

Experimental and Clinical Studies on The Rapid Erectile Effect and The Effect of Treatment of Impotence by Koryo Medicine, Psychogenic Impotence

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ABSTRACT

Background and aim: As society develops, the incidence of psychogenic impotence is increasing, but effective therapeutics are not developed. Some Koryo medicines have rapid penile erection and high efficacy in treating impotence. The aim of this study was to investigate the experimental and clinical effects of a "Impotence capsule" containing Bark of root of mulberry, safflower, *Achyranthes japonica*, *Epimedium* and Ginkgo leaves on psychogenic impotence. **Methods:** The "Impotence capsule" was formulated as: Safflower (powder) 4.0, *Achyranthes japonica*(powder)3.0, *Epimedium* herba (aqueous extract)3.0, Ginkgo leaves (aqueous extract)3.0, Jujube (aqueous extract)1.0, and Safflower and *Achyranthes japonica* were pulverized and passed through sieve No.100 (1 medicine). The aqueous extracts were prepared at 100 °C for Bark of root of mulberry, Ginkgo leaves, and Jujube and at 60 °C for *Epimedium* herba (2 medicine). Mixing of No. 1 and No. 2 medicine, kneaded with honey, pulverized to make granules and prepared the capsule with a weight of 0.1g. The drug was mixed with the basal diet at a dose of 0.3 g/kg in the impotence model rats(Wista) to allow natural intake for 10 days before model formation and 10 days after model formation, and sperm count and sperm motility were examined. The psychogenic impotence patients were given a "Impotence capsule" twice at a time, three times a day, before meals for 20 days, and the effect of sperm count, sperm motility, penile erection and clinical signs of the impotence were investigated. **Results:** In animals and patients of impotence, sperm count, sperm motility increased, penile erection effect in patients with psychogenic impotence was rapid and clinical signs of impotence was improve. **Conclusions:** The "Impotence capsule" consisting of several Koryo medicines improves semen appearance and has the rapid penile erection effect and relieves clinical symptoms in patients with impotence.

Keywords : Impotence, Sexual Function, Erectile Dysfunction, Infertility, Mulberry, Ginkgo Leaves, *Epimedium* Herba, Sildenafil.

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INTRODUCTION

As society develops gradually, human's mental morality and material cultural life develop, and with this, the impotence is becoming a major area of medicine that arouses public interest. Impotence is a disease

that causes loss of male genital function or atrophy[1, 2]. There are many cases where sexual appetite is present, but when penis is not erected, it is often impossible to live sexually, and there is partly a lack of sexual appetite[3]. In a word, the impotence is a disease that is not

erectile, has a weak erectile strength, and cannot be intercoursed with women, due to the disorder of the erectile of the male penis. Impotence is a cause of masturbation, excessive sexual activity, and mental fatigue, and there are also psychogenic impotence caused by discord or long living separately in married life, and impotence caused by psychiatric disorders or genital trauma[3,4]. The symptoms of the impotence are those in which the penis does not erect from the beginning, and when it erect, it will soon wither and become unable the sexual life[5,6,7]. Mental condition is always depressed, memory is poor, sleepless, headache, genital regions are always cold and dull, testes are painful, and often have a desire to urinate[8]. The impotence is an independent disease, sometimes manifested as a complication of a disease, and has a clinical feature of no persistent erection of the penis at the time of sexual intercourse. Psychogenic impotence is a common disease in men and includes several physiological and psychological factors[9,10,11]. In Asia, the diagnostic rate of patients with psychogenic impotence tends to be lower than in Europe[12]. There are several pharmacological and surgical treatments for people suffering from erection disorder(ED), and sildenafil is used in men, while surgical methods are flexible and inflatable tools. However, these treatments also have many disadvantages in increasing sexual appetite[13,14].

