To Evaluate the Clinical Efficacy of Tila E Hadaf in the Management of Erectile Dysfunction

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Abstract

The effect of erectile dysfunction potentially interferes with men?s self esteem, confidence, relationship, and overall sense of well being. The problem is increasing in all segments of the sexually active male population and affects both men and his partner. In younger man increase is attributed to substance abuse, such as recreation drugs and alcohol. Middle aged men are affected by medical conditions such as diabetes, hypertension, sexual diseases, organ transplant, coronary artery bypass surgeries and cancer, or the therapy of these problems. The older population is living longer, fuller lives and expects to remain sexually active, regardless of any existing medical conditions. Stress factors associated with modern life styles are affecting men of all ages and contribute greatly to the overall causes of erectile failure. Early identification, behavior modification and increased therapeutic options may improve patient?s outcome. By improving the knowledge and therapeutic options, it may be possible to identify patients at risk of erectile dysfunction and thus to lead a normal healthy life. The present study reveals that overall effect of Tila e Hadaf was found quite encouraging in the treatment of erectile dysfunction and significant improvement was observed in subjective parameters.

Index terms— erectile dysfunction, tila e hadaf.

1 I. Introduction

rectile dysfunction (ED) is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance (Impotence NIH Consensus Statement 1992). The researchers assessed the sexual function of 31,742 men between the ages of 53 and 90, who were enrolled in the Health Professionals Follow-up Study and had responded to a questionnaire mailed in 2000 that, among other questions related to health, asked about sexual function, physical activity, body weight, smoking and marital status. Men who had been diagnosed with prostate cancer were excluded from the findings. Thirty-three percent of the participants reported experiencing erectile dysfunction in the previous three months. ED was defined as the inability, without treatment, to have and maintain an erection adequate for intercourse (Feldman HA, Goldstein I, Hatzichristou DG).

Fewer than two percent of the men in the study who reported that they had erection problems experienced them before age 40, and four percent had experienced problems between age 40 and 49. From age 50 upwards, the percentage of men reporting ED increased dramatically with 26 percent between the ages of 50 to 59, 40 percent aged 60 to 69 years and 61 percent for men older than 70 having experienced ED. The Massachusetts Male Aging Study reported a prevalence of 52% in men aged 40 to 70 (Feldman HA et al 1994). It is estimated that in 1995 there were over 152 million men worldwide who experienced erectile dysfunction. With the ageing worldwide population, it has been projected that by the year 2025, 322 million men will have some degree of erectile dysfunction (Ayta IA, McKinlay JB, Krane RJ 1999). Data on the prevalence of ED in Asia are limited. A recent study conducted in Thailand reported an overall prevalence rate of 37.5% amongst men 40 to 70 years of age (Kongkanand A 2000). No observational studies on erectile dysfunction have been done in Delhi previously. With an ageing population, erectile dysfunction may become a significant health problem.

Keeping this fact in mind and a high prevalence of erectile dysfunction, this Pilot study was conducted in Ayurvedic and Unani Tibbia College Hospital by Department of Physiology to find out the clinical efficacy of Tila e Hadaf in the management of erectile dysfunction. The objective of this study was to test the clinical efficacy of Tila e Hadaf a branded Unani medicine manufactured by Sangam Pharmacy, 2922, Kithore, Didtrict Meerut, (UP)-250104, India on erectile dysfunction. This was an 8 week, randomized, single blind, observational study.. A total of 100 subjects were randomly selected. Medicine was supplied by the hospital store. Patients enrolled into study were given the information sheet having details about the nature of the study, the drug to be used, method of treatment and they were allowed to go through the contents of informed consent form accordingly to ask any question related to study, they were asked to sign the informed consent form.

2 c) Investigations

Investigations were carried out aiming: ? To exclude the patients with pathological conditions mentioned under exclusion criteria. ? To establish safety and validation of test drugs.

3 d) Study design

This study was designed as a Randomized single blind observational study.

4 e) Sample size

The sample size was fixed as 100 patients who fulfill the inclusive criteria for the study.

5 f) Study and data collection

The study is the test run study, conducted in different population with similar characteristic. The data for the study was collected from 100 married males based on objectives of the study; a structured questionnaire has been developed to assess the knowledge of regarding erectile dysfunction at A & U Tibbia college Hospital, Karol Bagh, New Delhi, from June 2012 to Dec 2012. A formal written permission was taken from Head of the Dept of physiology, A & U Tibbia College and Hospital to conduct the study.

6 i. Family type

The families were classified as follows:

Nuclear family : Married couple and their children, where the children are still regarded as dependant.

Joint family : Consists of number of married couples and their children who live in the same household.

ii.

