

Case Studies on Acupuncture Principles in Headaches

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Abstract

Objective: This observational cohort pilot study aimed to evaluate the effects of the acupuncture methods, Jiu Cang Zhen (JCZ) and Huang Guan (HG), on changes in headache intensity in an inpatient, multimodal Zuzach Headache Programme (ZHP). **Methods:** Study participants consisted of patients diagnosed with chronic headache disorder (headache ds, 30 days per month) or daily persistent headache. All patients received conventional therapies with active and passive approaches. The patient group was treated with JCZ and HG acupuncture methods, receiving a total of six to eight acupuncture sessions of 50 to 60 minutes each, during a 3–4-week multimodal ZHP at the RehaClinic Bad Zuzach. Pain intensity was quantified using a Numerical Rating Scale (NRS) before and after each acupuncture therapy session. **Results:** Ten patients were recruited, six women and four men, with a mean age of 41.7 (standard deviation, [SD] = 13.9). A reduction in headache intensity was reported by all patients in each of the sessions. The average NRS for pain was 4.21 (SD = 1.44) before acupuncture and 1.24 (SD = 0.93) after acupuncture (means first by number of sessions, then per $n = 10$ patients). This resulted in a mean difference of 2.97 (SD = 1.04), corresponding to a standardized response mean of 2.85 (95% confidence interval: 2.11–3.60, one-tailed $P < 0.001$), meaning there was a large effect. **Conclusions:** This pilot study shows that JCZ and HG are suitable acupuncture methods for reducing headache intensity in the treatment of headaches. A comparison with the conventional classical acupuncture methods from the acupuncture textbook for traditional Chinese medicine students in China, exploration with a larger patient group, and prolonged monitoring of pain behavior could be foci of follow-up investigations.

Keywords: Acupuncture, headache, migraine, medication-overuse headache, neurology

Introduction

Headaches are complex neurological disorders based, in most cases, on a disturbance of pain perception in the central pain matrix. The current International Classification of Headache Disorders (ICHD-3) distinguishes more than 300 types of headaches,^[1] of which migraines and cluster headaches are the most important primary types in clinical contexts, with headaches from medication overuse (MOH) being the most important secondary type.

Acupuncture is a complementary therapy used to treat headaches,^[2] migraine,^[3] and even to prevent episodic^[4] and chronic migraines.^[5] A nonpharmacological therapeutic approach, acupuncture, can often have an analgesic or pain-relieving effect.^[6,7]

Nowadays, traditional Chinese acupuncture methods are continuously being refined. Two such methods used in the treatment of headache disorders (HD) in the Zuzach Headache Programme (ZHP) are Jiu Cang Zhen (九藏针 Nine Depot Acupuncture) and Huang Guan (HG).

Jiu Cang Zhen

The basic concept of the Jiu Cang Zhen (JCZ) acupuncture method originated from *Huang Di Nei Jing* (《黄帝内经》 *Huangdi's Internal Classic*). The theory is described in *Su Wen* “San Bu Jiu Hou Lun” (《素问·三部九候论》 *Basic Question* “Discourse on the Three Sections and Nine Indicators”).^[8]

The theory depicts the human body as sectioned into three parts: upper, middle, and lower. The qi channels originate

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endogenously from these three sections. Each section contains three indicators heaven, earth, and man which are found in all sections. Three indicators from heaven, three from the earth, and three from man result in nine indicators.^[9]

All examinations to determine the health status of a patient are based on these sections. As for treatment, acupuncture is performed on these sections to eliminate diseases and to obtain a balanced harmony in the human body.^[9]

The middle section (abdomen) is selected in JCZ. The umbilicus is the center of the JCZ acupuncture method and the starting point for the selection of the acupuncture points.^[8] The selection of the radius varies on the analysis of the patient's health. A greater effect is achieved by narrowing the radius.

In traditional Chinese medicine (TCM), the syndromes are differentiated by investigating and evaluating the evidence accumulated from the four TCM diagnostic methods (inspection, listening-smelling, inquiry, and pulse-taking) in order to identify the nature of the individual's condition and specify the syndrome (e.g., syndrome differentiation between cold and heat or between asthenia and sthenia). For TCM sthenia (i.e., excess) syndromes, a narrower radius is set in the JCZ acupuncture method, whereas for TCM asthenia (i.e. deficiency) syndromes, a wider radius is set. JCZ can be applied in gastrointestinal, gynecological, and neurological diseases.^[8]

