISCOM, 1[7]; the Cochrane Complementary Medicine Field Trials Registry, 1[16]; bibliographic references, 1[14]; conference proceedings, 1[18]; and response to inquiry for unpublished studies, 1.[21] The latter, a retrospective cohort study on chronic pain, was subsequently excluded because data were not yet available by condition. Therefore, 7 studies were included in the review: 3 RCTs[14-16]; 3 prospective cohort studies (PCS),[17-19] defined as case series reports with outcomes measured within the same period as the intervention; and 1 retrospective cohort study (RCS),[20] defined as a case series report with outcomes measured only after intervention, such as through medical records review or follow-up survey. The studies are displayed as a ladder of evidence[22] with the least methodologically rigorous study design, RCSs, at the bottom and the most rigorous design, RCTs, at the top (Table 1).

The average age of patients participating in these studies ranged from 45 to 51 years. Women made up the majority of patients in all trials, but no trial reported responses by sex. The average duration of FMS symptoms was 6 to 12 years. Patient characteristics are given in Table 2.

Studies varied greatly in their methodologic quality. Although all RCTs reported randomization and enumerated the reason for and number of dropouts, only one[15] received a high methodologic score. The other 2[14,16] received a low-quality score because the designs precluded the ability to blind patients to group assignment and the method of randomization concealment was unclear. Of the cohort studies, none controlled for potential confounders, mentioned a blinded outcomes assessor, or reported dropouts. Therefore, none were rated as high quality. Two RCTs reported results based only on subjects who completed the study.[15,16] However, with the available data, intention-to-treat analysis was only possible for one of them.[15] The third RCT[14] had no dropouts, and so results are based on the entire patient population.

Randomized Controlled Trials

Deluze and colleagues[15] examined whether patients with FMS receiving real acupuncture fared better than patients receiving sham acupuncture (a procedure designed to mimic real acupuncture, but using nonacupuncture points and more superficial needle insertion than real acupuncture). The real acupuncture group fared significantly better ($P < .05$, Mann-Whitney two-tailed test) than patients in the sham group on 5 of 8 outcomes measured: pain relief, pain threshold, morning stiffness, patient's subjective global improvement rating, and physician's subjective global improvement rating. No long-term results were presented. Improvements for the sham acupuncture group neared

*A list of hand-searched conference titles and of the 98 institutions or individuals contacted by mail is available on the *Journal*'s Web site at www.jfp.denver.co.us.

TABLE 1

Treatment Characteristics and Outcomes of Studies of Acupuncture Treatment for Fibromyalgia

Author, year	Study Design	Experimental Treatment	Control Treatment	Outcomes	Follow-up
Lautenschlager, 1989[14]	RCT	6 total acupuncture treatments (n=17)	6 treatments of inactivated laser (n=20)	Pain relief, regional pain score, pain threshold	Immediate only
Deluze, 1992[15]	RCT	2 real EA (2-99 Hz) treatments, 2x weekly for 3 weeks (n=36)	2 sham EA treatments, 2x weekly for 3 weeks (n=34)	Pain relief, pain threshold, regional pain physician global assessment, medication use, regional pain score, sleep quality	Immediate only
Cassisi, 1995[16]	RCT	Acupuncture alone (n=14) or acupuncture + antidepressant (mianserine) (n=14)	Mianserine threshold, 30 mg daily (n=14) test, sleep quality	Pain relief, pain threshold, depression, sleep quality	Immediate, 1, 3, 6 months
Pasotti, 1990[17]	PCS	Manual acupuncture alone every 5 days 8-10 treatments total (n=12) or Manual acupuncture + antidepressant (amitryptiline) (n=13)	Physiatry (n=not reported)	Pain relief, pain threshold, number of tender points, anxiety, depression,	Immediate, 1, 3, 6, 9 months
Sprott, 1996[18]	PCS	EA. Other parameters not reported (n=29)	None	Pain relief, pain threshold, serum substance P	Immediate only
Radaelli, 1978[19]	PCS	5 EA (50-70 Hz) treatments on alternate days (n=35	None	Pain relief, range of motion	Not reported
Waylonis, 1977[20]	RCS	5-7 EA treatments; 1x weekly (n=62)	None	Pain relief relative to other therapies	Mean follow-up time 19.6 months post-treatment

RCT denotes randomized controlled trial; PCS, prospective cohort study; RCS, retrospective cohort study; EA, electroacupuncture.

statistical significance only for the pain intensity rating (P =.06, Wilcoxon two-tailed matched pairs test).

