
Complementary treatment in fibromyalgia: combination of somatic and abdominal acupuncture

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ABSTRACT

Fibromyalgia is a complex syndrome characterised by widespread pain associated with a variety of other signs and symptoms. The emerging consensus indicates that the best approach to treatment involves the combination of pharmacological and non-pharmacological interventions. Since acupuncture is a tool of traditional Chinese medicine increasingly used as an alternative or complementary therapy for the treatment of pain, the present study aimed to combine two different acupunctural methods (the somatic and abdominal one) in the treatment of 30 consecutive female FM patients and to evaluate the reduction of pain and the well-being state. The results showed a statistically significant reduction of the number of tender points and of pain. Moreover we observed a statistically significant reduction of FIQ, FAS, HAQ, disease activity VAS, ZSAS, ZSDS at the end of the treatment. In conclusion, these data suggest that the combination of two types of acupuncture could be a useful complementary treatment in FM patients, not only to control pain but also to improve associated symptoms and quality of life. As a result, acupuncture could be very useful to relieve pain in a multidisciplinary setting.

Introduction

Fibromyalgia (FM) is a complex syndrome characterised by chronic widespread pain with a duration of at least three months and tenderness upon pressure in at least 11 of 18 tender points, as defined by the American College of Rheumatology (ACR) criteria in 1990 (1). In addition to pain there may be a multitude of somatic symptoms including asthenia, sleep disturbance, anxiety, depression, irritable bowel syndrome, headache, dysmenorrhoea, paresthesia and dysesthesia in accordance with the ACR's 2010 preliminary diagnostic cri-

teria (2-4). The pathophysiology of FM is not completely understood. A combination of interactions among external stressors, behavioural constructs, neurotransmitters, hormones and immune factors appear to be involved (5). The disease is characterised by a central sensitisation with an amplification of pain perception but many mechanisms of disease remain unclear (6). Among these, autonomic nervous system (ANS) dysfunction could partially explain several multisystem features of FM (7,8). In particular Neuropeptide Y (NPY) is a stable neural indicator of sympathetic activity and seems to play an important role in modulating pain (9-11).

It is well known that complex syndromes, characterised by diverse and multisystem symptoms, like FM, require multidisciplinary treatment (12). The emerging consensus indicates that the best approach to treatment of FM involves the combination of pharmacological and non-pharmacological interventions (13). Various classes of neuromodulatory agents (*i.e.* drugs that help to restore noradrenergic- and serotonergic-mediated inhibitory pain pathways) reduce nociceptive signalling in ascending pain pathways and can improve symptom domains additional to pain including fatigue, disturbed sleep and cognition as demonstrated by well-designed controlled trials. However, not all patients could benefit from current approved treatments because of inadequate efficacy or lack of tolerability (14).

Several non-pharmacological interventions, particularly physical exercise and cognitive-behavioural therapy (CBT), gained good evidence of effectiveness as stand-alone adjunctive treatments for patients with chronic pain. Moreover many individuals suffering from FM use a variety of complementary or alternative medicine (CAM) interventions to treat and manage their symptoms (15).

The primary goal of FM treatment is

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pain reduction. Despite the increasing use of acupuncture for the treatment of pain, this technique is not mentioned among the recommended non-pharmacological interventions for FM management due to a lack of conclusive data on its effectiveness. (16, 17)

Acupuncture is a tool of Traditional Chinese Medicine (TCM) increasingly used as an alternative or complementary therapy for the treatment of pain based on the insertion of very thin needles into the subcutaneous tissue (15). The 2007 National Health Interview Survey (NHIS), which included a comprehensive survey of complementary and alternative medicines used by Americans, estimated that 3.1 million adults and 150,000 children underwent acupuncture in the previous year (17).

According to traditional Chinese medicine, FM results from the flow of blood and the imbalance that blocks or drains a person's internal energy (Qi), leading to the appearance of the symptoms that are characteristic of this syndrome (18-20).

This blockage may result from trauma, excess conditions such as infection, physical obstruction due to inflammation, or deficiency conditions such as immunosuppression. A TCM practitioner determines the cause of the obstruction by performing a syndrome differentiation and treats it using a variety of modalities (21).

