

## **SOLIFENACIN IS EFFECTIVE FOR THE TREATMENT OF OAB DRY PATIENTS: A POOLED ANALYSIS**

### Hypothesis / aims of study

Approximately 40%-50% of women and up to 80% of men with overactive bladder (OAB) syndrome do not experience incontinence.[1,2] Patients with OAB who experience symptoms of urgency and frequency in the absence of incontinence also report a significant impact of the disease on their quality of life.[2] Since incontinence is the most common symptom for which patients seek treatment, these 'OAB dry' patients are often underdiagnosed and undertreated. Solifenacin is a once daily oral antimuscarinic for the treatment of OAB. The recommended dose is 5 mg once daily and can be increased to 10 mg if well tolerated. Significant reductions in incontinence have been observed with solifenacin, and more than half of incontinent patients were restored to continence following 12 weeks of therapy.[3] It is also meaningful to determine if solifenacin improves symptoms of urgency, frequency, and nocturia in OAB dry patients. The purpose of this analysis was to determine the effects of solifenacin in OAB dry patients.

### Study design, materials and methods

A pooled analysis was conducted of 4 randomized, placebo-controlled 12-week, phase III studies. Patients received placebo or solifenacin 5 mg (2 studies) or 10 mg once daily. A subgroup of patients without incontinence at baseline was identified from a 3-day diary. The mean change from baseline to endpoint for urgency episodes/24 h, micturition frequency/24 h, nocturia, and volume voided/micturition were evaluated. The percent of patients with resolution of urgency, normalization of micturition frequency (<8/24 h) or resolution of nocturia at endpoint was also determined. Comparisons of mean change from baseline to endpoint for active drug vs placebo used an ANCOVA model with baseline as a covariate and center and treatment as fixed effects.

### Results

Of 2848 evaluable patients treated with placebo or solifenacin, 975 (34%) were continent at baseline. In this OAB dry subset of patients, solifenacin 5 mg and 10 mg were significantly ( $P<0.001$ ) more effective than placebo for improving urgency, micturition frequency, and volume voided/micturition. In addition, solifenacin 10 mg was significantly ( $P<0.01$ ) more effective than placebo for improving nocturia. Resolution of urgency occurred significantly ( $P<0.05$ ) more often with solifenacin 5 mg (37%) or 10 mg (33%) than with placebo (25%)(Figure 1). Significantly ( $P<0.05$ ) more OAB dry patients had normalization of micturition frequency with solifenacin 5 mg (29%) or 10 mg (35%) compared with placebo (19%). Resolution of nocturia occurred in 14%, 21%, and 13% of patients treated with solifenacin 5 mg, solifenacin 10 mg, and placebo, respectively ( $P<0.01$  for solifenacin 10 mg vs. placebo).

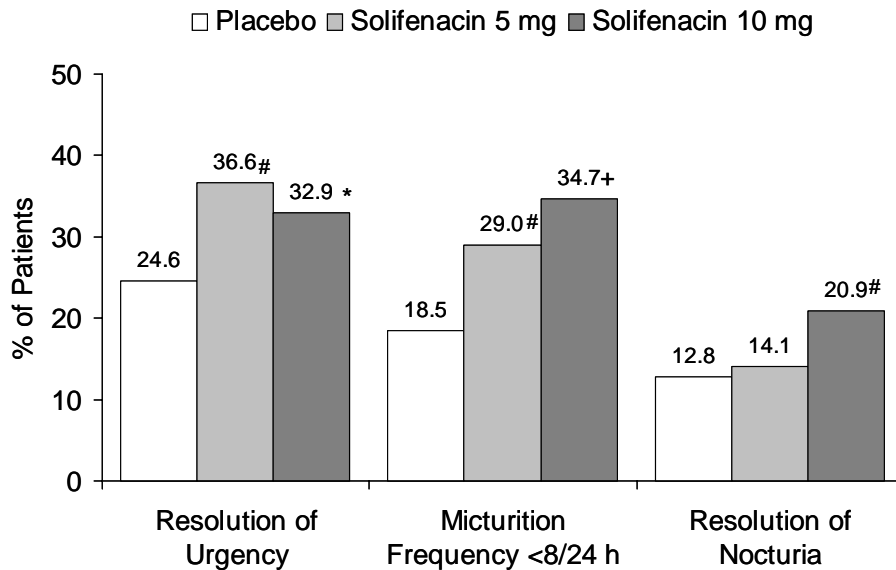


Figure 1. Percent of patients with resolution of urgency, normalization of micturitions (<8/24 hours) or resolution of nocturia at endpoint among patients who were continent at baseline. \* $P < 0.05$ , # $P < 0.01$ , + $P < 0.001$  vs. placebo

#### Interpretation of results

Solifenacin was significantly more effective than placebo in patients with OAB dry when assessed by mean change from baseline to endpoint for urgency episodes/24 hours, micturitions/24 hours, nocturia episodes/24 hours, and volume voided/micturition. In addition, the proportion of patients at endpoint with normalization of micturition frequency or resolution of urgency or nocturia also was significantly improved with solifenacin.

#### Concluding message

Solifenacin significantly reduced urgency episodes, micturition frequency, nocturia episodes, and increased volume voided in OAB dry patients. A larger proportion of OAB dry patients who received solifenacin reported resolution of urgency, normalization of micturitions or resolution of nocturia.

#### References:

1. How widespread are the symptoms of an overactive bladder and how are they managed? A population based prevalence study. *BJU Int.* 2001;87:1-8.
2. Prevalance and burden of overactive bladder in the United States. *World J Urol.* 2003;20:327-336.
3. Randomized, double-blind placebo controlled trial of the once daily antimuscarinic agent solifenacin succinate in patients with overactive bladder. *J Urol.* 2004;172:1919-1924.

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