Clinical Study

Clinical observation on Governor Vessel-regulating, liver-soothing and mind-calming needling for insomnia due to liver fire disturbing the heart

调督疏肝安神法治疗肝火扰心型失眠的临床观察

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Abstract

Objective: To compare the therapeutic effects between the Governor Vessel-regulating, liver-soothing and mind-calming needling and the routine acupuncture therapy for insomnia due to liver fire disturbing the heart.

Methods: A total of 50 cases with insomnia were randomly divided by the random numberl table into the two groups, 25 cases in each group. The observation group was treated with the Governor Vessel-regulating, liver-soothing and mind-calming needling, while the control group was treated with the routine acupuncture therapy. The two groups were treated for five sessions per week, ten sessions as a course. After 3-course treatment, the therapeutic effects and the improvement of Pittsburgh sleep quality index (PSQI) were observed.

Results: After treatment for three courses, the total effective rate was 100% in the treatment group and 92% in the control group. The difference in the therapeutic effect between the two groups was statistically significant (P<0.05). After the treatment, the sleep latency, sleep duration, habitual sleep efficiency, subjective sleep quality, sleeping disturbances, daytime dysfunction, and total PSQI scores in the patients of the two groups were obviously improved in comparing those before treatment, with significant differences (all P<0.01). After treatment, the inter-group differences in the sleep latency, sleep duration, habitual sleep efficiency and total PSQI scores were statistically significant (all P<0.01); the differences in the scores of sleeping disturbances and daytime dysfunction is not statistical significant (all P>0.05).

Conclusion: The therapeutic effect of Governor Vessel-regulating, liver-soothing and mind-calming needling is better for insomnia due to liver fire disturbing the heart than the routine acupuncture therapy.

Keywords: Acupuncture Therapy; Liver-fire Flaming-up; Soothing Liver; Governor Vessel; Insomnia

【摘要】目的:比较调督疏肝安神针刺法与常规针刺法治疗肝火扰心型失眠症的临床疗效。方法:将50例失眠 症患者按随机数字表随机分为2组,每组25例。观察组用调督疏肝安神针刺法治疗,对照组用常规针刺法治疗。 两组均每星期治疗5次,10次为1个疗程,治疗3个疗程后观察疗效及匹兹堡睡眠质量指数(Pittsburgh sleep quality index, PSQI)的改善情况。结果:治疗3个疗程后治疗组总有效率100%,对照组总有效率92%,两组疗效差 异有统计学意义(P<0.05)。治疗后,两组患者入睡时间、实际睡眠时间、睡眠效率、睡眠质量、睡眠障碍、日间 功能、PSQI 总分较治疗前有明显改善,差异均具有统计学意义(均 P<0.01)。治疗后两组入睡时间、实际睡眠时 间、睡眠效率、睡眠质量及 PSQI 总分差异均具有统计学意义(均 P<0.01);睡眠障碍和日间功能评分差异无统计 学意义(均 P>0.05)。结论:调督疏肝安神针刺法治疗肝火扰心型失眠症疗效优于常规针刺治疗。

【关键词】针刺疗法; 肝火上炎; 疏肝; 督脉; 失眠症

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Insomnia is an unsatisfied subjective experience about the time and quality of sleep coupled with functional impairment in daytime. Patients may present with difficulty falling asleep, difficulty maintaining sleep and dream-disturbed sleep. In severe cases, patients

symptoms often include dizziness, headache, low spirit and fatigue. These symptoms may severely affect the patients' quality of life (QOL)^[1]. In Chinese medicine, insomnia is known as 'sleeplessness' or 'inability to fall asleep'. According to the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine* issued by the State Administration of Traditional Chinese Medicine,

cannot sleep throughout the night. Associated

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insomnia can be categorized into five patterns: liver fire disturbing the heart, phlegm-heat disturbing the heart, disharmony between the heart and kidney, deficiency of the heart and spleen, and qi deficiency of the heart and gallbladder. Liver fire disturbing the heart is the most common pattern^[2]. We've treated patients with insomnia due to liver fire disturbing the heart between February 2014 and July 2015 using Governor Vessel-regulating, liver-soothing and mind-calming acupuncture method and compared with routine acupuncture protocol. The results are now summarized as follows

