Effects of Herbal vigRX on Premature Ejaculation: A randomized, double-blind study

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Objective : We conducted a double-blind, placebo-controlled study to determine the efficacy of an herbal sexual supplement (vigRX) on premature ejaculation (PE).
Method: A randomized double blind study was conducted on a fixed dose of herbal vigRX at Roozbeh Psychiatry Hospital, Tehran University of Medical Sciences. The sample consisted of 85 married patients diagnosed with primary PE according to Diagnostic and Statistical Manual of Mental Disorders. Each patient underwent diagnostic evaluation by one trained psychiatrist, using Structured Clinical Interview for DSM-IV-TR. Each patient was evaluated by researchers to exclude the organic sexual dysfunctions. The patients were randomly assigned in to two groups: group 1 consisting of 42 patients receiving placebo, and group 2 consisting of 43 patients receiving 540 mg herbal vigRX for a 4-week treatment course. The effects of the drug on the ejaculatory function in each group were assessed by the intravaginal ejaculation latency time (IELT), and the Chinese Index of Premature Ejaculation (CIPE) before and at the end of the treatment course. Statistical analysis was performed using SPSS software (15th version).
Results: The mean IELT increased 22.4 and 32.0 seconds in the placebo and the vigRX group respectively after the treatment course. The mean IELT differences between the two groups was not significant. The mean CIPE score increased 2.40 and 4.37 in the placebo and the vigRX group respectively .The mean CIPE score differences between the two groups was not significant.No side effect was reported by the subjects in neither groups during the treatment course.
Conclusion: Although the improvement in IELT and CIPE scores in the herbal vigRX group was more than the placebo group, this difference was not statistically significant. The increasing of IELT and CIPE score in the placebo group may be due to the placebo effects. Further studies with higher vigRX doses, greater sample size and longer treatment courses are warranted.

Keywords: *Ejaculation, Herbal medicine, Sexual dysfunction, Controlled trial*

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The most common male sexual disorder[1-2] is premature ejaculation (PE), also referred to as early ejaculation (EE) or rapid ejaculation (RE), and affects 30%-40% of sexually active men, (1-3) perhaps as many as 75% of men at some points in their lives.(4) PE has been defined as uncontrolled ejaculation with the essential feature of recurrent or persistent orgasm with minimal sexual stimulation before, on, or after penetration and before the person desires it.(5)
Different treatment approaches have been used for the treatment of PE including local anaesthetic sprays, propranolol and serotonin reuptake inhibitors (6–9).
Despite the increasing availability of effective conventional medical treatments, plant-derived and herbal remedies continue to provide a popular alternative for men and women seeking to improve their sex life (10). The benefits of herbal and other natural products (dietary supplements) are increasingly cited in the media (11). Traditional Chinese Medicine(TCM) which evolved out of the physiology and health, was a reflection of the processes observed in natural health. Herbal formulas constitute an important aspect of TCM treatment. However, understanding how herbs interact with one another in the context of complex herbal formulation is unclear from the western scientific perspective.(12) Nevertheless, the efficacy of most herbal agents in treating sexual problems remains uncertain. Therapists and consumers alike would benefit from an increased understanding of commonly used herbal agents on the market, their purported or supported effects, and their potential side effects (10). VigRX is a sexual

Table 1. Baseline data of patients

Variable	Group 1	Group 2	Pvalue
Mean age (years)	27.0±5.7	25.9±3.4	NS*
Mean IELT (seconds)	72.6±68.9	70.8±55.5	NS
Mean CIPE score	27.1±8.0	27.0±5.6	NS

*NS=Non Significant

Table 2. Comparison of intravaginal ejaculation latency time (IELT) score between two groups

group	mean IELT before treatment (seconds)	mean IELT after treatment (seconds)	mean IELT difference (seconds)	df	t	Pvalue
1(Placebo)	72.6±68.9	95.1±72.8	22.4±36.2	83	1.2	NS*
2(vigRX)	70.8±55.5	102.8±66.2	32.0±36.5			