Huang Guan

In TCM, cold is categorized as yin and heat as yang. There are five lines located on the head. Each of these lines contains five acupuncture points which disperse heat in all yang qi channels that flow in reverse (热逆).^[10] This topic is discussed in *Su Wen* "Shui Re Xue Lun" (《素问·水热穴论》 *Basic Questions* "Discourse on Holes to Treat Water and Heat") of *Huangdi's Internal Classic*.^[10]

In the case of long-term obstruction of the circulation of the upward flowing yangqi, the qi is converted into heat, which accumulates in the head area, and symptoms such as insomnia and/or headache occur. The HG acupuncture method (Imperial Crown), which eliminates heat, is based on the theory of piercing heat (热刺).^[8] Simplified, it is known as the acupuncture treatment of heat disease.

The classification and diagnosis of headaches in TCM follows the order of meridians, organ systems, and pathogenesis. By meridian: Yang Ming (frontal), Shao Yang (temporal), Tai Yang (occipital), and Jue Ying (parietal) headaches. By organ system: liver, kidney, and spleen. By pathogenesis: wind, cold, heat, dampness, qi and blood insufficiency, phlegm retention, blood congestion, and improper diet.

In the ZHP, acupuncture is used alongside other evidence-based therapeutic elements.^[11] This multimodal pain management

program is aimed especially at patients suffering headaches from MOH and/or chronic migraines. Administered under neurological medical supervision, it comprises the following therapeutic elements: psychoeducation and behavioral therapy, physiotherapy, endurance training, relaxation therapies, and manual therapies, as well as acupuncture.^[11]

Clinical experience in the application of JCZ and HG in the ZHP over 3 years of observation and implementation has shown that these two acupuncture methods showed larger effects in the treatment of headaches in comparison to other methods described in the acupuncture textbook for TCM students in China.^[12] Those classical approaches needle the following acupuncture points:

- Yang Ming headache: Yin Tang (EX-HN 3), Shang Xing (GV 23), Yang Bai (GB 14), Zan Zhu (BL 2) penetrating Yu Yao (Ex-HN 4) and Si Zhu Kong (TE 23), He Gu (LI 4), and Nei Ting (ST 44).
- Shao Yang headache: Tai Yang (EX-HN 5), Si Zhu Kong (TE 23), Jiao Sun (TE 20), Shuai Gu (GB 8), Feng Chi (GB 20), Wai Guan (TE 5), and Zu Lin Qi (GB 41).
- Tai Yang headache: Tian Zhu (BL 10), Feng Chi (GB 20), Hou Xi (SI 3), Shen Mai (BL 62), and Kun Lun (BL 60).
- Jue Yin headache: Bai Hui (GV 20), Tong Tian (BL 7), Tai Chong (LR 3), Xing Jian (LR 2), Tai Xi (KI 3), and Yong Quan (KI 1).
- Global headache: Bai Hui (GV 20), Yin Tang (Ex-HN 3), Tai Yang (EX-HN 5), Tou Wei (ST 8), Yang Bai (GB 14), He Gu (LI 4), Feng Chi (GB 20), and Wai Guan (TE 5).^[13]

Meridian and numeric codes are presented according to the standard acupuncture nomenclature published by the World Health Organization.^[13]

Aim

The aim of this observational cohort pilot study was to quantify acute changes in pain intensity in headache patients after the application of JCZ and HG acupuncture treatments. The hypothesis was that the pain would be reduced after each intervention.

Methods

Search strategy

Online research of databases such as PubMed, Cochrane Library, and AcuTrials using keywords such as acupuncture, headache, chronic tension-type headache, migraine, medication-overuse headache, Jiu Cang Zhen, and Huang Guan yielded no results.

Patients

Subjects in this pilot study were treated with the JCZ and HG acupuncture methods and participated in a 3–4-week, inpatient, multimodal ZHP at the RehaClinic Bad Zurzach. Inclusion criteria were as follows: suffering from chronic

headaches according to ICHD-3 (chronic migraine, MOH), i.e., occurring 15 d/month or more, willingness to participate, and sufficient language skills. The exclusion criteria were as follows: terminal illness, unwillingness to participate, and insufficient language skills.

The study was approved by the Ethics Committee of Aarau, Canton Aargau, Switzerland (EK AG 2008/026). Written, informed consent was obtained from all study participants.

Intervention

Two acupuncture sessions of 50 to 60 min each were administered per week for 3 to 4 weeks. All patients underwent, in total, six to eight acupuncture sessions with JCZ and HG methods. The patients were lying in a supine position during the acupuncture treatment. Sterile disposable 0.25 mm × 40 mm and 0.25 mm × 25 mm stainless-steel needles manufactured by asia-med GmbH (Pullach, Germany) were used for the treatment.

