

8-1-2015

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Halina Zyczynski

Michael E Albo

Howard B Goldman

Clifford Y Wai

Larry T Sirls

See next page for additional authors

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Recommended Citation

Zyczynski, H., Albo, M., Goldman, H., Wai, C., Sirls, L., Brubaker, L., Norton, P., Varner, R., Carmel, M., & Kim, H. (2015). Change in Overactive Bladder Symptoms After Surgery for Stress Urinary Incontinence in Women. *Obstetrics and Gynecology*, 126 (2), 423-430. <https://doi.org/10.1097/AOG.0000000000000929>

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Authors

Halina Zyczynski, Michael E Albo, Howard B Goldman, Clifford Y Wai, Larry T Sirls, Linda Brubaker, Peggy Norton, R E Varner, Maude Carmel, and Hae-Young Kim

Author(s) ORCID Identifier:

<http://orcid.org/0000-0001-7916-6625>



Published in final edited form as:

Obstet Gynecol. 2015 August ; 126(2): 423–430. doi:10.1097/AOG.0000000000000929.

Change in Overactive Bladder Symptoms After Surgery for Stress Urinary Incontinence in Women

Halina M. Zyczynski, MD¹, Michael E. Albo, MD², Howard B. Goldman, MD³, Clifford Y. Wai, MD⁴, Larry T. Sirls, MD⁵, Linda Brubaker, MD⁶, Peggy Norton, MD⁷, R.E. Varner, MD⁸, Maude Carmel, MD⁴, and Hae-Young Kim, DrPH⁹ for the Urinary Incontinence Treatment Network*

¹University of Pittsburgh, Magee-Womens Research Institute, Pittsburgh PA

²UC San Diego Health Systems, San Diego, CA

³Cleveland Clinic, Cleveland, OH

⁴University of Texas Southwestern, Dallas, TX

⁵William Beaumont Hospital Royal Oak, MI

⁶Loyola University Chicago Stritch School of Medicine, Maywood, IL

⁷University of Utah, Salt Lake City, UT

⁸University of Alabama at Birmingham, Birmingham, AL

⁹New England Research Institutes, Watertown, MA

Abstract

OBJECTIVE—To assess change in overactive bladder (OAB) symptoms up to 5-years after surgery and to identify associated predictors of change from baseline.

METHODS—This is a secondary analysis of data from three multicenter urinary incontinence surgical trials of women with stress predominant mixed urinary incontinence assigned to Burch colposuspension, autologous fascial sling, retropubic or transobturator midurethral slings. The primary outcome was improvement of 70% from baseline in symptoms measured by the Urinary Distress Inventory–Irritative (UDI-I) subscale. Surgical groups were compared within respective trials. Generalized linear models were fit using 1-year and up to 5-year data.

RESULTS—Significant improvements in UDI-I scores were reported by each surgical group one year after surgery ($p < 0.001$). Most women (50–71%) reported improvement in OAB symptoms. Improvements were similar between midurethral sling groups at 1-year (65.5% vs 70.7%, $p = 0.32$) (OR=0.83 [95% CI 0.57–1.20] for retropubic vs. transobturator sling) and throughout the 5-year follow-up period. More women reported OAB symptom improvement after Burch compared to

Corresponding Author: Halina Zyczynski, MD, 300 Halket Street, Pittsburgh, PA 15238, Tel: 412-641-1440, Fax: 412-641-1133, hzyczynski@mail.magee.edu.

*For a list of acknowledgments pertaining to this study, see the Appendixes online at <http://links.lww.com/xxx>.

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

Presented at the 2014 American Urological Association Annual Meeting May 16–21, 2014 Orlando, Florida.

pubovaginal sling (67.9% vs 56.6%, $p=0.01$) (OR=1.59 [95% CI 1.10–2.31] for Burch vs. sling); this group difference at 1-year persisted throughout the 5-year follow-up. At 1-year, 50.0–64.3% of patients reported 70% improvement in urgency incontinence. This proportion declined to 36.5–54.1% at 5-years ($p<0.001$). Preoperative use of anticholinergics and urodynamic parameters were not predictive of OAB symptom change after surgery.