The authors noted an interesting trend in the real acupuncture group: Approximately 25% had no benefit, 50% experienced satisfactory benefit, and the remaining 25% had unexpectedly large improvements with almost complete remissions. These proportions changed with intention-to-treat analysis: 42% had no benefit, 39% had satisfactory benefit, and 19% had an unexpectedly large benefit. By contrast, unexpectedly large symptom remissions were observed in only one individual in the sham acupuncture group. It is not clear which factors predisposed a patient to improvement. Disease of mild severity and short duration, often predictors in other pain populations, did not correlate with good response.[15]

Fifteen patients (21%) dropped out of the study. Among the dropouts, 4 were unrelated to the acupuncture procedure and 11 were related to the acupuncture procedure (6 experienced symptom exacerbations, 1 experienced transient ankle edema, and 4 cited the unpleasantness of needle insertion). Neither the reason nor rate of dropouts differed between sham and real acupuncture; nor did dropouts differ from those who completed the study on any baseline measures.

Cassisi and colleagues[16] randomized 42 patients using a 3-arm design to assess whether acupuncture alone, antidepressant (mianserine) alone, or the 2 treatments combined was most effective in relieving FMS symptoms of pain, sleep disturbance, and depression. Ten patients (24%) dropped out. A higher proportion, (5 of 24; 20.8%) dropped out because of intolerance of the antidepressant than intolerance of acupuncture (1 of 28; 3.8%).

Results were presented only as within group changes, not between groups. Compared with baseline assessments, the patients receiving acupuncture alone showed statistically significant improvement on pain relief

TABLE 2

Patient Characteristics in Studies of Acupuncture Treatment for Fibromyalgia

Author, year	Site	Inclusion Criteria	Mean Age of Sample, in Years	Mean Disease Duration, in Years
Lautenschlager, 1989[14]	Basel, Switzerland	NR	NR	NR
Deluze, 1992[15]	University Hospital Geneva, Switzerland	1990 ACR criteria	48	10.7
Cassisi, 1995[16]	University of Padova, Italy	1990 ACR criteria	51	12
Pasotti, 1990[17]	University of Bologna, Italy	NR	NR	NR
Sprott, 1996[18]	Frederick Schiller University, Germany	ACR criteria	48	6.1
Radaelli, 1978[19]	Regional General Hospital, Milan, Italy	NR	Age range 19 to 72	NR
Waylonis, 1977[20]	Riverside Methodist Hospital, Ohio USA	NR	39	NR

ACR denotes American College of Rheumatology; NR, not reported.

(P <.0001, t test), pain threshold (P <.02, t test) and depression (P =.03, t test), but not on sleep quality. Compared with baseline assessments, the antidepressant group showed a statistically significant improvement in depression (P =.006, t test) and pain relief (P <.05, t test), but not on sleep quality or pain thresholds. Compared with baseline assessments, only the combined treatment group significantly improved (P <.05, t test) on all outcomes, including sleep quality, pain relief, pain threshold, and depression. The authors concluded there may be a synergistic benefit of combining acupuncture with an antidepressant.

A 6-month follow-up showed that there was still long-term pain relief and pain threshold benefit, although the benefit had attenuated over time: Relapse occurred in 14.2%, 20.0%, and 0% of those who completed the study in the acupuncture alone, antidepressant alone, and combined treatment groups, respectively.

