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Pilot Study on the Effect of Botanical Medicine (*Tribulus terrestris*) on Serum Testosterone Level and Erectile Function in Aging Males With Partial Androgen Deficiency (PADAM)

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This study was conducted on 30 consecutive male patients presenting to Kasr-Al Ainy Andrology outpatient clinic complaining of manifestations of partial androgen deficiency in aging males (PADAM). In this study (750 mg/day) of *Tribulus terrestris* in 3 divided doses, each of 250 mg, as an endogenous testosterone enhancer had been tried for a duration of 3 months and the evaluation of its effect had been monitored for each patient concerning its effect on serum testosterone (total and free) and luteinizing hormone (LH), as well as its impact on erectile function, which was evaluated by the International Index of Erectile Function-5 (IIEF-5) questionnaire for those patients. Results showed a statistically significant difference in the level of testosterone (total and free) and IIEF-5, but no statistically significant difference in the level of LH before and after treatment. Also, the study showed statistically significant correlation between testosterone (total and free) and IIEF-5, but no statistically significant correlation between the level of LH and the IIEF-5 before and after treatment.

INTRODUCTION

Andropause is defined as the gradual decline of androgen levels with aging. The degree of this reduction differs from one individual to another, and not all aging men will show manifestations of hypogonadism to a clinically significant degree (Gooren, 1996). Andropause or partial androgen deficiency in aging males (PADAM) may present in terms of many manifestations, such as hot flushes similar to those of menopause, episodes of sweating, insomnia, nervousness, decreased physical activity and muscle strength, decreased libido, or erectile dysfunction (Tremblay & Morales, 1998). Androgen replacement therapy has proven beneficial in severely testosterone-deficient hypogonadal men, and male hypogonadism is the main clinical indication for testosterone (T) treatment (Bhasin et al., 2006).

Tribulus terrestris L. is found growing in subtropical areas around the world. It is commonly known as Gokhru, belonging to the family Zygophyllaceae, widely distributed throughout India. The fruits of *Tribulus terrestris* L. have been used in traditional Chinese medicine for the

treatment of many medical conditions, such as eye problems, edema, abdominal distension, sexual dysfunction, premature ejaculation, and infertility (Selvam, 2008). Extracts of the herb *T. terrestris* have also been used to manage the symptoms of low testosterone levels (McKay, 2004).

The current research indicates that the steroidal saponins, particularly the dominant saponins PTN (protodioscin), are responsible for the pharmacological activities of *Tribulus* concerning fertility and sexual functions (Gauthaman & Adaikan, 2005). The structure of PTN is very similar to dehydroepiandrosterone (DHEA), which is intimately involved in the male reproductive function through the production of testosterone.

PATIENTS AND METHODS

This study was carried out on 30 consecutive male patients attending the outpatient Clinic of Andrology, Kasr-Al Ainy Hospital, and Cairo University, who agreed to participate and met the inclusion criteria, listed below:

Inclusion criteria:

- Patients presenting with manifestations of partial androgen deficiency (PADAM), age: 40–70 years, complaining mainly of erectile dysfunction and low libido (T < 12 nmol/L and/or cFT < 250 pmol/L). cFT (calculate free testosterone).

Exclusion criteria:

- Major uncontrolled medical disorders.
- Chronic heavy smoker (smoking index more than 400).
- Small or moderate testicular volume (less than 13 ml).

All patients were subject to the following:

1. Approval of the ethical committee being obtained after getting signed informed consents from the participating patients, including the nature of the study, the needed investigations from them to be done, and finally intake of *Tribulus terrestris* three times daily for 3 months.
2. Personal and sexual history: We focused on special habits of medical importance, particularly smoking (type of smoking: cigarettes or shisha, number of cigarettes or hajjar per day, duration of smoking in years), alcohol intake, and drug abuse. We asked about the onset of the condition, and its course and duration: whether there is any morning erection, whether there is any erectile episode with visual or manual stimulation or extramarital relations, frequency of intercourse, and last sexual coitus. Level of libido was assessed by a 6-point scale (1 = *loss of libido*, 2 = *very weak*, 3 = *weak*, 4 = *moderate*, 5 = *strong*, 6 = *very strong*) in the study patients (unfortunately, there is no valid questionnaire to assess libido so we created a simple one to assess roughly the level of the libido in the study patients). All patients answered the Arabic version of the IIEF-5 questionnaire in a structured interview. It is a validated Arabic version of the IIEF-5 (Shamloul, Ghanem, & Abou-zeid, 2004).

3. Genital examination was done to detect any abnormality in the penis or the testis where the testis was measured using Prader's orchidometer (Prader, 1966) and radiologically using scrotal ultrasound (SONOLINE G40, Diagnostic Ultrasound Systems, Manufactured by Siemens AG, Erlangen, Germany) and testicular consistency (whether the testes are rubbery, firm, hard, or soft).
4. Patients with manifestations of PADAM were studied between 8 and 10 a.m.; venous blood was sampled for measurements of LH, testosterone (total and free), prolactin, and prostate-specific antigen (PSA). Both serum testosterone (total) and LH were measured using the electrochemiluminescence immunoassay (ECLIA), and testosterone (free) was measured using radioimmuno assay (RIA) (reference range: TT = 2.5–8.4 pg/ml, TF = 9.0–40.0 pg/ml and LH = 0.8–7.6 mIU/ml). (The hormones were measured using the ADVIA Centaur CP Immunoassay System and the kits were supplied by the manufacturer of the device). Free and bioavailable testosterone were calculated by the equation described by Vermeulen, Verdonck, and Kaufman (1999).