CONCLUSIONS—Most women with stress predominant mixed urinary incontinence experienced significant improvement in OAB symptoms after incontinence surgery although this initial improvement diminished over time. Obesity blunted symptom improvement.

Introduction

Stress urinary incontinence (SUI) surgery has high success rates, levels of satisfaction and durability (1–5). The urgency component of mixed urinary incontinence is considered a risk factor for treatment failure and reduced satisfaction (4, 6–9). The effect of surgery on bladder storage symptoms of the overactive bladder (OAB) syndrome (10) namely urinary urgency, frequency and nocturia with or without urgency urinary incontinence is poorly understood. In a multicenter study comparing Burch and autologous fascial slings, nearly all (92%) women with mixed incontinence expected their co-existent urgency, frequency and nocturia would also improve after their SUI surgery despite counseling efforts to the contrary (11). Thus, persistence of any storage symptoms, not just urgency incontinence, can deleteriously affect a patient's perception of surgical success and satisfaction.

OAB symptoms after surgery have been variably characterized as improved, persistent, exacerbated and new in onset (12–15). Most studies indicate that symptom improvement diminished over time. Studies reporting predictors of improvement have targeted baseline urodynamic study (UDS) parameters (12). With fewer UDS being done, identifying clinical parameters associated with change in OAB symptoms would help inform pre-operative counseling.

The databases of Urinary Incontinence Treatment Network (UITN) are the largest pool of longer-term outcomes from over 1800 well-characterized women who underwent surgery for stress-predominant mixed incontinence. We previously published on post-surgical change in the urgency incontinence component of mixed incontinence. The primary objective of this secondary analysis is to assess how anti-incontinence procedures comprehensively affect all OAB symptoms from 1 to 5 years postoperatively and to identify predictors of this symptom change.

Materials and Methods

This is a secondary analysis of previously unreported data from three UITN multicenter trials exploring the potential effects of procedures on symptoms of the OAB syndrome. The methods, population demographics and outcomes have been published (16–18). Eligibility criteria consistent across the three studies included predominant SUI defined as all of the following: self-reported SUI symptoms of >3 months duration, predominance of SUI symptoms on the Medical, Epidemiologic and Social Aspects of Aging (MESA) questionnaire and demonstrable leakage on provocative stress test (19). None of the studies

required discontinuation of OAB medications. The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) and its extended follow-up study followed women up to 5-years after randomization to the Burch colposuspension or autologous pubovaginal sling (17, 1). The Trial Of MidUrethral Slings (TOMUS) and its extended follow-up study queried women up to 5-years after randomization to retropubic or transobturator midurethral sling (18,19). Our analyses also included 1-year outcome data from women who underwent either a retropubic or transobturator midurethral sling procedure in the Value of Urodynamic Evaluations (ValUE) trial (14). IRB approval was maintained at clinical sites and the coordinating center and all patients provided written consent.

OAB symptoms were prospectively ascertained with two validated measures: the Irritative subscale of the Urogenital Distress Inventory (UDI-I) (20) and the urge symptom index of the Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire (20). The UDI-I (score range 0–100) queries the presence and bother associated with symptoms of frequency, urgency, urgency incontinence, nocturia, bedwetting and large volume leakage. Bother is recorded on a 4-point Likert scale (1= not at all to 4= greatly). The UDI-I was the primary outcome measure for the analyses in this study. The urge component of the MESA questionnaire queries how urine *loss* is experienced with 6 urge items including *loss* of urine preceded by an urge to urinate, or uncontrollable voiding with little or no warning, triggered by washing hands, cold weather or drinking cold beverages. Responses range from never, rarely, sometimes to often (score range 0–18). For this analysis, the MESA Urge score was transcribed to an Index which was expressed as a percentage of the total possible urge score (0–100%).

