

## Original Article

# Efficacy of Shenqi Eleven-Flavor Granules combined with electrothermal warm acupuncture in patients with “firm but not lasting” erectile dysfunction characterized by spleen-kidney deficiency: a single-center retrospective analysis

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**Abstract:** Objective: A retrospective analysis of the efficacy of Shenqi Eleven-Flavor Granules combined with electrothermal warm acupuncture for spleen and kidney deficiency type related “firm but not lasting” erections. Methods: This study utilized a retrospective cohort design to analyze the clinical data of 105 patients presenting with erection that is firm but not lasting, attributed to deficiency of both spleen and kidney. These patients were categorized into three groups, each consisting of 35 cases: the electroacupuncture group, the Yougui electroacupuncture group, and the Shenqi electroacupuncture group. The overall efficacy, International Index of Erectile Function (IIEF), Erectile Hardness Score (EHS), Erectile Quality Score, serum testosterone levels (T), and Traditional Chinese Medicine (TCM) Syndrome Score were analyzed among the three groups of patients. Results: Compared to the electroacupuncture and Yougui-electroacupuncture groups, the total effective rate, IIEF-5 score, EHS, EQS, T level, and satisfaction rate with erection duration during sexual activity were all higher in the Shenqi-electroacupuncture group (all  $P < 0.05$ ). Conversely, the TCM syndrome score was significantly lower in the Shenqi-electroacupuncture group ( $P < 0.05$ ). Conclusion: Shenqi Eleven-Flavor Granules combined with electrothermal warm acupuncture demonstrates definite clinical efficacy in the treatment of “firm but not lasting” erectile dysfunction due to spleen and kidney deficiency. This combined therapy effectively improves erectile function, prolongs erection duration, reduces TCM syndrome scores, and shows no serious adverse reactions.

**Keywords:** Erectile dysfunction, Shenqi Eleven-Flavor Granules, electrothermal warm acupuncture, TCM syndrome score, testosterone

## Introduction

Erectile dysfunction (ED) belongs to the category of “venereal impotence” in traditional Chinese medicine (TCM). It refers to the difficulty to achieve or maintain a satisfactory penile erection sufficient for sexual intercourse, including conditions such as a flaccid and non-erect penis, an erection that is not firm, or firm but not lasting, resulting in unsatisfactory sexual life for a course of more than 3 months [1]. Prolonged ED can severely impair patient’s psychological health, easily leading to negative emotions such as anxiety, depression, and

even fear of sexual activity, which has a significant effect on the patient’s marital life and family harmony.

Nowadays, the clinical symptoms of ED are more often manifested as erections that are “firm but not lasting”, rather than complete erectile failure. Phosphodiesterase type-5 (PDE-5) inhibitors are currently recommended as first-line pharmacological agents for ED and are effective in improving erectile function [2]. However, some patients exhibit inadequate responses or decreased efficacy after long-term use. Therefore, TCM-based treatments

have become a more readily acceptable alternative for many patients with mild to moderate ED. Increasing evidence suggests that some Chinese herbal medicines, including ginseng and *Astragalus membranaceus*, exert regulatory effects on the nitric oxide-cyclic guanosine monophosphate (NO-cGMP) signaling pathway through multi-component and multi-target mechanisms. When combined with acupuncture at specific acupoints, these herbs may offer effects comparable or even exceeding those of PDE5 inhibitors, thereby improving erectile function and providing a natural and safe option for the management of ED [3, 4].

TCM generally believes that the fundamental pathogenesis of ED is “deficiency mixed with stasis”. In excess syndromes, damp-heat accumulation, Qi stagnation, and blood stasis obstruct the flow of Qi and blood, resulting in dysfunction of Yin organs. In deficiency syndromes, visceral deficiency and insufficient Qi and blood lead to inadequate nourishment of *Zongjin*, ultimately resulting in erectile flaccidity due to deficiency [5]. Therefore, the primary therapeutic principle involve tonifying Qi and blood, strengthening the spleen, and reinforcing kidney. Commonly prescribed TCM formulations such as Yougui Pill, Bushenning Tablets, and Compound Xuanju Capsules, which function to tonify Qi and warm Yang, have demonstrated certain effects on enhancing libido and erection hardness; however, their effects on maintaining erection duration are not satisfactory. Shenqi Eleven-Flavor Granules are often used clinically for conditions associated with deficiency of Qi and blood in the spleen and kidney [6]. Its mechanism of action precisely correspond to the etiology of “firm but not lasting” erection in individuals with dual deficiency of the spleen and kidney. Furthermore, clinical observations have indicated that this formulation effectively prolongs the erectile state.

Based on this, the present study retrospectively analyzed the clinical data of 105 patients with erectile dysfunction characterized as “firm but not lasting” due to spleen and kidney deficiency, aiming to explore the therapeutic effect and safety of Shenqi Eleven-Flavor Granules combined with electrothermal warm acupuncture therapy for this condition and to provide a theoretical basis and clinical data support for the treatment of such patients.

## Materials and methods

### Sample size calculation

The sample size was calculated using GPower software based on one-way analysis of variance (ANOVA). For the primary outcome measure, based on previous research, we anticipated the intervention effect size to be approximately medium to large. With a two-tailed significance level set at  $\alpha=0.05$ , a statistical power of 80%, and an effect size of  $f=0.30$ , the required total sample size was approximately 105 cases, with 35 cases per group.

