Keywords

Erectile dysfunction

BIOVIS®

Tribulus terrestris

Alga *Ecklonia bicyclis*

Phytotherapy

Phytomedicine

Natural drugs

Antioxidant

Antifibrotic

Anti-aging

Nutraceutical

Analyzing the efficacy of a new natural compound made of the alga *Ecklonia bicyclis*, *Tribulus terrestris* and BIOVIS® in order to improve male sexual function

F. Iacono, D. Prezioso, A. Ruffo, G. Di Lauro, L. Romis and E. Illiano

F. Iacono, MD
School of Medicine and Surgery, University ''Federico II'', Naples, Italy

D. Prezioso, MD
School of Medicine and Surgery, University ''Federico II'', Naples, Italy

A. Ruffo, MD
School of Medicine and Surgery, Department of Urology, University ''Federico II'', Via S.Pansini 5, Naples, Italy 80131

G. Di Lauro, MD
Hospital Santa Maria delle Grazie, Pozzuoli, Naples, Italy

L. Romis, MD
Hospital Santa Maria delle Grazie, Pozzuoli, Naples, Italy

E. Illiano, MD
School of Medicine and Surgery, University ''Federico II'', Naples, Italy

E-mail:
antonio.ruffo7@gmail.com

Online 3 November 2011

Abstract

Background: We investigated the therapeutic efficacy of a new composite natural drug based on *Tribulus terrestris*, BIOVIS® and the alga *Ecklonia bicyclis* in order to improve male sexual function, selecting patients using the International Index of Erectile Function (IIEF), Nocturnal Penile Tumescence and Rigidity Testing (NPTR) using the RigiScan® device and hormonal levels.

Materials and methods: A total of 164 patients with erectile dysfunction (ED) were enrolled between September 2009 and January 2010. Patients were classified as having mild ($n = 64$), moderate ($n = 62$) or severe (I = 38) ED. Mean age was 53.1 years. A new compound (150 mg of the alga *Ecklonia bicyclis*, 396 mg of *Tribulus terrestris* and 144 mg of BIOVIS®) was administered to all patients twice a day for 60 days. The IIEF questionnaire was administered and NPTR testing was carried out using the Rigiscan® device both pre and post-treatment with all patients.

Results: 150 patients were evaluable, and their IIEF scores were all significantly improved, with an increase of 78% in the mild ED group, an 80% improvement in the moderate ED group, and an improvement of 108% in the severe ED group compared with the baseline. The mean IIEF scores for all the patients showed significant improvement after 8 weeks of treatment with this new composite drug (baseline 14.3 ± 1.5 to 26.2 ± 3.2; $P = 0.01$). Among other parameters penile rigidity and tumescence, as tested using the RigiScan® showed significant improvement for treated patients. Furthermore, no significant side effects were claimed.

Conclusion: The active components of these three natural compounds (namely protodioscin, a steroidal saponin, contained in *Tribulus terrestris*; the polyphenols, dieckol, florofucofuroeckol and bieckol, contained in the alga *Ecklonia bicyclis*; and the polymers of *d*-glucosamine and *n*-acetyl-*d*-glucosamine contained in BIOVIS®) when combined, seem to work in synergy not only improving erectile function but also stimulating testosterone-dependent sexual desire. Protodioscin is able to stimulate testosterone production and it also has an androgen-mimetic action, binding and activating the testosterone receptors. Polyphenols play an anti-nflammatory role, modulating the cytokines (lipopolisaccarids, TNF-alpha, IFN-gamma) with a potent antioxidant and antifibrotic effect. BIOVIS® acts on both the

non-adrenergic and non-cholinergic system (NANC) and on the endothelial cell system as a strong nitric oxide synthetase (NOS) stimulator. Our study demonstrated that this new composite drug was effective in the oral treatment of ED.

Introduction

The pharmacological treatment of erectile dysfunction (ED) has become a major tool in the therapeutic approach to impotence. This example of successful therapy largely depended on advances in clinical and basic research, which focused on the local mechanisms of penile erection. The introduction of oral phosphodiesterase-5 inhibitors (PDE5-i) in the late 1990s and early 2000s revolutionized the field of sexual medicine, having the great worth of inducing an erection in many men suffering the problem of ED, thus being an effective treatment of this disease. In fact, PDE5-i have become the most popular treatment and are currently the first-line monotherapy for ED, indicating that most patients prefer oral therapy [1]. However, a significant proportion of patients with complex ED will be therapeutic non-responders to PDE5-i monotherapy [2]. Furthermore, these drugs present various problems for the wide spectrum of co-morbidities in patients with ED [3], in particular the daily use of anti-hypertensive drugs in patients with cardiovascular disease can lead to dangerous side-effects [4].

Furthermore, the frequently reported side-effects, such as headache, muscular pains, hot flushes, tearing and so on, can affect normal sexual intercourse [3]. However, approximately 30% of patients are unresponsive to on-demand PDE5-i regimens due to both psychogenic and organic factors [5]. Also, after the initial enthusiasm, the psychological impact – artificial erections and ''planning'' for sexual intercourse – as well as a not yet proven curative effect, has limited the use of these drugs, leaving the field open for the further development of more natural drugs for improving male sexual function.

One such natural drug is based on a new composite of *Tribulus terrestris*, BIOVIS® and the alga *Ecklonia bicyclis*, all of which are used in many countries under different dosage regimens for the purpose of stimulating sexual function, although only a few studies have been carried out on their efficacy [6]. The combination of the active principles present in these three natural compounds work in synergy and have been shown, in our preliminary data [7], to have good efficacy for oral therapy of ED. In this study we investigated whether this new natural compound based on the alga *Ecklonia bicyclis*, *Tribulus terrestris* and BIOVIS® at an elevated dosage would be truly beneficial in improving male sexual function, according to currently available parameters including the International Index of Erectile Function (IIEF) score, hormonal levels, and Nocturnal Penile Tumescence and Rigidity (NPTR) score as tested using a Rigiscan®.

Materials and methods

Between September 2009 and January 2010, 164 patients with ED and without previous treatment for their ED were assessed for study inclusion. Exclusion criteria were a history of radical prostatectomy or spinal cord injury, serious neurological deficits such as multiple sclerosis and Parkinson's disease, genital abnormality, alcohol or drug abuse, a history of hormonal therapy, androgen ablation or cancer chemotherapy, previous use of nitrate drugs and a severe vasculogenic impotence. Patients with concomitant medical diseases were included in our study if they had stable disease with concurrent medical therapy for cardiovascular disease, diabetes and so forth.

The medical and psychosexual history of all patients was evaluated at baseline to detect co-morbidities. Organic co-morbidities included hypertension in 46 patients (28.1%), diabetes in 24 (14.6%) and abnormal total serum cholesterol in 14 (8.5%).

Furthermore, the IIEF questionnaire was administered to each patient and the baseline serum level of testosterone was checked. After completing the IIEF questionnaire, the patients were divided into three groups:

1) Group A: 64 patients (36.6%) classified as having mild ED (IIEF score >16).