Clinical efficacy of the shallow puncture and more-twirling acupuncture method in migraine treatment and its effects on serum 5-HT and β -EP levels

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Abstract.

BACKGROUND: The incidence rate for migraine is 12% worldwide, and recurrence is common, which seriously affects the physical and mental health of patients.

OBJECTIVE: To observe the clinical effect of Shallow Puncture and More Twirling method of acupuncture in treating migraine and its impact on serum 5-HT and β -EP.

METHODS: A total of 76 patients with migraine were randomized into a control group and acupuncture group with 38 cases in each. In the control group, patients were orally administered flunarizine hydrochloride before sleep, 2 capsules once daily for 4 weeks. In the acupuncture group, Shallow Puncture and More Twirling method was adopted for the acupoints of Sizhukong (SJ 23), Toulinqi (GB 15) Shuaigu (GB 8), Xuanlu (GB 5), Fengchi (GB 20), Waiguan (SJ 5), Zulinqi (GB 41). Patients were given acupuncture 3 times per week for 4 weeks. Then, the total VAS (Visual Analogue Scale) scores, composite score of migraine, serum level of 5-HT and β -EP, and the clinical efficacy differences were observed before and after treatment and the side-effects were recorded among the two groups.

RESULTS: The total VAS scores and composite score of migraine were significantly reduced among both groups after the treatment (P < 0.05), and the serum level of 5-HT and β -EP was significantly improved (P < 0.05). Compared with control group, the acupuncture group reported lower results in VAS score and migraine composite score (P < 0.05), and higher results in serum 5-HT and β -EP level (P < 0.05). The acupuncture group with shallow puncture and more twirling method showed a total effective rate of 86.5%, which is higher than the control group (78.4%). The difference is statistically significant (P < 0.05). **CONCLUSION:** Shallow Puncture and More Twirling method was superior to fluarizine hydrochloride in the treatment of clinical symptoms of migraine. Acupuncture also increases the serum level of 5-HT and β -EP in migraine.

Keywords: Shallow Puncture and More Twirling, acupuncture, migraine, clinical effect, randomized controlled trial

1. Introduction

Migraine is a neurological disorder characterized by recurrent unilateral or bilateral attacks of moderateto-severe headache that may be accompanied by nausea, fear of sound, and photophobia [1]. The incidence rate for migraine is 12% worldwide [2], and recurrence is common, which seriously affects physical and mental health of patients [3]. The World Health Organization (WHO) considers migraine the most

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Comparison of the general data for the 2 groups ($\chi \pm s$)						
Group	No. of patients	Gender		Age (years)	Duration of disease (years)	
		Male [n (%)]	Female $[n (\%)]$			
Control group	38	19 (51.4)	18 (48.6)	43.82 ± 9.63	3.41 ± 0.91	
Acupuncture group	38	16 (43.2)	21 (56.8)	42.73 ± 8.92	3.82 ± 1.33	

Table 1				
Comparison of the general data for the 2 groups $(\bar{\chi} \pm s)$				

disabling chronic disease [4]. Current medications for migraine are prone to drug resistance, addiction and toxic and side effects [5], whereas acupuncture shows efficacy with few adverse reactions in treating migraine [6] and thus has been listed as a recommended therapy by the WHO [7]. Based on the cutaneous region theory in *Huangdi's Internal Classics*, the "shallow puncture and more-twirling" acupuncture method was developed by Doctor Chen Lei, a famous Chinese medicine expert in Zhejiang Province. This method is effective in treating migraine [8,9], but the mechanism of action has not been elucidated. As a neurotransmitter and humoral transmitter, 5-HT is involved in important pathways for migraine in the central and peripheral areas. β -EP is an endogenous opioid peptide with potent analgesic effect, and the body's decreased ability to release β -EP can lead to an increase in vasoactive substances, thereby upregulating sensitivity to pain.

This study is a single-center, evaluator-blinded, randomized controlled trial to observe the effects of the shallow puncture and more-twirling method on patients with migraine (as determined using the visual analog scale (VAS) score and comprehensive headache score) and to measure serum 5-hydroxytryptamine (5-HT) and beta-endorphin (β -EP) levels before and after treatment, so as to investigate the mechanism of action of the shallow puncture and more-twirling method in the treatment of migraine.

