

A Comparative Randomized Prospective Study to Evaluate Efficacy and Safety of Combination of Tamsulosin and Tadalafil versus Tamsulosin or Tadalafil Alone in Patients with Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia

Introduction and Objective: Alpha1-blockers are the first-line monotherapy for lower urinary tract symptoms (LUTS). Phosphodiesterase type 5 (PDE5) inhibitors are the first-line treatment for erectile dysfunction (ED). Numerous studies have shown a significant association of ED with LUTS, but a causal relationship is not clear. The aim of the present study was to evaluate the efficacy of Tamsulosin and PDE 5 inhibitor, tadalafil in patients with LUTS due to BPH with or without ED.

Materials and Methods: In this randomized study a total of 85 men complaining of LUTS due to BPH were included. Twenty-nine patients received tamsulosin 0.4 mg/day alone (Group A), 28 patients received tadalafil 10mg/day (Group B) and combination therapy (tamsulosin and tadalafil both) was instituted in 28 patients (Group C). They were evaluated for International Prostatic Symptom Score (IPSS), International Index of Erectile Function questionnaire (IIEF5), Quality of Life (IPSS QoL), maximum urinary flow rate (Qmax), post void residual volume (PVR) and safety parameters before start of treatment and at 3 months following treatment.

Results: A significant improvement in IPSS score was observed in all the 3 groups, A, B and C (-50.90%, $p<0.05$; -33.50%, $p<0.05$ and -53.90%, $p<0.05$ respectively). IIEF5 score increased significantly in these 3 groups (+39.28%, $p<0.05$; +45.96%, $p<0.05$ and +60.23%, $p<0.05$ respectively). In all the 3 groups, a significant increase in Qmax and decrease in PVR were observed (33.99%, $p<0.05$; 29.78%, $p<0.05$ and 37.04%, $p<0.05$) and (-60.90%, $p<0.05$; -49.45%, $p<0.05$ and -62.97%, $p<0.05$ respectively). The QoL scores also improved (-73.35%, $p<0.05$; -70.26%, $p<0.05$ and -79.65%, $p<0.05$ respectively). Drop-out rate was 9.4% (noncompliance 3.5% and side-effects 5.9%). Side-effects were dyspepsia, heartburn, headache, flushing, myalgia and backache. None of the participants experienced any severe or serious adverse events.

Conclusions: Tamsulosin and tadalafil alone or in combination cause a significant improvement in patients with LUTS. Their erectile function also improves with these medications. The improvement is better with combination therapy as comparison to single agent alone.