In addition to conventional acupuncture, otherwise referred to as somatic acupuncture, that is based on the puncture of acupoints distributed throughout the body, there is a more recent method, introduced by founder Dr. Bo Yun Zi a little more than 20 years ago. This method uses a microsystem of acupoints located on the peri-umbilical abdominal zone. The body map (head-column-limbs) on the abdomen is represented taking the conformation of a turtle with the head upward. It is a technique that has proved to be very effective in the prompt reduction of pain.

The combination of these two methods could prove useful in reducing pain and symptoms related to FM. Thus far, studies of acupuncture-based approaches, despite their broad acceptance among patients and healthcare staff, have not

produced sufficient or conclusive evidence of its effectiveness in treating FM (22, 23).

Objectives

The present study aimed to combine the somatic and abdominal methods in the treatment of FM and consequently to evaluate the effectiveness of individualised acupuncture for these patients. Specifically the primary endpoint was the reduction of pain and the secondary one was the evaluation of the well-being state throughout the analysis of the variations in clinimetric scale scores (Fibromyalgia Impact Questionnaire (FIQ), Fibromyalgia Assessment Status (FAS), Health Assessment Questionnaire (HAQ), Visual Analogue Scale for pain and disease activity, Zung Self-Rating Anxiety and Depression Scale (ZSAS, ZSDS) (24-26).

Patients and methods

Patients

The study population consisted of consecutive female FM patients referred to the Clinic for the Diagnosis and Therapy of FM of the Unit of Rheumatology fulfilling both the 1990 and 2010 ACR criteria. All patients maintained consistent drug therapies for at least 3 months leading up the beginning of the study and were subjected to weekly acupuncture sessions for 10 weeks. Complete clinic (with TPs count) and clinimetric evaluation was performed at beginning (T0), in the middle (5th week) (T1) and at the end (T2) of acupuncture treatment.

Clinimetric evaluation

Patients completed the Fibromyalgia Impact Questionnaire (FIQ), Fibromyalgia Assessment Status (FAS), Health Assessment Questionnaire (HAQ), Visual Analogue Scale for pain and disease activity, Zung Self-Rating Anxiety and Depression Scale (ZSAS, ZSDS) at baseline (T0), midway through the treatment sessions (T1) and at the last session of acupuncture (T2) (24-26).

Acupuncture

All patients were treated with somatic and abdominal acupuncture once a week for 10 weeks.

An expert physician performed a prior diagnosis, in accordance with the principles of TCM and then selected the points for the treatment session, taking note of the diagnosis, the acupuncture points and the techniques employed. In the selection of acupoints, the operator had to consider the various zones affected by pain, as well as the presence of several related syndromes: insomnia and fatigue, fatigue and depression, insomnia and irritability.

Before each session, the physician re-evaluated the patient to determine whether his/her clinical situation had changed; if so, the selection of acupuncture points was reconsidered (27, 28).

Every session was performed in a restful room and with the patient lying face up or face down. Sterilised single-use stainless steel filiform needles, size 18x30 and 18x40 (Hwato-Suzhou Medical Appliance Factory, Suzhou, China), were used.

For the somatic portion of the treatment, a vertical puncture well was made, unless otherwise indicated, to the depth predetermined for each point (normally between 8–20 mm, depending on the location of the point). Following insertion, stimulation of the acupuncture point was performed using bidirectional rotation of the needle sleeve, to achieve the sensation known as Deqi, which is commonly described as a 'glowing' feeling and represents the flowing of qi. The needle was

Table 1. Demographic and clinical data at baseline.

	mean (95% CI)
Age (years)	48.24 (44.15-52.34)
Disease duration (months)	79.16 (51.45-106.88)
TP numbers	16.25 (15.43-17.06)
Pain VAS	76.66 (67.56-85.76)
FIQ	69.7 (64.65-74.74)
FAS	8.15 (7.54-8.76)
HAQ	1.29 (1.08-1.50)
Disease activity VAS	75.20 (68.60-81.81)
ZSAS	57.29 (52.31-62.27)
ZSDS	54.25 (49.01-59.48)

Fibromyalgia Impact Questionnaire (FIQ), Fibromyalgia Assessment Status (FAS), Health Assessment Questionnaire (HAQ), Visual Analogue Scale for pain and disease activity, Zung Self-Rating Anxiety and Depression Scale (ZSAS, ZSDS).

