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Evaluation of *Crocus sativus* L. (saffron) on male erectile dysfunction: A pilot study

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Abstract

In this study, the effect of *Crocus sativus* (saffron) was studied on male erectile dysfunction (ED). Twenty male patients with ED were followed for ten days in which each morning they took a tablet containing 200 mg of saffron. Patients underwent the nocturnal penile tumescence (NPT) test and the international index of erectile function questionnaire (IIEF-15) at the start of the treatment and at the end of the ten days. After the ten days of taking saffron there was a statistically significant improvement in tip rigidity and tip tumescence as well as base rigidity and base tumescence. ILEF-15 total scores were significantly higher in patients after saffron treatment (before treatment 22.15 ± 1.44; after treatment 39.20 ± 1.90, $p < 0.001$). Saffron showed a positive effect on sexual function with increased number and duration of erectile events seen in patients with ED even only after taking it for ten days.

Keywords: *Crocus sativus*; Saffron; Erectile dysfunction; Sexual activity; RigiScan; International index of erectile function questionnaire (ILEF-15)

Introduction

Erectile dysfunction (ED) affects more than 150 million males throughout the world (Porst et al. 2003). For the minority of causes, phosphodiestras 5-inhibitors, like sildenafil, tadalafil and vardenafil work to resolve ED, however due to various reasons such as adverse side-effects, cost and drug interactions many men stop using them and seek further help.

Saffron is the dried red stigma collected from the saffron plant (*Crocus sativus* L., Iridaceae family) which is widely cultivated in Iran (Ríos et al. 1996). Saffron has different activities such as anticancer (Nair et al. 1995; Abdullaev and Espinosa-Aguirre 2004), anticonvulsant (Hosseinzadeh and Khosravan 2002; Hosseinzadeh and Talebzadeh 2005), antidepressant (Hosseinzadeh et al. 2004; Akhondzadeh et al. 2005), anti-ischemia (Hosseinzadeh and Sadeghnia 2005; Hosseinzadeh et al. 2005), learning and memory improving properties (Abe and Saito 2000; Hosseinzadeh and Ziaei 2006). In traditional medicine, saffron is recommended as aphrodisiac agent (Madan et al. 1966). Recently, an aphrodisiac activity of saffron aqueous extract and its constituent crocin was shown in rat. Crocin, and saffron increased mounting, intromission and erection

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frequency behaviors during the sexual behavior study in rats (Hosseinzadeh et al. 2008). Thus, in this study the effect of saffron tablets was evaluated in patients with ED.

Materials and methods

Study design

This open clinical trial was conducted to evaluate the effect of saffron on 20 male patients with ED. The treatment period was for ten days, during this period patients received a tablet containing 200 mg of saffron each morning, except on the last day (day 10) where patients were scheduled for a Rigiscan, and thus each took double the dose of saffron.

In all ED patients, we advise vasoactive drugs injection in corpus spongiosum in office, before color Doppler sonography of penis as well as cavernosography and cavernosometry, also Rigiscan as needed. When it was clear that there is no underlying cause for ED, for example, diabetes mellitus (idiopathic) then, patients were included in the study.

60 percent of our patients were on long-term prescribed medication, but the other came for treatment for the first time.

Major exclusion criteria were when the cause of ED is clear, e.g. pelvic fracture, diabetes mellitus, etc.

Patients were voluntary consented and told about the drug. The age ranged between 26 to 62 years (43.78 ± 10.61). Before taking the tablets, patients asked to come to the Rigicsan room inside the urology department.

A single and isolated bedroom with a RigiScan, computer, printer and all other relevant equipment was prepared. The nocturnal penile tumescence (NPT) test was conducted during the night, for ten hours duration.

After removal of the RigiScan device and printing the profile, the international index of erectile function with 15 questions (ILEF-15) was applied to each patient. Thereafter on discharge patients were told to take one tablet daily except on day ten , where two tablets were taken and the second NPT test was conducted followed by the IIEF-15 once the rigiscan was removed.

There was no complication related neither to RigiScan test nor saffron usage.

Plant material

Crocus sativus L. stigma was taken from Novin Saffron Co. Mashhad, IR, Iran. It was formulated as tablets which each tablet contained 200 mg dried saffron stigma.

Quantification of crocin and safranal in saffron aqueous extract

Amounts of crocin and safranal in saffron aqueous extract were determined by a modified method as previously described (Hosseinzadeh et al. 2008). The quantities of crocin and safranal in *C. sativus* extract were about 19.7 and 0.25 mg/g, respectively.

Statistical analysis

The results obtained are expressed mean $\pm$ SEM and analyzed using Student's paired *t*-test. A value of $p < 0.05$ was considered statistically significant.

Results

All 20 participants returned after ten days for their second NPT and second IIEF-15. There was a statistically significant difference in tip rigidity and tip tumescence as well as base rigidity and base tumescence. Saffron tablets improved all these parameters ($p < 0.0001$) (Table 1).

Mean scores for the erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction were increased significantly after saffron treatment ($p < 0.0001$) (Table 2).

No major adverse events were reported during the clinical trial.

Discussion

Our research showed that saffron improved Rigiscan parameters (rigidity and tumescence) and sexual function domains: erectile function, sexual satisfaction, orgasm, sexual desire and overall satisfaction.

There is a growing worldwide trend in use of alternative medicine especially herbal medicine. For example Kaphle et al. (2006) investigated over a

Table 1. Effect of saffron tablets usage on number of episode per night and RigiScan parameters before and after treatment.

Parameters	Before treatment	After treatment	*p* value
Number of episode per night	1.85 ± 0.17	3.70 ± 0.26	$p < 0.0001$
Rigidity (%)			
Tip	33.65 ± 3.57	55.05 ± 3.63	$p < 0.0001$
Base	33.85 ± 3.11	57.25 ± 3.21	$p < 0.0001$
Tumescence (cm)			
Tip	1.11 ± 0.13	2.09 ± 0.14	$p < 0.0001$
Base	1.41 ± 0.14	2.53 ± 0.14	$p < 0.0001$