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Clinical Research Progress in Traditional Chinese Medicine for Treating Refractory Insomnia

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Abstract: *This paper reviews the research progress of traditional Chinese medicine (TCM) in the treatment of intractable insomnia in recent years. It summarizes the etiology, pathogenesis, syndrome differentiation classification and diagnostic and treatment criteria of the disease. Meanwhile, it comprehensively elaborates the latest research advances of monotherapies and combined TCM interventions, including oral Chinese herbal medicine, acupuncture, acupoint massage, cupping therapy, auricular point pressing with beans, and emotional therapy. Relevant studies have demonstrated that various TCM therapies can effectively improve sleep quality, prolong effective sleeping time and relieve accompanying clinical symptoms in patients with intractable insomnia. They can fundamentally regulate the imbalance of the human body and realize the treatment of both manifestation and root cause. By summarizing the current research achievements and clinical application status of TCM for intractable insomnia, this paper intends to clarify the advantages of TCM diagnosis and treatment, sort out the existing clinical problems, and provide references and theoretical basis for standardized clinical diagnosis and treatment, therapeutic scheme optimization and further scientific research innovation of this disease.*

Keywords: *Traditional Chinese Medicine; Chinese herbal medicine; Refractory insomnia; Syndrome differentiation and treatment; Acupuncture*

1. Introduction

Refractory insomnia, also known as chronic insomnia, is a persistent and recurrent sleep disorder characterized by difficulty falling asleep or maintaining prolonged sleep, resulting in insufficient total sleep duration and poor sleep quality[1]. Additionally, this condition may be accompanied by symptoms during daytime wakefulness, such as fatigue, poor concentration, memory impairment, and emotional instability. Epidemiological studies have shown that the prevalence of refractory insomnia increases progressively with age[2]. Modern medicine employs primarily pharmacological, psychological, and physical therapies for refractory insomnia management; however, most approaches carry risks of drug dependence, addiction, or adverse effects. Traditional Chinese Medicine (TCM) possesses extensive experience in treating refractory insomnia, offering unique advantages without side effects. This article reviews the clinical advancements in TCM-based treatments for refractory insomnia.

2. Understanding of Intractable Insomnia in Traditional Chinese Medicine

2.1 Etiology and Pathogenesis

The Huangdi Neijing describes insomnia as "inability to close the eyes," "inability to sleep," or "inability to lie down." Its etiology and pathogenesis are complex, often associated with emotional disturbances, dietary irregularities, imbalance between work and rest, and physical debilitation following illness. Emotional distress—such as anxiety, depression, or anger—can lead to stagnation of liver qi, which transforms into fire and disturbs the heart spirit, resulting in insomnia. Dietary indiscretion, particularly excessive consumption of spicy, greasy, or cold foods, impairs spleen and stomach function, disrupts nutrient transportation, generates phlegm-heat, and causes internal disturbance of the heart spirit, leading to insomnia. Excessive fatigue damages the heart and spleen, impairing qi and blood production; this results in inadequate nourishment for the heart and mental restlessness, thereby inducing insomnia. Chronic illness or advanced age can cause qi-blood deficiency

