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Urinary Incontinence Management Costs are Reduced Following Burch or Sling Surgery for Stress Incontinence

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Abstract

Objective—To estimate the effect of Burch and fascial sling surgery on out-of-pocket urinary incontinence (UI) management costs at 24 months post-operatively and identify predictors of change in cost among women enrolled in a randomized trial comparing these procedures.

Methods—Resources used for UI management (supplies, laundry, dry cleaning) were self-reported by 491 women at baseline and 24 months post-surgery and total out-of-pocket costs for UI management (in 2012 US dollars) were estimated. Data from the two surgical groups were combined to examine change in cost for UI management over 24 months. Univariate and bivariate

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changes in cost were analyzed using Wilcoxon signed rank test. Predictors of change in cost were examined using multivariate mixed models.

Results—At baseline mean ($\pm$ SD) age of participants was 53 ± 10 years, and frequency of weekly UI episodes was 23 ± 21 . Weekly UI episodes decreased by 86% at 24 months ($P<0.001$). Mean weekly cost was $\$16.60\pm \27 (median $\$9.39$) at baseline and $\$4.57\pm \15 (median $\$0.10$) at 24 months ($P<0.001$), a decrease of 72%. In multivariate analyses, cost decreased by $\$3.38\pm \0.77 per week for each decrease of 1 UI episode per day ($P<0.001$) and was strongly associated with greater improvement in UDI and IIQ scores ($P<0.001$) and decreased 24-hour pad weight ($P<0.02$).

Conclusion—Following Burch or fascial sling surgery, UI management cost at 24 months decreased by 72% ($\$625$ per woman per year) and was strongly associated with decreasing UI frequency. Reduced out-of-pocket expenses may be a benefit of these established urinary incontinence procedures.

Key words (MeSH subjects)

urinary incontinence; urinary incontinence – costs; costs and cost analysis

Introduction

Urinary incontinence (UI) affects almost half of middle aged and older women and is associated with substantial medical and psychological morbidity and diminished quality of life.^{1,2} The economic costs of UI are also substantial, accounting for over \$20 billion per year in the United States,^{3,4} with a majority attributed to resources used for incontinence management or “routine care” that patients pay out of pocket for absorbent pads, protection and laundry. Annual cost estimates vary widely between \$50 to \$1000 per person per year^{3–10} and increase with severity of UI.^{7,8,10} However, little information is available about the reduction of costs after treatment for incontinence, and we could not find primary data reporting the change in costs for UI management after stress incontinence surgery.

We previously reported estimated costs for incontinence management just prior to stress incontinence surgery among 665 women enrolled in a clinical trial, the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER).¹⁰ We now estimate the effect of Burch and fascial sling surgeries on out-of-pocket urinary incontinence management costs at 24 months post-operatively and identify baseline predictors of change in cost. We hypothesized that a decrease in UI frequency as a result of surgery would be associated with lower UI management costs.

Methods

This was a planned sub-analysis of data collected from SISTER, a multi-center, randomized, surgical trial in the United States comparing two common stress UI surgeries—Burch colposuspension and autologous rectus fascial sling.¹⁰ The trial of 655 community-dwelling, adult women, electing surgical treatment of stress-predominant urinary incontinence was conducted between February 2002 and June 2004. Eligibility requirements included documented pure or predominant symptoms of stress incontinence for at least 3 months and

a positive standardized urinary stress test. Details of the study design and primary results have been previously reported.^{11,12} The study protocol was approved by the Institutional Review Board at each of the participating institutions and written informed consent was obtained from all participants.

Data were collected at baseline (prior to randomization) and at 24 months following surgery, the primary endpoint of the trial, using self-report questionnaires, physical examinations and quantitative tests that included bladder diaries, weighed pad tests and urodynamic studies. We report on 491 women who provided complete cost data at both timepoints (75% of women randomized and 94% of women assessed for the primary outcome at 24 months). The 164 women excluded were younger ($49 (\pm 10)$ vs. $53 (\pm 10)$ years, $p < .01$), less educated (18% vs 28% with college degrees, $p < .01$), more likely to be diabetic (11% vs 6%, $p = .02$), smoke (21% vs. 12%, $p < .01$) and less likely to have pelvic organ prolapse (65% vs. 79% POP-Q stage $> I$, $p < .01$) and to have had non-surgical (38% vs. 48%, $p = .04$) or surgical (9% vs. 16%, $p = .03$) treatment for UI compared to women included in this cost analysis.