Improvement in OAB syndrome was defined as a 70% decrease from baseline in UDI-I and the MESA Urge Index. This study-specific definition of clinically meaningful improvement in symptoms was based upon analyses from network data demonstrating that a 70% reduction in incontinence episodes was associated with the highest level of patient reported satisfaction (unpublished). Differences in procedure outcomes were only compared within each trial due to differences in trial eligibility criteria and allowable concomitant procedures. Analyses were performed on data from all patients with baseline and at least one post-surgical time point including: at 1-year and annually up to 5-years after surgery. Time was treated as a continuous variable. Clinical, sociodemographic, procedure characteristics, urodynamic parameters and use of anticholinergic medications at baseline were assessed as potential predictors of change in bladder storage symptoms after surgery. They included age, race, parity, vaginal births, menopause and smoking status, BMI (25–<30, 30 kg/m²), POP-Q stage, baseline UDI-I score, MESA Urge Index), and urodynamic parameters of detrusor overactivity, bladder volume at first desire, strong desire and maximum cystometric capacity.

Generalized estimating equations with a logit link function and compound symmetric covariance structure were used to test the treatment effect on OAB symptom improvement over time, adjusting for baseline UDI-I scores. To identify predictors of symptom *improvement* at 1-year, univariable logistic regression models were fit modeling the probability of improvement as a function of each covariate separately, adjusting for treatment group and baseline symptom scores. Odds ratios and 95% confidence intervals

described the associations between clinical parameters and OAB symptom improvement. The backward elimination method was used to select the final multivariable logistic regression models. Treatment group and baseline OAB symptom score were forced to remain in the model. Spearman correlation examined the association between “improvement” in bladder storage symptoms and satisfaction with surgery. Self-reported satisfaction was assessed with the question, “How satisfied or dissatisfied are you with the result of bladder surgery related to the following symptoms: “urine leakage”, “an urgency to urinate such that you fear not making it to the bathroom in time” and “frequent urination”?” with a 5-point Likert-type response range of: completely dissatisfied through completely satisfied. Using medication audits from each time point, we analyzed the effect of surgery type on change in OAB medication use over time. Statistical analyses were performed at the Data Coordinating Center (New England Research Institute, Watertown, MA) with SAS software, release 9.3 (SAS Institute Inc., Cary, NC). A 5% two-sided significance level was used.

RESULTS

Most patients in the 3 trials reported symptoms of the OAB syndrome. Table 1 indicates the proportion of patients reporting moderate to great bother on at least one symptom in the UDI-I. At baseline, the mean UDI-I scores and mean MESA Urge Index indicated moderate bladder storage symptoms. Each SUI procedure group reported significant post-operative improvement from baseline in UDI-I scores 1-year after surgery ($p<0.001$). Over time, the proportion of women reporting 70% improvement in OAB symptoms by UDI-I gradually declined for each surgical group ($p<0.001$), although about half to two-thirds of remaining study participants continued to report this level of symptom relief 5-years after their index surgery (Figure 1, Tables 2 and 3).

More women reported *improvement* in OAB symptoms on the UDI-I in the Burch group compared to the fascial sling group at 1-year (67.9% vs 56.6%, $p=0.01$), (OR=1.59 [95% CI 1.10–2.31] for Burch vs. sling). This procedure advantage for the Burch persisted when analyses controlled for baseline symptom severity (UDI-I score) and was sustained through 5-years ($p=0.02$). We found the significant symptom *improvement* in each midurethral sling group at 1-year was also sustained through 5-years in the TOMUS study (Table 3). Additionally, the proportion of women reporting symptom *improvement* did not differ between the routes of sling at 1-year in TOMUS, (OR=0.83 [95% CI 0.57–1.20]).

