

Outcomes of Midurethral Slings in Women with Concomitant Preoperative Severe Lower Urinary Tract Voiding Symptoms

Michael S. Ingber, MD,¹ Ryan M. Krlin, MD,² Sandip P. Vasavada, MD,¹ Farzeen Firoozi, MD,¹ Howard B. Goldman, MD¹

¹Glickman Urological & Kidney Institute, Cleveland Clinic, Cleveland, OH ²Department of Urology, Louisiana State University Health Sciences Center, New Orleans, LA

Background: Women with stress urinary incontinence and concomitant obstructive (voiding) lower urinary tract symptoms (LUTS) represent a challenging patient population. Furthermore, their diagnosis and management remain incompletely studied and controversial. We evaluated the outcomes of midurethral sling procedures in women with severe obstructive LUTS.

Methods: We performed a post hoc analysis of women who were part of an institutional review board-approved study of midurethral sling surgery. Preoperatively and at 4–6 weeks postoperatively, patients completed the American Urological Association Symptom Score (AUASS) questionnaire. A postvoid residual urine test was obtained preoperatively, at the time of the voiding trial, and 4–6 weeks postoperatively. Three groups of patients with severe LUTS were then defined: Group A (AUASS ≥ 20), Group B (voiding subscale ≥ 12), and Group C (urodynamic obstruction). Patients could be included in more than one group. AUASS was again obtained at a medium-term follow-up of 31.6 months.

Results: Of 106 women completing follow-up, 30, 23, and 11 subjects met the criteria for groups A, B, and C, respectively. All had statistically significant improvements in storage and voiding subscales, as well as their stress urinary incontinence. No subject presented with retention or voiding dysfunction at follow-up. These improvements continued at medium-term follow-up with the exception of Group C that failed to demonstrate persistence of statistical improvement in AUASS subscales.

Conclusion: Patients with stress urinary incontinence and severe voiding LUTS can be treated safely with midurethral sling procedures. In both the short and medium term, these symptoms improve dramatically in the majority of patients.

Keywords: Lower urinary tract symptoms, suburethral slings, urinary incontinence–stress

Address correspondence to Ryan M. Krlin, MD, Department of Urology, Louisiana State University Health Sciences Center, 1542 Tulane Ave., Room 547, New Orleans, LA 70112. Tel: (504) 568-2207. Email: rkrli1@lsuhsc.edu

INTRODUCTION

Midurethral synthetic sling surgery has become the most common antiincontinence procedure performed in the developed world, with more than 1 million procedures performed in the last 2 decades.^{1,2} Many types of sling kits are available that allow placement of a mesh in either a retropubic or a transobturator fashion. Both methods have good outcomes, and long-term cure and significantly improved rates exceed 90%.³ However, the best modality to treat patients with complicated cases of stress incontinence is still debated.

Specifically, patients with concomitant voiding lower urinary tract symptoms (LUTS) and stress urinary incontinence represent a challenging subset to diagnose and manage.⁴ LUTS can include storage symptoms (urinary urgency, urinary frequency, urgency incontinence) and voiding symptoms (urinary hesitancy, urinary straining, decreased force of stream, incomplete emptying). A paucity of data exists in the

literature on LUTS in the female patient, likely because of its lower incidence compared to male obstruction related to benign prostatic hyperplasia and the lack of agreed-upon criteria. Additionally, dysfunctional voiding may be present in neurologically normal women with no prior urologic history and can further confound decision-making in this patient population.⁵ Nevertheless, an assortment of definitions of LUTS in women now exists based on objective and subjective criteria. Certain components of LUTS, such as a weak urinary stream and urinary hesitancy, are well-known complications of antiincontinence surgery. However, to our knowledge, no study has shown improvements when such symptoms exist at baseline. Our institution conducted a prospective study of women undergoing sling surgery to evaluate LUTS. We evaluated a population of women who underwent a midurethral sling procedure and had severe LUTS based on their American Urological Association Symptom Score (AUASS).

