

Original Article

Analysis of clinical efficacy levels of sibelium combined with acupuncture in the treatment of migraines

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Abstract: Objective: The aim of the current study was to examine the efficacy of Sibelium combined with acupuncture in the treatment of migraines. Methods: A total of 78 migraine patients were randomly divided into the control group and acupuncture group, with 39 cases in each group. Patients in the control group were treated with Sibelium, while patients in the acupuncture group were treated with acupuncture and Sibelium. Efficacy levels of treatments in both groups were analyzed after 2 months of treatment. Results: There were no statistically significant differences in age, weight, family history, and course of disease between the two groups (all $P > 0.05$). The duration of headache attacks in both groups decreased significantly during treatment (both $P < 0.05$). The duration of migraine attacks in the acupuncture group was 1.3 ± 0.2 hours, significantly lower than that in the control group ($P < 0.05$). The frequency of migraine attacks in the control group and acupuncture group decreased significantly during treatment (both $P < 0.05$). The acupuncture group had 2.7 ± 0.2 migraine attacks, significantly lower than that in the control group ($P < 0.05$). Visual analog scale (VAS) scores of both groups decreased significantly after treatment (both $P < 0.05$). VAS scores of the acupuncture group were significantly lower than those of the control group ($P < 0.05$). After treatment, fifteen patients in the acupuncture group were cured. A total of 21 patients showed effective treatment, while 3 patients showed ineffective treatment. Compared with the control group, differences were statistically significant ($P < 0.05$). In terms of concomitant symptoms of migraine attacks during treatment, the number of patients with symptoms, including nausea, vomiting, photophobia, and phonophobia, in the acupuncture group was significantly lower than that in the control group ($P < 0.05$). Conclusion: Sibelium combined with acupuncture can effectively alleviate clinical symptoms of migraine attacks. This method is superior to Sibelium monotherapy in terms of clinical efficacy. Therefore, it is worthy of promotion in clinic practice.

Keywords: Acupuncture, migraines, clinical efficacy

Introduction

Migraine attacks are a disorder caused by the abnormal regulatory function of blood vessels and nerves in the head. Migraine patients often experience periodic and severe headaches. In recent years, incidence rates have shown an upward trend, posing a serious threat to human health and quality of life levels [1]. At present, the pathogenesis of migraines is not clear. It may be related to mental stress, genetics, and hormonal changes, as well as other factors [2]. Calcium channel blockers, steroidal anti-inflammatory drugs, and other chemical drugs have been used to treat migraines. They can relieve headaches experienced by patients. However, they may cause nausea, vomiting, and other adverse reactions [3, 4]. Acupuncture has been

used to treat various kinds of pain, such as dysmenorrhea and gout. It can effectively reduce the frequency and degrees of headaches [5]. Studies have found that the recurrence rate of patients with acute gouty arthritis treated by acupuncture is 2.04%, significantly lower than that of patients treated with allopurinol [6]. The current study compared clinical efficacy levels of Sibelium monotherapy and Sibelium-acupuncture combination therapy in the treatment of migraines, aiming to provide a reference for clinical treatment.

Materials and methods

Patients

A total of 78 migraine patients, treated at Liaocheng People's Hospital, from March 2017

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Table 1. Comparison of general information between the two groups of patients

Group	Control group (n=39)	Acupuncture group (n=39)	t/ χ^2	P
Sex (male/female)	17/22	19/20	0.454	0.650
Age (years)	43.8±5.7	41.6±4.9	1.828	0.072
Course of disease (year)	3.2±0.4	3.3±0.2	1.396	0.168
Family history (n, %)	16 (41.03)	19 (48.72)	0.683	0.495

to May 2018, were randomly divided into the control group and acupuncture group, according to random table method. There were 39 cases in each group. There were 17 males and 22 females in the control group, aged 43.8±5.7 years. There were 19 males and 20 females in the acupuncture group, aged 41.6±4.9 years. All patients provided informed consent. The study was approved by the Ethics Committee of Liaocheng People's Hospital.

