

Evaluation of New Formulation (Verona X Tablet) in Patients with Erectile Dysfunction

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ABSTRACT

Introduction: Erectile dysfunction (ED) is highly prevalent affecting almost 50% of men in the 40-70 year age range especially in those who have co-morbidities like diabetes, atherosclerosis, hypertension etc. Over recent years, the use of complementary and alternative medicines has become increasingly popular, and ED is one condition for which herbal supplements are heavily promoted and easily accessible. Traditional herbs have been a revolutionary breakthrough in the management of ED and have become known worldwide as ‘instant’ treatment. Major progress has been made in this field and at present a number of herbs are identified as a sexual stimulator. This knowledge has led to the discovery of several new therapeutic targets and multiple medical approaches for the treatment of erectile dysfunction (ED). This research focuses on the combination of selected herb in the treatment of ED. **Aim:** To examine the effects of Verona X tablet therapy on ED using the five-item version of the International Inventory of Erectile Function (IIEF). **Methods:** In this multicenter, phase 2 trial, we collect 38 Subjects from different hospitals to receive Verona X tablet a 4-weeks treatment period. Subjects were instructed to take study drug twice a day; no restrictions were placed on food or alcohol intake. On 2nd and 4th weeks we take follow up and record the results. **Main Outcome Measures:** Improvement in erectile function (EF) was measured by International Index of Erectile Function (IIEF) questionnaire. **Results:** 38 patients were selected for the multicenter clinical trial. Out of 38 patient 36 patients documented the improvement in ED. At the follow-up endpoint, Verona X tablet found to be effective and the tolerability was good. No adverse events were reported during the study period. **Conclusion:** The results from the current meta-analysis have suggested that Verona X is an effective and well-tolerated therapy for erectile dysfunction. The findings of the present research highlight the need for more efficient performance of higher quality, large-sample, various-race, long-term, randomized controlled trials to verify the efficacy and safety of Verona X tablet.

Keywords: Erectile dysfunction, premature ejaculation, Herbal medicine, Verona X tablet

INTRODUCTION

Sexual health plays an important role in quality of life of both genders. In males, erectile dysfunction (ED) can lead to dissatisfaction in sexual life and deterioration of sexual well-being [1]. ED is defined as a consistent or recurrent

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inability of a man to attain and/or maintain penile erection sufficiently for sexual activity, which occurs as a result of a lack of blood flow to the penis [2]. Erectile dysfunction (ED) is highly prevalent affecting almost 50% of men in the 40–70 year age range, which corresponds to approximately 150 million men worldwide [3]. ED is generally considered as a manifestation

of a functional and/or structural abnormality affecting the penile circulation. Although modifying lifestyle risk factors can help, in most cases patients also need medication to improve or correct ED [4]. Phosphodiesterase type 5 (PDE-5) inhibitors have revolutionized the treatment of ED. However, despite their efficacy, they have limitations [5]. Especially patients suffering from diabetes and nerve-injury show a poor response to PDE-5 inhibitors or become refractory [6]. Erectile dysfunction (ED) is prevalent among older men, especially those with metabolic syndrome, diabetes, or cardiovascular disease, and it is expected to become more frequent worldwide [7, 8, 9,10]. Erectile dysfunction not due to psychogenic causes or to prostatectomy is usually due to endothelial dysfunction [11, 12]. Atherosclerotic disease and ED have similar risk factors, including diabetes, smoking, obesity, hypertension, and endothelial dysfunction, as well as hypercholesterolemia [13, 14]. ED is an important sexual health problem worldwide with the estimated prevalence of 52% among men aged 40–70 years [1]. The prevalence of ED increases with age, with the highest prevalence in men in their seventies and eighties of between 50–75% [1, 2]. Surveys among Asian countries showed that the prevalence of self-reported moderate ED in aging males (40–70 years) ranging from 17.7%, 22%, 28.3%, 32.2%, and 34% in Taiwan, Malaysia, China, Korea, and Japan, respectively [15]. Due to cultural differences in oriental countries compared to western countries including taboos and cultural restrictions, most Asian men with ED do not seek for formal medical treatment [16]. The Asian males study revealed that it was not uncommon for Asian men to consider traditional herbal medicine as a potential option to improve their sexual well-being [17]. In recent years a huge number of studies have been published aiming to find new therapeutic strategies for the treatment of ED. Since the literature on therapeutic targets has

often been reviewed in recent years [18, 19, 20, 6,21,22,23,24]. Modern phytochemicals have developed from traditional herbs. Phytochemicals focus their mechanism of healing action to the root cause, i.e. the inability to control the proper functions of the whole body system. Hence phytochemicals manage erectile dysfunction in the frame of sexual dysfunction as a whole entity. The present research focuses on the herbal treatment of the ED.

