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EFFECT OF FLUID MANAGEMENT ON FLUID INTAKE AND URGE INCONTINENCE IN A TRIAL FOR OVERACTIVE BLADDER IN WOMEN

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Abstract

Objectives—To explore whether instruction in fluid management resulted in changes in fluid intake and incontinence over a 10-week study period in women with urinary urge incontinence (UUI), as fluid management might be critical strategy in treating this condition.

Patients and Methods—In the Behavior Enhances Drug Reduction of Incontinence trial, women with predominant UUI were randomized to daily treatment with tolterodine or tolterodine combined with behavioral therapies among which were individualized instructions on fluid management. Patients in both groups received general fluid management instructions, while in the drug + behavior arm, those with excessive urine output (>2100ml/day) had additional individualized instruction during each of 4 study visits to learn behavioral strategies. Variables measured at baseline and at 10 weeks were: type of incontinence using the Medical, Epidemiological, and Social Aspects of Aging questionnaire, severity of incontinence by number of incontinence episodes based on a 7 day-diary, number of voids per 24h (F_{24}), urgency rating, 24h fluid intake (I_{24}) and 24 hr volume voided (V_{24}), volume average (V_{avg}), pad use, bothersomeness of UUI (Urogential Distress Inventory and Overactive Bladder questionnaire), and quality of life (Incontinence Impact Questionnaire-7, Short Form-12).

Results—Leak episodes per 24 hours, V_{24}, I_{24} and average urgency ratings all significantly decreased from baseline to 10 weeks ($p < 0.001$ for each). V_{avg} increased ($p < 0.001$), as did voids/L intake ($p = 0.01$). None of the changes in diary variable outcomes differed by treatment group after accounting for these changes between baseline and 10 weeks. In a multivariable model, treatment group was not associated with change in V_{24} from baseline to 10 weeks ($p=0.81$), but the difference in the number of accidents/diary day, F_{24}, I_{24} and average voids/day each were positively related with the change in V_{24} ($p<0.001$ for each). Patients had a response to fluid management instructions: the decrease in the percentage of women with a V_{24} >2100 ml between baseline and follow-up was statistically significant ($p= 0.01$ McNemar's test).

Conclusion—General fluid instructions can contribute to the reduction in UUI symptoms for women taking anticholinergic medications, but additional individualized instructions along with other behavioral therapies did little to further improve the outcome.

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Keywords

Overactive bladder; fluid management; women; urge; incontinence

Introduction

Overactive bladder (OAB) is a common condition marked by urinary urgency, frequency, nocturia, and urinary urge incontinence (UUI). While anticholinergic medication is the main pharmacologic intervention in these patients, fluid management is thought to be an important component in the treatment of OAB [1]. Although little is known about the effect of fluid management, women with UUI sometimes increase or decrease their fluid intake in an effort to self-treat their condition. In studies where treatment of UUI was assessed with a placebo-arm, improvement from keeping daily diaries recording fluids and voided volumes can be responsible for improvement rates as high as 30-35% [2] Furthermore, there is some evidence that even if patients are instructed to increase or decrease their fluid intake, compliance can be difficult[3]. Therefore, fluid management may be a critical strategy in the treatment of UUI, or possibly be an unhelpful suggestion to patients who are unlikely to benefit from this treatment. The aim of this planned ancillary analysis of a large randomized trial in UUI was to determine whether instruction in fluid management resulted in changes that could be detected over a 10-week study period.

