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Clinical research on insomnia treated by acupuncture at back-*shu* points*

针刺背俞穴治疗失眠的临床研究*

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ABSTRACT

Objective To observe the clinical therapeutic effect on insomnia treated with acupuncture at back-*shu* points. **Methods** Sixty-four cases of insomnia were selected and divided randomly into a back-*shu* points group (group A) and a conventional acupoints group (group B) by a computer generated allocation list, 32 cases in each one. In the trial group, acupuncture was applied at Xīnshū (心俞 BL 15), Gānshū (肝俞 BL 18), Píshū (脾俞 BL 20) and Géshū (膈俞 BL 17). In the control group, acupuncture was applied conventionally to Nèiguān (内关 PC 6), Shénmén (神门 HT 7), Sānyīnjiāo (三阴交 SP 6), Bǎihuì (百会 GV 20) and Sìshéncōng (四神聪 EX-HN 1). Ten treatments made a session. The efficacy was analyzed statistically after 3 sessions of treatment. **Results** There were significant differences between the two groups in the relief of sleep disorders after the treatment (P<0.01). The improvement in sleep efficiency was different significantly (P<0.05). The difference in sleep difficulty was significant in Chinese medicine (TCM) symptom score (P<0.05). **Conclusion** The clinical efficacy is achieved by either acupuncture at back-*shu* points or by acupuncture at conventional acupoints. The improvements of sleep efficiency and sleep disorder scores in PSQI, and sleep difficulty in TCM as well as the long-term efficacy are superior in group A as compared with those in group B.

KEY WORDS: insomnia; acupuncture therapy; back-*shu* points; BL 15; BL 18; BL 20; BL 17; randomized controlled trial

The morbidity of insomnia is increased yearly with the accelerated social pace and more stress from work and life. Long-term insomnia brings harmful effects physically and mentally, resulting in various problems. Nowadays, the modern medicine commonly adopts sedative-hypnotic drugs in the treatment of insomnia, but these drugs easily cause drug resistance, addiction, dependence and withdrawal reactions and leading to liver and kidney damage. Acupuncture achieves the good, quick, safe and reliable effect on insomnia and is easily accepted by patients. In recent years, the writers applied acupuncture to back-*shu* points in treatment of insomnia and have obtained satisfactory effects. In order to further explore the effective methods and promote clinical popularity, the report is as follows.

CLINICAL DATA

General data

All of 64 cases were outpatients and were diagnosed as insomnia in the Third Affiliated Hospital of Henan University of TCM from March 2007 to June 2010. The patients were randomized by a computer generated allocation list, into a back-*shu* points group (group A) and a conventional acupoints group (group B). There was no significant difference in the general data between the two groups (P>0.05), indicating

comparability between the groups, (Table 1). The trial was approved by the Ethics Committee.

Criteria of diagnosis, exclusion and dropping-out

Diagnostic criteria: based on *Guiding Principles of Clinical Research on New Drugs of Traditional Chinese Medicine* issued by the National Health Ministry in 1993 [1], including difficulty in falling asleep, easily waking up, unsound sleep or difficulty in falling into sleep after waking up, earlier waking up; feeling sleepy at day time, associated with headache, dizziness, palpitations, forgetfulness, dream-disturbed sleep; sleep less than 5 h a night; repeated attacks of insomnia in medical history.

Inclusive criteria: typical symptoms of insomnia, sickness duration over 28 days, aged from 18 to 65 years, in compliance with medical advice; signed the Informed Consent Form.

Exclusive criteria: incompliance with the diagnostic and inclusive criteria, received the other treatment which could affect the study result; complicated with severe and hazard primary diseases and mental disorder, such as the disorders of heart, brain, vessel, liver, kidney and hematopoietic system; in pregnancy or lactation; other related diseases in which insomnia was not the chief complain, SAS score >60 or SDS score >60.

Dropping-out criteria: failure in follow-up in clinical study, automatic dropping-out, failure to keep on treatment accidentally, poor compliance and incomplete data.

METHODS

Group A

Acupoints: Shéndào (神道 GV 11), Xīnshū (心俞 BL 15), Gānshū (肝俞 BL 18), Píshū (脾俞 BL 20), Géshū (膈俞 BL 17). Operation: the patient was in prone, after routine disinfection, the filiform needles, 0.25 mm×25 mm were used to insert perpendicularly at the acupoints. After the arrival of *qi*, the even needling technique was applied. The needles were retained for 30 min and manipulated once every 10 min.

Group B

Acupoints: Bǎihuì (百会 GV 20), Sìshéncōng (四神聪 EX-HN 1), Nèiguān (内关 PC 6), Shénmén (神门 HT 7), Sānyīnjiāo (三阴交 SP 6). Operation: the horizontal needle technique was used at GV 20 and EX-HN 1, 20 mm in depth; the perpendicular needle technique was at PC 6, 20 mm in depth; at HT 7, 15mm in depth and at SP 6, 30 mm in depth. The needling techniques were same as group A.

The treatment of 10 times made 1 session. The statistical analysis on the efficacy was conducted after 3 sessions of treatment in the two groups.

Observation indices

Using the Pittsburgh sleep quality index (PSQI) [2], as well as TCM symptom scale, the statistical analysis on each score was done before and after treatment. In TCM symptom scale, based on the clinical common accompanying symptoms of insomnia with the highest frequency of occurrence, the 8 groups of main clinical symptoms were collected, named difficulty in falling asleep, dream-disturbed sleep, feeling tired after waking up, palpitation and easily frightened, irritability, hot temper, forgetfulness, headache and dizziness, chest oppression and belching. The items were scored from 0 to 3 based on none (A), mild degree (B), moderate degree (C) and severe degree (D). The associated symptoms were evaluated in a short term.

Criteria of therapeutic effects

According to *Guiding Principles of Clinical Research on New Drugs of Traditional Chinese Medicine* issued by the National Health Ministry in 1993, cured: sleep time returned to normal or nocturnal sleep time more than 6 h, deep and sound sleep, feeling energetic after waking up; markedly effective: improved sleep condition, sleep time increased by more than 3 h, improved sleep quality; effective: alleviated symptoms, sleep time increased by less than 3 h as compared with before; failed: no obvious improvement or even getting worse after treatment.

Table 1 Comparison of general data between the two groups of insominia patients ($\bar{x}\pm s$)

Data set	Groups	Patients	Age (years)	Sick duration (d)	Mild (cases)	Moderate (cases)	Severe (cases)	PSQI integral
FAS	A	32	45.3±6.8	48.2±11.8	10	16	6	17.25±1.72
	B	32	44.3±5.6	46.7±12.7	9	18	5	17.12±1.58
PPS	A	31	45.7±7.8	48.5±13.5	10	15	6	17.16±1.67
	B	30	45.4±9.6	47.5±12.6	9	17	4	17.10±1.62