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### Permalink

<https://escholarship.org/uc/item/3k79n3c4>

### Journal

Investigative Urology, 199(1)

### ISSN

0021-0005

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### Publication Date

2018

### DOI

10.1016/j.juro.2017.07.087

Peer reviewed



# A Behavioral Weight Loss Program and Nonurinary Incontinence Lower Urinary Tract Symptoms in Overweight and Obese Women with Urinary Incontinence: A Secondary Data Analysis of PRIDE

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**Purpose:** We sought to determine whether a behavioral weight reduction intervention would improve nonurinary incontinence lower urinary tract storage symptoms at 6 months, including urinary frequency, nocturia and urgency, compared to a structured education program serving as the control group among overweight and obese women with urinary incontinence.

**Materials and Methods:** PRIDE (Program to Reduce Incontinence by Diet and Exercise) was a randomized clinical trial performed in 338 overweight or obese women with urinary incontinence. Participants were randomized, including 226 to 6-month behavioral weight loss intervention and 112 to the control group. All participants received a self-help behavioral treatment booklet to improve bladder control. On this secondary data analysis we examined changes in nonurinary incontinence lower urinary tract storage symptoms from baseline to 6 months and the impact of treatment allocation (intervention vs control), weight loss and physical activity.

**Results:** Nonurinary incontinence lower urinary tract storage symptoms were common at baseline, varying from 48% to 62%. In the 2 groups combined women experienced significant improvement in nocturia, urgency and International

### Abbreviations and Acronyms

- BMI = body mass index
- I-PSS = International Prostate Symptom Score
- LUTS = lower urinary tract symptoms
- PAS-P = Paffenbarger Physical Activity Score
- PRIDE = Program to Reduce Incontinence by Diet and Exercise
- UI = urinary incontinence

Accepted for publication July 18, 2017.

No direct or indirect commercial incentive associated with publishing this article.

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

Supported by National Institute of Diabetes and Digestive and Kidney Diseases Grants K24 DK080775 06 (LLS), U01 DK067861 and U01 DK067862, the Office of Research on Women’s Health, and Kevan and Anita Del Grande.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health.

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† Financial interest and/or other relationship with UpToDate.

**Editor’s Note:** This article is the third of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 312 and 313.

Prostate Symptom Score at 6 months (all  $p < 0.001$ ). However, lower urinary tract storage symptom outcomes at 6 months did not differ between the intervention and control groups. Similarly no difference was observed in the amount of weight lost (5% or greater vs less than 5%) or physical activity (1,500 kcal or greater expenditure per week compared to less than 1,500 kcal).

**Conclusions:** Lower urinary tract storage symptoms were common among overweight and obese women with urinary incontinence. The prevalence decreased significantly after 6 months independent of treatment group assignment, amount of weight lost or physical activity. These improvements may have been due to self-help behavioral educational materials, trial participation or repeat assessment of symptoms.

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**Key Words:** urination disorders, lower urinary tract symptoms, obesity, female, weight loss

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THE association of obesity and UI in women<sup>1-3</sup> and the beneficial effect of weight loss on UI<sup>4,5</sup> have been reported. Obesity also has a strong positive association with nonUI LUTS, including daytime urinary frequency, nocturia and urinary urgency.<sup>6,7</sup> NonUI LUTS produce a significant adverse effect on quality of life, increase the risk of hip fracture,<sup>8</sup> reduce work productivity<sup>9</sup> and cost more than \$20 billion annually to treat.<sup>1,10</sup>

Interestingly obese women may be more bothered by nonUI LUTS than nonobese women, possibly related to lack of mobility.<sup>11</sup> Several small studies have shown that increased physical activity<sup>12</sup> and surgically induced weight loss<sup>13</sup> improve nonUI LUTS. If effective, weight loss and increased physical activity together are attractive intervention options to improve nonUI LUTS as they are noninvasive and have been shown to improve other important adverse health outcomes.<sup>14</sup> However, the effect of a weight loss and physical activity intervention on nonUI LUTS remains uncertain.

