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Two-Year Results of Burch Compared With Midurethral Sling With Sacrocolpopexy: A Randomized Controlled Trial

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Abstract

Objectives—To compare 1- and 2-year urinary continence rates after Burch retropubic urethropexy versus retropubic midurethral sling for women with urinary incontinence undergoing sacrocolpopexy.

Methods—We conducted a planned secondary analysis of a multicenter, randomized, single-blinded trial comparing Burch with sling that enrolled participants from June 2009 to August 2013. Objective outcome measures of continence were assessed at 1- and 2-year follow-up through office visit and validated questionnaires. Overall continence was defined as negative stress test, no re-treatment for stress incontinence, and no self-reported urinary incontinence (International Consultation on Incontinence Questionnaire, Short Form, score, 0). Stress-specific continence was defined as fulfillment of first 2 criteria above and no self-reported stress-related incontinence. Primary outcomes were assessed with intention-to-treat and within-protocol analyses. Comparisons between groups were evaluated using χ^2 or Fisher exact test.

Results—The two groups were similar in all measured baseline features. Outcome assessments at 2 years were available for 48/57 patients (84%) in the sling group and 45/56 patients (80%) in the Burch group. With intention-to-treat analysis, the sling group had significantly higher rates of overall continence than the Burch group (49% [28/57] vs 29% [16/56]; 95% CI for absolute risk difference, 3.0–38.1; $P=.03$) at 1- but not 2-year follow-up (47% [27/57] vs 32% [18/56]; 95% CI for absolute risk difference, –2.6–33.1; $P=.10$). The sling group had significantly higher rates of stress-specific continence than the Burch group at 1-year (70% [40/57] vs 46% [26/56]; 95% CI for absolute risk difference, 6.1–41.4; $P=.01$) and 2-year (70% [40/57] vs 45% [25/56]; 95% CI for absolute risk difference 7.9–43.2; $P=.006$) follow-up. No difference was detected in prolapse

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recurrence, voiding dysfunction, antimuscarinic medication use, urgency incontinence, and patient satisfaction.

Conclusion—Among women with baseline urinary incontinence undergoing sacrocolpopexy, retropubic midurethral sling resulted in higher stress-specific continence rates than Burch retropubic urethropexy at 1- and 2-year follow-up.

Introduction

Pelvic organ prolapse (POP) can have a large effect on a woman's quality of life secondary to discomfort, decreased energy, and social isolation (1). In a contemporary population-based analysis, the risk of a woman undergoing surgery for prolapse by age 80 years was an estimated 13% (2). Although abdominal sacrocolpopexy is considered the gold standard operation for POP (3), the preferred approach to address coexistent stress urinary incontinence (SUI) is unclear—Burch retropubic urethropexy conveniently through the same abdominal incision or retropubic midurethral sling with a separate suburethral incision. This consideration is important given the volume of open sacrocolpopexies performed. In a study of POP procedures from 2005 to 2013, 30% of sacrocolpopexies were performed via open abdominal approach (4).

We previously conducted a randomized superiority trial comparing these anti-incontinence procedures during abdominal sacrocolpopexy (5). Although women undergoing midurethral sling reported greater satisfaction (78% vs 57%; $P=.04$), no difference was found in overall (midurethral sling vs Burch, 51% vs 41%; $P=.30$) and stress-specific continence (midurethral sling vs Burch, 74% vs 57%; $P=.06$) between the 2 treatment groups at 6-month follow-up (5). As part of a planned secondary analysis, we report continence (overall and stress-specific), voiding dysfunction, increased postvoid residual, de novo or resolution of urgency incontinence, incontinence severity, satisfaction, and adverse events at 1 and 2 years of follow-up.

Materials and Methods

This was a planned secondary analysis of a randomized, multicenter superiority trial comparing Burch retropubic urethropexy to retropubic midurethral sling in women with occult stress urinary incontinence or SUI undergoing concurrent abdominal sacrocolpopexy for symptomatic POP. The specific details of the trial have been previously published (5). The trial protocol was approved by the institutional review boards of the participating sites, was registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00934999) (NCT00934999), and is reported in accordance with the modified Consolidated Standards of Reporting Trials Statement (6). All participants provided written informed consent before enrollment.