The incidence of the impotence and age are positively correlated, and the incidence of impotence is increasing with longer span of life. Although psychogenic impotence does not pose serious risks to society and health, the patient suffers relatively large bodily torment and affects family well-being and social security. Sexual dysfunction in women is manifested by lack of sexual appetite, lubrication of the vagina, sensitivity and lack of congestion[15,16]. To satisfy sexual

intercourse, both partners must be psychologically and physically motivated, sexual organs must function, and also have sufficient sexual appetite[17]. Unfortunately, there are many side effects associated with medication, and vaginal lubricants do not treat the underlying cause and also do not treat the underlying cause of vaginal dryness[18]. Viagra, Methyltestosterone, Vitamin E and B1, Korean Insam, Antler tonic, Epimedium herba etc. are used for impotence, while Viagra, Methyltestosterone is used as a erection promoter, Koryo medicines is used as tonic [19,20].

Many methods have been introduced as folk medicine, among which are the testes of seals, the testes of yellow dogs, lobsters, penis and testes of deer, sea horses, crow meat, red dragonfly, garlic, etc. So far, treatment of impotence has been recognized that the use of Koryo medicines for a long period of time is effective. All of the herbal medicines used for impotence are known to have no immediate erectile effect and tonic effect. To overcome this shortcoming, several countries have developed drugs to treat the impotence as tonic effects, with rapid erectile effects, including the addition of Vigra (sildenafil) or Methyltestosterone, which have an immediate erectile effect on the prescription of Koryo medicine for the treatment of impotence. Typical drugs include 'Yang Chun Samrok' and 'Saesam tonic' prescribed by Viagra, Korean Insam, Antler tonic, Epimedium herba etc. Therefore, it is important to develop a medicine for the treatment of impotence which is composed of Koryo medicines that simultaneously rapid penile erection and tonic activities without the presence of Viagra. This study presents a small number of experimental and clinical trials on the effect of rapid erection and improvement of semen findings and the effect of the treatment of the impotence, a new herbal medicine for the impotence.

MATERIALS AND METHODS

Animal experiments

-Experimental animals

The experimental protocol was approved by the Scientific Review Committee of Haeju Medical University. Wistar rats (100-150 g body weight, 40 males) were breed under standard environmental conditions ($22\pm 2^{\circ}\text{C}$, 60-70% humidity, photoperiod from 7:00 a.m. to 7:00 p.m. Water was allowed to take freely and standard experimental diets were given once a day at 8:00 a.m. All animals were acclimatized to the environment for 7 days before the experiment.

-Formulation and preparation of Koryo medicines

The "Impotence capsule" was formulated as: Bark of root of mulberry (aqueous extract)6.0 Safflower (powder) 4.0, Achyranthes japonica(powder)3.0, Epimedii herba (aqueous extract)3.0, Ginkgo leaves (aqueous extract)3.0, Jujube (aqueous extract)1.0, and Safflower and Achyranthes japonica were pulverized and passed through sieve No.100 (1 medicine). The aqueous extracts were prepared at 100°C for Bark of root of Mulberry, Ginkgo leaves, and Jujube and at 60°C for Epimedii herba (2 medicine). Mixing of No. 1 and No. 2 medicine, kneaded with honey, pulverized to make granules and prepared the capsule with a weight of 0.1g.

-Experimental model and Drug administration

Experimental model : The rat scrotum was immersed in water at 43°C for 15 min, and after 30 min, a reproducible procedure was

applied three times to create a rat model of impotence.

Drug administration: The test drug was mixed with the basal diet at a dose of 0.3 g/kg, and then allowed to take it spontaneously by rats for 10 days before and 10 days after the impotence model formation. Semen was collected and examined in groups 1 (normal group), 2 (model group) and 3 (Koryo medicines administered to model group).

-Experimental parameters measurement and statistical analysis

On day 1 after model formation, rats were sacrificed by carotid artery dissection and semen from the epididymis were collected and measured for sperm number and sperm motility and compared between groups. The experimental values are expressed as mean (minimum-maximum).

All data were analyzed using SPSS software in Windows.