We previously performed a randomized clinical trial of a behavioral weight reduction intervention in overweight and obese women with UI, which resulted in reduced episodes of UI compared to a structured health education control intervention.<sup>4</sup> In this secondary data analysis we compared the effects of this behavioral weight reduction intervention with the control intervention on changes in nonUI LUTS. We hypothesized that the intensive behavioral weight reduction intervention would improve nonUI LUTS compared to the control intervention.

## MATERIALS AND METHODS

The PRIDE study was a randomized clinical trial that evaluated the effect of a lifestyle and behavior change intervention for weight loss compared to a structured health education program in overweight or obese women with UI. The design and the results of the study have been described previously.<sup>4</sup>

### Participants

Women were eligible for study if they were at least 30 years old, had a BMI of 25 to 50 kg/m<sup>2</sup> and at baseline

reported 10 or more UI episodes in a 1-week voiding diary (fig. 1). Women were excluded from study if they reported receiving medical therapy for UI or weight loss within the previous month, had a current urinary tract infection, or 4 or more urinary tract infections in the previous year, had a history of UI related to a neurological or functional cause, underwent previous surgery for UI, experienced pregnancy or parturition in the previous 6 months or had diabetes requiring medical therapy or hypertension uncontrolled by medication.

Between July 2004 and April 2006, 338 women from the local communities of Providence, Rhode Island and Birmingham, Alabama were recruited for the trial. Participants were randomized using a ratio of 2:1 to an intensive 6-month behavioral weight loss program or to a structured 4-session education program (control group). Institutional review board approval was obtained at the coordinating center and at each clinical site (Brown University, Providence, Rhode Island and University of Alabama at Birmingham, Birmingham, Alabama) and each participant provided written informed consent.

### Interventions

The intensive weight loss program was designed to produce an average weight loss of 7% to 9% of initial body weight by 6 months. At 6 months women in the intervention group had a mean weight loss from baseline of 8% (7.8 kg) compared with 1.6% (1.5 kg) in the control group ( $p < 0.001$ ). Women attended weekly 1-hour, expert led group sessions focused on nutrition, exercise and behavior change. This program included a decreased calorie diet (1,200 to 1,500 kcal per day) with a goal of providing no more than 30% of calories from fat. Participants were also encouraged to increase physical activity such as brisk walking or similar intensity exercise until they were active for at least 200 minutes per week. Women assigned to the control group participated in 4, 1-hour educational sessions during the 6 months, which included general information on weight loss, physical activity and healthy eating habits.

At randomization all participants were given a self-help behavioral treatment booklet with instructions for improving bladder control.<sup>15</sup> The booklet provides basic information about UI and step-by-step instructions on completing voiding diaries, pelvic floor muscle exercises, and techniques to prevent stress and urge UI, and control urinary urgency. UI or nonUI LUTS were not discussed further in the control group or the weight loss intervention group.

