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Traditional Chinese medicine diagnoses in a sample of women with fibromyalgia

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Abstract

Background—Traditional Chinese medicine (TCM) offers various treatment modalities guided by TCM diagnoses. In the United States, acupuncture is a commonly employed TCM method for treating a variety of chronic illnesses. Three systematic reviews have been reported recently, reaching differing conclusions about the efficacy of acupuncture for the treatment of fibromyalgia (FM). Among the FM acupuncture studies considered in these reviews, none used TCM diagnosis as an inclusion/exclusion criterion or adjusted treatment based on TCM diagnosis. Overlooking TCM diagnosis may be a reason for such disparate results.

Primary study objective—To obtain TCM diagnoses in a sample of women meeting 1990 American College of Rheumatology criteria for FM who were recruited for a yoga study and to investigate whether there is significant variability.

Methods/design—Two TCM practitioners conducted baseline TCM diagnostic examinations on 56 women with FM. A consensus diagnosis was reached based on standardised history, palpation and examination. Canonical discriminate analysis identified two baseline items which predicted TCM diagnosis.

Setting—School of Nursing, Oregon Health & Science University.

Participants—Women, ages 23–75, with FM recruited to a yoga intervention study

Results—Three primary TCM diagnoses were found in the population: Qi and Blood Deficiency (46.4%, CI 33.0% to 60.36%), Qi and Blood Stagnation (26.8%, CI 15.8% to 40.3%), and Liver Qi Stagnation (19.6%, CI 10.2% to 32.4%).

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Contributors SDM and CW conducted the traditional Chinese medicine diagnostic interviews and drafted the manuscript. KDJ conducted the baseline biomedical examinations and edited the manuscript. JWC conceived the original fi bromyalgia study which recruited the participants, and edited this manuscript. All authors read and approved the fi nal manuscript.

Competing interests None.

Patient consent Obtained.

Ethics approval The study was approved by Oregon Health & Science University Institutional Review Board.

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► An additional supplementary data is published online only. To view these fi les please visit the journal online (http://aim.bmj.com/content/29/4.toc).

Conclusion—It is likely that previous studies of FM were treating a heterogeneous study population where variable results might be expected. Future acupuncture studies should either control for TCM diagnosis or consider its usefulness as an inclusion/exclusion criterion.

BACKGROUND

Fibromyalgia (FM) is the second most commonly encountered diagnosis in rheumatology clinics in the USA, affecting between 11 and 15 million people. Current FM treatments generally provide 30–40% symptom relief and/or functional improvement. National surveys indicate that 15% of patients with FM have sought acupuncture treatment. Three systematic reviews 4–6 have been reported, reaching differing conclusions about the efficacy of acupuncture for the treatment of FM. None of the studies reviewed accounted for traditional Chinese medicine (TCM) diagnosis. Although expert opinion is available, 7–11 no research has examined the distribution of TCM diagnoses in the FM population, much less used them to guide TCM interventions. Variation in TCM diagnoses in study samples could account for the wide variability in treatment effects reported in acupuncture studies.

METHODS

Subjects

Fifty six subjects were recruited from a current separate study—modified yoga for FM symptom management. Inclusion/exclusion criteria and study outcomes are reported in the paper by Carson $et\ al.^{12}$

The women's ages ranged from 23 to 75, all met 1990 American College of Rheumatology criteria for FM, ¹³ and had been diagnosed with FM for at least 1 year. Before the modified yoga intervention each woman was assessed simultaneously by two TCM practitioners for TCM pattern diagnoses.

Two participants from the yoga study were excluded owing to the lack of a stable regimen and one was excluded owing to scheduling conflicts. All members recruited to the yoga study were included in this study.

