**Clinical Study** 

# Clinical observation on warm needling moxibustion for erectile dysfunction

# 温针灸治疗勃起功能障碍的临床疗效观察

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#### Abstract

Objective: To observe the therapeutic effect of warm needling moxibustion for erectile dysfunction (ED).

**Methods:** A total of 46 eligible ED patients were randomized into a treatment group (n=24) and a control group (n=22). The treatment group was intervened by warm needling moxibustion while the control group by conventional acupuncture treatment, for a total of 4 courses. The therapeutic effect was evaluated by the international index of erectile function 5 (IIEF-5).

**Results:** After 4 courses of treatment, the overall effective rate was 91.3% in the treatment group (23 completed), versus 75.0% in the control group (20 completed), with a significant difference (P<0.05). After the treatment, the change of IIEF-5 score in the treatment group was significantly different from that in the control group (P<0.05).

**Conclusion:** Warm needling moxibustion can produce a more significant efficacy than conventional acupuncture in the treatment of ED.

**Keywords:** Acupuncture Therapy; Moxibustion Therapy; Acupuncture-moxibustion Therapy; Warm Needling Therapy; Erectile Dysfunction; Male

【摘要】目的:观察温针灸治疗勃起功能障碍(ED)的临床效疗。方法:将46例ED患者采用简单随机分组方法分为2组,观察组24例采用温针灸治疗,对照组22例采用单纯针刺治疗,治疗周期为4个疗程。依据国际勃起功能指数(IIEF-5)评分评价临床疗效。结果:经过4个疗程的治疗,观察组的总有效率为91.3%(实际完成23例),对照组总有效率为75.0%(实际完成20例),两组差异具有统计学意义(P<0.05)。治疗后,两组治疗前后IIEF-5评分差值比较,差异具有统计学意义(P<0.05)。结论:温针灸治疗ED疗效优于单纯针刺疗法。 【关键词】针刺疗法;灸法;针灸疗法;温针疗法;勃起功能障碍;男性

【中图分类号】R246.2 【文献标志码】A

Erectile dysfunction (ED) has been defined as the persistent inability to achieve and/or maintain an erection sufficient for satisfactory sexual intercourse  $(>3 \text{ months})^{[1]}$ . Recently, ED has been one of the most common diseases in the world, estimated to affect 322 million males by  $2025^{[2]}$ . In traditional Chinese medicine (TCM), ED is related with sexual indulgence, depression, congenital deficiency and improper diet. The main pathogenic factors can be classified as liver stagnation, kidney deficiency, blood stasis and phlegm heat, and the main patterns are life-gate fire deficiency, emotional distrubance, heart-spleen deficiency and downward flow of damp-heat<sup>[3]</sup>. TCM and Western medicine both can produce certain therapeutic effects for ED<sup>[4]</sup>.

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ED. However, few studies have a randomized control design<sup>[5]</sup>. Warm needling moxibustion, a method combining acupuncture and moxibustion, has the function of dredging meridians, warming meridians to expel cold, and reinforcing the vital essence. We have studied the therapeutic effect of warm needling moxibustion on ED, and the results are reported as followed.

## 1 Clinical Data

#### 1.1 Selection criteria

This was based on the international index of erectile function 5 (IIEF-5), in which 5 aspects including confidence, hardness, maintaining of erection, completion of sexual intercourse and intercourse satisfaction were evaluated. Each aspect ranged from 0-5, the full score was 25, and  $\leq 21$  points would be diagnosed as ED. ED can be graded as: mild degree (I),

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scored 12-21; moderate degree (II), scored 8-11; severe degree (III), scored 5-7.

### 1.2 Inclusion criteria

The IIEF-5 score ranged from 5 to 21 points; aged between 20 and 65 years; with sexual desire, unable to erect, insufficient erection or unable to hold erection during intercourse and thus failed to penetrated vagina; duration  $\geq$ 3 months; informed consent signed.

#### 1.3 Exclusion criteria

Taking medicine which will affect sexual function in the recent 3 weeks; having serious liver, kidney or mental disorders; ED due to organic reasons or alcohol.

#### 1.4 Statistical method

The data were processed using the SPSS 21.0 version software. The mean  $\pm$  standard deviation ( $\overline{x} \pm s$ ) was used to describe the measurement data in normal distribution. The independent sample *t*-test was used for between-group comparison; the non-parametric test was used for data in abnormal distribution; the enumeration data comparison was conducted by the Chi-square test. A *P* value of less than 0.05 indicated a statistical significance.

