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Original Article

Disease-Related Factors Associated with Acupuncture Response in Patients with Chronic Tension-Type Headache: A Secondary Analysis of A Randomized Controlled Trial*

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ABSTRACT **Objective**: To explore the demographic and disease-related factors associated with acupuncture response in patients with chronic tension-type headache (CTTH). **Methods**: Using data from the randomized clinical trial (218 cases) consisting of 4 weeks of baseline assessment, 8 weeks of treatment, and 24 weeks of follow-up, participants were regrouped into responders (at least a 50% reduction in monthly headache days at week 16 compared with baseline) and non-responders. Twenty-three demographic and disease-related factors associated with acupuncture response in 183 participants were analyzed by multivariable logistic regression. **Results**: One hundred and nineteen (65.0%) participants were classified as responders. Four factors were significantly independently associated with acupuncture response, including treatment assignment, headache intensity at baseline, and 2 domains [general health (GH) and social functioning (SF)] from the 36-Item Short Form Health Survey quality of life questionnaire. Treatment assignment was associated with non-response: participants receiving true acupuncture were 3-time more likely to achieve a CTTH response than those receiving superficial acupuncture [odds ratio (OR) 0.322, 95% confidence interval (CI) 0.162 to 0.625, *P*=0.001]. Compared with patients with mild-intensity headache, patients with moderate-intensity headache were twice as likely to respond to acupuncture (OR 2.001, 95% CI 1.020 to 4.011, *P*=0.046). The likelihood of non-response increased by 4.5% with each unit increase in the GH grade (OR 0.955, 95% CI 0.917 to 0.993, *P*=0.024) while decreased by 3.8% with each unit increase in the SF grade (OR 1.038, 95% CI 1.009 to 1.069, *P*=0.011). **Conclusions**: Greater headache intensity, lower GH score, and higher SF score were associated with better acupuncture responses in CTTH patients. These 3 factors require independent validation as predictors of acupuncture effectiveness in CTTH.

KEYWORDS acupuncture, chronic tension-type headache, logistic regression, quality of life, Chinese medicine

Tension-type headache (TTH) is the most commonly seen primary headache in clinical practice. TTH occurs at any age and affects 38% of the global population.[1] Chronic TTH (CTTH) is defined when TTH occurs more than 15 times per month, and CTTH has a lifetime prevalence of 30%–78%.[2,3] Patients with TTH often present with mild-to-moderate intensity dull, pressing, or tight headaches that do not generally worsen with daily activities but may be accompanied by photophobia or phonophobia.[3] Frequent repeated headaches make CTTH patients suffer from mental anxiety, depression, and insomnia, which seriously affect their daily lives.[4-6]

The value of acupuncture as an effective treatment for headache is increasingly recognized, and numerous clinical trials[7-9] and systematic reviews[10,11] have shown that acupuncture significantly decreased the number of headache days, headache intensity, 36-Item Short Form Health Survey (SF-36) quality of life scores, and medication used in patients with CTTH. Our previous study demonstrated the effectiveness of 8-week acupuncture treatment for the

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prevention of CTTH.[12] However, the clinical effect of acupuncture is not only affected by specific factors, but also by non-specific factors, such as patient's general health, psychological status, and circumstances.[13,14] Therefore, the influence of these factors on the effect of acupuncture for CTTH must be taken into account. It has been shown that acupuncture is more effective in patients with chronic pain who live with other people, have experienced other treatment failures, and have a history of effective acupuncture treatment.[15] The mode of acupuncture stimulation, duration of needle retention, and frequency of treatment have also been shown to be important factors affecting acupuncture effect for TTH.[16] However, the effect of disease and patient factors on acupuncture effect in CTTH are unknown.

Therefore, here we performed a secondary analysis of a preliminary randomized controlled trial (RCT) to explore the impacts of different dimensions of the disease state, patient's psychological status, and quality of life on acupuncture effect in CTTH patients.