PATIENTS AND METHODS

This was a planned ancillary analysis of the USA National Institutes of Health-sponsored trial termed as BE-DRI: Behavior Enhances Drug Reduction of Incontinence, and was conducted by the Urinary Incontinence Treatment Network, which consists of nine clinical centers, a biostatistical coordinating center, and is sponsored by the National Institute of Diabetes, Digestive and Kidney Disorders (NIDDK). This unique trial randomized women with predominant UUI to daily treatment with anticholinergic medications or anticholinergic medications combined with behavioral modifications, among which were specific fluid management instructions (appendix). The primary study aims of BE-DRI were to determine whether adding behavioral training will increase the number of women who can discontinue drug therapy and sustain a significant reduction of incontinence; to test whether the short-term effectiveness of drug therapy can be enhanced by combining it with behavioral training; and to determine the cost-effectiveness of combined therapy." [4] In this ancillary analysis, our objectives were fourfold: (1) to describe the change in bladder diary variables from baseline to 10 weeks (end of active study treatment);(2) Investigate whether the change in bladder diary variables from baseline to 10 weeks varied by treatment group, time and the interaction of the two; (3) Because particular interest lines in investigating the 24-hr volume (V_{24}), consider how variables affect the change in V_{24} from baseline to 10 weeks including change from baseline to 10 weeks in incontinence severity, number of pads used per week, degree of urgency, health-related quality of life (HRQL) and bother symptoms;(4) Consider the effect of the added fluid management instructions by comparing V_{24} at baseline and 10 weeks by groups voiding > or <2.1 L/24 h.

Participants were 307 community-dwelling women with pure or predominant UUI for at least 3 months. The Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire was used to define predominant UUI (urge symptom index > stress symptom index) [5], To be eligible for the trial, women must have had7 or more episodes of incontinence on a 7-day bladder diary, be clinically eligible for both drug and behavioral training, be able to complete study assessments (per clinician judgment), be available for 8 months of follow-up, and provide informed consent to participate. The primary study had 2

stages, the first of which consisted of 10 weeks of drug therapy with sustained-release tolterodine alone or combined with behavioral training (pelvic floor muscle exercise training, bladder control techniques, fluid management) [6]. The intervention effect at the end of active therapy (stage 1) was considered for this analysis. All participants received information on general measures to improve bladder control, including avoidance of excessive fluid intake. Subjects with excessive urine output (>2100 mL per day) in the behavioral + drug arm were given additional individualized instruction during each of four study visits, as part of learning behavioral strategies.

The type of UI was measured as a percentage for each of the two subtypes of UI, stress UI and UUI using the MESA questionnaire[5]. Agreement between the MESA questions and a clinician's assessment has been reported as 87% for women [5].

The severity of UI was measured using a bladder diary and was defined by the number of UI episodes recorded in a 7-day diary [7-9]. Additional diary measures at baseline and 10 weeks included the number of voids per 24 hours (F_{24}) and per night (F_N) averaged across all 7 diary days. Urgency was measured for each void using the International Urgency Severity Scale. [10](Participants also recorded fluid intake and urine output for the first two days of each 7-day diary, and 24 hour fluid intake (I_{24}), voided volume (V_{24}), minimum (V_{min}), maximum (V_{max}) and average voided volumes (V_{avg}) were calculated. Voids per Liter of intake (#/L), average urgency rating, and percent of accidents for which urgency was rated as severe based on day 1 of the diary were also considered.

V_{24} was defined as that for the first two diary days that women reported. Information from one diary day was used when two complete diary days were not available. The change in V_{24} from baseline to 10 weeks was defined as the V_{avg} at baseline minus the V_{avg} at 10 weeks. Thus, a positive change value corresponded to a person having a larger volume voided at baseline than at 10 weeks.

Pad use was measured by self-report; women were asked to estimate the number of pads they used in a week, both at baseline and 10 weeks.

Bothersomeness of UI symptoms was measured by the Urogenital Distress Inventory (UDI) [11] to assess the degree to which UI symptoms are troubling to women, and by the Overactive Bladder Questionnaire (OABq) [12]. Adequate validity, reliability and sensitivity to change have been reported by the authors. Specific HRQL was measured with a validated condition-specific instrument, the Incontinence Impact Questionnaire (IIQ) [12] to measure the impact of UI on various activities, roles, and emotional states. The Short-Form Health Survey (SF-12) was used to measure general health-related quality of life [13]

Sociodemographic variables included age and race/ethnicity. Side-effects were considered as four separate dichotomous variables: the presence/absence of dry mouth, constipation, blurred vision, and confusion/difficulty thinking clearly. Because of the documented association between satisfaction and treatment adherence, patient satisfaction was assessed with questions including "How satisfied are you with your progress?" and "Overall, do you feel that you are much better, better, about the same, worse or much worse?".