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria in Western medicine

In reference to the diagnostic criteria for insomnia in the 3rd edition of *Chinese Classification and Diagnostic Criteria of Mental Disorders* (CCMD-3)^[3]: almost insomnia as the only symptom, including difficulty to fall in sleep, dreams, shallow sleep, early waking up, difficulty to fall in sleep after waking up, lassitude, discomfort after waking up or daytime sleepiness, etc; advanced concept about insomnia and extreme concern on insomnia; dissatisfaction about sleeping duration and quality, and obvious distress or defect of social functions; three times per week at least, for a month at least; exclusion of secondary insomnia caused by somatic diseases or mental disorders.

1.1.2 Criteria of TCM pattern identification

With reference to the diagnostic criteria for insomnia due to liver fire disturbing the heart in *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine* promulgated by the State Administration of Traditional Chinese Medicine in 1994^[2]: difficulty to fall in sleep due to vexation, stuffy sensation in the chest, hypochondriac pain, distending pain in the head, vertigo, flushed cheeks, red eyes, bitter taste in the mouth, difficult defecation, red tongue, yellow tongue coating, and wiry and rapid pulse.

1.2 Inclusion criteria

In conformity with the above-mentioned diagnostic criteria in Western medicine and criteria of pattern identification in Chinese medicine; without oral administration of any medications for insomnia within a week; age 18-70 years old, unlimited genders, able to continue the treatment by the plan, and sign the informed consent; above 7 points in Pittsburgh sleep quality index (PSQI), and over a month in the duration.

1.3 Exclusion criteria

Those not in conformity with the above inclusion criteria, accompanied by primary diseases seriously endangering the life, such as cardiocerebrovascular diseases, tumors, and blood diseases; patients with mental disorders; patients during pregnancy or lactation; those accepting other therapies; those unable to continue the treatment or unable to finish the planed course due to serious adverse reaction.

1.4 Statistical methods

The statistic analysis was processed by SPSS 20.0 version statistical software. The measurement data were expressed by mean ± standard deviation (\overline{x} ±s). The *t*-test of independent samples was adopted for comparison between the groups. The paired *t*-test was adopted for comparison within the groups. Chi-square test was used for the counting data between the groups. P < 0.05 was used to express a statistical significance in the difference.

1.5 General data

Totally, 50 cases with insomnia due to liver fire disturbing the heart were recruited from the Acupuncture Department of the First Affiliated Hospital of Guangxi University of Chinese Medicine. The patients were randomly divided into an observation group or a control group by the random number table. In the observation group, the age ranged from 25 to 70 years old and the duration ranged from 2 months to 6 years, and the PSQI score ranged from 9 points to 18 points. In the control group, the age ranged from 28 to 68 years old and the duration ranged from 2 months to 6.5 years, and the PSQI score ranged from 9 points to 17 points. In the comparison of the general data between the two groups, there were no statistically significant differences (all P > 0.05), indicating that the two groups were comparable (Table 1).

2 Therapeutic Methods

2.1 Observation group

The patients in the observation group were treated with the Governor Vessel-regulating, liver-soothing and mind-calming needling.

Table 1. Comparison of baseline data between the two groups

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Crowns		Gender (case)		Average age	Average duration	PSQI score		
Gloups	n	Male	Female	$(\overline{x} \pm s, year)$	$(\overline{x} \pm s, \text{month})$	$(x \pm s, point)$		
Observation	25	3	22	46.6±14.2	16.1±17.3	13.0±2.2		
Medication	25	2	23	48.8±9.1	16.0±18.1	12.8±2.5		

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Major points: Shenting (GV 24), Baihui (GV 20), Sishencong (EX-HN 1), Yintang (GV 29), Shuigou (GV 26), bilateral Fengchi (GB 20), Taichong (LR 3).

