

Research on the Mechanism of Action of Traditional Chinese and Western Medicine and the Course of Treatment for Shenrongbian Pills in the Treatment of Impotence and Premature Ejaculation

Chunlei Chen^{1*}, Wei Yang², Bei Zhang³, Zheng Li⁴

¹Department of Surgery IV, Shanghai Municipal Hospital of Traditional Chinese Medicine Affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai 200071, China

²Department of Integrated Traditional Chinese and Western Medicine, People's Hospital of BiYang County, Zhumadian 463700, Henan, China

³Health Management Center, Shanghai Municipal Hospital of Traditional Chinese Medicine Affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai 200071, China

⁴Department of Inpatient and Medical Record Management, The Eighth Medical Center of the Chinese PLA General Hospital, Beijing 100091, China

**Author to whom correspondence should be addressed.*

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Abstract: Objective: To investigate the clinical efficacy, mechanism of action of traditional Chinese and Western medicine, and reasonable treatment regimen of Shenrongbian pills in the treatment of impotence and premature ejaculation caused by kidney-Yang deficiency. Methods: A total of 160 patients with impotence and premature ejaculation caused by kidney-Yang deficiency admitted to our hospital from January 2023 to January 2024 were randomly divided into an observation group (80 cases) and a control group (80 cases). The observation group was treated with Shenrongbian pills; the control group was treated with sildenafil citrate tablets combined with dapoxetine. The International Index of Erectile Function (IIEF-5), intravaginal ejaculatory latency time (IELT), traditional Chinese medicine kidney-Yang deficiency syndrome score, overall clinical response rate, and safety were compared between the two groups before and after treatment. Results: There was no significant difference in the IIEF-5 scores and IELT between the two groups before treatment ($P > 0.05$). After 3 months and 6 months of treatment, both indicators improved significantly in both groups ($P < 0.05$), and the improvement in the observation group was more significant than that in the control group, with a more pronounced difference at 6 months ($P < 0.001$); there was no significant difference in the total traditional Chinese medicine syndrome scores between the two groups before treatment ($P > 0.05$). After 3 and 6 months of treatment, the traditional Chinese medicine (TCM) syndrome scores in the observation group were significantly lower than those in the control group ($P < 0.05$), and continued to decrease with prolonged treatment duration. The improvement in scores in the control group was not significant ($P > 0.05$). After 6 months of treatment, the overall response rate in the observation group was 93.75%, significantly higher than the 81.25% in the control group ($\chi^2 = 5.714$, $P = 0.017 < 0.05$). In the observation group, there was 1 case of dizziness and 2 cases of gastric discomfort, with an adverse reaction rate of 3.75%. In the control group, there were 4 cases of headache, 2 cases of facial flushing, and 1 case of abnormal vision, with an incidence rate of 12.5%. Conclusion: Shenrongbian pill, through

mechanisms such as warming and tonifying the kidney-Yang, harmonizing Yin and Yang, improving microcirculation, and regulating endocrine function, can significantly improve sexual function and systemic symptoms in patients with impotence and premature ejaculation due to kidney-Yang deficiency. It is highly safe, with a recommended treatment duration of 3–6 months, and its efficacy shows an increasing trend with prolonged treatment.

Keywords: Impotence; Kidney-Yang deficiency; Mechanism of action; Premature ejaculation; Shenrongbian pill; Treatment duration

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1. Introduction

Erectile dysfunction (ED) and premature ejaculation (PE) are the most prevalent sexual dysfunction disorders among men, with their incidence rates showing a yearly upward trend due to increased social pressure and lifestyle changes. These conditions not only directly affect sexual quality but also trigger psychological issues such as anxiety and low self-esteem in patients, leading to strained marital relationships and even family breakdown, thereby causing multidimensional damage to patients' physical and mental health and social functioning^[1].

Modern medicine posits that their onset is closely related to psychological factors, neurovascular dysfunction, and endocrine disorders. Treatment primarily involves medications such as PDE5 inhibitors (phosphodiesterase type 5 inhibitors, PDE5), but these have limitations including multiple adverse reactions and the need for on-demand use. Long-term use may also result in adverse reactions such as headaches and flushing^[2]. Topical anesthetics can prolong ejaculatory latency but often lead to a loss of sexual pleasure. These treatment approaches mostly focus on symptom relief and are difficult to fundamentally improve the overall functional state of patients, especially those with chronic conditions accompanied by systemic symptoms.

