



Research paper

When east meets west: Understanding the traditional Chinese medicine diagnoses on insomnia by Western medicine symptomatology

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ARTICLE INFO

Keywords:

Insomnia

Classification

Diagnosis

Pattern

Traditional chinese medicine

Cross-sectional study

ABSTRACT

Introduction: Insomnia sub-classification by the Western diagnostic systems has unsatisfactory validity and reliability. On the contrary, traditional Chinese medicine (TCM) diagnosis is sometimes used to guide treatment decisions. This cross-sectional study compared groups of insomnia patients with different TCM diagnoses in terms of Western medicine symptomatology.

Methods: Baseline data of two randomized controlled trials on insomnia were studied. TCM diagnosis was made by consensus between two TCM practitioners, with the help of a 92-item symptom checklist designed for TCM diagnosis in subjects with insomnia. Other data include sleep diary and actigraphy, insomnia symptoms, general sleep disturbances, comorbid medical and psychiatric disorders, physical and psychiatric symptoms, and sleep-related dysfunctional cognitions and behaviors.

Results: The four commonest TCM diagnoses among 365 subjects with insomnia disorder (mean age 51.7 years; 77.3% females) were *dual deficiency of the heart-spleen*, *non-interaction between the heart and kidney*, *depressed liver qi transforming into fire*, and *yin deficiency with effulgent fire*, with prevalence 31.8%, 25.8%, 18.4%, and 10.1%, respectively. We found minimal interrelationships between the TCM and Western medicine systems. Only the mean Hamilton Depression Rating Scale score was significantly lower in *non-interaction between the heart and kidney* compared to *dual deficiency of the heart-spleen* and *yin deficiency with effulgent fire* (ANOVA: $F[3310] = 4.64, p = 0.003$).

Conclusion: Limited by an excessive focus on sleep-related variables, our results show minimal relationships between the TCM and Western diagnostic systems of insomnia. An integrative TCM-Western approach in clinical practice may be a key to personalized treatment of insomnia.

1. Introduction

Insomnia is a prevalent disorder. Nearly one-third of the adult population experience insomnia symptoms and approximately 9–15% have insomnia symptoms accompanied by daytime consequences [1]. The recognition of insomnia as a health problem can be traced back to more than 2000 years ago in ancient Chinese medical texts [2]. Different theories of traditional Chinese medicine (TCM) have been developed to explain patterns of body disharmony and the most accepted categorization is a description in terms of eight major parameters: *yin* and *yang*, *external* and *internal*, *hot* and *cold*, and *excess* and *deficiency*, in addition to body systems such as *qi*, *blood*, and *body-fluid* differentiation and *zangfu* differentiation. A recent systematic review showed that *dual deficiency of the heart-spleen*, *yin deficiency with effulgent fire*, *depressed liver qi transforming into fire*, and *non-interaction between the heart and kidney* were the four commonest TCM diagnoses in people with

insomnia [3]. The disharmony of the organs eventually disturbs the function of *shen* (or spirit) which is responsible for mental activities including one's mentality, consciousness, thinking, and feeling; hence the principle of TCM treatment for insomnia is to restore the function of *shen* or nourish *shen* [2]. The theory-based TCM diagnoses are sometimes used to guide treatment decisions; however, empirical data is fairly scarce. A systematic review found that *Gui Pi Tang*, *An Shen Ding Zhi Wan*, and *Wen Dan Tang* were more commonly used for *dual deficiency of the heart-spleen*, *internal disturbance of phlegm-heat*, and *qi deficiency of the heart and gallbladder*, respectively, but the treatment for other TCM diagnoses were inconsistent [4].

Our previous study has shown that the response to acupuncture is different for different TCM diagnoses for insomnia [5]. Using an improvement by eight points or more on Insomnia Severity Index (ISI) [6], a self-report questionnaire, to denote treatment response, subjects with *depressed liver qi transforming into fire* had the highest response rate of

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36.6%, while the lowest response rate occurred in *yin deficiency with effulgent fire* at 13.0%, however the difference was not statistically significant. In another analysis, we further explored whether an integrative Chinese-Western diagnostic approach could be useful for predicting treatment response. We found that the presence of comorbid depression in subjects with *non-interaction between the heart and kidney* was associated with a significantly higher response rate than those of the same TCM diagnosis but without comorbid depression (39.0% vs. 17.9%) [7]. For other TCM diagnoses, comorbid depression did not significantly influence the response rate to acupuncture for insomnia.

The Western nosology in the diagnosis and classification of insomnia is based on frequency and duration of insomnia, functional impairment, and relationship with medical, psychiatric, and specific sleep disorders, while the widely accepted etiological models of insomnia include cognitive, behavioral, and hyperarousal models. Insomnia can be classified into acute or chronic, primary or comorbid, or based on etiological factors, such as pathophysiological insomnia, sleep state misperception, and inadequate sleep hygiene. The rationale for classifying insomnia into subtypes is to develop personalized treatment with better outcomes. There have been attempts to identify insomnia subtypes using cluster analysis, but the findings are inconsistent [8,9]. In addition, the reliability and validity of insomnia subtypes is not satisfactory. A previous study found that psychophysiological insomnia and inadequate sleep hygiene had variable diagnostic accuracy across study sites, while the diagnosis of sleep state misperception was poorly supported [10]. The use of specific treatment for insomnia subtypes has not been proven in randomized controlled trials [11]. In view of the deficiencies of both theory-based TCM diagnoses and Western medicine concepts of insomnia, it may be worthwhile to explore an integrative Chinese-Western diagnostic approach. A better understanding of the connection between the Chinese and Western systems may be the first step.

