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INTRODUCTION & OBJECTIVES: In order to assess the efficacy and tolerability of long-term combined therapy of herbal drug Prostamol Uno and tamsulosin in patients with BPH, the multicenter randomized prospective study was conducted.

MATERIAL & METHODS: 158 patients with II stage BPH were randomized into 2 groups. In group 1, 128 patients were treated with combination of Prostamol Uno (extract of *Serenoa repens*, pharmaceutical company "Berlin Chemie Menarini Group") – 1 capsule at night, and tamsulosin (0,4 mg daily). Group 2 patients (n=30) were treated with doxazosin (2 mg daily at night) and finasterid (5 mg once per day). Efficacy of these drugs was estimated on the 3rd and 12th month of treatment. The main criteria were: changes in IPSS scores, prostate volume and residual urine volume (assessed by ultrasound), PSA levels, urinary flow velocity and peak flow rate (assessed by uroflowmetry).

RESULTS: There were no significant differences between 2 groups before and after treatment in prostate volumes and PSA levels. There was a significant decreasing of residual urine levels in both groups (-39,3 ml (-78%) vs. -26,4 ml (-58,6%) in Group 1 and Group 2, respectively). Changes of IPSS scores were also significant in both groups before and after treatment (15,2±2,7 vs. 5,5±1,3 in Group 1 (p<0,01) and 14,6±1,9 vs. 6,2±1,4 in Group 2 (p<0,01)). There was no difference in IPSS decreasing between 2 groups. Due to long treatment duration, the tolerability of combination therapy becomes a very important question. In Group 1, just 3 of 128 patients (2,3%) had adverse effects (dizziness, retrograde ejaculation) and all of them had mild severity. In Group 2 13 of 30 patients (43,3%) had dizziness and headache due to the decreased blood pressure, and/or sexual dysfunction. This difference was significant between 2 groups.

CONCLUSIONS: Combination therapy of herbal drug Prostamol Uno and alfa-blocker tamsulosin is an effective treatment regimen in patients with II stage BPH, which improves flow rates and IPSS scores as well as combination of alfa-blocker and 5-alfa-reductase inhibitor, but with better tolerability and less side effects (2,3% vs. 43,3%).