



Effectiveness of Individualised Homoeopathic Medicine in Fibromyalgia: A Prospective Case Series

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ABSTRACT

Background: Fibromyalgia is a chronic pain syndrome with widespread musculoskeletal pain, fatigue, unrefreshing sleep and cognitive difficulty. Usual drug treatment gives only modest benefit, and many patients turn to complementary options, including homoeopathy.

Objectives: To assess whether individualised homoeopathic treatment lowers pain in fibromyalgia, measured with the Wong-Baker FACES Pain Rating Scale, and to record the medicines most often prescribed.

Methods: A prospective case series of 30 patients who met the 2016 American College of Rheumatology (ACR) criteria for fibromyalgia was carried out over 18 months. Patients came from institutional and peripheral outpatient departments, camps and the investigator's own practice and were chosen by simple random sampling. Each case was recorded in a standard format, repertorised, and treated with one individualised medicine chosen on symptom similarity and checked against the Materia Medica. Pain was scored from 0 to 10 before treatment and at the end of the study. A drop of 2 points or more was rated Improved. Scores were compared with a paired t-test.

Results: Nineteen patients (63.3%) were women, and most (76.7%) were aged 20 to 39 years. The mean pain score fell from 7.40 to 2.93, a mean reduction of 4.47 points (95% CI 3.79 to 5.14; $t = 13.48$, $df = 29$, $p < 0.001$). Twenty-eight patients (93.3%) were Improved and two (6.7%) were not. Seventeen different medicines were used; *Rhus toxicodendron* was the commonest (4 patients), followed by *Arnica*, *Bryonia alba* and *Ruta graveolens* (3 each).

Conclusion: Pain scores fell markedly after individualised homoeopathic treatment in this small series. Because the study had no control group and a short, variable follow-up, the result cannot be attributed to the medicines alone. Controlled studies with longer follow-up are needed.

Keywords: Fibromyalgia; Homoeopathy; Individualised prescribing; Wong-Baker FACES Pain Rating Scale; Case series; *Rhus toxicodendron*

1. Introduction

Fibromyalgia is a chronic pain syndrome. Its main features are persistent widespread musculoskeletal pain, marked fatigue, disturbed sleep, difficulty with thinking and physical function, and psychological distress [1]. The eleventh revision of the International Classification of Diseases (ICD-11) places it under chronic primary pain [1]. It is a non-inflammatory, non-autoimmune condition, and the cognitive difficulty is often called "fibro fog" [2].

The condition has a long history. Froiep described firm, tender areas in the muscles of patients labelled as rheumatic in 1850, and Gowers introduced the term fibrositis in 1940 for tenderness on gentle pressure without visible inflammation [3]. The ACR published its first classification criteria in 1990 and revised them substantially in 2016 [4,5]. The 2016 criteria rely on the Widespread Pain Index (WPI) and the Symptom Severity Score (SSS). A patient qualifies with a WPI of 7 or more and an SSS of 5 or more, or a WPI of 4 to 6 and an SSS of 9 or more, together with pain in at least four of five body regions and symptoms lasting three months or longer [4,5]. No laboratory test confirms the diagnosis, so it rests on clinical assessment [6,7].

The International Association for the Study of Pain classes fibromyalgia as nociplastic pain, a term that has replaced the older label of central pain, and its hallmarks are diffuse hyperalgesia and allodynia [8]. The central problem is amplified pain processing within the nervous system, not continuing damage at the painful site [8]. Quantitative sensory testing and functional MRI have shown altered brain responses to stimuli that are not normally painful [9]. This shared central mechanism is also thought to explain why fibromyalgia often coexists with irritable bowel syndrome, chronic headache, temporomandibular disorder, interstitial cystitis and other pelvic pain syndromes [10,11].

Estimates of prevalence run from 2% to 4% of the world's population [9,12,13]. Published figures range widely, from 0.2% to 6.6% in general-population surveys, and depend on the criteria used, the population studied and the country [12–14]. Women are affected more often than men, although the ratio depends on the setting. One European study reported 1.7 women per man and a United States study 6.8 [15]. Data from India are limited. In one government hospital in Kerala, 298 of 2,300 consecutive neurology outpatients (about 13%) met the 2016 criteria [16]. A hospital figure of this kind cannot be read as a population rate.

Treatment is difficult. European guidance advises patient education and non-drug measures first, gives its only strong recommendation to exercise, and notes that the size of effect for most treatments is modest [17]. Antidepressants, anticonvulsants and analgesics often give only partial relief [17,18], and many patients look for complementary options [19]. In individualised homoeopathy the medicine is chosen from the whole symptom picture of the patient, including mental and general features, and not from the diagnostic label alone [20,21].

The homoeopathic evidence in fibromyalgia is small. It consists of a few randomised trials [20,22], reviews that judge it preliminary or unproven [23–25], and a handful of case reports [26,27]. We therefore recorded a series of patients, with the pain score and the medicine for each, to describe what happened under routine individualised care.

2. Aim and Objectives

Aim: To evaluate the effectiveness of homoeopathic medicine in fibromyalgia.