The proportion of patients achieving 70% improvement in incontinence on the MESA Urge Index at 1-year ranged from 50.0% to 64.3% (Tables 2,3 and 4). Again, this proportion declined over time in all groups to 36.5% – 54.1% at 5-years ($p<0.001$) (Tables 2 and 3, Figure 2). When surgical groups were compared within study, averaging the outcomes over all time points, we found no significant differences in the proportions who met our definition of *improvement* on the MESA Urge Index. Throughout the 5-year follow-up, the proportion of women reporting worsening of symptoms on the UDI-I ranged from 13.4–29.1% (Burch), 19.8–30.2% (autologous sling) and 11.7–21.4% (transobturator midurethral sling) and 11.0–21.3% (retropubic midurethral sling).

A minority of patients reported preoperative and postoperative use of anticholinergic medication for OAB symptoms (7.2%–11.6% and 5.4%–11.3% respectively) (Table 5). We found that surgery type had no effect on use of OAB medication at any time points.

The satisfaction women reported with their surgery positively correlated with the magnitude of reduction in their OAB symptoms at all given time points, in all three trials. Patients with greater improvement in baseline OAB symptoms as measured by the UDI-I were more likely to express satisfaction with their surgery regarding overall urine leakage ($p<0.001$), their feeling of urgency ($p<0.001$) and their frequency of urination ($p<0.001$).

We identified few clinical parameters that were strongly associated with postoperative change in storage symptoms at 1-year. In the SISTER trial, OAB symptom *improvement* on UDI-I was positively associated with hormone replacement therapy in menopausal women (adjusted OR 1.64 [95% CI 1.01–2.67]). Conversely, more vaginal births (OR 0.84, [95% CI 0.75–0.95]) and BMI ≥ 30 (compared to BMI 25– <30 , OR 0.57, [95% CI 0.36–0.88]) reduced the likelihood of symptom *improvement* after SUI surgery.

Urodynamic data were analyzed from SISTER ($n=528$), TOMUS ($n=528$) and ValUE ($n=269$) patients. Notably, we found no association in any trials between change in bladder storage symptoms and route of midurethral sling, increasing age, presence of pelvic organ prolapse, concomitant surgery, and urodynamic parameters of detrusor overactivity, bladder volume at first desire, strong desire or maximum cystometric capacity.

Discussion

The majority of women seeking surgery for SUI experience concomitant OAB symptoms. Reassuringly, this analysis found that 57–71% of women with stress predominant mixed incontinence can expect a 70% improvement in their co-existing urinary frequency, nocturia, urgency and urgency incontinence one year after surgery. Although the number of women reporting *improvement* declined over time, half to two thirds (46–65%) maintained this level of symptom improvement up to 5 years after surgery.

The extent of OAB symptom *improvement* was blunted by obesity and differed among the surgical groups indicating that presurgical counseling needs to be individualized and procedure specific. Interestingly, potentially relevant clinical factors such as age, smoking, preoperative use of anticholinergic medication and various urodynamic parameters were not predictors of postoperative improvement of the OAB syndrome.

The literature on the incidence of OAB symptoms after SUI surgery includes large series, RCTs, and reviews (3,8,12–15,21,22). We are limited in our ability to compare our findings to these studies because of differences in outcome measures, definitions of OAB symptoms and endpoints. Most studies, including our previously published outcomes of the SISTER and TOMUS trials, have focused on post-surgical *de novo* urgency urinary incontinence and individual OAB symptoms. A few studies evaluated persistence or worsening of discrete OAB symptoms. In comparison, this analysis reports on change in all symptoms of the OAB syndrome.

Post-surgical OAB symptom improvement and subsequent recurrence have been reported by others. Duckett et al reported that 29 of 46 (63%) women with idiopathic detrusor overactivity and stress incontinence experienced complete resolution of OAB symptoms after a TVT at a median follow-up of 12 (6–26) months. (22). Holmgren et al reported an 60% cure rate of urgency and urgency incontinence up to 4 years after midurethral sling in 1113 women with pre-operative mixed incontinence. This improvement declined to 40% at 5 years and 30% at 4–8 years. They attributed the deterioration of their overall success rate to an increase in urgency urinary incontinence symptoms (23).