Study design and procedures

Two graduate-level prepared (MAcOM, MTOM) TCM practitioners, each with at least 5 years of clinical experience, simultaneously diagnosed the participants using a consensus model based on diagnostic criteria published in Maciocia, ⁷ a text commonly used in US acupuncture schools, and from which US Oriental medicine board certification examinations are procured. 14 The diagnostic process included a patient questionnaire (see supplementary data) for subjective report and history, palpation of the radial artery on each wrist and visual examination of the tongue by a standardised technique. Participants filled out the questionnaire which was then made available to both practitioners. Each form was reviewed by one of the practitioners for missing data and any necessary clarifications before the physical examination. The physical examination began with each practitioner palpating the radial artery on each wrist; after each practitioner had examined the six traditional pulses they were documented separately. Together, both practitioners examined the tongue and again, documented their impressions. After each examination, the practitioners independently diagnosed the participants. Practitioners were not allowed to discuss the patient or diagnoses during the visit and were observed by a third investigator (KDJ). Diagnostic disagreements were maintained and are described in the 'Results' section. Additional questionnaires assessing FM and functional deficits at baseline included the Fibromyalgia Impact Questionnaire Revised (FIQ-R) which measured function and FMspecific symptoms ¹⁵; the Vanderbilt Multidimensional Pain Coping Inventory ¹⁶ and number

and type of comorbid conditions. Physical examinations included total myalgic score based on a tender point examination (4 kg of pressure for 4 s on American College of Rheumatology sites), ¹³ timed chair rise ¹⁷ and balance with eyes open and closed (Sensory Integration for Balance Test). ¹⁸

Statistical methodology

Prevalence of TCM diagnosis was calculated with a 95% confidence level using binomial exact intervals. Canonical discriminant analysis was conducted to determine if a linear combination of items could discriminate between naturally occurring diagnoses. This was completed with baseline questionnaire items using Stata 11.1, College Station. This study was reviewed and approved by the Oregon Health & Science University Institutional Review Board.

RESULTS

The practitioners agreed upon 54 of 56 primary diagnoses (96.4%). Disagreement about the two diagnoses was due to rating differences between the primary and secondary diagnosis.

The study population had an average age of 53.7 (SD 11.4), were primarily Caucasian (92.7%), well educated (58.8% college degree or higher) and currently married or in a partnered relationship (69.8%). Over 50% of the participants reported having FM symptoms for more than 10 years. These characteristics are similar to those of subjects with FM in other clinical trials.³¹⁹

The practitioners discussed the two cases and reached a consensus as presented in table 1.

Three primary TCM diagnoses were found in this sample: Qi and Blood Deficiency, Qi and Blood Stagnation and Liver Qi Stagnation. Table 1 shows the primary and secondary diagnoses and their CIs. Participants had a mean of 4.6 TCM diagnoses (range 36) with all having one of these three diagnoses as either primary or secondary diagnosis. The TCM diagnoses did not differ in the FIQ-R total or Total Myalgic Score. Subscales of FIQ-R differences were also not significant. Reliability coefficients for the measures can be found in the primary outcome manuscript. ¹²

Canonical discriminant analysis identified two factors which discriminated between four categories—the three main diagnoses and a combined group of all other diagnoses. The factors include two variable: self-reported temporomandibular joint disorders (binary yes/no) and reappraising coping skills (range 0.83–4). The first factor (canonical correlation = 0.49, p=0.0026) primarily uses self-reported TMD to distinguish between those with stagnation (Liver Qi Stagnation and Qi and Blood Stagnation) and all others. The second factor (canonical correlation = 0.34, p=0.047) primarily distinguishes diagnoses with a combined Qi and blood involvement. Table 2 shows the correct classification, and prior rates, and table 3 presents the standardised canonical discriminant function for both dimensions and group means on canonical variables.

As the factors failed to distinguish Liver Qi Stagnation, the category was combined with Qi and Blood Stagnation and a post hoc canonical discriminant analysis restricting the variables to the two previously identified was completed to identify excess conditions (Liver Qi Stagnation and Qi and Blood Stagnation) versus deficiency conditions (Qi and Blood Xu, Kidney Yin Xu and Spleen Qi Xu). The single factor had a canonical correlation of 0.45 (p=0.0032). Self-reported temporomandibular joint disorders were primarily indicative of excess conditions while reappraising coping skills was primarily associated with deficiency

conditions. See tables 2 and 3 for the classification rates and standardised discriminant coefficients and group means for this analysis.

