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WEIGHT LOSS: A NOVEL AND EFFECTIVE TREATMENT FOR URINARY INCONTINENCE

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Abstract

Purpose—We evaluated the effect of weight loss on urinary incontinence (UI) in overweight and obese women.

Materials and Methods—A randomized, controlled clinical trial was conducted among overweight and obese women experiencing at least 4 UI episodes per week. Women were randomly assigned to a 3-month liquid diet weight reduction program (24 in the immediate intervention group) or a wait-list delayed intervention group (24 in the wait-list control group). Participants in the wait-list control group began the weight reduction program in month 3 of the study. All women were followed for 6 months after completing the weight reduction program. Wilcoxon tests were used to compare intergroup differences in change in weekly UI episodes and quality of life scores.

Results—A total of 48 women were randomized and 40 were assessed 3 months after randomization. Median (with 25% to 75% interquartile range [IQR]) baseline age was 52 years (IQR 47 to 59), weight was 97 kg (IQR 87 to 106) and UI episodes were 21 weekly (IQR 11 to 33). Women in the immediate intervention group had a 16 kg (IQR 9 to 20) weight reduction compared with 0 kg (IQR −2 to 2) in the wait-list control group ($p < 0.0001$). The immediate intervention group experienced a 60% reduction (IQR 30% to 89%) in weekly UI episodes compared with 15% (IQR −9% to 25%) in the wait-list control group ($p < 0.0005$) and had greater improvement in quality of

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life scores. Stress ($p = 0.003$) and urge ($p = 0.03$) incontinent episodes decreased in the immediate intervention vs wait-list control group. Following the weight reduction program the wait-list control group experienced a similar median reduction in weekly UI episodes (71%). Among all 40 women mean weekly UI episodes decreased 54% (95% CI 40% to 69%) after weight reduction and the improvement was maintained for 6 months.

Conclusions—Weight reduction is an effective treatment for overweight and obese women with UI. Weight loss of 5% to 10% has an efficacy similar to that of other nonsurgical treatments and should be considered a first line therapy for incontinence.

Keywords

urinary incontinence; obesity; diet therapy; weight loss; female

More than 13 million Americans, including 25% of reproductive age women and up to 50% of postmenopausal women, are affected by urinary incontinence. Weight is an identified risk factor for urinary incontinence, with each 5-unit increase in body mass index (BMI) associated with a 60% to 100% increased risk of daily incontinence.¹⁻³ More than 50% of American women are overweight (BMI 25 to 30 kg/m²) or obese (BMI 30 kg/m² or greater) and the prevalence of obesity is increasing by almost 6% yearly.⁴ Obesity directly contributes to more than 300,000 deaths per year, is associated with medical comorbidities including heart disease, diabetes, cancer and depression, and adversely affects quality of life.^{4,5}

Since weight is a modifiable risk factor for incontinence, weight reduction may be an effective treatment for incontinence. Evidence indicates that massive weight loss (45 to 50 kg) improves incontinence in morbidly obese women after bariatric surgery.^{6,7} In a prospective cohort study of overweight and obese incontinent women, those achieving a weight loss of 5% or greater had at least a 50% reduction in incontinence frequency ($p = 0.03$).⁸ To determine if urinary incontinence improves after weight loss in overweight or obese women, we conducted this randomized, controlled clinical trial to compare incontinence improvement between groups randomized to a weight reduction program or wait-list control.

METHODS

Participants

Participants were recruited from a consecutive sample of women meeting eligibility criteria, and included women 18 to 80 years old with BMI between 25 and 45 kg/m², urinary incontinence for at least 3 months and at least 4 incontinent episodes in a 7-day urinary diary. Prior incontinence therapies (including surgery) were not exclusions from study eligibility. Participants currently using incontinence therapy were included in the study but were asked to not change treatment during study. Exclusion criteria included pregnancy, urinary tract infection, significant medical condition, pelvic cancer, neurological condition possibly associated with incontinence, interstitial cystitis or potential inability to complete the study. This study was approved by the University of California, San Francisco and the California Pacific Medical Center (San Francisco, California) Institutional Review Boards.

Study design and interventions

Following completion of a 7-day urinary diary, eligible women underwent a baseline evaluation. Demographic characteristics, medical and incontinence histories, and quality of life were ascertained using self-reported questionnaires. Gynecological and physical examinations were performed. A volunteer sample of 23 women underwent standardized urodynamic evaluation at baseline and 3 months to evaluate the objective effect of weight reduction on the lower urinary tract.⁹

Women were then randomized to either immediate (immediate intervention, 20) or delayed (wait-list control, 19) enrollment in the weight reduction program. Women in the immediate intervention group began the weight reduction program and continued for 3 months. Women in the wait-list control group had no intervention for 3 months and then entered the weight reduction program. Women were followed for 6 months after completing the weight reduction program.

