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ORIGINAL ARTICLE

Tribulus terrestris versus placebo in the treatment of erectile dysfunction: A prospective, randomized, double-blind study☆

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Impotence;
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Herbal medicine;
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Testosterone;
Libido;
Placebo and Chinese medicine

Abstract

Objectives: To evaluate the possible effects of *Tribulus terrestris* herbal medicine in the erectile dysfunction treatment and to quantify its potential impact on serum testosterone levels.
Design and methods: A prospective, randomized, double-blind and placebo-controlled study including 30 healthy men selected from 100 patients who presented themselves spontaneously complaining of erectile dysfunction, ≥40 years of age, nonsmokers, not undergoing treatment for prostate cancer or erectile dysfunction, no dyslipidemia, no phosphodiesterase inhibitor use, and no hormonal manipulation, and if present, hypertension and/or diabetes mellitus should be controlled. International Index of Erectile Function (IIEF-5) and serum testosterone were obtained before randomization and after 30 days of study. The patients were randomized into two groups of fifteen subjects each. The study group received 800 mg of *Tribulus terrestris*, divided into two doses per day for 30 days, and the control group received placebo administered in the same way.
Results: The groups were statistically equivalent in all aspects evaluated. The mean (SD) age was 60 (9.4) and 62.9 (7.9) years, $p = 0.36$, for intervention and placebo groups, respectively. Before treatment, the intervention group showed mean IIEF-5 of 13.2 (5–21) and mean total testosterone 417.1 ng/dl (270.7–548.4 ng/dl); the placebo group showed mean IIEF-5 of 11.6 (6–21) and mean total testosterone 442.7 ng/dl (301–609.1 ng/dl). After treatment, the intervention group showed mean IIEF-5 of 15.3 (5–21) and mean total testosterone 409.3 ng/dl (216.9–760.8 ng/dl); the placebo group showed mean IIEF-5 of 13.7 (6–21) and mean total testosterone 466.3 ng/dl (264.3–934.3 ng/dl). The time factor caused statistically significant changes in both the groups for IIEF-5 only ($p = 0.0004$); however, there was no difference between the two groups ($p = 0.7914$).

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Conclusions: At the dose and interval studied, *Tribulus terrestris* was not more effective than placebo in improving symptoms of erectile dysfunction or serum total testosterone.

PALABRAS CLAVE
Impotencia;
Disfunción sexual;
Fitoterapia;
Medicina alternativa;
Testosterona;
Libido;
Placebo y medicina china

Tribulus terrestris versus placebo en el tratamiento de la disfunción eréctil: un estudio aleatorizado, prospectivo y doble ciego

Resumen

Objetivos: Evaluar los posibles efectos de la fitoterapia con tribulus terrestris en el tratamiento de la disfunción eréctil y cuantificar su impacto potencial en los niveles de testosterona sérica.
Diseño y métodos: Estudio prospectivo, aleatorizado, doble ciego y controlado con placebo incluyendo 30 hombres sanos seleccionados entre 100 pacientes que se presentaron espontáneamente con disfunción eréctil, ≥40 años de edad, no fumadores, no sometidos a tratamiento para el cáncer de próstata o disfunción eréctil, sin dislipidemia, sin uso de inhibidores de la fosfodiesterasa, sin manipulación hormonal y si presentaban hipertensión y/o diabetes mellitus debían ser controlados. El índice internacional de función eréctil (IIFE-5) y la testosterona sérica se obtuvieron antes de la aleatorización y después de 30 días de estudio. Los pacientes fueron divididos aleatoriamente en 2 grupos de 15 sujetos cada uno. El grupo de estudio recibió 800 mg de Tribulus terrestris, divididos en 2 dosis al día durante 30 días y el grupo control recibió placebo administrado de la misma manera.
Resultados: Los grupos fueron estadísticamente equivalentes en todos los aspectos evaluados. La media de edad (DE) fue de 60 (9,4) y 62,9 (7,9) – p = 0,36 – para la intervención y los grupos de placebo, respectivamente. Antes del tratamiento el grupo de intervención mostró una media de IIFE-5 de 13,2 (5–21) y la media de testosterona total de 417,1 ng/dl (270,7–548,4 ng/dl); el grupo de placebo mostró una media de IIFE-5 de 11,6 (6–21) y una media de testosterona total de 442,7 ng/dl (301–609,1 ng/dl). Después del tratamiento el grupo de intervención mostró una media de IIFE-5 de 15,3 (5–21) y una media de testosterona total de 409,3 ng/dl (216,9–760,8 ng/dl); el grupo placebo mostró una media de IIFE-5 de 13,7 (6–21) y una media de testosterona total de 466,3 ng/dl (264,3–934,3 ng/dl). El factor tiempo causó cambios estadísticamente significativos en ambos grupos solo para IIFE-5 (p = 0,0004), sin embargo no hubo ninguna diferencia entre los 2 grupos (p = 0,7914).
Conclusiones: A la dosis y el intervalo estudiado Tribulus terrestris no fue más eficaz que el placebo en la mejora de los síntomas de la disfunción eréctil o la testosterona sérica total.

Introduction

Tribulus terrestris is a herb belonging to the family Zygophyllaceae,[1] mostly from southern temperate zones of Europe. It has been used for centuries in traditional Chinese medicine, and also in Indian system of medicine, in order to improve libido and sexual performance.[2] Some authors have confirmed this effect in rabbits and primates.[3]

Studies also show an increase in the level of free testosterone in guinea pigs.[4] These effects could be due to the presence of saponins and flavonoids in the compound, which would act on the fat-soluble steroids.[5–7]

Dell'Agli et al. tested possible inhibitory effects on the enzyme phosphodiesterase-5.[8] Rogerson et al. studied the possible increase in human skeletal muscle with supplementation of Tribulus for a period of five weeks.[9] Other authors have attempted to confirm these effects in humans, but they were unsuccessful, possibly due to limitations in study design and sample size.[10,11]

Methods

The local Ethics Committee approved this prospective, randomized, double-blind and placebo-controlled study. Data collection occurred from September 2009 to April 2010, in a urology outpatient clinic. The subjects were evaluated with history and physical examination directed to the genitals and femoral pulses bilaterally. No patient had abnormal physical examination.

Inclusion criteria were as follows:

- Male;
- Minimum age 40 years;
- Erectile dysfunction treatment-naive;
- Consenting to participate;

Exclusion criteria were as follows:

- Illiterate individuals;
- Smoking;
- Dyslipidemia (abnormal serum cholesterol or triglycerides);
- Uncontrolled diabetes mellitus (fasting glucose > 150 mg/dl);
- Uncontrolled hypertension (diastolic blood pressure > 90 mmHg);
- Prior pelvic radiotherapy;
- Previous pelvic surgery;
- Use of phosphodiesterase-5 inhibitor.