### General information

A total of 105 patients diagnosed with erectile dysfunction (ED) were enrolled from the Reproductive Medicine Center of Anhui Provincial Hospital of Traditional Chinese Medicine between January 2025 and June 2025. These patients met the study's predefined criteria for the Spleen and Kidney Deficiency Type, specifically presenting with “firm but not lasting”. Subsequently, they were divided into the electroacupuncture group (receiving electrothermal warm acupuncture, 35 cases), the Yougui electroacupuncture group (receiving Yougui Capsules combined with electrothermal warm acupuncture, 35 cases), and the Shenqi electroacupuncture group (receiving Shenqi Eleven-Flavor Granules combined with electrothermal warm acupuncture, 35 cases) according to the intervention method. This study was approved by the Ethics Committee of Anhui Provincial Hospital of Traditional Chinese Medicine (Approval No.: 2026AH23).

### Diagnostic criteria

The diagnostic criteria were established with reference to the *Chinese Guidelines for Diagnosis and Treatment of Andrological Diseases and Expert Consensus* [7], the International Index of Erectile Function-5 (IIEF-5) [8], and the definition of “firm but not lasting” erection formulated in this study. Erectile dysfunction was defined as the inability to maintain sufficient penile erection time to achieve satisfactory sexual intercourse, with a course of disease more than 3 months and an IIEF-5 score  $\leq 22$  points. The diagnosis of spleen and kidney deficiency syndrome referred to the *Guidelines for*

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*Integrated Traditional Chinese and Western Medicine Multi-disciplinary Diagnosis and Treatment of Erectile Dysfunction (2022 Edition)* [5]. The primary clinical manifestations included firm but not lasting erection accompanied by dizziness and tinnitus, soreness of waist and knees; secondary symptoms included fatigue and somnolence, limb weakness, frequent nocturia, a pale and swollen tongue with tooth marks, a white and slippery tongue coating, and deep, slow, or weak pulse.

### *Inclusion criteria*

Fulfillment of the western medicine diagnostic criteria for erectile dysfunction characterized by “firm but not lasting” erections; Fulfillment of the TCM syndrome diagnostic criteria; Erectile Hardness Score (EHS) of grade 3; Age between 20 and 40 years; A regular sexual life with a fixed partner (once or twice weekly) for at least 3 months, with persistent inability to achieve satisfactory sexual intercourse for both partners.

### *Exclusion criteria*

ED complicated by diseases such as hypertension or diabetes; ED caused by penile trauma, congenital or acquired penile anatomical abnormalities; use of any drugs that affect erectile function within the past 7 days before enrollment; Inability to cooperate with the treatment plan; Recent use of androgen therapy [9].

### *Methods*

#### *Treatment methods*

Patients in the electroacupuncture group were given periodic electrothermal warm acupuncture alone. Patients in the Yougui-electroacupuncture group were given additional Yougui Capsules (Jiangxi Yintao Pharmaceutical Co., Ltd.; SFDA approval number: Z20030134; specification: 0.45 g) at a dose of 0.9 g orally, three times daily before meal, for a duration of 4 weeks on the basis of acupuncture. Patients in the Shenqi-electroacupuncture group were additionally prescribed with Shenqi Eleven-Flavor Granules (Jiangxi Shangao Pharmaceutical Co., Ltd.; SFDA approval number: Z109-80002; specification: 2 g/bag) at a dose of 2 g orally, three times daily before meal, for a duration of 4 weeks.

Electrothermal warm acupuncture was performed using a Longcheng HT-2 warm acupuncture and electroacupuncture comprehensive therapeutic instrument (Medical Device Product Technical Requirement No.: Su Xie Zhun 20162260007). Patients were placed in the supine position, and specific acupoints were selected: Guanyuan (CV4), Qihai (CV6), Zusanli (ST36), Xuehai (SP10), and Sanyinjiao (SP6) (Acupoint localization referred to the specific acupoint locations detailed in the *10th edition textbook of Acupuncture and Moxibustion*). After routine disinfection, disposable sterile acupuncture needles (0.25\*40 mm; Guizhou Andy Medical Equipment Co., Ltd.; Medical Device Registration Certificate No.: Qian Xie Zhun 20202270002) were inserted using reinforcing manipulation. Following needle insertion, the needles were obliquely advanced towards the perineum, and lifting-thrusting reinforcing manipulation was performed to elicit characteristic sensation of *Deqi*, including soreness, numbness, and distension. The output electrode of the electrothermal warm acupuncture therapeutic device was connected to the acupuncture needle at about 0.5 cm above the skin. Sparse-dense wave was applied (sparse wave/dense wave: 5 Hz/50 Hz; Pulse width: 0.5 ms for sparse waves, and 0.1 ms for dense waves; alternation period: 4 seconds). The intensity was gradually increased from zero to a level tolerable for patients. Subsequently, the heating function was activated and maintained at a constant temperature of 40°C, and treatment timing was initiated [10]. Each session lasted 30 minutes, with a course of three times per week for a total of 4 weeks.

