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Clinical Study

Clinical observation of Tuina plus electroacupuncture for migraine due to liver-Yang hyperactivity

推拿联合电针治疗肝阳上亢型偏头痛的临床观察

KE Meijia (柯美家), HU Yanping (胡艳平), HE Shenghua (何生华)
Wuhan Hospital of Traditional Chinese Medicine, Hubei Province, Wuhan 430000, China

Abstract

Objective: To observe the clinical efficacy of Tuina (Chinese therapeutic massage) plus electroacupuncture in treating migraine due to liver-Yang hyperactivity and the effects on the serum levels of calcitonin gene-related peptide (CGRP) and prostaglandin (PG) E_2.

Methods: A total of 122 patients with migraine due to liver-Yang hyperactivity were recruited and randomized into a control group and an observation group, each consisting of 61 cases. The control group was given Tong Nao Huo Luo acupuncture (acupuncture treatment for unblocking brain collaterals), and the observation group was Tuina treatment focusing on cervical Ashi points in addition to the intervention received by the control group. Both groups were treated once daily for 21 consecutive days. When the intervention finished, the two groups were observed for changes in the headache score, symptom and sign scores of traditional Chinese medicine (TCM), the severity of impact on life, and serum CGRP and PGE_2 levels. The clinical efficacy was compared after 21 d of treatment.

Results: The observation group had a higher total effective rate than the control group, 90.2% versus 73.8% (P<0.05); after treatment, the headache and TCM symptom and sign scores decreased in both groups (P<0.05) and were lower in the observation group than in the control group (P<0.05); the migraine's impact on life was less severe in the observation group than in the control group (P<0.05); the levels of serum CGRP and PGE_2 dropped in the two groups (P<0.05) and were lower in the observation group (P<0.05).

Conclusion: Tong Nao Huo Luo acupuncture can produce more significant efficacy in treating migraine due to liver-Yang hyperactivity when combined with cervical Tuina at Ashi points, better alleviating the headache, improving TCM symptoms and body signs, and reducing the impact of headache on life. The mechanism may be associated with inhibiting the expression of serum pain factors CGRP and PGE_2.

Keywords: Tuina; Massage; Acupuncture Therapy; Points, Ashi; Calcitonin Gene-related Peptide; Prostaglandin E_2; Liver-Yang Hyperactivity; Migraine

【摘要】目的: 观察推拿联合电针治疗肝阳上亢型偏头痛的临床疗效及对血清降钙素基因相关肽(CGRP)和前列腺素(PG)E_2水平的影响。**方法:** 选取肝阳上亢型偏头痛患者122例, 随机分为对照组和观察组, 每组61例。对照组予通脑活络针刺治疗; 观察组在对照组干预基础上加用颈部阿是穴推拿治疗。两组均每日治疗1次, 连续治疗21 d。治疗结束后观察两组头痛评分、中医症状和体征评分、对生活影响程度以及血清CGRP和PGE_2水平的变化。治疗21 d后比较两组临床疗效。**结果:** 观察组总有效率90.2%, 高于对照组的73.8%(P<0.05); 治疗后, 两组头痛评分及中医症状和体征评分均低于同组治疗前(P<0.05), 且观察组评分均低于对照组(P<0.05)。治疗后, 观察组偏头痛对生活影响程度轻于对照组(P<0.05)。治疗后, 两组血清CGRP和PGE_2水平均低于同组治疗前(P<0.05), 且观察组水平均低于对照组(P<0.05)。**结论:** 相比单独通脑活络针刺治疗, 通脑活络针刺联合颈部阿是穴推拿治疗肝阳上亢型偏头痛的疗效更好, 且能更好地缓解头痛, 改善中医症状和体征, 减轻偏头痛对生活的影响。其机制可能与抑制CGRP和PGE_2血清疼痛因子的表达有关。

【关键词】推拿; 按摩; 针刺疗法; 穴, 阿是; 降钙素基因相关肽; 前列腺素E_2; 肝阳上亢; 偏头痛
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Migraine is a primary chronic neurovascular headache, with unilateral episodic pulsatile headache as the primary symptom, sometimes presenting symptoms like vomiting, nausea, fear of sound, and photophobia and mental symptoms such as anxiety and depression can be found in severe cases[1]. To date, the etiology and pathogenesis of migraine are still vague. Western medicine advocates symptomatic treatments, using medications such as non-steroidal anti-inflammatory drugs and ergotamine for treatment. Indeed, these drugs can quickly reduce headaches, but

