Published in final edited form as:

J Urol. 2010 September ; 184(3): 1005–1010. doi:10.1016/j.juro.2010.05.031.

Effect of Weight Loss on Urinary Incontinence in Overweight and Obese Women: Results at 12 and 18 Months

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Abstract

Purpose—Initial weight loss improves urinary incontinence in overweight and obese women. In this study we examined the longer term effects of a weight loss intervention on urinary incontinence.

Materials and Methods—Overweight and obese women (mean $\pm$ SD age 53 ± 10 years) with 10 or more urinary incontinence episodes weekly were randomized to an 18-month behavioral weight loss intervention (226) or control group (112). Outcome measures were collected at 12 and 18 months.

Results—At baseline women had a mean body mass index of 36 ± 6 kg/m² and reported a mean of 24 ± 18 incontinence episodes weekly. Of the patients 86% completed 18-month measurements. The percent weight loss in the intervention group averaged 8.0%, 7.5% and 5.5% at 6, 12 and 18 months, respectively, vs approximately 1.5% in the control group (all values $p < 0.001$). Compared with controls at 12 months the intervention group reported a greater percent reduction in weekly stress urinary incontinence episodes (65% vs 47%, $p < 0.001$), and a greater proportion achieved at least a 70% decrease in weekly total and stress urinary incontinence episodes. At 18 months a greater proportion of women in the weight loss intervention group had more than 70%

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[†]Financial interest and/or other relationship with Jenny Craig, Inc.

[‡]Financial interest and/or other relationship with Xanodyne, University of California, San Francisco, Pfizer and American Geriatrics Society.

[§]Financial interest and/or other relationship with Pfizer, Astellas and Johnson & Johnson.

Study received local institutional review board approval.

Clinical Trial Registration NCT00091988 (www.clinicaltrials.gov).

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improvement in urge incontinence episodes but there were no significant differences between the groups for stress or total urinary incontinence. The intervention group also reported greater satisfaction with changes in urinary incontinence than the control group at 6, 12 and 18 months.

Conclusions—Weight loss intervention reduced the frequency of stress incontinence episodes through 12 months and improved patient satisfaction with changes in incontinence through 18 months. Improving weight loss maintenance may provide longer term benefits for urinary incontinence.

Keywords

urinary incontinence; obesity; weight loss; behavior therapy; randomized controlled trial

Urinary incontinence is a significant health problem for women, affecting more than 13 million women in the United States and profoundly impacting quality of life.^{1–4} Epidemiological studies suggest that obesity is a strong risk factor for incontinence^{1,5–7} and several small studies, most of them uncontrolled, have suggested that weight loss may decrease the frequency of UI.^{8–10} Recently we reported the 6-month results of a randomized clinical trial in 338 overweight and obese women showing a 47% decrease in mean weekly total incontinence episodes in the intervention group vs 28% in the control group, primarily due to a reduction in stress incontinence episodes.¹¹ After the initial 6-month treatment period women continued to participate in the weight loss intervention or control group for an additional 12 months. We examined whether the beneficial effects of the behavioral weight reduction intervention on UI were maintained at 12 and 18 months.

MATERIALS AND METHODS

Subjects

A total of 338 participants were recruited in Providence, Rhode Island and Birmingham, Alabama between July 2004 and April 2006. Eligibility criteria included being at least 30 years old, having a BMI of 25 to 50 kg/m², reporting at least 10 UI episodes on a 7-day voiding diary at baseline and agreeing not to initiate new treatments for incontinence or weight reduction during the trial. Details of the study design, inclusion and exclusion criteria, and the primary results at 6 months have been reported previously.¹¹

Design

Eligible participants were randomly allocated in a 2:1 ratio to a 6-month intensive behavioral weight loss program (intervention, 226) or a structured education program (control, 112) and followed through 18 months. Participants assigned to the weight loss program received a 6-month, group based behavioral weight loss intervention, after which they underwent a second randomization with their group to a motivationally focused maintenance program (110) or a standard skills based maintenance approach (111). The secondary randomization allowed the comparison of 2 approaches to weight loss maintenance. The primary aim was to compare the long-term effects of the intervention and control groups, and the secondary aim was to compare the effects of motivation and skills based maintenance programs on changes in continence. All participants signed a consent form approved by the local institutional review board for the 18-month trial.

