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Journal

Obstetrics and Gynecology, 120(2, Part 1)

ISSN

1099-3630

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Publication Date

2012-08-01

DOI

10.1097/aog.0b013e31825dd268

Peer reviewed



Published in final edited form as:

Obstet Gynecol. 2012 August ; 120(2 Pt 1): 277–283. doi:10.1097/AOG.0b013e31825dd268.

Decrease in Urinary Incontinence Management Costs in Women Enrolled in a Clinical Trial of Weight Loss to Treat Urinary Incontinence

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Abstract

Objective—To estimate the effect of a decrease in urinary incontinence frequency on urinary incontinence management costs among women enrolled in a clinical trial of a weight loss intervention and to identify factors that predict change in cost.

Methods—This is a secondary cohort analysis of 338 obese and overweight women with 10 weekly episodes of urinary incontinence enrolled in an 18-month randomized clinical trial of a weight loss intervention compared to a structured education program to treat urinary incontinence. Quantities of resources used for incontinence management, including pads, additional laundry, and dry cleaning were reported by participants. Direct costs for urinary incontinence management (“cost”) were calculated by multiplying resources used by national resource costs (in 2006 U.S. dollars). Randomized groups were combined to examine the effects of change in incontinence frequency on cost. Possible predictors of change in cost were examined using generalized estimating equations controlling for factors associated with change in cost in univariable analyses.

Results—Mean (\pm SD) age was 53 \pm 10 years and baseline weight was 97 \pm 17 kg. Mean weekly urinary incontinence frequency was 24 \pm 18 at baseline and decreased by 37% at 6 months and 60% at 18 months follow-up (both $P < 0.001$). At baseline, adjusted mean cost was \$7.76 \pm \$14 per week, with costs increasing significantly with greater incontinence frequency. Mean cost decreased by 54% at 6 months and 81% at 18 months (both $P < 0.001$). In multivariable analyses, cost

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Financial Disclosure: The authors did not report any potential conflicts of interest.

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independently decreased by 23% for each decrease of seven urinary incontinence episodes per week and 21% for each 5 kg of weight lost ($P < 0.001$ for both).

Conclusion—In obese and overweight women enrolled in a clinical trial of weight loss for urinary incontinence, incontinence management cost decreased by 81% at 18 months (\$327 per woman per year) and was strongly and independently associated with decreasing incontinence frequency.

Introduction

Urinary incontinence is highly prevalent among middle aged and older women and is costly, exceeding \$20 billion per year in direct costs in the United States.^{1, 2} Approximately one-half to three-quarters of the costs of incontinence are attributed to resources used for incontinence management or “routine care” such as absorbent pads, protection and laundry. Despite the burden of urinary incontinence there are few primary data on urinary incontinence management costs and cost estimates vary widely between studies (\$50 to \$1000 per person per year) and by method of cost determination.¹⁻⁸ While increased frequency of urinary incontinence is associated with higher incontinence management costs, it is not known whether successful incontinence treatment can decrease costs for urinary incontinence management.

We previously conducted a randomized clinical trial of a weight loss and maintenance program among obese and overweight women with urinary incontinence. Briefly, women in the weight loss group had greater reduction in body weight compared to the control group at 6-months (−8.0% vs. −1.6%; $P < 0.01$) and 18-months (−5.5% vs. −1.5%; $P < 0.001$) and greater decrease in weekly incontinence episode frequency compared to the control group at 6-months (−47% vs. −28%; $P = 0.04$) but not at 18-months (−61% vs. −54%; $P = 0.31$).⁹⁻¹¹ We estimated the effect of change in urinary incontinence frequency on urinary incontinence management costs and consider factors that may predict change in cost in these women.

Methods

From July 2004 through April 2006, 338 overweight and obese community-dwelling adult women with at least 10 urinary incontinence episodes per week were enrolled in a randomized clinical trial to determine whether an 18-month weight loss and maintenance intervention would significantly reduce the frequency of incontinent episodes at 6- and 18-months follow-up compared to a structured education program control group. Details of the design and results of the clinical trial have been previously reported.⁹⁻¹¹ As a “minimal treatment” for incontinence all participants were given at time of randomization a self-help behavioral treatment booklet with instructions for improving bladder control.^{9, 12} The study was approved by the institutional review board at each site and written consent was obtained from all participants before enrollment.