*NS=Non Significant

Table 3. Comparison of Index of Premature Ejaculation (CIPE) score between two groups

group	mean CIPE score before treatment	mean CIPE score after treatment	mean CIPE difference	df	t	Pvalue
1(Placebo)	27.1±8.0	29.5±6.7	2.4±5.0	83	0.162	NS*
2(vigRX)	27.0±5.6	31.4±6.3	4.3±4.1			

*NS=Non Significant

includes: Epimedium Leaf Extract [20:1] 15mg , Cuscuta Seed Extract [4:1] 25mg, Ginkgo Biloba Leaf 100mg, Asian Ginseng Root 100mg, Saw Palmetto Berry - Fructus Serenoae 100mg, Muira Pauma Bark Extract [4:1] 50mg, Catuaba Bark Extract [4:1] 50mg, Hawthorn Berry - Fructus Crataegi 100mg. VigRX is recommended for various sexual dysfunctions including PE(13-14) We conducted a double-blind, placebo-controlled study to determine the efficacy and probable side effects of this supplement on PE.

Materials and Method

This is a randomized double blind fixed dose study which conducted in Roozbeh Psychiatry Hospital in Tehran University of Medical Sciences (TUMS) during July 2007 to March 2009. Ninety nine married male patients were studied. They applied to TUMS Departments of Psychiatry and Urology and were diagnosed with primary PE according to DSM-IV-TR. (5). After complete description of the study to the volunteers, the written informed consent including necessary details of the study was obtained from each patient. Each patient underwent a diagnostic evaluation by one trained psychiatrist using Structured Clinical Interview for DSM-IV-TR. To exclude organic sexual dysfunctions, each patient was evaluated by researchers. Exclusion criteria were as follows: the presence of erectile dysfunction and inhibited male orgasm, a severe physical or mental illness, the history of alcohol and any substance abuse or dependence.The

Results

Fourteen patients dropped out of the study during the presence of any endocrinological state or taking any psychotropic medications within the last 2 weeks prior to the study. All the patients were heterosexual. The patients who completed the treatment course, 42 patients were in group 1 (placebo), and 43 in group 2 (vigRX). The mean age, mean IELT and mean CIPE score in both groups were obtained. The baseline data were compared in the two groups and was not statistically significant (Table 1).

The mean IELT was 95.1±72.8 seconds and 102.8±66.2 seconds in group 1 and 2 respectively at the end of the treatment course. The mean IELT increased after the 4-week treatment in both groups but it increased more in group 2. The mean IELT differences between the two groups was not statistically significant. (Table 2).

The mean CIPE score increased 2.4±5.0 and 4.3±4.1 in group 1 and 2 respectively. CIPE score increased after the 4- week -treatment in both groups but more in group 2. The mean CIPE score differences between the two groups was not statistically significant (Table 3).

No side effect was reported by the subjects in both groups during the treatment course.

Discussion

In this study, we examined the efficacy of vigRX as a sexual complementary herbal drug which contains eight herbal supplements including: Epimedium Leaf Extract, Cuscuta Seed Extract, Ginko Biloba Leaf, Asian Red Ginseng - Panax Ginseng, Saw Palmetto

Berry, Muira Pauma Bark Extract, Catuaba Bark Extract and Hawthorn Berry in the treatment of primary PE .

Although patients who received vigRX showed more improvement in IELT and CIPE scores compared with those who received placebo , the differences between the two groups was not statistically significant. On the other hand increasing of IELT and CIPE score in the placebo group may indicating placebo effects in patients who were studied. No side effect was seen in the patients in both groups during the treatment course.

In an open trial study was done by Cohen et al ginkgo biloba was found to be 84% effective in treating antidepressant-induced sexual dysfunction predominantly caused by selective serotonin reuptake inhibitors(16).

In a triple–blind randomized , placebo-controlled,clinical trial of ginkgo biloba carried out by Wheathly although some spectacular individual responses was seen but there was no statistically significances in sexual improvement and side effects between two groups(17).