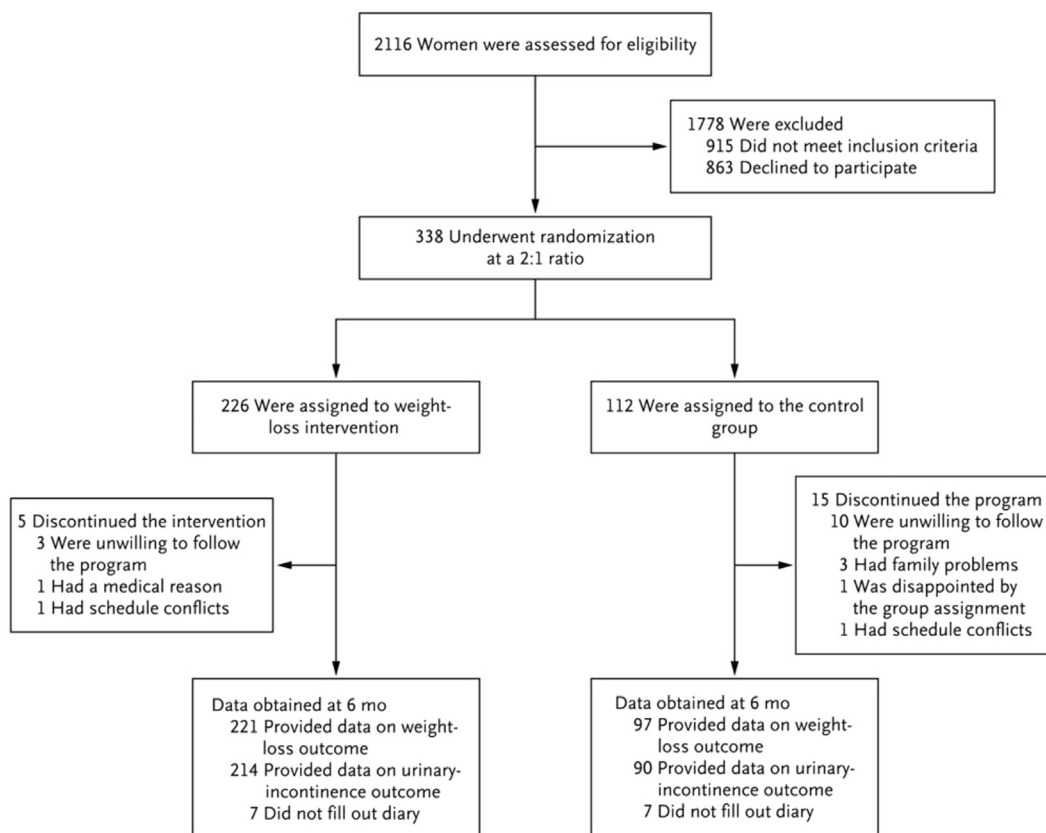


Figure 1. PRIDE study participants flow diagram

## Outcomes

All demographics and outcomes were obtained at baseline and after 6 months of study participation. NonUI LUTS, including daytime urinary frequency, nocturia and urinary urgency, were measured by a participant completed 7-day voiding diary and self-reported questionnaires completed at baseline and 6 months. Using standard definitions we defined daytime urinary frequency as urinating 8 or more times during waking hours, nocturia as urinating 2 or more times per night and urinary urgency as experiencing a sudden strong urge to urinate without leakage at least weekly.<sup>16,17</sup> I-PSS, which has been validated for use in women, was administered to obtain the composite outcome of nonUI LUTS.<sup>18</sup> Women with I-PSS 8 or greater were defined as having nonUI LUTS.<sup>19</sup> Incident cases of nonUI LUTS were defined as those that developed de novo during the 6-month study period. Remission was defined as cases in which nonUI LUTS were present at baseline but not present at 6 months.

The demographic and health characteristics assessed included age, race, education level, relationship status, body mass index in kg/m<sup>2</sup>, type 2 diabetes not requiring medical therapy, current tobacco and alcohol use, menopause status, hysterectomy history and parity. PAS-P was applied to measure physical activity with an estimated expenditure of greater than 1,500 kcal per week considered high activity.<sup>20</sup>

## Statistical Analysis

We categorized the percent of weight loss into 2 groups, including less than 5% plus increase vs weight loss 5% or greater. We categorized physical activity levels into high and low groups, including the less than 1,500 kcal per week PAS-P vs the 1,500 kcal or greater per week PAS-P. We then examined changes in nonUI LUTS from baseline to 6 months in the 2 randomized groups by comparing the symptom change in the treatment groups (intervention vs control), weight loss and physical activity categories.

The chi-square test was applied to compare the proportion of women with nonUI LUTS at baseline and 6 months. Logistic regression was done to assess the odds of remission and new symptom onset at 6 months stratified by nonUI LUTS, treatment group, weight loss and physical activity level.