Data were collected at baseline (prior to randomization) and at 6 and 18 months after randomization. Resources used for urinary incontinence management or “routine care” were assessed by the question “During a typical week, how many of each of the supplies listed below do you use specifically for your urine leakage?” Supplies included pantyliners or minipads, maxipads, incontinence pads, urethral inserts, toilet paper (number of changes) and paper towels (number of sheets). Laundry was assessed by the question “During a typical week, how many loads of wash do you do because of your urine leakage?” and dry cleaning by “During a typical week, how many items of clothing do you dry clean because of your urine leakage?” Women recorded the number of each type of clothing dry cleaned per week, including pants, skirts, dresses, suits and blouses.

National unit costs were estimated for each type of supply by a survey of 14 stores in 6 states and one national internet source accessed in 2006.⁵ The cost of a load of laundry and dry cleaning was estimated by a survey of five Laundromats and five dry cleaners in each of four geographically distant areas in the United States.⁵ To approximate home laundering cost, we used 80% of the mean Laundromat cost (\$2.24 per load) to adjust for Laundromat-related expenses such as rent and profit. The cost of dry cleaning was estimated as pants \$5.03, skirt \$5.35, blouse \$5.45, dress \$9.45, 2-piece suit \$9.64. Because routine care costs are paid out-of-pocket by women in the United States, the analysis is from the patient's perspective.

Demographic characteristics, medical history, and other factors potentially associated with costs were assessed by self-reported questionnaires. Incontinence symptom bother was measured by the 19-item Urogenital Distress Inventory (UDI) and UI-specific quality of life was measured using the 30-item Incontinence Impact Questionnaire (IIQ).¹³ Both the UDI and IIQ are scored from 0 to 400, with higher scores indicating more severe UI symptoms or life impact. A difference of 16 on the IIQ and 11 on the UDI are considered clinically significant.¹⁴ Frequency of urinary incontinence was assessed by a participant completed 7-day voiding diary that included time of each void and each incontinence episode, which was identified by the participant as stress (involuntary loss of urine with coughing, sneezing, straining, or exercise), urgency (loss of urine associated with a strong need or urge to void) or other. The amount of urine lost involuntarily was quantified using a 24-hour pad test using methods standardized by the International Continence Society.¹⁵

Mean costs for urinary incontinence management ("cost") were calculated by multiplying units of resources used by the mean cost per unit and presented in 2006 United States dollars (\$2006). Because the distribution of the cost data was skewed, we calculated the median and 25th and 75th percentiles (interquartile range [IQR]) as well as mean and standard deviation (SD) for total routine care costs. We report both mean and median cost estimates because the aggregate costs to society are best summarized by mean cost times the number of people affected while the cost for individuals is best summarized by median cost.⁶

Statistical methods

We compared baseline demographic and clinical characteristics by treatment group using linear mixed models for continuous variables and generalized estimating equations (GEE) multinomial models for categorical variables to account for recruitment clusters (a recruitment wave consisted of one control group and two weight-loss groups). At baseline, separate generalized linear gamma models were used to assess the association of weekly incontinence episode frequency, 24-hour involuntary urine loss, IIQ, and UDI with urinary incontinence management cost. Multivariable models adjusted for age, race (white/non-white), clinical site, and the baseline characteristics associated with p -values < 0.2 in both univariable and multivariable models (marital status, weight, hysterectomy, ever smoking > 100 cigarettes, SF-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores).

Since no significant differences were observed between the two intervention groups for cost at baseline or change in cost from baseline to 6 or 18 months (all $P > 0.05$), the groups were combined to examine the effects of change in incontinence cost from baseline to 18 months. To estimate the effect of treatment on cost at 6 and 18 months, we used GEE gamma repeated measures models, adjusting for clinical site, with robust standard errors to account for intervention clusters.¹⁶ The gamma model is useful for badly right-skewed outcomes like costs.¹⁷ Analyses were implemented in SAS Version 9.1 (SAS Institute, Cary, NC) and STATA Version 10.0 (STATA Corp, College Station, TX).

Results

Baseline

At baseline among all study participants the mean (\pm SD) age was 53 ± 10 years, weight was 97 ± 17 kg, total number of weekly urinary incontinence episodes was 24 ± 18 and 19% were African American. Annual household income was $<\$40,000$ for 27%, $\$40,000$ - $\$99,999$ for 53%, and $\$100,000$ for 20% of participants. No differences were observed between the weight loss and control group participants on baseline characteristics (Table 1).