METHODS

Overview of Original Trial

A detailed protocol of the RCT was reported previously.[12] Briefly, the trial was a parallel design, patient- and assessor-blinded RCT conducted at the Teaching Hospital of Chengdu University of Traditional Chinese Medicine from June 1, 2017 to September 10, 2020. In the trial, patients received 4 weeks of baseline assessment (before randomization, week –4 to week 0), 8 weeks of treatment (week 1 to week 8), and 24 weeks of follow-up (week 9 to week 32). A total of 1,230 potential candidates were screened, of whom 218 subjects were included, 110 in the true acupuncture (TA) group and 108 in the superficial acupuncture (SA) group. The primary outcome was the proportion of participants with at least a 50% reduction in monthly headache days at week 16. Secondary outcomes included the number of monthly headache days, headache intensity, use of medication to relieve headache symptoms, and safety outcome. The Regional Institutional Review Board of Trials for Traditional Chinese Medicine in Sichuan Province reviewed the protocol, which also conformed to the Helsinki declaration. Every participant was well informed and signed an informed consent form, and the trial was registered on clinicaltrials.gov (No. NCT03133884).

Secondary Analysis Design

To explore factors related to acupuncture effectiveness for treatment of CTTH, the TA and SA data were re-analyzed, and patients with no less than 50% of the total number of planned treatments were included in the analysis. The monthly headache days at week 16 were compared with those at week 0, and those with a reduction of ⩾50% were defined as the "response group" and those with <50% reduction were defined as the "non-response group".

In this analysis, we hypothesized that the baseline characteristics of participants may be associated with acupuncture response. The following factors from the baseline period were included in the analysis: (1) demographic data [sex, body mass index (BMI), ethnicity, marital status, income level, education degree level]; (2) history of chronic headache (disease course, auras, headache location, headache features, mean duration of headache, accompanying symptoms, headache remission); (3) history of headache over 4-week baseline [monthly headache days, headache intensity, mean Visual Analog Scale score, mean headache duration, number of accompanying symptoms, medication to relieve acute headache symptoms]; (4) SF-36 score [including physical functioning, role-physical, role-emotional, health transition, general health (GH), vitality, social functioning (SF), mental health, and bodily pain domains]; (5) Hamilton Anxiety Scale (HAMA) score, and (6) Hamilton Depression Scale (HAMD) score. In addition, considering that treatment assignment could impact the results, so it was also included in the model.

Statistical Analysis

R software (v4.1.0, https://www.r-project.org/) was used for statistical analysis. Univariable comparisons of demographic and disease-related factors between the response and non-response groups were performed using the compareGroups package. Qualitative variables are expressed as counts and percentages and were compared using the Chi-squared test or Fisher's exact test. Quantitative variables are described as mean ± standard deviation ($\bar{x} \pm s$) or medians with interquartile ranges (IQRs). Normally distributed and non-normally distributed quantitative variables were compared using Student's *t*-test and the Mann-Whitney U test, respectively. In the univariable analysis, variables significant at the 0.25 level were selected as candidates for multivariate logistic regression.[17] Before

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performing logistic regression analysis, the variance inflation factor (VIF) was used to detect multicollinearity between independent variables. Then the candidate variables were used in multivariable logistic regression analysis using the glm function of the AER package to identify independent risk factors after adjusting for potential confounders. *P*-values <0.05 were considered statistically significant.

RESULTS

Univariable Analysis

The 23 demographic and disease-related factors in responders are shown in Table 1. A total of 183 participants were analyzed, of whom 119 (65.0%) were classified as responders. Among them, 74 participants (62.2%) were from the TA group and 45 (37.8%) were from the SA group. The univariable analysis indicated that treatment assignment, monthly headache days, and SF were related to acupuncture response (*P*<0.05). Moreover, preliminary analyses showed 20 factors, such as sex, BMI, ethnicity, marital status, income level, course of disease, accompanying symptoms, HAMA, HAMD, etc., were not significant (*P*>0.05).