ISSN 2618-1584 Vol. 8, Issue 4: 36-42, DOI: 10.25236/FMSR.2026.080405

and yin deficiency of the liver and kidneys; when yin deficiency fails to restrain yang, deficient heat rises and disturbs the heart spirit, also contributing to insomnia. The Ling Shu·Da Huo Lun states: "Wei qi cannot enter yin and remains in yang... When yang qi is abundant, yang energy is strong; when it cannot enter yin, yin qi becomes deficient, hence inability to close the eyes." The Ling Shu·Xie Ke explains: "Wei qi moves through yang during daytime and through yin at night... When pathogenic factors invade the five zang and six fu organs, Wei qi is confined to the exterior and moves through yang, unable to enter yin... Thus, inability to close the eyes." Disharmony between nutritive qi and defensive qi, along with insufficient nutritive yin, constitutes the pathological basis of insomnia. Guided primarily by Traditional Chinese Medicine principles, combined with modern lifestyle considerations and clinical experience, this approach emphasizes the functions of the heart and liver while addressing those of the spleen and kidneys. Long-term clinical practice has revealed that patients with refractory insomnia often experience prolonged conditions, sometimes lasting decades without achieving restful sleep. After seeking medical help repeatedly, they consistently fail to obtain normal sleep, which significantly impairs their daily life and work performance. During consultations, these patients frequently present with psychological symptoms such as anxiety and depression. Targeting the heart and liver meridians is particularly effective: restoring the heart's function in governing mental functions, nourishing liver blood, regulating liver qi, while also strengthening the spleen, harmonizing the stomach, tonifying the kidneys, and replenishing vital essence can yield remarkable therapeutic results[3].

Traditional Chinese Medicine holds that the "spirit" is the governing force of human life activities and plays a crucial regulatory role in physiological functions. The Jingyue Quanshu: Insomnia states: "Sleep originates from yin, with the spirit as its primary regulator; when the spirit is at peace, sleep follows; when the spirit is restless, sleep is impaired." As a vital physiological process, sleep is likewise governed by the spirit. Based on this principle, modern acupuncture practitioners emphasize the importance of spirit regulation in insomnia treatment, developing various spirit-regulating acupuncture techniques. The fundamental pathogenesis of refractory insomnia lies in spiritual restlessness, and the key to treatment lies in spirit regulation—this approach must not only focus on the functions of the heart and brain but also prioritize the impact of harmonization among the five zang organs on spiritual well-being.

2.2 Dialectical Classification

Based on clinical symptoms and signs, Traditional Chinese Medicine employs syndrome differentiation to classify refractory insomnia. Common patterns include: Liver depression transforming into fire syndrome, characterized by insomnia with frequent dreams, irritability, dizziness, bitter taste in the mouth, and dry throat; Phlegm-heat disturbing internal harmony syndrome, presenting with restlessness, insomnia, chest tightness, epigastric fullness, nausea, belching, and head heaviness; Deficiency of both heart and spleen syndrome, marked by difficulty falling asleep, frequent dreaming and early awakening, palpitations, forgetfulness, fatigue, and poor appetite; Heart-kidney disharmony syndrome, manifesting as restlessness, sleep difficulties, palpitations, vivid dreams, soreness and weakness in the lower back and knees, hot flashes, and night sweats; Deficiency of heart and gallbladder qi syndrome, featuring irritability, insomnia, easy startle response, timidity, palpitations, shortness of breath, and spontaneous sweating. Accurate syndrome differentiation provides a foundation for targeted treatment.

3. Methods of Traditional Chinese Medicine for Treating Refractory Insomnia

The "Jingui Yaolue" states: "When diagnosing liver disorders, recognizing that liver pathologies can affect the spleen, priority should be given to strengthening the spleen." This not only highlights the biochemical regulatory relationships among the five zang organs but also illustrates, through the example of 'liver disease transmitting to the spleen,' how pathogenic factors mutually influence each other under pathological conditions. Refractory insomnia manifests not only as dysfunction in a single organ (e.g., impaired liver dispersion or inadequate nourishment of the heart) but, due to its prolonged course, often involves multiple organs. For instance, excessive wood overacting on earth may lead to liver stagnation and spleen deficiency; insufficient earth generating metal may result in spleen deficiency affecting the lungs, demonstrating the pathological characteristic of 'disruption in one organ affecting multiple organs.' The text further emphasizes, "When the fundamental functions of the five zang organs are unimpeded, the individual achieves harmony," underscoring that abundant essence and qi, along with smooth circulation of blood, qi, and meridians, coupled with overall coordination among

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the zang organs, form the essential foundation for mental tranquility and personal well-being. Therefore, clinical treatment must not only identify primary symptoms to regulate corresponding zang organs but also adopt a holistic approach to restore their interdependent biochemical relationships, thereby achieving harmonious organ function and mental peace.