### *Observation indicators*

*Primary outcome measures:* (1) IIEF-5 score: The IIEF-5 is currently the most commonly used tool for the assessment of erectile function, covering the aspects of erectile confidence, erection frequency, ability to maintain erection, and satisfaction with sexual intercourse. The total score ranges from 5 to 25, with 22-25 points indicating normal erectile function. Lower scores indicate poorer erectile function [11]. (2) EHS score: The EHS reflects the ability to achieve sufficient penile rigidity for vaginal penetration and is also an important indicator for assessing erectile function. Erectile hardness is classified into 4 grades from weak to

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strong: Grade 1, no penile enlargement or erection (“flaccid and not rising”); Grade 2, penile enlargement without sufficient rigidity for penetration (“rising but not firm”); Grade 3, rigidity sufficient for penetration but not completely hard (“firm but not lasting”); Grade 4, fully rigid erection with sufficient hardness, considered normal function. Grades 1 to 4 correspond to scores of 1-4, respectively. (3) Erectile Quality Score (EQS): The EQS consists of 15 items encompassing five dimensions: erectile ability, duration, erection hardness, penile sensitivity upon stimulation, and overall perception of the entire erection process. Each item is scored from 0 to 4. The total score ranges from 0 to 60, with higher scores indicating better erection quality [12]. The EQS was calculated as the sum of score for answered items plus the average score of answered items multiplied by the number of unanswered questions. (4) TCM syndrome score: Five symptoms, including firm but not lasting erection, soreness of waist and knees, dizziness and tinnitus, fatigue, and frequent nocturia, were scored 0, 1, 2, and 3 points for no symptoms, mild, moderate, and severe. The total TCM syndrome score was calculated as the sum of the score for each item. The TCM symptom scores were recorded before treatment and four weeks after treatment.

It should be noted that penile hemodynamic assessment is an effective method for evaluating the vascular function of the penis [13]. Currently, color Doppler ultrasound combined with intracavernosal injection (ICI) is commonly employed to assess cavernosum vasodilation. However, this study focused on patients who experienced firm but not sustained erections. Given that erectile rigidity at the initiation of sexual activity was generally adequate, indicating no significant impairment in vasodilation, and considering that ICI is an invasive procedure that many patients were reluctant to undergo, penile hemodynamics was not used as an observation index in this research.

*Secondary outcome measures:* (1) Serum testosterone (T) level: 3-5 ml of venous blood was collected from patients before and after treatment, and serum was separated for analysis. Serum T level was detected using a chemiluminescent immunoassay (kit was supplied by Siemens Medical Diagnostics Products Co.,

Ltd., with Medical Device Registration Certificate No.: National Medical Equipment Injection 20182400442). (2) Satisfaction with erection duration: Patient satisfaction with erection duration was classified into four levels: very satisfied (erection duration fully met the requirements of sexual activity), relatively satisfied (erection duration was prolonged compared with before treatment but still did not fully meet the requirements of sexual activity); average (erection duration was slightly prolonged compared with before treatment but remained insufficient), and dissatisfied (no significant improvement compared with before treatment). The total satisfaction rate = (very satisfied cases + satisfied cases + average cases)/total cases \* 100% [14].

### Efficacy evaluation criteria

Based on the IIEF-5, the *Guiding Principles for Clinical Research of New Chinese Medicines*, and clinical practice, the efficacy evaluation criteria were established as follows.

**Cure:** Erection duration was prolonged sufficiently to fully satisfy the requirements of sexual activity; the IIEF-5 score was  $\geq 22$ ; TCM symptoms disappeared; and TCM syndrome score decreased by  $\geq 80\%$ .

**Remarkably effective:** Erection duration was prolonged compared with that before treatment, but still did not fully satisfy the requirements of sexual activity; the IIEF-5 score increased by  $\geq 50\%$  compared with that before treatment; TCM symptoms were significantly improved; and TCM syndrome score decreases by 60%-80%.

**Effective:** Erection duration was slightly prolonged compared with that before treatment, but remained insufficient for sexual life; the IIEF-5 score increased by 25%-50% compared with that before treatment; TCM symptoms were improved to some extent; and TCM syndrome score decreased by 30%-60%.

**Ineffective:** No significant improvement in erection duration was observed compared with that before treatment; the IIEF-5 score increased by  $< 25\%$  compared; TCM symptoms showed no significant improvement; and the TCM syndrome score decreased by  $< 30\%$ .

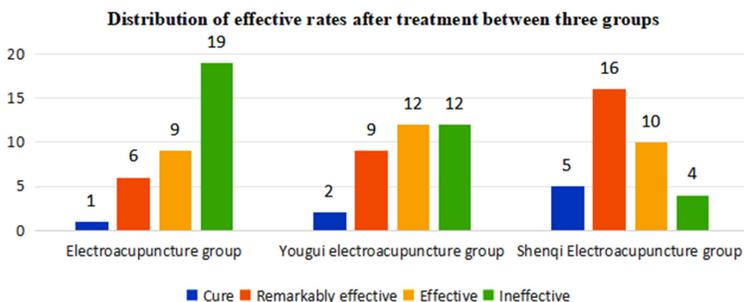
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**Table 1.** Comparison of general characteristics among three groups

Group	n	Age (years)	Body mass index (kg/m <sup>2</sup> )	Disease duration (months)
Electroacupuncture group	35	30.97±4.01	23.00±1.91	8.51±2.96
Yougui-electroacupuncture group	35	31.37±4.15	22.94±2.05	9.03±3.20
Shenqi-electroacupuncture group	35	30.71±3.95	22.37±2.14	8.66±2.84
F		0.235	1.018	0.273
P		0.791	0.365	0.762

**Table 2.** Comparison of clinical efficacy among three groups [n (%)]

Group	n	Cure	Remarkably effective	Effective	Ineffective	Total effective cases	Total effective rate (%)
Electroacupuncture group	35	1	6	9	19	16	45.7
Yougui-electroacupuncture group	35	2	9	12	12	23	65.7
Shenqi-electroacupuncture group	35	5	16	10	4	31	88.6
χ <sup>2</sup>							14.486
P							0.001



**Figure 1.** Distribution of effective rates after treatment in the three groups.

Overall effective rate was calculated as the sum of cured, markedly effective, and effective cases divided by total number of cases, multiplied by 100% [15].