Lautenschlager and coworkers[14] reported the results of an RCT in which the treatment group received a total of 6 acupuncture treatments and the placebo group received 6 treatments with a deactivated laser instrument. At the end of the series, the acupuncture group had significantly improved on 3 outcomes compared with the placebo group: pain intensity (P =.03, Wilcoxon test), localized pain rating (P =.009, Wilcoxon test) and pain thresholds (P =.008, t test). Three-month follow-up data was presented in combination with data from a nonrandomized pilot study. The combined data suggested that no significant difference between acupuncture and placebo could be observed at 3-month follow-up.

Prospective Cohort Studies

Passotti and colleagues[17] assessed 3 treatment groups: acupuncture alone, acupuncture plus antidepressant (amitriptyline), and conventional physiatry. Patients with the most severe FMS were placed in the acupuncture plus antidepressant group. Because equivalence between groups was neither intended nor achieved, the study was not classified as a controlled clinical trial, but rather a prospective cohort study with multiple arms.

On all pain relief measures the acupuncture and acupuncture plus antidepressant groups fared statistically better (P <.05, t test) than the conventional physiatry group. The treatments comprising conventional physiatry were not reported. At 6-month follow-up, the acupuncture group still fared significantly better (P <.05, t test) than the physiatry group on pain measures, as well as the psychological measures of anxiety, depression, hostility, and somatization. At the 6-month follow-up, however, the acupuncture plus antidepressant group (compared with physiatry) retained significant (P <.05, t test) improvement only on pain thresholds, not on any psychological indices.

Sprott and colleagues[18] examined 29 patients with fibromyalgia to determine whether the biochemical, as well as clinical, indicators could be improved with acupuncture. After acupuncture, sleep quality and pain

relief improved significantly (P <.01, statistical test not specified) as did the biochemical markers of serum serotonin and serum substance P. The authors concluded that the biochemical improvements confirm the involvement of pain-modulating molecules in FMS.

Radaelli and Buzzi[19] reported the results of 35 cases of trapezius fibromyositis. Patients had previously received a variety of pharmacologic and physical treatment modalities. After an average of 5 acupuncture sessions, 29 (82.8%) patients received sufficient pain relief to terminate therapy, and they continued to feel better; 3 (8.6%) patients had experienced initial relief but later returned to therapy because of relapses; 2 (5.7%) patients reported only mild amelioration of symptoms; and 1 (2.9%) reported no benefit.

Retrospective Cohort Studies

Waylonis[20] polled 62 fibrositis patients previously treated at a physical medicine clinic. Thirty-nine patients responded to the survey. Their mean length of follow-up at the time of survey completion was 19.6 months. Patients had received a variety of interventions while at the clinic, including acupuncture, medication, cortisone injections, physical therapy, whirlpool treatment, ultrasound, diathermy, and manipulation. More than half of the survey responders had received 4 to 10 different types of therapy at the clinic with which to compare acupuncture. A postal survey asked patients to specify which treatment gave them the best results, the longest lasting results and the estimated duration of benefit, and the least results. Acupuncture was rated as providing the best and longest lasting pain relief by 29 (46%) of the respondents.

When asked to assess the extent of the relief provided by acupuncture, 8 (20.5%) reported total relief; 18 (46.2%) partial relief (50% to 90% improved); 5 (12.8%) had borderline relief (10% to 40% improved); 7 (17.9%) had no relief; and 1 (2.6%) had aggravated symptoms. Among those who improved, the duration of relief from acupuncture varied from less than 1 day (7 patients) to 10 months or longer (6 patients).

DISCUSSION

This section synthesizes the existing evidence to determine what can be said of the efficacy of acupuncture for FMS. We will focus on the available evidence from the one high-quality RCT and rely on the low-quality RCTs and cohort designs to generate hypotheses rather than conclusive statements.