Nearly 92% (N=311) of women reported some costs associated with incontinence management at baseline and over 75% of women reported using absorbent pads, the most commonly used resource category. The mean (median) estimated cost for urinary incontinence management was $\$7.76 \pm 14.40$ ($\$3.79$, IQR ($\0.87, $\$7.66$)) per week (Table 2) at baseline or a mean (median) annual cost of $\$403$ ($\$197$).

In univariable analysis, baseline mean weekly incontinence management cost increased by 15% for each increase of 7 total incontinence episodes per week (1 episode per day) and 18% for each increase of 7 urgency incontinence episodes per week (both $P<0.01$; Table 3). Increased costs were also associated with greater 24-hour involuntary urine loss (pad weight) and poorer (higher) IIQ and UDI scores. In multivariable adjusted models, cost increased by 11% with each increase of 7 incontinence episodes per week ($P<0.01$). Using pad weight instead of episode frequency as a measure of incontinence severity, we observed a 5% increase in cost for every 10 gram increase in 24-hour pad weight ($P<0.01$). Costs also increased with poorer incontinence-specific quality of life (12% increase in costs for each 16 point increase in IIQ score [$P<0.001$] and 4% increase in costs for each 11 point increase in UDI score [$P=0.049$]). There was no association between age, ethnicity, annual household income, or type of incontinence and costs in the adjusted models.

6- and 18-month follow-up

Changes in weight and UI frequency by treatment group have been reported previously.⁹

Cost data were available for 318 (94%) women at 6 months and 292 (86%) women at 18 months. Change in mean weekly costs for incontinence management were similar in the weight loss group and the control group at 6-months ($-\$3.28$ vs. $-\$2.88$; $P = 0.27$) and at 18 months ($-\$3.93$ vs. $-\$5.16$; $P = 0.79$). Change in median weekly costs and the proportion of women reporting any costs at 6 and 18-months (data not presented) were also similar in the two groups. Therefore all subsequent analyses were performed on the combined randomized groups.

Among all women, we observed significant decreases in weight, weekly incontinence episode frequency, and pad weight from baseline to 6 and 18 months (all $P < 0.001$; Table 4). The proportion of women reporting any costs associated with incontinence decreased from 92% (311 of 338) at baseline to 79% (252 of 318) at 6 months and 68% (200 of 292) at 18 months ($p < 0.001$ for both). Reductions of mean costs were observed in all cost categories (Table 4). Total mean incontinence management costs, adjusted for clinical site, reduced by an average of 54% at 6 months and 81% at 18 months ($P < 0.001$ for both). For a woman with mean baseline cost of $\$7.76$ per week, this would amount to a reduction of $\$4.19$ per week at 6 months, and $\$6.29$ per week at 18 months. Median costs also decreased from $\$3.79$ per week at baseline to $\$1.97$ per week at 6 months and $\$0.69$ per week at 18 months (Wilcoxon signed rank sum test P -value effect of time on cost < 0.001 for both comparisons).

In multivariable analyses, decreases in total, stress, and urgency urinary incontinence frequency were each strongly and independently associated with reduction in costs at 6 and

18 months (Table 5). For example, for every decrease of seven total incontinence episodes per week, we observed an 18% decrease in mean weekly cost at 6 months and a 23% decrease at 18 months (both $P<0.001$). Decreased 24-hour pad weight was associated with reductions in cost only at 18 months ($P<0.006$). Greater improvement in IIQ and UDI scores were also associated with decreased cost at 6 and 18 months ($P<0.001$). In addition, decreases in costs were independently associated with weight loss at 6 and 18 months: for every 5 kg decrease in weight, we observed a 22% decrease in mean weekly cost at 6 months and a 21% decrease at 18 months (both $P<0.001$). However, randomization group was not a significant predictor of change in cost at either 6 or 18 months. Decreases in cost were also associated with non-white race at 6 months (45% (95% CI 13%, 65%) greater decrease in weekly cost compared to white race).

Discussion

Among overweight and obese women with urinary incontinence who participated in a clinical weight loss trial, we observed a significant decrease in incontinence resource use and out-of-pocket costs for urinary incontinence management following improvement in incontinence frequency. On average, at 18 months after randomization, women reported a 60% decrease in weekly incontinence episodes and 81% decrease in incontinence management costs. This represents an annual savings of \$327 per participant.

