

**Solifenacin is minimally effective for overactive bladder**

**Clinical question** Is solifenacin (Vesicare) useful in the management of overactive bladder syndrome?

**Bottom line** Solifenacin is minimally more effective than placebo in reducing the symptoms of overactive bladder syndrome. It remains uncertain whether minimal reduction in episodes of nocturia and urinary incontinence improve patients' quality of life or reduce morbidity from falls.

**Synopsis** Solifenacin is a once-daily antimuscarinic, similar to tolterodine (Detrusitol) and oxybutynin, approved for treatment of urge incontinence or increased urinary frequency and urgency as can occur in patients with overactive bladder syndrome (OBS). OBS is defined as urgency, with or without urge incontinence, usually with frequency and nocturia. The investigators randomised (uncertain allocation concealment) 911 men and women, 18 years or older, with symptoms of OBS for three months or more, to once-daily treatment with solifenacin 5mg or 10mg, or placebo. Follow-up occurred for 99 per cent of patients for 12 weeks. Individuals assessing outcomes were blinded to treatment assignment. Data were analysed using modified intention to treat, meaning that only patients taking at least one dose and returning for at least one post-treatment visit were included.

Compared with placebo, patients taking either dose of solifenacin reported a significant decrease in mean daily urgency episodes ( $-2.0$  vs  $-2.9$ , clinically equivalent to one fewer urgency episode per day) and mean number of all incontinence episodes ( $-1.3$  vs  $-1.6$ , clinically equivalent to one fewer incontinence episode every three days). Only the 10mg dose of solifenacin reduced mean nightly nocturia episodes significantly more than placebo ( $-0.7$  vs  $-0.5$ , clinically equivalent to one fewer micturition every five nights). The main adverse side effect — dry mouth — was reported in 7.7 per cent and 23 per cent of patients treated with solifenacin 5mg and 10mg, respectively, compared with 2.3 per cent of the placebo group.

**Level of evidence** 1b— (individual randomised controlled trial with wide confidence interval).

**Reference** Cardozo L, Lisec M, Millard R, et al. Randomized, double-blind placebo controlled trial of the once daily antimuscarinic agent solifenacin succinate in patients with overactive bladder. *Journal of Urology* 2004;172:1919–24.

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