Obese women are 43% less likely to experience relief from their OAB symptoms compared to women who are overweight or normal weight. This is not surprising, given that obesity is an established risk factor for OAB syndrome and urinary incontinence (24,25). In a 5-year study of 1481 women, Handa found obesity to increase the odds of urinary urgency (odds ratio 2.89 [CI:2.00, 4.17]), urgency incontinence (odds ratio 2.63 [CI: 1.83, 3.78]), nocturia (odds ratio 1.67 [CI:1.21, 2.30]) and frequency (odds ratio 1.67 [CI:1.21, 2.30]).

In contrast to obesity, the urodynamic variables we evaluated were not predictive of change in OAB symptoms. Our analyses do not support their use in counselling women similar to our study population. Our finding differs from that of Kenton et al., who reported that detrusor overactivity at baseline in the SISTEr patients increased their odds of urgency urinary incontinence nearly 2-fold (OR 2.20, 95% CI 1.08–4.49, $p=0.030$). Their findings were specific to the Burch and autologous sling procedures which comprised less than half of our dataset. They were also limited to urgency urinary incontinence, one of four storage symptoms reflected in our analyses.

A strength of this analysis is its generalizability. The results reflect the long-term surgical outcomes of over 1600 well-characterized women with mixed incontinence after 4 different incontinence procedures. All storage symptoms of the OAB syndrome, not just urgency urinary incontinence, were quantified using validated, patient-reported measures preoperatively and annually for up to 5-years.

Several limitations are acknowledged. To report on a clinically meaningful improvement in OAB symptoms we created a non-validated definition of symptom improvement. This was justified by the absence of an established threshold of change in score on the UDI-I. We measured *improvement in all* OAB symptoms rather than the presence or absence of individual symptoms or the absolute change in the mean UDI-I scores. We felt this would be most useful in pre-operative counselling. None of the trials included a control group therefore we have not provided absolute evidence that SUI procedures reduce OAB symptoms. Lastly, a minority of our patients were taking anticholinergic medications before surgery. This may explain why none of the procedures influenced their use post-operatively and limits the generalizability of our findings in women who are using OAB medications pre-operatively. They may represent a population with more severe OAB symptoms or less tolerance.

Based upon our analyses, clinicians can counsel their patients planning a midurethral sling for stress predominant mixed incontinence that 65–71% can expect a significant

improvement in coexistent OAB symptoms. The symptom improvement does diminish over time and is less likely in obese patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

