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Original article

Beneficial effects of fenugreek glycoside supplementation in male subjects during resistance training: A randomized controlled pilot study

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Abstract

Purpose: To evaluate the efficacy and safety of the glycoside fraction of fenugreek (*Trigonella foenum-graecum*) seeds (Fenu-FG) on physiological parameters related to muscle anabolism, androgenic hormones, and body fat in healthy male subjects during an 8-week resistance training program using a prospective, randomized, double-blind, placebo controlled design.

Methods: Sixty healthy male subjects were randomized to ingest capsules of Fenu-FG (1 capsule of 300 mg, twice per day) or the matching placebo at a 1:1 ratio. The subjects participated in a supervised 4-day per week resistance-training program for 8 weeks. The outcome measurements were recorded at recruitment (baseline) and at the end of the treatment (8 weeks). The efficacy outcome included serum testosterone (total and free) levels, muscle strength and repetitions to failure, metabolic markers for anabolic activity (serum creatinine and blood urea nitrogen), and % body fat. The standard safety measurements such as adverse events monitoring, vital signs, hematology, biochemistry, and urinalysis were performed.

Results: Fenu-FG supplementation demonstrated significant anabolic and androgenic activity as compared with the placebo. Fenu-FG treated subjects showed significant improvements in body fat without a reduction in muscle strength or repetitions to failure. The Fenu-FG supplementation was found to be safe and well-tolerated.

Conclusion: Fenu-FG supplementation showed beneficial effects in male subjects during resistance training without any clinical side effects.

Keywords: Anabolic; Androgenic; Fenugreek seeds; Glycosides; Randomized controlled study; Resistance training

1. Introduction

Athletes use many nutritional supplements to improve their performance regardless of nutritional status.[1] Therefore, interest in safer nutritional therapies and supplements for muscle building and performance enhancement is rising.

All performance enhancing supplements are regulated by the World Anti-Doping Code as defined by the World Anti-Doping Agency.[2–5] Many traditional herbal medicines are being investigated as safer alternatives for their nutritional benefits and performance enhancement. However, they need to be scientifically evaluated for their efficacy and safety in the relevant populations using standardized procedures such as randomized double-blind placebo controlled studies.[6,7]

Fenugreek, *Trigonella foenum-groecum* L. (Fabaceae) seeds extract is a component of many nutritional dietary products that are recommended for athletes and exercising male subjects. Fenugreek seeds, a spice and food grain, has traditional history of medicinal use in the management of type 2 diabetes mellitus in Egypt, Southern Europe, India, Asia, and North Africa.[8] Fenugreek seeds extract is certified as a GRAS (generally recognized as safe) item under clause §182.20 (essential oils, oleoresins and natural extractives including distillates) by the US Food and Drug Administration.

Traditionally, fenugreek seeds have been reported to be useful in hormonal regulation, in particular for male impotence and as a galactagogue in lactating mothers.[9] In India, ground fenugreek seeds mixed with jaggery are recommended for females after childbirth for their anabolic effects to develop and

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strengthen muscles.[10] Recent studies on fenugreek seeds extracts support their effectiveness in promoting lean body mass, and lowering cholesterol.[11] Fenugreek extract is reported to enhance endurance capacity and the utilization of fatty acids as an energy source in male mice.[12] One recent study on fenugreek extract reported fat reducing effects greater than placebo in young, healthy resistance-exercising males.[13] These effects are purported to be mediated through an aromatase and 5α reductase inhibition, thereby increasing total testosterone levels by blocking its conversion to estrogen and dihydrotestosterone, respectively.[13] Increased testosterone levels are known to increase muscle size and strength in men[14] with downstream benefits on body weight, body fat, muscle size, strength, libido, energy, and mood.[15,16] Increased total testosterone levels could potentially affect serum free/bioavailable testosterone concentrations, resulting in escalated delivery and use by muscle cells to enhance protein synthesis, thus positively influencing strength and body fat. However, direct evidence for the androgenic effects of fenugreek seeds extract or its components in clinical practice is lacking.