First Author: KE Meijia, bachelor, attending physician
Corresponding Author: HE Shenghua, M.M., chief physician.
E-mail: 34125814@qq.com

they are limited by adverse reactions and drug dependence[2]. Traditional Chinese medicine (TCM) holds that migraine is mainly due to external contraction of the six pathogenic factors or disordered Qi-blood disharmony in the Zang-Fu organs caused by internal damage, and liver-Yang hyperactivity is the predominant pattern. Liver-kidney Yin deficiency and liver-Yang hyperactivity can cause Qi and blood to ascend and affect the brain, ultimately leading to migraine[3]. For migraine due to liver-Yang hyperactivity, the treatment principle should be to circulate Qi-blood, unblock meridians and collaterals, regulate Zang-Fu organs, and balance Yin and Yang. TCM usually simultaneously treats symptoms and systematically regulates the whole body, and the commonly used therapies include cervical muscle tender points Tuina (Chinese therapeutic massage)[4] and acupuncture-moxibustion[5]. Cervical muscle tender points Tuina, also named cervical Ashi points Tuina, is an external therapy of TCM that promotes Qi-blood circulation in the brain by stimulating tender points to finally mitigate topical symptoms such as pain and distending in the head[6]. Acupuncture therapy is well-accepted by patients as it can effectively treat migraine due to liver-Yang hyperactivity while causing few adverse reactions[7]. This trial observed the clinical efficacy of cervical Ashi points Tuina plus Tong Nao Huo Luo acupuncture (acupuncture treatment for unblocking brain collaterals) in treating migraine due to liver-Yang hyperactivity and the effects on the serum levels of calcitonin gene-related peptide (CGRP) and prostaglandin (PG) E_2, to provide reference for TCM treatment of migraine.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria in Western medicine

The diagnostic criteria were made based on the criteria for migraine with aura and migraine without aura in the *Expert Consensus on the Diagnosis, Prevention, and Treatment of Migraine* as well as pertinent literature[8].

1.1.2 Diagnostic criteria in TCM

The diagnostic criteria for headaches due to liver-Yang hyperactivity in the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine* were consulted[9]. Primary symptoms: distending pain in the head, irritated, bitter mouth, and red eyes; secondary symptoms: dry mouth and flush; tongue and pulse: red tongue with yellowish coating, wiry or rapid pulse.

1.2 Inclusion criteria

Met the above diagnostic criteria; ages between 18 and 65 years; the nervous system was normal; informed of the trial's content and signed the informed consent form.

1.3 Exclusion criteria

Secondary headache; those with organic disorders; those with mental disorders; those with swelling or infection in the areas to be treated with acupuncture or Tuina; alcoholics and drug addicts; pregnant or breast-feeding women; those who recently took part in other clinical trials.

1.4 Elimination criteria

Those who did not meet the inclusion criteria or who met the exclusion criteria but were recruited for mistake; did not finish the intervention as required.

1.5 Statistical methods

The statistical analysis software SPSS version 20.0 was adopted. The measurement data that concurrently conformed to normal distribution and homogeneity of variance were expressed as mean ± standard deviation ($\bar{x} \pm s$) and analyzed using the *t*-test. The count data were described using cases or percentages and processed using the Chi-square test. The ranked data were examined using the rank-sum test. $P<0.05$ suggested statistical significance.

1.6 General data

A total of 122 patients with migraine due to liver-Yang hyperactivity were recruited between January 2021 and January 2023 from our hospital. They were divided into a control group and an observation group using the random number table method, with 61 cases in each group. This trial was approved by the Ethics Committee of Wuhan Hospital of Traditional Chinese Medicine, Hubei Province (Approval No. Lun-21003). There were no significant differences in comparing the general data between the two groups ($P>0.05$), indicating comparability. The details are shown in Table 1.

