Efficacy and Safety of Solifenacin in Male Patients: Results of the Non-Interventional Study "Male Overactive Bladder on Vesicare: MOVE"

Introduction and Objectives: Solifenacin (Vesicare®) improves all symptoms of overactive bladder (OAB) with significant efficacy and safety in randomised controlled trials (RCT). Due to the specific setting RCTs do not necessarily reflect application in a general care setting. This bias is even more evident in male patients, who usually represent a minority in RCTs on anticholinergic drugs. The non-interventional study MOVE assesses efficacy and safety of flexible dose solifenacin in a male population.
Materials and Methods: From 04/2011 to 11/2011, treatment data over 12 weeks of male patients with OAB-symptoms receiving solifenacin treatment were assessed in 251 German urological offices. Patients suspicious for relevant bladder outlet obstruction were excluded from the study. Changes in symptom severity, quality of life and bladder emptying were evaluated by medical history, IUSS, modified KHQ, IPSS and clinical examination, respectively. Adverse events were documented.
Results: A total of 799 patients were assessed. Mean age was 67.4 years. Most compromising symptoms of current voiding disorder were urinary urgency prevalent in 46% followed by increased micturition frequency found in 45%. Previous therapy with alpha-blocking and anticholinergic agents other than solifencin were noted in 61% and 40%, respectively. 87% of patients were started on solifenacin 5mg; by the end of the study (mean treatment duration 13.6 weeks) 24% of patients increased dose to 10mg. Mean number of micturitions, episodes of urinary urgency over 24 hours and nocturia decreased from 11.9 to 8.3, 9.2 to 4.8, and 3.2 to 1.8 from baseline, respectively. IPSS decreased from 15.4 at the initial visit to 9.4 at the final visit, respectively. Differentiating between IPSS questions concerning storage or voiding symptoms, the score decreased from 9.3 to 5.0 for storage and 6.2 to 4.4 for voiding symptoms. Quality of life increased significantly. Serious adverse events did not occur. No increase in residual urine nor urinary retention were reported. There were 95% of patients who continued solifenacin beyond end of study.
Conclusion: This large series demonstrates efficacious and safe treatment of OAB symptoms in male patients with solifenacin 5/10 mg in the general care setting without tendency to developing urinary retention.