METHODS

A total of 38 patients fulfilling the diagnostic criteria of ED as per the International Index of Erectile Function (IIEF) questionnaire with or without DM were selected from the OPD of Memon medical complex Hospital and Shamsheer khan khyber hospital, irrespective of religion, cast, occupation, etc.

Eligibility

- Age eligible for study 18 years and above.
- Gender eligible for study: Males

Inclusion Criteria:

- Patients with erectile dysfunction, premature ejaculation, impotency and Impaired Spermatogenesis.
- Patients 18 years and above.
- Patients should be the resident of the city in which the trial is conducted.

Exclusion Criteria

- Hypersensitivity to any of the ingredients of the preparation.
- Patients less than 18 years of age.
- Patients who were prescribed other medication for erectile dysfunction, premature ejaculation, impotency and Impaired Spermatogenesis.
- Patients who were prescribed sedative/hypnotics.

Concomitant medication

- Patients having DM were allowed to

continue their anti diabetic drugs during the course of treatment.

- ii) Psychological counseling therapy was given in all the patients.

This study consisted of a 4 weeks treatment period, followed by a 2nd and 4th week follow-ups. All patients were informed about the time to onset and duration of the effects of Verona X tablet. All patients took an oral dose of Verona X tablet twice daily. Participants were asked not to take any other medication for the ED. The volunteers had interview appointments every 2 weeks to fill out the IIEF-5 questionnaire and received the next batch of Verona X tablet.

OUTCOME MEASURES

The IIEF questionnaire was used to evaluate the treatment effect on the sexual functioning in subjects of this study. It evaluates several aspects of sexual function over five important domains: Erectile Function (EF), Sexual Desire (SD), Orgasmic Function (OF), Intercourse satisfaction (IS), and Overall satisfaction (OS). The IIEF was administered at baseline and 2&4-week intervals.

Treatment satisfaction of subjects and their female partners was assessed through responses to the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire. Seminal parameters and serum testosterone levels were assessed at baseline and end of study. Safety was evaluated through incidence of adverse events, changes in laboratory parameters and subject's rating for tolerability of treatment. Subjects were also asked to declare whether they wished to continue with the trial medication. Additionally, at study end, investigators rated response to therapy as excellent, good, fair or poor.

RESULT

In this study we collected the 38 patient from different hospitals. The age group of patient

is 30-70 years. Out of 38 patient 36 patient responded that Verona X tablet is very effective, 2 patient were reported no improvement in their symptoms. All patients were reported that there is no adverse effect noted during and after the treatment with Verona X tablet. As a result of twice daily administration of Verona X tablet the study patients showed significantly increase in their major symptoms i.e. ED. No abrupt changes in pulse rate or BP, and no significant changes in mean sitting or standing heart rate, or systolic and diastolic BP were observed. In all patients no new pathological findings were observed.

CONCLUSION

The results from the current meta-analysis have suggested that Verona X is an effective and well-tolerated therapy for erectile dysfunction. There is a dire need to develop some of the existing potent, traditional remedies for erectile dysfunction into scientifically acceptable natural medicines. The goals of medicines, whether allopathic, traditional or complementary, are the same, namely, to benefit patients therapeutically and improve their quality of life. Based on these assumptions, one can look forward to a near future of integrated orthodox and traditional medicines, and hope that experimental and clinical research in traditional, complementary and alternative medicines will help to develop affordable, safe and effective natural medicines for erectile dysfunction, rather than criticizing and marginalising unorthodox medicines, ethnomedical claims and traditional findings. With traditional health practitioners, pharmacists, orthodox medical practitioners, nurses, botanists, chemists, pharmacologists, toxicologists and other scientists working together collaboratively for a common purpose, the future of scientifically developed, affordable, safe and effective natural medicines for ED will certainly be in sight. Now is the time to ensure that future availability of

scientifically formulated, safe and effective traditional medicines for the treatment of erectile dysfunction is not an elusive dream, but an imminent reality.