The reported costs of urinary incontinence at baseline were substantial. Over 90% of women reported some costs associated with incontinence management, spending a mean of \$7.76 per week or over \$400 per year out-of-pocket for urinary incontinence management. This expenditure is also 0.5-1.0% of the median annual household income of women in the study (\$40,000-\$59,999) which is comparable to the mean annual out-of-pocket spending on prescription drugs for workers with health insurance benefits.¹⁸ Costs reported at study entry by this cohort were similar to costs observed in cross-sectional studies of women with incontinence.^{1-8, 19-21} Similar to previous studies, we observed that patient costs for urinary incontinence management were strongly associated with urinary incontinence frequency, but not with annual household income.⁵⁻⁷

Marked decreases in costs associated with incontinence of greater than 50% were observed in this trial. The strongest independent predictor of a reduction in cost was a decrease in total incontinence episode frequency, with mean cost decreasing by 18% (\$1.40 per week) for each decrease of 7 urinary incontinence episodes per week. This suggests that women use fewer resources to manage urinary incontinence as the frequency of incontinence decreases. Other significant predictors of reduction in cost were improvement in UDI and IIQ scores. Interestingly, there was an association between change in 24-hour weight and change in cost only at 18 months, possibly suggesting a lag in time between decreased frequency of incontinence or volume of loss and a reduction in resource use and/or the inherent lack of reproducibility of pad testing. The significance of the association between weight loss with decreased incontinence management costs independent of change in incontinence frequency remains uncertain.

Prior cross-sectional studies have observed that African American women report higher costs for incontinence management compared to white women.^{5, 6} At baseline in this study, we observed a trend toward non-white women (84% of non-white women were African American) reporting higher costs associated with incontinence compared to white women (53% higher costs (-7%, 152%); $P=0.09$ in multivariable analyses). Independent of baseline incontinence frequency, baseline costs, and change in incontinence frequency, non-white women had greater reduction in cost compared to white women ($P=0.007$) at 6 months, an association that was not observed at 18 months. These data suggest that urinary incontinence

management costs for African American women may be more responsive to changes in incontinence frequency than for white women.

In a prior report,⁹ we observed a greater decrease in incontinence frequency in the weight loss group compared to the control group at 6 months. However, we found no difference in change in incontinence management cost over the same time period when the behavioral weight reduction group was compared to the control group. Thus, decreased incontinence frequency predicted decreased incontinence management cost regardless of randomized group assignment. Our inability to show a difference in cost reduction when randomized groups were compared may be due to no difference between groups in volume of urine lost estimated by the 24-hour pad test and/or insufficient power to detect a difference.

In contrast to incontinence costs for diagnosis, treatment, and institutionalization, a majority of routine care costs for incontinence incurred by community-dwelling people are paid out-of-pocket without reimbursement by third-party payers. This places a large cost burden directly on individuals, most often the elderly and women, who are adversely affected by disease as well as the cost of care. As we observed in this study, this cost burden may be reduced by other approaches to effective treatment for incontinence.

We studied overweight and obese community-dwelling women with urinary incontinence enrolled in a randomized clinical trial of weight loss. Therefore, these results may not be generalizable to other women with incontinence or those who undergo other incontinence treatments. Pads, laundry and dry cleaning may also have been used for reasons other than urinary incontinence resulting in overestimating resource use for urinary incontinence. Recall of resource use during a typical week was used to minimize participant burden. Although prior reports have found both over- and under-report their utilization of resources for management of urinary incontinence,^{5, 20} the fact that costs were reduced similarly in the randomized groups in this non-blinded trials suggests that women accurately reported resource use.

In summary, we found that managing urinary incontinence was associated with substantial costs, and that a reduction in incontinence frequency was associated with a significant reduction in incontinence management costs among obese and overweight women with urinary incontinence. A decrease in the frequency of episodes was the strongest predictor of a reduction in incontinence management costs through 18 months. The trade-off between the costs of incontinence treatment and benefits in both patient-focused outcomes and decreased incontinence management costs should be explored with cost-utility analyses. The substantial incontinence-related costs incurred by women with urinary incontinence and the reduction of costs we observed with decreased incontinence frequency suggests that other effective incontinence treatments may be cost-effective.

