● Research Article

Short-term complementary and alternative medicine on quality of life in women with fibromyalgia

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ABSTRACT

BACKGROUND: Fibromyalgia (FMS) is a syndrome characterized by chronic widespread musculoskeletal pain, whose etiology is not completely understood. Different therapeutic approaches have been used with inconsistent results. This observation does not invalidate the continued search for alternative treatments aimed at improving quality of life (QoL) in FMS.

OBJECTIVE: This study compared three classical traditional Chinese medicine (TCM) therapies: acupuncture (AC), electroacupuncture (EAC) and moxibustion (MX) in the management of pain and promotion of QoL in FMS patients.

DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS: A preliminary, group-assigned, comparative study enrolled 30 women, mean age (46.90±9.24) years (range 20–60 years), who met the 1990 American College of Rheumatology criteria for FMS diagnosis and a pain-pressure threshold (PPT) < 4 kg/cm². The study was conducted in a teaching tertiary-care medical institution from May 2010 through April 2012. AC, EAC and MX were delivered for 30 min, once a week, for 8 weeks, bilaterally at Neiguan (PC6), Hegu (LI4), Yanglingquan (GB34), Sanyinjiao (SP6) and Taichong (LR3) acupoints.

MAIN OUTCOME MEASURES: Each week, immediately before treatment and after treatment, subjects were tested for PPTs, Wong-Baker Faces Pain Scale (WBFPS; for pain intensity) and Medical Outcomes Study 36-item Short Form Health Survey (SF-36: for QoL).

RESULTS: There was no significant improvement in pain or reduction of tender points in any of the groups studied, at the end of the 8th session. Significant improvement of QoL was perceived in vitality (after AC treatment) and in mental health (after EAC and MX treatments).

CONCLUSION: TCM therapies (AC, EAC and MX) promoted an improvement in the QoL in two areas (vitality and mental health) in FMS women. Further large-scale clinical trials are required to confirm this effect.

Keywords: quality of life; medicine, Chinese traditional; acupuncture therapy; women


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1 Introduction

Pain, whether acute or chronic, unleashes various symptoms in humans, such as changes in sleep patterns, appetite and libido, irritability, decreased ability to concentrate, as well as difficulties in professional and social activities[1].

Fibromyalgia (FMS) is a syndrome characterized by chronic widespread musculoskeletal pain whose etiology is not yet completely understood. FMS’s main symptom is musculoskeletal pain, which may be linked to one or many of its FMS-associated complaints: chronic fatigue, cognitive dysfunction, sleep disturbances, morning stiffness, gastrointestinal symptoms, headache, irritable bowel syndrome, interstitial cystitis (painful bladder syndrome), temporomandibular disorder (TMD), depression and anxiety[2]. FMS is regarded as the prototype of chronic central pain syndrome for the widespread pain that fluctuates spontaneously. Chronic pain and fatigue interfere negatively and intensely on the quality of life (QoL) of FMS patients[2]. To date, the treatment of FMS has not been definitively established, and currently available treatments are insufficient to relieve persistent symptoms, improve functional limitations and QoL in most patients. Clinical evidence advocates a multifaceted program emphasizing education, certain medications, exercise, and cognitive behavioral therapy[3]. Even though, or perhaps, because, there are many different treatment approaches available in traditional Chinese medicine (TCM), FMS treatment outcomes have been promising, but inconsistent[4-6].

The evaluation of alternative and complementary approaches in the treatment of FMS is limited by the shortage of adequate clinical trials. The alternative therapies available for the treatment of FMS are numerous, unregulated and often easily found in popular ads. These treatments range from the sensible to the bizarre—including the use of infrared radiation, special mattresses or towelettes—although none of these “therapies” have been properly validated[7].

Currently there is no clinical evidence for a treatment that provides complete pain relief in patients with FMS. This observation does not invalidate the continued search for alternative treatments aimed at improving QoL in FMS. Any kind of treatment that improves QoL in FMS patients should be valued. With this in mind, this study aims to compare the results obtained from classical TCM treatments, namely acupuncture (AC), electroacupuncture (EAC) and moxibustion (MX), in the management of pain and improvement of QoL in FMS patients.

2 Materials and methods

2.1 Samples

Forty-nine women from the Outpatient Pain Service of the Walter Cantidio University Hospital (HUWC) of the Federal University of Ceará from May 2010 through April 2012 were recruited to participate in the study. Subjects were excluded if they were younger than 20 or older than 60 years of age, presented any psychiatric disorder, blood or heart diseases, pregnancy or illnesses included in the differential diagnosis of FMS, as described by the American College of Rheumatology (ACR). Thirty women with a mean age of 46.90 years (SD: ±9.24, range: 20–60) met the 1990 ACR criteria for FMS diagnosis and presented a pain-pressure threshold (PPT) < 4 kg/cm², verified with a Fischer algometer[8] applied to the right biceps brachii muscle. All included patients signed a written informed consent after procedures were explained to them. Participants were fully informed about benefits and risks of the study and about the possibility to withdraw from it at any time without affecting the treatment they received. The study was approved by the Ethics Committee of the HUWC. Figure 1 presents a flowchart of the study timeline and participation.