7 Occupation of subjects

The occupation of the parents was recorded as the determinant of the SES.

iii.

8 Literacy of the subjects

The data related to the literacy of the subjects was assessed to know the educational status and the socioeconomic status. iv.

9 Socioeconomic status (SES)

The SES was assesses by using the Kuppuswami's SES Scale for Urban population, 1976. Due to changes in the economy to year, the classification or scale was modified accordingly. The latest SES scale is of 2012.

10 g) Duration of protocol

The treatment period of test formulation was determined as 60 days. Laung (Cloves)100 mg **??**Tajuddin , Ahmad S. 2004). Aqarqarha (Anacyclus pyrethrum)100 mg. Roghan Zaitun (Olive oil) qs.

11 i) Method of preparation and mode of administration of test drug

The Tila e Hadaf for trial formulation was provided by Sangam Pharmacy Meerut. Tila Hadaf was dispensed to the patients allocating in test group in the transparent glass bottle in sufficient quantity to last for 7 days.

12 i. Dosage

To be rubbed on the penis. Just 4-5 drops are to be massaged on the male organ 1-2 times a day. j) Follow up during treatment Two month study was divided into eight visits of follow up, which were made at an interval of 7 days. At every visit, patients were asked about the progression or regression in their symptoms, and subjected to assess the clinical findings. Concomitant treatment was not allowed during study.

13 o) Documentation

The case record form and consent forms properly documented throughout the study.

In view of the nature of the problem selected for the study and the objectives to be accomplished, this study designed as a Randomized single blind observational study was found appropriate.

14 i. Mechanism of action of Tila e Hadaf in Erectile dysfunction

Tila e Hadaf manufactured by Sangam Pharmacy, is special oil with all unique natural ingradients known for ages as per unani ssystem of medicines to treat the erectile dysfunction. Tila e Hadaf helps supply the penis with all the essential nutrients it needs. Besides offering natural gains in the length and girth of the penis they improve many aspects of penis health. It is natural penis enhancement oil that increases blood flow to the penile erectile chambers which leads to a harder and long-lasting erection when aroused. Gives enhanced sexual pleasure and more intense orgasm. It has been proven to be safe and without any known side-effects. It is an effective remedy to normalize the hypersensitization of male organ due to spermatorrhea, premature ejaculation or excess of coitus.

The sensitivity of the sexual organs increases abnormally as a result of masturbation, hyper sensitiveness, premature ejaculation, nocturnal emission (wet dream), spermatorrhoea and excessive sexual intercourse. It becomes essential to bring the sensitivity of the sexual organs to normal level in order to cure the said diseases. Excessive nocturnal emission (wet dream) and spermatorrhoea cause pricking on the gland which produces Mazi (a fine liquid that flows before the discharge of semen), such a pricking causes frequent erection and pain in testicles. Such conditions adversely affect the growth of the penis.

Tila Hadaf is the compound of such components which give potency to the male sexual organs and bring their sensitiveness to a normal level. They also regulate the circulation of blood and give energy to the nerves and muscles of penis. Its use makes away with the harmful effects of masturbation. Tila Hadaf also potentiates nerves and muscles of the male organ.

15 III. Observation and Result

The sample of 100 married male from A & U Tibbia College Hospital, Karol Bagh Delhi was taken from the population, by using convenient sampling. The personal data obtained include age, educational status, occupation, family income, religion, type of family, duration of married life, and place of residence. Figure 2 shows that in educational status majority of married males (31.00%) had studied upto secondary, 28% had primary education, 24% had higher secondary education and 17% had graduate and above educational qualification. This shows that majority of participants were having secondary education. Figure shows that majority of married males 32% were unemployed, 25% were skilled, 19% were semiskilled, and 24% were unskilled worker respectively.

Thus it is seen that most of the married males had an occupation. Figure 4 shows that out of total 100 married males in the study 25% were from upper middle (2) SES, 45% were from lower middle (3) SES, and 30% were from upper lower (4) SES. Maximum numbers, 45 (45.00%) were from lower middle (3) SES. This can be attributed to lower educational and occupational status of subjects (Figure 4). Figure **??** depicts that 67% of the subjects were from urban area whereas 33% of the subjects were from rural area. This shows that majority of the cases were from urban area.

Table 1 : Distribution of subjects according to situation in terms of a full erection. **??**0 depicts that at the end of treatment, 8% of the subjects had got grade 0 meanwhile no improvement, whereas 25% of the subjects had got grade I, 50% of the subjects had got grade II, and 17% of the subjects got grade III improvement respectively. This shows majority of the cases had got grade II and were having satisfactory improvement.

