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

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Abstract

Purpose—To investigate the long-term relationships between dry mouth, fluid intake and overactive bladder symptoms in women undergoing treatment with fesoterodine. We hypothesize that women who experience dry mouth will 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, women without dry mouth (n=407) significantly reduced their fluid intake (mean decrease of 172.1 mL, median decrease of 118.3 mL, p= 0.02), while women with dry mouth (n=91) did not (mean decrease of 95.8 mL, median decrease of 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% versus 47.2%, p=0.03). On multivariable analysis, Black/ African American 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 women from restricting fluid intake, but does not diminish treatment efficacy.

Keywords

overactive bladder; dry mouth; fluid intake; urgency incontinence; caffeine

Introduction

Overactive bladder (OAB) is a common condition that can impair the quality of life of women.^{1, 2} While multiple therapies are available for OAB, fluid modification is a key component of therapy,³ as several studies have demonstrated that increased fluid intake can aggravate urinary urgency, frequency, and urgency incontinence episodes in patients with OAB.⁴⁻⁶

In addition to fluid normalization, anticholinergic therapy is also included in the first line management of women with OAB.³ Though treatment with anticholinergic therapy can improve symptoms, dry mouth is the most common side effect.⁷ Potentially, women taking anticholinergics may increase their fluid intake to combat their dry mouth and worsen their urinary symptoms. The interaction between dry mouth, fluid intake and symptom improvement in women with OAB who are prescribed an anticholinergic is unclear. 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 is to investigate the long-term relationships between dry mouth, fluid intake and overactive bladder symptoms in women undergoing treatment with anticholinergic medication. We hypothesize that women who experience dry mouth from anticholinergic therapy will increase their fluid intake and worsen their urinary symptoms.

Materials and Methods

Study Design

We conducted a prospective study that was ancillary to the open-label Bringing Simple Urge Incontinence Diagnosis and Treatment to Providers trial (BRIDGES)⁸. The open-label BRIDGES trial was a multicenter, open-label trial investigating the long-term efficacy and safety of fesoterodine for women with urgency-predominant urinary incontinence, diagnosed by the 3 Incontinence Questions questionnaire. The methods and results of the open-label BRIDGES trial have been previously reported.⁸ In brief, open-label 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 (UUI)⁹. 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 (figure 1).

Study Outcomes and Instruments

Fluid intake and behavior were assessed using the Questionnaire Based Voiding Diary (QVD). The QVD contains 25 items assigned to 4 subscales, including the type and amount of fluid intake (10 items) and fluid intake behavior (5 items). The 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 five-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 responses “sometimes”, “most of the time”, or “all of the time.” The QVD has been demonstrated to be internally consistent, reproducible, and responsive to change.^{10, 11}

We also measured OAB symptoms at baseline of open label study and 9 months later. OAB symptoms were assessed using the Patient Perception of Bladder Condition questionnaire (PPBC).¹² The PPBC is a single item questionnaire that measures the patient’s perception of bladder improvement on a 5-point Likert scale. 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 to not prompt subjects into reporting 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

We divided women into two groups: women who reported dry mouth at any time point in the open-label study, and women 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 two 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 two groups using Chi-square and McNemar tests. We used these tests to also compare fluid intake in the subgroup of women allocated to the placebo group in the preceding RCT. Multiple logistic regression was used to determine if baseline fluid intake and the 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, adherence and treatment assignment group during the preceding RCT as covariates.

To ensure an adequate sample size, information from published non-related studies was used. The mean fluid intake in women with urinary incontinence was 93.2 ± 48.9 ounces¹⁰. A 25% difference in fluid intake had previously been shown to worsen urinary symptoms in

patients with OAB,⁵ and approximately 30% of women receiving anticholinergics report dry mouth.⁷ Therefore, at an alpha of 0.05, studying the fluid intake of 498 women was determined to provide over 90% power to detect a 25% difference in total fluid intake between the dry mouth and no dry mouth groups. All data was analyzed using STATA 12.1 (Stata Corp., College Station, TX).

Results

Participants

Of the 498 women who participated in the open-label BRIDGES trial, complete fluid intake data was available for 444 (89%) women (figure 2). Women who did not contribute complete fluid intake data did not have a higher percentage of dry mouth than women who did provide fluid intake data (22.2% vs 17.8% $p=0.43$). Mean age and median BMI of participants were 56.9 (SD 13.8) years and 30.6 (IQR 10.2) kg/m^2 , respectively, 68% were Caucasian, and 21% were Black/African-American. Over 70% of women were post-menopausal and half (49%) had received the active drug fesoterodine during the immediately preceding RCT.