2.2 Group assignment

Patients admitted to the study (n=30) were divided into three groups (n=10): Group AC (acupuncture), Group EAC (electroacupuncture) and Group MX (moxibustion). Patients were allocated to the groups as they accepted to participate in the study. The first 5 patients were placed in Group AC, the next 5 patients in Group EAC and the other 5 patients in Group MX. This process was repeated twice, for a total of 10 patients in each group.

2.3 Treatments

Before the beginning of the treatment, all patients were allowed to rest for 15 min. In Group AC, stainless 0.25 mm × 40 mm acupuncture needles (Dong Bang Acupuncture, Inc, Chingnam, Korea) were inserted bilaterally observing the following sequence: Neiguan (PC6), Hegu (LI4), Yanglingquan (GB34), Sanyinjiao (SP6) and Taichong (LR3) starting at the left side of the patient. Needle insertion depth varied from 0.5–1.5 cm and the needles were rotated in both clockwise and counter-clockwise directions, alternately, in order to induce a feeling described in TCM as “The Qi”. After insertion, needles were retained for 30 min before removal.

Needle insertion in the EAC group followed the same
protocol. After needle insertion, electrodes were connected to all needles and to an electrostimulator (model NKL-608; NKL Produtos Eletrônicos, Brusque, Santa Catarina, Brasil). Pulsed square waves, 10 Hz, 10 mA, were applied for 30 min.

In the MX group, the same bilateral acupoints as used in the Groups AC and EAC (PC6, LI4, GB34, SP6 and LR3) were stimulated, starting at the left side of the patient using fine MX sticks (Artemia sinensis, Chinese brand Wu Yan Ai Tiao). The smoldered end of the stick was held 2 cm away from each acupoint and it was moved through all ten points, spending 3 minutes warming each acupoint. The temperature of the local area was kept at (43 ± 2)°C.

In all groups, the procedure was repeated once every week for 8 weeks. At the conclusion of each day of therapy the patients were allowed to go home and were instructed to continue their other treatments including physiotherapy, analgesics, anti-inflammatory agents and tricyclic antidepressants.

2.4 Research instruments

Perception of pain was evaluated by the Wong-Baker Faces Pain Scale (WBFPS). Pressure algometry was used in this study to measure the applied force necessary to elicit a verbal report of “pain” at each tender point. A Fischer dolorimeter®[8] with a rubber disc of 1 cm was applied normal to the skin at all 18 ACR tender points before the treatments (timepoint T0) and at the conclusion of the treatment (timepoint T1).

The QoL assessment tool Medical Outcomes Study 36-item Short Form Health Survey (SF-36) was developed by Ware Jr. and Sherbourne[9] in 1992 and translated, adapted and validated for the Portuguese language (Brasil SF-36) by Ciconelli et al.[10]. The SF-36 is a multidimensional instrument, consisting of 11 questions and 36 items distributed in 8 fields, which evaluate eight different dimensions (also called components or scales) of QoL: functional capacity (10 items), physical aspects (4 items), pain level (2 items), general health (5 items), vitality (4 items), social aspects (2 items), emotional aspects (3 items) and mental health (5 items). The last item is a comparative question about the current perception of health compared to a year ago. The score in each domain ranges from 0 to 100, with a higher score representing a higher QoL.[11]

2.5 Statistical analyses

All statistical analyses were performed with commercially available software (Graphpad Prism 5.0; GraphPad Software, San Diego, California, USA, www.graphpad.com). To ensure the appropriateness of parametric testing, all data were examined for normality, using Kolmogorov-Smirnov test (with Dalal-Wilkinson-Lilliefors P Value). Repeated measures analysis of variance (ANOVA) followed by Tukey’s multiple comparison tests were used to compare before (T0) and after (T1) treatments. Non-parametric data were analyzed using Wilcoxon signed rank test. Friedman’s tests were run to compare all T0 subgroups; T1 subgroups were compared in the same way. The Wilcoxon test was applied to SF-36 data, considering that the participants are assessed on two occasions (before and after treatments).

3 Results

3.1 Demographics and clinical variables

Most women (n=23, 77%) were 41 years or older. Widespread musculoskeletal pain present for more than 3 months and morning stiffness affected most patients. TMD affected almost all patients (n=29, 96.6%). Demographic data and main clinical characteristics of our patients are shown in Table 1.