Table 1 Comparison of the general data between the two groups

Group	*n*	Gender/case		Age/year ($\bar{x} \pm s$)	Disease duration/month ($\bar{x} \pm s$)	Monthly attack frequency/number ($\bar{x} \pm s$)	Monthly attack duration/hour ($\bar{x} \pm s$)
		Male	Female				
Observation	61	20	41	39.5±8.6	25.5±8.0	3.39±1.02	14.37±3.21
Control	61	23	38	40.1±8.5	26.7±8.1	3.51±1.07	14.69±2.88
Statistical value		0.323[1)]		0.374[2)]	0.805[2)]	0.634[2)]	0.580[2)]
P-value		0.570		0.709	0.422	0.527	0.563

Note: 1) χ^2-value; 2) *t*-value.

2 Treatment Methods

2.1 Control group

The control group was treated with Tong Nao Huo Luo acupuncture.

Points on the head: Sishencong (EX-HN1), Baihui (GV20), Shuigou (GV26), and Fengfu (GV16) as well as Xuanli (GB6), Shuaigu (GB8), and Jiaosun (TE20) on the affected side and bilateral Taiyang (EX-HN5) and Fengchi (GB20).

Points on the trunk: Quchi (LI11), Shousanli (LI10), Waiguan (TE5), Tongli (HT5), Hegu (LI4), Zusanli (ST36), Kunlun (BL60), Sanyinjiao (SP6), Yanglingquan (GB34), and Jiexi (ST41).

Methods: Stainless steel needles of 0.38 mm in diameter and 15-75 mm in length were selected for treatment. The needles of 65 mm in length were used to puncture from Sishenchong (EX-HN5) toward Baihui (GV20) and Xuanli (GB6), respectively, and from Shuaigu (GB8) toward Jiaosun (TE20), all forming a 15° angle between the needle and the skin with high-frequency small-amplitude twirling and lifting-thrusting manipulations performed afterward. Fengchi (GB20) was punctured using needles of 75 mm in length with the needle tip toward the contralateral lower orbit reaching 2.0-2.5 Cun deep with high-frequency small-amplitude balanced reinforcing and reducing manipulations applied. Taiyang (EX-HN5) was punctured perpendicularly using needles of 15 mm in length with high-frequency small-amplitude twirling and lifting-thrusting manipulations applied. Shuigou (GV26) and Fengfu (GV16) were punctured perpendicularly using needles of 65 mm in length. The rest of the points were punctured according to the routine procedures. After all points were treated with thrusting-lifting and twirling manipulations for 1 min, they were connected to the G6805-Ⅰ low-frequency pulsed electroacupuncture (EA) apparatus, with the needle handles at the head points connected to the negative pole and the needle handles at the trunk points to the positive pole. For EA settings, the continuous wave and 100 Hz were selected with a bearable current intensity. The stimulation lasted 20 min each time, once daily for 21 consecutive days.

2.2 Observation group

The observation group was treated with cervical Ashi point Tuina in addition to the intervention in the control group.

The treated regions: Positive reaction spots like topical tender points, subcutaneous nodes, and cord-like nodules, 2-3 spots each time.

Methods: The pressing, kneading, and grasping manipulations were applied with a moderate force, 20-30 min each time, once daily for 21 d consecutively.

3 Outcome Observation

3.1 Outcome measures

3.1.1 Clinical efficacy

The efficacy was evaluated by consulting the *Indications and Efficacy Evaluation of New Chinese Medicines*[10] in combination with the reduction rate of the TCM symptom and sign score. TCM symptom and sign score reduction rate = (Pre-treatment TCM symptom and sign score – Post-treatment TCM symptom and sign score) ÷ Pre-treatment TCM symptom and sign score × 100%.

Cured: TCM symptoms and body signs were completely or substantially gone, and the TCM symptom and sign score reduction rate was ≥90%.

Markedly effective: TCM symptoms and body signs improved significantly, and the TCM symptom and sign score reduction rate was ≥50% but <90%.

Effective: TCM symptoms and body signs showed improvement, and the TCM symptom and sign score reduction rate was ≥20% but <50%.

Invalid: TCM symptoms and body signs did not show notable improvements or even became worse, and the TCM symptom and sign score reduction rate was <20%.

3.1.2 Headache score[11]

Before and after the intervention, the headache was scored by 4 dimensions, attack frequency, duration, intensity, and accompanying symptoms, from 0 to 21 points. A higher score indicated more serious headache symptoms.