Fenugreek seeds are rich in steroidal compounds like glycosides and saponins including diosgenin, yamogenin, gitogenin, tigogenin, and neotigogens. Diosgenin is an important precursor for the synthesis of a number of sex hormones.[17] Diosgenin, a steroidal sapogenin, is reported to augment overall weight and muscle growth in rats.[18] Moreover, diosgenin is reported to improve glucose metabolism by promoting adipocyte differentiation and inhibiting inflammation in adipose tissues.[19] We have previously shown the efficacy of the glycoside fraction of fenugreek seeds (Fenu-FG) on testosterone levels in immature castrated male rats.[20] Recently, the excellent safety profile of sub-chronic (90-day) administration of Fenu-FG without any effects on body weight has been demonstrated in rats.[21]

Taking clues from both traditional and modern literature regarding the androgenic potential and safety of fenugreek glycosides, the present pilot study investigated furostanol glycosides-based fenugreek seeds extract (Fenu-FG) supplementation using a prospective, randomized, double blind, placebo-controlled design in healthy male subjects during an 8-week resistance training programme.

2. Materials and methods

2.1. Study design and protocol

This study was designed as a prospective, double-blind, randomized, placebo controlled study in male subjects and conducted using good clinical practice and ethical guidelines of Helsinki Declaration. The study protocol was assessed and approved by the Independent Institutional Human Ethics Committee. Inclusion criteria were the male healthy volunteers aged between 18 and 35 years, with normal health status based on clinical and laboratory examination, willing to sign the written informed consent form, and trained for resistance exercise at least for 1 month. The exclusion criteria were the subjects with any one of the following: (1) Subjects with elevated resting heart rate (>100 beats per min) or blood pressure (BP) (systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg); (2) Subjects with history of medical or surgical events that may affect the study outcome or place the subject at risk, including cardiovascular disease, gastrointestinal problems, metabolic, renal, hepatic, neurological or active musculoskeletal disorders; (3) Subjects with history of orthopaedic injury or surgery within the last year; (4) Subjects with known hypersensitivity to herbal drugs/nutritional supplement/foods; (5) Subjects who were consuming/have received any performance enhancing therapy during last 2 months; (6) Subjects undergoing any weight loss or diet plan during the trial period; (7) Chronic alcoholics; (8) Drug abusers; (9) Subjects who participated in any other clinical trial during last 30 days and simultaneous participation in another clinical trial; and (10) Subjects with any condition which in the opinion of the investigator makes the subject unsuitable for inclusion.

2.2. Screening and familiarization (Visit 1)

Potential participants (subjects) that were believed to meet eligibility criteria during Visit 1 (screening visit) were then invited to attend an entry/familiarization session. During this session, they signed informed-consent statements and completed personal and medical histories. Subjects meeting entry criteria were familiarized with the study protocol via a verbal and written explanation outlining the study design. This included describing the training program, familiarizing subjects with the tests to be performed. Then the baseline assessments such as medical history, demography physical examination, laboratory investigations, clinical examination were performed and recorded in case report forms (CRFs) for the subjects who consented for the study.

Then subjects reported to the human performance laboratory for baseline assessments for height (cm), body weight (kg), heart rate (bpm), respiratory rate (per min), body temperature (°F), systolic blood pressure (mmHg), and diastolic blood pressure (mmHg). Body mass index (BMI) was calculated as per formula: Weight (kg)/Height^2 (m). The lean body mass (kg) was calculated as per James's formula for male[22] as: 1.10 × Weight (kg) − 128 × Weight^2 (kg)/100 × Height^2 (m).

Demographic and clinical characteristics of all recruited subjects, intent-to-treat population, are listed by group in Table 1. At baseline, subjects were found uniform with no statistical significance between the treatment groups with respect to demographic (age, weight, height) and physiological characteristics (heart rate, respiratory rate, body temperature, BMI). Fifty-five out of the 60 recruited subjects (Fenu-FG = 29, Placebo = 26) consumed at least 1 dose of treatment were considered as "per protocol", or "PP population". Five subjects (Fenu-FG = 1, Placebo = 4) were dropped out of study for reasons not related to treatment (such as inconvenience or moved out of the area or not adhering to the training protocol).

2.3. Randomization and baseline assessments visit (Visit 2)

Sixty eligible subjects were randomized to receive 1 of the 2 treatments, namely Fenu-FG (1 capsule, 300 mg, twice a day)