3.2 Medication used by all patients

Patients reported using 19 types of medications during the study. The most commonly used were nonsteroidal anti-inflammatory drugs (15 patients, 50%), selective serotonin re-uptake inhibitors (10 patients, 33.3%), tricyclic antidepressants (9 patients, 30%) and antacids (8 patients, 26.6%).

3.3 Painful perceptions evaluated by the WBFPS

There was no significant improvement of pain in any of the groups studied, at the end of the 8th session (T1), compared to the first session (T0) (P>0.05). No significant differences among the 3 groups were detected (P>0.05). see Figure 2.

3.4 Measuring sensitivity to pain induced by compression (tender points)

Pressure algometry was used in this study to measure the applied force necessary to elicit a verbal report of “pain” at each point. A Fischer dolorimeter®[7] with a rubber disc of 1 cm was applied normal to the skin to all 18 ACR tender points. There were no differences in applied force between T0 and T1 (Figure 3).

3.5 QoL

The application of the SF-36 questionnaire to 30 women with FMS found no changes in QoL in 6 dimensions: functional capacity, physical aspects, pain level, general health, social aspects and emotional aspects. However, significant improvement of QoL was found in vitality, after AC treatment (Figure 4) and in mental health, after EAC (Figure 5) and MX (Figure 6) treatments.

4 Discussion

Management of FMS is challenging. This paper compared three different treatment approaches intended to reduce pain and to improve the QoL in FMS patients. Based on clinical results obtained in our daily practice we hypothesized that AC would be more effective than some
Table 1  Demographic data and clinical variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th></th>
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<th>Total, n (%)</th>
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<tbody>
<tr>
<td></td>
<td>AC</td>
<td>EAC</td>
<td>MX</td>
<td></td>
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<tr>
<td><strong>Demographic data</strong></td>
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<td><strong>Marital status</strong></td>
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<tr>
<td>Married</td>
<td>6</td>
<td>5</td>
<td>4</td>
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</tr>
<tr>
<td>Unmarried</td>
<td>0</td>
<td>5</td>
<td>3</td>
<td>8 (27)</td>
</tr>
<tr>
<td>Separated/divorced/widowed/others</td>
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<td>0</td>
<td>3</td>
<td>7 (23)</td>
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<tr>
<td>Elementary school</td>
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<td>9</td>
<td>9</td>
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<td><strong>Age</strong></td>
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<td>20–40 years</td>
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<td><strong>Most frequent symptoms</strong></td>
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<tr>
<td>Widespread musculoskeletal pain &gt;3 months</td>
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<td>10</td>
<td>9</td>
<td>28 (93.3)</td>
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<tr>
<td>Muscular fatigue</td>
<td>8</td>
<td>9</td>
<td>9</td>
<td>26 (86.6)</td>
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<tr>
<td>Morning stiffness</td>
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<td>8</td>
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<tr>
<td>Depression</td>
<td>8</td>
<td>6</td>
<td>7</td>
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<td>Interrupted sleep</td>
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<td>7</td>
<td>6</td>
<td>19 (63.3)</td>
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<tr>
<td>Headache</td>
<td>8</td>
<td>9</td>
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<td>26 (86.6)</td>
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<tr>
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<td>Osteoporosis</td>
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<td>1</td>
<td>4 (13.3)</td>
</tr>
</tbody>
</table>

AC: acupuncture; EAC: electroacupuncture; MX: moxibustion.

Figure 2  Painful perceptions evaluated by the Wong-Baker Faces Pain Scale
Boxes represent patients’ pain perception before (T0) and at the end of treatments (T1). Treatments (AC: acupuncture; EAC: electroacupuncture; MX: moxibustion) were applied once every week for eight weeks. Values were not significantly different (Wilcoxon signed rank test, $P$>0.05)

Figure 3  Number of tender points with pain-pressure threshold <4 kg/cm², evaluated by Fischer algometry
Bars represent number of tender points before (T0) and at the end of treatments (T1). Treatments (AC: acupuncture; EAC: electroacupuncture; MX: moxibustion) were applied once every week for eight weeks. Values were not significantly different (repeated measures analysis of variance/Tukey’s multiple comparison tests, $P$>0.05).
Chronic pain and fatigue affect the QoL of patients with FMS negatively and intensely. The FMS is regarded as the prototype of chronic central pain syndrome for its widespread pain that fluctuates spontaneously\[^2\]. FMS presents the highest rates of pain, stress, psychoactive and functional incapacity, when compared with other rheumatic diseases\[^12,13\].

