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# The Advantages of Shenrongbian Pills Combined with PDE5 Inhibitors in the Treatment of Impotence

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**Abstract:** Objective: To investigate the clinical advantages of Shenrongbian Pills combined with PDE5 inhibitors in the treatment of impotence. Methods: A total of 160 patients with impotence were randomly divided into a combination therapy group and a monotherapy group, with 80 patients in each group. The combination therapy group was treated with Shenrongbian Pills combined with PDE5 inhibitors, while the monotherapy group was treated with PDE5 inhibitors alone. The clinical efficacy, symptom improvement, onset time, and incidence of adverse reactions were compared between the two groups. Results: The total effective rate in the combination therapy group was significantly higher than that in the monotherapy group ($P<0.05$). The combination therapy group showed superior improvement in impotence symptoms and symptoms related to kidney yang deficiency compared to the monotherapy group ($P<0.05$). There was no significant difference in the initial onset time between the two groups ($P>0.05$), but the sustained onset time in the combination therapy group was significantly longer than that in the monotherapy group ($P<0.05$). The incidence of adverse reactions did not differ significantly between the two groups ($P>0.05$). Conclusion: The combination of Shenrongbian Pills and PDE5 inhibitors demonstrates significant advantages in the treatment of impotence, as it not only provides rapid onset of action but also offers root-cause conditioning, potent nourishment, and addresses both symptoms and underlying causes, with good safety.

**Keywords:** Shenrongbian Pills; PDE5 inhibitors; impotence; combination therapy; clinical advantages

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## 1. Introduction

Impotence, also known as erectile dysfunction (ED), is a common sexual dysfunction disorder in males. Its incidence rate gradually increases with age, seriously affecting patients' quality of life and family harmony [1]. Currently, there are

numerous clinical treatment methods for impotence, among which PDE5 inhibitors (phosphodiesterase type 5 inhibitors, PDE5) are commonly used Western medications known for their rapid onset. Traditional Chinese medicine (TCM) also boasts a long history and unique advantages in treating impotence, with Shenrongbian Pills being a classic representative. The pathogenesis of impotence is complex, involving multiple systems such as the nervous, endocrine, and vascular systems. From a modern medical perspective, it is primarily related to dysfunction in the relaxation of penile corpus cavernosum smooth muscle, abnormal penile hemodynamics, hormonal imbalances, and psychological factors [2]. From the perspective of TCM, impotence is mostly associated with kidney-yang deficiency. Kidney-yang deficiency is an important TCM syndrome characterized by the decline of yang qi in the kidneys, leading to a weakened warming function. Kidney-yang deficiency can result in sexual dysfunction, manifesting as impotence and premature ejaculation, along with other symptoms such as soreness or cold pain in the lower back and knees, aversion to cold, morning diarrhea, and frequent nocturia [3]. PDE5 inhibitors are currently the first-line treatment for impotence. Their mechanism of action involves selectively inhibiting type 5 phosphodiesterase (PDE5) in the penile corpus cavernosum, reducing the degradation of cyclic guanosine monophosphate (cGMP), thereby promoting the relaxation of penile corpus cavernosum smooth muscle, increasing penile blood flow, and achieving penile erection [4]. PDE5 inhibitors are known for their rapid onset, typically taking effect within 30 minutes to 1 hour after administration, quickly improving patients' erectile function and enhancing sexual quality of life. Shenrongbian Pills originated from "Shenrong Decoction," as recorded in "Treatise on Differentiation and Treatment of Warm Diseases" (1798) by Wu Jutong, a renowned medical expert in the Qing Dynasty. After centuries of clinical practice and inheritance, the formula of Shenrongbian Pills has been continuously optimized and refined, becoming a classic prescription for treating sexual dysfunction caused by kidney-yang deficiency [5]. The formula of Shenrongbian Pills contains four types of animal penis medicinal materials: donkey penis, ox penis, dog penis, and mink penis. Traditional Chinese medicine (TCM) holds that animal penises possess the effects of nourishing the kidney and strengthening yang, as well as replenishing essence and marrow. Adhering to the theory of "like cures like," they can effectively replenish kidney yang qi and alleviate various symptoms caused by kidney yang deficiency [6]. The formula of Shenrongbian Pills emphasizes the balance of yin and yang. It not only incorporates various warm and yang-tonifying medicinal herbs but also combines them with cold and yin-nourishing herbs (two yin herbs and two cold herbs). The two yin herbs are Goji berries and Rehmannia glutinosa (prepared), while the two cold herbs are Asparagus cochinchinensis and Lycium barbarum cortex. This combination imparts a warm yet non-drying characteristic to the entire formula, ensuring that while it warms and tonifies kidney yang qi, it does not cause adverse reactions such as internal heat [7]. Shenrongbian Pills can improve sexual dysfunction (impotence, premature ejaculation) caused by kidney yang deficiency, as well as other symptoms such as soreness or cold pain in the lower back and knees, aversion to cold, morning diarrhea, and frequent nocturia. Its mechanism of action involves nourishing kidney yang qi, regulating the body's endocrine and immune systems, fundamentally improving the patient's constitution, and achieving both symptomatic relief and root cause treatment [8]. This study aims to explore the advantages of combining Shenrongbian Pills with PDE5 inhibitors in the treatment of impotence, providing a reference for clinical treatment. The findings are reported as follows.