Clinical trials

-Study population

As a preparatory phase for large-scale clinical trials, clinical trials were conducted at the South Hwanghae Provincial General Hospital and the South Hwanghae Provincial Koryo Hospital in South Hwanghae Province of the DPRK under the conditions of small scale on the basis of the results of animal experiments. Fifty-six subjects were included: patients with impotence ($n=36$, male) and relatively healthy individuals ($n=20$, male) and were divided into the group of Koryoe medicine treatment and control group. The general characteristics of the study population are as follows:

Table 1: General characteristics of the study population

General characteristics of patients	N=56
Age, mean $\pm$ SD	44.6 $\pm$ 9.8
Sex	
Men (n, %)	56(100.0)
Body mass index(kg/m ²), mean $\pm$ SD	26.23 $\pm$ 3.43
Impotence, n(%)	36(64.3)

General characteristics of patients	N=56
Clinical symptoms	36(100.0)
• Erectile dysfunction (mild, moderate, severe) ^a , n(%).	20(55.6)
• Loss of libido, n(%)	9(25.0)
• Sexual dreams, n(%)	5(13.9)
• Night erection, n(%).	8(22.2)
• Early ejaculation, n(%).	34(94.4)
• Delayed and lost ejaculation, n(%)	36(100.0)
• Weakening and loss of sexual comfort, n(%)	23(63.9)
• Headache, n(%)	33(91.7)
• Insomnia, n(%)	29(80.6)
• Smoking, n(%)	30(83.3)
• Alcohol use, n (%)	
Examination findings	13.5±2.5
• Sperm count, ×10 ⁹ /L	30.5±5.4
• Sperm motility rate, %	

a: Mild erectile dysfunction - there is sexual appetite but immediately decline after penile erection, Moderate erectile dysfunction - there is sexual appetite but not erectile, Severe case erectile dysfunction - there is no sexual appetitesexual and erectile dysfunction.

Drug administration

Patients were given a “Impotence capsule” two tablets at a time, three times a day before meals for 20 days.

-Evaluation methods and laboratory test parameters measurement

Statistical analysis evaluation methods:

According to the patient's complaints and changes in semen appearance, Cure (normal sexual intercourse without ED, sperm count >60 × 10⁹/L, sperm motility >75%) was assessed to 3 points, Improvement (normal sexual intercourse without ED 1 to 2 times per month, sperm number 30 to 59 × 10⁹/L, sperm motility ratio 50 to 74%) was assessed to 2 points, and Invariant (ED, sperm number >29 × 10⁹/L, sperm motility < 49%) were assessed to 1 points, and exacerbation (worse than initial stage progression) were assessed to 0 points.

Measurement of laboratory parameters:

Sperm count and sperm motility were measured and compared in healthy subjects

and patients before and after drug administration. Statistics : All data were statistically processed using SPSS software in Windows, and the results of the table are expressed as mean (minimum-maximum).

RESULT

Experimental results

Table 2 shows the changes in sperm count and sperm motility when the normal, impotence model and model rats were administered with Koryo medicine. When the model group of impotence rats were compared with normal group of rats, sperm count and sperm motility were significantly reduced ($p < 0.001$).

The Koryo medicine group had a significant increase in sperm count and sperm motility ($p < 0.001$) compared to the model group. These results suggest that the “Impotence capsule” has a significant effect on restoring reduced sexual function. Therefore, the use of the “Impotence capsule” for the patients with the

impotence suggests that it may be effective in improving their lowered sexual function and in

male infertility, and further clinical trials are worthy.

Table 2: Levels of sperm count and sperm motility in normal rats, experimental impotemce and Koryo medicine rats groups. Experimental parameters

Experimental index	Normal group (n=10)	Model group (n=10)	Koryo medicine group (n=10)	P value Δ
• Sperm count, $\times 10^9/L$	0.50(452-543)	0.44(388-502)**	0.48(469-510)	0.0009
• Sperm motility rate, %	51.5(39-68)	40.6(30-52)**	47.5(39-55)	0.0021

Comparison between Group 1 (normal group) and Group 2 (model group), Group 2 (model group) and Group 3 (Koryo medicine group) and () numbers are minimum and maximum values.