Inclusion criteria: Patients examined by cranial Doppler ultrasounds scans, meeting the diagnostic criteria for migraines [7]; Patients receiving acupuncture treatment for migraines for the first time; Patients aged between 18 and 60 years old.

Exclusion criteria: Patients suffering from cardiac, liver, or kidney diseases; Patients that were pregnant or preparing for lactation; Patients with a history of head and neck injuries; Patients with a history of cerebral hemorrhaging, cerebral ischemic disease, hydrocephalus, or intracranial tumors; Patients with a history of hypertension; Patients with a history of mental illness.

Treatment

Patients in the control group were treated with Sibeliem. The dosage of Sibeliem capsules (Xi'an Janssen Pharmaceutical Ltd.) was 5 mg/day for 2 months. Patients in the acupuncture group received Sibeliem plus acupuncture treatment. They were placed in a lateral position and acupuncture points, including Shuaigu, Fengchi, Neiguan, Yongquan, and Taichong, were disinfected with medicinal alcohol. A No. 28 filiform needle (1.5 cun) was inserted into the acupoints at a depth of about 0.8-1 cun, with a retention time of about 50 minutes. They received acupuncture treatment once a day for 2 months.

Observation indexes and efficacy criteria

Age, sex, course of disease, body mass index, and other clinic data of the migraine patients were recorded. Duration and frequency of headache attacks, Visual analog scale (VAS) scores of patients during headache attacks, and concomitant symptoms (including nausea, vomiting, photophobia, phonophobia, fatigue, and weakness) were observed during treatment. Efficacy levels of treatment were divided into 3 categories, including cure, effective, and ineffective. 1) Cure: Patients with no headache attacks within 3 months after treatment; 2) Effective treatment: Headaches significantly improved within 3 months after treatment (shorter duration of headache attacks, fewer headache attacks, and lower VAS scores); and 3) Ineffective treatment: Symptoms showed no improvement or even worsened.

Statistical methods

SPSS 21.0 statistical software was used to analyze test data. Measurement data are expressed as mean ± standard deviation ($\bar{x} \pm sd$). Student's t-tests were used to compare data between groups. Moreover, χ^2 tests were used to compare enumeration data. Mann-Whitney U-tests were used to evaluate clinical efficacy levels of the treatments. $P < 0.05$ indicates statistically significant differences.

Results

Comparison of general information between the two groups

There were no statistically significant differences in age, sex, course of disease, and family history between the two groups (all $P > 0.05$). See **Table 1**.

Comparison of duration of migraine attacks between the two groups during treatment

There were no statistically significant differences in the duration of migraine attacks between the two groups before treatment ($P > 0.05$). The duration of migraine attacks in both groups decreased significantly during treatment (both $P < 0.05$). The duration of migraine attacks for the acupuncture group was 1.3±0.2 hours, sig-

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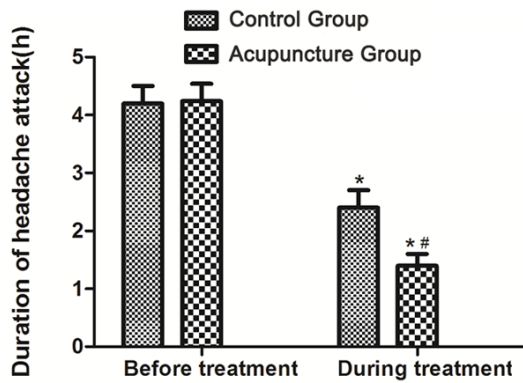


Figure 1. Changes in the duration of headache attacks of the two groups during treatment. Compared with before treatment, * $P < 0.05$; compared with the control group, # $P < 0.05$.

