

## ORIGINAL RESEARCH—ERECTILE DYSFUNCTION

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### Tianeptine Can Be Effective in Men with Depression and Erectile Dysfunction

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#### ABSTRACT

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**Introduction.** Erectile dysfunction (ED) and depression are highly prevalent medical disorders affecting men of diverse cultures throughout the world. Tianeptine is a new antidepressant drug with less adverse effects on sexual functions.

**Aim.** To evaluate the efficacy of tianeptine in the treatment of mild to moderate depression with ED.

**Methods and Main Outcome Measures.** A randomized, double-blind, placebo-controlled, crossover trial. Subjects were assigned either tianeptine or matching placebo, each for 8 weeks. All patients were followed up on monthly basis where they were asked to complete three assessment questionnaires, namely, Anxiety and Depression Scale, Brief Sexual Inventory, and Quality-of-life and erection questionnaire. All patients were asked a global assessment question. Treatment-responsive subjects were defined as study participants who had scores 1–16 on the Anxiety and depression Scale, showed normal erectile function on the Brief Sexual Inventory, and answered “yes” to the global assessment question.

**Results.** Of the 237 consecutive men complaining of ED of >6 months and screened for this study, 110 patients met our inclusive criteria; 42 declined to participate. The remaining 68 patients were randomly assigned to treatment. Significant improvement ( $P < 0.05$ ) was observed during the active drug phase in all three assessments questionnaires, in comparison with the placebo phase. Forty-eight patients (72.7%) of the subjects during the active drug phase were classified as responders, while 19 (27.9%) of the subjects during placebo phase were classified as responders.

**Conclusions.** Tianeptine could be considered an effective therapy for the treatment of depression and ED. Further large-scale multicentered studies are warranted. **El-Shafey H, Atteya A, el-Magd SA, Hassanein A, Fathy A, and Shamloul R. Tianeptine can be effective in men with depression and erectile dysfunction. J Sex Med 2006;3:910–917.**

**Key Words.** Erectile Dysfunction; Tianeptine; Depression

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#### Introduction

Erectile dysfunction (ED) and depression are highly prevalent medical disorders affecting men of diverse cultures throughout the world. In a comprehensive review of the epidemiology of ED, Kubin et al. [1] cited ED prevalence rates ranging from 5% to 49% reported by studies conducted in Europe [2,3] and the United States [4,5] among

men aged 18–80 years. All five studies showed a positive relationship between ED and age.

Regarding the prevalence of depression, a recent systematic review of 34 community-based studies conducted in 15 countries showed that the weighted average prevalence of depression among individuals aged 55 years and older ranged from 1.8% for major depressive disorder (MDD) ( $N = 22,794$  in 16 studies), to 10.2% for minor

depression ( $N = 8,857$  in 6 studies), to 13.3% for all depressive syndromes deemed clinically relevant ( $N = 46,075$  in 28 studies) [6].

Several recent studies identified a significant relationship between ED and depression in various age groups [7,8]. The relationship between depression and ED appears to be bidirectional: the presence of or alteration in one of these conditions may be the cause, consequence, or modifier of the other [9,10]. For example, in depressed men, ED may be a symptom of depression or a treatment-emergent side-effect of antidepressant medication [11]. Alternatively, men with ED may develop depression as a reaction to the biopsychosocial stress commonly associated with loss of sexual functioning [12]. Between 5% and 80% of patients taking antidepressants, particularly the selective serotonin reuptake inhibitors (SSRIs), experience side-effects related to sexual function such as ED, delayed ejaculation, and anorgasmia [13–15]. It is also possible that because ED and depression are highly prevalent conditions, they can be coincidentally comorbid and, thus, etiologically unrelated [16].

Accurate identification of the incidence of antidepressant drug-induced sexual dysfunctions has proved troublesome, as disturbances of the sexual response can only be detected in a reliable fashion when systematic inquiries are made before and during the course of treatment [17]. Tianeptine is an antidepressant agent with a distinct neurochemical profile. It increases serotonin (5-hydroxytryptamine [5-HT]) presynaptic uptake in the brain (in contrast with most antidepressant agents) and reduces stress-induced atrophy of neuronal dendrites. Like the SSRIs and in contrast with most tricyclic antidepressant agents, tianeptine does not appear to be associated with adverse cognitive, psychomotor, sleep, cardiovascular, or body weight effects [18].

Tianeptine does not appear to bind any of the 5-HT receptors,  $\alpha_1$  and  $\alpha_2$  and muscarinic receptors, which may be associated with antidepressant-induced sexual dysfunction [19]. Also, tianeptine lacks anticholinergic effects that would potentially impair sexual arousal. Furthermore, although tianeptine is not a dopamine reuptake inhibitor [19], it has been shown to increase dopamine in rat frontal cortex and nucleus accumbens [20,21], a property that might enhance sexual function. Moreover, tianeptine has been reported to have acceptable effects on sexual desire [22] and one of the recommended antidepressants for depressed patients with sexual complications [23].

The aim of this study was to evaluate the efficacy of tianeptine in the treatment of mild to moderate depression with ED.

### Methods and Main Outcome Measures

This study was under supervision of a dual specialty team consisting of an andrologist and a psychiatrist. The study included 237 consecutive men who came to our clinic with a chief complaint of ED completed the Brief Sexual Inventory [24]. Men showing ED according to the Brief Sexual Inventory were referred to a psychiatrist and asked to complete the Anxiety and Depression Scale, which is a 90-question depression inventory written in simple formal Arabic and validated for usage in Egyptians (age range, 20–60 years) (Appendix I) [25]. Questions 1–30, 31–60, 61–90 evaluated the presence and extent of depression, anxiety, and social introversion, respectively. Each question is answered by either yes or no; yes is given a score of 1, and no is given a score of 0. Concerning depression, scores of 0–16, 17–20,  $\geq 21$  are considered normal, borderline, and significantly positive, respectively. Men who met criteria for depressive disorder (score of  $\geq 21$  on the Anxiety and Depression Scale) underwent a complete physical examination, provided urine and blood for a baseline laboratory evaluation, and returned 4 weeks later for a second psychiatric interview. Subjects who continued to meet inclusion criteria were randomly assigned to treatment. Institutional review boards at each site reviewed and approved the protocol, and all men gave written informed consent.

All subjects included in this study fulfilled the following criteria: (i) male, 18 years or older with a stable relationship with a female partner for the 6-month period before the screening interview; (ii) ED for at least 6 months prior to the study; and (iii) diagnosis of depressive disorder at both interviews.

Exclusion criteria were: (i) presence of another current axis I psychiatric disorder, including substance abuse or dependence; (ii) current use of any antidepressant medication; (iii) abnormal serum hormone levels (i.e., prolactin, testosterone, or thyroid); or (iv) history of major organ disease or poorly controlled diabetes.

### Study Design

This study was a 16-week, randomized, double-blind, placebo-controlled, crossover trial. Subjects

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