Adjunct points: Zhongchong (PC 9) and Dadun (LR 1) were added with bleeding method for insomnia through all night.

Method: After routine disinfection, stainless steel filiform needles of 0.25 mm in diameter and 25-40 mm in length were selected. After the patient took the sitting position, the needles were inserted into the bilateral Fengchi (GB 20) firstly, with the needle tip toward the nose tip, for 0.8-1.2 cun. After the needling sensation was obtained, the needles were retained in Fengchi (GB 20). Then, the patient took a supine position, Shenting (GV 24) was punctured with the needle by an angle of 15° with the scalp, toward Baihui (GV 20), for 0.5-0.8 cun. In puncturing Baihui (GV 20), the needle was inserted toward the nape shallowly for 0.5-0.8 cun. In puncturing Sishencong (EX-HN 1), the needle was inserted by an angle of 15° with the scalp, toward Baihui (GV 20), for about 0.5-0.8 cun. In puncturing Yintang (GV 29), the needle was inserted subcutaneously downward for 0.5-0.8 cun. Shuigou (GV 26) was punctured upward obliguely for 0.3-0.5 cun. After the needling sensation appeared, the needles were manipulated by the moderate needling technique. Taichong (LR 3) was punctured perpendicularly for 0.5-0.8 cun, and the sedating technique was used after the arrival of the needling sensation.

2.2 Control group

Points: Shenmen (HT 7), Neiguan (PC 6), Anmian [Extra, at the midpoint between Yifeng (TE 17) and Fengchi (GB 20)], Xingjian (LR 2), Xiaxi (GB 43), Baihui (GV 20)^[4].

Method: Except Baihui (GV 20), the rest points were punctured bilaterally. After routine disinfection, stainless steel filiform needles of 0.25 mm in diameter and 25-40 mm in length were selected. After the patient took a sitting position, Anmian [Extra, at the midpoint between Yifeng (TE 17) and Fengchi (GB 20)] was punctured perpendicularly for 0.8-1.2 cun firstly. After the arrival of the needling sensation, the patient took a supine position. Then, Baihui (GV 20) was punctured by the needle by an angel of 15° with the scalp, subcutaneously toward the nape, for 0.8-1.2 cun. Shenmen (HT 7) and Neiguan (PC 6) were punctured for 0.5-0.8 cun perpendicularly. After the needling sensation appeared in the above points, the needles were manipulated by the even reinforcing-reducing manipulation. Xingjian (LR 2) and Xiaxi (GB 43) were punctured perpendicularly for 0.3-0.5 cun, and the reducing manipulation was used after the arrival of the needling sensation.

Both the two groups were treated once per day. The needles were retained for 30 min each time. Five treatments were given per week (from Monday to

Friday, and rest on Saturday and Sunday). Ten sessions made a course and totally three courses were given.

3 Observation of Therapeutic Effects

3.1 Observed items

The sleeping quality was assessed by PSQI, composed of 19 self-assessed items and 5 other-assessed items. Only the questions of 19 self-assessed items were scored. The 19 self-assessed questions formed 7 factors. Beside the situation of medications, there were totally 6 factors. Each factor was scored by 0-3 points, 0 point meaning no difficulty, 3 points meaning much difficulty. The scores of all factors were added as total PSQI scores. The total scores ranged from 0-18 points, the higher the scores, the worse the sleeping quality.

3.2 Criteria of therapeutic effects

With reference to the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*^[2], the therapeutic effects were assessed based upon the score-reducing rate of PSQI and improvement of the clinical symptoms^[5].

PSQI score-reducing rate = (Total score before treatment — Total score after treatment) \div Total score before treatment \times 100%.