2. Materials and methods

2.1. General data

Seventy-six patients with migraine who visited our hospital from June 2020 to March 2022 were enrolled and randomly assigned to a control group (medication, n = 38) and an acupuncture group (shallow puncture and more-twirling method, n = 38) using a random number table. General data (including gender, age and disease course) were not significantly different between the 2 groups, indicating that the 2 groups were comparable (p > 0.05) (Table 1). This study was reviewed by the Ethics Committee of Ningbo Traditional Chinese Medicine Hospital, and informed consent was obtained from all patients.

2.2. Diagnostic criteria

Patients were diagnosed with migraine in accordance with the diagnostic criteria in the International Classification of Headache Disorders (ICHD-3) [1] formulated by the International Headache Society (IHS) in 2013.

2.3. Inclusion criteria

The inclusion criteria were as follows: (1) patients who met the diagnostic criteria, (2) patients with ≥ 2 migraine attacks in the last 3 months, (3) patients aged 18–65 years, regardless of gender, with a disease course ≥ 12 months and a comprehensive headache score ≥ 7 points, and (4) patients who signed the informed consent form.

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2.4. Exclusion criteria

The exclusion criteria were as follows: (1) pregnant or lactating women, (2) patients with serious primary diseases of the brain and organs (heart, liver, kidney and hematopoietic system), e.g., Parkinson's disease, extrapyramidal diseases or psychiatric disorders, (3) patients with specific types of migraine complications (e.g., ophthalmoplegia and hemiplegic), and (4) patients with a history of oral administration of preventive drugs or abuse of drugs for migraine within 1 month before enrollment.

2.5. Criteria for trial suspension

The criteria for trial suspension included the following: (1) adverse events or serious adverse events during the trial, (2) poor compliance, (3) request to withdraw from the trial or voluntary withdrawal from the trial, and (4) taking other analgesic drugs during the trial.

3. Methods

3.1. Treatment protocols

3.1.1. Control group

Patients in the control group were orally administered flunarizine hydrochloride capsules (strength: 5 mg/capsule; approval No.: NMPA H10930003; manufacturer: Xian Janssen Pharmaceutical Ltd.) before sleep (2 capsules once daily for 4 weeks).

3.1.2. Acupuncture group

Patients in the acupuncture group were treated with acupuncture using the shallow puncture and more-twirling method. The acupuncture points included Sizhukong (affected side), Toulinqi (affected side), Shuaigu (affected side), Xuanlu (affected side), Fengchi (affected side), Waiguan (affected side), and Zulinqi (affected side). First, the patient lay in a lateral position with the affected side upwards. Then, the acupuncture points were routinely disinfected, and 0.25×25 mm stainless filiform needles were prepared. The acupuncture point was first pressed with the index finger of the left hand, and then, using the nail-pressing method, a cross mark was made with the nail of the index finger at the center of the acupuncture point. The needle was gently twirled (90–120°) with the right hand at the center of the cross mark, with slight pressure. Next, the needle was slowly inserted 2–3 mm through the skin, followed by rapid twirling 200 times, at a frequency of 200 times/min and an amplitude < 180°; a sense of qi should occur in the local area. Subsequently, the needle was retained for 30 minutes, during which the shallow puncture and more-twirling method was performed once. The acupuncture treatment was conducted 3 times per week for a total of 4 weeks.

3.2. Observation indicators

3.2.1. VAS score

The VAS score was recorded before and after treatment using the following method. A 10-cm horizontal line was drawn on paper, and numbers from 0 to 10 were marked at 1-cm intervals. Numbers from "0" (no pain) to "10" (severe pain) represented a gradual increase in pain.

