



Clinical Study on the Treatment of Erectile Dysfunction of Heart Gallbladder Qi Deficiency Type with Ethnic Medicine Huixin Grass Loading

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Abstract

Objective: To observe the therapeutic effect of traditional Chinese medicine (TCM) loaded with Western medicine on erectile dysfunction (heart and gallbladder “Qi” deficiency type), explore its clinical efficacy and safety, and provide new clinical ideas and methods for the application of TCM in the treatment of erectile dysfunction based on syndrome differentiation. **Method:** 80 patients who met the inclusion criteria for this clinical study and received treatment at the Men's Outpatient Department of Zhuhai Hospital of Guangdong Provincial Hospital of Traditional Chinese Medicine from December 2023 to December 2024 were selected and divided into two groups using a random number table method, with 40 patients in each group. The control group received daily basic treatment medication: Tadalafil tablets, orally taken after lunch, 5 mg/time, once a day, for 8 weeks; The observation treatment group added 15g of *Houttuynia cordata* to the control group, which was decocted in water twice a day and taken orally in the morning and evening. The treatment course is 8 weeks, and the clinical efficacy of the two groups of patients is objectively evaluated by observing the clinical efficacy rate (primary efficacy indicator), the efficacy rate of traditional Chinese medicine syndrome (secondary efficacy indicator), the improvement of international erectile function (IIEF-5) score, traditional Chinese medicine syndrome score, audio-visual stimulation erection test (AVSS), and erection hardness (EHS) score before and after treatment. **Result:** The treatment group completed 40 cases, while the control group completed 39 cases. After treatment, the clinical effective rates of the observation group and the control group were 85.00% and 69.23%, respectively, and the difference between the observation group and the control group was statistically significant ($p < 0.05$); The effective rates of traditional Chinese medicine syndrome in the observation group and the control group were 87.50% and 33.33%, respectively, and the difference between the observation group and the control group was statistically significant ($p < 0.01$); After treatment, the IIEF-5 scores of the observation group and the control group were 21.00 (19.25–23.75) and 18.00 (14.00–21.00) points, respectively. The difference between the observation group and the control group was statistically significant ($p < 0.05$); After treatment, the TCM syndrome scores of the observation group and the control group were 2.00 (2.00–6.00) points and 12.00 (6.00–20.00) points, respectively. The difference between the observation group and the control group was statistically significant ($p < 0.01$); After the treatment, the results of AVSS showed that the tip average rigidity of the observation group and the control group were 53.91 ± 11.98

and 47.63 ± 14.80 , respectively, and the base average rigidity was 68.00 (53.75, 74.50) and 57.13 ± 9.38 , respectively. The duration of tip erection was 11.53 ± 4.85 and 6.22 ± 1.93 , respectively, and the duration of base erection was 11.28 ± 4.11 and 8.81 ± 3.50 , respectively. The tip penile tumescence was 38.27 ± 6.48 and 33.44 ± 5.82 , respectively, and the base penile tumescence was 38.64 ± 6.49 and 34.44 ± 5.80 , respectively. The differences between the observation group and the control group were statistically significant ($p < 0.005$, $p < 0.001$); After treatment, the EHS scores of the observation group and the control group were 3.00 (3.00–4.00) points and 2.00 (2.00–3.00) points, respectively. The difference between the observation group and the control group was statistically significant ($p < 0.05$). *Conclusion:* Western medicine loaded with Huixincao can significantly improve the clinical efficacy of erectile dysfunction of heart and gallbladder “Qi” deficiency type, and can significantly improve ED and its associated clinical symptoms, improve patients’ traditional Chinese medicine symptoms, and have a good drug safety.

Keywords

Erectile dysfunction; Heart-gallbladder “Qi” deficiency; Huixincao; Tadalafil; Efficacy

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1. Introduction

Erectile dysfunction (ED) refers to the persistent inability of men to achieve or maintain sufficient penile erection to complete satisfactory sexual activity, and is a common and frequently occurring disease in adult males ^[1]. Penile erection is closely related to neurological, endocrine, and vascular factors, and psychological and psychological factors also play important roles ^[2]. In recent years, many scientific studies have shown that ED is an early symptom and danger signal of cardiovascular diseases (CVD), which can affect the quality of life of patients and their partners ^[3]. ED and CVD share common risk factors, and most CVD treatments can also improve erectile function ^[4]. Huixin Grass is a traditional herbal medicine of ethnic minorities in China. It is good at nourishing the heart and calming the nerves, calming and invigorating the “Yang”, clearing the liver and improving the eyesight. At present, its research and application are mainly concentrated in the field of cardiovascular diseases, with antioxidant, hypolipidemic, anti-atherosclerosis and other effects. Given the efficacy of Huixincao in treating CVD and our experience in using traditional Chinese medicine formulas containing Huixincao to treat ED in clinical practice, this study observed the effect of Huixincao loaded with tadalafil in the treatment of ED and explore its role in treating heart gallbladder “Qi” deficiency type ED ^[5,6].

