



Efficacy of Swiss Oats

In the management of Male Menopause as measured by change in andropause score and testosterone levels

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Introduction

The progressive deterioration in the physiological and psychosexual functions of the aging male has been a growing concern. Recent studies have shown that the decline in androgens may be responsible, though not solely, for the symptoms of degenerating sense of well-being, lack of energy, decline in cognitive performance, loss of sexual libido and potency associated with aging. In this light, interest in hormonal replacement or manipulation to prevent these symptoms is increasing.

Currently, several diet supplements have been marketed to counteract the symptoms of aging through hormonal manipulation. One of these products is a preparation of green oats (*avena sativa*) extract. Green oats has anecdotally been known to improve vitality and endurance and improve sexual performance. Clinical studies have been done which has shown improvement in muscle strength and effective treatment of erectile dysfunction with intake of *avena sativa*.

This study aimed to determine the efficacy of the *avena sativa* in the management of male menopause in terms of change in symptom severity, total testosterone and free testosterone level with its intake. It also assessed its safety profile.

Methodology

This is a self-controlled trial designed to determine the efficacy of Swiss oats in the management of male menopause. The end points for the study were change in andropause score, change in total testosterone levels and change in free testosterone levels.

Patients were prospectively recruited. Males, with a minimum age of 40, having a minimum andropause score of 10, with normal full blood count and liver function tests, not on any testosterone replacement therapy or any other sexual enhancer, without significant, uncontrolled medical condition, and not suffering from prostate cancer or sleep

apnea, were included in the study. A medical history and physical examination were performed. All patients enrolled in the study were asked to accomplish an andropause score sheet. A baseline serum total testosterone level and free testosterone level were also determined.

The subjects were then placed on a twice a day regimen of 30 mg Swiss oats to be taken regularly. After 28 days, the subjects were reevaluated. A second andropause scoring was done, and a post-treatment total testosterone level and free testosterone level determination was done. Compliance was assessed and a review of any side effects was ascertained.

Statistical Analysis

Pre- and post-treatment andropause scores, total testosterone levels were compared. Statistical analysis was done using the T-test on all three parameters.

Possible determinants of the response to intake of Swiss oats as measured by the change in andropause score, change in total testosterone level and change in free testosterone level were also studied. A correlation analysis between age, baseline andropause score, total testosterone level and free testosterone level and the response parameters was performed.

Data collation and statistical analysis was done using the SPSS 8.0.

A minimum sample size of 74 cases was computed to detect a difference in at least 20% in total testosterone levels pre and post-treatment on a statistical level of a 95% confidence interval and a power of 80%.

Study population

Eighty patients were enrolled in the study. There were four drop outs due to protocol violation. Three of these patients were excluded because of poor compliance and one was excluded the patient received depot testosterone injection during treatment.

The study population aged from 40 to 79 years, with a mean of 53.5 years (SD = 9.42). Majority were in the 40 - 60 year age group (Figure 1). More than 80% of the population was Chinese. The mean baseline andropause score was 17.03 (SD = 6.68) with a range of 10 - 37, majority had scores from 10 to 19 (Figure 2). Nearly all of the patients had normal baseline total testosterone levels, with a population mean of 14.13ng/ml (SD = 5.11). About 12% of the population had hypogonadal levels (Figure 3). The mean free testosterone level of the population was 26.18 pmol/L (SD = 13.87). Majority of the patients had normal free testosterone levels (Figure 4). In nearly 20%, free testosterone level was below the normal limit. There was one subject with an elevated free testosterone level.

