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Treatment with solifenacin increases warning time and improves symptoms of overactive bladder: results from VENUS, a randomized, double-blind, placebo-controlled trial.

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Abstract

OBJECTIVES: In this double-blind, placebo-controlled trial, we assessed the efficacy and tolerability of solifenacin treatment for overactive bladder (OAB) with a focus on urgency-related endpoints. Changes in number of urgency episodes were evaluated as the primary endpoint; secondary endpoints included changes in conventional diary-based OAB symptoms. We also measured warning time (defined as the time from first sensation of urgency to voiding).

METHODS: We randomized patients (n = 739) to once-daily solifenacin or placebo for 12 weeks. Solifenacin 5 mg or matching placebo was administered for 4 weeks; dose could be maintained or adjusted at weeks 4 and 8. Participants completed 3-day micturition diaries at multiple study visits; warning time was recorded at baseline and week 12.

RESULTS: At study end, the mean number of urgency episodes per 24 hours decreased by 3.91 (from 6.15 to 2.24) with solifenacin and by 2.73 (from 6.03 to 3.30) with placebo (P < .0001 between groups). Other diary-recorded symptoms (incontinence and micturition frequency) were also significantly more reduced with solifenacin compared with placebo. Median warning time increased 31.5 seconds (baseline, 67.8 seconds) with solifenacin, significantly longer (P = .008) than the median increase of 12.0 seconds (baseline, 65.0 seconds) observed with placebo.

CONCLUSIONS: Solifenacin treatment significantly reduced episodes of urgency and other key symptoms of OAB. Solifenacin is the first antimuscarinic to demonstrate significant warning time improvement at approved dosing, as shown in a large OAB study population. This is the largest OAB clinical trial yet conducted to evaluate warning time and diary variables in the same study population.

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