Intervention

The weight reduction intervention was a 3-month intensive group based medical and behavioral weight loss program. Participants were placed on a standard low calorie liquid diet (800 kcal per day or less), encouraged to increase physical activity gradually until they were exercising 60 minutes daily, and were taught standard cognitive and behavioral skills to assist in modifying eating and exercise habits. Participants met weekly in group sessions led by a nutritionist, exercise physiologist or behavioral therapist and followed a structured protocol.

Outcome measures

A 7-day voiding diary was used to measure the primary outcome of percent change in number of weekly urinary incontinent episodes.^{10,11} The diary included frequency of voids and incontinent episodes classified by clinical type (urge, stress, other) along with time of occurrence (waking and bedtime). It has good to excellent reliability for total, stress and urge incontinence episodes.¹⁰ Detailed instructions on diary completion were given by the research staff, and simple instructions and a sample of a completed diary were included with each diary. Weight of the women in light clothing was measured to the nearest 0.5 kg using a calibrated standard balance beam scale. Standing height was measured in millimeters with a wall mounted Harpenden stadiometer. Body mass index was calculated as weight in kg divided by the square of height in meters. Waist circumference was measured in centimeters at the minimum circumference, usually the umbilicus, between the iliac crests and lower ribs.

Quality of life measures included the Incontinence Impact Questionnaire (IIQ), Urogenital Distress Inventory (UDI) and Short Form 36 (SF-36).^{12,13} The IIQ assesses incontinence specific quality of life and the UDI quantifies incontinence symptom bother. Both measures are scored on a continuous scale (IIQ range 0 to 400, UDI range 0 to 300) with higher scores indicating greater effect on quality of life. Urodynamic evaluation included cystometrogram (sitting at 45 degrees of recline), urethral pressure profile and pressure flow voiding studies. Measurements conformed to the recommendations of the International Continence Society.⁹

Randomization and blinding

Participants were randomized with equal probability to the immediate intervention or the wait-list control arm. Randomization was stratified by type of incontinence, either stress only and stress predominate mixed incontinence (mixed stress incontinence) or urge only and urge predominate mixed incontinence (mixed urge incontinence). Treatment within strata was assigned in randomly permuted blocks of 4. The randomization codes were prepared by computer generated random numbers and placed in sealed, opaque envelopes numbered consecutively with the randomization sequence number. When study eligibility was confirmed, the next numbered envelope was selected and the envelope was opened to reveal the study group assignment. While participants could not be blinded to their group assignment, research investigators assessing outcomes and statistical analysts were blinded to treatment status.

Statistical analyses

The chi-square and Wilcoxon tests were used as appropriate to check for baseline differences between the immediate intervention and wait-list control groups. Wilcoxon tests were then

used to assess intergroup differences in percent changes in continuous primary and secondary study outcomes from baseline to the end of the intervention. This analysis was by intent to treat without regard to adherence to the weight loss program or achieved weight loss. To examine sensitivity to the imbalance in age at baseline, we used age adjusted linear regression models to compare percent changes from baseline to 3 months. The 40 women with 3-month outcomes provided 80% power to detect an intergroup difference of 40% to 45% improvement in incontinence frequency, which was the magnitude of improvement observed in a prospective cohort study with a similar population and intervention.⁸

In supplementary analyses the chi-square and Wilcoxon tests were used to compare baseline characteristics of women included in the primary analysis to those of women who did not complete the first 3 months of followup. The association of weight loss and change in urodynamic measures was examined using the Spearman correlation coefficient. In addition, we used linear mixed models to assess the effects of the weight reduction program in the combined immediate intervention and wait-list control groups (cohort study). In these analyses data from the end of the 3-month randomized trial were used as the baseline for the control group, and right skewed outcomes were log transformed to achieve approximate normality. We compared mean values of study outcomes before and after the intervention, and checked for trends in the posttreatment period, as well as for intergroup differences at comparable times and differences in the magnitude of the changes. Finally we assessed the correlation between post-intervention increases in weight and incontinence frequency, both estimated by the least squares slope of the 2 or 3 measurements for each participant.

RESULTS

A total of 48 women were recruited and randomized between January 1999 and March 2000. The flow of participants through each stage of the study is shown in figure 1. Demographic and clinical characteristics of all participants were similar in the 2 groups at randomization except for age (table 1). There were no differences at baseline between the groups in severity or type of incontinence, quality of life scores or findings on urogynecological examination (data not presented). Baseline weight and incontinent frequency were similar at baseline for the 2 groups. The 40 women who completed the first 3 months of the trial were similar in demographic and clinical characteristics to the 8 women who did not complete the first 3 months of the trial.