Summary statistics for the difference in bladder diary variables between baseline and 10 weeks were calculated using paired t tests for differences in bladder diary information between the time-points. For simplicity, only complete cases (those with information at both baseline and 10 weeks) were considered. Linear regression models were fitted to predict the change in diary variables from baseline to 10 weeks controlling for treatment group, time and the interaction of time and treatment group.

Multivariable linear regression models were fit to further investigate the relationship between change in V_{24} between baseline and 10 weeks controlling for other variables. Multivariable model development started by fitting separate models to predict V_{24} controlling for treatment group and each covariate. If a covariate reached statistical significance ($p < 0.05$) in the bivariate model, then it was considered in the multivariable modeling. When the final model was determined, model fitting procedures included calculation of R^2 and sensitivity analysis.

Covariates considered when modeling included age, race/ethnicity, treatment (drug only/ drug plus behavior), symptom bother (UDI), HRQL based on IIQ, SF-12, and OABq, diary data, UI severity based on the stress and urge scales of the MESA, satisfaction with treatment and with progress, and side-effects of drug.

In the models, standardized regression coefficients were calculated as the parameter estimates divided by the sample standard deviation of the change in V_{24} from baseline to 10 weeks divided by the sample standard deviation of each covariate. By standardizing the regression coefficients, we could compare the magnitude of each regression coefficient to ascertain which effect was the largest.

Fisher's exact tests were used to assess differences in independent proportions, and McNemar's test was used to test for paired proportion differences.

Results

The two treatment groups had similar baseline characteristics (Table I); Table 1 also compares the two groups for satisfaction and side effects after 10-weeks of treatment. The drug + behavior group was more satisfied with the treatment ($p = 0.03$) than the drug only group and possibly more satisfied with progress ($p = 0.08$).

For study Objectives 1 and 2: The interaction of time and treatment was significant when predicting the change in F_{24} from baseline to 10 weeks (Table II). There was also a significant interaction of time and treatment for V_{min}. Specifically, V_{min} increased from baseline to 10 weeks for both the drug and drug + behavior groups, but the increase was larger for the drug + behavior group.

Many of the diary variables changed significantly from baseline to 10 weeks, but did not vary by treatment (Table II). Leak episodes per 24 hours, V_{24}, I_{24} and average urgency ratings all significantly decreased from baseline to 10 weeks ($p < 0.001$ for each, Table II). V_{avg} increased ($p < 0.001$), as did #/L ($p = 0.01$). None of the changes in diary variable outcomes differed by treatment group after accounting for these changes between baseline and 10 weeks.

For Study Objective 3, when predicting the change in V_{24} from baseline to 10 weeks, treatment did not predict change ($p = 0.81$), but tthe number of accidents per diary day between baseline and 10 weeks, he difference in F_{24}, difference in fluid intake and the difference in the average number of voids per diary day all were positively related with the change in V_{24} ($p < 0.001$ for each). The R^2 value for the multivariable model was 0.72, meaning that over 70% of the variability in the change in V_{24} from baseline to 10 weeks was accounted for by the variables considered in the model. A plot of the estimate of the errors versus the predicted values looked random, indicating that the model fit was reasonable.

For Study Objective 4, there were 77/267 women who reported a V_{24} of > 2100ml at baseline, with nearly equal distribution by treatment group (40/135 drug only, 37/132 drug plus behavior; Fisher's exact test, $p = 0.79$). At 10 weeks, there were 46/227 women who

reported a V_{24} of > 2100 ml, with nearly equal proportions by treatment group (24/118 drug only, 22/109 drug plus behavior; Fisher's exact test, p > 0.99). The decrease in the percentage of women with a V_{24} > 2100ml between baseline and follow-up was statistically significant (P= 0.01, McNemar's test).