3.1.3 TCM symptom and sign scores[10]

The TCM symptoms and signs were scored before and after treatment. The primary symptoms were scored 0, 2, 4, 6, and 8 points, matching no, occasional, sometimes, frequently, and always, respectively; the secondary symptoms were scored 0, 1, 2, 3, and 4 points at each corresponding level. The higher the score, the worse the symptoms were.

3.1.4 Laboratory indicators

Each patient donated 5 mL of fasting blood via the cubital vein before and after treatment to detect the levels of CGRP and PGE_2 in the serum using the enzyme-linked immunosorbent assay. The kit was from Shanghai Enzyme-linked Biotechnology Co., Ltd., China.

3.1.5 Severity of impact on life

The headache impact test-6 (HIT-6)[12] was used before and after the intervention to assess the headache's impact on the patient's life, with 6 questions scored 36-78 points. This scale values the impact intensity at 4 levels: the HIT-6 score in the range of 36-49 points as no or mild impact; 50-55 points, moderate impact; 56-59 points, significant impact; 60-78 points, severe impact.

3.2 Treatment results

3.2.1 Comparison of the clinical efficacy

The therapeutic efficacy was assessed when the 21-day treatment finished. The total effective rate was 90.2% in the observation group, higher than 73.8% in the control group (*P*<0.05). The details are shown in Table 2.

3.2.2 Comparison of the headache score

Before treatment, there was no significant difference in the headache score between the two groups (*P*>0.05). After treatment, the headache score dropped in both groups (*P*<0.05) and was lower in the observation group than in the control group (*P*<0.05). See Table 3.

3.2.3 Comparison of the TCM symptom and sign scores

Before treatment, the two groups were statistically equivalent in comparing the TCM symptom and sign scores (*P*>0.05). After treatment, the TCM symptom and sign scores decreased in the two groups (*P*<0.05) and were lower in the observation group than in the control group (*P*<0.05). The data are shown in Table 4.

3.2.4 Comparison of the serum CGRP and PGE_2 levels

Before treatment, the CGRP and PGE_2 levels showed no significant differences between the two groups (*P*>0.05). After treatment, the CGRP and PGE_2 levels dropped in both groups (*P*<0.05) and were lower in the observation group than in the control group (*P*<0.05). The details are shown in Table 5.

3.2.5 Comparison of the severity of impact on life

Before treatment, the difference was insignificant between the two groups regarding the impact of headaches on the patient's life (*P*>0.05). After treatment, the impact was milder in the observation group compared to the control group (*P*<0.05). The data are detailed in Table 6.

Table 2 Comparison of the clinical efficacy between the two groups **Unit: case**

Group	*n*	Cured	Markedly effective	Effective	Invalid	Total effective rate/%
Observation	61	4	21	30	6	90.2
Control	61	0	15	30	16	73.8
Statistical value			2.690[1)]			5.546[2)]
P-value			0.007			0.019

Note: 1) *Z*-value; 2) χ^2-value.

Table 3 Comparison of the headache score ($\bar{x}$ ±*s*) **Unit: point**

Item	Time	Observation group (*n*=61)	Control group (*n*=61)	*t*-value	*P*-value
Attack frequency	Before treatment	3.97±1.22	4.32±1.29	1.540	0.126
	After treatment	2.19±0.67	2.94±0.72	5.956	<0.001
	t-value	9.988	7.296		
	P-value	<0.001	<0.001		
Attack duration	Before treatment	3.63±1.11	3.88±1.25	1.168	0.245
	After treatment	2.18±0.56	2.80±0.62	5.796	<0.001
	t-value	9.109	6.045		
	P-value	<0.001	<0.001		
Headache severity	Before treatment	4.63±1.31	4.41±1.22	0.960	0.339
	After treatment	2.18±0.64	2.76±0.79	4.455	<0.001
	t-value	13.124	8.866		
	P-value	<0.001	<0.001		
Accompanying symptoms	Before treatment	1.83±0.55	1.82±0.59	0.097	0.923
	After treatment	0.72±0.17	0.96±0.28	5.722	<0.001
	t-value	15.060	10.285		
	P-value	<0.001	<0.001		