Randomized, controlled trial

The 20 women in the immediate intervention group achieved a median (with 25% to 75% interquartile range [IQR]) weight loss of 16 kg (IQR 9 to 20) compared with 0 kg (IQR -2 to 2) in the 19 in the wait-list control group ($p < 0.0001$, table 2). This corresponded with a BMI reduction from 35 (IQR 31 to 40) to 28 kg/m² (IQR 26 to 34) or 16% in the immediate intervention group and no change in the wait-list control group ($p < 0.0001$).

Women in the immediate intervention group had a median reduction in weekly incontinent episodes of 60% (mean $\pm$ standard deviation 51% $\pm$ 49%) compared with a median of 15% (mean 5% $\pm$ 42%) in the wait-list control group ($p < 0.0005$, table 2). In the immediate intervention group 16% (3) women were 100% improved (dry), 37% (7) were at least 75% improved and 58% (11) at least 50% improved in weekly incontinence frequency. In contrast 10% (2) women in the wait-list control group were at least 50% improved ($p = 0.003$) and the remaining participants had less than 50% improvement in weekly incontinence frequency.

Stress ($p = 0.003$) and urge ($p = 0.03$) incontinent episodes decreased in the immediate intervention vs wait-list control group. There was no change in diurnal or nocturnal micturition frequency in either group after the intervention (data not presented). Women in the immediate

intervention group experienced improvements in IIQ and UDI scores, as well as the SF-36 Physical Component Score (table 2). Primary results were unchanged in sensitivity analyses using linear regression models with and without adjustment for age.

Urodynamic study outcomes

At baseline the immediate intervention and wait-list control groups had similar urodynamic measurements, and all measures were within the normal range, except that genuine stress incontinence, detrusor instability and/or low Valsalva leak point pressure may have been observed.⁹ At 3 months urodynamic findings were similar between the 2 groups and no change was observed from baseline to 3 months in either group. However, we observed significant correlations between weight change and changes in urodynamic findings, including decreased initial intravesical pressure (Spearman $r = 0.52$, $p = 0.01$), decreased intravesical pressure at maximum capacity ($r = 0.62$, $p = 0.001$) and increased Valsalva leak point pressure ($r = 0.57$, $p = 0.03$).

Cohort study

We also evaluated outcomes among all participants at 3, 6 and 9 months after initiation of their weight reduction program. Following the weight reduction program the wait-list control group experienced reductions similar to those of the immediate intervention group in weight and weekly incontinent frequency. For all outcomes of interest, changes from baseline to followup were statistically significant and sustained (table 3, fig. 2).

The reductions in weight ($p = 0.04$) and BMI ($p = 0.07$) were larger among wait-list controls than in the intervention group. In addition, weight and BMI increased during followup (both $p < 0.0001$) but these increases were not associated with concurrent post-intervention changes in incontinence frequency ($p = 0.45$). For the other end points patterns were similar in the 2 groups, and there were no statistically significant temporal trends in the overall means between 3 and 9 months.

Six months after completing the weight reduction program (9 months), 18% (7) of women were 100% improved, 35% (14) were at least 75% improved and 50% (20) at least 50% improved in weekly incontinence frequency. Among women achieving a clinically feasible weight loss of 5% or greater, 58% (21 of 36) experienced reduction in incontinence frequency of 50% or greater, compared with 25% (1 of 4) women achieving less than 5% weight loss ($p = 0.001$). Similarly 63% (12 of 19) of women who lost 3% or greater in waist circumference experienced 50% or greater reduction in incontinence frequency compared with 5% (1 of 21) achieving less waist circumference loss ($p < 0.0005$). In a 2-predictor logistic model of this end point, reduction in waist circumference ($p = 0.02$) appeared to explain the effect of reduction in BMI ($p = 0.17$).

DISCUSSION

In this randomized, controlled trial, women assigned to a weight reduction program were more likely to experience markedly improved incontinence and quality of life at 3 months. Moreover, 50% reductions in incontinence frequency were observed among women who lost as little as 5% to 10% of baseline weight. This is equivalent to a woman 5 feet 6 inches tall who weighs 200 pounds (BMI 31.4 kg/m²) losing 10 to 20 pounds (BMI 29.8 to 28.2 kg/m²), and is a reasonable goal for many overweight and obese women.¹⁴ Therefore, weight reduction is a clinically feasible treatment option for incontinence. In the cohort study we observed sustained improvement in urinary incontinence and quality of life for 6 months after weight reduction. We found a 50% to 60% reduction in weekly incontinent episodes with weight loss, which is comparable to the improvement observed with other behavioral therapies and with

pharmacological therapy.¹⁵ Like other behavioral therapies, supervised weight reduction is safe and has few side effects.