3.1 Traditional Chinese Medicine Treatment

Traditional Chinese medicine classic formulas demonstrate significant efficacy in treating refractory insomnia. The Suanzaoren Decoction from the "Treatise on Cold Damage Diseases" (Shanghan Lun), composed of Suanzaoren (Jujube Seed), Glycyrrhiza uralensis, Anemarrhena asphodeloides, Poria cocos, and Chuanxiong rhizome, exhibits effects of nourishing blood, calming the mind, clearing heat, and alleviating irritability, and is commonly used for insomnia caused by liver blood deficiency or internal heat disturbance. Jia Hongli[4] achieved excellent therapeutic outcomes by modifying Suanzaoren Decoction for refractory insomnia, effectively improving patients 'sleep quality and associated symptoms. Wang Kai[5] applied Dahuang-Huanglian-Xie Xin Decoction with precise syndrome differentiation, yielding notable efficacy. Liu Yang [6]employed the Hua Tan Qu Yu Formula to treat insomnia due to phlegm-stasis interaction, significantly enhancing sleep quality, prolonging sleep duration, alleviating anxiety and depression, and elevating neurotransmitter levels. Wang Tongfu [7]concluded that modified Anshen Dingzhi Pill demonstrates definitive efficacy in treating refractory insomnia, improving patients' quality of life and warranting clinical promotion. Zhao Haidan[8] observed through clinical studies that modified Wen Dan Decoction effectively improves sleep quality in refractory insomnia patients with low adverse reaction rates and high safety profiles. Wang Binxiang et al. [9]combined Zhi Gancao Decoction with Gui Pi Decoction modified with lorazepam for elderly patients with refractory insomnia, showing significant improvements in sleep quality with minimal side effects. This formula integrates Zhi Gancao Decoction from the“Shanghan Lun”and Gui Pi Decoction from the“Jisheng Fang”, addressing the fundamental pathogenesis of refractory insomnia as dual deficiency of heart qi and spleen-blood, thus balancing qi-tonification, spleen strengthening, blood nourishment, and mental calming. In addition to the application of classical prescriptions, numerous practitioners of traditional Chinese medicine have developed proprietary formulas based on clinical experience for treating refractory insomnia. For instance, Jia Haibo and colleagues formulated the Anshen Yangxue Decoction in combination with warm acupuncture and auricular acupressure therapy for such cases. This decoction is composed of traditional Chinese herbs including Scutellaria baicalensis, Pseudostellaria heterophylla, Ophiopogon japonicus, Schisandra chinensis, Albizia julibrissin, Strychnos nux-vomica, Polygonatum sibiricum, Corydalis yanhusuo, Angelica sinensis, sprouted barley malt, and licorice root, with additional modifications tailored to individual syndrome patterns, demonstrating significant efficacy in improving patients' sleep quality[10].

3.2 Acupuncture Therapy

Acupuncture exhibits therapeutic effects in dredging meridians, harmonizing yin and yang, reinforcing healthy qi, and eliminating pathogenic factors, playing a pivotal role in the treatment of refractory insomnia. Feng Chengcheng et al. [11]employed the "Fundamental Strengthening and Spirit Regulation Acupuncture Technique" for managing refractory insomnia, targeting acupoints such as Baihui , Shenting , Sishencong, Qihai , Tianshu , Zusanli, Neiguan, Taichong, and Taixi, with a focus on regulating the body's essence, qi, and spirit through balanced tonification and drainage techniques, achieving significant efficacy. Chu Jiangbo et al.[12] summarized Professor Sui Minghe's use of the "Nine Sleep Needles" (acupoints: Baihui, Shenting, Yintang, Tianshu, Neiguan, Sanyinjiao, Zusanli, Shenmai, and Zhaohai) to treat refractory insomnia, which effectively regulates the primordial spirit, balances the middle energizer, connects the heart and kidneys, and harmonizes yin and yang, demonstrating excellent outcomes in improving sleep quality and reducing dependence on hypnotics, thereby providing additional therapeutic options for acupuncture-based management of refractory insomnia. Yang Yue et al. [13]demonstrated that the Qin-style "Eight Head Needles" combined with eszopiclone significantly alleviated insomnia and anxiety symptoms in elderly patients with refractory insomnia, with superior overall efficacy compared to eszopiclone monotherapy. Wang Mindan[14]employed acupuncture at the Anshen acupoint combined with warm needling at Sanyinjiao for refractory insomnia, achieving ideal clinical outcomes and markedly enhancing sleep quality and life expectancy. Pan Chen conducted a clinical trial investigating the efficacy of warm needling combined with Anshen Yangxue Decoction in treating refractory insomnia and its impact on sleep architecture, concluding that this approach improves sleep structure, enhances sleep quality, and boosts therapeutic outcomes. Wu Zuolin [15]utilized the Yin-Yang Harmonization Acupuncture Technique for