The aim of the study was to compare groups of insomnia patients with different TCM diagnoses in terms of Western medicine symptomatology. Symptoms relevant to the diagnosis, classification, and understanding of insomnia, including sleep diary and actigraphy variables, insomnia symptoms, general sleep disturbances, the presence of comorbid medical and psychiatric disorders, physical and psychiatric symptoms, and sleep-related dysfunctional cognitions and maladaptive behaviors, were examined. The findings may help practitioners better understand the meaning of TCM diagnoses in terms of the Western concept of insomnia.

2. Methods

2.1. Subjects

We pooled the baseline data of two randomized controlled trials of acupuncture for insomnia (ClinicalTrials.gov #NCT01707706 and #NCT01891097). Primary analysis of the studies has been published [12,13]. There are minor differences in inclusion criteria, but participants from both studies had to be: (1) ethnic Chinese; (2) aged ≥ 18 years; (3) having insomnia at least three nights per week for at least three months; and (4) fulfilling criteria A and B of the DSM-IV diagnosis of primary insomnia [14] or criteria A to E of the DSM-5 diagnosis of insomnia disorder [15]. Other inclusion criteria of Study #NCT01707706 were the presence of past major depressive episodes and an ISI score ≥ 15 at baseline; for Study #NCT01891097, participants had to have sleep onset latency or wake after sleep onset > 30 min and sleep efficiency $< 85\%$ for at least three nights based on 1-week sleep diary. The major exclusion criteria were: (1) a 17-item Hamilton Depression Rating Scale (HDRS₁₇) [16] score > 18 ; (2) a significant suicidal risk according to the HDRS₁₇ item on suicide (score ≥ 3); (3) previous diagnosis of schizophrenia or other psychotic disorders or current alcohol or substance use disorder; (4) any unstable psychiatric conditions or serious physical illnesses; (5) any sleep

disorders, including sleep phase disorders, parasomnia, obstructive sleep apnea (apnea-hypopnea index ≥ 10), or periodic limb movement disorder (periodic limb movement disorder index ≥ 15) detected during screening or by in-laboratory overnight polysomnography; and (6) currently pregnant or breast-feeding. Study #NCT01707706 had 975 subjects assessed by telephone, 439 in person, and 150 randomized, while Study #NCT01891097 screened 841 subjects, 413 in person, and 224 randomized. Of the 374 participants who were randomized, 365 subjects (97.6%) had TCM diagnosis available and was the sample of this secondary analysis.

2.2. Study procedure

All study procedures were reviewed and approved by the local institutional review board (HKU/HA HKW IRB UW08-417 and UW12-340). Subjects were recruited from the community and regional psychiatric clinics. Screening interviews were conducted by research assistants with undergraduate psychology background. An experienced clinician took a sleep history and administered a structured interview for psychiatric disorders. A Chinese medicine practitioner who had more than three years' clinical experience (FL) formulated the TCM diagnosis with the help of a standardized symptom checklist. A final TCM diagnosis was made after discussion with a senior Chinese medicine practitioner (WY). The 92-item symptom checklist consists of 13 sleep-related, 61 non-sleep-related, 11 tongue, and 7 pulse items (Supplementary file). The development of the checklist was based on a systematic review [3], which summarized the clinical features of the top 10 TCM diagnoses of insomnia, equivalent to roughly 80% of the total sample. To avoid the symptom checklist becoming too lengthy, rarer TCM diagnoses were not included. Symptoms included in the checklist had to be mentioned as clinical features of the TCM diagnoses in at least 10% of the reviewed studies; thus both common and less common features were listed. We also reviewed a standard TCM textbook, the *Traditional Chinese Internal Medicine* 1985, 1997, 2003 and 2007 versions [17–20] for additional symptoms. The non-sleep-related items were subdivided under categories on eating, taste and appetite (12 items), emotions (11 items), chest and abdominal function (8 items), bladder and bowel function (6 items), headache, dizziness and tinnitus (6 items), coldness, hotness and sweating (5 items), menstruation and sexual function (4 items), complexion (4 items), limbs and back (3 items), and energy (3 items). The items were rated as 0 or 1, denoting absence or presence of the symptoms or signs.

2.3. Measures

2.3.1. Sociodemographic variables and medical and psychiatric history

Participants reported their age, gender, number of years in full-time education, marital status, occupation, duration of insomnia, and medical and psychiatric history.

ISI

The ISI is a 7-item self-rating scale that was used to assess the subjects' perceived severity of insomnia symptoms and the associated functional impairment [6]. The ISI is a 5-point Likert scale with higher scores indicating more severe insomnia. We used the Chinese version of ISI, known to be valid and reliable [21].

2.3.2. Pittsburgh sleep quality index (PSQI)

The PSQI is a 19-item, 7-component scale that are designed to assess subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications, and daytime dysfunction. The coverage of PSQI is more comprehensive than the ISI and is regarded as a standard research assessment of general sleep disturbances. Higher score is indicative of greater sleep disturbances [22]. We used the Chinese version of PSQI, which is valid and reliable [23].

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