Clinical Study on Tiaoqi Dingxian Prescription Combined with Western Medicine for Epilepsy of Qi Constraint and Phlegm Stagnation Type

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Abstract [**Objectives**] To observe the clinical effect of Tiaoqi Dingxian prescription combined with western medicine on epilepsy of qi constraint and phlegm stagnation type. [**Methods**] A total of 60 cases of patients of epilepsy of qi constraint and phlegm stagnation type admitted to Maoming Hospital Affiliated to Guangzhou University of Chinese Medicine from June 2023 to July 2024 were selected as the research subjects. They were randomly divided into the control group and the observation group using a random number table method, with 30 cases in each group. The control group was treated with levetiracetam, while the observation group was treated with Tiaoqi Dingxian prescription on the basis of the control group. Both groups were treated for 3 months, and the clinical efficacy, frequency and duration of epilepsy onset, improvement of electroencephalogram (EEG), Quality of Life in Epilepsy Inventory (QOLIE-31) scores, traditional Chinese medicine (TCM) syndrome scores, and incidence of adverse reactions were evaluated in both groups. [**Results**] The total effective rate in the observation group was 93.33% (28/30), compared to 73.33% (22/30) in the control group, with a statistically significant difference ($P<0.05$). Following treatment, the frequency and duration of epilepsy onset in both groups were decreased when compared to the pre-treatment period ($P<0.05$), and the frequency and duration of epilepsy onset in the observation group were lower than those in the control group ($P<0.05$). Following treatment, the EEG grading of both groups was improved when compared with that before treatment ($P<0.05$), and the EEG grading in the observation group was better than that in the control group ($P<0.05$). Following treatment, the QOLIE-31 scores in both groups, including epilepsy-related concerns, overall health, emotional health, energy, cognitive function, drug effects, and social function, were increased when compared to the scores recorded prior to treatment ($P<0.05$), and all scores in the observation group were higher than those in the control group ($P<0.05$). Following treatment, the TCM syndrome scores in both groups were decreased when compared to those prior to treatment ($P<0.05$), and the scores in the observation group were lower than those in the control group ($P<0.05$). The incidence of adverse reactions was observed to be 6.67% (2/30) in the observation group and 13.33% (4/30) in the control group, with no significant difference between the two groups ($P>0.05$). [**Conclusions**] The combination of Tiaoqi Dingxian prescription and levetiracetam in the treatment of epilepsy of qi constraint and phlegm stagnation type can improve clinical efficacy, alleviate patient's symptoms and quality of life, and has good safety.

Key words Epilepsy, Qi constraint and phlegm stagnation, Tiaoqi Dingxian prescription, Levetiracetam, Quality of Life in Epilepsy Inventory (QOLIE-31)

1 Introduction

Epilepsy is recognized as the second most prevalent neurological disorder following cerebrovascular disease, characterized primarily by motor-sensory disturbances, alterations in mental consciousness, and autonomic dysfunction[1]. According to traditional Chinese medicine (TCM), epilepsy is primarily attributed to an imbalance in visceral qi, disruptions in vital activity, an excess of yin and yang, and a loss of control over the primordial spirit. Notably, the presence of phlegm is considered a significant contributing factor. Consequently, the principal treatment approach involves the regulation of qi, the elimination of phlegm, and the awakening of the spirit to achieve enlightenment[2-3]. Tiaoqi Dingxian prescription is an empirical formulation developed by Professor Yu Hengwang. This prescription is composed of the combination and modification of Sini powder and Dingxian pill. It is recognized for its therapeutic effects, which include the dispersion of liver qi to alleviate depression, the drying of dampness and resolution of phlegm, the calming of the liver and extinguishing of wind, as well as the tranquilization of the mind. The intervention demonstrates a significant therapeutic effect on epilepsy of qi constraint and phlegm stagnation type in clinical practice. In this study, we investigated the clinical efficacy of the Tiaoqi Dingxian prescription in conjunction with levetiracetam tablets for the treatment of epilepsy of qi constraint and phlegm stagnation type. Additionally, we assessed the impact of this combined treatment on patients' quality of life. The findings are presented below.

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2 Clinical data and methods

2.1 Clinical data

2.1.1 Diagnostic criteria. The diagnostic criteria for epilepsy, as outlined in the *Clinical Diagnosis and Treatment Guidelines: Epilepsy Volume*[4], include the following: the occurrence of two non-induced epilepsy that are at least 24 h apart; alternatively, a single non-induced (or reflex) epilepsy accompanied by a minimum 60% risk of recurrence within the subsequent 10 years; or a confirmed diagnosis of a specific epilepsy syndrome.