Cure: Normal sleep (sleep over 6 h each night) continuously for over one month; occasionally poor sleep, but not over 2 d, together with disappearance of the symptoms, PSQI score-reducing rate \geq 90%.

Remarkable effect: Sleep for 4-6 h each night, occasionally insomnia, but not continuously for over 4 d, by disappearance of most symptoms, with PSQI score-reducing rate in 60%-89%.

Effect: Sleep for 3-5 h per night, occasionally insomnia, but not continuously for over 6 d, with PSQI score-reducing rate in 30%-59%.

Failure: There was no obvious change in sleep before and after the treatment, but the symptoms were alleviated and PSQI score-reducing rate $\leq 30\%$.

3.3 Results

3.3.1 Comparison of PSQI score

After treatment, the sleep latency, sleep duration, habitual sleep efficiency, subjective sleep quality, sleeping disturbances, daytime dysfunction, and total PSQI score in the patients of the two groups were obviously improved than before treatment, with statistically significant differences (all P < 0.01). After treatment, the inter-group differences in the sleep latency, sleep duration, habitual sleep efficiency, subjective sleep quality, and total PSQI score were statistically significant (all P < 0.01); the differences in the scores of sleeping disturbances and daytime dysfunction were not statistical significant (all P > 0.05). The results showed that the therapeutic effect was better in the Governor Vessel-regulating, liver-soothing

and mind-calming needling than that in the routine acupuncture therapy for insomnia due to liver fire disturbing the heart (Table 2).

3.3.2 Comparison of therapeutic effects

After treatment, the total effective rate was 100% in the observation group and 92% in the control group. By the rank-sum test, the difference in the therapeutic effect between the two groups was statistically significant (P < 0.05), indicating that the therapeutic effect was better in the Governor Vessel-regulating, liver-soothing and mind-calming needling than in the routine acupuncture therapy for insomnia due to liver fire disturbing the heart (Table 3).

Fable 2. Comparison of PSQI score before a	nd after treatment between the two grou	ips
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Groups	n	Time	Sleep latency $(\overline{x} \pm s, \text{hour})$	Sleep duration $(\overline{x} \pm s, \text{hour})$	Habitual sleep efficiency $(\overline{x} \pm s, \%)$	Subjective sleep quality $(\overline{x} \pm s, point)$	Sleeping disturbances ($\overline{x} \pm s$, point)	Daytime dysfunction ($\overline{x} \pm s$, point)	Total PSQI score ($\overline{x} \pm s$, point)
Observation 25	25	BT	3.0±0.8	3.5±0.8	43.25±10.51	2.56±0.58	2.28±0.74	2.04±0.61	13.00±2.18
	25	AT	$0.9 \pm 0.4^{(1)2)}$	$6.9{\pm}0.8^{(1)2)}$	$86.25 \pm 9.88^{1)2)}$	$0.56\pm0.51^{1)2)}$	$0.68{\pm}0.56^{1)}$	$0.80{\pm}0.65^{1)}$	$2.04{\pm}1.70^{1)2)}$
Control 2:	25	BT	3.2±1.3	3.4±1.1	42.00±13.92	2.48±0.71	2.32±0.69	2.20±0.58	12.76±2.52
	23	AT	$1.5\pm0.7^{1)}$	$5.4{\pm}0.8^{1)}$	$67.25{\pm}10.09^{1)}$	$1.08{\pm}0.70^{1)}$	$0.76{\pm}0.52^{1)}$	$0.76{\pm}0.60^{1)}$	$3.68 {\pm} 2.04^{1)}$

Note: BT=Before treatment; AT=After treatment; compared with the same group before treatment, 1) P < 0.01; compared with the control group after treatment, 1) P < 0.01

Table 3.	Comparison	of clinical	effect after	treatment	between	the two groups
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Groups	п	Cure	Remarkable effect	Effect	Failure	Total effective rate (%)
Observation	25	13	10	2	0	100.0 ¹⁾
Control	25	7	9	7	2	92.0