2. Data and methods

2.1. Clinical data

80 patients who received treatment at the Men’s Clinic of Zhuhai Hospital of Guangdong Provincial Hospital of Traditional Chinese Medicine from December 2023 to December 2024 met the inclusion criteria for this trial. They would be randomly divided into an observation group and a control group, with 40 patients in each group, using a random number table method. The average age of the observation group was 35.45 ± 7.45 years, with a disease course of 12.50 (6.00 to 26.00) months; The average age of the control group was 35.00 ± 8.58 years, with a disease course of 12.00 (6.00 to 26.00) months. There was no statistically significant difference in age and disease duration between the two groups ($p > 0.05$). This study was approved by the Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine (Approval Number: BF2023-199). All operations strictly comply with relevant ethical regulations.

2.2. Diagnostic criteria

2.2.1. Diagnostic criteria for erectile dysfunction

According to the 2022 edition of the Diagnosis and Treatment Guidelines for Erectile Dysfunction by the Chinese Medical Association, the diagnostic criteria are as follows the penis cannot sustain and maintain sufficient erection to complete satisfactory sexual activity, and the

disease course is more than 3 months ^[1].

2.2.2. Diagnostic and differentiation criteria for heart and gallbladder “Qi” deficiency syndrome

The differentiation criteria for heart and gallbladder “Qi” deficiency syndrome: According to the “Andrology of Traditional Chinese Medicine” and the “Guiding Principles for Clinical Research of New Chinese Medicine Drugs”, the traditional Chinese medicine differentiation criteria for heart and gallbladder “Qi” deficiency syndrome are formulated as follows ^[7,8].

(1) Main symptoms (main efficacy indicators)

Weak or short erection, or even inability to achieve erection for more than 3 months

(2) Symptoms (secondary efficacy indicators)

Palpitations, timidity, easy startle, good fear and anxiety, insomnia, frequent dreams, fatigue and shortness of breath

(3) Tongue veins

The tongue texture is light, the coating is thin and white, and the veins are thin

According to the three main symptoms and syndromes, combined with tongue and pulse, it can be diagnosed as heart gallbladder “Qi” deficiency type impotence. Establish the following symptom grading and

quantification table for erectile dysfunction (heart and gallbladder “Qi” deficiency type), as shown in **Table 1**.

2.3. Inclusion criteria

- (1) Male aged 20–50 years old
- (2) Meets the Western diseases and Traditional Chinese Medicine diagnostic criteria for erectile dysfunction
- (3) The total score of the International Index of Erectile Dysfunction-5 (IIEF-5) is ≤ 21 points
- (4) Voluntarily participate and sign an informed consent form

2.4. Exclusion criteria

- (1) Erectile dysfunction caused by spinal cord injury or severe organic diseases
- (2) Abnormal genitalia and secondary sexual characteristics
- (3) Patients with underlying diseases such as hypotension or hypertension, diabetes and other serious cardiovascular and cerebrovascular diseases
- (4) History of pelvic surgery
- (5) Long term use of drugs that affect sexual function

Table 1. Quantitative grading table of symptoms of erectile dysfunction (heart gallbladder “Qi” deficiency type)

Heart and Gallbladder “Qi” Deficiency Type Erectile Dysfunction	Symptoms	Absent (0 points)	Mild (2 points)	Moderate (4 points)	Severe (6 points)
Primary symptom	Erectile dysfunction		Transient erection	Erection not firm enough	Unable to achieve or maintain erection during intercourse
	Timidity and palpitations		Occasional	Frequent	Persistent
	Insomnia with vivid dreams		Occasional	Frequent	Persistent
Secondary symptoms	Dizziness		Occasional	Frequent	Persistent
	Shortness of breath		Occasional	Frequent	Persistent
	Spontaneous sweating		Occasional	Frequent	Persistent
	Fatigue and lassitude		Occasional	Frequent	Persistent
Tongue and pulse (1 point if present)	Pale or red tongue				
	Thin white coating				
	Thin pulse				