We performed sensitivity analysis to determine whether improvement in stress, urge and mixed UI correlated with improvement in urinary frequency, urgency, nocturia and I-PSS. Stress UI remission was marginally associated with urinary frequency remission (Pearson  $r = 0.16$ ,  $p = 0.06$ ). UI remission was marginally associated with urinary frequency (Pearson  $r = 0.15$ ,  $p = 0.06$ ) and urgency remission (Pearson  $r = 0.14$ ,  $p = 0.06$ ), and associated with improvement in I-PSS (Pearson  $r = 0.21$ ,  $p = 0.005$ ). No other significant correlations were observed.

The study had 80% power to detect a 15% to 17% difference between the 2 treatment groups, assuming a type 1 error rate of 0.05 and a comparison group failure rate between 18% and 52%. Analyses included only participants who completed baseline and followup assessments, representing 90% of randomized participants.

## RESULTS

There were no significant differences in selected clinical and demographic baseline characteristics between women assigned to the weight loss program and those in the control group (table 1). In the overall study cohort mean  $\pm$  SD age was  $53 \pm 11$  years, mean BMI was  $36 \pm 5$  kg/m<sup>2</sup> and 77.5% of participants were white. In the intervention group 64 women (30%) vs 67 controls (75%) had less than 5% weight loss at 6 months. In the intervention group 123 women (56%) and 69 controls (73%) had metabolized less than 1,500 kcal per week. NonUI LUTS were common at baseline with 48% of women reporting daytime frequency, 50% reporting nocturia, 62% reporting urgency and 62% reporting I-PSS 8 or greater. In the overall cohort the prevalence of nonUI LUTS decreased significantly from baseline to 6 months for nocturia (51% to 41%,  $p = 0.009$ ), urinary urgency (62% to 43%,  $p < 0.001$ ) and I-PSS greater than 8 (62% to 37%,  $p < 0.001$ ) but not for daytime frequency (51% to 46%,  $p = 0.221$ ).

There were no significant differences between women randomized to the intervention vs the control group for all nonUI LUTS outcomes, including frequency, nocturia, urinary urgency and I-PSS greater than 8 (table 2). The comparative improvement across treatment designation in frequency, nocturia and urgency ranged from  $-1\%$  to  $-6\%$  and favored the intervention group. However, none of these comparisons reached statistical

**Table 1.** Baseline demographic characteristics of participants by treatment group

	Intervention	Usual Care
No. participants	226	112
Mean $\pm$ SD age	$53 \pm 10$	$53 \pm 10$
No. race (%):		
Nonwhite	55 (24)	21 (19)
White	171 (76)	91 (81)
No. education beyond high school (%)	200 (89)	93 (83)
No. relationship status (%):		
Married or living with partner	166 (74)	90 (80)
Single, widowed or divorced	57 (26)	22 (20)
Mean $\pm$ SD BMI (kg/m <sup>2</sup> )	$36 \pm 6$	$36 \pm 5$
No. diabetes (%):		
Current (%)	9 (4)	1 (1)
No. current (%):		
Smoking	14 (6)	4 (4)
Alcohol use	154 (68)	74 (66)
No. postmenopausal (%)	115 (55)	62 (58)
No. hysterectomy (%)	70 (31)	29 (26)
Mean $\pm$ SD parity	$2 \pm 1$	$2 \pm 1$

No significant difference between groups.

