

COMBINATION THERAPY WITH SOLIFENACIN 10 MG AND TAMSULOSIN 0,4 MG ORAL FOR URGENCY URINARY INCONTINENCE IN MEN. EFFICACY AND SAFETY RESULTS

Hypothesis / aims of study

Urgency Urinary Incontinence is particularly disagreeable in men with lower urinary tract symptoms but may not be adequately treated by α -blocker monotherapy. To assess the efficacy and safety of a fixed-dose combination of solifenacin and an oral formulation of tamsulosine compared with tamsulosin monotherapy in men with moderate to severe incontinence and urgency symptoms.

Study design, materials and methods

The study enrolled 90 eligible men ≥ 50 yr of age with an International Prostate Symptom Score (IPSS) ≥ 13 and urine maximum flow rate (Q_{max}) > 7 and ≤ 15 ml/s, two or more urgency symptoms per 24h and one or more incontinence episodes per 24h were selected at 2 Hospital in one country from 2008 to 2012. 45 patients were randomised to tamsulosin 0.4 mg monotherapy and 45 patients with solifenacin 10 mg plus tamsulosin 0.4 mg.

The primary outcome measure was the relative variation in total International Prostate Symptom Score (IPSS) and Total Urgency and Frequency Score (TUFS). Secondary outcomes included quality of life (QoL) measure Incontinence Quality of Life (I-QoL).

Results

Reductions in total IPSS and TUFS were observed with both solifenacin 10 mg plus tamsulosin 0,4 mg (-7.5 and 8.3, respectively) compared with tamsulosin 0,4mg monotherapy (-6.0 and 6.4, respectively). The therapy with solifenacin 10 mg plus tamsulosin 0.4 mg improved quality of life (QoL) with low incidences of incontinence episodes.

An increase in Q_{max} was observed in both groups.

Active treatments were well tolerated, and discontinuation rates due to adverse events were low in 2 groups. The most frequent adverse event with tamsulosin in monotherapy and with solifenacin was a reduced or absent ejaculation during orgasm (25%), a reversible effect as a consequence of the potent and selective α 1A-adrenoreceptor antagonism of the drug.

Interpretation of results

Combination therapy with solifenacin and tamsulosin were superior to tamsulosin monotherapy in the IPSS storage as well as in I-QoL due to urinary symptoms, with low incidences of acute urinary retention.

Concluding message

Solifenacin 10 mg plus tamsulosin 0.4mg is an effective and well-tolerated treatment for the relief of both urgency symptoms and incontinence in patients with lower urinary tract symptoms suggestive of bladder outlet obstruction thought to be associated with benign prostatic hyperplasia, and showed a significant effect on nocturia.

References

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3. Kaplan Sa, Roehrborn CG, Gong J, Sun F, Guan Z. Add-on fesoterodine for residual storage symptoms suggestive of overactive bladder in men receiving alpha-blocker treatment for lower urinary tract symptoms. BJU Int 2012, 109:1831-40

Disclosures

Funding: NONE **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Because the study use solifenacin 10 mg and tamsulosin 0.4 that are two drugs introduced in FDA and EMA listing of authorized generics. **Helsinki:** Yes **Informed Consent:** Yes