Interventions

Structured education program (control group)—Participants randomized to the control group were offered 7, 1-hour group education sessions (months 1, 2, 3, 4, 6, 9 and 15). These sessions followed a structured protocol, and provided general information about

weight loss, physical activity and healthy eating. Groups were led by the same therapists who conducted the weight control program. Participants also were given a self-help incontinence behavioral treatment booklet with instructions for improving bladder control, but no further information was provided pertaining to incontinence at the sessions or followup visits.¹²

Behavioral weight loss program (intervention group)—Participants assigned to the weight loss intervention received the same self-help incontinence booklet as the control group with no further attention to incontinence during the program. Participants in the intervention met in groups of 10 to 15, with 1-hour sessions held weekly for 6 months and then biweekly for 12 months.¹¹ Groups were led by 2 therapists and followed a structured protocol. The program was modeled after those used in the Diabetes Prevention Program¹³ and Look AHEAD (Action for Health in Diabetes),^{14,15} and was designed to produce an average loss of 7% to 9% of initial body weight within 6 months. The program included a calorie and fat restricted diet of 1,200 to 1,800 kcal daily, depending on initial weight, with less than 30% of calories from fat. To improve adherence participants were given sample meal plans and vouchers for meal replacement products (Slim-FastTM). Participants were encouraged to gradually increase physical activity to 200 minutes per week of brisk walking or activities of similar intensity and were given pedometers to monitor their daily steps. Behavior modification techniques, including self-monitoring of diet and exercise, were emphasized throughout the program.¹¹

After 6 months participants in the weight loss intervention were randomized to a motivationally focused or skills based weight maintenance program. Both maintenance programs reinforced the same weight loss maintenance messages related to diet and exercise, but focused on the refinement of behavioral skills or motivation for weight loss maintenance.¹⁶

Assessments

Assessments were completed at baseline, and at 6, 12 and 18 months by staff who were masked to the intervention assignment. The figure shows the number of participants at each assessment. Weight and height were measured at baseline with participants wearing street clothes, without shoes, using a calibrated digital scale (Tanita® BWB 800) and wall mounted stadiometer. Physical activity was calculated using the Paffenbarger Physical Activity Questionnaire.¹⁷

Urinary incontinence was assessed with a 7-day voiding diary.¹⁸ Participants were trained to record the time of each void and each incontinence episode, and to identify each episode as stress (involuntary loss of urine associated with coughing, sneezing, straining or exercise), urge (loss of urine associated with a strong need or urge to void) or other. Voiding diaries were reviewed by assessment staff. As a secondary outcome we assessed 24-hour involuntary urine loss with a standardized pad test.¹⁹ Participants were also asked whether, compared to baseline, incontinence episodes were less frequent (yes, no, uncertain), leakage was smaller (yes, no, uncertain) and whether leakage was improved (5-point scale), and were asked to rate overall satisfaction with changes in incontinence (5-point scale).²⁰ Demographic characteristics as well as medical, behavioral and incontinence histories were ascertained using self-reported questionnaires.

Statistical Methods

The primary analyses compared the intervention and control groups on UI frequency. This comparison used generalized estimating equations negative binomial models with robust standard errors to account for correlation between baseline, and 6, 12 and 18-month

outcomes, adjusting for clinical site. We also elected a priori to compare the proportion of women in the intervention and control groups who reported at least a 70% reduction in incontinence episode frequency from baseline using logistic regression models. The 70% criterion was used because it has been reported as a threshold for improvement in patient satisfaction.²⁰

Since attrition in weight loss studies commonly masks weight regain we used adaptations of multiple imputation for the incontinence and weight outcomes. For both groups we imputed missing incontinence frequencies as if the participant had been assigned to the control group in which average weight loss was minimal but there was some reduction in incontinence frequency. We imputed missing weights assuming that dropouts in both groups on average returned to baseline weight.¹¹ Summary effect estimates and standard errors were calculated using standard methods for multiply imputed data.²¹ Using the observed within-subject correlation of the baseline and followup frequencies as well as the observed scale factor for overdispersion, the sample size provided 80% power in 2-sided tests with a type I error of 5% to detect differences of 41% and 44% in comparisons of intervention and control, and 48% and 52% in comparisons of motivation and skills based maintenance in the reduction of UI frequency from baseline to 12 and 18-month followup visits.

We also assessed the percent of women who reported that overall leakage was better or much better and those who reported being moderately or very satisfied with the changes in incontinence (score of 1 or 2 on a 5-point scale). All statistical analyses were performed using SAS® Version 9.2 with $p < 0.05$ considered statistically significant.