**Table 2.** NonUI LUTS at baseline and 6 months by treatment group, and weight loss and exercise at 6 months

	No. Daytime Frequency (%) <sup>*</sup>	No. Nocturia (%) <sup>†</sup>	No. Urinary Urgency (%)	No. I-PSS 8 or Greater (%)
<i>Overall</i>				
Intervention:				
Baseline	109 (48)	112 (50)	138 (61)	137 (61)
6 Mos	93 (43)	83 (38)	89 (40)	76 (35)
Control:				
Baseline	63 (56)	61 (54)	71 (63)	72 (64)
6 Mos	47 (52)	47 (48)	46 (47)	40 (41)
% Net effect	-1	-6	-5	-3
<i>Wt loss</i>				
Intervention (less than 5%, no change + increase):				
Baseline	72 (50)	73 (51)	87 (61)	89 (62)
6 Mos	56 (43)	58 (41)	66 (46)	57 (40)
Control (5% or greater):				
Baseline	100 (51)	100 (51)	122 (63)	120 (62)
6 Mos	84 (49)	72 (41)	69 (39)	59 (34)
% Net effect	5	0	-9	-6
<i>Paffenbarger Physical Activity Score</i>				
Intervention (less than 1,500 kcal/wk):				
Baseline	93 (50)	99 (53)	117 (63)	117 (63)
6 Mos	79 (44)	73 (39)	87 (47)	72 (39)
Control (1,500 kcal/wk or greater):				
Baseline	62 (50)	58 (47)	69 (56)	72 (59)
6 Mos	57 (48)	51 (41)	44 (36)	39 (32)
% Net effect	4	8	-4	-3

Numbers in groups differ based on followup completeness, net effect compares percent improvement in nonUI LUTS by treatment group, 6-month weight loss and 6-month exercise, and no net effect comparisons were statistically significant.

\* Eight or greater voids during waking hours.

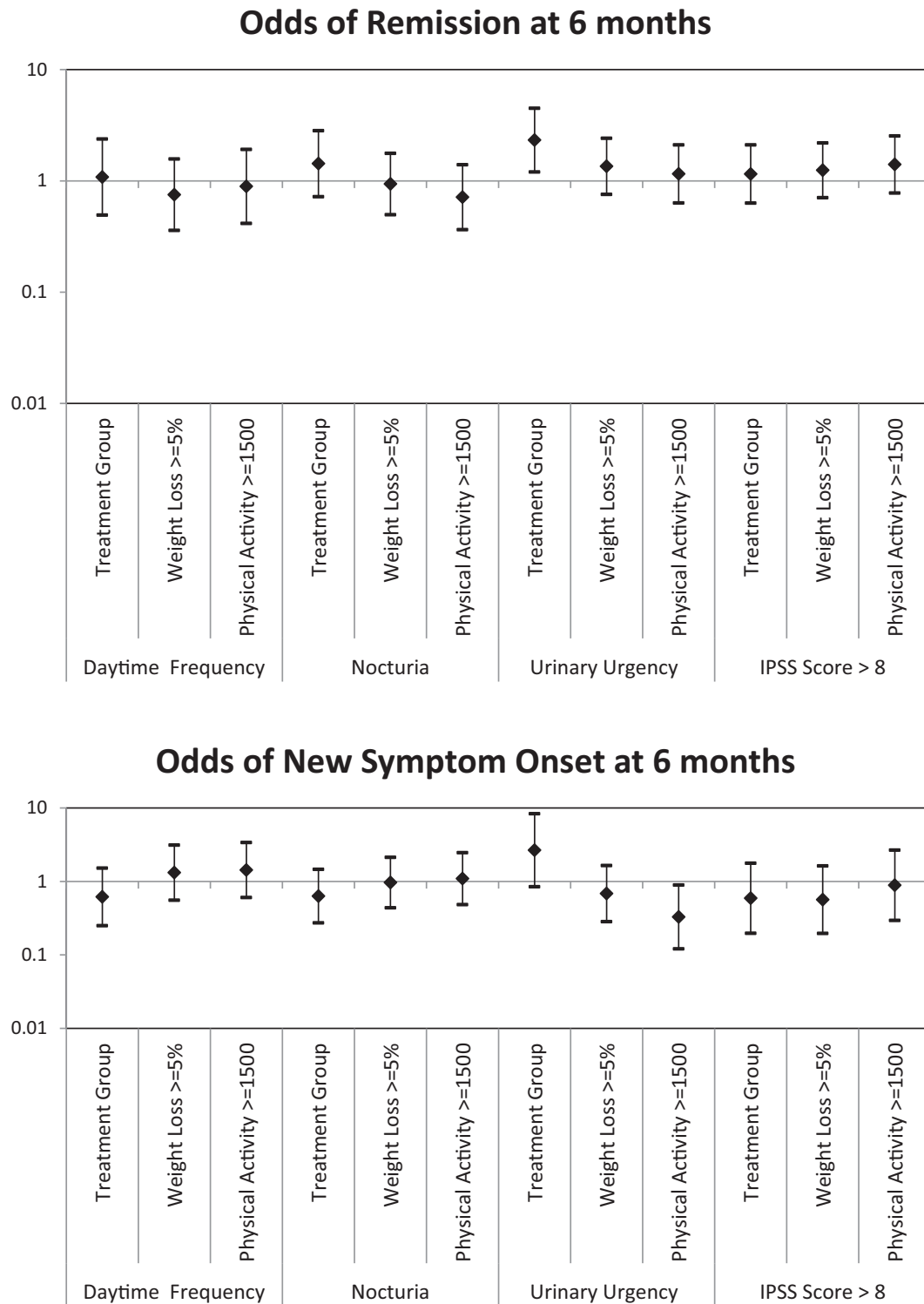
† Two or greater voids at night.

