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A COMPARATIVE STUDY ON THE EFFICACY OF SOLIFENACIN SUCCINATE IN PATIENTS WITH URINARY FREQUENCY WITH OR WITHOUT URGENCY

Hypothesis / aims of study

Patients with overactive bladder (OAB) often have trouble perceiving urinary urgency because of difficulties in distinguishing between urgency and desire to void¹⁻³. Empirical antimuscarinic treatment of patients with frequency only may be reasonable if conservative management has failed.

We compared the efficacy of solifenacin in patients with frequency with or without urgency.

Study design, materials and methods

This multicenter, 12-week, open-label, comparative, non-inferiority study was based on the hypothesis, "The efficacy of solifenacin for frequency only is non-inferior to the efficacy of solifenacin for frequency with urgency". The study population consisted of men and women (≥ 18 years old) who had the symptom of frequency without (Group 1) or with (Group 2) urgency for more than 3 months. Frequency was determined on the basis of 3-day bladder diaries and defined as an average micturition frequency $\geq 8/24$ hours and urgency was defined as a score ≥ 3 on the urinary sensation scale. All patients received solifenacin 5mg once daily. At the week 4 visit, the dose could be increased to 10mg based on discussion between the subject and investigator regarding treatment efficacy and tolerability. Primary efficacy variable: daily frequency change at 12 weeks relative to baseline. Secondary efficacy variables: change at 12 weeks relative to baseline in PPBC (Patients' Perception of Bladder Condition), OABSS (OAB Symptom Score), and BSW (Benefit, Satisfaction, Willingness to continue) questionnaire scores. Safety was evaluated by adverse events and measuring maximal urinary flow rate and post-void residual urine.

Results

Of the 286 enrolled patients, 240 (83.9%) completed the study (without urgency n=115; with urgency n=125) (Figure 1). Full dataset analysis revealed that the groups without and with urgency exhibited significant reductions in daily micturition frequency (-2.49 ± 3.71 and -2.63 ± 4.19 , respectively, $p=0.176$) (Table 1). The lower limit of the 95% two-sided CI of the comparison of the two group means was -1.14 , which is smaller than the -0.8 margin of clinical equivalence. The two groups did not differ in mean voided volume or improvement in PPBC, OABSS, or BSW scores. Both tolerated the treatment well.

Interpretation of results

It was not possible to verify that the solifenacin efficacy for frequency alone was non-inferior to its efficacy for OAB. Nevertheless, solifenacin was effective for frequency regardless of urgency.

Concluding message

The 12-week solifenacin treatment was effective in all patients with frequency, regardless of whether they also had urgency.

Figure 1. Participation flowchart

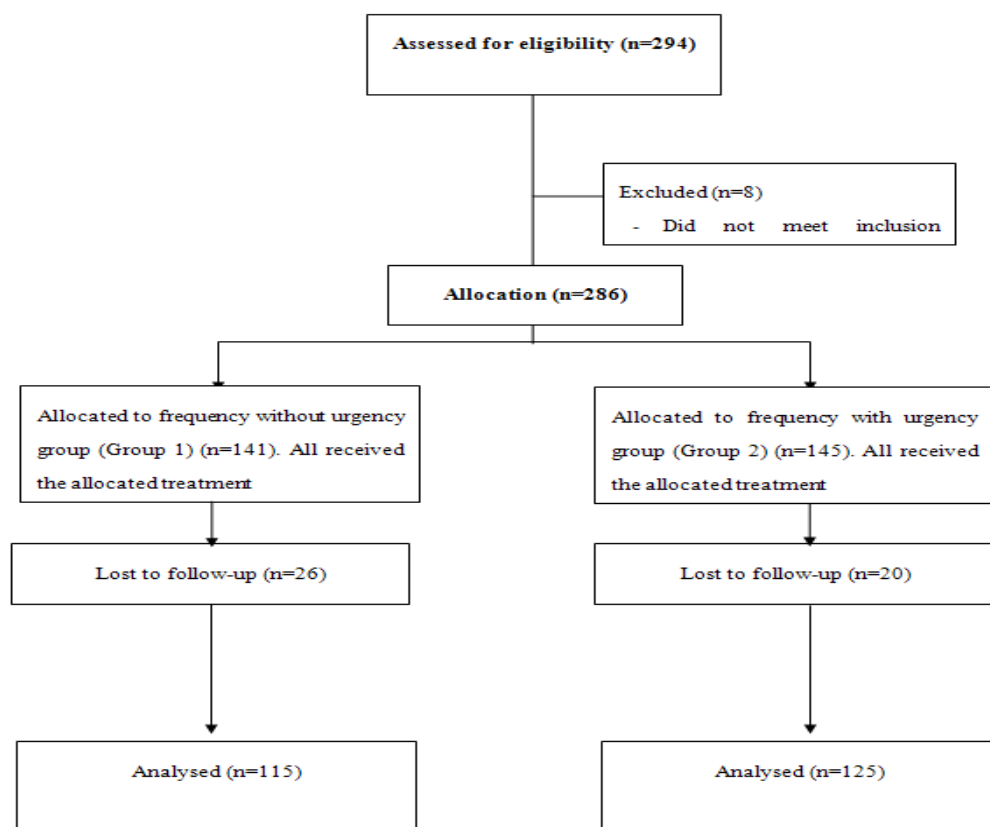


Table 1. Non-inferior analysis of solifenacin with the daily mean voiding frequency in patients with urinary frequency and urgency or frequency only [FAS group]

Variables	Frequency without urgency group (Group 1)	Frequency with urgency group (Group 2)	p- value
Baseline	12.32 ± 3.27	13.16 ± 4.26	0.0860*
Week 12	9.82 ± 3.88	10.52 ± 4.64	0.2087*
Change from baseline	-2.49 ± 3.71	-2.63 ± 4.19	0.7823*
95% CI	-3.17, -1.81	-3.37, -1.90	
95% CI for difference	-1.14, 0.86†		

References

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Disclosures

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