## 2. Materials and Methods

### 2.1. General Information

A total of 160 patients with impotence who were treated at our hospital from January 2023 to January 2024 were selected as the study subjects. Inclusion criteria: meeting the TCM and Western medicine diagnostic criteria for impotence; TCM differentiation as kidney yang deficiency syndrome; no recent use of any medications for impotence or medications that could affect treatment outcomes; age between 25 and 60 years; informed consent obtained from patients and their families, with signed informed consent forms. Exclusion criteria: severe diseases of vital organs such as the heart, liver, and kidneys; mental illness; allergy to the medications used in this study; recent use of other medications for impotence. The 160 patients were randomly divided into a combination therapy group and a monotherapy group, with 80 patients in

each group. In the combination therapy group, the age range was 25-58 years, with an average age of (42.52±6.84) years; the disease duration ranged from 6 months to 5 years, with an average of (2.31±1.14) years. In the monotherapy group, the patients were aged between 26 and 60 years, with an average age of (43.21 ± 7.18) years; their disease duration ranged from 8 months to 5 years, with an average of (2.52 ± 1.24) years. There was no statistically significant difference ($P > 0.05$) in general information such as age and disease duration between the two groups, indicating comparability.

## 2.2. Methods

Monotherapy Group: Patients were treated with a PDE5 inhibitor (sildenafil), administered orally at a dose of 50 mg, taken 1 hour before sexual activity.

Combination Therapy Group: On the basis of the treatment in the monotherapy group, patients additionally received Shenrongbian Pills (comprising deer antler, dog penis (parched), mink penis (parched), donkey penis (parched), morinda officinalis, ox penis (parched), dodder seed (roasted), actinolite (calcined), prepared aconite root, sparrow, epimedium (processed), cynomorium songaricum, eucommia bark (charred), dark plum salt, semen allii tuberosi, clove, sulfur (processed), psoralea fruit (salt-fried), hippocampus (processed), wolfberry fruit, prepared rehmannia root, cortex lycii radicis, asparagus root, stone sparrow (calcined), amomum fruit, licorice root, cyathula root, cassia bark, and red ginseng), manufactured by Dalian Meiluo Traditional Chinese Medicine Co., Ltd., with approval number Z21020982. The pills were taken orally at a dose of 10 pills each time, twice daily (morning and evening). It was recommended to take the pills 1-2 hours before meals with light salt water or plain water. For patients with chronic conditions, a 15-day continuous treatment course was recommended, followed by a 2-day break, before resuming treatment for a second course. The recommended treatment duration was 3-6 months.

Both groups of patients received continuous treatment for 3 months. During the treatment period, they were advised to avoid using other medications for erectile dysfunction and to maintain regular sexual activity.

## 2.3. Observation Indicators

### 2.3.1. Clinical Efficacy

Efficacy was evaluated based on the International Index of Erectile Function (IIEF-5) scoring criteria. Cure: An IIEF-5 score ≥ 22 points, with normal erectile function enabling satisfactory sexual activity. Markedly effective: An increase in IIEF-5 score of ≥ 10 points from the pre-treatment score, but < 22 points, with significant improvement in erectile function allowing completion of sexual activity. Effective: An increase in IIEF-5 score of ≥ 5 points from the pre-treatment score, but < 10 points, with some improvement in erectile function enabling completion of sexual activity with difficulty. Ineffective: An increase in IIEF-5 score of < 5 points from the pre-treatment score, with no significant improvement in erectile function, preventing completion of sexual activity. The overall effective rate = (Number of cured cases + Number of markedly effective cases + Number of effective cases) / Total number of cases × 100%.