### Statistical analysis

Statistical analyses were analyzed using SPSS version 26.0. Categorical variables were presented as n (%), and comparisons were performed using the Chi-square test, with Bonferroni correction applied for *post hoc* pairwise comparisons. Continuous variables were expressed as mean ± standard deviation ( $\bar{x} \pm s$ ), and one-way ANOVA was used for comparisons among multiple groups, followed by LSD *post hoc* analysis for pairwise comparisons. Ordinal data were analyzed using non-parametric tests. A two-sided *P*-value <0.05 was considered significant.

## Results

### Comparison of baseline characteristics among the three groups

No significant differences were observed in general data among the three groups of patients ( $P > 0.05$ , **Table 1**), indicating inter-group comparability.

### Comparison of clinical efficacy among the three groups

The total effective rate was 45.7% in the electroacupuncture group, 65.7% in the Yougui-electroacupuncture group, and 88.6% in the Shenqi-electroacupuncture group. The clinical efficacy in the Shenqi-electroacupuncture group was superior to the other two groups ( $P < 0.01$ ), as detailed in **Table 2** and **Figure 1**.

### Comparison of erectile function among the three groups

Before treatment, no significant differences were observed in IIEF-5 score, EHS, or EQS among the three groups. After treatment, these scores significantly increased in all three groups, with the Shenqi-electroacupuncture group demonstrating significantly higher scores

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**Table 3.** Comparison of IIEF-5 and EQS before and after treatment among three groups ( $\bar{x} \pm s$ , points)

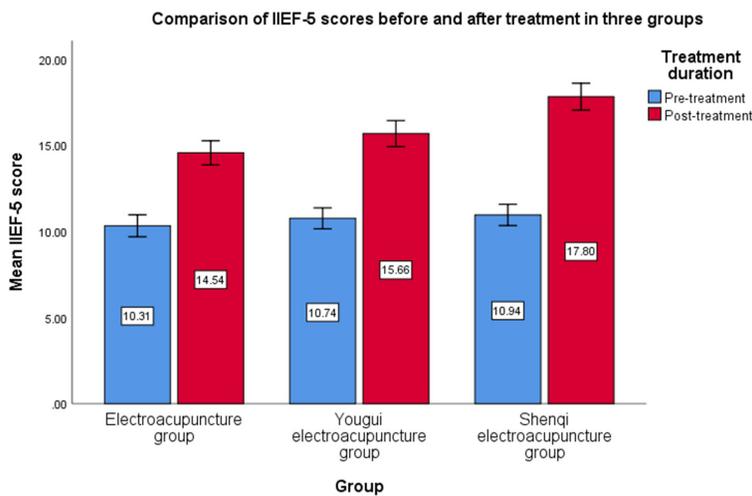
Group	n	IIEF-5 scores		EQS scores	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Electroacupuncture group	35	10.31±1.86	14.54±2.03	35.17±3.04	37.46±4.16
Yougui-electroacupuncture group	35	10.74±1.77	15.66±2.20	34.74±3.59	38.54±4.29
Shenqi-electroacupuncture group	35	10.94±1.80	17.80±2.27	34.66±3.11	42.71±4.72
F		1.102	20.375	0.251	13.955
P		0.336	<0.001	0.779	<0.001

Notes: IIEF-5, International Index of Erectile Function-5; EQS, Event Quality Score.

**Table 4.** Comparison of EHS grade distribution before and after treatment among three groups [n]

Group	Pre-treatment				Post-treatment			
	Grade 1	Grade 2	Grade 3	Grade 4	Grade 1	Grade 2	Grade 3	Grade 4
Electroacupuncture group	0	0	35	0	0	0	27	8
Yougui-electroacupuncture group	0	0	35	0	0	0	23	12
Shenqi-electroacupuncture group	0	0	35	0	0	0	14	21
H		<0.001				10.543		
P		>0.990				0.005		

Note: EHS, Erection Hardness Score.



**Figure 2.** Comparison of IIEF-5 scores before and after treatment among the three groups.

than the other two groups ( $P < 0.05$ ), as shown in **Tables 3, 4** and **Figures 2, 3**.

### Comparison of TCM syndrome scores among the three groups

No significant differences in pre-treatment TCM syndrome scores were observed among the three groups. After treatment, the TCM syndrome scores decreased in all three groups,

with the Shenqi-electroacupuncture group demonstrating significantly lower scores compared with the other two groups ( $P < 0.01$ ), as detailed in **Table 5** and **Figure 4**.

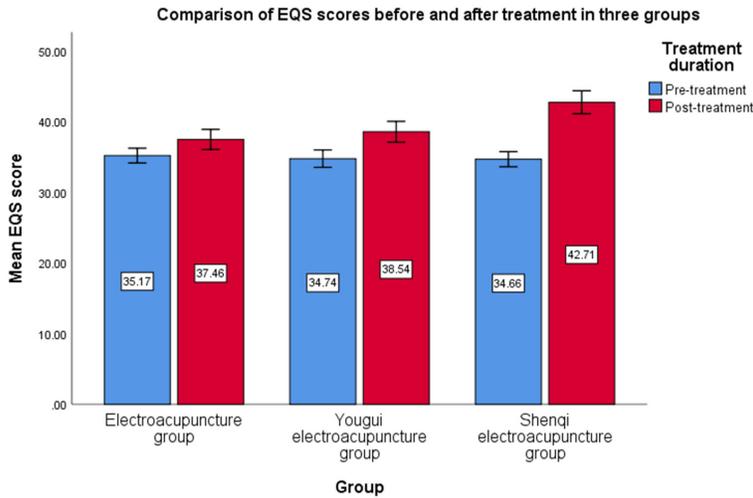
### Comparison of testosterone levels among the three groups

Before treatment, there was no significant difference in serum T levels among the three groups ( $P > 0.05$ ). After treatment, serum T levels increased in all three groups, with the Shenqi-electroacupuncture group showing the highest serum T levels ( $P < 0.01$ ), as detailed in **Table 6**.