significance and the percent of improvement was modest.

The impact of the amount of weight loss on nonUI LUTS was examined in the entire cohort after 6 months of study participation (table 2). There were no significant differences in nonUI LUTS outcomes in participants who lost less than 5% body weight or had no change or weight gain compared to those who reduced more than 5% of body weight.

The impact of weekly physical activity on nonUI LUTS was examined by comparing women who reported engaging in activity which expended less than vs greater than 1,500 kilocalories per week (table 2). No significant differences were seen between the groups with high vs low activity.

In addition to changes in prevalent cases of nonUI LUTS, we examined the odds of nonUI LUTS remission or new onset (incident) cases based on treatment group, percent weight loss and activity level (fig. 2). Randomization to the intervention group, the percent of weight lost and the physical activity level did not influence remission or incident



**Figure 2.** Tornado plots show remission and new onset incident nonUI LUTS ORs stratified by treatment group, weight loss achieved and physical activity performed.

nonUI LUTS cases. However, randomization to the intervention group increased the odds of remission in participants with urgency (OR 2.3, 95% CI 1.2–4.4).

## DISCUSSION

Regardless of treatment assignment, at 6 months the overall cohort reported significant improvement in multiple nonUI LUTS domains.

Improvement in self-reported nonUI LUTS was independent of treatment assignment and the amount of weight loss or physical activity. This suggests that factor(s) associated with trial participation may have improved nonUI LUTS outcomes. However, the study was not designed to determine whether the self-help behavioral UI treatment intervention received by the 2 groups, completion of the voiding diary or some other factor may have been responsible for reducing the frequency of nonUI LUTS.

Previous studies have shown an association of LUTS with obesity and physical inactivity.<sup>21,22</sup> Previously we found that women enrolled in PRIDE who were randomized to the intensive lifestyle intervention group had significantly reduced UI. At 6 months the mean weekly number of overall UI episodes had decreased by 47% in the intervention group compared with 28% in the control group ( $p = 0.01$ ). Compared with the control group the intervention group experienced a greater decrease in the frequency of stress UI episodes ( $p = 0.02$ ).<sup>4</sup>

In contrast to the UI results, we now report that women assigned to the weight loss intervention did not experience a significantly greater reduction in nonUI LUTS than the control group. Previous longitudinal research demonstrated the dynamic nature of LUTS, including UI and overactive bladder,<sup>23</sup> which may in part explain the improvement seen in the overall cohort. In that prospective, population based study spanning 16 years the incidence of UI and overactive bladder was 21% and 20% while the remission rate was 34% and 43%, respectively. Our results are similar with incidence in 20% of cases and remission in approximately 40%. A systematic review of longitudinal studies revealed a similar dynamic progression of incidence and remission of urinary symptoms while also demonstrating that many patients experienced sustained symptoms with time.<sup>24</sup>