AUA SYMPTOM SCORE

PATIENT NAME: _____ TODAY'S DATE: _____

(Circle One Number on Each Line)	Not at All	Less Than 1 Time in 5	Less Than Half the Time	About Half the Time	More Than Half the Time	Almost Always
Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
During the past month or so, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
During the past month or so, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
During the past month or so, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
During the past month or so, how often have you had a weak urinary stream?	0	1	2	3	4	5
During the past month or so, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	1 Time	2 Times	3 Times	4 Times	5 or More Times
Over the past month, how many times per night did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

Add the score for each number above and write the total in the space to the right. TOTAL: _____

SYMPTOM SCORE: 1-7 (Mild) 8-19 (Moderate) 20-35 (Severe)

QUALITY OF LIFE

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
How would you feel if you had to live with your urinary condition the way it is now, no better, no worse, for the rest of your life?	0	1	2	3	4	5	6

Figure. American Urological Association Symptom Score.⁶

METHODS

This study was conducted as a planned post hoc analysis of data obtained from an institutional review board-approved prospective study of midurethral sling procedures performed at our institution. Subjects who were scheduled to undergo isolated midurethral synthetic sling surgery were recruited in the office setting of 4 fellowship-trained urologists in female pelvic medicine and reconstructive surgery. Informed consent to participate in the study was obtained. Patients who had had prior antiincontinence procedures were included in the study population. Women who required concomitant pelvic organ prolapse surgery, urethrolisis, or other procedures were excluded from participation.

Subjects completed an AUASS questionnaire at their preoperative visit to determine subjective voiding (obstructive) symptoms. Postvoid residual measurements were recorded at the preoperative visit, at the time of the voiding trial, and 4-6

weeks postoperatively. Urodynamic investigations were performed at the discretion of the surgeon.

The AUASS was developed initially for evaluating male patients with benign prostatic hyperplasia with obstructive and irritative voiding symptoms.⁶ Subsequent studies evaluated sex differences between AUASSs and found no evidence of a sex difference when evaluating women with this tool.^{7,8} Scarpero et al further demonstrated that the AUASS accurately reflects LUTS in women and is a good indicator of the “degree of bother” and effect on quality of life.⁹ The AUASS is determined by a 7-item questionnaire that asks about both storage symptoms and obstructive symptoms (Figure).⁶ Each item is scored 0-5 based on frequency of urinary complaints, and the total score is 0-35. Patients with scores ≥ 20 are defined as the severe symptom group. The 7 items can be further divided into storage questions (questions 2, 4, and 7) and voiding questions (questions 1, 3, 5, and 6).

Table 1. Baseline Demographics for Patients with an AUASS ≥ 20 (n=30)

Variable	n	%
Married	20	66.7
Caucasian	28	93.3
Employed	16	53.3
Medical Condition		
Diabetes	3	10.0
Neurogenic bladder	5	16.7
Mixed incontinence	25	83.3
Surgical History		
Prior antiincontinence surgery	11	36.7
Prior hysterectomy	20	66.7
Prior prolapse surgery	8	26.7
Type of Sling		
Transobturator	13	43.3
Retropubic	17	56.7

AUASS, American Urological Association Symptom Score.

An eighth question asks about quality of life related to urinary symptoms and is scored from 0 (delighted) to 6 (terrible).

Definitions of Severe LUTS

We evaluated 3 categories of patients with severe LUTS. First, we evaluated subjects with a total score ≥ 20 on the AUASS questionnaire (Group A). Second, to evaluate patients who had primarily outlet-related symptoms, we evaluated the patients with a voiding score ≥ 12 (Group B). This score on the voiding subscale corresponds to an average of having such voiding-related symptoms (questions 1, 3, 5, and 6) "about half the time" or more often. Last, to evaluate obstruction as a possible etiology of severe LUTS, our third group was based on urodynamic definitions of obstruction (Group C). We defined urodynamic outlet obstruction as a maximum flow of ≤ 12 mL/s, with a detrusor pressure at maximum flow of ≥ 20 cmH₂O.¹⁰ Patients could be included in one or more of these 3 categories of LUTS.

Operative Procedure

The choice of midurethral sling was determined by the surgeon. All 4 surgeons routinely perform retropubic and transobturator sling surgery, and both modalities were used in this patient population. All sling procedures were performed under general or local anesthetic with intravenous sedation. No subject had a spinal anesthetic. All patients had a voiding trial within 1 hour of arrival to recovery, during which 300 mL of fluid was instilled in a retrograde fashion through the Foley catheter.