Logistic Regression

After univariable analyses, 7 factors, including treatment assignment, feature of headache, monthly headache days at baseline, headache intensity at baseline, mean duration of headache at baseline, GH, and SF, were identified for subsequent logistic regression with backward elimination, which revealed 4 factors significantly associated with acupuncture response, i.e. treatment assignment, headache intensity at baseline, and 2 domains of SF-36 (GH and SF, *P*<0.05, Table 2). Treatment assignment was associated with non-response: participants receiving TA were 3-time more likely to achieve a CTTH response than those receiving SA (OR 0.322, 95% CI 0.162 to 0.625, *P*=0.001). The odds of acupuncture response in patients with moderate-intensity headache

Table 1. Demographic and Disease-Related Factors of Acupuncture Response in Patients with CTTH [Case (%)]

Variable	All (183 cases)	Non-response group (64 cases)	Response group (119 cases)	OR	95% CI	*P*-value
Treatment assignment						0.001
True acupuncture	97 (53.0)	23 (35.9)	74 (62.2)	Ref.	Ref.	
Superficial acupuncture	86 (47.0)	41 (64.1)	45 (37.8)	0.34	0.18 to 0.64	
Demographic characteristics						
Sex						0.339
Male	48 (26.2)	20 (31.2)	28 (23.5)	Ref.	Ref.	
Female	135 (73.8)	44 (68.8)	91 (76.5)	1.48	0.74 to 2.91	
BMI [kg/m^2, $\bar{x} \pm s$]	22.40 ± 2.96	22.60 ± 2.74	22.30 ± 3.08	0.97	0.87 to 1.07	0.483
Ethnicity						1.000
Minority	5 (2.7)	2 (3.1)	3 (2.5)	Ref.	Ref.	
Han	178 (97.3)	62 (96.9)	116 (97.5)	1.27	0.14 to 8.58	
Marital status						0.678
Married	153 (83.6)	55 (85.9)	98 (82.4)	Ref.	Ref.	
Unmarried	30 (16.4)	9 (14.1)	21 (17.6)	1.30	0.57 to 3.19	
Income level						0.444
≤6500	139 (76.0)	46 (71.9)	93 (78.2)	Ref.	Ref.	
>6500	44 (24.0)	18 (28.1)	26 (21.8)	0.71	0.36 to 1.46	
Education background						
Not highly educated	106 (57.9)	36 (56.2)	70 (58.8)	Ref.	Ref.	
Highly educated	77 (42.1)	28 (43.8)	49 (41.2)	0.90	0.49 to 1.67	
Clinical features of disease						
Course of disease [Year, median (IQR 25–75)]	9.0 [3.0, 15.2]	8.7 [2.4, 15.0]	9.0 [3.5, 16.0]	1.00	0.98 to 1.03	0.623
Aura						0.778
No	151 (82.5)	54 (84.4)	97 (81.5)	Ref.	Ref.	

(To Be Continued)