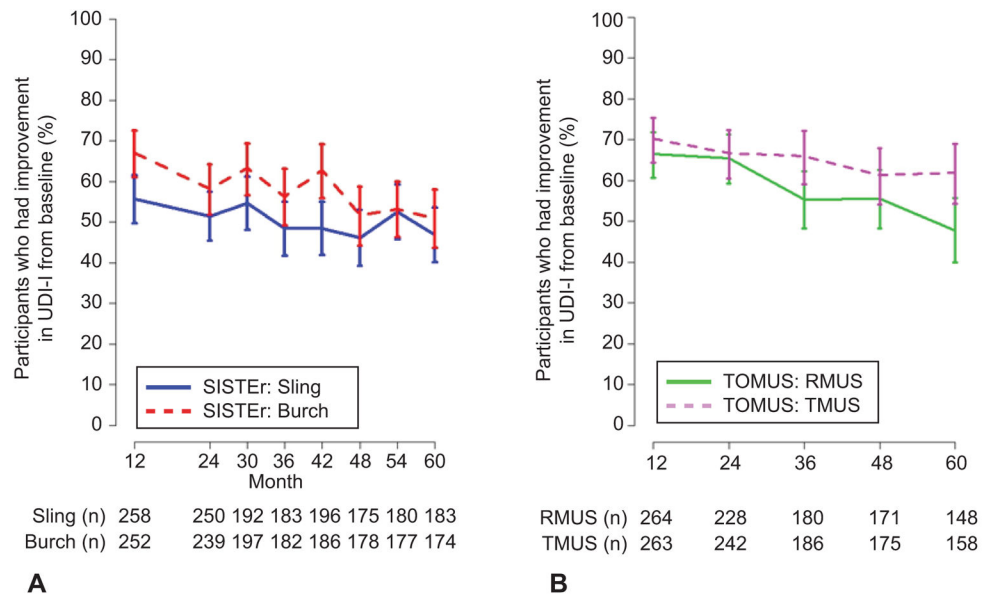
Acknowledgments

Supported by cooperative agreements (U01 DK58225, U01 DK58229, U01 DK58234, U01 DK58231, U01 DK60379, U01 DK60380, U01 DK60393, U01 DK60395, U01 DK60397, and U01 DK60401) from the National Institute of Diabetes and Digestive and Kidney Diseases and by the National Institute of Child Health and Human Development.

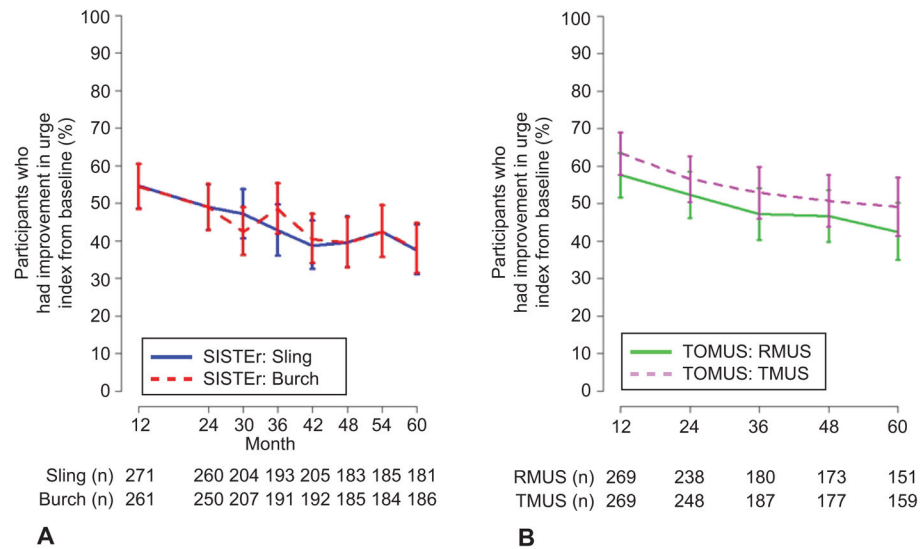
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**Figure 1.**

Percentage of participants who had 70% improvement from baseline in overactive bladder symptoms as measured on the Urogenital Distress Inventory-Irritative (UDI-I) subscale over time. Error bars indicate 95% confidence intervals. SISTER (Stress Incontinence Surgical Treatment Efficacy trial) (A), TOMUS (Trial of Midurethral Slings) (B). RMUS, retropubic midurethral sling; TMUS, transobturator midurethral sling.

**Figure 2.**

Percentage of participants who had 70% improvement from baseline in urgency urinary incontinence as measured by the Medical, Epidemiologic, and Social Aspects of Aging questionnaire urge index over time. Error bars indicate 95% confidence intervals. SISTEr (Stress Incontinence Surgical Treatment Efficacy trial) (A), TOMUS (Trial of Midurethral Slings) (B). RMUS, retropubic midurethral sling; TMUS, transobturator midurethral sling.