DISCUSSION

Most current research into the effectiveness of TCM has resulted in uncertainty in interpreting the outcomes. One major source of the uncertainty is that TCM diagnosis has not been considered—either in the protocol or the exclusion criteria. Therefore it is not known whether the poor results are due to the ineffectiveness of TCM treatments or whether the study did not apply the most appropriate treatment (either giving a treatment that is more generic or one focused on a specific diagnosis and hoping that most people will respond). TCM diagnoses—unlike many Western biomedical diagnoses—are syndromes or a constellation of signs that form patterns, rather than specific diagnoses. These syndromes or patterns group together signs and symptoms, which collectively describe the disease state, much like the definition of FM¹³²⁰ or TMD. ¹⁹ Further, TCM diagnoses do not have a one-to-one correspondence to Western biomedical diagnoses. For example, if one were to hold the TCM diagnosis constant, for this example, Qi and Blood Stagnation, but impose no constraints on the Western biomedical diagnosis, one might have such disparate diagnoses as osteoarthritis, endometriosis or acute injury.

This study illustrates, that by holding the Western biomedical diagnosis constant (FM), the resultant TCM diagnoses are varied—each with their own clinical presentation, treatment protocol, course of treatment and outcomes. Qi and Blood Stagnation is characterised by pain that is widespread, both dull and sharp in nature. Pain associated with Qi and Blood Stagnation is improved with low impact exercise. ⁷¹⁰ It is best treated with a combined approach of acupuncture and herbs. Clinical experience suggests that patients with Qi and Blood Stagnation often see improvement after 4 weeks of treatment and are the easiest of the TCM diagnoses in FM to treat.

Liver Qi Stagnation is similar to Qi and Blood Stagnation in that both are excess conditions. Liver Qi Stagnation is improved with exercise and worsens with lack of activity. These patients often have depression, which also improves with activity. Liver Qi Stagnation can be treated with acupuncture only but requires patient lifestyle changes, including reduction of stress, increased activity and dietary modifications.

Qi and Blood Deficiency is a very different syndrome. Patients with Qi and Blood Deficiency have dull diffuse pain and tend to be very lethargic. Strenuous exercise worsens all the symptoms, including pain. This syndrome has a much longer course of treatment (3–6 months). The ideal modality for this is herbal rather than acupuncture. Patients with this diagnosis tend to have setbacks in their treatment as they tend to overextend themselves when they start feeling better instead of moderating their activities.⁷¹⁰

Similar results have been found in two TMD samples²¹²² and the authors' clinical experience suggests that many chronic pain or central sensitivity syndromes have varied TCM diagnoses.

This diagnostic variation presents a major challenge for TCM practitioners who attempt to accurately interpret study results where diagnoses are either not performed or published.

In this particular study, the three main diagnoses have differing and mutually exclusive characteristics. Qi and Blood Deficiency is, as the name implies, a deficient condition and characterised by dull pain and very low energy that is aggravated by activity. Deficient conditions are generally slow to improve, and respond less favourably to forceful acupuncture and more favourably to herbal treatment. Qi and Blood Stagnation and Liver Qi

Stagnation, however, are excess conditions that respond more quickly to treatment, and generally respond more favourably to acupuncture. They both have a tendency towards sharp, localised pain. Liver Qi Stagnation has the further characteristic that it can be related to a stressful lifestyle, and thus substantial lifestyle changes to reduce stress, as well as exercise are important co-interventions. With such differing characteristics in a sample of FM participants, it is easy to see that FM has a heterogeneous clinical presentation, not only from a TCM viewpoint, but from a biomedical perspective as well. Similarly to the variety of biomedical interventions, pharmaceutical and lifestyle recommendations, TCM practitioners have a wide variety of interventions, including varieties of acupuncture techniques, herbal formulas, massage and lifestyle change recommendations. Thus, it is clear that no single treatment protocol could produce constant, positive results using a TCM model assuming point specificity.