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Variable	All (183 cases)	Non-response group (64 cases)	Response group (119 cases)	OR	95% CI	*P*-value
Yes	32 (17.5)	10 (15.6)	22 (18.5)	1.21	0.54 to 2.88	
Location of headache						0.936
Fixed	145 (79.2)	50 (78.1)	95 (79.8)	Ref.	Ref.	
Unfixed	38 (20.8)	14 (21.9)	24 (20.2)	0.90	0.43 to 1.94	
Feature of headache						0.120
Throbbing	39 (21.3)	9 (14.1)	30 (25.2)	Ref.	Ref.	
Swelling	105 (57.4)	39 (60.9)	66 (55.5)	0.51	0.21 to 1.17	
Crushing	32 (17.5)	15 (23.4)	17 (14.3)	0.35	0.12 to 0.96	
Others	7 (3.8)	1 (1.6)	6 (5.0)	1.62	0.22 to 46.1	
Mean duration of headache						0.990
≤4 h	53 (29.0)	18 (28.1)	35 (29.4)	Ref.	Ref.	
>4 h	130 (71.0)	46 (71.9)	84 (70.6)	0.94	0.47 to 1.84	
Accompanying symptoms						0.586
No	108 (59.0)	40 (62.5)	68 (57.1)	Ref.	Ref.	
Yes	75 (41.0)	24 (37.5)	51 (42.9)	1.25	0.67 to 2.35	
Remission of headache						1.000
Remission on medication	82 (44.8)	29 (45.3)	53 (44.5)	Ref.	Ref.	
Spontaneous remission	101 (55.2)	35 (54.7)	66 (55.5)	1.03	0.56 to 1.91	
Disease status at 4-week baseline						
Monthly headache days [Median (IQR 25–75)]	23.0 [15.0, 28.0]	26.5 [15.8, 28.0]	20.0 [15.0, 28.0]	0.94	0.89 to 0.99	0.026
Headache intensity						0.086
Mild	98 (53.6)	41 (64.1)	57 (47.9)	Ref.	Ref.	
Moderate	79 (43.2)	21 (32.8)	58 (48.7)	1.97	1.05 to 3.80	
Severe	6 (3.3)	2 (3.1)	4 (3.4)	1.39	0.24 to 11.6	
Mean VAS score ($\bar{x} \pm s$)	4.47 ± 1.74	4.46 ± 1.78	4.48 ± 1.72	1.01	0.85 to 1.20	0.929
Mean duration of headache [h, median (IQR 25–75)]	6.6 [4.0, 12.0]	7.4 [5.0, 12.1]	6.3 [3.3, 12.0]	0.96	0.91 to 1.02	0.132
Number of accompanying symptoms [Median (IQR 25–75)]	0.0 [0.0, 5.0]	0.0 [0.0, 4.0]	0.0 [0.0, 6.0]	1.01	0.96 to 1.07	0.378
Acute medication						1.000
No	123 (67.2)	43 (67.2)	80 (67.2)	Ref.	Ref.	
Yes	60 (32.8)	21 (32.8)	39 (32.8)	1.00	0.52 to 1.93	
SF-36 [Score, median (IQR 25–75)]						
Physical functioning	95.0 [90.0, 100.0]	95.0 [90.0, 100.0]	95.0 [90.0, 100.0]	1.01	0.98 to 1.04	0.825
Role-physical	50.0 [0.0, 100.0]	50.0 [0.0, 100.0]	50.0 [0.0, 100.0]	1.00	0.99 to 1.01	0.940
Role-emotional	33.3 [0.0, 100.0]	33.3 [0.0, 100.0]	33.3 [0.0, 100.0]	1.00	0.99 to 1.00	0.344
Health transition	50.0 [50.0, 75.0]	75.0 [50.0, 75.0]	50.0 [50.0, 75.0]	1.00	0.98 to 1.01	0.650
General health	45.0 [40.0, 52.0]	48.5 [40.0, 52.0]	45.0 [40.0, 52.0]	0.97	0.94 to 1.01	0.125
Vitality	55.0 [50.0, 60.0]	55.0 [50.0, 60.0]	55.0 [50.0, 60.0]	1.00	0.97 to 1.03	0.779
Social functioning	62.5 [50.0, 62.5]	56.2 [50.0, 62.5]	62.5 [50.0, 62.5]	1.03	1.01 to 1.06	0.039
Mental health	56.0 [52.0, 64.0]	60.0 [52.0, 64.0]	56.0 [52.0, 64.0]	0.99	0.96 to 1.02	0.608
Bodily pain	31.0 [22.0, 32.0]	22.0 [22.0, 41.0]	31.0 [22.0, 31.5]	0.99	0.97 to 1.01	0.776
HAMA [Score, median (IQR 25–75)]	11.0 [7.0, 16.0]	11.5 [7.0, 16.0]	10.0 [7.0, 15.5]	1.00	0.95 to 1.05	0.395
HAMD [Score, median (IQR 25–75)]	8.0 [5.0, 12.0]	9.0 [5.0, 12.0]	8.0 [5.0, 12.0]	1.00	0.94 to 1.05	0.682

Notes: CTTH: chronic tension-type headache; OR: odds ratio; CI: confidence interval; Ref.: reference; BMI: body mass index; VAS: Visual Analog Scale; HAMA: Hamilton Anxiety Scale; HAMD: Hamilton Depression Scale; SF-36: 36-Item Short Form Health Survey; IQR: interquartile range; the same below