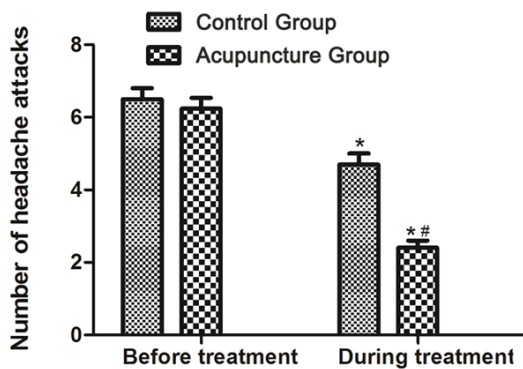


Figure 2. Changes in the number of migraine attacks of the two groups during treatment. Compared with before treatment, * $P < 0.05$; compared with the control group, # $P < 0.05$.

nificantly lower than that for the control group ($P < 0.05$). See **Figure 1**.

Comparison of frequency of migraine attacks between the two groups

There were no statistically significant differences in the frequency of migraine attacks between the two groups before treatment ($P > 0.05$). The frequency of migraine attacks in both groups decreased significantly during treatment (both $P < 0.05$). Patients in the acupuncture group had 2.7 ± 0.2 migraine attacks during treatment, significantly lower than that in the control group ($P < 0.05$). See **Figure 2**.

Comparison of VAS scores between the two groups after treatment

There were no statistically significant differences in VAS scores between the two groups before

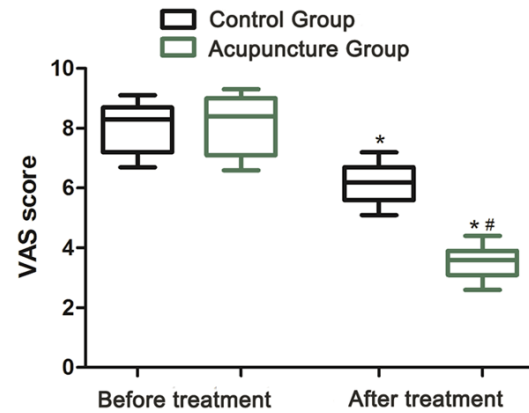


Figure 3. Changes in VAS scores of the two groups after treatment. Compared with before treatment, * $P < 0.05$; compared with the control group, # $P < 0.05$. VAS, visual analogue scale.

treatment ($P > 0.05$). VAS scores of the two groups decreased significantly after treatment (both $P < 0.05$). VAS scores of the acupuncture group were significantly lower than those of the control group ($P < 0.05$). See **Figure 3**.

Comparison of efficacy of treatment between the two groups

patients in the acupuncture group were cured, while 21 patients showed effective treatment and 3 patients showed ineffective treatment. There were significant differences between the two groups ($P < 0.05$). See **Table 2**.

Comparison of concomitant symptoms of migraine attacks during treatment between the two groups

The number of patients experiencing nausea and vomiting in the acupuncture group was significantly lower than that in the control group ($P < 0.05$). The number of patients experiencing photophobia and phonophobia in the acupuncture group was also significantly lower than that in the control group ($P < 0.05$). There were no statistically significant differences in the number of patients experiencing fatigue and weakness between the two groups ($P > 0.05$). See **Table 3**.

Discussion

Migraine attacks, with a complex pathogenesis, have been widely thought to be closely related to vasomotor dysfunction of intracranial blood vessels and blood-brain barrier disruption [8]. Some studies have found that the

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Table 2. Comparison of efficacy of treatment between the two groups (n, %)

Index	Cure	Effective	Ineffective
Control group (n=39)	7 (17.95)	22 (56.41)	10 (25.64)
Acupuncture group (n=39)	15 (38.46)	21 (53.85)	3 (7.69)
U		2.013	
P		0.044	

Note: U stands for Mann-Whitney U-test.