Table II. Reduction of TP number and pain VAS after each treatment.

	T0			T1			T2		
	Before	After	<i>p</i>	Before	After	<i>p</i>	Before	After	<i>p</i>
TP mean (95% CI)	16.25 (15.43-17.06)	13.53 (11.63-15.42)	0.03	13.16 (11.46-14.87)	10.95 (8.74-13.17)	0.001	12.87 (11.16-14.58)	10.04 (7.8-12.27)	0.001
pain VAS mean (95% CI)	76.66 (67.56-85.76)	52 (44.68-59.31)	0.001	66.04 (56.21-75.86)	30 (20.93-39.06)	< 0.0001	50.41 (38.24-62.58)	31.66 (20.55-41.78)	0.002

maintained in place for 20 minutes. At treatment completion the needles were withdrawn. The following acupoints were used: 23 Du, YINTANG (Extra), 4 IC, 36 S, 6 MP, 9 MP, 7 P, 3 R, 3 F, 3 IT, 62 V, 6 R, 6 PC, and 6 TR (29). For the abdominal portion of the treatment the puncture simply penetrated the abdominal skin without any rotation or movement. The abdominal acupoints selected were 12 and 4 Ren, 25 St bilaterally, 15 MP bilaterally, 24 St points bilaterally. 9 Ren and extra points have been used for the pain located above the diaphragm, 26 St points bilaterally, 11 and 17 K and the extra points have been used for the pain located in the lower part of the diaphragm (29).

Statistical analysis

Differences before and after treatment have been analysed with Wilcoxon test for paired samples. Data are presented as means and confidential intervals. A *p*-value <0.05 has been considered statistically significant. All calculations were carried out with MedCalc Software (version 12.3.0, Mariakerke, Belgium).

Results

We enrolled 30 consecutive FM patients. Six of them dropped out (2 for inefficacy after 5 treatments and 4 for poor compliance). Nine of the remaining 24 patients were free of any medication while the others maintained a stable drug therapy for at least 3 months leading up to study initiation. All patients completed the planned course of acupuncture. Table I shows demographic and clinical data of patients at baseline. The results highlighted the reduction of the number of the TP tenderness and of the pain VAS both immediately after every acupuncture treatment (Table II) and consequentially throughout the

treatment period (*p*=0.0001, *p*=0.0001) with the maintenance of that improvement (Fig. 1-2). Concerning the secondary end point we observed a statistically significant reduction of FIQ, FAS, HAQ, disease activity VAS, ZSAS, ZSDS at the end of the treatment in comparison to baseline (Table III).

Discussion

Acupuncture is a method used in TCM. This technique, characterised by the

insertion of thin needles into the subcutaneous and/or muscle tissue intends to treat osteoarticular and internal pathologies of various nature. Western medicine considers acupuncture to be a technique that affects the balance between the central nervous, endocrine and immune systems by initiating the release of various chemical mediators into the bloodstream. In fact, it has been proven that many diseases have a modified picture of the same chemical