Table 2. Potential Factors Related to Acupuncture Response by Backward Logistic Regression

Variable	Model 1			Model 2		
	OR	95% CI	*P*-value	OR	95% CI	*P*-value
Treatment assignment	0.329	0.161 to 0.653	0.002	0.322	0.162 to 0.625	0.001
Headache intensity						
Mild *vs*. moderate	2.117	1.043 to 4.406	0.040	2.001	1.020 to 4.011	0.046
Mild *vs*. severe	1.584	0.243 to 14.162	0.644	1.963	0.317 to 16.555	0.485
Moderate *vs*. severe	0.748	0.111 to 6.870	0.774	0.981	0.154 to 8.404	0.984
SF-36						
General health	0.952	0.911 to 0.991	0.020	0.955	0.917 to 0.993	0.024
Social functioning	1.033	1.003 to 1.065	0.036	1.038	1.009 to 1.069	0.011

Notes: Model 1: adjusted for treatment assignment, feature of headache, monthly headache days at baseline, headache intensity at baseline, mean duration of headache, general health, and social functioning. Model 2: adjusted for treatment assignment, headache intensity at baseline, general health, and social functioning.

were twice that of those with mild-intensity headache (OR 2.001, 95% CI 1.020 to 4.011, *P*=0.046). Further, combining the data from moderate- and severe-intensity patients, the results of logistic regression analyses revealed that the effect of headache intensity on acupuncture response persisted (OR 2.00, 95% CI 1.034 to 3.939, *P*=0.042). The likelihood of non-response increased by 4.5% with each unit increase in the GH grade (OR 0.955, 95% CI 0.917 to 0.993, *P*=0.024) while decreased by 3.8% with each unit increase in the SF grade (OR 1.038, 95% CI 1.009 to 1.069, *P*=0.011). There were no collinearities between variables in the multivariable logistic regression analysis (VIFs<5).

DISCUSSION

After pooling the data, this analysis showed that treatment assignment, headache intensity at baseline, GH grade, and SF grade were the potential factors related to acupuncture response in CTTH patients. Factors such as sex, BMI, ethnicity, marital status, income level, education degree level, history of chronic headache, HAMA score, and HAMD score were not associated with acupuncture response.

Treatment assignment is a critical factor affecting efficacy. Deqi sensation of acupuncture is closely related to the depth, currently a "hot topic" in acupuncture research.[18] Although SA is often used as a control group, many studies have shown that it has efficacy,[10] sometimes not even inferior to TA.[9,19,20] SA techniques might also have similar effects on biomarkers as the so-called "real acupuncture" techniques,[21] for example similar blood oxygen level-dependent signal responses between superficial and deep needling.[22] We therefore combined the SA and TA groups for efficacy analysis. However, there is increasing evidence that TA has a more significant effect on headache than SA,[10,12,23] consistent with our results. A meta-analysis summarizing 28 functional magnetic resonance imaging studies found that common activation patterns in the sensorimotor cortical network and deactivation patterns in the limbic-paralimbic-neocortical network were stronger after acupuncture stimulation than after tactile stimulation.[24] This may also be due to stronger neuronal sensation, as the sensory pattern of the acupuncture Deqi sensation extended far from the stimulated site, whereas tactile stimulation was localized.[25]

With respect to headache intensity, our results indicated greater acupuncture responses in CTTH patients with moderate-intensity headaches compared to those with mild-intensity headaches. Only 6 patients in this cohort had severe headache intensity, and the response to acupuncture in these patients was not statistically different to that of mild- and moderate-intensity patients in the logistic regression model. The relationship was the same when data from moderate- and severe-intensity patients were combined. In studies of stress management and antidepressant treatment for CTTH, patients with more severe headaches were similarly found to have better treatment outcomes than those with milder headaches.[26] However, other study has shown no association between headache severity and efficacy.[27] We speculate that these conflicting findings may be related to differences in the type of headache, intervention, and follow-up time in different studies. Further studies are now needed to understand the prognostic impact of monthly headache days and headache intensity at baseline.