Few groups have examined the effect of an exercise and weight loss intervention on nonUI LUTS. In a study of 21 obese elderly Korean women who underwent a cardiovascular and resistance exercise intervention daily for 52 weeks the participants experienced significant improvements in nonUI LUTS from baseline.<sup>12</sup> At 1 year the group had lost a mean of 2.6 kg while frequency, nocturia and urgency improved with a 35%, 27% and 7% reduction in prevalence, respectively. In the current study women in the weight loss intervention also experienced improvement in lower nonUI LUTS from baseline to 6-month followup, including 5% for

frequency, 12% for nocturia and 21% for urgency. However, as noted these improvements did not significantly differ from those reported by the control group.

In a cohort study 1 year after bariatric surgery 47 women lost a mean of 37.4 kg.<sup>25</sup> They reported significant improvement in overall BFLUTS (Bristol Female Lower Urinary Tract Symptom) score,<sup>26</sup> nocturia and urgency. However, 15% of participants had worse scores at 1 year. There was no correlation between improvement and the degree of weight lost but there was a correlation between LUTS improvement and insulin resistance improvement. Interestingly improvement in urinary symptoms was typically achieved by 6 weeks postoperatively before most of the weight loss was obtained and the symptoms remained stable until 1 year. Lack of a control group in these other studies made it difficult to interpret these results.

The strengths of this study are that more than 20% of the cohort was nonwhite and subjects were recruited from 2 communities, likely increasing generalizability. In addition, the behavioral intervention was well designed and achieved desired weight loss goals. The cohort was well characterized with patient reported outcomes using validated measures.

Several limitations of this research should be noted. All participants in PRIDE had UI at baseline but not all had nonUI LUTS, which may have limited our ability to detect a change in LUTS in women without UI. Furthermore, study participants were clinical trial volunteers and may have differed from the general population. The control group underwent 4 healthy lifestyle educational sessions, which was likely more extensive than what overweight women in the general population who present with LUTS would receive. This may have decreased the impact of the intervention between the groups.

This study was a post hoc, secondary analysis of a randomized clinical trial with the sample size selected to assess changes in UI. It was underpowered to detect changes in nonUI LUTS. Also, we made multiple comparisons, potentially increasing the risk of type 1 error.

## CONCLUSIONS

NonUI LUTS were common among overweight and obese women with UI. The prevalence decreased significantly after 6 months independent of treatment group assignment, amount of weight lost or physical activity. Improvements

in overweight and obese women with nonUI LUTS could have been due to the provision of written self-help behavioral educational

materials, increased attention to LUTS due to trial participation and/or repeat assessment of symptoms.

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## EDITORIAL COMMENT

In the PRIDE study, a randomized, prospective, intensive behavioral therapy program, the effect of weight loss by exercise and diet on urinary incontinence was studied in women (reference 4 in article). The control arm received a short instructional program. Significant improvement in UI occurred at the 6-month interval with significant weight loss and quality of life improvement. At 12 and 18 months objective measures of UI were not maintained but subjects reported subjective UI

improvement, better quality of life and maintained weight loss.<sup>1</sup>

Breyer et al performed a secondary analysis of the PRIDE study to examine the nonUI symptoms of frequency, urgency, nocturia and I-PSS. No difference was found in the primary measures between the control and interventional groups at 6 months. A difference was found in the measures except for frequency between baseline and the 6-month interval in each study arm.



These studies show differences in subject perception and objective reporting of urinary symptoms and urinary incontinence following intensive or instructional behavioral interventions for weight loss. The authors suggest that provision of behavioral materials, repeat symptom assessment or attention given to symptoms may be the reason. The subject mental state, personal motivation and

treatment compliance may also be factors altering these outcomes.

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