2.1.2 Syndrome differentiation criteria. In accordance with the *Criteria for Diagnosis and Therapeutic Effect of Diseases and Syndromes in Traditional Chinese Medicine*[5], epilepsy is classified under the syndrome of qi constraint and phlegm stagnation. The primary symptoms associated with this syndrome include loss of consciousness, fixed gaze, facial asymmetry (crooked mouth and

eyes), involuntary movements of the extremities (twitching of hands and feet), wheezing due to phlegm retention in the throat, and dizziness. Secondary symptoms may manifest as vocalizations, upward qi rebellion, palpitations, headaches, nausea, and vomiting. The pulse characteristics typically observed include a pale tongue, a white greasy coating, and a thready and slippery pulse.

2.1.3 Inclusion criteria. The participants must meet the aforementioned diagnostic and differential criteria, be between 18 and 70 years of age, possess normal intelligence, and demonstrate the ability to accurately assess their own circumstances. Additionally, they must be adequately informed and provide their signature on an informed consent form.

2.1.4 Exclusion criteria. The excluded population comprises individuals with a combination of significant diseases affecting the heart, liver, and kidneys; those who are pregnant or lactating; individuals with coexisting major psychosocial disorders; and participants who are concurrently engaged in clinical trials for other pharmacological agents.

2.1.5 General information. A total of 60 cases of epilepsy of qi constraint and phlegm stagnation type, admitted to Maoming Hospital Affiliated to Guangzhou University of Chinese Medicine between June 2023 and July 2024, were selected for this study. The participants were randomly assigned to either the control group or the observation group, with each group comprising 30 cases, utilizing a random number table method. In the observation group, there were 17 males and 13 females, with ages ranging from 29 to 65 years and a mean age of (50.46 ± 8.91) years. In the control group, there were 18 males and 12 females, with ages ranging from 25 to 70 years and an average age of (54.73 ± 12.69) years. The general information of the two groups were comparable, and the difference was not statistically significant ($P > 0.05$). This study received approval from the Ethics Committee of Maoming Hospital Affiliated to Guangzhou University of Chinese Medicine (Approval No.: 2024041902).

2.2 Treatment methods

2.2.1 Control group. Levetiracetam tablets (UCB Pharma, SFDA approval No.: H20227147) were administered orally at a dosage of 20 – 30 mg/kg per administration, twice daily.

2.2.2 Observation group. Based on the control group, the Tiaoqi Dingxian prescription was incorporated into the observation group. This prescription comprised 30 g of Ostreae Concha, 15 g each of Rhizoma Gastrodiae and Rhizoma Pinelliae, 12 g of Radix Bupleuri, and 10 g each of Fructus Aurantii Immaturus, Caulis Bambusae in Taenia, Arisaema Cum Bile, and Pheretima. The prescription was adjusted based on the presenting symptoms: if the phlegm was dense, an additional 10 g of Exocarpium Citri Rubrum should be included; if the stool was dry and hard, an additional 3 g of Radix et Rhizoma Rhei was recommended; and if there was a deficiency in qi and blood, an additional 20 g of Astragali Radix and 10 g of Radix Salviae Miltiorrhizae should be incorporated. The treatment regimen consisted of one dose per day, comprising 200 mL of the decocted medicinal liquid, administered twice daily, with both groups undergoing treatment for 3 months.

2.3 Observation indicators and statistical methods

2.3.1 Observation indicators. (i) Frequency and duration of epilepsy onset. The control of epilepsy was assessed in accordance with the *Clinical Diagnosis and Treatment Guidelines: Epilepsy Volume* (2023 Revision)[4]. The evaluation of epilepsy control was conducted by calculating the monthly average frequency of epilepsy onset over the preceding 3 months. (ii) Electroencephalogram (EEG) grading. The EEGs of the patients were evaluated and classified as normal, mildly abnormal, moderately abnormal, or severely abnormal both prior to and following treatment, in accordance with the established standards in *Clinical Electroencephalography*[6]. (iii) Quality of Life in Epilepsy (QOLIE-31)[7] scoring. The quality of life of the patients was assessed both prior to and following treatment, encompassing seven dimensions: epilepsy-related concerns, overall health, emotional health, energy, cognitive function, drug effects, and social function. A higher score in these areas indicated an improved quality of life. (iv) TCM syndrome scoring. In accordance with the *Guiding Principles for Clinical Research of New Chinese Medicines (Trial)*[8], the symptoms of epilepsy were assessed both prior to and following treatment in the two groups, with higher scores indicating more severe symptoms. (v) Total clinical effective rate. (vi) Safety. Adverse effects, including mild dizziness, somnolence, alterations in liver and kidney function, as well as changes in blood routine and prothrombin time (PT) were observed in both groups during the treatment period.

