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REDUCING THE SYMPTOMS OF OVERACTIVE BLADDER AND URINARY INCONTINENCE: RESULTS OF A TWO-MONTH RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL

Hypothesis / aims of study

To assess the effectiveness of UroLogic™, a nutritional supplement containing *Equisetum arvense* and *Crataeva nurvala*, in reducing the symptoms of overactive bladder (OAB) and urinary incontinence (UI).

Study design, materials and methods

Effectiveness of UroLogic™, in reducing the symptoms of overactive bladder (OAB) and urinary incontinence (UI) was evaluated in a randomized, double-blind, placebo-controlled trial. Individuals (men and women, age range 29-88 years) received either UroLogic™ (n=46) or a placebo (n=27) daily for two months.
To assess the effect on quality of life the participants completed an Incontinence Impact Questionnaire (IIQ) and a Urogenital Distress Inventory (UDI) at the beginning of the study (baseline), and again after one and two months of treatment. Mean scores were computed separately over all IIQ items dealing with OAB and UI interference in daily activities (Interference) and all UDI items dealing with distress caused by OAB and UI (Distress).
Efficacy of UroLogic™ and the placebo treatment was assessed by subjective quantitative measurements recorded during interview, at baseline, month 1 and month 2. These included; daily frequency of urination, daily frequency of nocturia, weekly frequency of day time incontinence episodes and weekly frequency of night time incontinence episodes.
Sample size was calculated to achieve a power of 80%. To determine if there was a reduction in bothered rating and the quantitative measures of frequency and leakage, mean values were compared using a paired t-test between baseline and month 1 and baseline and month 2 in each of the active and placebo treatment groups. To determine if there was a statistical difference in treatment effects between the active and placebo, change scores were calculated and compared using a t-test, assuming equal variances.

Results

Results revealed a significant improvement in symptoms after one month compared to baseline for both UroLogic™ and placebo subjects. Between month one and two; however, subjects treated with UroLogic™ generally maintained this improvement, whereas those on placebo generally returned to baseline level. Moreover, treatment with UroLogic™ for two months reduced the frequency (p=0.042) and or leakage of urination in 85% of participants. Quality of life measures supported this effectiveness with a significant reduction in participant distress to frequent urination (p=0.035), small amounts of leakage (p=0.002) and leakage due to urgency (p=0.001). Compared to placebo, women in the active group showed a significant improvement in quality of life in relation to how much UI and OAB interferes with daily life with respect to travel greater than 30 minutes from home (p=0.035) and feeling frustrated (p=0.031).

Interpretation of results

The results of this study indicate that in subjects who met the inclusion criteria and complied with the instructions given:

- UroLogic™ is a suitable and effective treatment for both men and women.
- UroLogic™ is effective in reducing symptoms of urinary incontinence, including frequency, nocturia, urgency and bladder discomfort.
- Symptom relief occurred after 4 weeks of treatment, with the severity of symptoms reducing further by month 2.
- UroLogic™ significantly improves quality of life and is associated with reducing the negative impact of incontinence on everyday activities.

The positive results observed in this study after administration of the preparation are likely to be a result of a tonic effect on the muscles of the pelvic floor, an increased ability for the urinary bladder to completely empty and decreased residual urine volume or improved tone of the bladder. These results have highlighted a role for the use of herbal medicines in the management of urinary incontinence.

A vast number of drug medications that were taken concurrently with the test product during the study had both direct and indirect effects on bladder function. The most common side effect on the bladder for many of these medications is urinary frequency.

In vitro testing of UroLogic™ on immortalized hepatocytes showed that UroLogic does not interfere with liver enzymes involved in drug metabolism.

The results of the study showed a significant reduction in urinary frequency highlighting that UroLogic™ can be used concurrently with drug medications and still produce a therapeutic effect.

Concluding message

In conclusion, the results of the study supported the effectiveness of UroLogic™ in reducing symptoms of UI and OAB, even when used concurrently with common drug medications.

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HUMAN SUBJECTS: This study was approved by the Stanford University Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.