Acknowledgments

Supported by Grant Number 5RO1 DK070196. The Program to Reduce Incontinence by Diet and Exercise (PRIDE) was supported by grant numbers U01DK067860, U01 DK067861 and U01 DK067862 from the National Institute of Diabetes and Digestive and Kidney Diseases. Funding for PRIDE was also provided by the Office of Research on Women's Health National Institutes of Health. The content of this report 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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Table 1
Baseline Characteristics of Program to Reduce Incontinence by Diet and Exercise
Participants by Treatment Group

Characteristic	Total (n=338)
Age (yrs), mean (\pm SD)	53 (\pm 10)
White race, n (%)	262 (78)
Education high school or more, n (%)	293 (87)
Annual household income	
Less than \$40,000	72 (27)
\$40,000-\$99,999	142 (53)
\$100,000 or more	54 (20)
Self-reported health status, n (%)	
Excellent or very good	151 (45)
Good	150 (44)
Fair or poor	37 (11)
Weight (kg), mean (\pm SD)	97 (\pm 17)
BMI (kg/m ²)	36 (\pm 6)
Urinary incontinence type, n (%) [*]	
Urgency or urgency-predominant	149 (44)
Stress or stress-predominant	75 (22)
Mixed	114 (34)
Number of urinary incontinence episodes per week, mean (\pm SD) [†]	
Total	24 (\pm 18)
Urgency	14 (\pm 14)
Stress	10 (\pm 11)
24-hour pad test (grams)	33 (\pm 55)
IIQ [‡]	109 (\pm 71)
UDI [‡]	166 (\pm 52)

SD, standard deviation; BMI, body mass index; IIQ, Incontinence Impact Questionnaire; UDI, Urinary Distress Inventory.

^{*} Urinary incontinence type was classified by investigators based on participant's designation of incontinence type for each incontinent episode on a 7-day voiding diary as stress only, stress predominant (stress episodes comprised at least 2/3 of the total), urgency only, urgency predominant (urgency episodes comprised at least 2/3 of the total), or mixed incontinence if at least two types were reported but no type comprised at least 2/3 of the total.

[†] Based on 7-day voiding diary

[‡] The IIQ and UDI are scored from 0 to 400, with higher scores indicating a more severe effect on life or urinary incontinence symptoms.

Table 2
Weekly Urinary Incontinence Management Costs at Baseline by Resource Category in the Total Cohort in 2006 U.S. Dollars

Item	Number (%) Using the Resource	Baseline Cost per Week*		Percentage of Total Estimated Cost
		Mean (\pm SD)	Median (IQR)	
Total cost	311 (92)	7.76 (\pm 14.40)	3.79 (0.87, 7.66)	100
Absorbent pads	260 (77)	1.51 (\pm 2.43)	0.66 (0.12, 2.02)	19
Paper towels ortoilet paper	81 (24)	0.03 (\pm 0.12)	0.00 (0.00, 0.00)	0
Laundry	181 (54)	2.72 (\pm 3.70)	2.24 (0.00, 4.48)	35
Dry cleaning	53 (16)	3.50 (\pm 12.47)	0.00 (0.00, 0.00)	45

SD, standard deviation; IQR, 25%-75% interquartile range.

* Costs are presented in 2006 U.S. dollars and were calculated as the number used multiplied by unit cost. Unit costs for each item were mini pads \$0.062, maxi pads \$0.164, incontinence pads \$0.316, diapers \$2.60, toilet paper \$0.0024 per sheet, paper towel \$0.075 per sheet and laundry \$2.24 per load.

Table 3
Factors Associated With Weekly Urinary Incontinence Management Costs at Baseline in Univariable and Multivariable Linear Regression

Predictor	Univariable Analysis		Multivariable Analysis	
	Change in Cost (95% CI) [*]	<i>P</i>	Change in Cost (95% CI) ^{*, †}	<i>P</i>
Urinary incontinence episodes, per seven episodes per week [‡]				
Total	15% (5%, 25%)	0.002	11% (2%, 20%)	0.010
Stress	10% (-4%, 25%)	0.163	13% (0.2%, 26%)	0.047
Urgency	18% (5%, 33%)	0.006	11% (-0.5%, 24%)	0.060
Pad weight (per 10 gram)	5% (0.3%, 11%)	0.037	6% (2%, 11%)	0.005
IIQ (per 16 score) [§]	10% (6%, 14%)	<0.001	12% (7%, 16%)	<0.001
UDI (per 11 score) [§]	4% (0.1%, 8%)	0.046	4% (0.0%, 8%)	0.049

CI, confidence interval; IIQ, Incontinence Impact Questionnaire; UDI, Urogenital Distress Inventory.

