Uretin – High effectiveness in key symptoms of female overactive bladder syndrome and top level of patients' satisfaction

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Study Summary

- EFLA®940 Pumpkin seed extract – Cucurbitae Sem extr.s.sicc
- SoyLife® 40 – Soy germ extract

To investigate the efficacy and safety of a product consisting of a defined mixture of EFLA®940 and SoyLife® 40 (Soy germ extract) a placebo-controlled, randomized clinical trial was conducted in Korea on women suffering from bladder related voiding dysfunction.

Study Design

Subjects: 120 women aged 35-70 years (60 placebo/60 test group)

Test substance: 500 mg Tablets containing 218.75 mg of Pumpkin seed extract (EFLA®940) and 31.25 mg of Soy germ extract (SoyLife® 40)

Dosage: 4 Tablets per day

Duration: 12 weeks Subjects were asked to maintain a healthy daily lifestyle including diet and exercise; health functional foods, medicines or non-medicine products that could affect the research results were prohibited.

A bladder diary was evaluated to measure the day and night amounts and frequency of urination and the frequency of urgency and incontinence. At each clinic visit flow rate and remaining urine were measured, a survey was conducted using OAB-q V8 (Overactive Bladder Questionnaire V8 Symptom Irritation scale) to evaluate the improvement of overactive bladder syndrome and quality of life, and SQoL-F (sexual quality of life questionnaire – female) to evaluate the improvement of the quality of sexual life.

For safety evaluation, vital signs, blood and urine tests were performed at each visit. The presence of unexpected reactions and adverse effects were evaluated through interviews with the individual subjects.

Statistical analysis: Changes in blood, overactive bladder syndrome and urine dysfunction of each group by period were analyzed using a paired t-test, and a comparison between groups about the improvement level of each element at week 12 after taking the trial product was conducted through an unpaired t-test. In each statistical analysis, $p<0.05$ was considered to be statistically significant. Only those subjects that were compliant

to the treatment and completed all measurements including the 12 weeks measurements were included in the statistical analyses for all time points.

Results

There is a significant decrease of the key symptoms of overactive bladder syndrome and voiding symptoms, demonstrated by a decrease of the daily average frequency of urination, a decrease of the daily average frequency of urgency and a decrease of average frequency of nocturia. These decreases amount for each parameter at an average of 30% are shown graphically in the following way:

- Decrease of the daily average frequency of urination with statistical significance in the test group (– 27%)

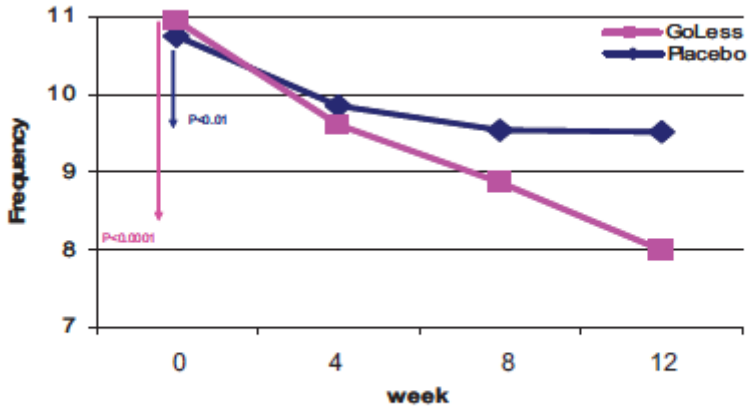

Fig 1. Changes of daily average frequency of urination (times)

- Significant decrease of the daily average frequency of urgency in the test group (- 31 %)

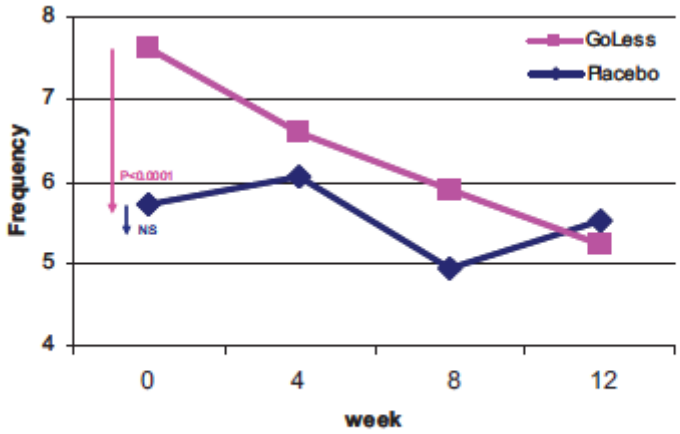

Fig 2. Changes of daily average frequency of urgency (times)