In addition to headache-related variables, previous study has also focused on associations between psychological, emotional, health-related variables and outcomes in CTTH.[28] GH is an important domain in the SF-36 health survey and reflects the individual's evaluation of health status and its development trend. We found that lower GH scores, i.e., worse self-evaluation of health status, were associated with better responses to acupuncture in CTTH patients. We hypothesize that patients with low GH scores are more conscious of their health status and are more likely to expect better treatment outcomes. Indeed, in some acupuncture studies, patients with higher treatment expectations were found to benefit more from acupuncture for headache treatment.[29,30]

SF is one of the dimensions of the Mental Component Scale (MCS). We found that baseline SF scores were positively correlated with acupuncture efficacy, i.e., the higher the SF score at baseline, the better the mental health status of the patients and the greater the efficacy of acupuncture. A study has shown that the mental health items in SF-36 have some reference value in predicting outcomes of lumbar degenerative disease after surgery,[31] while other study has shown that the SF-36 MCS is not associated with acupuncture efficacy.[32] In general, few studies have explored whether the baseline SF-36 is relevant to acupuncture efficacy. Moreover, because the SF-36 scale is a subjective evaluation of quality of life, there may be recall bias when completing the questionnaire and not all information may be accurate. Therefore, it is necessary to reduce bias and conduct further studies to explore the relationship between baseline SF-36 and acupuncture efficacy.

Anxiety and depression, as major psychological symptoms in clinical practice, are the most common comorbidities in headache sufferers.[33] We found no significant association between HAMD or HAMA scores and acupuncture response in CTTH patients. Similarly, a secondary analysis reported that acupuncture responses in insomnia were not related to HAMD.[34] However, there is some evidence that anxiety and depression are potential prognostic factors for headache.[35] We speculate that there are 2 reasons for this. First, CTTH patients in the current study had mean HAMD and HAMA scores of 8 and 11, respectively, reflecting an overall low severity of anxiety/depressive symptoms unlikely to majorly influence the outcome of headache treatment. Second, multiple lines of evidence suggest that acupuncture effectively improves anxiety/depression symptoms, suggesting that acupuncture may alleviate both headache and psychological symptoms in CTTH patients.[9,36] Thus, anxiety/depression may have less of an impact on acupuncture treatment relative to the reduced therapeutic response to pain medication.[26,37]

In addition to considering the above significant factors, reducing the number of days that patients suffer with headaches is an important goal in the treatment of CTTH. However, the relationship between monthly headache days at baseline and the treatment effect of CTTH remains uncertain. One study found that baseline headache frequency was not associated with the effectiveness of preventive treatment,[27] consistent with our findings, while another study reported that a higher headache frequency predicted a good response to treatment.[38] This difference may be related to the type of disease and intervention.

This secondary analysis has some limitations. First, because this is a secondary analysis of an RCT and the sample size was small, there may be insufficient power to determine significant associations. Second, because we only assessed the factors collected in the original protocol, some potential factors related to headache prognosis such as sleep, stress, and employment could not be explored. Third, our study was conducted in only 1 center in China, so it may not be generalizable to other regions or countries, especially with respect to some socio-demographic factors.

In conclusion, we showed that greater headache intensity, lower GH scores, and higher SF scores were associated with better acupuncture responses in CTTH patients. These 3 factors should be further assessed and validated as predictors of acupuncture efficacy in CTTH and perhaps other pain conditions.

Conflict of Interest

The authors declare no competing interests.

Author Contributions

Cao W, Wang L, and Hou TH: conceptualization; Zou ZH, Yang Q, and Chen SJ: investigation; Hou TH, Zheng H, and Wang HY: data curation; Shi YZ, Zheng QH, and Qin D: methodology; Xiao XJ and Li Y: project administration; Li Y:

supervision, validation; Cao W and Wang L: writing–original draft; Cao W and Xiao XJ: writing–review & editing. All authors have read and approved the final manuscript.

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Data Availability Statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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