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refractory insomnia, achieving remarkable improvements in insomnia, anxiety, and sleep-onset difficulties while significantly enhancing clinical efficacy. Pei Yuzhu [16]summarized Professor Ji Laixi's clinical experience in utilizing the advanced combination techniques of "New Nine Needling" for treating refractory insomnia. These techniques—including plum-blossom needle, fine needle "Insomnia Formula", auricular acupoint stimulation combined with specific electromagnetic wave therapy, and small needle-knife therapy—were applied based on syndrome differentiation to provide targeted treatment: plum-blossom needle was employed to activate meridian function; fine needle "Insomnia Formula" provided symptomatic relief; needle-knife therapy facilitated cerebral blood flow improvement; and chronic auricular acupoint stimulation regulated mental state, collectively achieving the therapeutic effects of calming the mind and soothing the nerves[17].

3.3 Other Specialized Therapies

3.3.1 Acupoint Massage and Cupping Therapy

Acupoint massage and cupping therapy can stimulate specific acupoints to regulate qi and blood circulation, thereby improving sleep quality. Zhu Xiaomin's study demonstrated that combining bamboo cupping with acupoint massage significantly enhances sleep quality in patients with refractory insomnia, reduces neural tension, calms the mind, promotes meridian circulation, and alleviates stress, yielding remarkable clinical outcomes worthy of widespread adoption[18]. Liu Hongping[19] employed Shushen Decoction combined with acupoint cupping (targeting Shenmen and Sanyinjiao acupoints) alongside traditional Chinese herbal decoctions to unblock meridians and harmonize internal organs. Jiang Xiling[20] treated chronic refractory insomnia by applying bloodletting and cupping techniques at the Beishu acupoints on five zang organs; after one treatment course, the patient's sleep quality markedly improved, with all symptoms resolved after two additional courses and no recurrence observed during three months of follow-up. Wang Qiuping's comparative studies confirmed that the "yin-yang harmonization" approach integrating acupuncture with acupoint massage effectively addresses refractory insomnia by improving sleep symptoms, daytime drowsiness, anxiety, and neurotransmitter levels while demonstrating good safety profiles[21]. Zang Ping et al.' s research shows that this combination therapy effectively alleviates clinical manifestations of yin-yang imbalance-related insomnia, modulates neurotransmitter levels, enhances sleep quality, and reduces anxiety and drowsiness, making it highly recommended for clinical application[22].