For the 181 women whose V_{24} was less than 2100 ml at 10 wks, the mean (SD, median, range) V_{24} was 1346 (409, 1350, 300-2100) mL. For the 46 women who reported on their diary a V_{24} > 2100 ml at 10 wks, the corresponding values were 2680 (539, 2595, 2115-4905) mL. Interestingly, the percentage of severe urgency ratings did not differ according to V_{24} status (<2100ml vs 2100 ml+) (two sample t test, p = 0.70).

Discussion

The aim of this 10 week (first phase) BE-DRI study was to examine the effect of the behavioral training and anticholinergic medication on outcome variables and to determine if there was a difference in these variables by treatment groups and over time. There was a significant reduction from baseline in the number of leakage episodes recorded in a 7-day diary in women on anti-cholinergic drug treatment. Not only did the leakage episodes decrease by 74% but the number of leakage episodes rated with urgency rated as severe dropped from 22 to 7%.

The leakage episodes decreased despite no significant change in intake and output variables as recorded on bladder diary. While the mean V_{24} of patients decreased by ~ 250 ml and the intake decreased similarly by ~ 200 ml, F_{24}, N_{24}, V_{avg}, V_{max} and #/L all remain unchanged. In addition, behavioral training did not affect any of the voiding diary measures nor did it appear to change fluid intake significantly even in women with excessive fluid consumption (> 2100 L/24 hours). One of the issues in treating patients with OAB and UUI is that its pathophysiology is not completely understood. Is it a behavioral problem or due to pathophysiological changes in the bladder? Many clinicians have advocated behavioral treatments to patients and have used voiding diaries to direct specific instruction on fluid intake, voiding frequency, and limiting fluid consumption in the evening. Some studies have suggested that women with OAB/detrusor overactivity have significantly lower mean bladder functional capacity and increased urinary frequency. [1415, 16]

In the present study, the baseline intake and bladder diary variables in women withUUI were not significantly different from asymptomatic women, as reported in other studies (Table 3) [15-18]suggesting that the problem is not behavioral or resulting from diminished bladder capacities. The V_{24} appears to be significantly higher in the last 3 studies in the table 3 [15, 16]than in the other two [17, 18]. This most likely represents the dramatic increase in fluid consumption in the USA; between 1977 and 1996, the average soft drink portion increased by 48% and the consumption of bottled water increased 908% [19, 20]. When discussing urinary volume it is critical that fluid intake is accounted for. One useful measure is to calculate the urinary frequency in terms of the #/L. In the present study, #/Lvoids was similar to that of asymptomatic American women. Of note, the side-effects were equally distributed in both groups. Although they were relatively high for mouth dryness and constipation, they apparently did not affect the reduction in fluid intake in both arms.

These findings support that there is a strong sensory component to UUI and that anticholinergic medications act through this mechanism. Despite insignificant changes in bladder capacities, #/L, fluid intake and urine output, women using anti-cholinergic drugs like tolterodine significantly reduced the number of leakage episodes, the average urgency rating, and the percent of severe leakage episodes. Consistent with neurological diseases, behavior changes including fluid management did little to change the pathophysiology,

although it may be perceived by the patient as helpful. Therefore, the additional benefit of behavioral therapy could be that despite the same average urgency ratings as the drug alone group, the drug + behavior group was better able to manage urgency and had fewer daily voids.

The strengths of the present study include diary data that had stringent quality control values in addition to a low rate of missing or incomplete bladder diaries. The diaries that were included in the study were 100% baseline and 88% at 10 weeks. In addition, the diary variables were well-distributed allowing us to use normal statistical tests, increasing the power to detect a statistically significant difference.

The study's weaknesses include only 2 days with a complete 24-hour intake and output measurements for each 7-day bladder diary. A records of ≥ 3 days would have been ideal but much more burdensome for the patients, Also, the decision for fluid management was set at a daily urine production of 2100 ml when we could have used the ICS definition of polyuria of 40ml/kg/day. Also, we chose not to investigate diary variables at 8 months, which was the endpoint of the primary study. Since the baseline and 10 week diary variables were not different between the treatment arms it is hard to imagine the benefit of an eight-month analysis. The variables of V_{24} and I_{24} changed from baseline to 10 weeks, but they did not vary with treatment arm, and thus are unlikely to change practice patterns.