Postoperative Care

Subjects failing the voiding trial returned to the office within 48-72 hours for a repeat trial. All other subjects were telephoned within the first week to ensure that they were voiding without problems and had no signs or symptoms of urinary tract infection. Subjects had a postoperative visit 4-6

Table 2. Baseline Urodynamic Parameters for Patients with an AUASS ≥ 20 (n=28)

Urodynamic Parameter	Mean	SD
Abdominal leak-point pressure, cmH ₂ O	108.7	40.0
Detrusor pressure at maximum flow rate, cmH ₂ O	26.3	22.3
Maximum flow rate, mL/s	17.1	9.8
Postvoid residual urine, mL	27.6	35.2

AUASS, American Urological Association Symptom Score.

weeks after surgery. At the follow-up visit, each subject had a repeat postvoid residual check and completed a postoperative AUASS questionnaire. To obtain medium-term follow-up, patients were contacted more than 2 years after surgery and administered the AUASS questionnaire by trained study personnel.

Statistical Analysis

Statistical calculations were carried out using SAS 9.2 (SAS Institute, Inc.). Preoperative values of the AUASS were compared to postoperative values using the paired Student *t* test. Identical calculations were performed to analyze voiding scores, symptom subscores, and postvoid residual measurements.

RESULTS

A total of 106 women underwent solitary sling surgery at our institution and completed their follow-up. Using the definitions of a preoperative AUASS ≥ 20 , a voiding score ≥ 12 , or uroodynamically proven obstruction, 30, 23, and 11 women were classified as having severe symptoms, respectively. All but 2 (93.3%) of the 30 subjects with LUTS had baseline urodynamic evaluations. Baseline demographic data and urodynamic parameters are shown in Tables 1 and 2. The mean body mass index of the study population was 31 ± 7.3 kg/m².

All groups had significant improvements in total AUASS, storage score, and voiding score after sling surgery (Table 3). These significant improvements persisted to medium-term follow-up (mean time of 31.6 [range, 27-35] months) with the exception of Group C (urodynamic obstruction).

Postvoid residual values at baseline, at the time of the voiding trial, and at the follow-up visit are shown in Table 4. At the time of the immediate postoperative voiding trial, residual volumes increased significantly but then dropped to nearly the preoperative value at the postoperative follow-up visit. No differences were seen between subjects who had a retropubic sling or a transobturator sling with respect to urodynamic evidence of obstruction, AUASS, voiding scores, or storage scores.

Five of the 30 patients with an AUASS ≥ 20 failed the initial voiding trial and required catheterization upon discharge. However, all 5 passed the subsequent voiding trial within 48-72 hours. Two of the 30 (6.7%) patients developed a symptomatic urinary tract infection prior to their postoperative visit and required antibiotic therapy. No patient returned to the office or had any emergency department visits related to acute voiding dysfunction or urinary retention.

Table 3. AUASS Total Scores and Subscores by Group

Parameter	Preoperative		Postoperative (short-term, 4-6 weeks)			Postoperative (medium-term, 27-35 months)		
	Mean	SD	Mean	SD	P Value	Mean	SD	P Value
Group A								
Patients with AUASS ≥ 20 (n=30)								
AUA storage score	11.87	2.16	3.77	3.07	<0.0001	8.33	4.39	0.0013
AUA voiding score	12.73	3.34	5.53	3.43	<0.0001	7.53	4.82	<0.0001
Total AUASS	24.57	3.79	9.30	5.90	<0.0001	15.87	8.45	<0.0001
AUA QOL score	5.00	1.36	1.60	1.48	<0.0001			
Group B								
Patients with voiding score ≥ 12 (n=23)								
AUA storage score	11.61	2.27	4.82	3.00	<0.0001	8.27	4.86	0.0096
AUA voiding score	14.74	2.72	4.82	3.56	<0.0001	8.72	5.64	0.0002
Total AUASS	26.35	3.82	9.65	5.52	<0.0001	17.00	10.00	0.0004
AUA QOL score	5.17	1.07	1.24	1.25	<0.0001			
Group C								
Patients with BOO on UDS (n=11)								
AUA storage score	8.55	3.72	5.18	3.31	0.0171	10.00	4.47	0.4783
AUA voiding score	6.91	5.80	2.09	2.39	0.0202	9.57	7.07	0.7562
Total AUASS	15.45	8.45	6.82	4.47	0.0014	19.57	10.73	0.6209
AUA QOL score	4.82	0.98	1.36	1.12	<0.0001			

AUA, American Urological Association; AUASS, American Urological Association Symptom Score; BOO, bladder outlet obstruction; QOL, quality of life; SD, standard deviation; UDS, urodynamics.

