Brief Communication:

Investigation of efficacy of an herbal product (Habb-E-Munish) in the treatment of ED Using IIEF-5 scores and its effect on liver and renal functions

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Abstract:

Background and Rationale: Incidence of erectile dysfunction is rising in both developing and developed countries including Bangladesh. Even in this 21st century people attracted to the herbal and/alternative medicine. The present study was aimed to evaluate the effect of Haab-e-Munish in the treatment using the International Index of Erectile Function-5 (IIEF-5) questionnaire. ***Material and Methods***: A total 33 married male subjects participated in this study. The study was approved by the Research and Ethics Committee of the Ibn Sina Medical College & Hospital. Informed written consent was obtained from each participant. Data were expressed as mean±SD and were managed by SPSS for Windows Version 17. P<0.05 was considered significant. ***Results***: Mean (SD) age of the participants was 36.8±7.7. Basic data like pulse, blood pressure, serum creatinine, urea and alanine aminotransferase (ALT) were unchanged compared to the baseline. IIEF Score of all five functional domain demonstrated significant improvement from the baseline. ***Conclusion***: Herbal preparation Haab-e-Munish has positive effect in improving erectile dysfunctions and is safe for liver and kidney function on short term basis.

Keywords: IIEF-5, erectile dysfunction, alternative medicine.

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Introduction:

Erectile dysfunction (ED) is the inability to achieve and maintain an erection sufficient to permit satisfactory sexual intercourse[1,2]. It mainly affects middle-aged and older men.[3] Recent reports suggests increasingly more people are suffering from ED which is attributed to the work related stress and expected to rise further in coming years, particularly in developing countries.[4,5] Many factors may contribute in the development of ED which includes physical, psychological co-morbidities, medications and insufficiency of androgen, in particular testosterone. It was observed that of men between 30-70 years with ED 24% had testosterone level below normal and 5.6% symptoms of androgen deficiency.[6] Medical conditions like hypertension, diabetes cardiovascular disease linked to ED. There are quite a few numbers of drugs that have side effects related to ED and decreased libido in varying degree.[7]

Treatment of impotence dates back to ancient Chinese text. One of the treatment options to treat impotence was use of potion which used 22 ingredients and Egyptian Papyrus Ebers also documented treatment of impotence, dated back to 1600BC.[8] By 1973

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urologists started using implantable and inflatable prosthesis to treat ED.[7] In was in 1998 major breakthrough occurred in the treatment of ED when sildenafil became the first oral drug to be approved by FDA and later in 2003 two more drug tadalafil and vardenafil, similar phosphodiesterase-5 inhibitor oral medications for treating ED introduced into the market.[8]

Among the behavioral factors smoking, excessive alcohol abuse and illicit drug use are associated with ED.[9-11] Endothelial dysfunctions, CVD and ED have been found closely associated in epidemiological studies. However, role of endothelium in erectile function has only become clear when PDE5 inhibitors revolutionized treatment of ED.[10]

Tremendous progress has been made in the field of modern medicine though, there is ever growing interest among people for using complementary and alternative medicine.[12] This is not different from peoples view point in respect to seeking treatment for ED. A number of pharmaceutical companies have their alternate medicine wings and these products are registered with drug administration. One preparation 'Munish®'['Habb-E-Munish' active ingredients such as Myrica sapida (Kay- phal), Cinnamomum zeylanicum (Daruchini), Mabuya carinata (Regmahi), Qurcus infectoria (Majoophal), Syzygium aromaticum (Laubanga), Centipeda minima (Hachuti), Hyoscyamus niger (Khorasani Jain), Strychnos nux–vomica (Kuchila), Piper nigrum (Golmorich), Piper longum (Pipul), Crocus sativus (Zafran), Castorium (Jundabedostor), Ref: Bangladesh National Uninani Formulari] is used for the treatment of ED, however, data are lacking regarding its efficacy and adverse and/or side effects. The present study was undertaken to evaluate its efficacy and acute metabolic abnormalities.

Materials and Methods:

A total 33 married male subjects consecutively consenting to volunteer the study. All of them were detailed about the nature and purpose of the study. Ethical approval was taken from the Research and Ethics Committee of the Ibn Sina Medical College & Hospital. Informed consent was taken from each and every patient.

Upon consenting to volunteer the study the subjects were interviewed using the International Index of Erectile Function-5 (IIEF-5) questionnaire. Thorough medical and drug history was taken. Married patients with no detectable physical defects and having consented were included in the study. Those patients on aphrodisiac medicine and had comorbid diseases; stroke, ischemic heart disease, diabetes mellitus with or without any neuropathy and gross malnutrition, which could hamper the study outcome were excluded. Blood sample was collected for basal evaluation of liver and kidney function status. On completion of baseline interview and collection of blood samples treatment was initiated with tablet Habb-e-Munish (Munish) taken 12 hourly (in the morning and night before going to bed) for six weeks. After 6 weeks interview of the volunteers was done using IIEF-5 questionnaire. Blood samples were taken for evaluation of liver function test and renal function status.