2.3.2 Statistical methods. All data in this study were analyzed and processed using SPSS 26.0 statistical software. Count data were expressed as percentages (%), and the chi-square (χ^2) test or corrected χ^2 test was employed. Measurement data that conformed to a normal distribution were presented as mean ± standard deviation ($\bar{x} \pm s$). A paired-sample *t*-test was utilized for intra-group comparisons, while an independent-sample *t*-test was applied for inter-group comparisons. For continuous variables that did not meet the assumptions of normal distribution, the rank-sum test was selected as a non-parametric alternative. A difference was considered statistically significant when $P < 0.05$.

3 Efficacy criteria and treatment outcomes

3.1 Efficacy criteria At the conclusion of the treatment, the clinical efficacy was evaluated in accordance with the *Guiding Principles for Clinical Research of New Chinese Medicines (Trial)*[8]. Clinical control: clinical symptoms and signs disappeared or basically disappeared, with a reduction in the TCM symptom score of 95% or greater. Markedly effective: clinical symptoms and signs showed significant improvement, with a reduction in the TCM syndrome score between 70% and 94%. Effective: clinical symptoms and signs showed slight improvement, with a reduction in the TCM syndrome score between 30% and 69%. Ineffective: clinical symptoms and signs did not demonstrate significant improvement or worsened, with a reduction in the TCM syndrome

score of less than 30%.

3.2 Clinical efficacy The clinical efficacy is presented in Table 1. The total effective rate was 93.33% in the observation group and 73.33% in the control group. The difference between the two groups was statistically significant ($P<0.05$).

3.3 Frequency and duration of epilepsy onset The frequency and duration of epilepsy onset are presented in Table 2. Prior to treatment, no statistically significant differences were observed in the frequency and duration of epilepsy onset between the two groups ($P>0.05$). Following treatment, both the frequency and duration of epilepsy onset in the two groups were significantly reduced compared to pre-treatment levels ($P<0.05$). Furthermore, the frequency and duration of epilepsy onset in the observation group were significantly lower than those in the control group ($P<0.05$).

Table 1 Comparison of clinical efficacy between the two groups ($n=30$)

Group	Markedly effective // case	Effective // case	Total effective rate // %
Observation	5	23	93.33
Control	4	18	73.33
χ^2			4.320
P			0.038

Table 2 Comparison of frequency and duration of epilepsy onset between the two groups ($n=30$, $\bar{x}\pm s$)

Group	Frequency // times/month		Duration // min/time	
	Prior to treatment	Following treatment	Prior to treatment	Following treatment
Observation	4.03±1.30	2.43±0.86①②	3.55±0.77	1.87±0.80①②
Control	3.97±1.27	3.53±1.22①	3.73±0.64	3.28±0.72①

NOTE ① Compared to the pre-treatment measurements within this group, $P<0.05$; ② Compared to the control group following treatment, $P<0.05$.

3.4 EEG grading The EEG grading results are presented in Table 3. Prior to treatment, no statistically significant difference in EEG grading was observed between the two groups ($P>0.05$). Following treatment, both groups exhibited an improvement in EEG grading compared to their pre-treatment levels ($P<0.05$). Furthermore, the enhancement in EEG grading within the observation group was significantly greater than that observed in the control group ($P<0.05$).

Table 3 Comparison of EEG grading between the two groups ($n=30$)

Group	Time	Mild	Moderate	Severe	Normal	$Z_{intragroup}$	$P_{intragroup}$
Observation	Prior to treatment	5	14	7	4	3.962	<0.001
	Following treatment	17	9	0	4		
Control	Prior to treatment	4	15	7	4	2.309	0.021
	Following treatment	10	14	3	3		
$Z_{intergroup}$	2.051						
$P_{intergroup}$	0.040						

3.5 QOLIE-31 scoring The QOLIE-31 scoring results are presented in Table 4. Prior to treatment, there were no statistically significant differences in the QOLIE-31 scale scores related to epilepsy-related concerns, overall health, emotional health, energy, cognitive function, drug effect, and social function between the two groups ($P>0.05$). Following treatment, the QOLIE-31 scale scores for both groups showed a significant increase compared to the pre-treatment scores ($P<0.05$), with the observation group exhibiting higher scores than the control group ($P<0.05$).

