

An integrative Chinese-Western diagnostic approach to predict a positive response to acupuncture

BACKGROUND

Our recent paper published in *Acupuncture in Medicine* showed that the response to acupuncture was difficult to predict; the only significant predictor of a positive response to 3 weeks of thrice-weekly traditional needle acupuncture for insomnia was educational level.¹ In view of this challenging situation, we explored whether an integrative Chinese-Western diagnostic approach could be useful for predicting treatment response.

TRADITIONAL CHINESE MEDICINE THEORY

Over the years, different theories of Traditional Chinese Medicine (TCM) have been developed to understand illnesses and bodily disharmony and are sometimes used to guide TCM therapies, including acupuncture. The most accepted categorisation is a description in terms of *Yin* and *Yang*, *external* and *internal*, *hot* and *cold*, and *excess* and *deficiency*, in addition to *Qi*, *Blood*, *body-fluid* and *zang-fu* differentiation. We have earlier examined the response to acupuncture in different TCM patterns. Although response rates varied, being highest for *Liver-qi stagnation transforming into fire* (at 36.6%) and lowest for *Hyperactivity of fire due to yin deficiency* (at 13.0%), these differences were not statistically significant.² In the present analysis, we explored the interaction of TCM pattern with clinical features relevant to the Western diagnostic system. Comorbid anxiety and depressive symptoms were examined as they are poor prognostic factors for pharmacological and psychological treatment of insomnia.

METHODS

We pooled the data from two randomised controlled trials of acupuncture for insomnia (trial registration no. #NCT01707706 and #NCT01891097). Subjects were ethnic Chinese, aged ≥ 18 years, reported having had insomnia at least three nights per week for at least 3 months, and fulfilled the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) (study #NCT01707706) or 5th edition (DSM-5) (study #NCT01891097) diagnostic criteria for insomnia disorder. Other details are available at www.clinicaltrials.gov. The primary analysis of study #NCT01707706 has been published.³ TCM diagnosis was formulated with the help of a 92-item symptom checklist specially designed for the TCM diagnosis of insomnia.⁴ Of 252 participants who received acupuncture or acupuncture plus auricular acupuncture, 205 subjects (81.3%) met criteria for one of the four

most common TCM diagnoses and had 1 week post-treatment data. Acupuncture points used included bilateral ear *Shenmen*, *Sishencong*, PC6 (*Neiguan*), HT7 (*Shenmen*), SP6 (*Sanyinjiao*), *Yintang* and GV20 (*Baihui*). *De qi* was achieved if possible. An electrical stimulator was connected to all needles and delivered a constant current, with a brief pulse stimulus at 4 Hz frequency. The needles were left for 30 min and then removed. For auricular acupuncture, ear *Shenmen*, *Heart*, *Kidney*, *Liver*, *Spleen*, *Occiput*, and *Subcortex* were used. Acupuncture treatment was performed thrice weekly for 3 consecutive weeks. The primary outcome was the Insomnia Severity Index (ISI), with scores ranging from 0 to 28. A dichotomous measure of response, defined as an improvement by 8 points or more, was used. Comorbid anxiety and depressive symptoms were measured using the Hospital Anxiety and Depression Scale (HADS). A subscale score of 8

Table 1 Sample characteristics

Variables	Total (n=205)
Age, years	52.4 \pm 9.7
Sex, male/female	46/159
Education, years	10.9 \pm 3.7
Marital status	
Never married	25 (12.2)
Married/cohabiting	141 (68.6)
Divorced/widowed	39 (19.0)
Occupation	
Professional and associate professional	16 (7.8)
Skilled and semi-skilled worker	43 (21.0)
Unskilled worker	19 (9.3)
Retired	36 (17.6)
Unemployed/housework	91 (44.4)
Insomnia duration, years	11.6 \pm 9.7
Lifetime psychiatric disorder	
Insomnia disorder	100 (48.8)
MDD/MADD	89 (43.4)
Anxiety disorders/other diagnoses	16 (7.8)
Chronic medical illnesses*	56 (27.3)
ISI total score	19.2 \pm 3.9
HADS depression score	7.2 \pm 4.2
HADS anxiety score	8.2 \pm 4.5

*Participants were on regular medications for medical illnesses.

HADS, Hospital Anxiety and Depression Scale; ISI, Insomnia Severity Index; MDD, major depressive disorder; MADD, mixed anxiety depressive disorder.