### Comparison of satisfaction rate among the three groups

After treatment, the duration of erection during sexual activity was generally prolonged in all three groups compared to before treatment. The overall satisfaction rate with erection duration during sexual activity in the Shenqi-electroacupuncture group was 85.7%, significantly higher than 60.0% in the Yougui-ele-

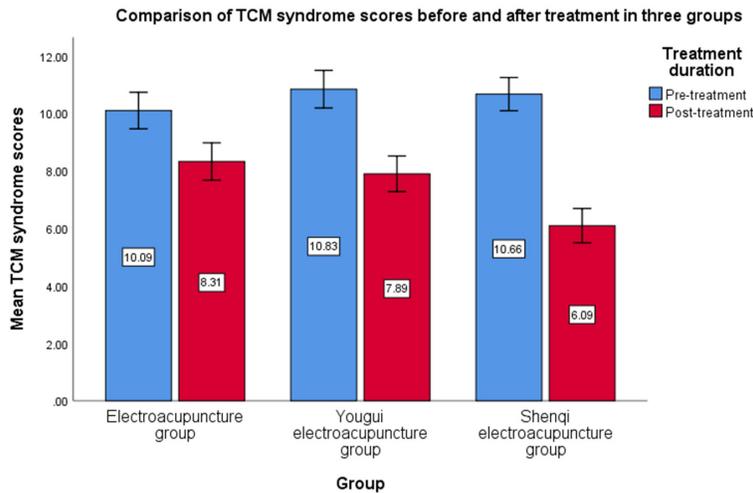
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**Figure 3.** Comparison of EQS before and after treatment among the three groups.

**Table 5.** Comparison of TCM syndrome scores before and after treatment among the three groups ( $\bar{x} \pm s$ , points)

Group	n	Pre-treatment	Post-treatment
Electroacupuncture group	35	10.09±1.85	8.31±1.89
Yougui-electroacupuncture group	35	10.83±1.90	7.89±1.81
Shenqi-electroacupuncture group	35	10.66±1.68	6.09±1.74
F		1.609	14.865
P		0.205	<0.001



**Figure 4.** Comparison of TCM syndrome scores before and after treatment among the three groups.

ctroacupuncture group and 54.3% in the electroacupuncture group ( $P < 0.05$ ), as detailed in **Table 7**.

### Comparison of safety profile among the three groups

From treatment initiation to 1 month after its discontinuation, mild treatment-related adverse events were observed in patients across three groups. A total of 23 adverse events were observed, primarily presenting as puncture site bleeding or subcutaneous ecchymosis (16 cases). All these events occurred following the acupuncture needling, and were classified as 'mild' in severity. Puncture site bleeding was promptly controlled by immediate compression with a sterile dry cotton swab. Subcutaneous ecchymoses were generally less than 2 cm in diameter, were not associated with exacerbated pain or functional impairment, required no specific intervention, and all resolved spontaneously within 3 to 5 days. The remaining minor adverse reactions were attributed to oral medications, and these reactions resolved spontaneously without specific intervention and did not lead to any treatment interruption or study withdrawal. There were no significant differences in adverse reactions among the three groups ( $P > 0.05$ ), as detailed in **Table 8**.

### Discussion

Penile erection is a neuromuscular activity controlled by the central nervous system, which is jointly influenced by multiple biological factors, including penile anatomical structure, neural reflexes, blood circulation, and endocrine regulation, as well as non-biological factors such as psychological and social influences. Abnormalities in any factor may lead to erectile dysfunction

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**Table 6.** Comparison of testosterone levels before and after treatment among the three groups ( $\bar{x} \pm s$ , nmol/L)

Group	n	Pre-treatment	Post-treatment
Electroacupuncture group	35	10.57±1.69	11.61±1.81
Yougui-electroacupuncture group	35	10.49±1.81	13.16±1.78
Shenqi-electroacupuncture group	35	10.10±1.62	13.79±2.08
F		0.744	12.318
P		0.478	<0.001

[16]. ED is commonly classified into three degrees: “soft and not erect”, “erect but not firm”, and “firm but not lasting”. Among them, “firm but not lasting” type of ED is particularly prevalent and represents one of the most challenging sexual function disorders. Patients with this condition typically present with normal or mildly decreased libido and normal erectile initiation at the beginning of sexual activity, with initially adequate penile rigidity. However, during sexual intercourse, slight distraction or several minutes of sustained activity may lead to an involuntary loss of rigidity, resulting in insufficient penile hardness and, in severe cases, the inability to complete sexual intercourse.

At present, PDE5 inhibitors are the first-line therapy for ED. Their mechanism of action involves selective inhibition of PDE5, thereby enhancing the activity of the nitric oxide-cyclic guanosine monophosphate (NO-cGMP) signaling pathway. This leads to a significant and sustained increase in intracellular cGMP levels within corpus cavernosum smooth muscle cells, subsequently activating protein kinase G (PKG). The activation of PKG ultimately results in smooth muscle relaxation and vasodilation, thereby promoting penile erection. Although the mechanism of action of PDE5 inhibitors has been clearly elucidated in modern medicine, many patients are more inclined towards TCM treatments due to concerns regarding medication side effects and dependency. Furthermore, accumulating evidence suggest that certain Chinese herbal medicines and acupuncture at specific acupoints can exert similar therapeutic effects by modulating the same NO-cGMP signaling pathway. Based on these findings, the present study was designed to evaluate the clinical efficacy of a TCM-based therapeutic approach for the treatment of “firm but not lasting” type erectile dysfunction in patients with the TCM syndrome of spleen-kidney deficiency.