DISCUSSION

Our planned post hoc analysis shows that in patients with severe LUTS and concomitant stress urinary incontinence, both retropubic and transobturator slings are safe and effective in the short and medium terms. The management of patients presenting with concomitant stress incontinence and severe LUTS is often challenging. Only one prior study, Ballert et al in 2008, has evaluated LUTS with the AUASS before and after midurethral sling surgery.¹¹ In that series, the authors reported on 100 consecutive patients who underwent solitary sling surgery and had a statistically significant decrease of 3.6 points in total AUASS after surgery. Voiding scales were also calculated, but, unlike our study, no significant change was seen after surgery. The population was a heterogeneous cohort, and the mean preoperative total AUASS was 14.1.

Table 4. Postvoid Residual Urine for Patients with an AUASS ≥ 20 at Baseline, Time of Voiding Trial, and Follow-Up

Time Point	Postvoid Residual Urine, mL		P Value
	Mean	SD	
Preoperative	27.6	35.3	0.0016, ^a 0.2975 ^b
Voiding trial in recovery	123.9	143.2	
Postoperative	41.7	58.6	

AUASS, American Urological Association Symptom Score.

^aCompared to the voiding trial.

^bCompared to the postoperative time point.

Clearly, our population, with a mean AUASS of 24.6 at baseline, demonstrated much more severe symptoms at baseline than the patients evaluated in the Ballert et al study.

A possible explanation for why subjects with stress urinary incontinence have such high AUASSs relates to so-called “defensive voiding.” Patients with stress urinary incontinence may realize that leakage is more common with a full bladder. As a result, these patients might void with a higher frequency to keep their bladders empty. In a study evaluating voiding diaries in subjects with stress urinary incontinence and overactive bladder, not surprisingly, the overactive bladder population had a higher daytime voiding frequency than the pure stress urinary incontinent population.¹² Interestingly, however, subjects with pure stress urinary incontinence had high voiding frequency (median 74th reference population percentile) and relatively low volume per void (median 29th reference population percentile). This could potentially explain some of the baseline complaints in our study. In addition, patients with prior antiincontinence procedures were not excluded, and residual changes to the outlet after prior surgeries could persist and increase the baseline AUASS. Improvement of storage symptoms after sling surgery has been well documented in prior studies.^{11,13} However, the idea that placement of a sling might improve LUTS and potentially obstructive symptoms is counterintuitive. While it is reasonable to assume that a tension-free sling should not worsen obstructive symptoms, the improvement of these symptoms in many patients was unexpected. A possible explanation is that patients with stress urinary incontinence may guard to prevent leakage, leading to an element of dysfunctional

voiding that may resolve when the fear of stress urinary incontinence is gone.

Furthermore, afferent nerve fibers in the urethra are known to facilitate voiding by activating bladder parasympathetics.¹⁴ Frequent stimulation of these afferent nerves secondary to incontinence could lead to sensations of the need to void to which the patient responds by contracting the pelvic floor, developing a form of dysfunctional voiding. Correction of urinary incontinence may, in fact, aid by eliminating this urethral stimulation and breaking this dysfunctional cycle, thus facilitating flow. Regardless, in the medium term the only patients who did not continue to have significant improvement in the obstructive symptoms were those with urodynamically documented obstruction. Patients who had only subjective obstructive symptoms continued to show improvement.

Our study has several limitations. We evaluated short-term results at 4-6 weeks postoperatively with the AUASS and postvoid residual test but for logistical reasons were unable to obtain a repeat postvoid residual test for the medium-term follow-up. Although voiding LUTS improved in the short term and persisted to the medium-term follow-up, whether such symptoms will revert to baseline in the long term remains to be determined, but reversion to baseline seems unlikely, as there is no trend toward that at present. Similarly, we did not obtain quality of life scores at medium-term follow-up. Last, while urodynamic evaluations were performed in all but 2 patients preoperatively, we did not obtain postoperative studies. Prior studies have shown significant changes in peak flow 1 year after sling surgery.¹⁵ The impact of slings on flow and voiding pressures in our severe symptom group is unknown.