Data are expressed as mean \pm SD or n (%).

Table 2 Insomnia Severity Index (ISI) change scores by Traditional Chinese Medicine diagnosis and comorbid anxiety and depression

	Heart-kidney non-interaction (n=80)		Deficiency of both the heart and spleen (n=61)		Liver-qi stagnation transforming into fire (n=41)		Hyperactivity of fire due to yin deficiency (n=23)		χ^2	p Value
T0-T1										
ISI total change score	4.9±5.1		3.7±4.2		5.7±5.3		4.8±6.5			0.35
ISI change score ≥8	23 (28.8)		13 (21.3)		15 (36.6)		3 (13.0)		5.35	0.15
	Depress – (n=39)	Depress + (n=41)	Depress – (n=41)	Depress + (n=20)	Depress – (n=15)	Depress + (n=26)	Depress – (n=12)	Depress + (n=11)		
ISI total change score	4.2±5.3	5.5±4.8	3.3±4.2	4.6±4.2	4.9±4.8	6.2±5.7	2.9±6.6	6.8±6.6	7.15	0.005
ISI change score ≥8	7 (17.9)	16 (39.0)*	8 (19.5)	5 (25.0)	4 (26.7)	11 (42.3)	1 (8.3)	2 (18.2)		0.41
	Anxiety – (n=37)	Anxiety + (n=43)	Anxiety – (n=32)	Anxiety + (n=29)	Anxiety – (n=13)	Anxiety + (n=28)	Anxiety – (n=12)	Anxiety + (n=11)		
ISI total change score	4.8±5.5	4.9±4.7	2.9±4.5	4.6±3.7	6.3±6.2	5.4±5.0	4.6±7.8	5.0±5.1	6.26	0.42
ISI change score ≥8	9 (24.3)	14 (32.6)	7 (21.9)	6 (20.7)	5 (38.5)	10 (35.7)	2 (16.7)	1 (9.1)		0.51

T0, baseline; T1, 1 week post-treatment. Depress ±, absence or presence of depression. Values are expressed as mean±SD or n (%). p values based on Kruskal-Wallis or χ^2 test. * $\chi^2=4.3$, p=0.04 (within-pattern comparison).

or above was used to denote at least mild anxiety or depressive symptoms.

RESULTS

Table 1 presents the participants' sociodemographic and clinical characteristics. A positive response at 1 week post-treatment was found in 54 of the 205 subjects (26.3%). There was no significant difference in the response rate and ISI change score between patients with different TCM diagnoses (table 2). When depression was included as a subgroup, there was a significant difference in ISI change score, with greater improvements in *Hyperactivity of fire due to yin deficiency* and *Liver-qi stagnation transforming into fire* comorbid with depression, while those without comorbid depression and diagnosed with *Hyperactivity of fire due to yin deficiency* and *Deficiency of both the heart and spleen* had lesser improvements. Among subjects diagnosed with *Heart-kidney non-interaction*, those with comorbid depression had a significantly higher response rate. There was no significant interaction between comorbid anxiety and TCM patterns.

DISCUSSION

We showed that comorbid depression was a favourable factor predicting a positive response to acupuncture in subjects with insomnia. It is possible that insomnia comorbid with depression responds

better to our acupuncture regimen, which includes acupuncture points traditionally used for depression, for example, HT7, *Yintang* and GV20.⁵ For subjects who were diagnosed with *Heart-kidney non-interaction*, the presence of comorbid depression produced significantly higher response rates than those without comorbid depression. We believe that a Western-TCM integrative approach may bring new insights to the understanding of insomnia and may be useful for selecting suitable patients for acupuncture.

Ka-Fai Chung,¹ Wing-Fai Yeung,^{1,2} Chung-Yin Leung, Yee-Man Yu²

¹Department of Psychiatry, University of Hong Kong, Hong Kong, China

²School of Nursing, Hong Kong Polytechnic University, Hong Kong, China

Correspondence to Dr Ka-Fai Chung, Department of Psychiatry, University of Hong Kong, Hong Kong SAR, China; kfchung@hku.hk

Contributors KC and WFY designed the study, performed data analysis, interpreted the results, and drafted the manuscript. WFY, YMY, and CYL were responsible for data collection. All authors declare that they have substantial contributions to the study, including drafting or revising the work, read and approved the manuscript, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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