^{*} Estimate represents the percent change in costs associated with a change of 7 incontinence episodes per week for urinary incontinence, 10 grams for 24-hr involuntary urine loss, 16 points for IIQ, and 11 points for UDI.

[†] Adjusted for age, ethnicity, marital status, ever smoking, SF-36 Physical Component Score and Mental Component Score, hysterectomy, weight, and clinic site.

[‡] Based on 7-day voiding diary.

[§] The IIQ and UDI are scored on a scale of 0-400, with a higher score representing greater effect.

Table 4
Change in Weight, Urinary Incontinence Episode Frequency, Pad Weight, and Management Costs by Resource Category at 6 Months and 18 Months in the Total Cohort

	Mean Change From Baseline (95% CI)			
	6 Months (n=318)	<i>P</i>	18 Months (n=292)	<i>P</i>
Weight	-6% (-7%, -6%)	<0.001	-5% (-6%, -4%)	<0.001
Number of urinary incontinence episodes per week [*]	-37% (-45%, -30%)	<0.001	-60% (-65%, -55%)	<0.001
24-hour pad weight	-43% (-50%, -36%)	<0.001	-54% (-61%, -47%)	<0.001
Total cost [†]	-54% (-71%, -36%)	<0.001	-81% (-107%, -56%)	<0.001
Absorbent pads [†]	-15% (-30%, 1.1%)	0.068	-29% (-49%, -9%)	0.004
Paper towels or toilet paper [†]	-19% (-60%, 22%)	0.362	-61% (-93%, -30%)	<0.001
Laundry [†]	-71% (-88%, -55%)	<0.001	-87% (-113%, -61%)	<0.001
Dry cleaning [†]	-65% (-106%, -24%)	0.002	-107% (-161%, -54%)	<0.001
Total cost [†]	-54% (-71%, -36%)	<0.001	-81% (-107%, -56%)	<0.001

CI, confidence interval.

^{*} Based on 7-day voiding diary.

[†] Under the gamma model used for analysis, expected absolute reductions in costs depend on the baseline level. Thus for a woman with average baseline costs, the expected reductions at 6 and 18 months would be \$4.19 and \$6.29 for total costs, \$0.23 and \$0.44 for absorbent pads, \$0.01 and \$0.02 for paper, \$1.93 and \$2.37 for laundry, and \$2.28 and \$3.75 for dry cleaning.

Table 5
Factors Associated With Change in Weekly Incontinence Management Costs at 6 and 18 Months in Multivariable Linear Regression

Effect of Change	6 Months		18 Months	
	Change in Cost (95% CI) [*]	<i>P</i> [†]	Change in Cost (95% CI) [*]	<i>P</i> [†]
Change in total incontinence episodes (per seven episodes per week) [‡]	18% (9%, 27%)	<0.001	23% (14%, 31%)	<0.001
Change in stress incontinence episodes (per seven episodes per week) [‡]	32% (15%, 46%)	<0.001	33% (18%, 44%)	<0.001
Change in urgency incontinence episodes (per seven episodes per week) [‡]	17% (6%, 26%)	0.003	28% (19%, 36%)	<0.001
Change in 24-hr involuntary urine loss (per 10 grams)	3% (2%, 8%)	0.213	6% (2%, 9%)	0.006
Change in IIQ (per 16 points) [§]	12% (6%, 17%)	<0.001	13% (9%, 17%)	<0.001
Change in UDI (per 11 points) [§]	7% (4%, 11%)	<0.001	10% (7%, 12%)	<0.001
Change in weight (per 5 kg)	22% (9%, 33%)	<0.001	21% (9%, 30%)	<0.001

CI, confidence interval; IIQ, Incontinence Impact Questionnaire; UDI, Urogenital Distress Inventory.

^{*} Estimate represents the percent reduction in costs at each follow-up timepoint associated with clinically meaningful decreases of seven incontinence episodes per week for urinary incontinence, 10 grams for 24-hr involuntary urine loss, 16 points for IIQ, and 11 points for UDI.

[†] Separate models were used to estimate the effect of decreases in total, stress and urgency incontinence frequency, 24-hour involuntary urine loss, IIQ, and UDI. All models controlled for age, ethnicity, clinical site, baseline weight, change in weight, type of incontinence at baseline, and the respective baseline measure of primary predictor of reduction.

[‡] Based on 7-day voiding diary.

[§] The IIQ and UDI are scored on a scale of 0-400, with a higher score representing greater effect.