CONCLUSION

We have shown that patients with stress urinary incontinence and severe voiding LUTS based on a variety of definitions can be treated safely with midurethral slings. No worsening of obstructive symptoms occurs, and in the short and medium term, severe symptoms seem to improve dramatically, resulting in significant improvement in quality of life for the majority of patients.

ACKNOWLEDGMENTS

Dr Michael Ingber is a consultant for American Medical Systems, a speaker for Allergan and Warner Chilcott, and a scientific advisor for TheraCoat and HeatBio. Dr Sandip Vasavada is a consultant for American Medical Systems and Allergan. Dr Howard B. Goldman is a consultant for Allergan and Medtronic and a speaker for Astellas, Teva, and Medtronic. Otherwise, the authors have no financial or proprietary interest in the subject matter of this article.

This study was approved by the institutional review board and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Informed consent to participate in this study was obtained from all patients.

The authors thank Dr Courtenay Moore and Dr Raymond Rackley for contributing patients to this study.

REFERENCES

1. Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. *BJOG*. 2007 May;114(5):522-531. Erratum in: *BJOG*. 2007 Oct;114(10):1311.
2. Cody J, Wyness L, Wallace S, et al. Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence. *Health Technol Assess*. 2003;7(21):iii, 1-189.
3. Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Aug;19(8):1043-1047. doi: 10.1007/s00192-008-0666-z.
4. Bradley CS, Rovner ES. Urodynamically defined stress urinary incontinence and bladder outlet obstruction coexist in women. *J Urol*. 2004 Feb;171(2 Pt 1):757-760; discussion 760-761.
5. Carlson KV, Rome S, Nitti VW. Dysfunctional voiding in women. *J Urol*. 2001 Jan;165(1):143-7; discussion 147-148.
6. Barry MJ, Fowler FJ Jr, O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J Urol*. 1992 Nov;148(5):1549-1557; discussion 1564.
7. Lepor H, Machi G. Comparison of AUA symptom index in unselected males and females between fifty-five and seventy-nine years of age. *Urology*. 1993 Jul;42(1):36-40; discussion 40-41.
8. Chai TC, Belville WD, McGuire EJ, Nyquist L. Specificity of the American Urological Association voiding symptom index: comparison of unselected and selected samples of both sexes. *J Urol*. 1993 Nov;150(5 Pt 2):1710-1713.
9. Scarpero HM, Fiske J, Xue X, Nitti VW. American Urological Association Symptom Index for lower urinary tract symptoms in women: correlation with degree of bother and impact on quality of life. *Urology*. 2003 Jun;61(6):1118-1122.
10. Blaivas JG, Groutz A. Bladder outlet obstruction nomogram for women with lower urinary tract symptomatology. *Neurourol Urodyn*. 2000;19(5):553-564.
11. Ballert KN, Kanofsky JA, Nitti VW. Effect of tension-free vaginal tape and TVT-obturator on lower urinary tract symptoms other than stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Mar;19(3):335-340.
12. Parsons M, Amundsen CL, Cardozo L, Vella M, Webster GD, Coats AC; Bladder Diary Research Team. Bladder diary patterns in detrusor overactivity and urodynamic stress incontinence. *Neurourol Urodyn*. 2007;26(6):800-806.
13. Laurikainen E, Valpas A, Kivelä A, et al. Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. *Obstet Gynecol*. 2007 Jan;109(1):4-11.
14. Sadananda P, Vahabi B, Drake MJ. Bladder outlet physiology in the context of lower urinary tract dysfunction. *Neurourol Urodyn*. 2011 Jun;30(5):708-713. doi: 10.1002/nau.21137.
15. Sander P, Møller LM, Rudnicki PM, Lose G. Does the tension-free vaginal tape procedure affect the voiding phase? Pressure-flow studies before and 1 year after surgery. *BJU Int*. 2002 May; 89(7):694-698.

This article meets the Accreditation Council for Graduate Medical Education and the American Board of Medical Specialties Maintenance of Certification competencies for Patient Care, Medical Knowledge, and Practice-Based Learning and Improvement.