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DARIFENACIN – WHAT DOES IT ADD? REAL LIFE EXPERIENCES IN DIFFERENT PATIENT GROUPS

Hypothesis / aims of study

Efficacy and safety of Darifenacin in difficuilt patients subgroups should be investigated.

Study design, materials and methods

This retrospective investigator initiated trial of open label use of Darifenacin in two different centers looks for efficacy and safety in different patient groups . Patients were subdivided in elderly and frail elderly, neurogenic patients as Multiple Sclerosis, Parkinson's disease, stroke, patients suffering from painful bladder syndrom, de-novo urgency (post TVT) and OAB patients who in addition suffered from an irritative bowel syndrom. Patients were enrolled and treated for at least 12 weeks since February 2005. They were all investigated following the ICI guidelines for patient's history, questionnaire, clinical investigation, micturition diary, urin sample and post void residual by ultrasound. Neurogenic patients in addition had an urodynamic investigation. The follow-up included frequency, bladder capacity, incontinence episodes and side effects. Two third of the patients were pretreated with other antimuscarinics and had discontinued their treatment due to side effects like dry mouth, constipation, CNS, arrythmia, stomache problems and accommodation deficiency, or lack of efficacy. Pretreatment drugs prescribed: Oxybutinin IR and ER and transdermal, Propiverin, Solifenacin, Tolterodin and Trospiumchlorid.

Results

Diagnosis of the enrolled patients comprised elderly: 65-75 years n=16 mean=69,12, frail elderly: >75 years n=19 mean=80,84, neurogenic patients n=15, painful bladder syndrom n=3 and de-novo Urgency (post TVT) n=1. In addition to their overactive bladder 6 patients suffered from an irratative bowel syndrom. 31 patients (52%) used the possibility of an dose escalation to 15mg Darifenacin.

Elderly and frail elderly: functional bladder capacity increased from 227,5ml (range 170-350ml) to 313,26ml (range 140-600ml). Frequency decreased from 11.54 (range 8-16) to 9.11 (range 5-15). Incontinence episodes decreased from 2.5 (range 0-5 per day) to 0.85 (range 0-2 per day). In 3 cases incontinence episodes were due to SUI. Safety: Severe constipation n=2 (had comparable constipation with other antimuscarinics), dry mouth n=4 with n=3 withdrawals, „bad" taste n=2 and lack of efficacy n=2.

Neurogenic patients: functional bladder capacity increased from 274ml (range 220-350ml) to 372ml (range 300-480ml). Frequency decreased from 10 (range 8-12) to 8 (range 5-12). Incontinence episodes decreased from 3.8 (range 2-6) to 1.8 (range 0-4). 3 patients were classified as lack of efficacy and changed to other treatments, 1 patient suffering from severe MS had dizziness as side effect and all 4 patients discontinued the treatment.

Painful bladder syndrom: all 3 patients did not respond to Darifenacin but did not show any side effects either.

De novo Urgency: functional bladder capacity improved from 280 to 400ml, Frequency decreased from 8-10 to 6-8, incontinence episodes decreased from 3 to 1 per day.

All patients who suffered from an irritative bowel syndrom beside their OAB had a decrease of their bowel openings from 3-4 to 1-2 per day without constipation.

Interpretation of results

In the elderly and frail elderly Drifenacin was efficacious and safe. The same was found in neurogenic patients. As all other antimuscarinics Darifenacin was not effectiv in painful bladder syndrom. An interesting therapeutic option are patients suffering from OAB and in addition irritative bowel syndrom who should good efficacy for both of their symtoms.

Concluding message

Darifenacin was found to be efficacious and safe especially in special patient subgroups who are on risk for antimuscarinic side effects. These trends have to be confirmed in multicentric randomized controlled trials in the near future.

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HUMAN SUBJECTS: This study did not need ethical approval because Ethical approval is not necessary since the study is a retrospective, post-marketing study with a drug that has been approved by the necessary authorities for the German market ; please note that all other ethical questions do not apply for this matter but followed the Declaration of Helsinki Informed consent was obtained from the patients.