Results from the high-quality RCT[15] report that persons receiving real acupuncture compared with sham acupuncture for FMS symptoms experienced significant improvements in both subjective pain reductions (as measured by self-reports), and objective improvements in pain thresholds, (as measured by blinded assessors using algometry). Through the use of sham acupuncture for the control group, the investigators were able to blind patients to the group assignment and demonstrate that improvements could not be attributed to the placebo effect alone. Although reductions in medication use in the real acupuncture group compared with the sham group were not statistically significant (P =.09), they may be clinically important and physicians should be aware that a patient's medication needs may change when acupuncture is administered.

One important observation is that exacerbations of FMS-related pain with acupuncture are documented in 2 RCTs.[15,16] In the study by Deluze and colleagues,[15] for example, exacerbations were one of the major reasons for early withdrawal. Although exacerbations of painful conditions rarely appear in the acupuncture literature,[23] a study by Hong and Hsueh[24] may provide biologic plausibility for their occurence in FMS patients. Observing the responses to trigger-point injections in patients with myofascial and FMS or myofascial pain alone, the researchers noted that postinjection soreness persisted for significantly longer periods in the patients with FMS. The researchers postulate the abnormal levels of neuropeptides associated with FMS result in pain amplification and augmented responses to needle trauma. Physicians should be aware that a small proportion of FMS patients may feel worse with acupuncture.

IMPLICATIONS FOR RESEARCH

There are 3 important questions that are raised but not adequately answered from the existing studies.

Can booster doses sustain benefit in responders?

The only high-quality RCT does not report long-term follow-up, and therefore the question of how long relief can be expected from a series of acupuncture treatments remains unanswered. The studies in this review that looked at duration of benefit suggest that it varies from less than 1 day to 10 to 12 months, with a general observation that once acupuncture treatments stop, benefit attenuates over time.[14,16,17,19,20] The use of periodic booster doses of acupuncture has been anecdotally reported in 2 cohort studies[19,20] as an effective way to sustain benefit once regular weekly or biweekly acupuncture sessions have stopped, but the efficacy of booster doses remains a hypothesis to be tested under rigorously controlled conditions.

What is the optimal acupuncture treatment for FMS?

The acupuncture approach used in the high-quality RCT,[15] a combination of low and high electrical frequencies, is consistent with laboratory data suggesting that optimal pain relief is achieved by combining low (2-4 Hz) and high (50-100 Hz) frequencies.[25] The combined frequencies are believed to complement each other (ie, low-frequency acupuncture is associated with endorphin release and cumulative effects, and high-frequency acupuncture is

associated with serotonin release and short-lived effects). Especially for a disease like FMS, where both cumulative and serotonergic effects are desired, examining whether the combined frequency approach is superior to other approaches, such as manual acupuncture, will be an important hypothesis to test in future studies.

DOES ACUPUNCTURE WORK SYNERGISTICALLY WITH ANTIDEPRESSANT MEDICATION?

Cassisi and colleagues[16] found that the combined use of acupuncture and antidepressants was more globally effective across the many dimensions of pain, depression, and sleep than either acupuncture or antidepressant alone, suggesting that the synergistic benefits of acupuncture plus medication improve a variety of outcomes. However, because of the small sample size, the high drop-out rate, and the lack of between-groups analysis, this trial should be considered as raising the question, not answering it.

RECOMMENDATIONS FOR CLINICAL PRACTICE

The limited amount of high-quality evidence, derived from one RCT, suggests that real acupuncture is more effective than sham acupuncture for relieving pain, increasing pain thresholds, improving global ratings, and reducing morning stiffness of FMS. Some patients report no benefit, however, and a few report an exacerbation of their FMS-related pain with acupuncture. Results from lower-quality studies are consistent with these findings. Because the only high-quality RCT does not provide follow-up data, the duration of benefit after the acupuncture series stops is not known.

Further high-quality RCTs are needed to provide more robust effectiveness data and address important questions not answered by the current evidence, such as the value of booster doses, the optimal acupuncture procedures, and possible synergistic effects of acupuncture with antidepressants. This review may be helpful in providing clinicians with the practical information necessary to advise patients with FMS of the potential benefits and risks of acupuncture treatment.

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