JCZ was applied first. Eight follow-up points were selected on the outer radius of Tian Shu (ST-25). These eight acupuncture needles were set toward the center, and four acupuncture needles in the inner radius were set toward the outer radius. The angle of the acupuncture technique was 45° [Figure 1].

After 25 to 30 min, the needles on the abdomen were removed. Subsequently, the HG method was applied on the forehead for another 25 to 30 min. The selected acupuncture points for the HG method were Shen Ting (GV 24), Tou Lin Qi (GB 15), and Tou Wei (ST 8). Five acupuncture needles were inserted horizontally (<15°) [Figure 2].

Measures

The documentation was carried out by means of a pain questionnaire with a numerical rating scale (NRS; 0 = no pain to 10 = the worst imaginable pain).^[14] Patients were requested

to indicate the intensity of their pain on the NRS before and immediately after each of the acupuncture sessions.

Analysis

Anonymized data were analyzed using IBM SPSS Statistics 25 for Windows (IBM Corp., Armonk, NY, USA). Descriptive data were presented as mean and standard deviation (SD) and compared by the *t*-test for paired samples. An alpha level of $\alpha = 0.05$ (5%) was used to evaluate the significance of the test results. The standardized response mean (SRM) = mean of the differences (pre-post)/SD of the differences was calculated to express the differences as effect sizes.^[15,16] To condense the SRMs of the patients with multiple sessions, the calculation rules of independently distributed variables were applied.^[17] The same was analogously done for the sessions with multiple patients. By using the *t* (*n* - 1) value of the *t*-distribution, the 95% confidence interval (CI) was calculated for the SRM. SRMs ≥ 0.80 were considered large effects.^[15,16]

As a *priori* calculation of the sample size necessary to carry out the research, a paired sample *t*-test was made using the G*Power computer program.^[18] Based on the work of Salaffi *et al.*, an SRM = 1.20 was required to achieve minimal clinically important differences for the NRS.^[19] This effect size follows from the recommendation to use a reduction in pain by 2 points on the 0–10 NRS as the cutoff value for a clinically important outcome, divided by the upper bound SD reported in Salaffi *et al.*^[19] Using a significance level of $\alpha = 0.05$ and a target power of $1 - \beta = 0.95$, a necessary sample size of 10 patients was calculated.

Results

Six women and four men were included in the study, with the diagnoses listed in Table 1. The mean age was 41.7 years (SD = 13.9, range: 18–61 years). Of the ten patients,

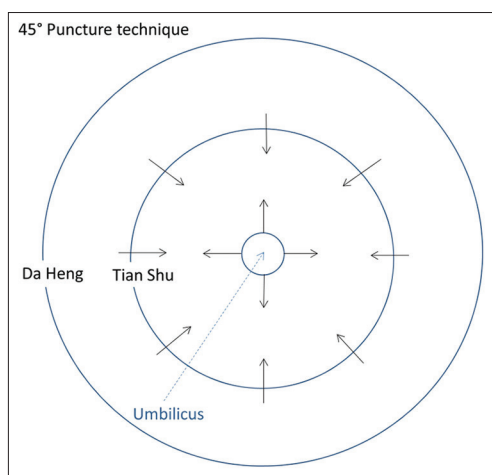


Figure 1 Schematic diagram of the puncture technique 45° and puncture site in Jiu Cang Zhen. Modified to Zhu YZ^[6]

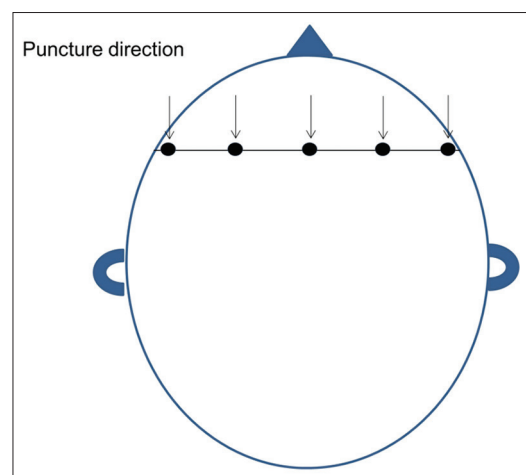


Figure 2 Schematic diagram of the puncture direction and puncture site in Huang Guan. Modified to Zhy YZ^[6]

two received eight therapeutic applications, two received seven therapeutic applications, and the remaining six received six applications of the JCZ and HG acupuncture methods [Tables 2 and 3].