Resources used for UI management or “routine care” by study participants were assessed by the question “Over the past 7 days, please record the average number of supplies you used each day for your urinary incontinence.” Absorbent supplies included pantyliners, minipads, maxipads, incontinence pads, diapers, urethral inserts/occlusive devices, toilet paper, and paper towels. Laundry use was assessed by the question “How many loads of wash did you do during the last 7 days because of your incontinence?” and dry cleaning by “How many items of clothing did you dry clean during the last 7 days because of your incontinence?”¹⁰

For generalizability, we estimated national unit costs for each type of supply, a load of laundry and each item of dry cleaning using a survey of 14 stores in 6 states and one national internet source.^{7,10} Primary cost data were collected in 2006 and the cost estimates were inflated to 2012 United States dollars using the general consumer price index and a multiple of 1.116 (<ftp://ftp.bls.gov/pub/special.requests/cpi/cpiiai.txt>). Mean out-of-pocket urinary incontinence management cost (“cost”) was calculated by multiplying units of resources used by the mean cost per unit. Since the distribution of the cost data were 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 multiplied by the number of people affected, while the cost to a typical woman who incurs any costs is best summarized by the median.⁸ To minimize the outlier effect observed for some cost categories, Winsorization at the 90th percentile were also performed; specifically, costs and measures of incontinence above or below the 95th or 5th percentile respectively were reset to that limit for all multivariate analyses.¹³ Summary and univariable statistics were computed for women with any reported costs. Because routine care costs are paid out-of-pocket by affected women in the United States, the analysis is from the patient's perspective.

Factors thought *a priori* to be associated with change in cost were assessed by self-report of demographic characteristics and medical history.¹¹ Frequency of UI was assessed by participant completed 3-day voiding diary and reported by quartiles. We used total UI

episodes per day for the primary variable to represent UI severity in this study.^{10,14} Classification of type of UI was determined by the Michigan Epidemiological Study of Aging (MESA) questionnaire¹⁵ and defined as “stress only” if only stress UI symptoms were reported or “mixed” UI if both urine stress and urge UI symptoms were reported. By design all women with mixed UI had predominately stress UI symptoms. The amount of urine involuntarily lost was measured by 24-hour pad test weight. Condition-specific quality of life instruments (Incontinence Impact Questionnaire (IIQ), Urogenital Distress Inventory (UDI))¹⁶ were administered. Pelvic organ prolapse was assessed by physical examination (Pelvic Organ Prolapse Quantification (POP-Q)¹⁷) and fecal and flatal incontinence were identified by self-report of “leaking or loss of control of liquid or solid stool or gas.”

We compared baseline demographic and clinical characteristics of the Burch and sling groups using chi square and Anova tests. Since no significant differences were observed between the two groups for either cost at baseline or change in cost from baseline to 24 months (all $P>0.05$), the groups were combined to examine the effects of change in incontinence cost from baseline to 24 months. An intervention indicator was included in all multivariate models. Univariate and bivariate changes in cost were analyzed using Wilcoxon signed rank test. Factors measured at baseline considered *a priori* as possible predictors of change in cost were examined using multivariate mixed models, including age, ethnicity, education, baseline body mass index (BMI), annual household income, report of 3 urinary tract infections (UTIs) per year, POP-Q stage, fecal incontinence, diabetes, prior non-surgical UI treatment, menopause, smoking, surgery group and accounting for site clusters. Our sample provided 80% power to detect a change of cost of \$2.63 per week. To assess whether “successful” treatment was associated with greater reduction of cost compared to failed treatment, we compared cost among women who experienced success for overall urinary-incontinence measures as defined for the clinical trial (defined as a negative pad test, no urinary incontinence recorded in a 3-day diary, negative cough and Valsalva stress tests, no self-reported symptoms, and no retreatment for the condition)¹¹ and success for stress incontinence specifically (defined as meeting the latter three criteria) using multivariable mixed models. A p-value of < 0.05 was considered statistically significant. All analyses were carried out using SAS Version 9.1 (SAS Institute, Cary, NC).