- (6) Participants in other clinical trials
- (7) Other special patients, such as those with mental illnesses, allergies, and those who abuse drugs on a regular basis

2.5. Elimination criteria

- (1) Those whose syndrome types change during the treatment process
- (2) Those with poor compliance
- (3) Automatically withdraw from this trial
- (4) Those with incomplete information

2.6. Standard for detachment

- (1) Automatically exit the experimenter
- (2) Missing persons
- (3) Concurrent with other diseases or adverse reactions

2.7. Treatment methods

All enrolled patients were treated with conventional Western medicine in accordance with the 2022 edition of the Diagnosis and Treatment Guidelines for Erectile Dysfunction ^[1]. The control group patients took the western medicine Tadalafil tablets alone (Menarini International Trading (Shanghai) Co., Ltd., product batch number: D451385). Take orally after lunch, 5 mg/time, once a day; On the basis of Western medicine treatment, the observation group patients were given 15 g of Huixincuo decoction pieces (Yunnan Xinglin Tang Biotechnology Co., Ltd., product batch number: 211103), one dose per day, 300 mL of water decoction juice, and 150 mL in the morning and 150 mL in the evening. Both groups were treated and observed for 8 weeks. Sexual activity can be carried out during the treatment period without additional requirements.

2.8. Observation indicators

Statistically analyze two main efficacy indicators (clinical effective rate), secondary efficacy indicators (traditional Chinese medicine syndrome score), IIEF-5 score before and after treatment, erection hardness score, and safety indicators.

2.8.1. Clinical efficacy rate

- (1) Clinical cure

IIEF-5 score ≥ 22 points after medication

- (2) Significant effect
Total score increased by ≥ 5 points
- (3) Effective
The total score has been increased to 2–4 points
- (4) Invalid
Total score increase ≤ 1 point

2.8.2. TCM syndrome score

- (1) Complete relief
TCM primary and secondary symptoms disappear or disappear basically, TCM syndrome score $\geq 95\%$
- (2) Partial relief
Both the primary and secondary symptoms of traditional Chinese medicine have been significantly improved, and the symptom score has been reduced by $< 95\%$
- (3) Effective
Both the primary and secondary symptoms of traditional Chinese medicine have improved, and the symptom score has decreased by $< 70\%$
- (4) Invalid
The main and secondary symptoms of traditional Chinese medicine have not shown significant improvement, and even worsened, with a decrease in symptom scores of less than 30%.

2.8.3. IIEF-5 score

The International Erectile Dysfunction Rating Scale is used for evaluation, with a total of 5 questions, each worth 0–5 points. IIEF-5 score ≤ 7 points is severe, 8–11 points are moderate, 12–16 points are mild to moderate, 17–21 points are mild, and 22–25 points are no ED.

2.8.4. Audiovisual stimulus erectile testing (AVSS)

Rigiscan Plus system (GOTOP Medical Inc.) is used to measure the average rigidity and duration of the tip and base penile erection. The normal values are: tip average rigidity $\geq 40.5\%$, duration of tip penile erection ≥ 4 minutes and 45 seconds, base average rigidity of the root $\geq 48.5\%$, duration of base penile erection ≥ 7 minutes and 45 seconds ^[9, 10].

2.8.5. Erection hardness score (EHS)

It is divided into 5 levels, with scores ranging from 0 to 4.

2.8.6. Safety indicators

Safety indicators include blood routine, urine routine, liver function, kidney function, electrocardiogram, and adverse reactions or events.

3. Statistical methods

SPSS 22.0 was used for data statistics processing and analysis. If the measurement data follows a normal distribution and conforms to homogeneity of variance, one-way analysis of variance will be used for intergroup comparison, LSD method for pairwise comparison, paired sample *t*-test for intra group comparison, and mean $\pm$ standard deviation ($\bar{x} \pm s$) will be used; The distribution is non normal. K-W test is used for intergroup comparison, Bonferroni correction is used for pairwise comparison, and Wilcoxon test is used for intra group comparison, expressed as median (M) and quartiles (P25, P75); Rank sum test is used for grade data, represented by [example (%)]. $p < 0.05$ indicates statistical significance.