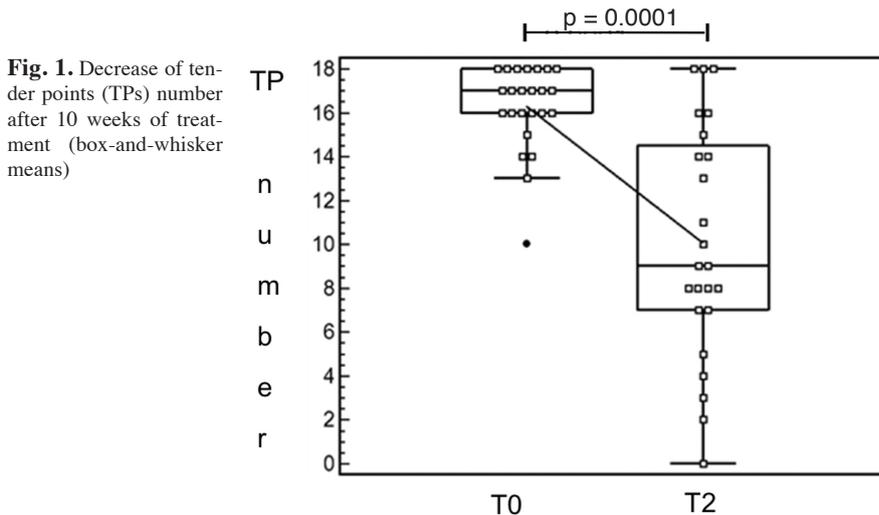


Fig. 1. Decrease of tender points (TPs) number after 10 weeks of treatment (box-and-whisker means)

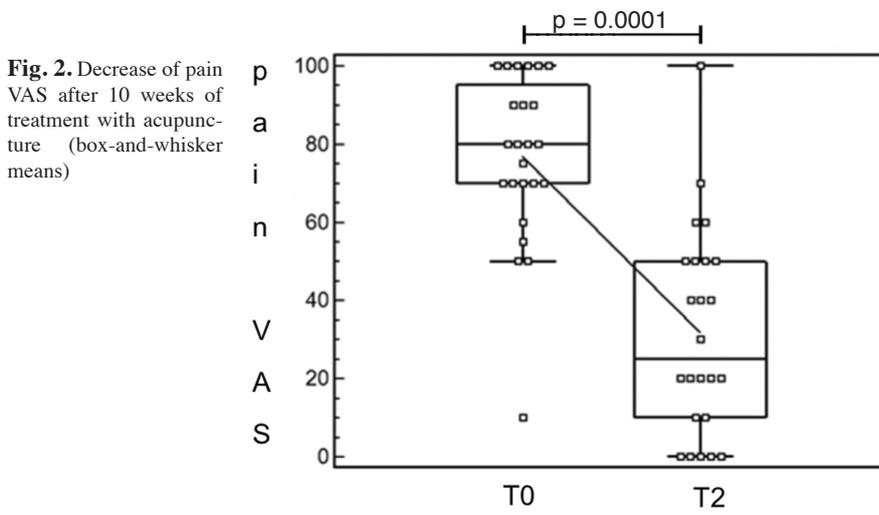


Fig. 2. Decrease of pain VAS after 10 weeks of treatment with acupuncture (box-and-whisker means)

Table III. Decrease of clinimetric scale scores following acupuncture treatment.

	T0	T2	<i>p</i>
FIQ mean (95% CI)	69.7 (64.65-74.74)	45.29 (36.65-53.92)	<0.0001
FAS mean (95% CI)	8.15 (7.54-8.76)	6.54 (5.66-7.42)	0.0006
HAQ mean (95% CI)	1.29 (1.08-1.50)	0.95 (0.72-1.17)	0.0019
Disease activity VAS mean (95% CI)	75.20 (68.60-81.81)	51.04 (40.77-61.30)	0.0001
ZSAS mean (95% CI)	57.29 (52.31-62.27)	49.29 (45.16-53.41)	0.0002
ZSDS mean (95% CI)	54.25 (49.01-59.48)	48.29 (43.97-52.61)	0.002

Fibromyalgia Impact Questionnaire (FIQ), Fibromyalgia Assessment Status (FAS), Health Assessment Questionnaire (HAQ), Visual Analogue Scale (VAS) for pain and disease activity, Zung Self-Rating Anxiety and Depression Scale (ZSAS, ZSDS).

mediators and that acupuncture treatment results in a normalisation of their quantity in the blood. The substance P, interleukins 1 and 6, enkephalin, beta-endorphins, TNF and NPY are among the studied mediators and there is an extended literature regarding their variation in response to acupuncture application. In TCM health is seen as the result of the balance of energy, called qi, in the body. When this balance is modified, health is compromised and symptoms occurs. It is believed that qi flows through channels called meridians and that the acupuncture, with the insertion of needles along these meridians, restores the energy balance and health to the patients (27).

In addition to conventional acupuncture, there is a more recent method that was introduced by its founder Dr Bo Yun Zi just over 20 years ago. Dr Bo integrated ideas from surgical procedures into his abdominal acupuncture system and created a new application protocol in order to decrease learning time for students, improve efficacy and increase reproducibility.