RESULTS

Four hundred and ninety one women provided information on urinary incontinence management cost at both baseline and 24 months post-surgery. They had a mean ($\pm$ standard deviation) age of 53 (± 10) years and most were white (80%; Table 1). The distribution of reported annual household income was $< \$40,000$ (37%), $\$40,000$ – $\$99,999$ (44%) and $\$100,000$ (19%). At baseline, most (85%) women reported at least daily frequency of urinary incontinence, with a mean of 23 (± 21) incontinent episodes per week. No differences were observed between the Burch and fascial sling group participants for baseline characteristics. At 24 months after surgery, the average number of incontinence episodes per week reported on voiding diaries decreased from 23 to 3 (a decrease of 86%, $p<0.001$) and 68% of the women were dry on subjective and objective assessment, meeting the criteria for successful treatment.

Mean and median weekly out-of-pocket urinary incontinence management cost per participant were $\$16.60 \pm \27.49 and $\$9.39$ (25th to 75th percentile interquartile range (IQR) $\$3.78$, $\$19.75$; range $\$0$ – $\$248$) at baseline and decreased to $\$4.57 \pm \15.37 and $\$0.10$ (IQR $\$0$, $\$3.39$; range $\$0$ – $\$238$) at 24 months ($P<0.001$; Table 2). This represents a decrease of 72% ($\$625$ per woman per year) in annual mean cost for all women. The reduction in weekly cost for both surgery groups did not differ significantly ($-\$12.09$ for Burch vs. $-\$11.98$ for fascial sling; $P=0.49$). Among the various cost categories, absorbent supplies were the most costly, accounting for 63% of total patient costs for UI management with 84% of women reporting use of absorbent pads at baseline. Over one-half of the women reported additional loads of laundry (19% of total costs), and 12% reported additional dry cleaning each week for UI (12% of total costs). There was a similar reduction of approximately 70% (range 60–90%) in each of these cost categories at 24 months.

The proportion of women reporting any UI management cost decreased from 95% ($N=464$) at baseline to 50% ($N=246$) at 24 months ($P<.0001$). Mean and median weekly costs among women who continued using incontinence management resources decreased by approximately one-half from $\$17.57 \pm \27.97 and $\$9.92$ (IQR $\$4.88$, $\$21.06$; range $\$0.10$ – $\$277$) at baseline to $\$9.12 \pm \20.75 and $\$3.39$ (IQR $\$1.04$, $\$7.73$; range $\$0.10$ – $\$238$) at 24 months. Approximately 53% of women who reported baseline use of resources for incontinence management reported no resource use at 24 months following surgery.

In multivariate analyses, cost decreased by a mean ($\pm$ standard error) of $\$3.38 \pm \0.77 per week for each decrease of one UI episode per day ($P<0.0001$) and was strongly associated with greater improvement in UDI, IIQ, MESA Stress and Urge scores ($P<0.0001$ for all) and decreased 24-hour pad weight ($P=.02$; Table 3). Change in weekly UI management cost was not associated with baseline incontinence frequency, annual household income or surgical group. Surgical success for incontinence was associated with a greater reduction in cost ($-\$4.32 \pm 1.14$ per week; $P<.001$) than surgical failure as was surgical success for stress incontinence ($-\$5.46 \pm 1.16$ per week; $P<.0001$).

DISCUSSION

In this large-scale, randomized clinical trial of urinary incontinence surgery with primary data on UI management costs, we observed a decrease in UI management cost of 72% ($\$625$ per woman per year) at 24 months after Burch and fascial sling surgery combined. The decrease in cost was associated with improvement in incontinence following surgery and associated with surgical success, defined as no incontinence on subjective and objective measures. The number of incontinence episodes per week decreased by 86%, with 68% of the women reporting they were dry. Over the same time period, the proportion of women reporting any cost decreased by almost one-half, from 95% to 50%.