In traditional Chinese medicine, these conditions are classified under the categories of “impotence” and “PE,” with the core pathological mechanism being the decline of kidney-Yang. Treatment focuses on warming and tonifying kidney-Yang, as well as replenishing essence and marrow^[3]. Shenrongbian pill originates from the “Shenrong Decoction” in Wu Jutong's “Differentiation and Treatment of Warm Diseases” from the Qing Dynasty. After centuries of inheritance, it has become a classic original prescription. Its formulation features four types of animal penises (ox penis, donkey penis, dog penis, and mink penis) as the principal ingredients, supplemented by precious medicinal herbs such as red ginseng and deer antler. It exerts the effects of “nourishing and replenishing with the shapes of four animal penises.” Paired with two Yin-nourishing herbs (wolfberries and prepared rehmannia root) and two cooling herbs (asparagus root and lycium root bark), it achieves a “warming yet non-drying” effect. This herbal remedy not only improves sexual dysfunction but also alleviates symptoms of kidney-Yang deficiency, such as soreness and weakness in the lower back and knees, aversion to cold, and cold limbs, reflecting the characteristic of “addressing both symptoms and root causes.”

This study systematically explores the efficacy and mechanism of action of Shenrongbian pill in treating impotence and premature ejaculation due to kidney-Yang deficiency, aiming to provide a basis for clinical medication.

2. Materials and methods

2.1. General information

A total of 160 patients diagnosed with impotence and PE due to kidney-Yang deficiency at the andrology clinic of our hospital were randomly divided into an observation group (80 cases) and a control group (80 cases). The observation group had an age range of 25–55 years, with an average age of (38.62 ± 7.21) years; the disease duration ranged from 6 months to 10 years, with an average of (3.22 ± 1.83) years. The control group had an age range of 26–54 years, with an average age of $(37.95$

± 6.89) years; the disease duration ranged from 8 months to 9 years, with an average of (3.12 ± 1.69) years. There were no statistically significant differences in baseline data between the two groups ($P > 0.05$), indicating comparability.

The inclusion criteria are as follows:

- (1) Meeting the aforementioned diagnostic criteria of both traditional Chinese and Western medicine (Western medicine diagnosis: in accordance with the “Guidelines for the Diagnosis and Treatment of Erectile Dysfunction” (2016 edition) and the “Guidelines for the Diagnosis and Treatment of Premature Ejaculation” (2018 edition); IIEF-5 score ≤ 21 ; IELT ≤ 2 minutes; traditional Chinese medicine diagnosis: based on the “Diagnostic Efficacy Criteria for Traditional Chinese Medicine Syndromes,” diagnosed as kidney-Yang deficiency syndrome: primary symptoms include impotence and premature ejaculation; secondary symptoms include soreness and cold pain in the lower back and knees, aversion to cold, cold limbs, morning diarrhea, frequent nocturia (≥ 2 times/night), pale tongue with white coating, and deep, thin, and weak pulse);
- (2) Aged between 20 and 60 years;
- (3) Informed consent from the patient and their spouse.

The exclusion criteria are as follows:

- (1) Sexual dysfunction caused by organic lesions (such as diabetes, lumbar spine lesions, etc.);
- (2) Use of similar medications in the past month;
- (3) Allergy to the components of this medication;
- (4) Patients with mental disorders.

2.2. Therapeutic methods

The control group received treatment with sildenafil citrate tablets (50 mg per tablet) combined with dapoxetine (30 mg per tablet), taken one hour before sexual activity, with a maximum of one dose per day. The treatment was continuously observed for six months. The observation group was administered Shenrongbian pills (specification: 2.3 g per 10 pills), with a dosage of 10 pills taken twice daily, 1 to 2 hours before breakfast and dinner, accompanied by light salt water or plain water^[4]. Each treatment course lasted 15 days, followed by a 2-day break before the next course, continuing for a total of six months.

2.3. Observation indicators

The observation indicators are as listed:

- (1) International Index of Erectile Function (IIEF-5), encompassing five items such as erectile confidence and erectile maintenance, with a total score of 25 points. Higher scores indicate better function;
- (2) Intravaginal Ejaculatory Latency Time (IELT), the time from insertion to ejaculation was recorded by the spouse using a stopwatch;
- (3) TCM syndrome score, where six secondary symptoms, including lumbar and knee weakness, aversion to cold, and cold limbs, were scored (0-3 points per item). Higher total scores indicate more severe symptoms;
- (4) Clinical efficacy was determined based on improvements in IIEF-5 scores and IELT. Recovery: IIEF-5 score ≥ 22 points, IELT ≥ 3 minutes; Marked effectiveness: IIEF-5 score increased by ≥ 10 points, IELT increased by ≥ 2 minutes; Effective: IIEF-5 score increased by 5 to 9 points, IELT increased by 1 to 1.9 minutes; Ineffective: Did not meet the aforementioned criteria. The total effective rate = (number of recovered cases + number of markedly effective cases + number of effective cases) / total number of cases $\times 100\%$;
- (5) Safety Indicators such as adverse reactions (dizziness, headache, gastrointestinal discomfort, facial flushing, visual abnormalities, etc.) were monitored.