- Decrease of the average frequency of nocturia with statistical significance in the test group (- 31 %)

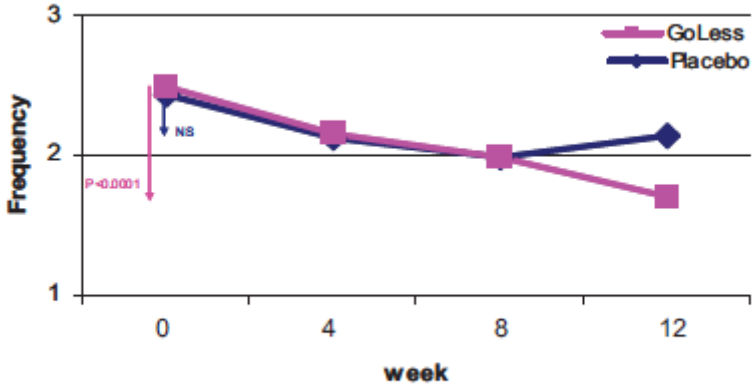

Fig 3. Changes of daily average frequency of nocturia (times)

Not only symptoms of overactive bladder syndrome, but also the quality of life and the satisfaction level were positively assessed by the patients.

- Significant improvement of quality of life (22%), measured on the OAB-q V8 Symptom Irritation Index at week 12
- High satisfaction level of the treated patients: positive response by 90.5% of the test group and will to continuation of therapy by 95.2% (compared to 56.1% rsp. 46.3% of the placebo group)

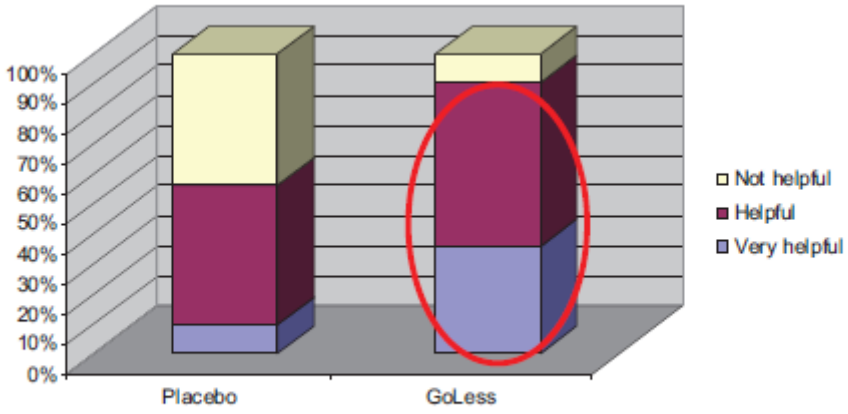

Fig 4. Subjective satisfaction level of participants in the trial (week 12)

Safety

- No particular findings in blood and urine tests
- All adverse reactions were temporary and minor, and none lead to drop outs from the trial

Conclusion

12-week Supplementation with the mixture of Pumpkin seed extract EFLA®940 and Soylife® 40 Soy germ extract lead to statistically significant improvements from placebo in urination frequency, nocturia frequency, frequency of urgency, urgency score and overactive bladder irritation scale.

The most important symptom in the definition of overactive bladder syndrome is urgency. Furthermore, the most important key element of the success of the improvement of overactive bladder syndrome is the improvement of elements related to urgency, since the biggest inconvenience, in practice, for people suffering from overactive bladder syndrome is urgency. In this clinical trial, there was a statistically significant improvement at week 12 in the average frequency of urgency and the average urgency score for the test group, compared to placebo.

Women with overactive bladder syndrome were able to confirm the functionality of EFLA®940 and SoyLife® 40 in voiding health through this human trial, and the role of these products can be positively considered, regarding the costs, adverse effects, reduced compliance and recurrence rate of the pharmacological treatment and behaviour modification treatment that has become popular recently. In conclusion, the combination of EFLA®940 and SoyLife® 40 provides fundamental assistance to the voiding health of women with overactive bladder syndrome.