4. Results

A total of 80 patients were included, with 1 automatically withdrawing from the control group. Ultimately, a total of 79 patients were included, including 40 in the observation group and 39 in the control group.

4.1. Comparison of clinical efficacy between two groups after treatment

(1) Main efficacy indicators

After treatment, 16 cases were cured, 15 cases showed significant improvement, 3 cases were effective, and 6 cases were ineffective in the observation group, with a clinical effective rate of 85.00%; In the control group, 7 cases were cured, 14 cases showed significant improvement, 6 cases were effective, and 12 cases were ineffective, with a clinical effective rate of 69.23%. The difference in efficacy levels between the two groups was statistically significant ($p < 0.01$).

(2) Secondary efficacy indicators

After treatment, 20 cases were clinically controlled, 11 cases showed significant improvement, 4 cases were effective, and 5 cases were ineffective in the observation group.

The effective rate of traditional Chinese medicine syndrome was 87.50%; In the control group, 4 cases were clinically controlled, 3 cases showed significant improvement, 6 cases were effective, and 26 cases were ineffective. The effective rate of traditional Chinese medicine syndrome was 33.33%. The difference in efficacy levels between the two groups was statistically significant ($p < 0.01$), as shown in **Table 2**.

Table 2. Comparison of clinical efficacy between two groups of patients

Group	No. of case	Cure	Primary efficacy indicators markedly		Efficacy rate	Cure	Secondary Efficacy Indicators Markedly		Efficacy rate
			Effective	Ineffective			Effective	Ineffective	
Observation	40	16	15 3	6	85.00%#	20	11 4	5	87.50%#
Observation	39	7	14 6	12	69.23%	4	3 6	26	33.33%

Compared with the control group, # $p < 0.01$

Table 3. Comparison of IIEF-5 scores between two groups of patients before and after treatment [score, M (P25, P75)]

Group	Number of cases	Pre-treatment	Post-treatment
Observation	40	10.00 (8.25, 15.00)	21.00 (19.25, 23.75)*
Control	39	10.00 (7.00, 13.00)	18.00 (14.00, 21.00)

Compared with the control group * $p < 0.05$

4.2. Comparison of IIEF-5 scores between two groups of patients before and after treatment

There was no statistically significant difference in IIEF-5 scores between the two groups of patients before treatment ($p > 0.05$); After treatment, the IIEF-5 scores of both groups of patients significantly increased ($p < 0.05$), and the IIEF-5 score of the observation group was better than that of the control group ($p < 0.05$), as shown in Table 3.

4.3. Comparison of traditional Chinese medicine syndrome scores between two groups of patients before and after treatment

The comparison of TCM syndrome scores between the two groups of patients before treatment showed no statistically significant difference ($p > 0.05$); After treatment, the TCM syndrome scores of both groups significantly decreased ($p < 0.01$), and the TCM syndrome scores of the observation group were significantly better than those of the control group ($p < 0.01$), as shown in Table 4.

4.4. Comparison of AVSS test values before and after treatment between two groups of patients

Tip and base average rigidity, duration of tip and base erection, tip and base penile tumescence were compared between the two groups of patients before and after treatment, and there was no statistically significant difference ($p > 0.05$); After treatment, the detection values of AVSS in both groups improved significantly ($p < 0.005$, $p < 0.001$), and the improvement degree in the observation group was significantly better than that in the control group ($p < 0.05$, $p < 0.01$, $p < 0.005$, $p < 0.001$), as shown in Table 5–10.

4.5. Comparison of EHS scores between two groups of patients before and after treatment

There was no statistically significant difference in EHS scores between the two groups of patients before treatment ($p > 0.05$); After treatment, the EHS scores of both the observation group and the control group patients significantly increased ($p < 0.01$), and the EHS scores of the observation group were better than those of the control group ($p < 0.01$), as shown in Table 11.

4.6. Safety indicators

There were no changes in blood routine, liver and kidney function, electrocardiogram, etc. before and after treatment in both groups of patients, and no adverse reactions or events occurred during the treatment period.

5. Discussion

ED is a common male disease, and according to statistics, over 150 million men worldwide suffer from varying degrees of ED; Among males aged 40 and above in China, 40.6% suffer from ED^[11,12]. The risk factors for ED are related to age, lifestyle, genetics, and cardiovascular disease^[13].