Tribulus terrestris samples were collected from the natural habitats during flowering; then the air-dried plant sample was rinsed with water and dried. After evaporation of the solvent, the residues were powdered (250 mg) and extracted with 500 ml of 70% ethanol (or methanol or acetonitril or hexane) in a Soxhlet apparatus and the extracts were evaporated to dryness by a rotatory evaporator (Hussain, Abbas, Heba, & Amir, 2009). All patients were given *Tribulus terrestris* at a dose of 750 mg/day in 3 divided doses for duration of 3 months with estimation of testosterone (total and free) and LH, in addition to evaluation of erection, which was done by IIEF-5 before and after treatment.

RESULTS

This study was carried out on 30 consecutive male patients attending the outpatient clinic of Andrology, Kasr-Al Ainy Hospital, Cairo University with mean age of 55.93 ± 5.988 years and aimed at evaluating the effect of the *Tribulus terrestris* at a dose of 750 mg/day on serum testosterone level (total and free) as well as LH and its impact on IIEF-5 in males presenting with manifestations of partial androgen deficiency (PADAM) before and after treatment for 3 months duration.

The statistical analysis of the data collected from the study was conducted using an IBM program known as Statistical Package for the Social Sciences version 20 (SPSS 20) and the results are given in Table 1.

Using the paired *t*-test, there was a statistically significant difference in testosterone (total and free) and IIEF-5 before and after treatment with *Tribulus terrestris* but not with LH. Also, our study using Spearman's correlation significance two-tailed test showed statistically significant correlation between the level of total testosterone and IIEF-5 before and after exposure where the *p* value before was .001* and .054*, respectively, and after, the *p* value became .003* and .013*, respectively (asterisk indicates significant). Also, it showed a statistically significant correlation between IIEF and free testosterone before and after exposure where the *p* value before was .001* and .025*, respectively, and after, the *p* value became .013* and .024*, respectively. On the other hand, there was no statistically significant correlation between IIEF and LH before and after

TABLE 1
Changes in the Different Parameters Concerning Testosterone (Total and Free), LH, and IIEF-5 Before and After Treatment With *Tribulus terrestris*

| Parameter | Number (n) | Mean | Standard deviation (SD) | Minimum | Maximum | Median | p Value |
|-----------------|------------|--------|-------------------------|---------|---------|--------|---------|
| TT (before) | n = 30 | 2.133 | 0.1954 | 1.60 | 2.40 | 2.15 | .026* |
| TT (after) | | 2.837 | 1.698 | 1.90 | 9.10 | 2.30 | |
| TF (before) | | 7.303 | 1.352 | 4.10 | 8.80 | 7.85 | .034* |
| TF (after) | | 7.720 | 1.171 | 5.10 | 10.10 | 7.95 | |
| LH (before) | | 6.977 | 0.696 | 5.90 | 9.00 | 6.90 | .697 |
| LH (after) | | 7.030 | 0.777 | 5.80 | 8.90 | 7.00 | |
| IIEF-5 (before) | | 12.482 | 1.250 | 7 | 18 | 12.50 | .000* |
| IIEF-5 (after) | | 15.962 | 1.102 | 11 | 21 | 16.00 | |

*Statistically significant.

exposure where the *p* value before was .074 and .077, respectively, and after, the *p* value became .067 and .080, respectively.

DISCUSSION

Our study showed that the level of total testosterone of the patients before treatment was 2.133 ± 0.1954 and after treatment was 2.837 ± 1.698 , and this showed a statistically significant difference (*p* value = .026). It also showed that the level of free testosterone of the patients before treatment was 7.303 ± 1.352 and after treatment was 7.720 ± 1.171 , and this showed a statistically significant difference (*p* value = .034); in addition, the level of LH of the patients before treatment was 6.977 ± 0.696 and after treatment was 7.030 ± 0.777 , and this showed no statistically significant difference (*p* value = .697). In addition, the IIEF-5 score before treatment was 12.482 ± 1.250 and after treatment was 15.962 ± 1.102 , and this showed a statistically significant difference (*p* value = .000).

Also, this showed a statistically significant correlation between the levels of testosterone (total and free) and IIEF-5 before and after treatment. In contrast, it showed no statistically significant correlation between the level of LH and IIEF-5 before and after treatment. Consistent with our finding, a study performed in 2008 stated that the aphrodisiac effect of *Tribulus terrestris* is due to the presence of protodioscin, which leads to an increase in some of the sex hormones, and this may explain its role in mild to moderate ED (Gauthaman & Ganesan, 2008). Also, several studies investigated *Tribulus terrestris* as an ingredient of an herbal mixture, which proved to be effective in ED (Kam et al., 2012; Sansalone et al., 2014). On the other hand, a study performed in 2014 did not find any beneficial effect of this compound (Santos, Reis, Destro-Saade, Luiza-Reis, & Fregonesi, 2014).

CONCLUSION

We concluded that *Tribulus terrestris* may be a promising herbal medicine for the treatment of aging patients with erectile dysfunction suffering from partial androgen deficiency. However, we

recommend doing further studies on a larger scale (increasing the sample size) and changing the study design to be a double-blind randomized placebo controlled study.

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