### 2.3.2. Symptom Improvement

The improvement of kidney-yang deficiency-related symptoms (such as soreness or cold pain in the lower back and knees, aversion to cold, morning diarrhea, frequent nocturia, clear and excessive vaginal discharge, etc.) in both groups before and after treatment was observed and recorded. Symptom scoring was used for evaluation, with each symptom categorized into four levels: none, mild, moderate, and severe, assigned 0, 1, 2, and 3 points respectively. The total score was the sum of scores for each symptom, with higher scores indicating more severe symptoms.

### 2.3.3. Onset Time

The initial time (from medication intake to the first effective erection enabling completion of sexual activity) and the duration of effectiveness (from the first effective erection to the time when erectile function could no longer meet sexual demands) after each medication intake were recorded for both groups.

#### 2.3.4. Incidence of Adverse Reactions

Adverse reactions experienced by both groups during treatment, such as headache, facial flushing, dizziness, and nausea, were observed and recorded.

### 2.4. Statistical Methods

Data analysis was conducted using SPSS 22.0 statistical software. Continuous data are presented as mean ± standard deviation ($\bar{x} \pm \bar{x} \pm s$), and comparisons between groups were made using the t-test. Categorical data are expressed as rates (%), and the $\chi^2$ test was employed. A P-value of less than 0.05 was considered statistically significant.

## 3. Results

### 3.1. Comparison of Clinical Efficacy Between Two Groups of Patients

The total effective rate in the combination therapy group was 92.50%, significantly higher than the 77.50% observed in the monotherapy group, with a statistically significant difference (P<0.05), as shown in **Table 1**.

**Table 1.** Comparison of Clinical Efficacy Between Two Groups of Patients (Cases, %)

| Group | Cured | Markedly Effective | Effective | Ineffective | Total Effective Rate |
|---|---|---|---|---|---|
| Combination Therapy Group (n=80) | 35 (43.75) | 28 (35.00) | 11 (13.75) | 6 (7.50) | 74 (92.50) |
| Monotherapy Group (n=80) | 20 (25.00) | 26 (32.50) | 16 (20.00) | 18 (22.50) | 62 (77.50) |
| $\chi^2$ | | | | | 7.059 |
| P-value | | | | | <0.05 |

### 3.2. Comparison of Symptom Scores Before and After Treatment Between Two Groups of Patients

Before treatment, there was no statistically significant difference in symptom scores between the two groups (P>0.05). After treatment, symptom scores in both groups significantly decreased (P<0.05), with the combination therapy group showing significantly lower scores than the monotherapy group, a statistically significant difference (P<0.05). See **Table 2**.

**Table 2.** Comparison of Symptom Scores Before and After Treatment Between Two Groups of Patients (mean ± standard deviation, points)

| Group | n | Before Treatment | After Treatment |
|---|---|---|---|
| Combination Therapy Group | 80 | 12.51 ± 3.22 | 4.22 ± 1.51 |
| Monotherapy Group | 80 | 12.82 ± 3.54 | 7.62 ± 2.11 |
| t-value | | 0.580 | 11.721 |
| p-value | | >0.05 | <0.05 |

### 3.3. Comparison of Onset Time Between Two Groups of Patients

There was no statistically significant difference in the initial onset time between the two groups (P>0.05); however, the duration of the effect in the combination therapy group was significantly longer than that in the monotherapy group, with a statistically significant difference (P<0.05). See **Table 3**.

**Table 3.** Comparison of Onset Time Between Two Groups of Patients (mean ± standard deviation, minutes)

| Group | n | InitialOnsetTime(min) | DurationofEffect(min) |
|---|---|---|---|
| Combination Therapy | 80 | 25.21 ± 10.54 | 60.54 ± 30.23 |
| Monotherapy | 80 | 27.14 ± 11.22 | 40.32 ± 25.61 |
| t-value | | 1.121 | 4.565 |
| p-value | | >0.05 | <0.05 |

### 3.4. Comparison of the Incidence of Adverse Reactions Between the Two Groups

In the combination therapy group, there were 2 cases of headache, 1 case of facial flushing, and 1 case of dizziness, resulting in an adverse reaction rate of 5.00%. In the monotherapy group, there were 3 cases of headache, 2 cases of facial flushing, 1 case of dizziness, and 1 case of nausea, leading to an adverse reaction rate of 8.75%. There was no statistically significant difference in the incidence of adverse reactions between the two groups ($P > 0.05$).