3.2.2. Comprehensive headache score

The comprehensive headache score was evaluated before and after treatment with reference to the

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Guiding Principles for Clinical Research of New Chinese Medicines [10]. Headache was scored based on its degree (6 points for requiring bed rest during the attack, 4 points for affecting work, 2 points for not affecting work, and 0 points for no headache), duration of pain (0 points for no headache, 1 point for less than 2 hours, 2 points for 2–6 hours, 3 points for 6–24 hours, 4 points for 24–72 hours, and 5 points for longer than 72 hours), number of attacks (6 points for more than 5 times/month, 4 points for 3–4 times/month, 2 points for 1–2 times/month, and 0 points for no attacks), and concomitant symptoms (3 points for nausea, vomiting and photophobia, 2 points for 2 of the above symptoms, 1 point for one of the above symptoms, and 0 points for no concomitant symptoms).

3.2.3. Serum 5-hydroxytryptamine (5-HT) and beta-endorphin (β -EP) levels

Before and after treatment, 5 mL of nonanticoagulated blood was collected from the elbow vein of each patient in both groups. After sitting for 15 min, the blood samples were centrifuged at high speed, and the supernatant was harvested and stored in a freezer at -80° C. Then, the serum 5-HT and β -EP levels were measured by ELISA.

3.3. Evaluation criteria for clinical efficacy

Clinical efficacy was evaluated using the nimodipine method with reference to the *Guiding Principles* for Clinical Research of New Chinese Medicines [10]. The calculation formula (nimodipine method) was as follows: [(pretreatment comprehensive headache score – posttreatment comprehensive headache score)/pretreatment comprehensive headache score] × 100%. Clinical efficacy involved the following aspects: (1) clinical cure: clinical symptoms and signs disappeared or basically disappeared, and the comprehensive score declined by \geq 95%, (2) significantly effective: clinical symptoms and signs improved significantly, and the comprehensive score declined by \geq 30%, and (4) ineffective: clinical symptoms and signs digns did not improve significantly or even worsened, and the comprehensive score declined by < 30%.

3.4. Safety evaluation

Adverse events (including local hematoma, fainting during acupuncture, sticking of needles, and infections) occurring during treatment as well as their extent and duration were observed and recorded.

3.5. Statistical analysis

SPSS 22.0 software was used for statistical analyses. Measurement data are expressed as ($\chi \pm s$). Measurement data with a normal distribution and homogeneity of variance were analyzed using the *t*-test, and those not conforming to a normal distribution were analyzed using the nonparametric rank-sum test. p < 0.05 was considered statistically significant.

4. Computer simulation and results

4.1. Comparisons of VAS scores and comprehensive headache scores between the 2 groups

Before treatment, the VAS scores and comprehensive headache scores were not significantly different and thus were comparable between the 2 groups (p > 0.05). After treatment, the VAS scores and comprehensive headache scores for patients in both groups were notably lower than those before treatment

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Comparisons of VAS scores and comprehensive headache scores between the 2 groups ($\bar{\chi} \pm s$)						
Group	Patients	VAS score (points)		Comprehensive headache score (points)		
		Before treatment	After treatment	Before treatment	After treatment	
Control group	38	6.53 ± 1.96	$3.82 \pm 1.37^{\Delta}$	15.32 ± 2.43	$8.13 \pm 1.51^{\Delta}$	
Acupuncture group	38	6.24 ± 1.60	$2.63\pm0.99^{\Delta*}$	15.08 ± 2.32	$4.89\pm1.42^{\Delta*}$	
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 Table 2

 Comparisons of VAS scores and comprehensive headache scores between the 2 groups ($\bar{\chi} \pm s$)

Note: $^{\Delta}p < 0.05 vs.$ the same group before treatment; $^{*}p < 0.05 vs.$ control group.

Table 3 Comparisons of serum 5-HT and β -EP levels between the 2 groups ($\bar{\chi} \pm s$, ng/ml)							
Group	Patients	5-	·HT	<i>β</i> -EP			
		Before treatment	After treatment	Before treatment	After treatment		
Control group	38	61.56 ± 4.76	$119.69\pm11.96^{\Delta}$	156.2 ± 23.157	$209.36\pm11.28^{\Delta}$		
Acupuncture group	38	61.45 ± 5.04	$147.99 \pm 10.94^{\Delta *}$	154.19 ± 26.51	$245.49 \pm 8.94^{\Delta *}$		

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Note: $^{\Delta}p < 0.05 vs.$ the same group before treatment; $^{*}p < 0.05 vs.$ control group.