The economic costs of UI were substantial for the women we studied; prior to surgery, they incurred a mean of over $\$860$ per year out of pocket expenses for UI management. This expenditure represents almost 1.5% of the median annual household income of women in the study ($\$50,000$ – $\$59,999$), which is comparable to the mean annual out-of-pocket spending on prescription drugs for workers with health insurance benefits.¹⁸

Since costs for UI management were strongly associated with UI episode frequency in a previous SISTER cross-sectional analysis and in other reports,^{7,8,10} we anticipated that a decrease in UI frequency as a result of surgery would be associated with lower UI management costs. This change in UI management cost was observed in a study among obese and overweight women enrolled in a clinical trial of weight loss for UI.¹⁹ Similar to the current study, that study found that incontinence management cost decreased significantly by 81% at 18 months (\$327 per woman per year) and was strongly and independently associated with decreasing incontinence frequency. These two studies suggest that it is the decrease in UI frequency -- not the specific intervention to achieve the improvement -- that correlates with decreased costs. Therefore, any effective UI therapy may result in decreased out-of-pocket costs for UI management.

We found the strongest independent predictor of a reduction in cost to be a decrease in UI episodes, with cost decreasing by \$3.38 per week for each decrease of 7 UI episodes per week. This finding is consistent with the concept of women using fewer resources to manage UI as its frequency decreases. Change in UI frequency was the strongest predictor of change in UI management cost, with other significant predictors being improvement in UDI, IIQ, and MESA Stress and Urge scores and decreased 24-hour pad weight.

Despite the substantial decrease in UI management costs observed overall, one-half of the women continued to report UI-related expenditures. However, women with any UI-related expenditures reported spending, on average, over 50% less per week (mostly associated with reduction in absorbent products) compared to what they spent prior to surgery.

There were several strengths of our study. We uniformly assessed cost and obtained primary data for resource utilization from a large cohort of women recruited from nine locations across the United States. Our duration of cost assessment from surgery was 24 months, likely sufficient time to observe an effect on use of resources to manage incontinence. Combining the two surgery groups permitted us to estimate UI management cost reductions in two traditional surgical procedures for stress incontinence. We assume that reductions in UI management costs would be similar or greater for mid-urethral slings, now done more frequently than the study procedures in the SISTER trial.

Our findings should be considered within the context of some limitations. We studied community-dwelling women enrolled in a clinical trial conducted at tertiary care medical centers. In addition, we report data on a subset of participants enrolled in the study (75%) for whom we had complete cost data at both baseline and 24 months. Therefore, our results may not be applicable to women seeking surgery for incontinence in other settings, to all women electing surgical treatment, or those electing non-surgical treatment.. Furthermore, it is possible that pads, laundry and dry cleaning may also have been used for non-urinary incontinence reasons and this may have increased the estimates of incontinence-related resource use. Women were queried about resource use during a typical week. Since individuals may over- or under-report their utilization of resources;^{7,20} systematic variance in this discrepancy may bias our findings. While this analysis was not intended to include all intervention costs (i.e., surgery) and benefits, formal cost-effectiveness and cost-utility

analyses would be informative to examine cost in relationship to change in utilities and whether the intervention is worth' of the savings from the patients' perspective.

In summary, using primary cost and outcome data we showed a substantial reduction of UI management costs after Burch colposuspension and rectus fascial sling surgery for urinary stress incontinence. Reduction of out-of-pocket expenses can be included in the benefits of these established surgeries for women with urinary incontinence.

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APPENDIX

A list of the Urinary Incontinence Treatment Network Investigators during the time of the SISTER trial is given below.