The traditional Chinese medicine disease of erectile dysfunction (ED) is called “impotence” or “muscle weakness”. This disease often occurs due to improper sexual activity, emotional disorders, and irregular diet, resulting in dampness, heat, blood stasis, depression, deficiency, and other factors affecting the tendons^[14]. In ancient times, medical practitioners believed that the treatment of erectile dysfunction was mainly attributed to the kidneys, and the syndrome differentiation was often based on kidney “Yang” deficiency and decline. The rule of law for tonifying the kidneys and strengthening “Yang” was commonly used. However, modern people have depression, anxiety and fear due to high work pressure, family conflicts and other factors, or psychological impotence caused by excessive inhibition of sexual excitement in the cerebral cortex due to failure of first sexual intercourse and excessive mental pressure, or mixed impotence caused by primary diseases such as diabetes, high blood pressure, cardiovascular and cerebrovascular diseases, so the diagnosis and treatment of this disease has changed significantly compared with the traditional kidney “Yang” deficiency type. Traditional Chinese Medicine believes that the heart contains the spirit, which is an official of the monarch and governs the physiological activities of the human body; Gallbladder “Qi” flows through the heart, and when the gallbladder “Qi” is abundant, one can make a decision.

The “Collection of Famous Physicians” records: “The storage and release of essence are nothing but obedience to the heart.” When Jun Huo is aroused by desire, the corresponding fire follows, and the heart “Qi” flows

Table 4. Comparison of traditional Chinese medicine syndrome scores between two groups of patients before and after treatment [Score, M (P25, P75)]

Group	Number of cases	Pre-treatment	Post-treatment
Observation	40	21.00 (14.50, 37.50)	2.00 (2.00, 6.00)#
Control	39	24.00 (14.00, 38.00)	12.00 (6.00, 20.00)#

Compared with the control group # $p < 0.01$ **Table 5.** Tip average rigidity before and after treatment for both groups [$\bar{x} \pm s$ or M (P25–P75)]

Group	Number of cases	Pre-treatment	Post-treatment	<i>t</i>	<i>p</i>
Observation	40	34.91 $\pm$ 8.23	53.91 $\pm$ 11.98	-8.186	0.000
Control	39	33.91 $\pm$ 9.56	47.63 $\pm$ 14.80	-4.091	0.000

Table 6. Base average rigidity before and after treatment for both groups [$\bar{x} \pm s$ or M (P25–P75)]

Group	Number of cases	Pre-treatment	Post-treatment	<i>t/Z</i>	<i>p</i>
Observation	40	39.50 $\pm$ 13.24	68.00 (53.75, 74.50)	-4.762	0.000
Control	39	40.82 $\pm$ 11.04	57.13 $\pm$ 9.38	-6.217	0.000

Table 7. Duration of tip erection before and after treatment for two groups ($\bar{x} \pm s$)

Group	Number of cases	Pre-treatment	Post-treatment	<i>t/Z</i>	<i>p</i>
Observation	40	0.50 (0.00, 2.00)	11.53 $\pm$ 4.85	-4.911	0.000
Control	39	0.00 (0.00, 3.75)	6.22 $\pm$ 1.93	-3.718	0.000

Table 8. Duration of base erection before and after treatment for two groups [$\bar{x} \pm s$ or M (P25–P75)]

Group	Number of cases	Pre-treatment	Post-treatment	<i>t/Z</i>	<i>p</i>
Observation	40	0.50 (0.00, 3.00)	11.28 $\pm$ 4.11	-4.933	0.000
Control	39	1.75 (0.50, 4.12)	8.81 $\pm$ 3.50	3.806	0.000

Table 9. Tip penile tumescence before and after treatment in two groups ($\bar{x} \pm s$)

Group	Number of cases	Pre-treatment	Post-treatment	<i>t/Z</i>	<i>p</i>
Observation	40	29.74 $\pm$ 11.66	38.27 $\pm$ 6.48	-4.180	0.000
Control	39	27.15 $\pm$ 7.63	33.44 $\pm$ 5.82	-3.646	0.001

Table 10. Base penile tumescence before and after treatment in two groups [$\bar{x} \pm s$ or M(P25–P75)]

Group	Number of cases	Pre-treatment	Post-treatment	<i>t/Z</i>	<i>p</i>
Observation	40	29.32 $\pm$ 6.09	38.64 $\pm$ 6.49	-6.752	0.000
Control	39	28.50 (25.00, 34.00)	34.44 $\pm$ 5.80	-1.520	0.128