Table 4 Comparison of the symptom and sign scores of traditional Chinese medicine ($\bar{x}$ ±*s*) **Unit: point**

Item	Time	Observation group (*n*=61)	Control group (*n*=61)	*t*-value	*P*-value
Distending pain in the head	Before treatment	4.67±1.32	4.59±1.24	0.345	0.731
	After treatment	2.39±0.71	3.05±0.84	4.687	<0.001
	t-value	11.881	8.031		
	P-value	<0.001	<0.001		
Irritation	Before treatment	2.53±0.64	2.46±0.53	0.658	0.512
	After treatment	1.69±0.42	2.00±0.49	3.752	<0.001
	t-value	8.570	4.977		
	P-value	<0.001	<0.001		
Bitter mouth	Before treatment	1.20±0.33	1.17±0.31	0.517	0.606
	After treatment	0.74±0.15	0.95±0.24	5.795	<0.001
	t-value	9.911	4.383		
	P-value	<0.001	<0.001		
Red eyes	Before treatment	1.79±0.59	1.87±0.60	0.743	0.459
	After treatment	1.26±0.21	1.55±0.32	5.918	<0.001
	t-value	6.610	3.675		
	P-value	<0.001	<0.001		
Dry mouth	Before treatment	1.46±0.54	1.54±0.44	0.897	0.372
	After treatment	0.86±0.14	1.03±0.29	4.123	<0.001
	t-value	8.400	7.559		
	P-value	<0.001	<0.001		
Flush	Before treatment	1.02±0.29	0.98±0.31	0.736	0.463
	After treatment	0.47±0.05	0.60±0.18	5.435	<0.001
	t-value	14.597	8.279		
	P-value	<0.001	<0.001		
Red tongue with yellowish coating	Before treatment	0.85±0.22	0.87±0.19	0.537	0.592
	After treatment	0.49±0.15	0.62±0.13	5.115	<0.001
	t-value	10.560	8.481		
	P-value	<0.001	<0.001		
Wiry or rapid pulse	Before treatment	1.20±0.35	1.17±0.36	0.467	0.642
	After treatment	0.77±0.18	0.95±0.22	4.946	<0.001
	t-value	8.533	4.073		
	P-value	<0.001	<0.001		

Table 5 Comparison of the serum CGRP and PGE_2 levels ($\bar{x}$ ±*s*) **Unit: pg/mL**

Item	Time	Observation group (*n*=61)	Control group (*n*=61)	*t*-value	*P*-value
CGRP	Before treatment	53.95±5.31	52.26±6.03	1.643	0.103
	After treatment	39.39±4.63	43.83±5.29	4.933	<0.001
	t-value	16.141	8.208		
	P-value	<0.001	<0.001		
PGE_2	Before treatment	441.17±27.54	438.76±30.11	0.461	4.496
	After treatment	304.29±24.22	327.19±31.56	0.645	<0.001
	t-value	29.150	19.977		
	P-value	<0.001	<0.001		

Note: CGRP=Calcitonin gene-related peptide; PGE_2=Prostaglandin E_2.

Table 6 Comparison of the severity of impact on life **Unit: case**

Group	*n*	Before treatment				After treatment			
		No or mild impact	Moderate impact	Significant impact	Severe impact	No or mild impact	Moderate impact	Significant impact	Severe impact
Observation	61	0	19	33	9	28	26	7	0
Control	61	2	22	26	11	15	34	10	2
Statistical value		3.250				2.470			
P-value		0.355				0.014			

4 Discussion

It is known that the incidence rate of migraine is about 14.7% in the general population, with a ratio of 1:2 between males and females[13]. In recent years, people have been taking more and more pressure from life and work as society's development speeds, making migraines more common. Besides moderate-to-severe pulsatile headache on one side of the head and autonomic dysfunction, migraine may also cause sleep disturbances and mental disorders like anxiety and depression in chronic cases. It not only hurts the patient's physical and mental health but also brings a financial burden to the family and society. Therefore, migraine has become an urgent medical issue.