In conclusion, UI is costly, contributes to depression, social isolation and sexual and relationship dysfunction. Among the several types of UI, UUI has the greatest impact on HRQL. Anticholinergic medications and behavior therapy have both been used as treatments to help women who have UUI symptoms. In this prospectively planned supplementary analysis of the BE-DRI study, we examined the 10-week effect of behavioral therapy in women who received anticholinergic therapy. There were equally significant reductions in leakage episodes and urgency severity in women who received behavioral therapy and those who did not. Changes in bladder diary and fluid intake also did not vary significantly between women who received behavioral therapy and those who did not, possibly because all women received basic fluid instruction. When all women were combined, we also found that the only change in bladder diary variables and fluid intake were V_{24} and I_{24}. Thus 10 weeks of behavior therapy does not appear to play an immediate and useful role in women who are taking anticholinergic medications and also appears to have minimal impact on fluid intake in this population.

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APPENDIX 1

Fluid management instructions

(All therapists received 2 days of centralized training and were certified using a case-based role-play with an expert observer. In one case they played the patient and in the evaluation case they were the therapist. The main points of counselling they were taught were to reinforce the instructions on the handout shown below. For the individualized instruction, at the first treatment visit the patient's output as recorded on their diary was reviewed with them and the relationship between intake and output explained. They were advised that normalizing their fluid intake would help to improve their incontinence. At each subsequent visit they were questioned on their progress in normalizing their fluid intake and helpful suggestions were given as necessary.

Normal fluid intake is 50 to 70 ounces (1oz = 30ml) of liquid each day. This means that each day, you should consume the equivalent of 6 to 8 eight-ounce glasses of liquids (any beverages and soups), much of which can be in the form of solid foods.

This should produce a healthy 40-50 ounces of urine in 24 hours. If you voided more than this volume on your diary, you may want to adjust your intake to produce more normal amounts of urine. People who work in hot climates or exercise heavily need more fluids because of loss through perspiration, but their urine output should still be approximately 40-50 ounces.

Spread out your consumption of liquids rather than consuming a lot at one time, and try to avoid fluids within a few hours of going to bed. Don't drink fluids overnight. If your urine output is less than 40 ounces in 24 hours, and cannot be explained by losses due to urine leakage, you may need to drink more fluids.

APPENDIX 2

Term nomenclature

V_{24}= Voided volume over 24 hours

F_{24}= Voiding frequency over 24 hours

F_D= Voiding frequency during day

F_N= Voiding frequency during night

I_{24}= Fluid intake over 24 hours

V_{max}= Maximum bladder volume

V_{min}= Minimum bladder volume

V_{avg}= Average bladder volume

#/L = number of voids/L intake

OAB = overactive bladder

(U)UI = urinary urge Incontinence

BE-DRI = Behaviour Enhances Drug Reduction of Incontinence

HRQL = health-related quality of life

MESA = Medical, Epidemiological, and Social Aspects of Aging;

UDI = Urogenital Distress Inventory; OAB, Questionnaire

IIQ, Incontinence Impact Questionnaire

SF-12, Short-Form Health Survey.

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Table I

Summary Demographics by treatment groups at baseline, and satisfaction and side-effects