Table 11. Comparison of EHS scores between two groups of patients before and after treatment [score, M (P25, P75)]

Group	Number of cases	Pre-treatment	Post-treatment
Observation	40	2.00 (1.00, 2.00)	3.00 (3.00, 4.00) #
Control	39	2.00 (1.00, 2.00)	2.00 (2.00, 3.00) #

Compared with the control group # $p < 0.01$

down to the liver and kidneys, leading to the development of “Yang” affairs ^[15]. In addition, modern people have high mental pressure and heavy psychological burden, so heart gallbladder “Qi” deficiency type impotence is more common in clinical practice. This type of patient is often due to weak heart and “Qi”, and often manifests as physical timidity, timidity when faced with problems, suspicion and anxiety, palpitations and insomnia, hesitation and hesitation, and fear of sexual activity; Or due to mental disturbance, unable to communicate with the liver and kidneys, and unable to excite the “Yang” pathway; Or due to poor emotions, inability to make decisions, weak gallbladder “Qi” leading to poor “Qi” flow, insufficient heart and gallbladder “Qi”, weak and timid heart can cause weak and weak tendons, and even complete inability to achieve erection ^[16]. Traditional Chinese medicine can differentiate it as heart and gallbladder “Qi” deficiency syndrome, while modern medicine is more common in psychological and mixed erectile dysfunction.

Modern medicine believes that penile erection relies on peripheral neurovascular and non-adrenergic non-cholinergic mechanisms (NANC). When sexually stimulated, the parasympathetic nervous system, NANC nerve endings, and endothelial cells in the penile sponge synthesize and release nitric oxide (NO) under the catalysis of nitric oxide synthase (NOS). On the one hand, NO activates potassium ion channel ATPase to induce smooth muscle cell membrane overactivation, blocking the opening of voltage dependent calcium ion channels, thereby reducing intracellular calcium ion concentration; On the other hand, NO activates soluble guanylate cyclase (GC) in the cytoplasm, which converts 5-guanine triphosphate (GTP) into cyclic guanosine monophosphate (cGMP). cGMP, as the second messenger molecule in cells, can reduce the calcium ion concentration in the cytoplasm of smooth muscle cells, causing smooth muscle relaxation and inducing penile erection ^[17-19].

ED and CVD have the same risk factors, such as age, hyperlipidemia, smoking, etc., and can also induce endothelial dysfunction due to depression, diabetes, hypertension, obesity, metabolic syndrome and bad lifestyle, so ED is closely related to CVD ^[18, 19]. Meanwhile, ED is an independent risk factor for CVD and also a warning signal for the body to develop

other chronic diseases ^[20]. Therefore, in clinical practice, the first choice for ED treatment is phosphodiesterase type 5 inhibitor (PDE5i), which mainly produces type 5 phosphodiesterase and can promote the hydrolysis of cyclic guanosine monophosphate in the corpus cavernosum, maintain the tension of smooth muscle in the corpus cavernosum of the penis, and improve the blood flow and endothelial function of the cavernous arteries. Secondly, with the growth of age, or some metabolic diseases such as diabetes, the body is mostly in a state of oxidative stress, which can cause the reduction of NO and the increase of endothelin-1 (ET-1), resulting in the weakening of relaxation and the strengthening of contraction of the smooth muscle of the penis cavernous body, and at the same time damaging the vascular endothelium of small vessels, thereby aggravating ED ^[13]. Therefore, PDE5i such as tadalafil are commonly used in clinical practice to treat this disease. Although PDE5i is a first-line treatment drug, some patients still have poor efficacy after taking it, and there are also some patients whose initial use of PDE5i treatment is effective and improves erectile dysfunction. However, various physical adverse symptoms can easily lead to poor efficacy or recurrence of ED ^[21]. ED patients, due to long-term and recurrent physical symptoms, also experience increased psychological burden, forming a vicious cycle ^[21,22]. Therefore, it is urgent to introduce drugs that can improve erectile function and relieve psychological and physical symptoms in combination with tadalafil for the treatment of ED.