Note: Compared with the control group, 1) P < 0.05

4 Discussion

We spend 1/3 of our life sleeping. Since sufficient sleep guarantees our wellness, poor sleep quality for a long period of time may severely threaten our physical and mental health. A number of surveys have shown that approximately 30% population across the world experience difficulty sleeping and 45.5% Chinese population experience insomnia in varying degrees. Apparently, insomnia has become a public health issue that requires immediate solution^[6-7]. In Chinese medicine, insomnia is categorized into five patterns and the most common pattern is liver fire disturbing the heart. Specifically, emotional distress may cause liver gi stagnation, which, over time, may transform into fire to affect the function of the liver in storing the ethereal soul. As a result, liver fire may affect the heart mind and brain, leading to restlessness and insomnia^[8-9]. Since this pattern is located in the heart and brain. In the consideration of the pathogenesis and pathologic position of insomnia due to liver fire disturbing the heart, the author treated it by the Governor Vessel-regulating, liver-soothing and mind-calming needling, with the points mainly selected from the Governor Vessel and liver meridian, such as Shenting (GV 24), Baihui (GV 20), Sishencong (EX-HN 1), Yintang (GV 29), Shuigou (GV 26), Fengchi (GB 20), and Taichong (LR 3). From the perspective of the pathways of

and its branch also communicates with the brain. Moreover, its branch is closely related to the heart. Therefore, to regulate the Governor Vessel can directly calm down the primary spirit and tranquilize the heart and mind^[10]. Acupuncture at Baihui (GV 20) and Shenting (GV 24) can dredge the Governor Vessel, wake up the brain and stabilize the mind and calm down the spirit^[11]. Shuigou (GV 26) has the effects to wake up the brain and open the aperture, and is a major point of the brain-refreshing and orifice-opening needling technique of Academician Shi Xue-min. After acupuncture, the patient's emotion, spirit and sleep can be improved. Therefore, it is a major point in the treatment of insomnia due to liver fire disturbing the heart^[12]. Yintang (GV 29) is situated on the pathway of the Governor Vessel and can be used to regulate the Governor Vessel and calm down the mind. Sishencong (EX-HN 1) is a major point for treating the emotional and mental diseases and has a good effect to calm down the mind. Fengchi (GB 20) is a crossing point of Foot Shaoyang Meridian, Yang Link Vessel, and Yang Heel Vessel and is related to the eyelids and heart via the meridians. Therefore, acupuncture at Fengchi (GB 20) can calm down the heart and tranquilize the mind^[13-15]. Taichong (LR 3) is the Shu-Stream point and Yuan-Primary point of the Liver Meridian and can be used to soothe the liver, regulate qi, smoothen qi

meridians, the Governor Vessel directly enters the brain,

activity by acupuncture, producing a better effect to ease tension and relieve spiritual stress^[16-19]. For insomnia through the night due to hyperactivity of the liver fire, the bleeding method was added at Zhongchong (PC 9) and Dadun (LR 1) for reducing fire, calming down the heart and tranquilizing the spirit. All points were used in combination to realize the effects to soothe the liver, calm down the heart and tranquilize the spirit. After the treatment for three courses, the sleep latency, actual sleep duration, habitual sleep efficiency, and total PSQI scores in the patients of the two groups were statistically different from those before treatment (all $P \le 0.01$), indicating that the sleeping quality is certainly improved in the patients of the two groups. After treatment, the differences in the above items between the two groups were statistically significant (all $P \le 0.01$). The differences in the total effective rate between the two groups are statistically significant ($P \le 0.05$). These findings show that the therapeutic effects are better in the observation group than in the control group, indicating that the Governor Vessel-regulating, liver-soothing and mind-calming needling is better in the therapeutic effects than the routine acupuncture in the treatment of insomnia due to liver fire disturbing the heart and needs further popularizing in clinic.

Conflict of Interest

There was no potential conflict of interest in this article.

Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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