16 IV. Conclusion

Satisfactory sex life is an important influencing factor for a harmonious marriage and relationship. Sexual problems like erectile dysfunction deeply effects personal life causing isolation, frustration and decreased self-esteem, which may extend into their job performance and interaction with others.

Keeping this fact of high prevalence of ED in mind, A clinical study was carried out under Prof. Dr Yusuf Jamal, Department of Physiology in Ayurvedic and Unani Tibbia College & Hospital to evaluate the efficacy of a Unani formulation named Tila e Hadaf in the management of erectile dysfunction. The results of the study revealed that:

Majority of the married males (30.00%) were between the age group of 26-30 years, 23.00% were in age group between 21-25 years, 29.00% were between the age group of 31-35 years and only 19.00% were in the age group of more than 36 year. Thus it is seen most of the married males participated in the study were below 50 years of age.

The present study shows that in educational status majority of married males (31.00%) had studied up to secondary, 28% had primary education, 24% had higher secondary education and 17% had graduate and above educational qualification. This shows that majority of participants were having secondary education.

The present study reveals that majority of married males 32% were unemployed, 25% were skilled, 19% were semiskilled, and 24% were unskilled worker respectively. Thus it is seen that most of the married males had an occupation.

The present study shows that out of total 100 married males in the study 25% were from upper middle (2) SES, 45% were from lower middle (3) SES, and 30% were from upper lower (4) SES. Maximum numbers, 45 (45.00%) were from lower middle (3) SES. This can be attributed to lower educational and occupational status of subjects.

The present study reveals that 60% of the subjects were from Hindu community, 36% subjects were from Muslim community and 4% from other communities.. This shows that majority of the subjects were from Hindu community.

The present study depicts that 55% of the subjects were fromo nuclear family and 45% were from joint family. Hence it is clear majority of the subjects participating in the study were from nuclear family.

The present study shows that 34% of the subjects had 0-5 years duration of married life, 24% subjects had 6-10 years duration of married life, 31% subjects had 11-15 years duration of married life, and 11% subjects had more than 15 years duration of married life.

The present study depicts that 67% of the subjects were from urban area whereas 33% of the subjects were from rural area. This shows that majority of the cases were from urban area.

The present study depicts that 51% of the subjects had never got a full rigid erection and 49% had got full rigid erection in some situations. Hence it is clear majority of the subjects 51.00% participating in the study never got a full rigid erection.

The present study depicts that at the end of study, 8% of the subjects had got grade 0 meaning no improvement, whereas 25% of the subjects had got grade I, 50% of the subjects had got grade II, and 17% of the subjects got grade III improvement respectively. This shows majority of the cases had got grade II and were having satisfactory improvement.

The present study reveals that overall effect of Tila e Hadaf was found quite encouraging in the treatment of erectile dysfunction and significant improvement was observed in subjective parameters. No clinically significant side effects were observed in test group and overall compliance to the treatment was found excellent. These results conclude that the test drug Tila e Hadaf is a cheap, safe, and effective treatment for erectile dysfunctions.

Figure 1:

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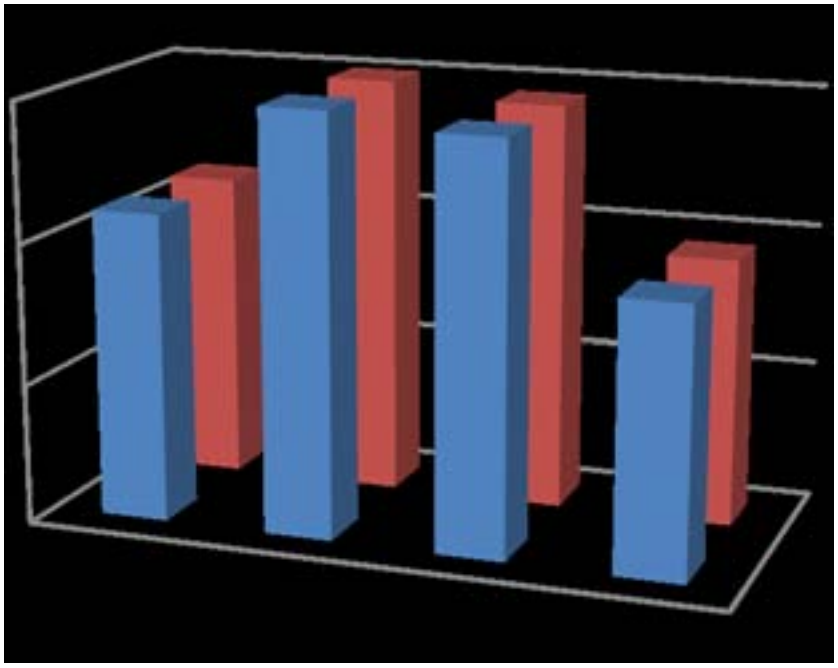