After each acupuncture session, all ten patients reported a significant reduction in pain intensity after the application of the JCZ and HG acupuncture methods [Table 2]. The intra-individual SRMs ranged from 2.04 to 8.29. Before the treatment, patients indicated a mean degree of pain of 4.21, falling to a mean of 1.24 after the treatment, which resulted in an overall mean difference of 2.97 (SD = 1.04), SRM = 2.85 (95%-CI: 2.11–3.60, one-tailed $P < 0.001$).

The headache reduction per therapeutic unit was then analyzed across all patients per session. The intra-session SRMs ranged from 1.61 to 2.84. Before the treatment, patients indicated a mean degree of pain of $m = 3.93$, falling to a mean of 1.14 after the treatment, which resulted in an overall mean difference of

2.78 (SD = 1.31), SRM = 2.13 (95%-CI: 1.04–3.22, one-tailed $P < 0.035$). No inferential statistical test could be carried out for the eighth therapeutic unit since only two patients received it. Neither side effects nor acupuncture intolerance was observed for any of the patients.

Discussion

In this pilot study, very large short-term pain reductions were observed overall patients (SRM=2.97) and all sessions (SRM=2.78) after the application of JCZ and HG acupuncture techniques. The size of those effects may be clinically relevant because SRMs ≥ 0.50 are very likely to be subjectively perceived by the patients.^[15] However, Salaffi *et al.* advised to only consider a pain reduction of at least 2 points on a 0–10 NRS as clinically relevant. With respect to the upper bound SD reported in the referenced research, a SRM higher than 1.20 was interpreted as a large effect for this study.

The study's hypothesis that the subjectively perceived headaches are less severe after the application of the JCZ and HG acupuncture therapy has been confirmed. Both the analysis of differences in pain intensity per patient across therapeutic applications and the analysis of the individual therapeutic units across all patients showed an acute significant reduction of headaches after the application of the JCZ and HG acupuncture methods.

Daily observation, patient interviews, and their spontaneous feedback over the course of a year led to the conclusion that the implementation of the two acupuncture methods had a substantially bigger effect on the diminution of headaches in comparison to individually customized TCM treatments, according to the TCM syndrome differentiation mentioned above. However, which of the two methods achieved the best effect could not be evaluated because they were administered together.

Table 1 Patients and diagnoses

Sex	Diagnosis	ICHD-3
Female	State after meningoencephalitis of unclear etiology 3/2016 with chronic headache	9.1
Male	Medication-overuse headache	8.2
Female	Chronic migraine	1.3
Female	Medication-overuse headache	8.2
Male	Persistent headache attributed to craniotomy, intraventricular central neurocytoma (WHO Grade II), craniotomy, transcallosal resection, January 29, 2018	5.6
Female	Chronic migraine	1.3
Male	Chronic migraine	1.3
Female	Medication-overuse headache	8.2
Male	New daily persistent headache	4.10
Female	Persistent headache attributed to traumatic injury to the head	5.2

ICHD: international classification of headache disorders; WHO: World Health Organization.

Table 2 Results of pain intensity assessment using the numerical rating scale for patients with headache disorder before (pre) and after (post) acupuncture treatments by patient

Patient No.	n	Pre-treatment		Post-treatment		Difference		SRM
		Arithmetic mean	SD	Arithmetic mean	SD	Arithmetic mean	SD	
1	7	2.71	1.25	0.57	0.53	2.14	0.90	2.38
2	8	5.88	1.64	2.75	1.28	3.13	0.84	3.74
3	6	8.00	1.79	5.50	2.07	2.50	0.55	4.56
4	7	6.57	0.79	2.14	1.07	4.43	0.53	8.29
5	6	3.33	1.03	0.00	0.00	3.33	1.03	3.23
6	6	3.67	1.63	0.67	0.82	3.00	1.26	2.37
7	6	3.67	1.63	0.50	0.55	3.17	1.17	2.71
8	6	4.33	2.34	0.17	0.41	4.17	2.02	2.04
9	6	2.33	0.52	0.00	0.00	2.33	0.52	4.52
10	8	1.63	0.74	0.13	0.35	1.50	0.54	2.81
Total		4.21	1.44	1.24	0.93	2.97	1.04	2.85

n: Number of sessions; SD: Standard deviation; SRM: Standardized response mean.