RESULTS

Characteristics of participants in the intervention and control groups were similar at baseline with mean age 53 (± 10) years, BMI 36 (± 6) kg/m², total weekly UI episodes 24 (± 18) and 19% black (table 1). The groups were also similar in terms of other baseline characteristics and there were no significant differences between women who were subsequently randomized to skills based or motivational weight loss maintenance programs.¹¹

Assessments were attended by 94%, 90% and 86% of women at 6, 12 and 18 months, respectively, with no significant differences between treatment groups (see figure). Participants who dropped out of the study had a higher number of baseline UI episodes than completers (28 ± 19 vs 24 ± 18 , respectively, $p = 0.03$), but dropouts in the intervention and control groups did not differ. Other baseline variables including age, race, BMI and type of incontinence were not significantly associated with retention at 6, 12 or 18 months.

As shown in table 2 women in the intervention group had a significantly greater weight loss than those in the control group at 12 (-7.5% and -1.7% , $p < 0.001$) and 18 months (-5.5% and -1.6% , $p < 0.001$). At 12 months women in the intervention group reported a greater percent reduction in weekly stress incontinence episodes than those in the control group (-66% vs -45% , $p < 0.001$) and reported a nonsignificant trend toward greater percent reduction in total UI episodes (-57% vs -45% , $p = 0.08$). Although both groups continued to show large decreases in weekly incontinence episode frequency from baseline, differences between the groups for total and stress incontinence episodes were no longer significant at 18 months. There were no differences between the groups for mean change in 24-hour involuntary urine loss at any point, and no differences between the skills based and motivation based maintenance groups. At 12 months a greater proportion of women in the intervention group than in the control group achieved at least a 70% reduction in total (46% vs 31%, $p < 0.01$) and stress incontinence episodes (64% vs 48%, $p = 0.01$) with a trend for urge incontinence (47% vs 35%, $p < 0.07$) (table 3). At 18 months the only significant

difference between the groups was in the proportion of participants achieving at least a 70% reduction in urge incontinence episodes (47% intervention vs 34% control, $p = 0.03$). There were no differences between the skills based and motivation based maintenance groups in the proportion achieving at least a 70% reduction in incontinence episode frequency (data not shown).

The self-report data suggest a more sustained benefit of the intervention on participant satisfaction with incontinence (table 4). A greater percentage of participants in the intervention group than in the control group reported improvement in incontinence and indicated being moderately or very satisfied with the overall change in incontinence.

DISCUSSION

We previously reported that overweight and obese women in a weight loss intervention had significantly greater reductions in stress and total incontinence episodes than those in a control group at 6 months. We now demonstrate that decreased stress incontinence episode frequency was maintained at 12 months with a trend toward continued reduction in total incontinence episode frequency. However, at 18 months there were no statistically significant differences in the reduction of weekly incontinence episode frequency between the groups despite a substantial difference in weight loss and greater participant satisfaction with improvements in UI.

The lifestyle intervention appeared to be effective in reducing stress incontinence episodes at 6 and 12 months but had little effect on urge incontinence episodes. It has been suggested that obesity, specifically central adiposity, may contribute to incontinence by increasing intra-abdominal pressure, which in turn leads to increased bladder pressure and urethral mobility.^{8,9,11} Reducing this cascade via weight reduction might lead to greater reductions in stress incontinence than in urge episodes. Further study of the mechanisms related to the effects of weight reduction on incontinence may help explain this difference.

The effect of the lifestyle intervention on reductions in stress and total incontinence episodes, relative to the control group, was greater at 6 and 12 months than at 18 months. This finding may relate to the fact that there was a 5.8% difference in weight loss between the groups at months 6 and 12, but only a 3.9% difference at 18 months. Increasing the magnitude of the weight loss or preventing weight regain may increase the beneficial effects on incontinence. However, it is important to note that the lack of significant differences in incontinence between the groups at 18 months did not result from relapses in incontinence in the intervention group, but rather from increasingly large reductions in the control group. The improvements in UI reported by the control group may reflect regression to the mean, increased awareness of bladder habits or measurement error due to repeated self-report assessments. There was no evidence that use of the incontinence booklet or differences in baseline incontinence episodes between dropouts in the intervention and control groups explained these improvements in the control group.

While the voiding diaries were the primary outcome measure for this trial, the observation that women in the intervention group reported sustained benefits relative to controls in their perceived frequency and magnitude of leakage, and greater overall satisfaction with changes in incontinence through 18 months, is an important finding supporting the use of lifestyle intervention as a first line treatment for overweight and obese women with UI. Greater perceived improvements in incontinence in the intervention group may be due to the weight loss, and overall satisfaction with health and appearance. Alternatively these self-report items may capture information about incontinence that is not reflected in the voiding diary or pad weights.

