

# Impact of Dry Mouth on Fluid Intake and Overactive Bladder Symptoms in Women taking Fesoterodine

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**Purpose:** We investigated the long-term relationships between dry mouth, fluid intake and overactive bladder symptoms in women undergoing treatment with fesoterodine. We hypothesized that women who experienced dry mouth would increase their fluid intake and worsen their urinary symptoms.

**Materials and Methods:** We conducted a prospective ancillary study to a 9-month open-label trial of fesoterodine for women with urgency urinary incontinence. Fluid intake was measured and compared according to reported dry mouth. Multivariable analysis was used to study the interaction between dry mouth, fluid intake and urinary symptoms.

**Results:** During the study 407 women without dry mouth significantly reduced their fluid intake (mean decrease 172.1 ml, median 118.3 ml,  $p = 0.02$ ), while 91 women with dry mouth did not (mean decrease 95.8 ml, median 118.3 ml,  $p = 0.54$ ). On univariable analysis a greater proportion of women who experienced dry mouth reported improvement in their urinary symptoms compared to women without dry mouth (60.5% vs 47.2%,  $p = 0.03$ ). On multivariable analysis black women were less likely to report dry mouth (OR 0.4, 95% CI 0.2–0.9,  $p = 0.03$ ) and older women were less likely to report improvement in urinary symptoms (OR 0.98, 95% CI 0.96–0.99,  $p = 0.003$ ). Factors not associated with improvement in urinary symptoms on multiple regression were dry mouth, baseline fluid intake volume, change in fluid intake volume and caffeine intake volume.

**Conclusions:** In women with overactive bladder receiving fesoterodine dry mouth may prevent restriction of fluid intake but does not diminish treatment efficacy.

## Abbreviations and Acronyms

BRIDGES = Bringing Simple Urge Incontinence Diagnosis and Treatment to Providers trial  
OAB = overactive bladder  
QVD = Questionnaire Based Voiding Diary  
RCT = randomized controlled trial

Accepted for publication December 1, 2015.  
No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

Supported by Pfizer Inc.

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† Financial interest and/or other relationship with Allergan.

**Key Words:** caffeine; urinary bladder, overactive; urinary incontinence, urge; water-electrolyte balance; xerostomia

OVERACTIVE bladder is a common condition that can impair quality of life in women.<sup>1,2</sup> While multiple therapies are available for overactive bladder, fluid modification is a key component of treatment,<sup>3</sup> as several

studies have demonstrated that increased fluid intake can aggravate urinary urgency, frequency and urgency incontinence episodes.<sup>4–6</sup>

In addition to fluid normalization, anticholinergic therapy is included in

the first-line management of OAB.<sup>3</sup> Although treatment with anticholinergic therapy can improve symptoms, dry mouth is a common side effect.<sup>7</sup> Women taking anticholinergics could potentially increase their fluid intake to combat dry mouth and worsen their urinary symptoms. The interaction between dry mouth, fluid intake and symptom improvement is unclear in women with OAB who are prescribed an anticholinergic. Understanding this relationship is important because it may help to elucidate a potential reason for diminished efficacy of anticholinergic treatment.

In this study our primary aim was to investigate the long-term relationships between dry mouth, fluid intake and overactive bladder symptoms in women undergoing treatment with anticholinergic medication. We hypothesized that women who experienced dry mouth from anticholinergic therapy would increase their fluid intake and worsen their urinary symptoms.

## MATERIALS AND METHODS

### Study Design

We conducted a prospective study that was ancillary to BRIDGES, a multicenter open-label trial investigating the long-term efficacy and safety of fesoterodine for women with urgency predominant urinary incontinence diagnosed according to the 3 Incontinence Questions questionnaire. The methods and results of BRIDGES have been reported previously.<sup>8</sup> Briefly, BRIDGES was a 9-month longitudinal cohort study of women who had previously completed a 12-week randomized placebo controlled trial of fesoterodine for urgency urinary incontinence.<sup>9</sup> For this ancillary fluid intake study fluid intake and behavior were assessed at the beginning of the open-label treatment with fesoterodine and at 9 months after treatment (fig. 1).

### Study Outcomes and Instruments

Fluid intake and behavior were assessed using the Questionnaire Based Voiding Diary. The QVD contains 25 items assigned to 4 subscales, including type and amount of fluid intake (10 items) and fluid intake behavior (5). Volume of fluid intake on the QVD can be calculated by multiplying the number of drinks per day for each fluid type by the size of each drink. The QVD also measures the fluid intake behaviors of drinking large amounts of caffeinated tea and coffee, drinking large amounts

of carbonated beverages, drinking extra fluids to lose or maintain weight, drinking fluid even when not thirsty and restricting fluid to control urinary symptoms. Fluid intake behavior responses are scored on a 5-level Likert scale as “never,” “occasionally,” “sometimes,” “most of the time” and “all of the time.” For the purpose of this study we defined the presence of a behavior as the response “sometimes,” “most of the time” or “all of the time.” The QVD has been shown to be internally consistent, reproducible and responsive to change.<sup>10,11</sup>

We also measured OAB symptoms at baseline of the open-label study and 9 months later. OAB symptoms were assessed using the Patient Perception of Bladder Condition questionnaire, a single item instrument that measures patient perception of bladder improvement on a 5-point Likert scale.<sup>12</sup> Treatment efficacy was defined as a 1-point or greater improvement. Adherence to fesoterodine therapy was measured by patient self-report at the study visits.

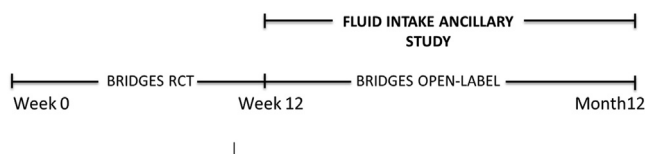
Dry mouth was assessed by self-report of adverse events. At each contact in the open-label trial subjects were asked to report any adverse event. Study coordinators at all sites were trained not to prompt subjects to report any specific adverse event, including dry mouth. For women who reported dry mouth the intensity (mild, moderate or severe) and pattern (every day, intermittent, continuous or once) were recorded.

### Statistical Analysis

Women were divided into 2 groups, ie those who reported dry mouth at any time in the open-label study and those who did not report dry mouth during the study. We treated dry mouth as a dichotomous variable (yes/no) because 1) the report of dry mouth was not prompted by study staff, and, therefore, all reports of dry mouth were considered clinically significant, and 2) women reported different intensities and frequencies of dry mouth at different contact periods. Our primary outcome was change in total fluid intake from the open-label baseline to 9 months after treatment with fesoterodine, and our secondary outcome was change in OAB symptoms. Fluid intake and OAB symptom improvement were compared in the 2 groups using Mann-Whitney U and Wilcoxon signed-rank tests.

We compared the proportion of women with a specific fluid intake behavior and proportions of women reporting dry mouth in the 2 groups using chi-square and McNemar testing. We also used these tests to compare fluid intake in the subgroup of women allocated to receive placebo in the preceding RCT. Multiple logistic regression was used to determine if baseline fluid intake and change in fluid intake during the treatment period could predict self-reported dry mouth. A multiple logistic regression model was also created to assess the effects of baseline fluid intake, change in fluid intake, caffeine intake and dry mouth on urinary symptoms. The multiple logistic regression models included age, race/ethnicity, treatment adherence and treatment assignment group during the preceding RCT as covariates.

To ensure an adequate sample size, information from unrelated published studies was used. Mean  $\pm$  SD fluid intake in women with urinary incontinence is



**Figure 1.** Ancillary fluid intake study schema

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