3.3.2 Ear Acupoint Pressing with Beans

Ear acupoint pressure therapy involves applying seeds such as Vaccaria segetalis to specific ear acupoints to stimulate these points and regulate visceral functions. The "Lei Jing" states: "The meridians of the three yang and three yin channels of hands and feet all enter the ears." This therapy should be tailored based on the therapeutic characteristics of each acupoint, with selection guided by syndrome differentiation. For insomnia caused by liver fire disturbance, acupoints including Shenmen (PC6), Liver, Heart, Endocrine[5], and Subcortical are recommended. For insomnia due to deficiency of both heart and spleen, the primary acupoints are Heart, Sympathetic, Shenmen, and Subcortical, supplemented by Spleen, to regulate internal organs and improve sleep quality[23,24]. Zhu Qian's studies demonstrated that acupuncture combined with ear acupoint pressure therapy significantly alleviates neurasthenic symptoms in patients with refractory insomnia, showing remarkable clinical efficacy and warranting widespread application[25]. Gu Yu et al. [26]found that this combination therapy enhances treatment efficiency, improves sleep quality and anxiety/depression levels, restores serum BDNF expression, and strengthens sustained attention. Li Changcheng's research further confirmed that ear acupoint pressure therapy combined with balanced acupuncture effectively improves sleep quality, mental state, and attention span in patients with refractory insomnia, facilitating recovery[27]. Wen Lingli et al.employed auricular acupressure with bean application and point massage therapy to improve sleep quality in patients with refractory insomnia. The selected auricular points included the sympathetic center, Shenmen (SP6), Heart (CV1), Kidney (BL23), and Occipital region. Combined with techniques such as front auricular kneading, posterior auricular massage, auricular tip lifting, and auricularlobe massage, this approach effectively alleviated insomnia symptoms and enhanced sleep quality[28].

3.3.3 Traditional Chinese Medicine Emotional Therapy

In their study summarizing Professor Li Qiuyan's clinical experience in treating refractory insomnia, Wang Xujie et al. concluded that insomnia is associated with emotional distress in patients[29]. Yang Jingfang et al. [30] derived from Professor Lin Yiping's treatment experience that the primary approach

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should focus on regulating emotional states through Traditional Chinese Medicine (TCM) emotional intervention to improve sleep quality. Xiong Liang demonstrated significant clinical efficacy using Shugan Jieyu Anshen Decoction combined with TCM emotional therapy for refractory insomnia; this regimen regulated serum levels of 5-HT and β-EP, improved sleep quality without increasing adverse effects, and exhibited good safety profiles[31].

4. Summary

In summary, refractory insomnia has multiple etiological factors, complex pathogenesis, and diverse treatment approaches. Traditional Chinese Medicine (TCM) offers a reliable therapeutic framework for managing this condition by integrating syndrome differentiation and holistic perspectives. The disease mechanism is analyzed from aspects such as emotional imbalance, dietary irregularities, excessive physical exertion, and chronic illness-induced debility, with the core pathology identified as yin-yang imbalance. Furthermore, comprehensive syndrome classification systems provide a theoretical foundation for precision therapy. Clinical evidence demonstrates significant efficacy across various treatment modalities—including flexible application of classical formulas, innovative self-formulated prescriptions, acupuncture, acupoint massage, auricular pressure therapy, and TCM emotional regulation therapies—in improving sleep quality, alleviating associated symptoms, enhancing overall quality of life, while avoiding drug dependence and adverse effects, thereby highlighting the unique advantages of TCM's holistic approach and syndrome-specific treatment strategies. However, current research on TCM-based management of refractory insomnia remains limited: there is a lack of standardized guidelines on diagnosis, pathogenesis, and treatment principles bridging Western and TCM approaches; clinical studies often suffer from small sample sizes and inadequate methodological rigor, coupled with insufficient high-quality evidence-based data; although combined acupuncture and herbal therapy has shown promising results compared to sedative-hypnotics—with advantages such as minimal toxicity, no addiction potential, or dependency risk—most acupoints used remain empirically determined, lacking clear therapeutic principles or systematic protocols. In the future, it is essential to strengthen multicenter, large-sample, randomized controlled clinical studies to thoroughly elucidate the therapeutic mechanisms of Traditional Chinese Medicine (TCM), optimize and integrate various treatment modalities, and leverage modern scientific technologies to further enhance the scientific rigor and efficacy of TCM in treating refractory insomnia. This will enable TCM to better serve a broader population of insomnia patients and play a more significant role in improving sleep health.

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