Migraine should fall under the categories of "headache" or "head wind" in TCM. The term "headache" is initially found in the *Yin Yang Shi Yi Mai Jiu Jing* (*Moxibustion Classic of Eleven Yin-Yang Meridians*)[14]. The *Huang Di Nei Jing* (*Yellow Emperor's Inner Classic*) also records "head wind" and "headache"[15]. Through generations, physicians have summarized the causes of migraine as two types: exogenous factors and endogenous factors; pathogenesis involves "pain caused by insufficient nourishment" and "pain caused by stagnation". Liver-Yang hyperactivity is the most common pattern in migraine. The liver governs the free flow of Qi, acting to regulate emotions as well as Qi, blood, and fluid in the whole body. In turn, moodiness and Qi-blood deficiency can also hinder the liver's function of maintaining the free flow of Qi, causing stagnant Qi movement or generating internal wind and transforming into fire, thus leading to headaches[16]. Therefore, this trial took cervical Tuina at Ashi point as the assistant therapy and achieved more significant clinical efficacy in patients in the observation group, together with lower headache and TCM symptom scores compared to the control group (P<0.05), suggesting that incorporating cervical Tuina at Ashi point into Tong Nao Huo Luo acupuncture therapy can better improve the patient's symptoms.

The term "Ashi" is initially recorded in *Qian Jin Yao Fang* (*Important Formulas Worth a Thousand Gold Pieces*)[17]. Most migraine patients may experience cervical discomfort while the headache occurs. In this case, positive reaction spots like topical tender points on the head and neck, cord-like nodules, and subcutaneous nodes all count as Ashi points, also the optimal points for stimulation in treating migraine. Via mechanical stimulation to the neck, Ashi point Tuina can boost topical blood circulation, reduce the accumulation of inflammatory factors and pain-inducing substances, loosen up cervical tissue adhesions and muscle spasms to release or reduce the compression on cervical nerve roots and increase blood supply to the brain, finally mitigating the headache. Tong Nao Huo Luo acupuncture stresses scalp points and integrates points on the trunk in the treatment. The combination of scalp and trunk points forms a stereoscopic network. Scalp point acupuncture can enhance the activity of brain tissues and the transmission of brain nerve impulses to help maintain hemodynamic balance in the brain and regulate neuromuscular excitability. In the meantime, trunk point acupuncture is integrated to circulate Qi and blood and regulate the function of Zang-Fu organs to relieve headaches or head-distending symptoms and improve the quality of life[18].

It is reported that CGRP can induce migraine and is found to be highly expressed in chronic migraine[19]. As a potential drug target for chronic neuropathic pain, PGE_2 can be found in the damage of the nervous system. It is also distributed in some nerve endings, and its expression is positively correlated with pain intensity[20]. The present study found that the levels of CGRP and PGE_2 were lower in the observation group than in the control after the intervention (P<0.05), further testifying that cervical Tuina at Ashi point plus Tong Nao Huo Luo acupuncture can inhibit the expression of pain factors and release headache in people with migraine due to liver-Yang hyperactivity. Besides, the observation group experienced a milder impact on life compared to the control group (P<0.05), which is possibly due to the effect of cervical Tuina at Ashi point in reducing neck muscle tension and spasm, boosting Qi-blood circulation in the whole body, increasing blood and oxygen supply to the brain, and finally releasing the headache. Further, EA plus Tuina can also improve depression and anxiety in headache people[21]. Combining cervical Tuina at Ashi point and acupuncture can up-regulate the expression of analgesic substances, such as norepinephrine and endorphin, to suppress the expression of pain factors, improve migraine symptoms,

and lower the impact of migraine on the patient's life[22].

In summary, compared to the sole use of Tong Nao Huo Luo acupuncture, incorporating cervical Tuina at Ashi point into the treatment can enhance the clinical efficacy in treating migraine due to liver-Yang hyperactivity, reducing headache and other TCM symptoms and signs, inhibiting the secretion of serum CGRP and PGE_2, and lowering the impact of migraine on the patient's life, thus worth promoting in clinical practice.

Conflict of Interest

The authors declare that there is no potential conflict of interest in this article.

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Statement of Informed Consent

This trial was approved by the Ethics Committee of Wuhan Hospital of Traditional Chinese Medicine, Hubei Province (Approval No. Lun-21003). Informed consent was obtained from all individual participants.

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Translator: HONG Jue (洪珏)