Three areas are directly involved in the FMS framework: the musculoskeletal system, the neuroendocrine system and the psychological system\[^14\]. Given the complexity of symptoms and manifestations it is evident that clinical evaluation of treatment results of FMS is not an easy task.

In this study, the age of patients ranged from 21 to 60 years with most patients within the 40–50 years band (40%; Figure 1). More than two thirds (76.67%) of all patients were aged between 40 and 60 years. The average age was of 46.90 (SD: ± 9.24). Fifteen patients (50%) were married and one (3.3%) was a widow. Spontaneous demand occurred in 49 individuals but only 30 were accepted to participate in the study. Almost half (46.6%) of these subjects reported being physically active before the start of treatment.

As for clinical variables, widespread musculoskeletal pain present for more than 3 months was reported by 28 women (93.3%). Muscular fatigue, morning stiffness and headache affected 26 patients (86.6%). Depression was present in 21 individuals (70%). These complaints are frequent among FMS women\[^15,16\].

Comorbidities were present in all patients. TMD is the most common chronic orofacial pain condition that occurs in approximately one third of the general population\[^17\]. One of the first studies to report the frequent association between FMS and TMD was published in 1988 by Eriksson et al\[^18\]. TMD was a common complaint and it affected all but one patient in our study.

Measurements of PPT and the visual analog scale (VAS) have been used for assessing musculoskeletal pain and treatment efficacy in various patient populations\[^19,20\]. These procedures were utilized here to evaluate the efficacy of the various treatments used in reducing the pain and tenderness in the FMS patients.

It has been reported that there are no significant differences in the mean pain intensity scores when subjects are accessed using the Numeric Rating Scale, the Faces Pain Scale or the VAS\[^21\]. Although the WBFPS was initially used to evaluate pain in children, it has been used with success in adults with cognitive impairments\[^22\]. Whereas almost all individuals included in this study had a low level of education, we chose to use the WBFPS to evaluate their perception of pain before and after the other complementary methods of treatment used in FMS. The study showed that the AC, EAC and MX have similar effects in relation to the treatment of pain in FMS.
treatments.

The absence of significant differences in pain intensity and number of tender points evaluated before and after 8 sessions with 3 different treatments was not totally unexpected, considering the information available in the medical literature. Several studies have reported different results in FMS treatments using complementary and alternative therapies.\(^\text{[4,6,7,21]}\) One randomized sham-controlled study demonstrated no subjective improvement in pain between AC and sham AC.\(^\text{[4]}\) Itoh and Kitakoji\(^\text{[24]}\) studied the effects of AC in 16 FMS patients (13 women and 3 men) and concluded that the use of the AC/EAC reduced the intensity of pain and improved QoL after 5 weeks of treatment using AC on painful points for 16 min followed by EAC at the same points for 15 min. Recently, Deare et al.\(^\text{[25]}\) conducted a systematic review of the use of AC to treat FMS and concluded that AC improves pain and stiffness in people with FMS and that EAC is probably better than AC for reducing pain and stiffness, and improving of well-being, sleep and fatigue. The authors emphasize that these results may not be taken as definitive considering the small sample size, the scarcity of studies for each comparison and the lack of ideal sham AC.

Zhao and Zhu\(^\text{[5]}\) studied the clinical therapeutic effect of herb-partitioned MX combined with medication on FMS syndrome and concluded that there was no significant difference in the score of VAS before and after treatment ($P>0.05$). An earlier study suggested that EAC was more effective than sham therapy for FMS, but the study may not have been adequately blinded.\(^\text{[22]}\)

QoL is determined primarily by the health status. Both the patient and the health professional must be involved in the educational processes to better understand the factors associated with the disease, and thus draw up strategies to obtain an accurate diagnosis and proper treatment. Within this context, it is important that the health professional that cares for FMS individuals should pay special attention to the patient’s perception concerning their illness, and should provide empathy to help patients maintain positive feelings toward their health recovery. These professionals should be aware that adherence to treatment depends largely on the ability to maintain good interaction with patients.

Analysis of the results obtained from the SF-36 questionnaire demonstrated that the treatments used did not improve the QoL of women with FMS in 6 of the 8 dimensions: functional capacity, physical aspects, pain level, general health, social aspects and emotional aspects. However, there was significant improvement in 2 dimensions: vitality and mental health. The improvement of QoL in mental health was realized in both the EAC and the MX treatments. However, only the AC group had significantly increased QoL in patient vitality. While encouraging, these results were obtained from a small number of patients and should not be generalized. Larger studies are warranted.

5 Conclusion

TCM therapies (AC, EAC and MX) promoted an improvement in the QoL in two areas (vitality and mental health) in FMS women. Further larger-scale clinical trials are required to confirm this effect.

6 Disclosure statement

This study received no financial support. No competing financial interest exists for any of the authors.

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