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CLINICAL IMPLICATIONS

1. Following surgery for stress incontinence, mean out-of-pocket urinary incontinence management costs decreased by 72% from almost \$850 per year per woman at baseline to \$235 per year two years after surgery
2. Decrease urinary incontinence management cost was most strongly associated with improvement in incontinence following surgery
3. Since it appears to be a decrease in incontinence frequency that correlates with decreased costs and not the specific intervention to achieve the improvement, any effective incontinence therapy may result in decreased out-of-pocket costs for incontinence management
4. Reduction of out-of-pocket expenses is an additional benefit of treating urinary incontinence on women

Table 1
Baseline characteristics of SISTER participants overall and by surgery group (N=491)

	Total N=491	Burch N=239	Sling N=252	P-Value
Demographic Characteristics				
Age mean (SD)	52.8 (10.2)	53.2 (10.5)	52.5 (9.8)	0.47
Ethnicity	395 (80.4%)	200 (83.7%)	195 (77.4%)	0.25
White				
African American	35 (7.1%)	14 (5.9%)	21 (8.3%)	
Asian/Pacific Islander	4 (0.8%)	3 (1.3%)	1 (0.4%)	
Latina	53 (10.8%)	21 (8.8%)	32 (12.7%)	
Native American/Other	4 (0.8%)	1 (0.4%)	3 (1.2%)	
BMI (kg/m ²) mean (SD)	29.7 (5.9)	29.4 (6.1)	30.0 (5.7)	0.34
Annual Household Income				
< \$40,000	165 (36.7%)	77 (36.0%)	88 (37.3%)	0.94
\$40,000–\$99,999	197 (43.8%)	94 (43.9%)	103 (43.6%)	
\$100,000 or more	88 (19.6%)	43 (20.1%)	45 (19.1%)	
Education	166 (33.8%)	79 (33.1%)	87 (34.5%)	0.93
High school or less				
Some college/Bachelor's	263 (53.6%)	130 (54.4%)	133 (52.8%)	
Graduate degree	62 (12.6%)	30 (12.6%)	32 (12.7%)	
Reproductive History				
Parous	443 (90.2%)	218 (91.2%)	225 (89.3%)	0.47
# vaginal deliveries mean (SD)	2.5 (1.6)	2.6 (1.6)	2.5 (1.5)	0.56
Post menopausal	233 (47.5%)	122 (51.0%)	111 (44.0%)	0.12
Baseline Health and Medical History				
Diabetes	28 (5.7%)	18 (7.5%)	10 (4.0%)	0.09
Smoker	59 (12.2%)	22 (9.4%)	37 (14.7%)	0.08
> 3 urinary tract infections/year	33 (6.7%)	20 (8.4%)	13 (5.2%)	0.16
POP-Q				
Stage *	21 (4.3%)	10 (4.2%)	11 (4.4%)	0.82
Stage 0				
Stage I	84 (17.1%)	42 (17.6%)	42 (16.7%)	
Stage II	304 (61.9%)	149 (62.3%)	155 (61.5%)	
Stage III	67 (13.6%)	33 (13.8%)	34 (13.5%)	

	Total N=491	Burch N=239	Sling N=252	P-Value
Stage IV	15 (3.1%)	5 (2.1%)	10 (4.0%)	
Monthly fecal incontinence [‡]	78 (15.9%)	35 (14.6%)	43 (17.1%)	0.46
Urinary Incontinence				
Total UI episodes per day	3.2 (3.1)	3.4 (3.3)	3.0 (2.8)	0.19
24-hour Pad Weight (gms)	13.5 (23.5)	13.8 (20.7)	13.2 (25.9)	0.77
MESA Stress Index	71.6 (16.8)	72.4 (16.4)	70.8 (17.0)	0.28
MESA Urge Index	36.4 (21.9)	36.8 (22.1)	36.1 (21.7)	0.72
Non-surgical treatment for UI	234 (47.7%)	116 (48.5%)	118 (46.8%)	0.70
Prior surgery for UI	78 (15.9%)	41 (17.2%)	37 (14.7%)	0.45
Quality of Life Measures				
Total UDI score [‡]	149.8 (47.2)	149.4 (48.4)	150.2 (46.2)	0.86
Total IIQ score [‡]	168.7 (100.8)	172.9 (101.8)	164.7 (99.8)	0.37

SD=standard deviation; IQR = 25%–75% interquartile range; BMI=body mass index

* Based on POP-Q score

[‡] Fecal incontinence was identified by self-report of "leaking or loss of control of liquid or solid stool" and flatal incontinence by "leaking or loss of control of gas."