Table 1

Baseline Overactive bladder symptom prevalence and severity in trial populations

	Stress Incontinence Surgical Treatment Efficacy (SISTER) ¹ Trial			Trial Of MidUrethral Slings (TOMUS)			Value of Urodynamic Evaluations (ValUE) trial		
	Sling ² (N=294)	Burch (N=284)	Total (N=578)	RMUS ³ (N=273)	TMUS ⁴ (N=277)	Total (N=550)	RMUS ³ (N=350)	TMUS ⁴ (N=142)	Total (N=492)
Moderate or Great Bother on UDI-I ⁵ N (%)	267 (90.8%)	256 (90.1%)	522 (90.5%)	234 (85.7%)	250 (90.3%)	484 (88.0%)	287 (82.0%)	116 (81.7%)	403 (81.9%)
Age mean (SD)	51.9 (10.0)	52.8 (10.3)	52.4 (10.1)	53.2 (10.1)	53.5 (11.3)	53.4 (10.7)	51.8 (10.6)	51.7 (9.3)	51.8 (10.2)
UDI-I ⁵ scores N, mean (SD) ⁶	N=289 47.1 (25.5)	N=276 48.2 (24.3)	N=565 47.6 (24.9)	N=273 39.7 (26.0)	N=275 42.4 (24.1)	N=548 41.1 (25.1)	N=350 35.5 (23.7)	N=142 34.0 (23.3)	N=492 35.0 (23.6)
MESA Urge Index ⁷ N, mean (SD) ⁶	N=293 35.3 (21.8)	N=284 37.1 (21.8)	N=577 36.2 (21.8)	N=273 33.1 (21.9)	N=276 37.4 (21.5)	N=549 35.3 (21.8)	N=350 33.3 (21.3)	N=142 28.7 (21.2)	N=492 32.0 (21.3)

¹ Fascial Sling² Retropubic Mid-urethral Sling³ Transobturator Mid-urethral Sling⁴ Urogenital Distress Inventory-Irritative subscale (UDI-I)⁵ # of patients who had both baseline and any available follow-up data: UDI-I: N=565 in SISTER, N=548 in TOMUS, N=492 in ValUE
Mesa urge index: N=577 in SISTER, N=549 in TOMUS, N=492 in ValUE.⁶ Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire

Table 2

Percentage of patients who reported 70% improvement in Overactive Bladder symptoms from baseline in the Stress Incontinence Surgical Treatment Efficacy (SISTER) Trial

Stress Incontinence Surgical Treatment Efficacy (SISTER) Trial												
	UDI-1 ¹					MESA-Urge Index ²						
Month	Sling (N=294)		Burch (N=284)		Difference between groups OR (95% CI) p-value ³	Change in Improvement over time (in years): OR (95% CI) p-value ⁴	Sling (N=294)		Burch (N=284)		Difference between groups OR (95% CI) p-value ³	Change in Improvement over time (in years): OR (95% CI) p-value ⁴
	Total N	%	Total N	%			Total N	%	Total N	%		
12	258	56.6%	252	67.9%	OR: 0.72(95% CI: 0.55-0.95) p-value: 0.02	OR: 0.89 (95% CI: 0.86-0.93) p-value: <.001	271	55.4%	261	55.6%	OR: 0.99(95% CI: 0.76-1.30) p-value: 0.98	OR: 0.86(95% CI: 0.81-0.89) p-value: <.001
24	250	51.2%	239	59.8%			260	48.9%	250	49.2%		
30	192	52.6%	197	66.0%			204	46.1%	207	44.0%		
36	183	47.5%	182	59.3%			193	41.5%	191	51.3%		
42	196	48.5%	186	63.4%			205	38.5%	192	41.7%		
48	175	46.3%	178	55.6%			183	39.3%	185	40.5%		
54	180	52.8%	177	55.4%	185	42.7%	184	44.0%				
60	183	47.5%	174	53.5%	181	36.5%	186	39.3%				

¹ Urogenital Distress Inventory-Irritative subscale (UDI-I)

² Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire

³ P-value (from Type 3 Generalized score tests) to test the overall difference between two groups across all 5 years using the Generalized estimating equations with a logit link function after adjusting for baseline outcome value.