Table 4 Comparison of clinical efficacy between the 2 groups						
Group	Patients	Clinical cure	Significantly effective	Effective	Ineffective	Total effective rate (%)
Control group Acupuncture group	38 38	0 2 (5.4%)	8 (21.6%) 16 (43.2%)	21 (56.8%) 14 (37.8%)	8 (21.6%) 5 (13.5%)	78.4 86.5*

Note: *p < 0.05 vs. control group.

(p < 0.05). In contrast to the control group, the acupuncture group exhibited significantly lower VAS scores and comprehensive headache scores (p < 0.05) (Table 2).

4.2. Comparisons of serum 5-HT and β -EP levels

Before treatment, there were no statistically significant differences in serum 5-HT and β -EP levels between the 2 groups (p > 0.05), and thus, the 2 groups were comparable. After treatment, the serum levels of 5-HT and β -EP in both groups were markedly higher than those before treatment (p < 0.05). The serum levels of 5-HT and β -EP in the acupuncture group were higher than those in the control group (p < 0.05) (Table 3).

4.3. Comparison of clinical efficacy between the 2 groups

After treatment, the significantly effective rate, effective rate, ineffective rate and total effective rate were 21.6%, 56.8%, 21.61% and 78.4%, respectively, in the control group. On the contrast, the clinical cure rate, significantly effective rate, effective rate, ineffective rate and total effective rate were 5.4%, 43.2%, 37.8%, 15.5% and 86.5%, respectively, in the acupuncture group. The total effective rate was higher in the acupuncture group than in the control group (p < 0.05) (Table 4).

4.4. Safety evaluation

No adverse events occurred in the acupuncture group during treatment, indicating that this acupuncture method is relatively safe.

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5. Conclusion

Migraine is classified as "headache" and "head wind" in traditional Chinese medicine. Headache can be divided into 2 types based on causative factors: external contraction and internal damage. "The top part is first attacked in individuals who are affected by wind pathogen," and "only the wind can reach the high top." Wind pathogen is considered the main causative factor for headache, regardless of external contraction or internal damage. The first to be affected by the invasion of wind pathogen is the cutaneous region and then from the exterior to the interior, passing through the meridians into the zang-fu organs. As described in Plain Questions - Cutaneous Region Theory, "if the skin is attacked by the pathogenic qi, the striae and interstices will open, and then, the pathogenic qi will enter the collateral vessels, followed by meridians and zang-fu organs". Hence, the invasion path of pathogenic qi is from the cutaneous region to collateral vessels, meridians and zang-fu organs. The cutaneous region is the most superficial part of the meridian system and is the gateway of pathogenic qi in the body, contacting the body surface with the zang-fu organs, regulating the meridians, and opening and closing the striae and interstices. Therefore, relevant diseases can be treated via the function of the cutaneous region. The shallow puncture and more-twirling acupuncture method is an approach developed by Doctor Chen Lei, a famous Chinese medicine expert in Zhejiang Province, based on the cutaneous region theory. This method evolves from the traditional "skin needling method" and activates the meridian qi in the heaven of "heaven, human, and earth", namely the superficial part of the transport points, creating an itchy or numb sensation on the skin, from local to peripheral positions and even to distal and diseased zang-fu organs, referred to as "qi reaching the lesion". In addition, the shallow puncture method requires puncture of the skin first, the aim of which is to prevent the change in and block the entry and exit of the disease. After the retreating path of pathogenic qi is blocked, healthy qi is obtained, passing through the meridian system to activate the whole body meridian qi and intersect *via* multiple layers of pathways and to dispel the pathogenic qi. A significant wind-dispelling effect is then achieved. The more-twirling method enhances the regulatory effect of shallow puncture on the meridian points, activating blood and moving qi, so as to dispel wind pathogen by moving blood. The combination of these 2 methods can move blood to dispel wind and thus disperse pathogen, thus achieving an analgesic effect in treating migraine. Although the procedure seems simple, the needle should not be removed immediately once inserted. Moving and pushing qi occurs in the rapid twirling after the needle is inserted, thus unblocks meridians and harmonizes qi and the blood. For this reason, a fast and even twirl, the force applied by the needle tip and the maintenance of the needling sensation are crucial. Most doctors believe that the onset of migraine is related to wind, fire, phlegm, stasis and the deficiency of qi and blood, so traditional Chinese medicine treatment mostly adopts the method of dispelling wind, clearing fire, channeling and dissolving phlegm [11,12]. Data analysis [13,14] showed that the selection of migraine acupoints was mainly the Zushaoyang gallbladder meridian points, while Fengchi and Shuaigu were the main acupuncture point combinations. Studies [15] have shown that acupuncture points such as Sizhukong, Shuaigu, Fengchi can reduce intracranial blood flow velocity and improve the pain level of migraine patients.