Waynberg et al assessed the efficacy of a unique herbal formulation of Muira puama and Ginkgo biloba (Herbal vX) in 202 healthy women complaining of low sex drive. Responses showed significantly higher average total scores from baseline in 65% of the sample after using the supplement. Statistically significant improvements occurred in frequency of sexual desires, sexual intercourse, and sexual fantasies, as well as in satisfaction with sex life, intensity of sexual desires, excitement of fantasies, ability to reach orgasm, and intensity of orgasm (18).

Different and sometimes controversial results which reported in the literatures about herbal formulations may be due to the designing and methodology of the studies or individual differences in responding to these supplements.

Using of minimal recommended dosage, small sample size and short treatment course was the main limitations of our study so we recommended future studies with higher vigRX doses, greater sample size and longer treatment courses to further evaluation of the efficacy and probable side effects of this herbal supplement.

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References

1. Montorsi F. Prevalence of premature ejaculation: a global and regional perspective. J Sex Med 2005; 2 : 96-102.
2. Basile Fasolo C, Mirone V, Gentile V, Parazzini F, Ricci E; Andrology Prevention Week centers, et al.Premature ejaculation: prevalence and associated conditions in a sample of 12 558 men attending the andrology prevention week 2001-- a study of the Italian Society of Andrology (SIA). J Sex Med 2005; 2: 376-382.
3. Screponi E, Carosa E, Di Stasi SM, Pepe M, Carruba G, Jannini EA. Prevalence of chronic prostatitis in men with premature ejaculation. Urology 2001; 58: 198-202.
4. McMahon CG. Treatment of premature ejaculation with sertralin hydrochloride: a single-blind placebo controlled crossover study. J Urol 1998; 159: 1935-1938.
5. Sadock BJ. Abnormal sexuality and sexual dysfunctions. In: sadock BJ, sadock V,eds. synopsis of psychiatry, Philadelphia : lippincott Williams& wilkins;2003.
6. Hsu JH, Shen WW. Male sexual side effects associated with antidepressants: a descriptive clinical study of 32 patients. Int J Psychiatry Med 1995; 25: 191 – 201.
7. Shen WW, Hsu JH. Female sexual side effects associated with selective serotonin reuptake inhibitors: a descriptive clinical study of 33 patients. Int J Psychiatry Med 1995; 25:239 – 248.
8. Kowalsky A, Stanley RO, Dennerstein L, Burrows **G ,** Maguire **KP** . The sexual side effects of antidepressant medication: a double blind comparison of two antidepressants in a nonpsychiatric population. Br J Psychiatry 1985; 147: 413 – 418.
9. Rosen RC, Lane RM, Menza M: Effects of SSRIs on sexual function: a critical review. J Clin Psychopharmacol 1999; 19:67–85
10. Rowland DL, Tai W. A review of plant-derived and herbal approaches to the treatment of sexual dysfunctions. J Sex Marital Ther 2003;29:185-205.
11. Kelly JP, Kaufman DW, Kelley K, Rosenberg L, Anderson TE, Mitchell AA. Recent trends in use of herbal and other natural products. Arch Intern Med 2005;165:281-286.
12. Crimmel AS, Conner CS, Monga M. Withered Yang: A Review of Traditional Chinese Medical Treatment of Male Infertility and Erectile Dysfunction. J Androl 2001; 22: 173-182.
13. What's in VigRX? Available from: http://www.vitasprings.com/vigrx.html
14. Premature Ejaculation - Help for men. Available from: http://www.fixpe.com/
15. Yuan YM, Xin ZC, Jiang H, Guo YJ, Liu WJ, Tian L, et al. Sexual function of premature ejaculation patients assayed with Chinese Index of Premature Ejaculation. Asian J Androl 2004; 6: 121-126.
16. Cohen AJ, Bartlik B. Ginkgo Biloba for antidepressant-induced sexual dysfunction. J Sex Marital Ther 1988; 24;139-143.
17. Wheatley D. Triple–blind, placebo-controlled trial of ginkgo biloba in sexual dysfunction due to antidepressant drugs. Hum Psychopharmacol 2004; 19: 545-548.
18. Waynberg J, Brewer S. Effects of Herbal vX on libido and sexual activity in premenopausal and postmenopausal women. Adv Ther 2000; 17: 255-262.