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Clinical Study

Clinical study on acupuncture for primary insomnia

针刺治疗原发性失眠的临床研究

Shao Yue (邵悦)
Acupuncture Department, Hospital of Integrated Traditional Chinese and Western Medicine Affiliated to Zhejiang Chinese Medical University (Hangzhou Red Cross Hospital), Hangzhou 310003, China

Abstract

Objective: To observe the clinical effect of Acupuncture at Baihui (GV 20), Sishencong (EX-HN 1) and Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] for primary insomnia.

Methods: A total of 112 patients with primary insomnia were randomized into an acupuncture group and a medication group according to the visiting sequence, 56 cases in each group. The acupuncture group was intervened by acupuncture at Baihui (GV 20), Sishencong (EX-HN 1) and Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)], and points selected based on syndrome differentiation, while the medication group was by oral intake of zopiclone tablet. The Pittsburgh sleep quality index (PSQI) was measured before and after treatment, and the clinical efficacy was compared after 1 month of treatment.

Results: After treatment, subscales of PSQI and global score in the acupuncture group were improved, and intra-group comparisons showed statistical differences (all $P<0.05$); subscales of sleep quality, sleep latency, sleep duration and global score of PSQI in the medication group were improved, showing statistical differences (all $P<0.05$). Inter-group comparison of global and subscales scores of PSQI showed statistical differences (all $P<0.05$). The total effective rate in the acupuncture group was 92.9%, higher than 67.9% in the medication group, and between-group comparison showed a statistical difference ($P<0.05$).

Conclusion: Acupuncture at Baihui (GV 20), Sishencong (EX-HN 1) and Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] as the main treatment method can produce a better effect than oral intake of zopiclone tablet.

Keywords: Acupuncture Therapy; Point, Baihui (GV 20); Point, Sishencong (EX-HN 1); Point, Anmian (Extra); Points, Head and Neck; Point Selection Based on Syndrome Differentiation; Insomnia

【摘要】目的：观察针刺百会、四神聪和安眠穴为主治疗原发性失眠症的临床疗效。**方法**：选取原发性失眠症患者112例，按照入院先后顺序随机分成针刺组和药物组，每组56例。针刺组以针刺百会、四神聪和安眠穴为主,并配合辨证取穴；药物组以口服佐匹克隆片治疗。治疗前后进行匹茨堡睡眠指数(PSQI)评分，治疗1个月后比较两组临床疗效。**结果**：治疗后，治疗组PSQI各因子评分及总分均较本组治疗前明显下降，组内差异均具有统计学意义(均$P<0.05$)；药物组睡眠质量、入睡时间和睡眠时间评分以及PSQI总分与治疗前均有统计学差异(均$P<0.05$)。两组患者治疗后PSQI各因子评分及总分均具有统计学差异(均$P<0.05$)。针刺组总有效率92.9%，高于药物组的67.9%，组间差异具有统计学意义($P<0.05$)。**结论**：针刺百会、四神聪和安眠穴为主治疗原发性失眠症的临床疗效优于口服佐匹克隆片。

【关键词】针刺疗法；穴，百会；穴，四神聪；穴，安眠；穴位，头颈部；辨证选穴；失眠症
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Insomnia is the inability to obtain normal sleep. Patients with insomnia may experience difficulty falling asleep, interrupted sleep, dream-disturbed sleep, early-morning awakening with inability to return to sleep. It is typically followed by fatigue, low energy and daytime sleepiness. Studies have shown that primary insomnia affects approximately 6% of adult population[1]. Severe insomnia may cause anxiety, depression or panic, and low efficiency, which may greatly affect the patients' social activities. Myriad literature studies have suggested that acupuncture can significantly benefit sleep[2-3]. In this study, we used Baihui (GV 20), Sishencong (EX-HN 1) and Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] for primary insomnia and analyzed the action mechanism of scalp acupuncture. The report is now summarized as follows.

Author: Shao Yue, M.M., resident.
E-mail: jshaoyue@126.com

1 Clinical Materials

1.1 Diagnostic criteria

Referring to the diagnostic criteria of insomnia in

Chinese Classification and Diagnosis of Mental Diseases-3 (CCMD-3)[4].

1.2 Inclusion criteria

Conforming to the above diagnostic criteria; at least 3 times of onset every week, and the symptoms ≥1 month but ≤12 months; aged between 18 and 70 years old; informed consent.

1.3 Exclusion criteria

Insomnia caused by pathological mechanism; with primary fatal diseases of heart, liver, kidney or other systems; women during pregnancy or lactation; with coagulation disorder; Pittsburgh sleep quality index (PSQI) ＞17 points.

1.4 Dropout criteria

Those who failed to follow the treatment or a necessity to stop treatment; those who received other treatment or medication; incomplete clinical information which may affect data processing.