During the 9 month open label study period, 91 (18%) women reported dry mouth. Of these women, dry mouth was reported once throughout the open label study by 90%, twice by 8%, and 3 times by 2%. Half (54%) of the dry mouth complaints were mild in maximum intensity, while half (46%) were of moderate or severe intensity. Regarding frequency, 65% of women reported dry mouth occurring daily or continuously and 32% reported dry mouth occurring intermittently. Among women with mild symptoms, 56% reported 'daily' or 'continuous' symptoms. Baseline characteristics of women reporting dry mouth and those not reporting dry mouth are presented in Table 1. Black/African women were significantly less likely to report dry mouth than Caucasian women ($p=0.02$). Women who had received placebo during the preceding RCT were significantly more likely to report dry mouth than women who had received the active drug ($p < 0.001$). Table 2 shows the baseline fluid intake and fluid intake behavior of women who did or did not report dry mouth. Women who reported dry mouth consumed significantly less caffeinated soda and marginally less total fluid than women who did not report dry mouth. There were no differences in intake of other fluid types, or in self-reported fluid intake behaviors, at the baseline visit of the open-label study between the two groups. There were also no differences in fluid intake at the baseline visit of the open-label study according to the allocation group assignment in the preceding RCT (p values for all fluid intake types >0.05).

Change in Fluid Intake and Behavior during the Study

Table 3 presents change in fluid intake from the initial open-label study visit to study endpoint (month 9 visit). There was no significant change in the total fluid intake of subjects who reported dry mouth during the study period (mean change -95.8 ml, median change -118.3 ml, $p = 0.54$) while women who did not experience dry mouth significantly decreased their total fluid intake (mean change -172.1 ml, median change -118.3 mL, $p=0.02$). All women, irrespective of dry mouth status, decreased their caffeinated coffee consumption over the study period. When considering only those women who had been

allocated to the placebo group in the preceding RCT, the pattern of change of fluid intake was similar to that of the whole cohort. In this subgroup, the median fluid change in women reporting dry mouth was -132.8mL (IQR 1182.9mL, $p=0.65$) and in women without dry mouth the median fluid change was -294.6mL (IQR 1537.8mL, $p=0.06$).

Self-reported fluid intake behavior also changed during the study. Among women with dry mouth, a smaller proportion of women reported consuming large amounts of carbonated drinks at the end of the study compared to the initial study visit (6.2% versus 13.6%, $p=0.03$), and among women without dry mouth, a smaller proportion reported consuming extra fluids for weight related reasons at the end of the study compared to the initial study visit (10.3% versus 16%, $p=0.01$).

Risk Factors for Dry Mouth and Treatment Efficacy

In a multiple logistic regression model that included age, adherence, baseline total fluid intake, and the change in fluid intake during the study, Black/ African American race/ ethnicity was protective against dry mouth ($p=0.03$) as measured at 9 months after onset of the open label study, while being in the placebo group during the preceding the RCT was associated with increased odds of reporting dry mouth ($p<0.001$), table 4. Factors not associated with increased odds of reporting dry mouth were age, adherence, baseline total fluid intake, and change in fluid intake.

In terms of improvement in urinary symptoms, a greater percentage of women who reported dry mouth experienced a 1 point or more improvement in the Patient Perception of Bladder Condition compared to women who did not report dry mouth (60.5% versus 47.2%, $p=0.03$). In a simple logistic model, improvement in bladder condition was not related to a change in any type of fluid intake during the trial (OR's near 1.00 and p -values >0.05). In a multiple logistic regression model which included age, race/ethnicity, baseline total fluid intake, the change in total fluid intake, caffeine fluid intake, and adherence, older age was inversely associated with improvement in bladder condition($p=0.003$), while being in the placebo group during the preceding RCT was associated with improvement ($p=0.001$). Factors not associated with change in bladder condition were dry mouth, change in fluid intake, baseline fluid intake, caffeine intake and adherence (table 5). Notably, the relationship between dry mouth and improvement in bladder condition that was observed on univariable analysis was no longer significant (OR 1.6 95% CI 0.96–2.7, $p=0.07$).

Discussion

Fluid management represents an integral component of OAB treatment. The most important finding of this study is that in women with OAB receiving fesoterodine, dry mouth does not have a clinically meaningful impact on fluid intake. In our study, women with overactive bladder who were prescribed fesoterodine and reported dry mouth did not increase their fluid intake and were not less likely to experience improvement in urinary symptoms as women without dry mouth.

In this study, women with dry mouth did not change their total fluid intake, while women without dry mouth decreased their total fluid intake, albeit a median of only 118.3 mL.