#### 1.5 General data

Based on the diagnostic criteria in the 10th revision of *International Statistical Classification of Diseases and Related Health Problems* (ICD-10)<sup>[6]</sup>, 46 cases from the Acupuncture Department in Shanghai First People's Hospital, Shanghai Jiao Tong University School of Medicine were included and randomized into a treatment group (24 cases) and a control group (22 cases).

#### 2 Treatment Methods

#### 2.1 Treatment group

Acupoints: Qihai (CV 6), Guanyuan (CV 4), Zhongji (CV 3), Yaoyangguan (GV 3) and bilateral Taixi (KI 3), Shenshu (BL 23), Ciliao (BL 32) and Yanglingquan (GB 34).

Methods: The patient took a supine position after voiding the bladder. When the topical skin was sterilized by 75% alcohol, disposable filiform needles of 0.30 mm in diameter and 50 mm in length were obliquely punctured into Qihai (CV 6), Guanyuan (CV 4) and Zhongji (CV 3) respectively, all by an angle of 45 ° for 1.5 cun with even reinforcing-reducing manipulation to conduct the sensation towards the perineum. For Taixi (KI 3), the needle was punctured obliquely downward for 1 cun, and a moxa stick of 2 cm in length was put onto the handle of the needle to perform warm needling moxibustion upon the arrival of needling qi. A new piece of moxa stick would be put on when the first one was burnt out and cleared away. The needle was removed when the second moxa stick was finished, and the treatment lasted about 30 min. Then, the patient was asked to take a prone position. Shenshu (BL 23),

Yaoyangguan (GV 3) and Yanglingquan (GB 34) were punctured perpendicularly for 1.5 cun, Ciliao (BL 32) for 2 cun, with even reinforcing-reducing manipulation performed upon the qi arrival. Afterwards, the same warm needling moxibustion method was applied.

#### 2.2 Control group

Acupoints: Same as those used in the treatment group.

Methods: Same acupuncture sequence and needling method as those in the treatment group, and the needles were retained for 30 min after qi arrived, without moxibustion.

Both groups were treated once a day, 10 sessions as a course, with a 1-week interval between 2 courses, for 4 courses in total.

#### **3 Therapeutic Efficacy Observation**

#### **3.1 Observation indicators**

This was based on the comparison of IIEF-5 score before and after the treatment<sup>[7]</sup>.</sup>

Cure: All clinical symptoms disappeared, IIEF-5  $\geq$  22 points.

Improvement: Clinical symptoms improved significantly, IIEF-5 between 15-21 points or increased by more than 10 points.

Invalid: No changes in clinical symptoms and IIEF-5 point after the treatment.

#### 3.2 Result

During the treatment, 1 case in the treatment group dropped out because of going abroad; 2 cases in the control group dropped out for receiving other treatments. Finally, 43 cases finished the whole study, 23 in treatment group and 20 in the control group. There were no significant between-group differences in the baseline data (P > 0.05), indicating that the two group were comparable (Table 1).

Table 1. Baseline comparison

Group	n	Average age $(\overline{X} \pm s, year)$	Average course $(\overline{X} \pm s, \text{month})$
Treatment	23	43.0±12.4	28.2±6.2
Control	20	45.0±10.2	27.5±7.1

#### 3.2.1 Therapeutic efficacy comparison

After 4 courses of treatment, the overall effective rate in the treatment group was 91.3%, versus 75.0% in control group, and the between-group difference was statistically significant (P < 0.05), (Table 2).

#### 3.2.2 IIEF-5 score comparison

After 4 courses of treatment, there was a statistical difference between the changes of IIEF-5 scores between the two groups, indicating a better effect in the treatment group than that in the control group (Table 3).

Table 2. Detween-group comparison of the incrapeute energy							
Group	п	Cure	Improvement	Invalid	Total effective rate (%)		
Treatment	23	11	10	2	91.3 <sup>1)</sup>		
Control	20	10	5	5	75.0		

 Table 2. Between-group comparison of the therapeutic effect (case)

Note: Compared with the control group, 1) P<0.05

Table 3. Between-group comparison of IIEF-5 before and after the treatment ( $\overline{x}$	±s, point)
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Group	п	Before treatment	After treatment	Before- and after-treatment difference
Treatment	23	9.17±2.79	19.96±4.15 <sup>1)2)</sup>	$11.48 \pm 3.64^{2)}$
Control	20	8.75±2.63	18.15±6.52 <sup>1)</sup>	10.26±4.53

Note: Intra-group comparison, 1) P<0.05; compared with the control group, 2) P<0.05

#### 4 Discussion

ED is a common disease in andrology clinics. According to an American Massachusetts male aging study (MMAS), 52% male in their 40s'-70s' suffer from ED, and the morbidity of mild-to-severe ED is proportional to aging<sup>[8]</sup>. Domestic research also shows the incidence of ED increases with age<sup>[9]</sup>. Modern medicine holds that the cause of ED can be classified as psychogenic, organic and iatrogenic factors. The most common treatment methods for ED are medicine, surgery and gene therapy<sup>[10]</sup>, while the main side effects are drug tolerance, sequelae of surgery and unsteadiness of gene treatment techniques.