In this study, patients with migraine were divided into two groups, and the effects of the two groups were compared by using the relevant scoring indicators. The results indicated that the VAS scores and comprehensive headache scores of patients in the acupuncture group markedly improved after treatment compared with before treatment and were superior to those in the control group, further demonstrating the definite clinical efficacy of the shallow puncture and more-twirling acupuncture method for the treatment of migraine. The results of the study are also consistent with relevant reports [16]. Compared with the gastrointestinal and other adverse effects that the drugs may cause, and combined with the research

results, acupuncture for migraine has better clinical efficacy and lighter side effects which are more acceptable to patients.

Currently, there is no consensus on the pathogenesis of migraine, mainly involving the vascular theory, the cortical diffusion inhibition theory and the trigeminal vascular theory [17]. With in-depth research, the roles of 5-HT and β -EP in the pathogenesis of migraine have attracted increasing attention. 5-HT, which is a vital analgesic neurotransmitter and has some vascular activity, is principally distributed in the cerebral cortex and neuro synapses and has effects on nerves and blood vessels. During a migraine attack, the plasma level of 5-HT declines, whereas the level of 5-hydroxyindoleacetic acid (a metabolite of 5-HT) increases. Sumatriptan, amitriptyline and ergotamine are effective in treating migraine by directly or indirectly acting on 5-HT transmitters or receptors. β -EP, an important neurotransmitter of amino acids, is synthesized by the pituitary gland and is identified in the thalamus and pituitary gland. The dysfunction of human neurotransmitters caused by β -EP is reported to occur during migraine. In the case of a reduction in β -EP release, the ability to suppress the cytosolic activity of norepinephrine neurons is diminished, giving rise to the dysregulation of cervical vascular contraction and dilatation, with vascular changes consistent with those seen in patients with migraine in the early stage. Therefore, a growing number of studies have suggested that β -EP can relieve migraine [18].

According to a modern neurological study, the analgesic effect of acupuncture is mainly based on the effect of acupuncture on the nervous system and neurotransmitters [19]. In addition to an increase in the secretion of morphine-like substances in the brain, acupuncture can also facilitate the secretion of 5-HT and β -EP, resulting in the activation of the "midbrain limbic analgesic circuit" and, to a certain extent, control of the dorsal horn of the spinal cord, thus exerting an analgesic effect [20]. Moreover, acupuncture decreases the stimulation of 5-HT receptors on vascular smooth muscle [21], attenuates changes in cerebral vascular dilatation and contraction and relieves vasospasms, thus improving blood supply to the brain and relieving cerebral vasospasms. The results of this trial also indicated that serum 5-HT and β -EP levels in the acupuncture group were higher than those in the control group. As a result, the pain pathways were adjusted to increase the pain threshold and produce morphine-like analgesic effects. Nonetheless, further clinical studies and experiments are still needed to verify the exact mechanism of efficacy. Constrained by time and resources, inevitably there are certain limitations in e study, such as the lack of comparison of the efficacy between "shallow prick and multi-twist" acupuncture technique and ordinary acupuncture, no efficacy evaluation during the intervention process, limited follow-up after the intervention, and limited detection of upstream and downstream substances of relevant serum indicators, etc. We suggest that future research can improve from these areas.

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Conflict of interest

None to report.

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