Clinical trials results

Table 3 shows the changes of some symptoms in the control and Koryo medicine groups of patients with impotence. When comparing the different number of presentations of seven observational index in 15 control and 21 Koryo medicines, the Night erection and sexual comfort were found in all the observed cases, the sexual appetite was found in only 70%, and the delay of ejaculation and insomnia were found in only a few cases in the koryo medicines group. No sexual dreams and early ejaculations were observed.

However, in the control group, sexual appetite, night erection, and sexual comfort were rarely observed, and the presence of sexual dreams, ejaculatory delay, insomnia, and early ejaculation were found in all cases. This suggests that the “Impotence capsule” has the potential to restore symptoms in the patient with impotence. The changes in the appearance of semen in the impotence were examined by measuring sperm count and sperm motility, and the effect of night erection was examined in detail by the time of erection after drug use.

Table 3: Variation of subjective symptoms of patients with impotence in control and Koryo medicine groups.

Observational index	Number of index	Impotence	
		Control group* (n=15)	Koryo medicine group* (n=21)
• Sexual appetite	20/36(55.6)	0/10	7/10
• Sexual dreams	9/36(25.0)	4/4	0/5
• Night erection	5/36(13.9)	1/15	21/21
• Early ejaculation	8/36(22.2)	2/2	0/6
• Delayed ejaculation	34/36(94.4)	14/14	2/20
• Sexual comfort	36/36(100.0)	0/15	21/21
• Insomnia	33/36(91.7)	15/15	2/18

*: Number of index/number of observed index among total number, among total number (15 controls and 21 Koryo medicines).

Table 4 shows the change in the sperm appearance and time of penile erection in the penis patients in the control group and the Koryo medicine group. The number of sperm

and sperm motility in the Koryo medicine group were significantly increased ($p < 0.001$) compared to the control group. This indicates that the “Impotence capsule” not only

improves erectile dysfunction but also has a significant therapeutic effect on the impotence. On the other hand, the manifestation time of penile erection after drug use in patients with impotence suggests that penile erection occurs from 3 h after drug use, and is usually present within 72 h. The rapidity of this erectile effect is an effect that has not been seen in other Koryo medicines. So far, when Yohimbine, Sildenafil (Viagra), etc. were used, penile erection was rapidly observed within 1-2 hours, and the rapid development of penile erection could not be expected with the use of Koryo medicines.

Also, as not shown in Table 4, the penile erection effect is observed when the drug is administered three times a day, two tablets a time, then three doses are not administered every day and once before sleep, enough penile

erection is observed. This is the advantage of the “Impotence capsule” over other impotence drugs. Next, we analyzed the effect of treatment of impotence on the change of patient’s complaints and semen findings after drug use in the Koryo medicine group. According to the patient’s complaints and changes in semen appearance, Cure (normal sexual intercourse without ED, sperm count $>60 \times 10^9/L$, sperm motility $>75\%$) was assessed to 3 points, Improvement (normal sexual intercourse without ED 1 to 2 times per month, sperm number 30 to $59 \times 10^9/L$, sperm motility ratio 50 to 74%) was assessed to 2 points, and Invariant (ED, sperm number $>29 \times 10^9/L$, sperm motility $<49\%$) were assessed to 1 points, and exacerbation (worse than initial stage progression) were assessed to 0 points.

Table 4: Semen findings and changes in time of penile erection of patients with impotence in control and Koryo medicine groups.

Observational index	Control group (n=15)	Koryo medicine group (n=21)	Time of penile erection (h)	Koryo medicine group Δ (n=21)
•Sperm number, $\times 10^9/L$	40.8(23.5-71.8)	63.9(55.8-78.1)***	·2	0/21
•Sperm motility, %	52.7(42-75)	71.4(52-78)***	·3	5/21
			·4	4/21
			·5	3/21
			·6	3/21
			·12	2/21
			·24	1/21
			·48	2/21
			·72	1/21

***: $p < 0.001$ (compared to control group), and Δ : number of index/number of observed index.

Table 5 shows the treatment effect of impotence in the control and Koryomedicine groups. No cure or improvement was observed in the control group, and the Koryo medicine group had a high degree of cure and

improvement and no exacerbation ($p < 0.001$). Taken together, the above results suggest that the “Impotence capsule” is a drug that simultaneously exerts rapid penile erection and the treatment of impotence.