ED is referred to as “yin-wei” and “slackening of zongjin” in *Huangdi Neijing* [17]. In *Lin Zheng Zhi Nan Yi An-Veneral Impotence*, it is stated that “Slackening of zongjin occurs when yangming meridian is deficient” [18]. According to TCM theory, the pathological site of erectile dysfunction lies in the zongjin, primarily involv-

ing the spleen, kidney, and yangming meridians. In TCM, the kidney is responsible for governing storage and consolidation, thereby preserving essence and Qi, while the spleen governs transformation and transportation, promotes the ascending of clear Qi and serves as the source of Qi and blood generation. In accordance with the therapeutic principle of treating wilting disorders by exclusively targeting the Yangming meridian, clinical management of erectile dysfunction characterized as “firm but not lasting” should be placed on Qi-tonifying and blood-nourishing strategies to reinforce spleen and kidney function.

Shenqi Eleven-Flavor Granules, known for their kidney-tonifying, spleen-strengthening, Qi-tonifying, and blood-nourishing properties, were chosen as the investigational drug. Nitric oxide (NO), an active molecule synthesized by vascular endothelial cells, plays a critical role in vasodilation and blood circulation. This function is analogous to *ZongQi* in TCM theory, which circulates through the heart meridians and drives the movement of Qi and blood. Previous animal experiments demonstrated that reduced expression of endothelial nitric oxide synthase (eNOS), NO, and related proteins inhibited cavernosal smooth muscle relaxation, consequently impairing erectile function [19]. Compared to Yougui Capsules, Shenqi Eleven-Flavor Granules contain additional Qi-tonifying herbs, including ginseng and *Astragalus membranaceus*. Ginsenosides, the principal bioactive components of ginseng, are classified into three types: ginsenoside Rg1 promotes eNOS mRNA expression and enhances NO production via activation of the PI3K-Akt signaling pathway [20], whereas ginsenoside Rb1 increases NO production by inhibiting the protein kinase C (PKC) pathway [21]; In addition, *Astragali Radix* has been shown to upregulate neuronal nitric oxide synthase (nNOS) expres-

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**Table 7.** Comparison of overall satisfaction rate among the three groups [cases (%)]

Group	n	Very satisfied	Satisfied	Average	Dissatisfied	Total number of satisfied	Total satisfaction rate (%)
Electroacupuncture group	35	2	10	7	16	19	54.3
Yougui-electroacupuncture group	35	3	7	11	14	21	60.0
Shenqi-electroacupuncture group	35	8	18	4	5	30	85.7
$\chi^2$							8.829
P							0.012

**Table 8.** Comparison of incidence of adverse reactions during treatment among the three groups [n (%)]

Group	n	Nausea	Local bleeding or ecchymosis	Insomnia	Constipation	Total/Cases	Incidence of adverse reactions (%)
Electroacupuncture group	35	0	6	0	0	6	17.1
Yougui-electroacupuncture group	35	0	5	2	2	9	25.7
Shenqi-electroacupuncture group	35	2	5	0	1	8	22.9
$\chi^2$							0.779
P							0.677

sion in penile corpus cavernosum tissue. nNOS, by catalyzing L-arginine to generate NO, facilitates corpus cavernosum relaxation and penile erection [22]. The shared ingredients of Shenqi Eleven-Flavor Granules and Yougui Capsules, including *Rehmanniae Radix Praeparata* and *Radix Angelicae Sinensis*, promote the generation and smooth circulation of Qi and blood, thereby enhancing penile blood supply and improving erectile function [23]. Furthermore, the medicinal components of Shenqi Eleven-Flavor Granules may indirectly elevate intracellular cGMP levels by inhibiting the activity of phosphodiesterase-mediated cGMP degradation. This mechanism is similar to that of sildenafil. Studies have shown that rats treated with TCM preparations designed to warm Yang, invigorate the spleen, and replenish Qi exhibited significantly higher levels of NOS, NO, cGMP, and cAMP in their penile tissue compared to untreated normal animals [24].

This study demonstrated that the duration of erection during sexual activity was prolonged in all three groups after treatment. Notably, the Shenqi-electroacupuncture group exhibited the highest overall satisfaction rate regarding the duration of erection during sexual activity. This may be attributed to the effect of Shenqi Eleven-Flavor Granules in replenishing Qi and

nourishing blood. Sufficient Qi supports robust Yang, and abundant blood enhances vascular filling capacity. As penile erection and its maintenance are primarily depend on cavernosal vasodilation, improved blood supply and Qi can significantly enhance erectile sustainability. Furthermore, increased penile engorgement may augment frictional stimulation during intercourse, thereby contributing to improved sexual satisfaction [25].