Study-eligible women were at least 21 years of age; opted for an abdominal prolapse repair of symptomatic stage II or greater apical or anterior vaginal wall prolapse (POP quantification point Aa, Ba, or C at ≥ 1 cm) (7); had symptomatic stress or stress-predominant mixed urinary incontinence symptoms or occult SUI, and cystometric capacity ≥ 200 mL; signed written consent; and were willing to complete follow-up visits. Follow-up assessments consisted of completion of validated questionnaires and clinical examinations

both at 6 weeks, 6 months, 1 year, and 2 years after the randomized surgery. For this planned secondary analysis, the primary outcomes of overall continence and stress-specific continence were assessed at 1- and 2-year follow-up. Patients were considered overall continent if they had the following criteria: 1) negative standardized cough stress test performed by an observer to whom procedures were masked, 2) no interim surgical re-treatment of SUI, and 3) no self-reported urinary incontinence (ie, score of 0 on the International Consultation on Incontinence Questionnaire, Short Form [ICIQ]) (8). Stress-specific continence required fulfilling criteria 1 and 2 and having no self-reported stress-related incontinence leakage of urine (a response of *never* or *rarely* to 6 questions from the stress incontinence subscale of the Medical, Epidemiological, and Social Aspects of Aging questionnaire) (9). Patient satisfaction, voiding dysfunction, increased postvoid residual, apical or anterior prolapse failure, de novo or resolution of urgency incontinence, and incontinence severity were assessed as secondary outcomes (see previous publication for definitions) (4).

All women received an abdominal sacrocolpopexy, as described by Maher et al (10), with either a Burch modified Tanagho procedure (11) or a midurethral sling with a commercially available retropubic sling, as described by Ulmstein et al (5,12). All surgeons were fellowship trained and had experience with both anti-incontinence surgeries. Surgeon discretion was used to determine whether a posterior repair was needed at the time of surgery.

Primary outcome analyses conducted at 1- and 2-year follow-up were performed using an intention-to-treat (ITT) principle that included all randomly assigned patients; those who did not return for follow-up were considered not to be continent. A within-protocol analysis was also performed that included all patients with follow-up at the time of interest or who had interim re-treatment at or before the time of interest. Demographic variables and primary and secondary outcomes were compared between the 2 groups using 2-sample *t* test for continuous variables, Wilcoxon rank-sum test for ordinal measures, and χ^2 test or Fisher exact test for categorical variables. *P* values were 2-sided and considered significant when *P* < .05. Statistical analyses were performed with statistical software (SAS version 9.3; SAS Institute Inc).

Results

Women were enrolled in the study between June 1, 2009, and August 31, 2013 (Figure 1); baseline clinical and demographic patient characteristics are summarized in Table 1. The 2 groups were similar in all measured baseline features, including dynamic allocation variables (ie, age, body mass index, prior incontinence surgery, intrinsic sphincter deficiency, and prolapse stage). The majority of participants were postmenopausal, white, multiparous women with greater than a high school education.

Outcome follow-up assessments were available for 51 (89%) of the 57 patients in the retropubic midurethral sling group and 47 (84%) of the 56 patients in the Burch retropubic urethropexy group at 1 year and for 48 patients (84%) in the retropubic midurethral sling group and 45 patients (80%) in the Burch retropubic urethropexy group at 2 years.

Using the ITT principle, patients in the midurethral sling group had significantly higher rates of overall continence than patients in the Burch group (28/57 [49%] vs 16/56 [29%]; $P=.03$) at 1-year follow-up but not at 2-year follow-up (27/57 [47%] vs 18/56 [32%]; $P=.10$). Similar findings were observed for the within-protocol analyses. Women in the midurethral sling group had significantly higher rates of stress-specific continence than women in the Burch group at both 1-year (40/57 [70%] vs 26/56 [46%]; $P=.01$) and 2-year (40/57 [70%] vs 25/56 [45%]; $P=.006$) follow-up (Table 2).

The occurrence of each component of the composite continence primary outcome criteria at 2 years is shown in Figure 2. Most women were deemed incontinent because of a positive response to the ICIQ question “Do you leak urine?”. There was no difference between the groups in the proportion of women who had an ICIQ score >0 , needed repeat operation for SUI, had a positive stress test, or had an ICIQ score >0 and stress-specific symptoms at 2 years.

No difference was found between the 2 groups in patient perception of symptom improvement or incontinence severity at 2 years (Table 3). In addition, a similar proportion of patients reported satisfaction at 2 years with the midurethral sling and the Burch procedures (34/44 [77%] vs 29/42 [69%]; $P=.39$). Furthermore, no differences were observed between groups in the proportion of patients with apical or anterior prolapse failure, persistent voiding dysfunction, or a postvoid residual >150 mL. Likewise, no difference was detected in the rate of de novo urgency incontinence, antimuscarinic medication use, or rate of resolution of baseline urgency symptoms (Table 3). Two patients in the Burch group, versus none in the sling group, needed reoperation for incomplete bladder emptying.

A higher proportion of women in the midurethral sling group had mesh exposure related to the abdominal sacrocolpopexy and necessitating surgical revision than in the Burch group (7/56 [13%] vs 1/55 [2%]; $P=.06$) (2 women had no postoperative visit and therefore were not included in the denominators). In addition, 1 sling-related mesh exposure was identified; it resolved with topical estrogen therapy. No bladder perforations occurred during retropubic midurethral sling trocar passage. The 1 death noted during the trial was unrelated to study participation; cause of death was complications from drug overdose.