Overweight and obese women are at significantly increased risk for morbidities and mortality.⁴ Weight loss of 5% to 10% improves hypertension, hyperglycemia and hyperlipidemia, reduces the risk of type 2 diabetes, and results in improved mood and quality of life.^{14,16} The observation that weight reduction is an effective treatment for incontinence may help motivate women to lose weight and, since the prevalence of incontinence, overweight and obesity are so high, weight reduction for improved incontinence could have a dramatic impact on public health.⁴

While the mechanism of obesity exacerbating incontinence is unknown, it is hypothesized that excess body weight increases abdominal pressure which, in turn, increases bladder pressure and urethral mobility leading to stress urinary incontinence.^{6,17} As in prior studies we observed improvement in stress incontinence with weight reduction.^{6,17} Interestingly we also observed improvement in urge incontinence after weight loss. It is possible that increased abdominal pressure causes or exacerbates detrusor instability and results in urge incontinence.

We observed significant correlations between weight reduction and changes in bladder pressures that promote continence.^{2,6,8} Our clinical and urodynamic findings suggest that the treatment effect of weight reduction on incontinence is due to lower bladder pressure. In this study reduction in waist circumference and, therefore, pressure on the bladder were independent predictors of improved incontinence following weight reduction.

The primary intervention in our study was an aggressive low calorie liquid diet program which was chosen because it produces rapid and extensive weight loss. While this diet intervention may have affected incontinence outcomes, measures of incontinence were done when women were on a solid, not liquid, diet. We do not expect the weight loss method to affect the incontinence outcome. Since the weight reduction program included education on diet, behavioral modification and exercise, women were likely to have different dietary and exercise habits after completing the program. The effects of dietary composition, fluid consumption and exercise may affect incontinence but the direction of the effect is uncertain (ie these factors may decrease or increase incontinence frequency). We observed a difference in age between women randomized to the immediate and delayed weight loss groups. Since this was a blinded randomization, these differences were due to chance and their effects on the outcome of this trial are unknown.

CONCLUSIONS

Weight reduction of even 5% to 10% is an effective treatment for overweight and obese women with urinary incontinence. In addition, improvements in incontinence and quality of life were maintained for 6 months following weight loss. Weight reduction is a novel treatment for urinary incontinence with wide-ranging impact on personal and public health, and should be considered a first line, nonsurgical intervention for urinary incontinence.

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Fig. 1.
Flow of participants through study

FIG. 2.

Mean BMI and incontinence frequency by treatment group and time in cohort study. Outcomes among all participants are evaluated at 3, 6 and 9 months after initiation of weight reduction program. Data from end of 3-month randomized trial were used as baseline for wait-list control group. BMI increased during followup ($p < 0.0001$ for both groups) but increases were not associated with concurrent post-intervention changes in incontinence frequency ($p = 0.45$).

Table 1
Demographic and clinical characteristics of the 48 randomized participants

	Immediate Intervention Group		Waist-List Control Group		p Value [*]
Demographics					
Median age, (range)	50.5	(46–54)	57.5	(50–62)	0.006
No. race (%):					
White	18	(90)	17	(85)	1.00
Other	2	(10)	3	(15)	
Body habitus					
Median kg wt (range)	99	(87–107)	95	(80–105)	0.51
Median kg/m ² BMI (range)	34	(32–40)	36	(32–38)	0.77
No. kg/m ² BMI (%):					
25–Less than 30	2	(8)	4	(16)	
30–Less than 35	11	(46)	5	(21)	
35–Less than 40	7	(29)	11	(46)	
40–Less than 45	4	(17)	4	(17)	
Median cm waist circumference, (range)	106	(98–114)	104	(101–111)	0.28
Medical history					
Median parity (range)	1	(0–2)	0	(0–2)	0.29
No. menopausal (%) [†]	8	(40)	13	(65)	0.11
No. self-reported health status good or better (%) [†]	18	(90)	17	(85)	1.00
Incontinence history					
Median yrs incontinence symptoms (range)	5	(2–10)	7	(3–11)	0.19
No. using pads or protection (%)	16	(68)	18	(78)	0.37
No. urinary incontinence treatment (%) [†] :					
Medication	1	(5)	3	(15)	0.60
Surgery	1	(5)	3	(15)	0.60
Incontinence severity:					
Median incontinent episodes/wk (range) [†]	21	(11–33)	25	(11–30)	0.49
No. moderate (5–10 episodes/wk) (%)	5	(21)	3	(13)	0.70
No. severe (more than 10 episodes/wk) (%)	19	(79)	20	(87)	
No. incontinence type (%):					
Urge alone	3	(12)	2	(9)	0.40
Mixed urge predominate	9	(38)	11	(48)	
Stress alone	3	(12)	0	(0)	
Mixed stress predominate	9	(38)	10	(43)	

Values are expressed as median (25% to 75% interquartile range) or number (%). Percentages may not sum to 100 due to rounding.