The lifestyle intervention used in this study, which included diet, physical activity and behavioral strategies, resulted in an average weight loss from baseline of approximately 8% at 6 and 12 months, and 5% at 18-month followup. These weight losses were similar to those seen in Look AHEAD, a clinical trial of lifestyle intervention in overweight and obese participants with type 2 diabetes, and exceeded the results of several other trials, perhaps due to the inclusion of free meal replacement products, the high physical activity goal, the motivation afforded by the condition of incontinence and the ongoing contact provided throughout the 18 months of followup.^{22–24} Difficulties with the long-term maintenance of weight loss are typical of lifestyle interventions, perhaps reflecting decreasing adherence to lifestyle interventions over time, and support the need for further research to improve weight loss maintenance.

Strengths of this study include the randomized design, excellent retention, multidimensional approach to assessing impact on UI, conservative imputation approach used for missing data and the collection of outcomes by staff masked to treatment assignment. Limitations include the fact that the control group reported marked decreases in incontinence episodes over time that could not readily be explained. Urodynamic measures were conducted only on a subset of women at baseline and 6 months. Participants in this study had a BMI of 36 kg/m², and may have been particularly motivated and adherent. Therefore, their results may not accurately reflect weight loss and changes in UI that would be realized in the general population.

CONCLUSIONS

A behavioral weight loss intervention was more effective than an educational control program in decreasing stress related UI through 12 months, but the benefits at 18 months were more limited. Thus, lifestyle interventions should be considered the first line treatment for overweight and obese women reporting stress incontinence.

Acknowledgments

Supported by Grants U01DK067860, U01DK067861 and U01 DK067862 from the National Institute of Diabetes and Digestive and Kidney Diseases, as well as by the Office of Research on Women's Health.

Abbreviations and Acronyms

BMI	body mass index
UI	urinary incontinence

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Figure.
Study flow diagram

Table 1

Baseline participant characteristics

	Controls	Pooled Wt Loss	Skills Based Wt Loss Maintenance	Motivation Based Wt Loss Maintenance
No. pts	112	226	113	113
Mean pt age ($\pm$ SD)	53 ($\pm$ 10)	53 ($\pm$ 11)	52 ($\pm$ 10)	53 ($\pm$ 11)
No. race (%):				
White	91 (81)	171 (76)	80 (71)	91 (81)
Black	17 (15)	47 (21)	28 (25)	19 (17)
Other	4 (4)	8 (4)	5 (4)	3 (2)
No. education greater than high school (%)	93 (83)	200 (88)	97 (85)	103 (91)
Mean kg wt ($\pm$ SD)	95 ($\pm$ 16)	98 ($\pm$ 17)	100 ($\pm$ 19)	95 ($\pm$ 15)
Mean kg/m ² BMI ($\pm$ SD)	36 ($\pm$ 5)	36 ($\pm$ 6)	37 ($\pm$ 6)	36 ($\pm$ 5)
Mean incontinent episodes/wk ($\pm$ SD):				
Total	24 ($\pm$ 18)	24 ($\pm$ 18)	25 ($\pm$ 18)	24 ($\pm$ 18)
Stress	10 ($\pm$ 10)	9 ($\pm$ 11)	9 ($\pm$ 10)	9 ($\pm$ 13)
Urge	13 ($\pm$ 15)	14 ($\pm$ 14)	14 ($\pm$ 13)	14 ($\pm$ 15)
Mean gm 24-hr involuntary urine loss ($\pm$ SD)*	33 ($\pm$ 48)	31 ($\pm$ 41)	30 ($\pm$ 35)	29 ($\pm$ 42)

$p > 0.05$ for the comparison between weight loss and control groups, and for the comparison between the skills based and motivation based weight loss maintenance groups for all variables in the table.

* Measured by 24-hour increase in pad weight.