A component of this system involves the standardisation of acupoints and locating method: points are located using a combination of anatomical landmarks, they are measured by ruler and marked with a pen. It involves the use of a microsystem consisted of acupoints located on the periumbilical abdominal zone. The body map (head-column-limbs) on the abdomen is represented taking the conformation of a turtle with the head upward. It is a technique that has proved to be very effective in the prompt reduction of pain. A good manageability is presented because

the inserted needle does not require manipulation and therefore it is better tolerated by the patient. Regarding this fact it is necessary to mention that this technique allows to act remotely on the specific points of pain without acting directly on the trigger, which could accentuate the symptomatic pain, particularly in the case of FM.

The method of abdominal acupuncture also has the characteristic of using precise protocols that allow for repetition and standardisation of the treatment. However, its effectiveness depends on the absolute precision of the localisation of abdominal acupoints.

Acupuncture is increasingly being used as a complementary therapy. Back pain (34%), joint pain (16%) and neck pain (13.6%) are the most common reasons for its use; conditions such as arthritis, systemic lupus erythematosus, gout and FM grouped together represented 6.5% of acupuncture use (24).

After osteoarthritis, FM is the second most common rheumatologic condition in the United States affecting between 2 and 4% of the population (21), with consequent high costs (28). It is characterised by widespread pain associated with a variety of other signs and symptoms, including fatigue, sleep disorders, paresthesias, headache, anxiety, sicca symptoms, Raynaud's phenomenon and irritable bowel. Because of all of these characteristics it is a good candidate for acupuncture treatment. Recent studies have not provided conclusive evidence on the real effect of acupuncture for FM and its associated symptoms. A 12-week double blinded randomised control study in 100 patients with FM (29) did not find any

statistically significant difference between acupuncture treatment and sham acupuncture (placebo acupuncture) in non-specific acupuncture points. A review published in 2010 on 385 patients (31) pooled data from 7 RCT (29, 31-36) found a small analgesic effect due to acupuncture treatment but it was not maintained at follow-up.

To date, given these results, there is insufficient evidence to support a recommendation of acupuncture for the treatment of FM. Moreover, there is presently no literature on the use of abdominal acupuncture for the treatment of pain in patients with FM.

In the present study the choice to match the conventional acupuncture with the abdominal method was dictated by the following factors: 1) increase of analgesic and muscle relaxant effect in a short time 2) the possibility to prevent the skeletal muscle segments affected by pain symptoms from being contracted without the need to puncture trigger points. 3) the greater tolerability of abdominal puncture considering that, the insertion of the needles into the abdominal area is, in fact, painless.

In particular we obtained a statistically significant improvement in pain VAS and in TPs number even after the first session. This result was boosted gradually and maintained until the end of acupuncture treatment. Interestingly, in TCM the use of abdominal acupuncture is supposed to possess a strong capability to modulate the flow of qi, the energy, of the whole body and the effects of treatment are often instantaneous.

Furthermore, at treatment completion the scores of all the clinimetric scales administered to patients, including the FIQ, FAS, HAQ and ZSAS and ZSDS, were significantly improved. As a consequence, it is possible to state that also fatigue, sleep disturbances and morning stiffness ameliorate after acupuncture treatment.

So, both the first and the second end points of the study were achieved in a short time showing the ability of acupuncture in fast reduction of pain and in improving the well-being state of FM patients. In this study 6 patients dropped out, 4 of which for poor com-

pliance. In our opinion it should be highlighted that acupuncture treatment required considerable motivation from the patient, availability of time, adherence to the treatment. This can be considered a possible limitation.

To our knowledge, this is the first study that combine somatic and abdominal acupuncture in the treatment of FM. Matching these two methods we were able to achieve the goal using abdominal acupoints and reducing the average number of somatic acupoints, both in the distal and proximal portions of the affected body areas.

In conclusion, these data suggest that the combination of two types of acupuncture could be a useful complementary treatment in FM patients, not only to control pain but also to improve associated symptoms and quality of life. As a result, acupuncture could be very useful to reduce the abuse of drugs to relieve pain and the social costs.

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