- **Primary objective:** to reduce the pain score on the Wong-Baker FACES Pain Rating Scale in fibromyalgia.
- **Secondary objective:** to find the homoeopathic medicines most commonly used in fibromyalgia.

3. Materials and Methods

3.1 Design, setting and duration

This was a prospective case series lasting 18 months. Patients were recruited from the institutional outpatient department (OPD), peripheral OPDs, camps run by the institution, and the investigator's own OPD. There was no comparison group.

3.2 Participants

The source population was people with the signs and symptoms of fibromyalgia. Thirty patients were selected by simple random sampling from those who met the criteria below.

Inclusion criteria: patients of any age and either sex who gave consent and met the 2016 ACR criteria [4]: WPI of 7 or more with SSS of 5 or more, or WPI of 4 to 6 with SSS of 9 or more; generalised pain in at least four of five regions; and symptoms for at least three months.

Exclusion criteria: autoimmune disease; non-compliance with the study protocol; alcohol or drug misuse or psychiatric illness; long-term continuous use of steroids, opiates, methotrexate or TNF-alpha inhibitors; patients judged ineligible by the investigators; and refusal of consent.

Withdrawal criteria: irregular follow-up or stopping the medicine.

3.3 Ethical considerations

Informed consent was taken from every participant. Ethical approval for the study was obtained from the Ethical committee of Motiwala homoeopathic medical college and hospital, Nashik before start of the study.

3.4 Case taking, repertorisation and prescription

Each patient was interviewed and examined with a standard case record format. The symptoms were analysed, the totality was formed, and the case was repertorised with RADAR software. One individualised medicine was prescribed on the basis of symptom similarity, after checking the leading remedies against the Homoeopathic Materia Medica [21,28]. Follow-up visits were scheduled after one month.

3.5 Outcome measures

Pain was rated on the Wong-Baker FACES Pain Rating Scale, which shows six faces from smiling (0, no hurt) to crying (10, hurts worst) and asks the patient to choose the face that fits their pain [29]. The scale was developed for children and has been validated mainly in paediatric settings [30,31]. The score was recorded at baseline and again at the end of the study. A fall of at least 2 points was rated **Improved**, and no change or a rise was rated **Not Improved**. A fall of about 2 points, or about 30%, on an 11-point pain scale is generally accepted as clinically important [32].

3.6 Statistical analysis

Before and after scores were compared with a paired t-test (two-sided, significance at $p < 0.05$). The mean difference is given with its 95% confidence interval. A Wilcoxon signed-rank test was run as a check because the scale is ordinal. Counts and percentages describe the categorical data.

4. Results

4.1 Patient characteristics

All 30 patients were enrolled and analysed. Nineteen (63.3%) were women and 11 (36.7%) were men. Their ages ranged from the twenties to over 50 years, and 23 (76.7%) were between 20 and 39 years old (Table 1).

Table 1. Age and sex distribution of the patients (n = 30)

Characteristic	Number	Percentage
Female	19	63.3
Male	11	36.7
Age 20–29 years	10	33.3
Age 30–39 years	13	43.3
Age 40–49 years	6	20.0
Age 50 years and above	1	3.3

4.2 Change in pain score

The mean pain score was 7.40 (SD 1.43; range 6–10) before treatment and 2.93 (SD 1.39; range 0–7) afterwards. The mean reduction was 4.47 points (SD 1.81; standard error 0.33; 95% CI 3.79 to 5.14), about 60% of the baseline mean. The paired t-test gave $t = 13.48$ with 29 degrees of freedom ($p < 0.001$), and the Wilcoxon test agreed ($p < 0.001$). The reduction was 2 points or more in 28 patients, and all 28 also showed a fall of at least 30% [32]. In 21 patients the final score was 3 or less. No patient reported a one-point change, so the Improved and Not Improved definitions left no gap (Table 2, Figure 1).

Table 2. Pain scores before and after treatment (n = 30)

Measure	Before	After	Reduction
Mean score	7.40	2.93	4.47
Standard deviation	1.43	1.39	1.81
Median	7	3	4
Range	6–10	0–7	0–8
Paired t-test			$t = 13.48$, $df = 29$, $p < 0.001$

Figure 1. Average pain score of the 30 patients on the Wong-Baker FACES Pain Rating Scale before and after treatment.

4.3 Clinical outcome

Twenty-eight patients (93.3%) were rated Improved and two (6.7%) Not Improved. In both patients who did not improve, the score was unchanged (6 to 6 in one, 7 to 7 in the other).

4.4 Medicines prescribed

Seventeen different medicines were prescribed for the 30 patients (Table 3). *Rhus toxicodendron* was used most often (4 patients, 13.3%), followed by *Arnica*, *Bryonia alba* and *Ruta graveolens* (3 each, 10%). *Calcarea carbonica*, *Causticum*, *Cimicifuga* and *Gelsemium sempervirens* were each given to 2 patients, and nine other medicines to one patient each.