## 4. Discussion

As a classic prescription with a century-long heritage, Shenrongbianwan Pills are characterized by their "four-penis tonic, shape-replenishing shape" properties, effectively replenishing kidney yang and alleviating various symptoms caused by kidney yang deficiency. Additionally, its "warm but not dry" formula ensures that patients do not experience adverse reactions such as excessive internal heat during administration, enhancing patient compliance with the medication. Moreover, Shenrongbianwan Pills address both the symptoms and root causes, not only improving sexual dysfunction but also alleviating other symptoms of kidney yang deficiency, such as soreness or cold pain in the lower back and knees, and cold intolerance, thereby further enhancing patients' quality of life [9].

The results of this study indicate that the total effective rate of treating impotence with Shenrongbianwan Pills combined with PDE5 inhibitors is significantly higher than that of using PDE5 inhibitors alone. This outcome fully underscores the significant advantage of combination therapy in enhancing clinical efficacy. From the pathological mechanism of impotence, its onset involves issues such as smooth muscle relaxation dysfunction of the penile corpus cavernosum and hemodynamic abnormalities, as recognized by modern medicine, as well as being closely related to kidney yang deficiency in traditional Chinese medicine theory. Although monotherapy with PDE5 inhibitors can rapidly promote penile erection by inhibiting the activity of the PDE5 enzyme and increasing cGMP concentration, this effect primarily intervenes in a specific aspect of the erection process and fails to fundamentally address the underlying issues causing impotence.

The treatment regimen combining Shenrongbian Pills and PDE5 inhibitors achieves multi-target intervention in the pathological mechanisms of impotence. PDE5 inhibitors take effect rapidly, swiftly improving patients' erectile function, meeting their immediate needs, alleviating psychological stress, and enhancing treatment confidence. Shenrongbian Pills, from the perspective of traditional Chinese medicine (TCM) syndrome differentiation and treatment, target the core pathogenesis of kidney yang deficiency. By nourishing the kidney yang and regulating the body's overall functions, they work in synergy with PDE5 inhibitors. This combination not only rapidly improves symptoms but also gradually repairs damaged bodily functions, thereby enhancing the overall therapeutic effect.

The combined medication group also demonstrated significant advantages in improving symptoms associated with kidney yang deficiency. While the single-drug group could improve erectile function to some extent, its effectiveness in alleviating symptoms of kidney yang deficiency, such as soreness and coldness in the waist and knees, fear of cold, and morning diarrhea, was limited. In contrast, the various herbs in Shenrongbian Pills possess clear kidney-tonifying and yang-strengthening, as well as warming yang and dispersing cold properties, effectively targeting and improving these symptoms. This indicates that the combined medication approach not only focuses on the primary symptom of impotence

but also emphasizes the improvement of the patient's overall health, reflecting the TCM principles of "holistic concept" and "treatment based on syndrome differentiation."

In terms of onset time, there was no significant difference in the initial onset time between the two groups, which aligns with the rapid onset characteristic of PDE5 inhibitors, indicating that the combined medication did not affect the rapid onset effect of PDE5 inhibitors. However, the sustained onset time of the combined medication group was significantly longer than that of the single-drug group, a result of great clinical significance. The duration of action of PDE5 inhibitors is relatively short, often limited by factors such as drug metabolism rate. The addition of Shenrongbian Pills may extend the duration of erectile function by regulating the endocrine system, improving blood supply and tissue structure of the corpus cavernosum. This prolonged sustained onset time not only enhances patient satisfaction with sexual life but also reduces medication frequency and psychological burden, further improving their quality of life [10].

In conclusion, the treatment of impotence with Shenrongbian Pills combined with PDE5 inhibitors offers significant clinical advantages, and the combined medication regimen is relatively safe, making it worthy of clinical promotion and application.

## Disclosure statement

The author declares no conflict of interest.

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