Table 3 Results of pain intensity assessment using the numerical rating scale for patients with headache disorder before (pre) and after (post) acupuncture treatments by therapy session

Session	n	Pre-treatment		Post-treatment		Difference		SRM
		Arithmetic mean	SD	Arithmetic mean	SD	Arithmetic mean	SD	
1	10	4.90	2.51	1.70	2.31	3.20	1.14	2.81
2	10	4.10	2.23	1.20	1.99	2.90	1.10	2.64
3	10	4.00	2.50	1.30	2.26	2.70	0.95	2.84
4	10	4.60	2.83	1.40	2.31	3.20	1.48	2.16
5	10	4.10	2.42	1.20	1.31	2.90	1.66	1.75
6	10	4.20	2.04	1.10	1.60	3.10	1.37	2.26
7	6	3.50	2.38	0.75	0.96	2.75	1.71	1.61
8	2	2.00	1.41	0.50	0.70	1.50	-	-
Total		3.93	0.88	1.14	0.37	2.78	1.31	2.13

-Insufficient number of patients at the 8th time point to calculate a SD. n: number of patients; SD: standard deviation; SRM: standardized response mean.

In traditional Chinese migraine point acupuncture, the acute effects of ear acupuncture were lower than ours immediately after treatment.^[20] SRM=1.35 after traditional Chinese migraine point acupuncture ($n = 30$) versus SRM = 0.42 after “inappropriate” points, i.e. stomach and spleen points ($n = 30$). Pain relief increased comparably close to the Visual Analogue Scale=zero in the period up to 4 h after acupuncture for both methods.^[20] In secondary, postinjury chronic headache, traditional Chinese acupuncture versus usual care ($n = 11$ vs. $n = 8$) attained a standardized mean difference (SMD) =1.54, and ear acupuncture versus usual care attained ($n = 12$ vs. $n = 8$) SMD = 1.25 on NRS pain.^[21]

In the present study, observed effects were considerably above 1.00, which was estimated as the minimal clinically important difference and statistically significant above zero (no effect).^[19] Salaffi *et al.* examined which is the smallest clinically important pain reduction on the 0 to 10 cm NRS. The study was carried out in connection to chronic, musculoskeletal pain in 825 patients. The results showed that a reduction of 1 cm (1 point) on the NRS between pre- and post-intervention was equivalent to patients feeling “slightly better” after the intervention. A pain reduction of 2 cm (2 points) on the NRS between pre- and post-intervention was equivalent to patients indicating they felt “much better.”^[19]

The most significant limitation of this study is that the comparison to a control of the verum by a sham and/or placebo intervention was not performed. However, the use of sham acupuncture points on the head and the corpus is problematic, since there are very many acupuncture points in close proximity to one another on the head and on the body. These are not only the classical acupuncture points on the head but also entire zones used in other techniques such as Yamamoto New Scalp Acupuncture^[22] and Zhu’s Scalp Acupuncture.^[23] Therefore, it is not possible to clearly differentiate between traditional acupuncture points and nontraditional acupuncture points in terms of TCM. Ots *et al.*

provided some evidence that the selection of dermatomes for sham acupuncture points is relevant for the outcome of acupuncture trials and studies.^[24]

A further limitation of this study is the small number of patients.

Conclusions

The two acupuncture techniques, JCZ and HG, were well tolerated, and the pain intensity of the headaches was significantly diminished after each treatment session.

Subsequent follow-up studies with larger patient groups are needed, which could provide further results to support the use of these two acupuncture techniques, JCZ and HG, which could then be considered standard in the treatment of different headache disorders. Of course, evidence of the effects on pain relief has to be replicated and evaluated for a long-term.

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Patient consent

Written informed consents were obtained from all patients.

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Authors' contributions

Saroj Kumar Pradhan, Susanne Lehmann, and Felix Angst put forward the concept and designed this paper. Saroj Kumar Pradhan and Felix Angst analyzed the data. Saroj Kumar Pradhan, Felix Angst, Andreas Rudolf Gantenbein, Sebastian Frese, and Yi-Ming Li interpreted the results. Sebastian Frese, Susanne Lehmann, Andreas Rudolf Gantenbein, Yi-Ming Li, Felix Angst and Saroj Kumar Pradhan revised the manuscript.

Felix Angst, Andreas Rudolf Gantenbein, and Yi-Ming Li supervised this paper. All authors reviewed the manuscript and approved the final version for publication.

Ethical approval

This pilot study was approved by the Ethical Committee Aarau, Switzerland (EK AG 2008/026).

Advance: Additional Data for VALidation aNd Clinical Evaluation. Erhebung von Zusatzdaten zur Validierung und klinischen Evaluation.

Conflicts of interest

None.

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