Table 5: Treatment effects of impotence in control and Koryo medicine groups

Observational index	Control group Δ (n=15)	Koryo medicine group Δ (n=21)
• Cure	-	12/21
• Improvement	-	6/21
• Invariant	13/15	3/21
• Exacerbation	2/15	-
Marks	0.9(0-1)	2.4(1-3)***

***: $p < 0.001$ (compared to control group), and Δ : Number of index/number of observed index

DISCUSSION

As the proportion of mental work in society increases and the level of civilisation develops, psychogenic impotence is a particularly prevalent disease in men[3,4]. Psychogenic impotence is a silent disease in men, and it is not normal to marital life, which is a major hindrance to family harmony. Therefore, the treatment of psychogenic impotence has attracted much attention. Currently, worldwide patients with psychogenic impotence are dependent entirely on Viagra and maintain cohabitation. Although the use of Koryo medicines has been effective in treating impotence for a long time, the effect of penile erection is not rapid and therefore has not been of great interest to psychogenic impotence patients. Korean Insam, Antler tonic, Epimedium herba etc. are used for impotence. Many methods have been introduced as folk medicine, among which are the testes of seals, the testes of yellow dogs, lobsters, penis and testes of deer, sea horses, crow meat, red dragonfly, garlic, etc. Penile erection is a physiological phenomenon consisting of blood filling of the corpus cavernosus of penis, and papaverin, a drug that exerts this pharmacological action, has been shown to have a transient erectile effect by local infusion to the corpora cavernosum[8,9]. Viagra also has erectile effects due to the dilatation of the penile-corpus cavernosus vessels. The herbal medicine with immediate erectile effects, such as Viagra and Papaverin, has not yet been developed.

Koryo medicines are effective in treating psychogenic impotence, so the development of Koryo medicines that show the action of treating the impotence with immediate erectile effect is of great interest for the psychogenic impotence patients. The "Impotence capsule" is not as rapid as Viagra, but it has a rapid erectile effect as compared to other herba medicines and at the same time has effect on the treatment of impotence, so it is now an ideal treatment for psychogenic impotence. Safflower is hot, warm, affecting the liver and heart, and has anticoagulant, coronary vasodilation, cardiac, hypotensive, and immune resuscitation. Epimedium herba is used for impotence, tinnitus, amnesia, dysmenorrhea, and weakly person because it is strong in tendons and bones. Ginkgo leaves are used as lipid-lowering agents, vasodilators for atherosclerosis, hyperlipidemia, and heart ischemia resulting from coronary vascular circulatory disturbances, myocardial infarction, angina pectoris, and cerebral arteriosclerosis.

Achyranthes japonica acts on the liver and nerves, enhances blood circulation and relieves the engorgement. The "Impotence capsule" was prepared using the five herbal medicines described above, with penile erection occurring 3 to 4 hours after the first dose, most occurring within 3 days, and the penile erection effect is relatively rapid and 30 days of use, leading to the relief of psychogenic impotence. It is also safe to use for a long period of 1 to 2 months, with no side effects.

In this study, to provide a basis for a large clinical trial of the newly-developed “Impotence capsule” with herbal medicines, a small number of experimental and clinical trials have been presented on the effect of penile erection, semen findings, and changes in clinical signs of impotence in the impotence model and psychogenic impotence disease. Further large-scale clinical trials will be needed.

CONCLUSION

The “Impotence capsule” consisting of several Koryo medicines improves semen appearance, has penile erectile effect in patients with impotence, and relieves clinical symptoms.

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