[§] Based on 3-day voiding diary

[‡] The Incontinence Impact Questionnaire and Urogenital Distress Inventory are scored on a scale of 0–400, with a higher score representing greater impact.

Table 2

Weekly patient costs for incontinence management and change in cost at 24 Months overall and by item (in 2012 US dollars)

	Number (% of total) using this resource	Baseline Costs per Week*			Change in Cost at 24 months*	
		Mean (SD)	Median (IQR)	Percent of Total Cost	Mean (SD)	Median (IQR)
Total UI related cost	464 (95%)	16.60 (27.49)	9.39 (3.78, 19.75)	100%	-12.03 (29.22)	-6.38 (-16.85, - 1.45)
Pad cost	410 (84%)	10.49 (24.62)	4.94 (0.97, 11.81)	63%	-7.60 (26.18)	-3.22 (-9.62, 0.0)
Paper (Towels, Toilet Paper) cost	244 (50%)	0.96 (2.01)	0.0 (0.0, 1.31)	6%	-0.54 (2.26)	0 (-0.85, 0.0)
Incontinence-related laundry cost	276 (56%)	3.20(4. 20)	2.50 (0.0, 5.0)	19%	-2.60 (4.42)	-0 (-5.0, 0.0)
Dry Cleaning related cost	59 (12%)	1.97 (7.28)	0.0 (0.0, 0.0)	12%	-1.31 (8.37)	0 (0.0, 0.0)

* Costs are presented in 2012 United States dollars and were calculated as the number used * unit cost. Unit costs for each item were mini pads \$0.069, maxi pads \$0.183, incontinence pads \$0.353, diapers \$2.90, toilet paper \$0.0027 per sheet, paper towel \$0.017 per sheet and laundry \$3.12 per load. Unit costs for Dry Cleaning were estimated as pants \$5.61, skirt \$5.97, blouse \$6.08, dress \$10.55, 2-piece suit \$10.76.

Table 3

Factors Associated with Change in Weekly Incontinence Management Costs

	Mean (SD)	Median (IQR)	Adjusted* Estimate (SE)	P- Value*
Change in Incontinence Episodes per day [§]	-2.78 (3.20)	-2.00 (-4.00, -1.00)	3.38 (0.77)	<.0001
Change in 24-hr Pad Weight, per 1 gram	-9.03 (24.60)	-3.12 (-10.65, -0.28)	0.80 (0.33)	0.02
Change in UDI [‡] , per 11 units	-112.69 (58.45)	-115.15 (-150.51, -74.24)	0.85 (0.17)	<.0001
Change in IIQ [‡] , per 16 units	-135.16 (106.59)	-122.50 (-206.94, -56.94)	0.84 (0.17)	<.0001
Change in MESA Stress Index, per 10 units	-59.34 (24.52)	-63.00 (-78.00, -44.30)	1.33 (0.33)	<.0001
Change in MESA Urge Index, per 10 units	-21.83 (23.85)	-21.89 (-39.00, -5.44)	1.62 (0.41)	<.0001

SD = standard deviation; IQR = 25% to 75% interquartile range; SE = standard error

* Based on multivariate mixed models of 90% Winsorized change in cost; models additionally include age, ethnicity, education, income, baseline BMI, 3 or more UTIs, POP-Q stage, fecal incontinence, diabetes, prior non-surgical UI treatment, menopause, smoking, site, treatment group, and 90% Winsorized baseline value.

[§]Based on 3-day voiding diary[‡]The Incontinence Impact Questionnaire (IIQ) and Urogenital Distress Inventory (UDI) are scored on a scale of 0–400, with a higher score representing greater impact.