In addition to pharmacological treatments, acupuncture, a characteristic therapy of TCM with extensive clinical applications, regulates Qi and blood flow through meridian stimulation and reinforcement of Qi and blood, thereby unblocking meridians. In this study, electrothermal warm acupuncture, a novel acupuncture technique combining electrical pulse stimulation and thermal effects with traditional reinforcing needling methods, was employed. For patients with spleen and kidney deficiency-related erectile dysfunction, characterized by an erection that is “firm but not lasting”, specific acupoints identified via data mining [26] were selected based on the acupuncture principles of “reinforcing deficiency” and “moxibustion for sunk-en conditions”. These points, including Guanyuan, Qihai, Xuehai, Zusanli, and Sanyinjiao, were then stimulated with sparse-dense waves

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to enhance local metabolism, promote blood circulation, and improve tissue nutrition. Upon insertion of the needle into the skin, the physical stimulation (such as twisting, lifting, thrusting, and electroacupuncture) was transduced into biochemical signals, activating the NO-cGMP pathway, leading to cavernosal smooth muscle relaxation, vasodilation, and increased blood flow. Furthermore, electrothermal warm acupuncture converts electrical energy into thermal energy, maintaining a constant temperature of 40°C. Continuous thermal stimulation facilitates capillary dilation, promotes Qi circulation, and regulates blood flow, thereby improving erectile function. Moreover, the application of electrothermal warm acupuncture to specific acupoints can improve sexual function in patients with ED through neuromodulation and hormonal regulation [27].

With advances in modern technology, neural tracing techniques have become a valuable asset in exploring the neural connections between meridians, collaterals, and viscera. It has been demonstrated [28] that stimulation at Guanyuan (CV4) acupoint is transmitted by afferent neurons to the spinal cord and then to higher central structures such as the thalamus, thereby exerting a neuroregulatory effect on sexual function. Testosterone, a key hormone for maintaining male sexual function, is also influenced by electroacupuncture, warm needling, and moxibustion. These techniques have been shown to regulate the hypothalamus-pituitary-testis axis, promote sex hormone secretion, and increase serum T levels in animal models [29], aligning with the observed elevation in serum T levels in all three groups after treatment in this study.

Furthermore, post-treatment IIEF-5, EHS, EQS, and serum T level in the Shenqi-electroacupuncture group were significantly higher than in the other two groups. These findings further indicate that the combined treatment not only prolongs erection duration and improves penile hemodynamics, but also comprehensively enhances erectile function through neural regulation and hormonal modulation. Moreover, the overall response rate and improvement in TCM syndrome scores significantly improved in all three patient groups after treatment. From a TCM perspective, the vasodilatory effect mediated by the NO-cGMP path-

way correspond to the warming and nourishing action of *Mingmen Fire*, thereby alleviating symptoms such as lumbosacral soreness, knee weakness, and general fatigue.

Notably, the combination of Shenqi Eleven-Flavor Granules and electrothermal warm acupuncture demonstrated superior efficacy compared to both Yougui capsules combined with electrothermal warm acupuncture and electrothermal warm acupuncture alone. Throughout the treatment and follow-up period, the most common adverse event observed was mild pinprick bleeding, which is primarily caused by accidental puncture of subcutaneous capillaries. Immediate compression effectively controlled bleeding, confirming the safety of the procedure. Although bleeding may cause transient anxiety in patients, adequate pre-treatment counseling and post-event communication can effectively mitigate patient concerns and improve treatment compliance.

Nevertheless, certain limitations should be noted. First, some outcome measures were obtained by self-reported questionnaires, which may be subject to subjective bias. Future research could incorporate objective experimental methodologies to enhance data accuracy and strengthen mechanistic validation. Second, regarding treatment safety, it is necessary to comprehensively document coagulation values and patients' medication history to allow a more thorough evaluation of bleeding-related risk factors associated with acupuncture therapy.

### Conclusion

The combination of Shenqi Eleven-Flavor Granules and electrothermal warm acupuncture demonstrates a significant therapeutic effect on erectile dysfunction characterized by "firm but not lasting" due to spleen and kidney deficiency. This study provides new clinical evidence supporting an integrative Traditional Chinese Medicine-based treatment strategy for this specific ED subtype.

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## Disclosure of conflict of interest

None.