Variable	Drug Only		Drug + Behavior		p-value
	N	Mean (SD) or Percentage	N	Mean (SD) or Percentage	
Age	153	58 (13)	154	55 (14)	0.16
Race/Ethnicity					0.22
White	85	56	105	68	
Black	35	23	22	14	
Hispanic	17	11	13	8	
Other	15	10	13	8	
Missing	1	<1	1	<1	
Symptom/HRQL					
UDI	153	119 (50)	154	122 (49)	0.54
IIQ	153	153 (100)	154	154 (99)	0.91
Physical Health	147	45 (12)	150	45 (11)	0.48
Mental Health	147	49 (10)	150	48 (11)	0.32
OAB-Q	153	62 (24)	154	62 (24)	0.86
Urge score (MESA)	153	11 (3.2)	154	11 (3.5)	0.22
Stress score (MESA)	153	10 (6.0)	154	11 (6.3)	0.27
Pad Use					0.51
None	41	27	42	27	
Mini-pads	34	22	39	25	
Full pads	66	43	54	35	
Diapers	8	5	14	9	
Missing	4	3	5	3	
Satisfaction and side-effects (comparing results after 10 weeks of treatment)					
Satisfaction with treatment					0.03
Much better	46	30	63	41	
Better	60	39	57	37	
Same	28	18	13	8	

Variable	Drug Only		Drug + Behavior		p-value
	N	Mean (SD) or Percentage	N	Mean (SD) or Percentage	
Worse	4	3	1	<1	
Much worse	0	0	0	0	
Missing	15	10	20	13	
Satisfaction with progress					0.08
Completely	55	36	71	46	
Somewhat	73	48	59	38	
Not at all	10	6	4	3	
Missing	15	10	20	13	
Side effects					
Blurriness	15	10	14	9	0.83
Confusion	16	10	14	9	0.69
Constipation	64	42	63	41	0.87
Dry mouth	114	75	103	67	0.14

Table II

Mean (SD) of diary variables at baseline and 10 week visits by treatment group.

Diary Variable (in mL)	Baseline		10 weeks		p-values		
	Drug	Drug + Behavior	Drug	Drug + Behavior	Treatment	Time	Interaction Time by Treatment
Leak episodes/24 hr	3.7 (2.6)	3.7 (2.6)	1.1 (2.8)	0.8 (2.8)	0.41	<0.001	0.31
F_{24}	7.3 (3.7)	7.1 (3.7)	7.8 (3.8)	6.9 (3.9)	0.046	0.41	0.02
F_N	1.1 (1.2)	1.0 (1.2)	1.2 (1.3)	1.0 (1.3)	0.11	0.77	0.24
V_{24}	1877 (991)	1836 (999)	1677 (1036)	1599 (1065)	0.50	<0.001	0.70
I_{24}	2020 (989)	1924 (982)	1794 (1026)	1723 (1023)	0.30	<0.001	0.76
V_{max}	380 (212)	387 (212)	377 (222)	374 (228)	0.93	0.40	0.64
V_{min}	86 (67)	88 (67)	99 (70)	117 (73)	0.08	<0.001	0.01
V_{avg}	197 (98)	201 (99)	210 (100)	223 (102)	0.43	<0.001	0.41
#/L	4.4 (4.5)	4.0 (4.5)	4.9 (4.8)	4.6 (4.7)	0.31	0.01	0.94
Average Urgency Rating	1.5 (0.6)	1.5 (0.6)	1.0 (0.7)	1.0 (0.8)	0.83	<0.001	0.55

TABLE III

Comparison of diary results women with UUI (baseline) to studies with asymptomatic women

	[17]	[18]	[16]	[15]	**Present**
Patient Symptoms	asymptomatic	asymptomatic	asymptomatic	asymptomatic	UUI
Diary Duration, days	2	7	1	3	2
N women	151	32	300	161	307
Age, mean (range)	43 (19–81)	61 (20-89)	40 (18-91)	48 (20-81)	56 (21-87)
Mean (SD)					
V_{24} (mL)	1,430 (487)	1,332 (349)	1,759	1,730	1,868 (883)
F_{24}	5.8 (1.4)	8.0 (2.4)	8.3 (2.4)	7.1 (1.9)	7.2 (3.2)
Vmax (mL)	460 (174)	277 (95)	362 (161)	514 (190)	386 (172)
Vavg (mL)	250 (79)	175 (47)	216 (87)	245 (91)	199 (88)
Vmin (mL)				81 (47)	87 (51)
I_{24} (mL)			1927		1969 (845)
#/L			4 (median)		4.2 (3.8)

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