REFERENCES

1. Lewis RW, Fugl-Meyer KS, Bosch R, Fugl-Meyer AR, Laumann EO, Lizza E, et al. Epidemiology/risk factors of sexual dysfunction. *J Sex Med.* 2004,1(1):35–39.
2. Berookhim BM, Bar-Chama N. Medical implications of erectile dysfunction. *MedClin North Am.* 2011,95(1):213–221.
3. Mesquita JF, Ramos TF, Mesquita FP, BastosNetto JM, Bastos MG, Figueiredo AA. Prevalence of erectile dysfunction in chronic renal disease patients on conservative treatment. *Clinics (Sao Paulo)* 2012,67:181–3.
4. Glina S, Sharlip ID, Hellstrom WJ. Modifying risk factors to prevent and treat erectile dysfunction. *J Sex Med* 2012,10:115–9.
5. Shamloul R, Ghanem H. Erectile dysfunction. *Lancet* 2013,381:153–65.
6. Chung E, Brock GB. Emerging and novel therapeutic approaches in the treatment of male erectile dysfunction. *CurrUrol Rep* 2011,12:432–43.
7. Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates: Results of the Massachusetts Male Aging Study. *J Urol* 1994,151:54–61.
8. Ayta IA, McKinlay JB, Krane RJ. The likely worldwide increase in erectile dysfunction between 1995 and 2025 and some possible policy consequences. *BJU Int* 1999,84:50–6.
9. Jackson G. Erectile dysfunction: A marker of silent coronary artery disease. *Eur Heart J* 2006,27:2613–4.
10. Montorsi P, Ravagnani PM, Galli S, Rotatori F, Veglia F, Briganti A, Salonia A, Deho F, Rigatti P, Montorsi F, Fiorentini C. Association between erectile dysfunction and coronary artery disease. Role of coronary clinical presentation and extent of coronary vessels involvement: The COBRA trial. *Eur Heart J* 2006,27:2632–9.
11. Kostis JB, Rosen RC, Wilson AC. Central nervous system effects of HMG CoA reductase inhibitors: Lovastatin and pravastatin on sleep and cognitive performance in patients with hypercholesterolemia. *J ClinPharmacol* 1994,34:989–96.
12. Solomon H, Man JW, Jackson G. Erectile dysfunction and the cardiovascular patient: Endothelial dysfunction is the common denominator. *Heart* 2003,89:251–4.
13. Gandaglia G, Salonia A, Passoni N, Montorsi P, Briganti A, Montorsi F. Erectile dysfunction as a cardiovascular risk factor in patients with diabetes. *Endocrine* 2013,43:285–92.
14. Ryan JG, Gajraj J. Erectile dysfunction and its association with metabolic syndrome and endothelial function among patients with type 2 diabetes mellitus. *J Diabetes Complications* 2012,26:141–7.
15. Ismail SB, Wan Mohammad WM, George A, NikHussain NH, MusthapaKamalZM, Liske E. Randomized Clinical Trial on the Use of PHYSTA Freeze-Dried WaterExtract of *EurycomaLongifolia* for the Improvement of Quality of Life and Sexual Well-being in Men. *Evidence-based Complementary and Alternative Medicine.* 2012, eCAM; 2012,429268.
16. Low WY, Wong YL, Zulkifli SN, Tan HM. Malaysian cultural differences in knowledge, attitudes and practices related to erectile dysfunction: focusgroup discussions. *Int J Impot Res.* 2002,14(6):440–445.
17. Tan HM, Low WY, Ng CJ, Chen KK, Sugita M, Ishii N, et al. Prevalence and correlates

- of erectile dysfunction (ED) and treatment seeking for ED in Asianmen: the Asian men's attitudes to life events and sexuality (males) study. *J SexMed.* 2007,4(6):1582–1592.6
18. Albersen M, Shindel AW, Mwamukonda KB, Lue TF. The future is today: emerging drugs for the treatment of erectile dysfunction. *Expert OpinEmerg Drugs* 2010b,15: 467–80.
 19. Andersson KE. Mechanisms of penile erection and basis for pharmacological treatment of erectile dysfunction. *Pharmacol Rev* 2011,63:811–59.
 20. Burnett AL, Goldstein I, Andersson KE, Argiolas A, Christ G, Park K, et al. Future sexual medicine physiological treatment targets. *J Sex Med* 2010,7:3269–304.
 21. Decaluwe K, Pauwels B, Verpoest S, Van de Voorde J. New therapeutic targets for the treatment of erectile dysfunction. *J Sex Med* 2011,8:3271–90.
 22. Feifer A, Carrier S. Pharmacotherapy for erectile dysfunction. *Expert OpinInvestig Drugs* 2008,17:679–90.
 23. Hatzimouratidis K, Hatzichristou DG. Looking to the future for erectile dysfunction therapies. *Drugs* 2008,68:231–50.
 24. Williams SK, Melman A. Novel therapeutic targets for erectile dysfunction. *Maturitas* 2012,71:20–7.