1.5 Statistical methods

All data were processed by SPSS 19.0 version software. Measurement data were tested for normality and homogeneity. Those conforming to normal distribution was described by mean ± standard deviation ($\bar{x} \pm s$), independent *t*-test was used for inter-group comparison; those didn't conform to normal distribution were described by median and quartiles and tested by Mann-Whitney *U*; The enumeration data were analyzed by using Chi-square and normality test; a *P*-value less than 0.05 indicated a statistical significance.

1.6 General data

A total of 112 patients with primary insomnia visiting the Acupuncture Outpatient of Hospital of Integrated Traditional Chinese and Western Medicine Affiliated to Zhejiang Chinese Medical University between Jan 2015 and Sep 2016 were randomly allocated into an acupuncture group and a medication group according to their visiting sequence. Patients in both groups finished the whole treatment without exclusion and drop-out, with no severe adverse effect. General data comparison of both groups showed no statistical significances (all $P > 0.05$), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of general data

Group	*n*	Gender (case)		Mean age ($\bar{x} \pm s$, year)	Mean duration ($\bar{x} \pm s$, month)	Education level (case)	
		Male	Female			High school or below	University or above
Acupuncture	56	20	36	44.6±13.5	6.3±2.4	16	40
Medication	56	22	34	45.8±14.1	6.2±2.5	19	37

2 Treatment Methods

2.1 Acupuncture group

Patients in the acupuncture group received no sleeping pills during the treatment.

Major points: Baihui (GV 20), Sishencong (EX-HN 1) and Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)].

Adjunct points: Shenmen (HT 7), Taibai (SP 3), Zhizheng (SI 7) and Fenglong (ST 40) were added for syndrome of heart and spleen deficiency; Shenmen (HT 7), Zhizheng (SI 7), Qiuxu (GB 40) and Guangming (GB 37) for syndrome of timidity due to heart-deficiency; Taichong (LR 3) and Yangfu (GB 38) for syndrome of liver depression transforming into fire; Fenglong (ST 40), Neiting (ST 44) and Quchi (LI 11) for syndrome of phlegm heat; and Xuehai (SP 10) and Geshu (BL 17) for syndrome of blood stasis.

Methods: Location of points, depth and angle of insertion were based on *Science of Acupuncture and Moxibustion*[5]. Filiform needle of 0.25 mm in diameter and 40 mm in length was used. Manipulate the even reinforcing-reducing technique on main acupoints, and reinforcing or reducing manipulation according to syndrome differentiation on adjunct points, the needles were retained for 30 min. The treatment was done once a day, 10 d for a course of treatment. There was a 1-day interval between two courses. Patients were treated for a total of 3 courses.

2.2 Medication group

Patients in the medication group were treated with oral intake of zopiclone tablet (SFDA approval number: H19991411, produced by Jilin Pharmaceutical Co., Ltd., China), 7.5 mg each time, once a day for 30 d.

3 Results Observation

3.1 Observation items

Referring to the PSQI, in which 7 factors including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction were measured[6]. Number 0-3 was used to evaluate severity of the symptoms. PSQI score was the sum of the 7 factors, a higher score indicating a worse sleeping quality.

3.2 Therapeutic efficacy criteria

Referring to the *Guiding Principles for Clinical Study of New Chinese Medicines*[7] and PSQI decline rate.

PSQI decline rate＝(Pre-treatment global score－Post-treatment global score)÷Pre-treatment global score×100%.

Recovery: Sleep duration ＞ 5 h, with no uncomfortable feeling after awakening, PSQI decline rate ≥75%.

Marked effect: Recovery rate was substantially extended (3 h increase or above) or able to sustain 4-5 h of sleep, with an increase of sleeping depth, PSQI decline rate ≥50% but ＜75%.

Improvement: Improved sleeping quality, slight increase of sleep duration (within 3 h of increase) or able to sustain 3-4 h of sleep, PSQI decline rate ≥30% but ＜50%.

Failure: No improvement of symptoms or even aggravation, PSQI decline rate ＜30%.

3.3 Results

3.3.1 Comparison of subscales of PSQI

Before treatment, there were no significant between-group differences in PSQI global score and subscales scores. After treatment, PSQI global score and subscales scores were significantly improved in the acupuncture group, showing statistical significances (all $P<0.05$); in the medication group, sleep quality, sleep latency, sleep duration and PSQI global scores were significantly improved (all $P<0.05$), while there were no significant improvements in other 4 subscales (all $P>0.05$). After treatment, there were significant between-group differences in PSQI global score and subscales scores (all $P<0.05$), indicating symptoms in both groups improved and a better improvement in the acupuncture group (Table 2).

3.3.2 Comparison of therapeutic efficacy

After treatment, the total effective rate was 92.9% in the acupuncture group, versus 67.9% in the medication group, and the between-group comparison showed a statistical significance, indicating a better effect in the acupuncture group (Table 3).

