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Benign prostate hyperplasia symptoms/quality of life are improved by a newly developed whole tomato-based food supplement: phase ii, prospective, randomized double blind, placebo-controlled study**Pier Giorgio Natali***Center for Advanced Studies and Technology (CAST), G.d'Annunzio University, Chieti, Italy*

Objective: Benign prostatic hyperplasia (BPH), highly frequent in elderly men, is associated with chronic inflammation, cardiovascular risk factors and with the presence of sexually transmitted diseases. The main efficacy complains are lower urinary tract symptoms (LUTS) that significantly impair patients' quality of life. In two phase II prospective, randomized double-blinded, placebo-controlled study we evaluated the and safety of a novel whole tomato-based food supplement (WTFS) on LUTS of BPH patients

Methods: 40 patients with histologically proved BPH were randomized 1:1 to receive daily for 2 months 5g of WTFS or placebo. Patients were asked to fill the International Prostatic Symptom Score (IPSS) questionnaire before and after treatment. An additional cohort of 31 HIV+ patients with BPH constituted the validation group.

Results: Treatment significantly reduced LUTS since mean IPSS decreased from 9.05 ± 1.15 to 7.15 ± 1.04 (paired t-test, $P < 0.001$), and improved life quality ($P < 0.0001$). A trend toward a reduction of total PSA levels was observed, with significant changes only in the subgroup of patients with high baseline levels ($18.5 \text{ ng/mL} \pm 2.7$ vs 10.3 ± 2.1 , $P = 0.009$). Similarly, the in validation panel WTFS consumption was associated with a significant improvement of all BPH symptoms and quality of life, free/total PSA ratio, and diastolic blood pressure, with a trend in IL6 level reduction.

Conclusions: The new WTFS may represent a valid option for the treatment of symptomatic BPH patients. Unlike pharmacological treatments, the supplement is side effects free and highly accepted among patients.

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