Table 2

Percent changes in weight and urinary incontinence episodes

	Estimate of % Change (95% CI)					Wt Loss vs Control p Value	Skills vs Motivation p Value
	Control	Pooled Wt Loss	Skills Based Wt Loss		Motivation Based Wt Loss Maintenance		
			Maintenance				
6 Mos:							
Wt *	-1.6 (-2.7, -0.4)	-8.0 (-9.0, -7.0)	-8.0 (-9.6, -6.3)	-8.0 (-9.2, -6.7)	<0.001	0.99	
Total UI episodes/wk †	-28 (-41, -13)	-47 (-54, -40)	-42 (-50, -31)	-52 (-61, -41)	0.01	0.14	
Stress UI episodes/wk ‡	-33 (-50, -9)	-58 (-67, -46)	-54 (-67, -38)	-63 (-74, -48)	0.02	0.37	
Urge UI episodes/wk ‡	-26 (-44, -3)	-42 (-51, -32)	-34 (-44, -22)	-47 (-60, -29)	0.14	0.21	
24-Hr involuntary urine loss * ‡	-36 (-52, -15)	-45 (-53, -36)	-37 (-49, -21)	-53 (-62, -41)	0.37	0.06	
12 Mos:							
Wt *	-1.7 (-3.2, -0.2)	-7.5 (-8.6, -6.4)	-7.5 (-9.0, -5.9)	-7.6 (-9.2, -5.6)	<0.001	0.92	
Total UI episodes/wk †	-45 (-56, -32)	-57 (-63, -50)	-56 (-63, -48)	-58 (-67, -46)	0.08	0.82	
Stress UI episodes/wk ‡	-45 (-59, -27)	-66 (-71, -59)	-66 (-72, -58)	-66 (-75, -53)	<0.001	0.99	
Urge UI episodes/wk ‡	-48 (-63, -29)	-50 (-59, -39)	-48 (-60, -32)	-52 (-65, -35)	0.87	0.67	
24-Hr involuntary urine loss * ‡	-53 (-64, -39)	-58 (-62, -46)	-51 (-61, -39)	-63 (-71, -54)	0.49	0.09	
18 Mos:							
Wt *	-1.6 (-3.4, 0.7)	-5.5 (-6.7, -4.3)	-5.5 (-7.5, -3.6)	-5.5 (-7.1, -3.9)	-0.001	1.00	
Total UI episodes/wk †	-55 (-65, -43)	-62 (-67, -55)	-59 (-66, -50)	-65 (-72, -57)	0.3	0.29	
Stress UI episodes/wk ‡	-62 (-73, -48)	-69 (-76, -61)	-66 (-75, -52)	-73 (-80, -63)	0.32	0.29	
Urge UI episodes/wk ‡	-49 (-64, -28)	-56 (-64, -46)	-53 (-63, -40)	-60 (-70, -46)	0.46	0.42	
24-Hr involuntary urine loss * ‡	-52 (-65, -35)	-55 (-62, -46)	-49 (-60, -36)	-60 (-68, -50)	0.77	0.16	

* Using multiple imputation for missing values in mixed linear regression models to measure the effect of treatment on percent change from baseline.

[†] Using multiple imputation for missing values in repeated measures negative binomial models adjusted for clinic.

[‡] Estimated from 24-hour increase in pad weight log transformed.

Table 3

Women reporting a 70% or greater improvement in weekly UI episodes

	% Control (95% CI)	% Wt Loss (95% CI)	p Value
6 Mos:			
Total	22 (19, 27)	41 (37, 45)	<0.001
Stress	34 (28, 40)	51 (46, 59)	0.01
Urge	29 (24, 35)	41 (37, 45)	0.04
12 Mos:			
Total	31 (27, 37)	46 (40, 51)	0.01
Stress	48 (55, 41)	64 (69, 60)	0.01
Urge	35 (29, 40)	47 (41, 52)	0.07
18 Mos:			
Total	40 (35, 45)	46 (41, 51)	0.28
Stress	62 (57, 67)	61 (56, 66)	0.92
Urge	34 (29, 40)	47 (43, 52)	0.03

Multiple imputation used for missing values in logistic regression models to measure the effect of treatment on a 70% reduction in UI frequency.

Table 4

Positive changes in UI

	% Control	% Wt Loss	p Value *
6 Mos:			
Incontinent episodes are less frequent	53	73	<0.001
Urine leakage is now smaller	37	57	0.001
Overall leakage is better or much better	54	76	<0.001
Moderately or very satisfied with change in UI	47	76	<0.001
12 Mos:			
Incontinent episodes are less frequent	58	74	0.007
Urine leakage is now smaller	44	63	0.002
Overall leakage is better or much better	68	75	0.20
Moderately or very satisfied with change in UI	57	76	0.001
18 Mos:			
Incontinent episodes are less frequent	57	69	0.05
Urine leakage is now smaller	47	63	0.01
Overall leakage is better or much better	62	75	0.02
Moderately or very satisfied with change in UI	59	75	0.01

Complete case results presented with 313 participants at 6 months, 298 at 12 months and 291 at 18 months completing the satisfaction questionnaire.

* Chi-square test.