2.4. Statistical methods

SPSS 27.0 software was used. Continuous data were expressed as mean $\pm$ standard deviation (SD), and comparisons

between groups were made using the t-test. Categorical data were expressed as [n (%)], and comparisons were made using the χ^2 test. A P -value of < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of main symptom indicators before and after treatment between the two groups

Before treatment, there were no significant differences in IIEF-5 scores and IELT between the two groups ($P > 0.05$). After 3 and 6 months of treatment, both indicators significantly improved in both groups ($P > 0.05$), with the observation group showing a greater degree of improvement than the control group, and the difference being more pronounced at 6 months ($P < 0.001$). See **Table 1**.

Table 1. Comparison of IIEF-5 Scores and IELT before and after treatment between the two groups (mean $\pm$ SD)

Indicator	Group	Before Treatment	At 3 Months	At 6 Months
IIEF-5 (points)	Experimental (n=80)	11.21 $\pm$ 2.55	17.81 $\pm$ 2.91	22.35 $\pm$ 3.12
	Control (n=80)	10.82 $\pm$ 2.32	15.32 $\pm$ 2.62	18.67 $\pm$ 2.85
	t-value	1.012	5.689	7.789
	p-value	0.313	0.000	0.000
IELT (min)	Experimental (n=80)	1.21 $\pm$ 0.52	3.51 $\pm$ 1.12	5.28 $\pm$ 1.36
	Control (n=80)	1.19 $\pm$ 0.42	2.32 $\pm$ 0.81	3.15 $\pm$ 0.92
	t-value	0.268	7.701	11.603
	p-value	0.789	0.000	0.000

3.2. Comparison of TCM syndrome scores before and after treatment between the two groups

Before treatment, there was no significant difference in the total TCM syndrome scores between the two groups ($P > 0.05$). After 3 and 6 months of treatment, the TCM syndrome scores in the observation group were significantly lower than those in the control group ($P < 0.05$) and continued to decrease with prolonged treatment; the improvement in the control group was not significant ($P > 0.05$). See **Table 2**.

Table 2. Comparison of total TCM syndrome scores before and after treatment between the two groups

Group	Before Treatment	At 3 Months	At 6 Months
Experimental (n=80)	12.45 $\pm$ 3.20	6.82 $\pm$ 2.13	3.24 $\pm$ 1.56
Control (n=80)	12.38 $\pm$ 3.09	9.51 $\pm$ 2.52	7.81 $\pm$ 2.02
t-value	0.141	7.292	16.015
p-value	0.889	0.000	0.000

3.3. Comparison of clinical efficacy between the two groups

After 6 months of treatment, the overall response rate in the observation group was 93.75%, significantly higher than that in the control group at 81.25% ($\chi^2 = 5.714$, $P = 0.017 < 0.05$). See **Table 3**.

Table 3. Comparison of clinical efficacy between the two groups [n (%)]

Group	Cured	Markedly Effective	Effective	Ineffective	Total Effective Rate
Experimental (n=80)	35 (43.75%)	29 (36.25%)	11 (13.75%)	5 (6.25%)	75 (93.75%)
Control (n=80)	16 (20.00%)	20 (25.00%)	29 (36.25%)	15 (18.75%)	65 (81.25%)
χ^2					5.714
<i>p</i> -value					0.017

3.4. Comparison of adverse reaction incidence rates between the two groups

In the observation group, there was 1 case of dizziness and 2 cases of gastric discomfort, with an adverse reaction incidence rate of 3.75%; in the control group, there were 4 cases of headache, 2 cases of facial flushing, and 1 case of visual abnormalities, with an incidence rate of 12.5%. See **Table 4**.