Although women did not receive fluid management instructions as part of the protocol, women in the cohort as a whole changed their fluid intake pattern. Notably, both groups of women, irrespective of dry mouth decreased their caffeinated coffee consumption and may have also attempted fluid restriction to control their urinary symptoms. Our findings suggest that women without dry mouth are more successful in restricting fluid intake than women with dry mouth. In a prior study examining the effects of behavioral therapy/fluid management instruction on fluid intake over 10 weeks in women taking tolterodine, women with dry mouth decreased their fluid intake to control their urinary symptoms.¹³ In our study, women were not provided with fluid management instructions and were followed for 9 months; it is possible that women with dry mouth can restrict fluid intake for short periods but are unable to sustain this over a longer period. Regardless, any subtle changes in fluid intake that were experienced by women in our trial did not affect improvement in urinary symptoms.

Contrary to our hypothesis, dry mouth was actually associated with improvement in urinary symptoms. A larger percentage of women with dry mouth reported improvement in their bladder condition compared to women without dry mouth, and when considering other factors involved in treatment improvement, a positive relationship between dry mouth and treatment improvement approached statistical significance. Dry mouth may be a marker of pharmacological potency, and is not a major reason for lack of treatment efficacy.¹⁴ Although bothersome to patients, experiencing dry mouth does not appear to have an adverse effect on urinary symptoms in women with OAB.

Black/African American women had decreased odds of reporting dry mouth in our study and fluid intake did not explain this phenomenon. Previous literature has identified race/ethnicity to be associated with dry mouth. In a cross-sectional study of 2481 individuals, dry eye or dry mouth was more commonly reported by White subjects (29.6%) compared to African American individuals (21.5%)¹⁵. Identifying race/ethnicity as a risk factor for dry mouth may be useful for counseling.

A strength of our study includes the use of a validated fluid intake diary which measured a variety of fluid intake types and behaviors. A limitation to our study is that we did not record fluid intake data during the RCT that preceded the open-label study. However, we included RCT treatment assignment in our multivariable model and conducted a subgroup analysis of those women who were previously assigned to placebo during the preceding RCT. Our subgroup analysis showed that the pattern of fluid changes for this subgroup was similar to that of the whole cohort. Though we did not use a specific questionnaire to measure dry mouth, women's report of dry mouth was unprompted by the research staff and therefore clinically meaningful. We included women with mild symptoms in our dry mouth group because 56% of these women had 'daily' or 'continuous' symptoms.

Conclusion

In women with OAB receiving anticholinergic therapy, dry mouth may prevent women from restricting fluid intake; however, this does not have a clinically meaningful impact on

efficacy of treatment with fesoterodine. Similarly volume of fluid intake does not impact treatment efficacy of fesoterodine.

Acknowledgments

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Figure 1.
Ancillary fluid intake study schema

Figure 2.
Flow chart of women enrolled and analyzed

Table 1

Characteristics of the study sample as whole and according to dry mouth status

	Entire Group (n=498)	Dry Mouth Group (n=91)	No Dry Mouth Group (n=407)	P value
Age Mean (SD) (years)	56.9 (13.8)	59 (11.9)	56.4 (14.1)	0.11
Race/ethnicity, n (%)				0.02
White/Caucasian	340 (68.3)	70 (76.9)	270 (66.3)	
Black/African American	103 (20.7)	9 (1.2)	94 (23.1)	
Other	55 (11)	12 (13.2)	43 (10.6)	
Median (IQR) BMI (kg/m ²)	30.6 (10.2)	31.3 (10.4)	30.4 (10.4)	0.77
Self-reported "excellent" or "very good" overall health, n (%)	399 (80.1)	72 (79.1)	327 (80.3)	0.80
Current cigarette smoking, n (%)	66 (13.3)	10 (11)	56 (13.7)	0.48
Postmenopausal, n (%)	363 (73.2)	72 (79.1)	291 (71.9)	0.16
Parity 1, n (%)	400 (80.3)	73 (88)	327 (92.6)	0.16
Group Assignment during preceding RCT (fesoterodine)				
Active treatment group n (%)	244 (49)	24 (26.4)	220 (54.1)	<0.001
Placebo group, n (%)	254 (51)	67 (73.6)	187 (45.9)	<0.001