Table 4 Comparison of QOLIE-31 scoring between the two groups ($n=30$, $\bar{x}\pm s$) points

Indicator	Observation		Control	
	Prior to treatment	Following treatment	Prior to treatment	Following treatment
Epilepsy-related concerns	28.70±1.02	46.33±3.29①②	28.83±0.94	40.33±4.04①
Overall health	15.40±1.30	39.86±4.57①②	15.60±1.19	31.43±5.59①
Emotional health	16.70±1.02	40.33±4.21①②	16.83±0.94	32.46±5.26①
Energy	25.53±1.07	46.71±3.89①②	25.70±0.98	39.60±4.89①
Cognitive function	25.10±0.66	45.07±3.82①②	25.16±0.59	38.36±4.58①
Drug effect	33.10±0.66	47.87±2.86①②	33.16±0.59	42.73±3.48①
Social function	25.97±0.76	43.17±3.08①②	26.13±0.62	37.33±4.03①

NOTE ① Compared to the pre-treatment measurements within this group, $P<0.05$; ② Compared to the control group following treatment, $P<0.05$.

3.6 TCM syndrome scoring for epilepsy The TCM syndrome scoring for epilepsy is presented in Table 5. Prior to treatment, no statistically significant difference was observed in the TCM syndrome scores for epilepsy between the two groups ($P>0.05$).

Following treatment, the TCM syndrome scores for epilepsy in both groups were significantly lower than their respective pre-treatment scores ($P < 0.05$). Furthermore, the scores of the observation group were significantly lower than those of the control group ($P < 0.05$).

3.7 Incidence of adverse reactions The incidence of adverse reactions is presented in Table 6. In the observation group, the rate of adverse reactions was 6.67%, while in the control group, it was 13.33%. The difference between the two groups was not statistically significant ($P > 0.05$).

Table 5 Comparison of TCM syndrome scoring for epilepsy between the two groups ($n = 30$, $\bar{x} \pm s$) points

Group	Prior to treatment	Following treatment	t	P
Observation	40.33 ± 6.79	23.53 ± 4.51	11.29	< 0.001
Control	41.80 ± 6.86	35.07 ± 7.33	3.68	< 0.001
t	0.833	7.344		
P	0.408	< 0.001		

Table 6 Comparison of incidence of adverse reactions between the two groups ($n = 30$)

Group	Mild dizziness//case	Somnolence//case	Liver and kidney function//case	Blood routine//case	PT//case	Total//(case) %
Observation	1	0	0	0	1	2.000 (6.67)
Control	2	1	1	0	0	4.000 (13.33)
χ^2						0.185
P						0.667

4 Discussion

Modern medicine posits that epilepsy is a clinical syndrome characterized by highly synchronized abnormal discharges of neurons in the brain, which can arise from various etiological factors. The antiepileptic medications currently employed in clinical practice primarily consist of voltage-dependent sodium channel blockers, agents that increase intracerebral or synaptic levels of γ-aminobutyric acid (GABA), compounds that selectively enhance GABAA receptor-mediated effects, those that directly promote chloride ion influx, and calcium channel blockers, *etc.* Notable examples of these pharmacological agents include carbamazepine, sodium valproate, lamotrigine, and perampanel. However, it is important to acknowledge that these medications are associated with a range of adverse effects, including electrolyte imbalances, dizziness, headaches, nausea, vomiting, somnolence, and ataxia. In recent years, levetiracetam, classified as a novel antiepileptic drug, has demonstrated significant efficacy, safety, and tolerability in the management of epilepsy. Its indications have progressively expanded from serving as an adjunctive treatment for epileptic epilepsy to being utilized as monotherapy for newly diagnosed epilepsy. The mechanism of action involves the synaptic vesicle protein SV2A[9], which plays a crucial role in regulating the extracellular secretion of synaptic vesicles and the release of neurotransmitters, while selectively inhibiting epileptiform discharges. Nevertheless, prolonged administration of levetiracetam may result in adverse effects, including somnolence, dizziness, and amnesia.