Table 4. Comparison of adverse reaction incidence rates between the two groups

Adverse Reaction	Dizziness	Gastric Discomfort	Headache	Facial Flushing	Visual Disturbance	Total Incidence Rate
Experimental (n=80)	1 (1.25%)	2 (2.50%)	-	-	-	3 (3.75%)
Control (n=80)	-	-	4 (5%)	5 (6.25%)	1 (1.25%)	10 (12.5%)
χ^2						4.103
<i>p</i> -value						0.043

4. Discussion

Shenrongbian pills are derived from the “Shenrong Decoction” in Treatise on Differentiation and Treatment of Epidemic Febrile Diseases, with over 200 years of clinical validation. Wu Jutong believed that “in cases of Yang deficiency, Yang fails to transform Yin, leading to the predominance of Yin pathogens,” and thus proposed warming Yang and dispersing cold as the therapeutic principle^[5]. The modern formula adds four types of animal penises (ox penis, donkey penis, dog penis, and mink penis) to the original prescription, adhering to the “like cures like” theory to directly replenish kidney essence and invigorate Yang to treat impotence. Among them, ox penis and donkey penis enter the kidney meridian, capable of “tonifying kidney Qi and nourishing essence” (Compendium of Materia Medica); dog penis “enhances Yang and nourishes blood vessels” (Famous Physicians’ Records); mink penis is warm and potent, with a particularly strong Yang-boosting effect.

The synergistic action of the four penises directly targets the pathogenesis of kidney-Yang deficiency, providing a fundamental treatment for “impotence and spermatorrhea.” The formula also incorporates asparagus root, lycium root bark (cold in nature), wolfberry fruit, and prepared rehmannia root (Yin-nourishing) to counteract the warming and drying properties of the animal penises, ensuring that “tonifying Yang does not harm Yin”^[6]. In addition to improving sexual function, Shenrongbian pills significantly reduce symptom scores for soreness and weakness of the lower back and knees and frequent nocturia, reflecting the principle of “treating the root cause of the disease”. By tonifying kidney-Yang and consolidating kidney Qi, the formula strengthens “bones and tendons when kidney-Yang is sufficient and stabilizes the bladder,” achieving simultaneous improvement in local and systemic symptoms^[7].

From a Western medicine perspective, Shenrongbian pills can elevate serum testosterone levels, promote luteinizing

hormone (LH) secretion, and improve gonadal function, providing an endocrine basis for erectile and ejaculatory control^[8]. The IIEF-5 scores in the observation group significantly increased, confirming its role in improving vascular function. Additionally, it reduces serotonin (5-HT) reuptake, prolonging the ejaculatory latency period, while increasing dopamine levels to enhance sexual excitation transmission, thus providing bidirectional regulation of the ejaculatory reflex.

The results of this study showed that as the duration of treatment increases, the therapeutic effects of Shenrongbian pills gradually manifest and intensify. After three months of treatment, the IIEF-5 score, IELT, and TCM syndrome score for kidney-Yang deficiency in the observation group all demonstrated significant improvement. After six months of treatment, all indicators showed further enhancement. This indicates that Shenrongbian pills require a certain treatment duration to achieve optimal efficacy, with a recommended treatment course of 3–6 months. The reason may be that kidney-Yang deficiency syndrome is a chronic debilitating disease that requires long-term conditioning for recovery^[9].

As a traditional Chinese herbal preparation, Shenrongbian pills have a mild yet lasting effect, gradually replenishing kidney essence and warming kidney-Yang to achieve therapeutic goals. The dosing regimen of “15 consecutive days of administration followed by a 2-day break before continuing with the second course” ensures drug efficacy while minimizing drug accumulation in the body and reducing the risk of adverse reactions.

In contrast, the control group showed rapid onset but required on-demand administration and demonstrated limited improvement in systemic symptoms of kidney-Yang deficiency. Shenrongbian pills offer several advantages, including lasting efficacy with sustained effects after discontinuation, comprehensive improvement of systemic symptoms, minimal adverse reactions and high safety and suitability for long-term conditioning to fundamentally improve physical constitution.

Shenrongbian pills exhibit definite therapeutic effects in treating impotence and premature ejaculation caused by kidney-Yang deficiency. The mechanism involves a dual approach combining TCM principles of “warming kidney-Yang, replenishing essence and marrow, and harmonizing Yin and Yang” with Western medicine mechanisms of “regulating endocrine function, improving microcirculation, and modulating neurotransmitters,” achieving both symptomatic relief and root cause treatment^[10].

The clinically recommended treatment course is 3–6 months, using a regimen of “15-day treatment followed by a 2-day break,” which significantly enhances sexual function, improves kidney-Yang deficiency symptoms such as lumbar and knee soreness, and maintains high safety. As a century-old classic formula characterized by “four-organ tonification and warming without dryness,” it provides an ideal therapeutic option for patients with chronic sexual dysfunction caused by kidney-Yang deficiency.

Disclosure statement

The authors declare no conflict of interest.

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