A randomized controlled study of the efficacy of tadalafil monotherapy versus combination of tadalafil and mirabegron for the treatment of overactive bladder associated with benign prostatic hyperplasia (CONTACT Study)

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INTRODUCTION & OBJECTIVES

- α1-blockers have been used for the first line treatment of benign prostatic hyperplasia (BPH).
- Phosphodiesterase (PDE) inhibitors (tadalafil) are recently used for the treatment of BPH.
- The combination therapy or add-on of an anticholinergic or a β3-adrenergic agonist (mirabegron) with α1-blocker is recommended for the treatment of BPH with overactive bladder (OAB).
- The efficacy of add-on treatment of mirabegron with tadalafil has not been reported.

METHODS

Inclusion criteria
- BPH patients with remaining OAB after receiving tadalafil 5mg/day for ≥ 2 weeks (OABSS total score > 3, Urgency: > 1/week (OABSS urgency score ≥ 2))
- ≥ 50 age ≤ 90

Exclusion criteria
- Post-void residual urine (PVR) > 150 mL
- Maximum flow rate (Qmax) < 5 mL/s
- Anti-cholinergics, cholinergics, β-agonists or antagonists, α-blocker and any other agents: < 8 weeks prior to the study
-≤5-reductase inhibitors and anti androgenic drug: < 6 months prior to the study

Study design
- 12-week, multicenter, prospective, open, randomized controlled study

RESULTS

CONCLUSIONS

The present study is the first report on treatment of POES E3 inhibitor and B3 agonist combination regimen. The effect of tadalafil/mirabegron combination therapy on relieving OAB symptoms appeared to be greater than that of tadalafil monotherapy. Tadalafil/mirabegron combination therapy can be safely used.

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