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IMPROVEMENTS IN BLADDER CONDITION IN OAB AS PERCEIVED AND EXPERIENCED BY PATIENTS IN A SOLIFENACIN VS. TOLTERODINE MULTINATIONAL TRIAL (STAR STUDY)

Hypothesis / aims of study

The aim of the study was to compare the clinical profile of two new generation antimuscarinics: solifenacin (Vesicare®) with tolterodine ER (Detrusitol®) administered at the recommended doses (i.e. solifenacin 5 or 10mg and tolterodine 4 mg once daily) using both Patient Reported Outcomes and established Overactive Bladder (OAB) outcome measures.

Study design, materials and methods

The design was prospective, double blind, double-dummy, 2-arm, parallel-group, with a 12-week active treatment period for patients with symptoms of overactive bladder for $\geq$ 3 months and was subject to Ethics Committee approval. Patients were entered into a single-blind placebo-controlled period of 2 weeks to establish baseline and were then randomised to a double blind active treatment (solifenacin 5 mg or tolterodine ER 4 mg) period of 4 weeks at which point the patients had the option of either continuing on the original dose or requesting a dose increase for the remaining 8 week study period; all patients remained on the same double blind, double-dummied medication throughout but only those in the solifenacin group received an actual dose increase as this was not possible under SmPC recommendations for patients randomised to tolterodine ER. Outcome measures included change from baseline for: Perception of Bladder Condition (PBC); Treatment Benefit; episodes of micturition, total incontinence, urge incontinence, urgency; pad use; volume voided; adverse events.

Results

The ITT population consisted of 578 patients on solifenacin and 599 on tolterodine ER; demographics and baseline values were similar. Both antimuscarinics improved bladder condition assessed with the PBC but solifenacin out-performed tolterodine ER (baseline/change from baseline for solifenacin and tolterodine ER respectively: 4.43/-1.51 vs. 4.45/-1.33; $p < 0.006$). The vast majority of patients reported treatment benefit with 55.5% scoring the highest rating for solifenacin versus 43.9% for tolterodine ER. Patient perceptions of improvements in bladder condition and in obtaining treatment benefit were mirrored by the results for the objective outcome measures. Solifenacin was superior to tolterodine ER in decreasing urge incontinence (p=0.001); urgency episodes (p=0.035); incontinence episodes (p=0.005); and incontinent pad use (p=0.002). The typical antimuscarinic side effects (dry mouth, constipation and blurred vision) were observed in both the solifenacin and tolterodine arms. Discontinuation rates due to adverse events were 3.5% and 3.0%, for solifenacin and tolterodine ER, respectively; a very small percentage of patients withdrew because of insufficient therapeutic effect (1.2 and 2.0%, respectively).

Interpretation of results

Patient Reported Outcomes (PROs), such as the PBC and Treatment Benefit rating scales, provided evidence for therapeutic efficacy that reflected results obtained with established objective outcome measures and similarly demonstrated that although both solifenacin and tolterodine ER were effective treatments for OAB greater benefit was obtained following treatment with solifenacin.

Concluding message

(1) Patient Reported Outcomes are likely to have an increasingly important place in the assessment of efficacy and acceptability in OAB trials; (2) When compared according to dosing recommendations and on the basis of both objective and subjective endpoints solifenacin at a flexible dosing regimen of 5/10 mg, with the dose determined by patient wishes, was superior to tolterodine 4 mg ER.

FUNDING: Yamanouchi