Based on the above reasons, our department has used of Heartwarming Grass loaded Tadalafil to treat ED and achieved satisfactory therapeutic effects. Hui Xin Cao is a traditional medicine used by ethnic minorities in Yunnan. It has a light, slightly bitter, and calming nature, and can nourish the heart and liver meridians. It has the effects of nourishing the heart and calming the mind, promoting “Yang” and restoring the pulse, clearing the liver and improving vision, and calming the mind. According to the Yunnan Chinese Herbal Medicine Selections, Huixincao is “mild bitter in nature, with anti-inflammatory, sedative, and aphrodisiac properties. The whole plant is used as medicine, mainly for heart disease, neurasthenia, impotence, and other diseases.” At present, it is clinically used to treat cardiovascular diseases such as

coronary heart disease, myocardial ischemia, arrhythmia, as well as mental and neurological diseases such as insomnia, dementia, and neurasthenia ^[23–26]. It contains chemical components such as triterpenoids, amino acids, flavonoids, steroids, fatty acids, alkaloids, and has pharmacological effects such as reducing blood lipids and atherosclerosis, protecting myocardium, lowering blood pressure, eliminating free radicals, and anti-hypoxia ^[23]. First of all, Huixin Grass can significantly increase the activity of NOS in vascular endothelial cells, thereby promoting the synthesis of NO. The increase in the content of NO can relax vascular smooth muscle, inhibit the proliferation of vascular smooth muscle cells, and has an anti-atherosclerosis effect. NO participates in oxidative stress, promotes vasodilation, and plays a decisive role in penile erection, but its production requires catalysis by superoxide dismutase (SOD) ^[24]. Secondly, the extract of *Houttuynia cordata* can increase SOD activity and protect myocardial cells from hypoxia damage ^[25]. In addition, studies have shown that the active ingredients in *Houttuynia cordata* can block the aggregation of reactive oxygen species, clear reactive oxygen species free radicals, alleviate vascular smooth muscle and endothelial cell dysfunction, and improve erectile state ^[5].

According to the visual and auditory stimulation erection test (AVSS), it can be fully seen from **Tables 5, 6, 9, and 10** that after loading *Houttuynia cordata*, the average hardness and erectile swelling of the head and root of the penis in the treatment group were significantly improved compared to the control group treated with tadalafil alone; From **Tables 7 and 8**, it can be seen that on the basis of improved penile blood supply, the duration of erection at the head and root is also prolonged. In addition, the treatment of ED with Hui Xin Cao may also be related to regulating the central nervous system. Symptoms such as palpitations, timidity, anxiety, insomnia, and shortness of breath are common adverse psychological states in ED patients in clinical practice, directly leading to a decrease in penile rigidity, tumescence, and duration of erections.

Research has found that the chemical component ursolic acid in *Houttuynia cordata* can regulate the central monoaminergic system and improve negative emotions ^[26]. In this clinical study, the IIEF-5 score, EHS score, and effective rate of traditional Chinese medicine (TCM) syndrome in ED patients were significantly higher than those in the control group after treatment with Huixin grass. The TCM syndrome score was lower than that in the control group, indicating that Huixin grass can improve the central nervous system adverse psychological state of ED patients with heart and gallbladder “Qi” deficiency, thereby improving erection hardness and duration. From the above, it can be seen that Huixin Grass improves erectile dysfunction by regulating vascular and nervous system function, which is related to stimulating the release of NO in the corpus cavernosum of the penis, relaxing the smooth muscle of the corpus cavernosum, clearing reactive oxygen species, antioxidation, relieving vascular smooth muscle and endothelial cell dysfunction, and regulating the central nervous system to alleviate the adverse psychological state of ED patients.

This clinical study showed that the observation group treated with Huixincao loaded with tadalafil had significantly higher clinical total effective rate, TCM syndrome effective rate, IIEF-5 score, and EHS score than the control group, while the TCM syndrome score was significantly lower than the control group. This indicates that Huixincao can play a significant synergistic role in the treatment of heart gallbladder “Qi” deficiency type ED. In summary, loading tadalafil into Huixincao can significantly improve the clinical efficacy of ED in heart gallbladder “Qi” deficiency syndrome, which is significantly better than using tadalafil alone, and can significantly improve ED and its associated clinical symptoms. The mechanism by which Huixincao improves heart gallbladder “Qi” deficiency type ED may be related to increasing NO content, antioxidant stress, and regulating the central nervous system. It can provide a new method for clinical treatment of ED and is worth further research and promotion in clinical practice.

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Disclosure statement

The authors declare no conflict of interest.

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