

## FREQUENCY OF VOIDING PER HOUR IN UNTREATED OVERACTIVE BLADDER PATIENTS

### Hypothesis / aims of study

The voiding experience of untreated overactive bladder (OAB) patients is most often reported as average frequency of voids per day; However, an interesting question posed is: Does voiding frequency per hour vary during the course of a day, particularly after the first initial void upon waking in the morning? Data from a Phase III clinical study of trospium chloride in OAB patients provided over 55,000 individual baseline voiding diary entries in 658 untreated OAB patients for exploration of this question. The aim of this abstract is to evaluate the 24-hour frequency of toilet voids by presenting the frequency of voids by hour per patient over a 24 hour period, starting from 12 am (midnight) and also from waking. It is hoped this information may help physicians and researchers understand potential needs for modifications in specific dosing strategies of OAB medications.

### Study design, materials and methods

Baseline diary data was obtained from a 12-week double-blind, placebo-controlled study demonstrating the effects of trospium chloride vs. placebo in OAB patients. Eligible females and males were 18 years or older with OAB symptoms for at least 6 months, with a minimum urinary frequency of 70 toilet voids per 7 days (i.e., average  $\geq 10$  toilet voids per day), and symptoms of urgency as captured in a 7-day diary. All patients were required to have at least 7 urge urinary incontinence (UUI) episodes per week. Patients with incontinence that was predominately stress, insensate, or overflow in nature were excluded from the study, as were those with neurogenic bladder disorders, significant renal disease, uninvestigated hematuria, and urinary tract infection at washout or more than twice during the prior year. Also excluded from the study were patients with: significant bladder outlet obstruction, concurrent anticholinergic drug use or other drug therapy for overactive bladder within 21 days prior to randomization, bladder surgery within 6 months before randomization, cancer, interstitial cystitis, males with prostate-specific antigen (PSA)  $\geq 10$  ng/mL, diuretic use, estrogen therapy, and non-pharmacological bladder therapy that were not part of a stable, long-term program. Sample size in this study was based on efficacy outcomes, and is thus not reported here. Diary data were captured both prior and during treatment, however, only baseline values were used here. The start time of each void was captured for each patient during the 7-day baseline period, as was waking time. The mean frequency of voids per hour was performed 2 ways: Starting from midnight and from the time each patient awoke in the morning.

### Results

The patient population was predominantly female (81.5%) and the mean age was 61 years. Figure 1 presents the mean frequency of voids per hour from midnight. The hour with the highest frequency was the initial hour upon waking, and frequency of voids per hour continued to be highest in the first 3-4 hours after waking. Frequency decreased, but only slightly, from the morning to the remainder of the day. Figure 2 presents the mean frequency of voids per hour from waking time. Within the first hour of waking most patients experienced at least one void. On average, OAB patients generally voided approximately 0.6 voids in any given hour during waking hours, and approximately 0.25 voids in any given hour during sleep.

### Interpretation of results

OAB patients experienced a consistent pattern of voiding throughout the waking hours, with a reduction during sleep hours that remained consistent during the sleep hours. There did not appear to be any specific time point (other than the initial hour upon waking) where the frequency of voiding was significantly higher or lower than other time points.

Concluding message

Frequency of voiding is consistent during the waking hours as well as during the sleeping hours in OAB patients. Despite this relatively consistent pattern of void frequency, many clinicians and patients complain some once-daily formulations of OAB medications do not provide 24 hour coverage. Understanding the distribution per hour of void frequency and the other symptoms of OAB over a 24 hour period may lend itself to development of improved dosing strategies for OAB medications.

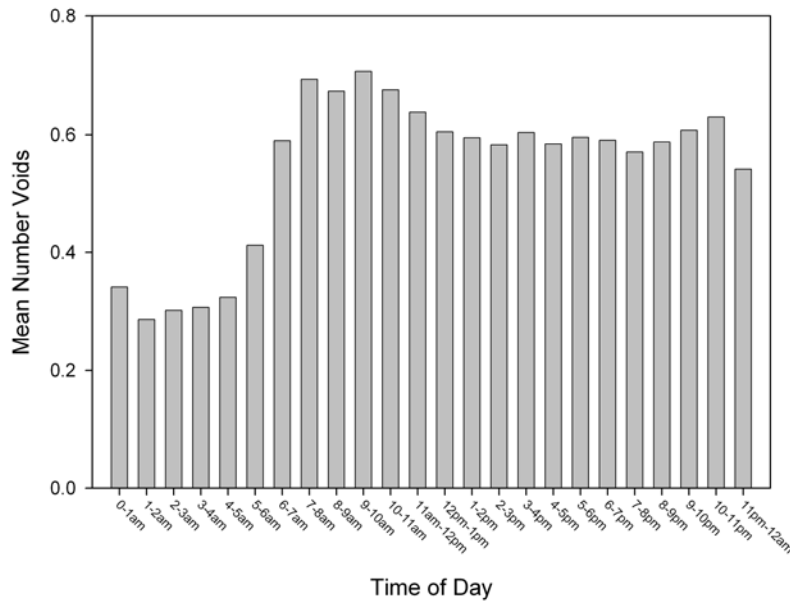


Figure 1: Frequency of Voids per Hour from 12 am

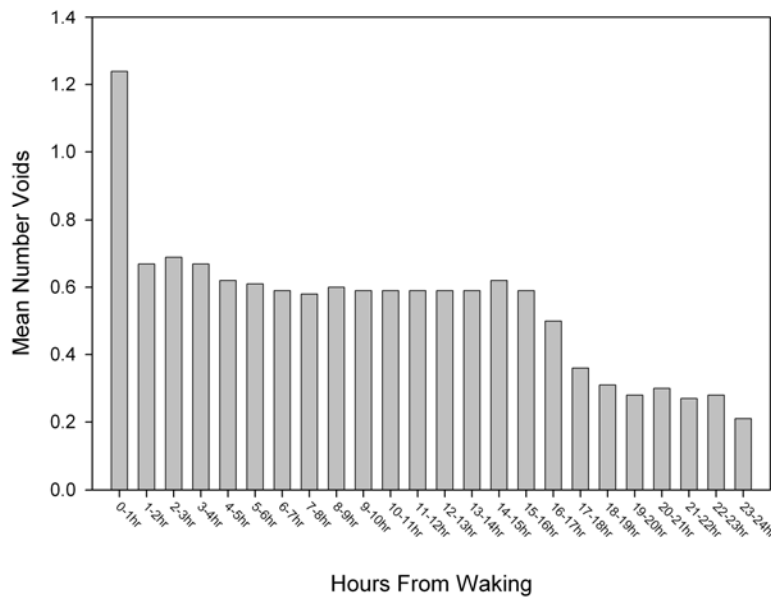


Figure 2: Frequency of Voids per Hour from Waking

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