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## References

- [1] Expert Consensus Group. Expert consensus on the integrated traditional Chinese and Western medicine diagnosis and treatment of erectile dysfunction. *Chin J Integr Tradit West Med Surg* 2022; 28: 763-768.
- [2] Zhao H, Yang SW, Kang CM, Li J, Tian YQ and Liu JH. Clinical study of Shugan Zhuyang Decoction combined with small-dose tadalafil in the treatment of patients with functional erectile dysfunction of kidney deficiency and liver depression type. *Chin J Hum Sexuality* 2024; 33: 140-144.
- [3] Chen LL, Jia WG, Su H and Wang WQ. Mechanism and clinical studies on ginseng for treatment of erectile dysfunction. *Drugs Clin* 2010; 25: 116-120.
- [4] Yue ZX, Guo FX, Liu L and Yi Q. Effect of Huangqi Jiuzi Tea for patients with Shen-Yang-deficiency type pre-diabetes concomitant with erectile dysfunction. *Chin J Androl* 2024; 38: 22-26, 57.
- [5] Yu WX and Wang H. Expert consensus on the integrated traditional Chinese and Western medicine diagnosis and treatment of erectile dysfunction (2022 Edition). *Chin J Androl* 2022; 36: 3-9.
- [6] Zhao SP. Clinical study on Shenqi Shiyiwei granules combined with Western medicine for chronic obstructive pulmonary disease of lung-kidney deficiency type at stable stage. *New Chin Med* 2021; 53: 56-59.
- [7] Wang XF, Zhu JC, Jiang H, Deng CH, Shang XJ, Huang YR and Wu B. Chinese guidelines and expert consensus on the diagnosis and treatment of male diseases (2016 Edition). Beijing: People's Medical Publishing House 2016; 27.
- [8] Zhu JC. Guidelines for the diagnosis and treatment of male erectile dysfunction. *Chin J Androl* 2004; 68-72.
- [9] Liu FX, Abdureyimujiang RZ, Liu WJ, Yang YD, Jin J, Xiong K and Adilijiang YM. Changes of liver function indexes and their relationship with IIEF-5, MSF-4 scores in erectile dysfunction patients. *Chin J Mod Med* 2020; 30: 47-51.
- [10] Xie JX, Jiang P and Guo J. Clinical observation on the treatment of Yin deficiency and fire excess syndrome of erectile dysfunction with electrothermal acupuncture combined with Zogui Pill. *China Naturopathy* 2023; 31: 59-61.
- [11] Yuan YM, Zhou S and Zhang K. Questionnaires on the diagnosis and treatment of erectile dysfunction. *Natl J Androl* 2008; 14: 1121-1125.
- [12] Bao H and Zhang ZS. Effect of vardenafil combined with Shugan Yiyang Capsules on patients with erectile dysfunction. *Chin Foreign Med Res* 2023; 21: 33-37.
- [13] He J, Liu JZ and He L. Color Doppler combined with pharmacological evaluation of penile corpus cavernosum vascular function. *J Imaging Res Med Appl* 2021; 5: 215-216.
- [14] Lei ZH. Effect of Longlu Capsule on sexual satisfaction of patients with erectile dysfunction of kidney-Yang deficiency type. *Inner Mong J Tradit Chin Med* 2022; 41: 53-55.
- [15] Wang ZQ, Guan Y, Liu CH, Sun DL and Shan WS. Clinical study on avanafil combined with Zhuyang Huoxue Formula in the treatment of erectile dysfunction. *Eval Anal Drug-Use China* 2024; 24: 651-654.
- [16] Hu HT, Zhang YD and Wang S. The mechanisms and progress of traditional Chinese medicine in the treatment of erectile dysfunction. *Chin J Hum Sexuality* 2025; 34: 87-93.
- [17] Qin G. A study on evolution of the term impotence and its classification and diagnosis. *Zhonghua Yi Shi Za Zhi* 2000; 30: 28-31.
- [18] Li JQ and Zhang W. Discussion on the clinical application of acupuncture in the treatment of impotence based on the theory of "treating impotence by focusing on Yangming". *Hunan J Tradit Chin Med* 2024; 40: 124-126.
- [19] Feng JL, Li HS, Sun S, Wang B, Zhang HN, Gao ZX, Mao PM, Sun LJ, Huang NW and Wang JS. Mechanisms of hypertension inducing erectile dysfunction via the cGMP/PKG signaling pathway: an investigation using transcriptomics and network pharmacology. *Zhonghua Nan Ke Xue* 2024; 30: 771-781.
- [20] Bi HN, Liu JH and Gao JT. Clinical study on Shugan Yishen Qiwei Decoction combined with tadalafil tablets for erectile dysfunction caused by SSRIs antidepressants. *New Chin Med* 2023; 55: 81-86.
- [21] Yang CK, Jiang CY, Wang XJ and Li J. Mechanism of ginsenoside in protection of blood vessels. *World J Integr Tradit West Med* 2022; 17: 1685-1690.
- [22] Zhou K, Ye MY, Zhao F, Ma K, Lv BD and Xu ZB. Effect of the Astragalus dose in Buyang Huanwu decoction on erectile dysfunction in rats with cavernous nerve injury. *Lab Anim Sci* 2020; 28: 788-795.

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- [23] Jia W, Wang F, Wang C, Lu YT, Guo WL, Li XD and Zhu DF. Efficacy of Shenqi Shiyiwei Granules combined with levothyroxine sodium tablets in the treatment of Hashimoto thyroiditis with syndrome of yang deficiency of spleen and kidney. *Chin Med Herald* 2023; 20: 77-81.
- [24] Chen JX, Wong ZW, Li L, Liang AJ, Chen Q, Ruan TC, Su GL and Zhou SH. Effect of Jianyang Tablets on erectile dysfunction in rats with liver depression and kidney deficiency syndrome. *J Guangzhou Univ Tradit Chin Med* 2025; 42: 2022-2027.
- [25] Zhou Y, Long J, Ji HX, Liu J, Tao JH and Li Y. Effect of hardness of penile head and hardness of penile root on sexual intercourse success rate in patients with mild erectile dysfunction. *Chin J Hum Sexuality* 2024; 33: 19-23.
- [26] Sun Y, Yang SQ, Li Z, Zhao Y, Chen SF and Geng Q. An analysis of point selection law of acupuncture and moxibustion in the treatment of erectile dysfunction based on data mining technology. *Henan Tradit Chin Med* 2022; 42: 115-120.
- [27] Chen L, Jiao CS, Zhao XJ, Fang LJ, Liao YY and Du YH. Research on mechanism of acupuncture and moxibustion on RN4 in treatment of erectile dysfunction in men. *J Clin Acupunct Moxibust* 2024; 40: 1-5.
- [28] Gao FF, Zhao JY, Xu ZF, Wang JQ and Lin XW. Application status of neural tracing techniques in research on correlation between meridians and Zang-Fu organs. *Shandong J Tradit Chin Med* 2025; 44: 942-948.
- [29] Yan MX, Li MZ, Ge PY, Lu CX, Xiao CH and Cui J. Effects of electroacupuncture with “tonifying the kidney and dispelling stasis” acupoint prescription on sexual function and penile vascular endothelial function in diabetic erectile dysfunction model rats. *J Tradit Chin Med* 2025; 66: 1265-1272.