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used to evaluate the statistical significance for the IPSS reduction in PSA and prostate volume. The statistical significance was intended for values of  $p < 0.05$ . From this preliminary we saw that the administration of red clover and of vitamin D to these dosages clearly improves the QoL of the patient with IPB as shown by the IPSS, has also determined a reduction of PSA and of prostate volume. The study showed a statistically significant improvement in IPSS  $p < 0.05$ , a reduction in PSA and prostate volume.

**Conclusion.** This therapy in the treatment of IPB has shown a clear improvement of LUTS and excellent tolerability of the product; the cycle of therapy can be prolonged longer and repeated. Therefore finds a use in the patient with LUTS.

## **PHYTOTHERAPY IN THE TREATMENT OF LUTS; EVALUATION OF THE EFFICACY OF A PRODUCT BASED ON RED CLOVER EXTRACT ISOFLAVONES AND VITAMIN D, IN THE REDUCTION OF THE SYMPTOMS OF PROSTATIC HYPERTROPHY**

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**Introduction.** Aim of the study is to evaluate the effectiveness of Red Clover associated with vitamin D in the therapy of the patient with prostatic hypertrophy and LUTS. *Trifolium pratense* extract contains various phytoestrogens, including *Genistein*, *Daidzein*, *Formononetin* and *Biochanin A*, the last two being the methylated form. Phytoestrogens have an anti-androgenic and anti-proliferative activity, as reported in the literature by several authors. Vitamin D has anti-cancer properties and inhibits the growth of prostate cancer.

**Materials and Methods.** We given 80 mg of red clover and 5 mcg of vitamin D3 to 50 patients in two daily doses for 60 days. In the study, patients were enrolled with LUTS, mean age of 62 years, all patients were not in therapy and had not undergone medical therapy for prostatic hypertrophy in the last 6 months. Before starting treatment, they did IPSS, PSA assay, transrectal ultrasound to evaluate prostate volume, uroflowmetry. The primary end point of the study is the assessment of the symptomatology using IPSS secondary end point reduction of prostate volume with transrectal ultrasound and variation of PSA. Patients reported no adverse events, side effects and did not discontinue treatment during treatment.

**Results.** All data were organized in a database and processed using SPSS software. The Fisher and X2 test was