Table 3. Comparison of concomitant symptoms of migraine attacks during treatment between the two groups (n, %)

Index	Nausea and vomiting	Photophobia and phonophobia	Fatigue and weakness
Control group (n=39)	12 (30.77)	10 (25.64)	9 (23.08)
Acupuncture group (n=39)	4 (10.26)	3 (7.69)	5 (12.82)
χ^2	2.243	2.217	1.180
P	0.025	0.033	0.238

degree of pain experienced by migraine patients is related to the vasomotion of intracranial blood vessels. Most patients have a narrowed vascular lumen, disturbing normal blood circulation [9]. Some studies have shown that abnormal secretion of serotonin, prostaglandin, and bradykinin may cause an increase of calcium levels in vascular smooth muscle cells. This stimulates abnormal contraction or relaxation of muscles surrounding the intracranial blood vessels, eventually leading to headaches [10]. Anti-serotonin agents, analgesics, and hyperbaric oxygen therapy have been used to treat migraines in Western medicine. However, these treatments have obvious side effects and can place patients at a high risk of delayed recovery or recurrence. Therefore, further improvements are necessary [11]. Some studies have demonstrated that the use of methadone as an analgesic can relieve pain felt by migraine patients. However, most patients are prone to drug dependence and relapse [12]. Acupuncture therapy, based on the theories of Traditional Chinese Medicine, is a means of treating migraine patients by stimulating specific acupoints with very thin needles. It is easy to perform and causes less damage to the bodies of patients [13]. Therefore, treatment of migraines by acupuncture is worthy of discussion.

Recurrent migraine attacks can have a serious impact on the daily lives of patients. Sibeliem is

commonly used in the treatment of migraines. It is a calcium channel blocker, which can specifically recognize and combine calcium channels in vascular smooth muscle cells. Thus, it can regulate transmembrane influx of calcium ions and inhibit platelet aggregation and serotonin release, achieving analgesic effects [14]. Some studies have found that Sibeliem can reduce levels of calcium ions in vascular smooth muscle cells and alleviate the headaches of patients. However, it has a high recurrence rate and a high incidence of adverse reactions, including vomiting and drowsiness [15]. Acupuncture mainly stimulates the body

through acupoints, regulating and improving the Qi and blood circulation. This helps to achieve the purpose of treating diseases [16]. The current study found that the duration of migraine attacks, VAS scores, and the frequency of migraine attacks in the control group decreased significantly after Sibeliem treatment, in accord with previous studies [17]. During treatment, the duration of migraine attacks in the acupuncture group was 1.3 ± 0.2 hours and the frequency of migraine attacks was 2.7 ± 0.2 times, significantly lower than levels in the control group. Results suggest that acupuncture can effectively ease patient pain. Some studies have found that acupuncture can effectively relieve pain caused by migraines, knee osteoarthritis, fibromyalgia, and other diseases [18]. Present results are consistent with the above findings.

Fifteen patients in the acupuncture group were cured, while 21 patients showed effective treatment and 3 patients showed ineffective treatment. Clinical efficacy levels of acupuncture treatment showed better results than those of Sibeliem monotherapy. Acupuncture is a Traditional Chinese Medicine treatment, which has been proved to provide good therapeutic effects for migraines, lumbar vertebrae hyperosteoegeny, and lumbar muscle strains in clinical practice [19]. The current study compared the concomitant symptoms of migraine attacks during treatment. It was found that the number

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of patients experiencing nausea, vomiting, photophobia, and phonophobia in the acupuncture group was significantly lower than that in the control group. Some studies have found that acupuncture can significantly reduce incidence rates of malignant vomiting and photophobia in patients with cervicogenic headaches [20, 21]. These results are consistent with present findings.

There were limitations to the current study. The number of patients in this study was small. Thus, the evaluation of clinical efficacy levels may have been affected by the subjective feelings of patients. This may have had a certain impact on the reliability of present results. Therefore, the mechanisms of acupuncture in the treatment of migraines require further investigation.

In conclusion, acupuncture can improve clinical efficacy levels of treatments for migraine patients and reduce incidence rates of adverse reactions. Therefore, it is worthy of promotion in clinical practice.

Disclosure of conflict of interest

None.

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