Table 2. Comparison of PSQI global score and subscales ($\bar{x}\pm s$, point)

Item	Acupuncture group (n=56)		Medication group (n=56)	
	Before treatment	After treatment	Before treatment	After treatment
Subjective sleep quality	2.22±0.67	1.29±0.58[1)2)]	2.24±0.54	1.83±0.61[1)]
Sleep latency	2.41±0.47	1.05±0.15[1)2)]	2.38±0.55	1.41±0.39[1)]
Sleep duration	1.77±0.67	0.76±0.66[1)2)]	1.74±0.67	1.32±0.43[1)]
Habitual sleep efficiency	1.84±0.09	1.32±0.04[1)2)]	1.94±0.66	1.90±0.35
Sleep disturbances	2.11±0.63	1.66±0.63[1)2)]	2.08±0.62	1.91±0.73
Use of sleeping medication	2.81±0.41	1.32±0.57[1)2)]	2.84±0.42	2.78±0.46
Daytime dysfunction	2.28±0.61	1.23±0.51[1)2)]	2.33±0.44	2.10±0.42
PSQI global score	12.67±4.56	7.34±2.56[1)2)]	12.78±4.51	9.93±3.22[1)]

Note: Inter-group comparison, 1) $P<0.05$; between-group comparison after treatment, 2) $P<0.05$

Table 3. Comparison of clinical efficacy (case)

Group	n	Recovery	Marked effect	Improvement	Failure	Total effective rate (%)
Acupuncture	56	10	18	24	4	92.9[1)]
Medication	56	3	12	23	18	67.9

Note: Between-group comparison, 1) $P<0.05$

4 Discussion

Insomnia pertains to *'Bu Mei'* or *'Bu De Wo'* (sleeplessness) in traditional Chinese medicine (TCM). Scholars in history made rich discussion on physiology and pathogenesis of insomnia, mostly based on the theory of imbalance between yin and yang, in which it holds that change of yin and yang within human body determines the sleep and awake cycle, and it is an inevitable phenomenon of yin yang alternation[8-9]. At the same time, TCM holds that sleep is closely linked with mental state, and brain is the house of the original spirit, therefore treatment of insomnia should be based on the adjustment of yin and yang, and focus on regulating spirit.

In this study, we used Acupuncture at Baihui (GV 20), Sishencong (EX-HN 1), Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] and combined other points according to syndrome differentiation for insomnia, and compared it with routine medicinal treatment. Baihui (GV 20) is on the top of the body, where yang qi is gathering, and also the crossing point of three hand and foot yang meridians and Governor Vessel[10-11]. Governor Vessel is the sea of yang meridians and has the function of regulating qi and blood in yang meridians. By

acupuncture at points of Governor Vessel, pathological state of yang failing to enter yin can be corrected. Acupuncture at Baihui (GV 20) has a good function of relieving fright and calming spirit[12-13]. Sishencong (EX-HN 1) points are surrounding Baihui (GV 20), and where yang qi from all yang meridians (two points on the front and back are located on Governor Vessel) gathers. It has the function of regulating yang qi. Points on the left and right side are adjacent to the Bladder Meridian. Since Bladder Meridian connects kidney and enters brain, such points have the function of refreshing brain and tonifying essence. They can regulate qi and blood from Taiyang Meridian and Governor Vessel to reach brain and propel yang spirit entering yin, which has a proven effect for insomnia[14-15]. Modern research has shown that nerves from the top of body can regulate awaking system on the posterior side of hypothalamus, and thus engage in the regulation of sleep mechanism. Acupuncture at the top of the head can stimulate lower brainstem and cerebral cortex, extent slow wave sleep and thus improve sleep quality[16-18]. Researches also have shown that acupuncture at top of the head can accelerate blood circulation in parietal region, increase energy metabolism of neurons, and activate sleep functions. Such evidences provide a solid proof for points like Baihui (GV 20) and Sishencong (EX-HN 1) in the treatment of insomnia[19-22]. Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] is the extra point and located at the midpoint of Yifeng (TE 17) and Fengchi (GB 20) where Yin and Yang Heel Vessels pass by. It connects meridian qi movement and has the function of nourishing heart and calming spirit[23]. Modern medical research shows that Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] is located between sternocleidomastoid and splenius capitis, and adjacent to occipital artery and vein, great auricular nerve and lesser occipital nerve[24]. Acupuncture at Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] has the function of improving micro-circulation, relieving brain vessels spasm, inhibiting abnormal brain discharge, reducing abnormal exciting status and therefore improving sleep quality[25-26].

In this study, PSQI global and subscales scores in the acupuncture group were all lower than those in the medication group, showing statistical significances (all $P<0.05$), and the total effective rate was higher in the acupuncture group ($P < 0.05$), indicating that acupuncture at Baihui (GV 20), Sishencong (EX-HN 1) and Anmian [Extra, locates at the midpoint between Yiming (EX-HN 14) and Fengchi (GB 20)] is an effective method for primary insomnia with easy manipulation, worth clinical popularization.

Conflict of Interest

The author declared that 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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Translator: Jia Yi-fan (贾一凡)