Data were expressed as mean±SD and managed by using Statistical Package for Social Science (SPSS). Unpaired Student's t-test was performed to calculate statistical difference. $P<0.05$ was taken as level of significance.

Results and Discussion:

Characteristics of the subjects are shown in table 1. Mean age of the subjects was in mid thirties. volunteers autonomic functions as judged by pulse and blood pressure, were within normal range. Hepatic and renal functional status was normal and did not show alteration after treatment with alternate medication (Table 1).

IIEF score of the functional domain were shown in table 2.

Table 1: Characteristics of the study subjects (n=32)

Variables	Values	
	Baseline	Follow up
Age (yrs)	36.8±7.7	-
Pulse (beats/min)	81±5	75±7
Blood pressure (mmHg)		
Systolic	118±6	112±9
Diastolic	79±5	75±8
Serum creatnine (mg/dl	1.02±0.09	0.99±0.11
Serum urea (mg/dl)	33.8±7.8	32.7±5.4
ALT (U/l)	42.3±14.7	40.5±10.3

Results were expressed as mean±SD

Mean erectile function was one third (10.82±1.40) of the possible total score (10) at the baseline, however, demonstrated significant improvement (29.58±0.75) after the treatment. For the erectile functional domain out of 33 only 1 (3.03%) had total score of 14 and rest had less. IIEF score of the rest of the functional domains was nearly half of the possible total and showed mean value close to the possible maximum score after the treatment (Table 2). At

baseline for all subjects IIEF score for orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction individual score was around 50% and reflected in its mean value.

Table 2: IIEF scores in each functional domain of the study subjects

Functional domains	Basal	Final
Erectile function (30)	10.82±1.40	29.58±0.75
Orgasmic function (10)	4.03±0.39	9.79±0.49
Sexual desire (10)	4.06±0.20	8.12±0.49
Intercourse satisfaction (15)	5.36±0.55	13.82±0.73
Overall satisfaction (10)	3.88±0.49	9.67±1.22

Results expressed as mean±SD.

Figure in the parenthesis indicates total possible score in each functional domain.

The finding of the study did not solve any problem regarding treatment of ED rather unmasked quite volume of unanswered questions. ED is mainly found among middle aged and older men.[3] In the present mean age was 36 years. Since large scale and/or population based data are lacking ED occurring in this younger age group may not be taken as it is normally happening. The alternative medicine practitioners practices according to their clinical guidelines. In initiating treatment for ED of these subjects they have not done any laboratory investigations, except blood level, to exclude androgen deficiency which is frequently responsible in ED. More over it is important to exclude the neuro-psychological causes and evaluation of cardiac function status at least by history of IHD and carrying out ECG and any hepatic and renal function disorders being judged by serum creatinine and liver enzymes.

The study demonstrated improvement in all five function domains of the IIEF Score (Table 2). In regard to sexual activity emotional and neurological drive are very importantly related to the sexual performance and bound to put on burden on cardiac and cerebral circulation. The drug 'Munish' was prescribed to the patients without any neurological and cardiac evaluation.

Men's psychological state plays important role in their ED. And psychosexual counseling has been recommended especially those are having discord with their partners[14]. It was observed that in case of stress related ED, when partners are involved in the therapy the problem is resolved in 50-70%.[15] Since data regarding evaluation of psychological state, which also include stress related factors, of these patients have been absent, the causal mechanism in the improvement in their sexual functions may not be explained, however, a psychological healing was very plausible. This has been compounded by the fact the study hand no placebo arm.

The best thing was that after treatment with Munish for six weeks no derangement was observed regarding hepatic and renal functions (Table 1). However, in the event of much longer treatment people might be at the risk of health hazard. This can only circumvented by carrying out chronic toxicity test of the formula. In this regard it may not be overstated that due to lack of sex education in our national curriculum and sex is a taboo in the society people are easy target to malicious practice when they are in need of help.

The present study is an eye opener for the researchers and they need to come forward and carryout properly designed study to evaluate the clinical benefit(s) of the alternative medicine and explore its mechanism of action and circumvent the detrimental effect(s).

Conclusion: Keeping in mind that though this is a pilot study involved small number of participants and having no control group, still from the results of this study we can comment that herbal preparation 'Munish' is safe for liver and kidney and have positive effect in improving erectile dysfunctions. The mechanism of action of this herbal product is beyond the scope of this study. Further study is needed before making final conclusion regarding efficacy and safety.

Ethical Approval: This study got Approval from Research and Ethics Committee of the Ibn Sina Medical College Hospital, although the subjects were willingly taking this herbal product as a 'dietary supplement'.

Conflict of interest: All the authors declare that they have no financial competing interests.

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Authors' contribution:

Conception and design of entire study: SFA, ZH, AKAM

Data Collection: MAH, MNA, HS, AAM

Statistical analysis: ZH

Drafting manuscript: NA, ZH, SFA, AKAM

Final approval of manuscript: all authors

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