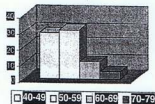


Figure 1. Age Distribution of Study Population

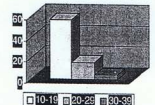


Figure 2. Age Distribution of Study Population According to Andropause Score

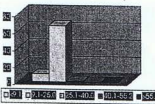


Figure 3. Frequency Distribution of Study Population According to Baseline Total Testosterone Level

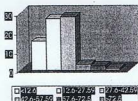


Figure 3. Frequency Distribution of Study Population According to Baseline Free Testosterone Level

Results

A. Effect on Andropause Score

The change in andropause score was, on the average, an improvement by 14% (SD = 25.81). There was a wide range of response to Swiss oats in terms of change in andropause score, from a worsening or increase in score by 90% to an improvement or decrease in score by 60%. Majority (65.8%) showed improvement in their symptoms score with at least 38% of the population showing a minimum decline in score by 20%. Symptom score did not change in 15.8% while 18.4% experienced an increase in the score. (Table 1)

Statistical analysis showed that there was a significant difference between the pre and post-treatment andropause scores.

Among the factors analyzed to determine any determinant for change in score, only the baseline andropause score was found to be significantly related. A positive correlation ($r = .239$, significant at $p = 0.05$) shows that the higher the baseline andropause score, the greater the improvement in the score.

Age, baseline total and baseline free testosterone levels were not found to be significantly correlated with the change in score. There was however a trend for older patients to improve and those with higher free testosterone levels to worsen their andropause symptoms with intake of Swiss oats.

B. Effect on Total Testosterone Level

The intake of Swiss oats produced a mean increase in total testosterone level of 9.7%. This change, however, was not found to be statistically significant. The response to the therapy ranged from a decrease of 87.8% to an increase of 215%. Nearly 60% of the study population showed an increase in their total testosterone levels but majority had a less than 20% increase from baseline. A notable portion of the population had a decrease in their total testosterone level although most had less than 20% decrease (Table 2).

Baseline total and free testosterone levels were found to be significantly related to the change in total testosterone levels with treatment. Both parameters showed negative correlations ($r = -.395$, $p < 0.01$ and $r = -.239$, $p < 0.05$). Age and baseline andropause score

were not found to be significantly related to the change in total testosterone levels.

C. Effect on Free Testosterone Level

The mean change in free testosterone level with intake of avena sativa was an increase of 29.5%. This change was found to be statistically significant ($p < 0.001$). The range of response was from a decrease in free testosterone levels by 33% to an increase of 316.6%. Majority (63.1%) of the patients experienced an increase (Table 3).

The factors found to be associated with the change in free testosterone were age ($r = 0.296$, $p < 0.01$) and baseline free testosterone level ($r = -.324$, $p < 0.01$). Baseline andropause score and total testosterone levels were not found to be related.

D. Adverse Events

Twelve (15.8%) patients reported mild and transient side effects with intake of avena sativa preparation. Majority had headaches and generalized feeling of warmth in the first few days of therapy which spontaneously resolved. Other symptoms included oral ulcers, constipation and dizziness (Table 4).

Recommendations

The investigators recommend the conduct of a randomized, blinded, placebo-controlled trial to verify the results, particularly on the effect of avena sativa on the patients' perception of his andropausal condition which is highly subjective and may be prone to the placebo effect.

In addition, more studies may be done to determine the effect of green oats on other physiologic parameters. Further studies are also encouraged to determine other factors that may predict those who will optimally benefit from this treatment.

Abstract

Many products have been recently marketed to counter the symptoms of male aging. This study aimed to determine the efficacy of Swiss oats in relieving andropause symptoms and improving total and free testosterone levels.

Seventy-six adult males who consulted for symptoms of male menopause were recruited and given 30 mgs of Swiss oats preparation twice a day. Andropause score, total and free testosterone levels were determined prior to start of therapy and after 28 days of treatment. The results for each parameter were compared pre and post-therapy and subjected to statistical analysis using paired-T test to determine any significant difference.

Majority (65.8%) of the patients showed significant improvement in their andropausal symptoms after intake of Swiss oats. Although there was no significant change in their total testosterone levels, there was a significant increase in the free testosterone levels in 63% of the subjects. There was a low incidence of adverse events (15%) with patients complaining of mild headache and feeling of warmth during the first few days of therapy.

Swiss oats is most beneficial to older patients, suffering from andropause to a moderate degree, with low to low normal baseline total and free testosterone levels.