Table 2

Baseline fluid intake and behavior, according to dry mouth status

<i>Fluid Intake, mL</i>	<i>Dry Mouth (n=91%)</i>		<i>No Dry Mouth (n=407%)</i>		<i>P value*</i>
	<i>Median (IQR)</i>	<i>Mean (SD)</i>	<i>Median (IQR)</i>	<i>Mean (SD)</i>	
Water	1419.5 (828.1)	1476 (1112.6)	1419.5 (1182.9)	1479.8 (970.4)	0.80
Caffeinated coffee	354.9 (709.8)	470.5 (534)	236.6 (709.8)	421.5 (546.5)	0.40
Decaffeinated coffee	0 (0)	135.6 (363.5)	0 (0)	102.2 (243.6)	0.78
Caffeinated tea	0 (354.9)	210 (393.5)	0 (236.6)	279.7 (685.1)	0.61
Decaffeinated tea	0 (236.6)	169.6 (394.2)	0 (0)	152.4 (446.3)	0.14
Caffeinated soda	0 (0)	147.2 (349.9)	0 (354.9)	350.5 (692.4)	<0.001
Decaffeinated soda	0 (0)	60.5 (167.5)	0 (0)	153.3 (491.2)	0.07
Milk	236.6 (354.9)	327.3 (529)	236.6 (473.2)	342.4 (468.4)	0.44
Fruit juice/drinks	0 (236.6)	211.6 (366.6)	236.6 (354.9)	342.3 (570.9)	0.08
Alcoholic drinks	0 (236.6)	114.4 (209.4)	0 (236.6)	105.4 (287.7)	0.37
Total	3016.5 (1419.5)	3334.5 (1808.7)	3193.9 (1892.7)	3742 (2068.1)	0.05
<i>Fluid Behavior,</i>	<i>n (%)</i>		<i>n (%)</i>		
Do you drink large amounts of caffeinated tea or coffee?	28 (31.1)		110 (27.1)		0.44
Do you drink large amounts of carbonated drinks?	11 (12.2)		71 (17.5)		0.22
Do you drink extra fluids to lose or maintain your weight?	16 (17.8)		61 (15)		0.51
Do you 'make yourself' drink fluid even if you are not thirsty?	22 (24.4)		92 (22.7)		0.72
Do you restrict or cut down on your fluid intake to control your urinary symptoms?	31 (34.4)		119 (29.3)		0.34

*Includes only subjects for whom fluid intake data was available

* Comparisons performed using Mann Whitney U and Chi-squared tests. The Mann Whitney U test compares the ranks of two samples, and not the sample medians. Thus, two samples can have different ranks and the same medians.

Table 3

Change in fluid intake from baseline to end of study according to dry mouth status

Fluid Intake, mL Median (IQR)	Dry Mouth (n=79) ¶			No Dry Mouth (n=365) ¶		
	Median (IQR)	Mean (SD)	P value*	Median (IQR)	Mean (SD)	P value*
Water	0 (768.9)	47.3 (1200.9)	0.16	0 (709.8)	54.3 (1063.3)	0.43
Caffeinated coffee	0 (118.3)	-87.6 (328.7)	0.01	0 (118.3)	-59 (361.9)	0.006
Decaffeinated coffee	0 (0)	-25.1 (287.1)	0.35	0 (0)	6.7 (233.8)	0.79
Caffeinated tea	0 (0)	39.4 (383.8)	0.57	0 (0)	-32.6 (562.2)	0.77
Decaffeinated tea	0 (0)	-14.6 (258.8)	0.65	0 (0)	-43.5 (394.6)	0.29
Caffeinated soda	0 (0)	17.5 (268.5)	0.44	0 (0)	-29.5 (543.8)	0.15
Decaffeinated soda	0 (0)	-23.4 (140.5)	0.16	0 (0)	-15.7 (440.9)	0.40
Milk	0 (118.3)	-54.0 (494.5)	0.52	0 (118.3)	-11.5 (420)	0.17
Fruit juice/drinks	0 (0)	-32.1 (374.6)	0.37	0 (118.3)	-31.9 (519.7)	0.33
Alcoholic drinks	0 (0)	27.7 (274.4)	0.54	0 (0)	-1.9 (300.8)	0.66
Total	-118.3 (1301.2)	-95.8 (1320)	0.54	-118.3 (1537.8)	-172.1 (1980.4)	0.02

¶ Includes only subjects for whom fluid intake data was available

* Comparing fluid intake at baseline open-label visit to study end point using Wilcoxon signed rank tests. The Wilcoxon signed rank test compares ranks in a paired sample and not the sample medians. Thus, a paired sample can have different ranks but the same medians

Table 4

Multiple logistic regression model for predictors of dry mouth

	OR	95%CI	P value
Age	1.0	1.0–1.0	0.41
Race / ethnicity (Black / African American)	0.4	0.2–0.9	0.03
Placebo group during the preceding RCT	3.4	2.0–5.9	<0.001
Baseline total fluid intake	1.0	1.0–1.0	0.12
Change in fluid intake	1.0	1.0–1.0	0.57
Adherence to fesoterodine	0.8	0.4–1.6	0.51

Table 5

Multiple logistic regression model for predictors of improvement in bladder symptoms (1 improvement in PPBC)

	OR	95%CI	P value
Age	0.98	0.96–0.99	0.003
Placebo group during the preceding RCT	1.9	1.3–2.8	0.001
Dry mouth	1.6	0.96–2.7	0.07
Adherence	1.0	0.6–1.7	0.98
Baseline fluid intake	1.0	1.0–1.0	0.39
Change in total fluid intake during the trial	1.0	1.0–1.0	0.62
Caffeine intake	1.0	1.0–1.0	0.87