The discriminant analysis results were interesting and suggest that with a larger sample size FM subtypes might be identified by TCM diagnosis. In this sample, participants who reported a history of TMD and scored high on the coping skill of reappraisal were 1.3 times more likely to have Qi and Blood Stagnation. While this study was simply characterising a sample, and not designed to predict TCM diagnosis from baseline questionnaires, it does illustrate that there may be traits and characteristics which may identify higher proportions of certain TCM diagnoses in those with FM.

Of particular interest to the TCM practitioner were the results of the post hoc analysis. Two diagnoses, Liver Qi Stagnation and Qi and Blood Stagnation, could not be distinguished using canonical discriminant analysis, but when combined could be easily distinguished from Qi and Blood Deficiency and other deficiency conditions (see table 2). This may have been an artefact of using a questionnaire for medical history, rather than the usual 30–45 min interview. However, TCM practitioners may want to take extra care to distinguish these two syndromes as they diagnose and treat their patients with FM.

This study had several weaknesses that should be addressed in future studies. First, the inclusion/exclusion criteria did not reflect the greater FM community as it excluded men and those who were not physically able to participate in a yoga study. Recruitment efforts probably had a similar effect on overall physical ability. Second, this was a small sample with only 56 participants. Future studies should include a larger sample to refine the estimates. Another weakness of the study was that the intake form had face validity but did not go through a rigorous test—re-test validation process. Lastly, ideally there would be additional diagnosticians who would diagnose independently. This would allow conflicting diagnoses to be classified as a separate category, which would allow greater independence among diagnoses and provide more authoritative results.

CONCLUSIONS

This study illustrates the need for further research to examine FM in relation to the use of TCM/acupuncture. In the absence of TCM diagnoses, previous studies certainly had heterogeneous populations, which may account for the variability in the reported results.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Summary points

Two practitioners made TCM diagnoses in women with fi bromyalgia

Three syndromes were consistently diagnosed

Table 1

Prevalence and CIs of primary and secondary traditional Chinese medicine (TCM) diagnoses

TOM Hannels	Primary diagnos	is	Secondary diagnosis	
TCM diagnosis	Prevalence (%)	Cl	Prevalence (%)	Cl
Qi and Blood Deficiency	46.4	33.0 to 60.36	5.4	1.1 to 14.9
Qi and Blood Stagnation	26.8	15.8 to 40.3	53.6	39.7 to 67.0
Liver Qi Stagnation	19.6	10.2 to 32.4	21.4	11.6 to 34.4
Kidney Yin Xu	3.6	0.5 to 12.2	16.1	7.6 to 28.3
Wind Cold Bi	1.8	0.4 to 9.6		
Spleen Qi Xu	1.8	0.4 to 9.6		
Damp phlegm accumulation			1.8	0.4 to 9.6
Kidney Qi Xu			1.8	0.4 to 9.6

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Table 2

Discriminant analysis classification rates (proportions) of a priori and post hoc analysis

A priori analysis	Liver Qi Stagnation	A priori analysis Liver Qi Stagnation Qi and Blood Stagnation Qi and Blood Deficiency Other Total	Qi and Blood Deficiency	Other	Total
Prior rates	0.196	0.268	0.464	0.072 1.000	1.000
Correct	0.00	0.786	0.615	0.250	0.509
Post hoc analysis	Excess		Deficiency		
Prior rates	0.455		0.545		1.000
Correct	0.840		0.721		0.775

Table 3
Standardised canonical discriminant function coefficients (coefficient) and group means on variables

A priori analysis			Post hoc analysis		
Coefficient	Function 1	Function 2	Coefficient	Function 1	
TMD	1.02	0.05	TMD	1.02	
Reappraising coping skills	-0.25	0.99	Reappraising coping skills	-0.26	
Group means	Function 1	Function 2	Group means	Function 1	
Liver Qi Stagnation	-0.38	-0.64	Excess	-0.52	
Qi and Blood Stagnation	-0.72	0.34	Deficiency	0.46	
Qi and Blood Xu	0.43	0.10			
Others	0.79	-0.11			

TMD, temporomandibular joint disorder.