⁴ P-value (from Type 3 Generalized score tests) to test the decrease in improvement over time using the Generalized estimating equations with a logit link function after adjusting for baseline outcome value. The tests of the hypothesis that the two treatment groups are parallel (the test for the interaction term of treatment and time effect) were not significant for all of 4 analyses.

Table 3

Percentage of patients who reported 70% improvement in Overactive Bladder symptoms from baseline in the Trial of MidUrethral Slings

Trial Of MidUrethral Slings (TOMUS)													
	UDI-1 ¹					MESA-Urge Index ²							
Month	Retropubic midurethral sling (N=273)		Transobturator midurethral sling (N=277)		Difference between groups OR (95% CI) p-value ³	Change in Improvement over time (in years): OR (95% CI) p-value ⁴		Retropubic midurethral sling (N=273)		Transobturator midurethral sling (N=277)	Difference between groups OR (95% CI) p-value ³	Change in Improvement over time (in years): OR (95% CI) p-value ⁴	
	Total N	%	Total N	%	OR: 0.77 (95% CI: 0.58–1.03) p-value: 0.08	OR: 0.86 (95% CI: 0.82–0.91) p-value: <.001	Total N	%	Total N	%	OR: 0.81 (95% CI: 0.62–1.06) p-value: 0.12	OR: 0.86 (95% CI: 0.82–0.91) p-value: <.001	
12	264	65.5%	263	70.7%				269	56.9%	269			64.3%
24	228	63.6%	242	67.4%				238	50.8%	248			57.3%
36	180	53.3%	186	68.3%				180	44.4%	187			55.6%
48	171	53.8%	175	64.6%				173	44.5%	177			54.8%
60	148	46.0%	158	64.6%			151	39.7%	159	54.1%			

¹ Urogenital Distress Inventory-Irritative subscale (UDI-I)

² Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire

³ P-value (from Type 3 Generalized score tests) to test the overall difference between two groups across all 5 years using the Generalized estimating equations with a logit link function after adjusting for baseline outcome value.

⁴ P-value (from Type 3 Generalized score tests) to test the decrease in improvement over time using the Generalized estimating equations with a logit link function after adjusting for baseline outcome value. The tests of the hypothesis that the two treatment groups are parallel (the test for the interaction term of treatment and time effect) were not significant for all of 4 analyses.

Table 4

Percentage of patients who reported 70% improvement in Overactive Bladder symptoms from baseline in the Value of Urodynamic Evaluations (Value) trial

Value of Urodynamic Evaluations (Value) trial											
		UDI-I ¹				MESA-Urge Index ²					
Month	Retropubic midurethral sling (N=350)		Transobuturator midurethral sling (N=142)		Difference between groups OR (95% CI) p-value ³		Retropubic midurethral sling (N=350)		Transobuturator midurethral sling (N=142)		Difference between groups OR (95% CI) p-value ³
	Total N	%	Total N	%			Total N	%	Total N	%	
12	350	70.9%	142	65.5%	OR: 1.26 (95% CI:0.82–1.93)	p-value: 0.29	350	56.3%	142	50.0%	OR: 1.16 (95% CI:0.77–1.74) p-value: 0.47

¹ Urogenital Distress Inventory-Irritative subscale (UDI-I)

² Medical, Epidemiologic, and Social Aspects of Aging (MESA) questionnaire

³ Logistic regression was used to test the difference between two groups at 12 months after adjusting for baseline outcome value.

Table 5

Percentage of patients by trial group reporting use of anticholinergic medications at each time point.

	Stress Incontinence Surgical Treatment Efficacy Trial ¹	Trial Of MidUrethral Slings ²	Value of Urodynamic Evaluations Trial ²
Baseline	7.2%	11.6%	9.8%
12 month	8.0%	8.5%	11.3%
24 month	5.4%	9.8%	
36 month	6.5%	5.7%	
48 month	5.2%	4.6%	
60 month	6.0%	3.9%	

¹ Burch colposuspension and Fascial Sling groups

² Retropubic and Transobturator Mid-urethral Sling groups