TCM holds that the general pathogenesis of ED includes deficiency and excess. The deficiency involves the liver, kidney, heart and spleen manifesting as gi, blood, yin-yang asthenia and emptiness of meridians; excess pattern is caused by liver stagnation and dampness, leading to obstruction of meridians and malnutrition of tendons<sup>[11]</sup>. The treatment principle is reinforcing the deficiency and reducing the excess. Tonifying the kidney is the key for treating deficiency pattern, and acupoints on the Conception Vessel and Spleen Meridian as well as the Back-Shu points are most commonly used. In this study, Qihai (CV 6), the gathering of congenital essence and the sea of gi in the body, can treat all gi-related diseases by facilitating the lower energizer, tonifying vitality and promoting qi flow; Guanyuan (CV 4) has the function of tonifying the kidney and vitality, nourishing yang qi and astringing; Zhongji (CV 3) has the function of tonifying the kidney, facilitating the bladder and clearing damp-heat. Acupuncture at Zhongji (CV 3) should obtain a sensation radiating towards the perineum and the lower abdomen to achieve a better therapeutic effect for genitourinary diseases<sup>[12]</sup>. As the Shu-Stream point and Yuan-Primary point of the Kidney Meridian, Taixi (KI 3) is punctured to tonify the kidney. Plus moxibustion, it can warm and tonify kidney yang<sup>[13]</sup>. Shenshu (BL 23), Dachangshu (BL 25) and Ciliao (BL 32) are located on the lumbosacral area and play a role of tonifying the kidney, strengthening waist and knee, supplementing the lower energizer and dredging meridians. The coordination of all the points can tonify kidney yang, facilitate blood flow in the local area and thus promote erection<sup>[14]</sup>. Penis is the convergence of tendons which depend on the nourishment of blood and dredging function of the liver.

Yanglingquan (GB 34) is the influential point of tendon, also the He-Sea point of the Gallbladder Meridian. Through puncturing Yanglingquan (GB 34), diseases caused by liver stagnation, damp-heat stagnation and malfunction of spleen yang can be treated<sup>[15]</sup>. Matching Yanglingquan (GB 34), Shenshu (BL 23) and Yaoyangguan (GV 3) has the function of tonifying without stagnation, dredging without diffusing and treating both symptoms and root causes, and thus can produce a good therapeutic effect for ED.

Warm needling moxibustion is the combination of acupuncture and moxibustion and has the dual merits of both methods. It has a function of dredging meridians, warming meridians to dispel cold and tonifying essence<sup>[16]</sup>. TCM stresses the integration of human and nature, the occurrence of ED is related to excessive mental stress, and the patients usually suffer from depression and declining confidence which may aggravate the condition. Therefore, erection is closely linked with mental condition<sup>[17-20]</sup>. As a result, acupuncture treatment should combine with psychological intervention to achieve a better effect.

This study shows that warm needling moxibustion has a better therapeutic effect than conventional acupuncture, which is similar to the result of the research by Han  $YI^{[21]}$ . Nevertheless, the sample size in this study is small and the mechanism of warm needling moxibustion for treating ED is still unknown, which requires further investigation.

#### **Conflict of Interest**

The authors declared that there was no potential conflict of interest in this article.

#### Acknowledgments

This work was supported by Three-year Action Plan of Shanghai Chinese Medicine Development (Academic Thoughts Inheritance Research for Yan's School of Suppurative Moxibustion (上海市中医药三年行动计划 "严氏化脓灸流派学术思想传承研究", No. ZYSNXD-CC-HPGC-FC-011); Academic Community Construction Project for Traditional Chinese Medicine Leading Personnel of Shanghai (上海市中医药领军人才 学术共同体建设项目, No. ZY3-RCPY-1-1001); The Medicine Leading Science and Technology Project of Shanghai Municipal Science and Technology Commission (上海市科学技术委员会医学引导类科技项目).

#### **Statement of Informed Consent**

Informed consent was obtained from all individual participants included in this study.

Received: 20 July 2016/Accepted: 21 August 2016

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