Figure 2:

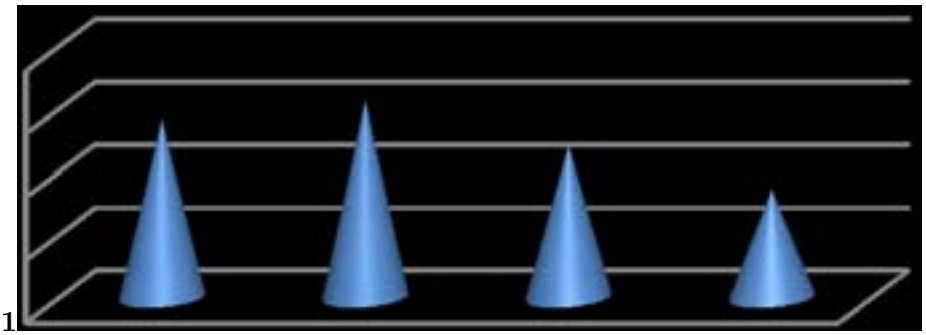

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Figure 3: Figure 1 :Figure 1

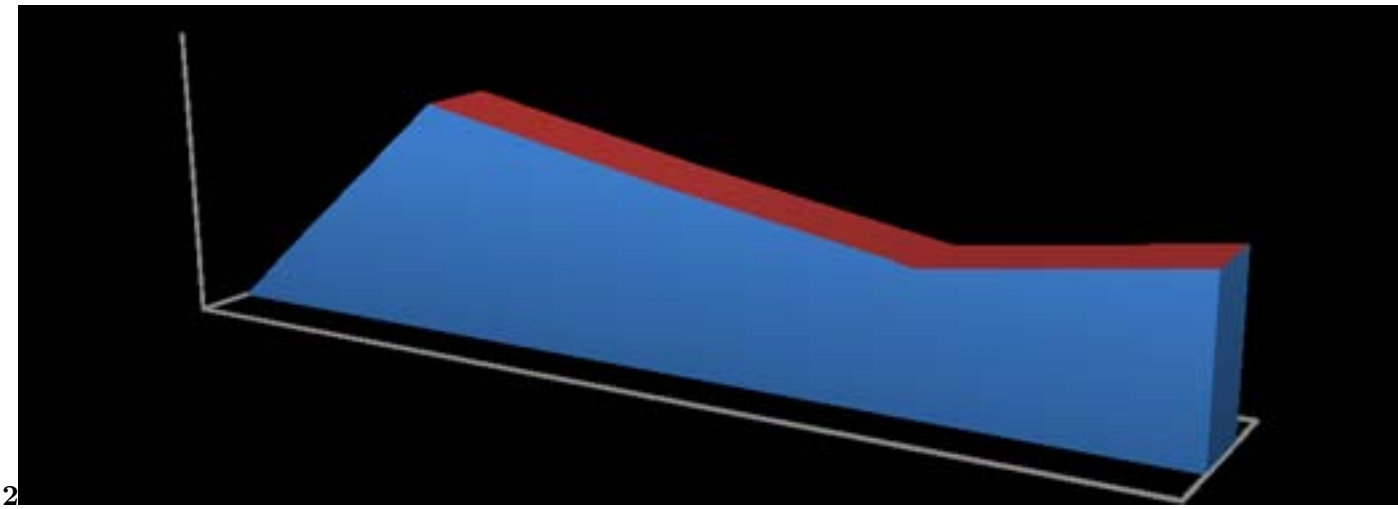

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Figure 4: Figure 2 :

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Figure 5: Figure 3 :

Figure 6:

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Figure 7: Figure 4 :

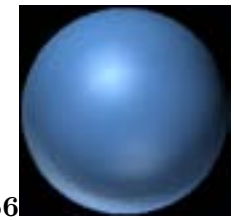
556 

Figure 8: Figure 5 :Figure 5 Figure 6 :

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Figure 9: Figure 6

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Figure 10: Figure 7 :

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Figure 11: Figure 7 Figure 8 :

Figure 12:

Figure 13:

erectile dysfunction increases from 17% to approximately 34%; the prevalence of complete erectile dysfunction increases from 5% to 15% as age increases from 40 to 70 years (Feldman HA, Goldstein I, Hatzichristou DG 1994).

Figure 14:

1

Figure 15: Table 1

2

Grade	Number of subjects	Percentage
Grade 0	8	8.00%
Grade I	25	25.00%
Grade II	50	50.00%
Grade III	17	17.00%

Figure 16: Table 2 :

2figure

Figure 17: Table 2 and figure

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