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TOLERABILITY OF SOLIFENACIN IN COMPARISON WITH OXYBUTYNYN IMMEDIATE RELEASE IN PATIENTS WITH OVERACTIVE BLADDER: RESULTS OF THE VECTOR STUDY

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INTRODUCTION AND OBJECTIVE: Various reimbursement plans mandate immediate release (IR) oxybutynin (oxy) as first line therapy for overactive bladder (OAB), however many patients discontinue therapy due to adverse events (AEs) such as dry mouth. The VECTOR (**VE**sicare in **C**omparison **T**o **O**xybutynin for ove**R**active bladder patients) study was designed to compare the tolerability of solifenacin (sol) versus oxy IR in patients with OAB. Efficacy rates were also compared.

METHODS: This was a Canadian, randomized, multicentre, prospective, double blind, double dummy study in 132 subjects with ≥ 1 urgency episode / 24 h with or without urgency incontinence and ≥ 8 micturitions / 24 h for ≥ 3 months. After a 2 wk washout period, patients received either sol 5mg daily or oxy IR 5mg TID for 8 wks, as per recommended daily dosages. The primary endpoint was the incidence and severity of dry mouth. All AEs were determined by direct questioning by the physician at each follow up visit. If reported, dry mouth severity was graded as mild, moderate, or severe. Episodes of urgency, micturition frequency, incontinence and nocturia were captured using a 3 day diary at baseline, wk 2, 4, and 8. Two validated patient reported outcome (PRO) measures, the Patient Perception of Bladder Condition and Overactive Bladder Questionnaire, were also used.

RESULTS: The study was completed by 92 (70%) subjects. Sol was associated with significantly fewer episodes of dry mouth (24/68 vs 53/64, $p < 0.0001$) of which 75% was mild in severity compared to 30% with oxy IR ($p = 0.001$). Sol was also associated with significantly fewer AEs ($p = 0.003$), lower severity of overall AEs ($p = 0.009$), and fewer treatment related AEs ($p = 0.0093$) compared to oxy IR. Significantly fewer subjects in the sol group (2/68) withdrew due to dry mouth compared to the oxy IR group (12/64), $p = 0.0032$. Both sol and oxy IR significantly reduced all diary recorded OAB symptoms and significantly improved PROs from baseline to study endpoint. No notable differences between the 2 groups were observed in OAB symptoms and PROs at study endpoint.

CONCLUSIONS: At efficacious doses, sol was associated with a significantly better tolerability profile compared to oxy IR and was similarly effective in improving OAB symptoms and PROs. This resulted in fewer withdrawals from therapy. The relatively high incidence of AEs in both groups may be explained as a result of the direct questioning methodology used and patients being informed that dry mouth was the primary study objective.

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