TCM categorizes epilepsy as a condition primarily influenced by emotional disturbances, congenital factors, dietary imbalances, excessive physical exertion, or traumatic brain injuries. These factors are believed to contribute to the onset of the disease through an imbalance in visceral qi, disruptions in vital activities, an excess of yin and yang, and a loss of control over the primordial spirit. Professor Yu Hengwang posits that contemporary society is characterized by a high level of stress, which leads to the accumulation of internal liver qi. Prolonged qi stagnation may subsequently transform into fire, resulting in the generation of wind. Furthermore, there is a prevalent inclination among individuals towards the consumption of rich and greasy foods, which can exacerbate the formation of dampness and phlegm. Consequently, a significant number of patients with epilepsy exhibit a constitution marked by qi stagnation and phlegm-dampness. When these individuals are exposed to pathogenic factors, the resultant phlegm turbidity can readily incite a combination of wind and fire, compounded by phlegm, thereby obstructing the heart orifices and precipitating the disease. Therefore, clinically, epilepsy is primarily characterized by the presence of qi constraint and phlegm stagnation. It has been identified that "qi constraint" serves as the principal pathological factor underlying this condition, consistently influencing its progression. In cases where there is a significant accumulation of heavy and viscous phlegm, this phlegm tends to become increasingly adhesive and resistant to dissolution, particularly when it accumulates internally in conjunction with wind. Responding to the characteristics of epilepsy, which is characterized by disordered qi movement, easily provoked liver wind, and dampness in the spleen resulting in phlegm production, leading to qi constraint and phlegm stagnation, as well as obstruction of the clear orifices, Professor Yu Hengwang, drawing upon the historical practices of medical practitioners, modified the traditional formulations of Sini powder and Dingxian pill, leading to the development of a novel formula Tiaoqi Dingxian prescription. In the formula, Radix Bupleuri serves to disperse stagnated liver qi to relieve depression, and regulate the cardinal organs, which facilitates the flow of qi and the removal of stagnant qi. The synergistic combination of Fructus Aurantii Immaturus and Radix Bupleuri creates a dynamic balance of rising and falling actions, which is essential for regulating qi and alleviating depression, exerting an effect of ascending the clear and descending the turbid. Rhizoma Gastrodiae is known for its ability to alleviate wind and

spasms, and dispel wind and facilitate the flow through the collaterals. Rhizoma Pinelliae is effective in drying dampness and transforming phlegm. Caulis Bambusae in Taenia is known for its ability to clear heat and transform phlegm, while Arisaema Cum Bile is characterized by its bitter properties, which are effective in drying dampness. The combination of the four medicinal agents will primarily eliminate evil influences, thereby enhancing the regulation of qi and the management of epilepsy. Ostreae Concha is known to subdue yang and nourish yin, thereby calming the mind and soothing the spirit. Pheretima is recognized for its ability to clear heat, subdue wind, and unblock meridians. The synergistic effects of the various herbs may facilitate liver soothing, regulate qi, eliminate heat, alleviate blood stasis, mitigate wind, and stabilize conditions associated with epilepsy.

The findings of this study indicate that the total clinical effective rate and the QOLIE-31 score for the observation group were significantly higher than those of the control group following treatment. Additionally, the TCM syndrome score, as well as the frequency and duration of epilepsy onset, were lower in the observation group compared to the control group. Furthermore, improvements in EEG grading were more pronounced in the observation group, and the incidence of adverse reactions was relatively low. These results suggest that the combination of Tiaoqi Dingxian prescription and levetiracetam in the treatment of epilepsy enhances clinical efficacy, effectively improves patients' EEG results, TCM syndrome manifestations, and overall quality of life, while also reducing the frequency and duration of epilepsy onset. The treatment appears to be both safe and reliable.

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functional and individualized rehabilitation, which can more effectively enhance patients' active engagement in training and expedite the functional reconstruction of the central nervous system[6]. The application of acupoint injection of nerve growth factors, in conjunction with task-oriented training, demonstrates a significant improvement in gait function in patients with post-stroke hemiplegia. The Gait Watch analysis system offers a precise and reliable quantitative assessment of this intervention, which is markedly more effective than single rehabilitation training or ordinary acupuncture combined with rehabilitation programs, presenting an efficient and straightforward treatment option for clinical practice. In future research, it is imperative to enhance investigations aimed at verifying the long-term efficacy of this therapy, elucidating its therapeutic mechanisms, and facilitating its broader clinical application.

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