Table 3. Medicines prescribed in the series (n = 30)

Medicine	Number of patients	Percentage
<i>Rhus toxicodendron</i>	4	13.3
<i>Arnica Montana</i>	3	10.0
<i>Bryonia alba</i>	3	10.0
<i>Ruta graveolens</i>	3	10.0
<i>Calcarea carbonica</i>	2	6.7
<i>Causticum</i>	2	6.7
<i>Cimicifuga racemosa</i>	2	6.7
<i>Gelsemium sempervirens</i>	2	6.7
Nine other medicines*	9	30.0

**Bellis perennis*, *Kali carbonicum*, *Kali phosphoricum*, *Kalmia latifolia*, *Natrum muriaticum*, *Nux vomica*, *Pulsatilla pratensis*, *Rhododendron* and *Sepia*, one patient each.

5. Discussion

Pain scores in this series fell by a mean of 4.47 points on a 10-point scale, and 28 of 30 patients improved. The size of the change is well above the 2-point or 30% level usually taken as clinically important [32]. For comparison, the EULAR review found that the effect of most fibromyalgia treatments is modest [17]. The two patients who did not improve showed no change, and neither worsened.

The result needs careful reading, because a case series cannot show that the medicines caused the change. Patients were enrolled while symptomatic, so some fall in pain would be expected as symptoms fluctuate. A long, attentive consultation can also reduce pain independently of the medicine, and the outcome was a single self-reported item recorded by the treating investigator without blinding. Other treatments the patients may have been taking were not analysed. A double-blind, placebo-controlled trial of 62 patients treated for three months found individualised remedies better than placebo for tender point pain, quality of life and global health [20]. A companion report from the same research group looked at patients who stayed with or switched from their assigned treatment and linked the choice to personal traits [33]. An earlier crossover trial reported benefit [22], but a re-analysis by Colquhoun found that each patient had been counted twice and that no significant effect remained after correction [34].

Reviews of the evidence are cautious. One review of four randomised trials found that all favoured homoeopathy but that none was free of serious flaws and that independent replication was missing, so effectiveness remained unproven [24]. A later review identified 10 case reports, 3 observational studies, 1 non-randomised trial and 4 randomised trials, and its pooled analysis of controlled trials showed lower pain intensity (standardised mean difference -0.54) and tender point count than placebo, although the authors called the conclusions preliminary [23]. An overview of 25 systematic reviews of complementary therapies judged the homoeopathy evidence inconclusive [25], and a review of 23 trials of complementary treatments found positive tendencies for homoeopathy in a single trial only [35]. Published case reports describe improvement with individually chosen medicines [26,27]. Our series is in line with these reports, but it is a lower level of evidence than a trial.

The pattern of prescribing reflects individualisation. Seventeen medicines were needed for 30 patients, and no medicine accounted for more than 4. *Rhus toxicodendron*, *Arnica*, *Bryonia* and *Ruta* are all described in the classical *Materia Medica* for stiffness, bruised soreness and pain that changes with movement or rest [21,28]. In the investigator's experience, the patients also carried a considerable emotional history. This was a clinical impression and was not measured. Psychological trauma is common in fibromyalgia and is linked to higher symptom severity [36], a physical injury in the months before onset is more common than in comparison patients [37], and gut-brain disorders add to the burden [11]. These associations are one reason a whole-person approach is attractive, but our design cannot test whether it contributed to the results.

The proportion of women (63.3%) is in line with the female predominance reported elsewhere [15], although clinic series often show a higher proportion than population surveys [15]. Most patients were between 20 and 39 years old. The reason for this younger profile was not examined.

5.1 Limitations

The sample was small, there was no control group, and patients came from a limited number of related settings, so the results may not apply to all patients with fibromyalgia. Follow-up was short and varied between patients, and we do not know whether the benefit lasts. The pain scale was designed for children, has been validated mainly in paediatric settings [30,31], and, as far as we found, has not been validated in fibromyalgia. It measures pain only and does not capture fatigue, sleep, mood or function. Assessment was not blinded. Some patients felt better after a few weeks and became irregular in attendance, and these patients had to be called back for assessment. Finally, recruiting patients who met the full 2016 criteria took considerable effort, because several patients with widespread pain did not reach the WPI and SSS thresholds or had an autoimmune disease.

5.2 Future research

A larger, multicentre, placebo-controlled or usual-care-controlled trial with blinded assessment is the logical next step. Longer follow-up would show whether the improvement lasts or relapses after treatment stops. Future studies could also add measures of fatigue, sleep, mood and function, since fibromyalgia often coexists with irritable bowel syndrome, chronic fatigue and mood disorders [10,18].

6. Conclusion

In this prospective series of 30 patients with fibromyalgia, the mean pain score fell from 7.40 to 2.93 after individualised homoeopathic treatment, and 28 patients (93.3%) improved. The wide range of medicines used shows that prescribing followed each patient's symptom picture. With a small sample, no control group and a short follow-up, the study cannot show that homoeopathic medicine caused the improvement. It supports the case for a controlled trial.

Declarations

Ethics approval and consent: Ethical committee of Motiwala homoeopathic medical college and hospital, Nashik; informed consent was obtained from all participants.

Conflict of interest: None

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