^{*} Categorical variables are based on chi-square tests and continuous variables are based on t tests or the Wilcoxon test where appropriate.

[†] These variables included only the participants who completed the first 3 months of the trial.

Table 2
Median weight, urinary incontinence and quality of life measurements at baseline and 3 months

		Median (25%–75% interquartile range)						
		Baseline	p Value	After Treatment		% Improvement*		p Value
Wt (kg):								
Immediate intervention	99	(86–109)	0.42	84	(71–91)	16	(9–20)	<0.0001
Wait-list control	94	(80–101)		96	(82–102)	0	(–2–2)	
Waist circumference (cm):								
Immediate intervention	108	(102–115)	0.28	96	(85–107)	8	(6–16)	0.001
Wait-list control	104	(101–110)		104	(100–112)	0	(–3–3)	
Total incontinent episodes/wk:								
Immediate intervention	21	(11–33)	0.49	4	(2–28)	60	(30–89)	0.0005
Wait-list control	25	(11–30)		17	(13–29)	15	(–9–25)	
Stress incontinent episodes/wk:								
Immediate intervention	8	(2–13)	0.48	0	(0–4)	92	(66–100)	0.003
Wait-list control	8	(3–15)		8	(1–15)	–5	(–33–63)	
Urge incontinent episodes/wk:								
Immediate intervention	8	(4–20)	0.24	2	(0–10)	70	(16–100)	0.03
Wait-list control	7	(2–13)		5	(3–14)	11	(–69–67)	
IIQ score:								
Immediate intervention	109	(53–143)	0.69	37	(11–86)	45	(19–82)	0.01
Wait-list control	99	(72–164)		89	(56–136)	2	(–11–31)	
UDI score:								
Immediate intervention	158	(142–192)	0.18	104	(67–122)	33	(19–53)	<0.0001
Wait-list control	200	(128–233)		195	(156–228)	–3	(–22–7)	
SF-36 physical component score:								
Immediate intervention	46	(42–51)	0.28	55	(49–58)	19	(0–30)	0.003
Wait-list control	47	(44–51)		47	(41–50)	1	(–9–7)	
SF-36 mental component score:								
Immediate intervention	48	(45–50)	0.19	48	(46–49)	5	(–15–16)	0.09
Wait-list control	48	(45–54)		51	(48–54)	0	(–0–0)	

* Positive value indicates improvement and negative value indicates worsening for each variable.

Table 3

Weight, urinary incontinence and quality of life measurements in all participants of cohort study at 3, 6 and 9 months

No. Participants	Mean ($\pm$ SD)				p Value *
	Baseline	3 Mos	6 Mos	9 Mos	
No. participants	40	37	31	31	
Wt (kg)	95 ($\pm$ 14)	79 ($\pm$ 13)	81 ($\pm$ 14)	84 ($\pm$ 14)	0.0001
BMI (kg/m^2)	33 ($\pm$ 5.4)	29 ($\pm$ 4)	30 ($\pm$ 5)	31 ($\pm$ 5)	0.0001
Waist circumference (cm)	106 ($\pm$ 10)	94 ($\pm$ 13)	93 ($\pm$ 12)	96 ($\pm$ 12)	0.0001
Weekly incontinent episodes	24 ($\pm$ 16)	11 ($\pm$ 14)	12 ($\pm$ 14)	12 ($\pm$ 16)	0.0001
IIQ	106 ($\pm$ 63)	63 ($\pm$ 59)	63 ($\pm$ 6)	53 ($\pm$ 50)	0.0001
UDI	176 ($\pm$ 54)	120 ($\pm$ 66)	123 ($\pm$ 57)	111 ($\pm$ 56)	0.0001
SF-36, physical component score	46 ($\pm$ 8)	54 ($\pm$ 6)	53 ($\pm$ 9)	53 ($\pm$ 7)	0.0001
SF-36, mental component score	50 ($\pm$ 5)	48 ($\pm$ 4)	48 ($\pm$ 6)	48 ($\pm$ 4)	0.04

* p Value for contrast between baseline and followup.