Discussion

We found that retropubic midurethral sling placement at the time of sacrocolpopexy was associated with significantly improved continence rates at 1- and 2-year follow-up compared with Burch retropubic urethropexy. This extends the findings from our previously reported multicenter superiority trial comparing retropubic midurethral sling to Burch procedure in women undergoing abdominal sacrocolpopexy (5). Whereas in our initial report of 6-month follow-up we found no statistically significant difference in the rate of overall and stress-specific continence between groups (5), herein we report that women undergoing retropubic midurethral sling had significantly greater stress-specific continence in the analyses of ITT and within protocol at 1- and 2-year follow-up. Similarly, women who received the sling also had greater overall continence than participants undergoing a Burch urethropexy in all

analyses at 1 year. No difference was found in patient satisfaction, incontinence severity, or rate of voiding dysfunction between groups. The difference in findings between the 6-month results in our original publication (5) and the 1- and 2-year results seen in the present study is likely secondary to a larger deterioration in overall and stress-specific continence rates in the Burch retropubic urethropexy group than in the retropubic midurethral sling group over time. Clinically, these findings can be used to better inform preoperative patient counseling and can aid in the selection of an anti-incontinence procedure to perform at the time of sacrocolpopexy.

A large, robustly designed, multicenter European trial comparing isolated Burch to retropubic midurethral sling similarly found no difference in continence rates between the procedures at 6-month and 2-year follow-up (13,14). However, the trial used a less stringent primary outcome (1-hour pad test) and was underpowered because of extensive loss to follow-up in both groups at 2 years (14). In contrast, a large multicenter trial, using a similarly stringent continence composite outcome, showed that Burch yielded inferior overall success (38% vs 47%) and stress-specific continence (49% vs 66%) rates compared with autologous pubovaginal sling at 2 years (15). This difference in overall continence persisted at 5 years (16).

More recently, participants in the Stress Incontinence Surgical Treatment Efficacy trial (15) and women in a large equivalence trial comparing retropubic and transobturator slings (17) were pooled to compare continence rates between autologous slings, Burch, and midurethral slings (18). Propensity score matching was used to minimize bias among the trials. In this analysis, the risk of failure at 2-year follow-up was 1.69 times higher for the Burch group than the midurethral sling group (95% CI, 1.20–2.36) (18). Moreover, women undergoing Burch were more likely to seek retreatment of SUI and reported more urgency incontinence symptoms, suggestive that the Burch may yield inferior continence results compared with midurethral sling (18).

The reason is unclear why continence following a Burch procedure would deteriorate with time. The opposing vectors for Burch (toward the anterior abdominal wall) and sacrocolpopexy (toward the sacrum) may result in diminished efficacy for Burch over time. Of note, a large multicenter equivalence trial comparing transobturator and retropubic slings noted equivalence for objective continence at 12, but not 24 or 60, months (17,19,20). These findings suggest that waning of efficacy with time may occur after different types of SUI operations and call for medium-term comparison studies in the future.

Although significant differences occurred in overall and stress-specific continence between groups in our study, we observed no significant differences in patient satisfaction or other secondary outcomes. Nevertheless, the direction of the comparisons consistently favored the retropubic midurethral sling, and hence these secondary outcomes may have been underpowered to reach significance at 12-month and 2-year follow-up. The overall sacrocolpopexy-related mesh exposure rate at 2 years (7.2% [8/111]) was similar to what has been previously reported in a randomized trial comparing sacrocolpopexy with and without concomitant Burch procedure (13% [20/158]) (21). Although the exposure rate was greater for the sling than the Burch group, this outcome was unrelated to the additional sling-related

mesh. Only 1 woman had a sling-related exposure, and it resolved with topical estrogen and did not require revision.

Our study had limitations. Its population was primarily postmenopausal white women from the US Midwest region who underwent open abdominal sacrocolpopexy. Hence, the generalizability of our findings to more racially diverse populations or those undergoing laparoscopic or robotic sacrocolpopexy is unclear. Likewise, all surgeons in the study underwent fellowship training at the same institution, allowing for standardization of surgical techniques and postoperative care. While this bolsters internal validity, it may limit generalizability.

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Abbreviations

ICIQ	International Consultation on Incontinence Questionnaire, Short Form
ITT	intention-to-treat
POP	pelvic organ prolapse
SUI	stress urinary incontinence

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Figure 1. Flow Diagram of enrollment, randomization, and analysis of trial participants. SUI, stress urinary incontinence.

Figure 2.

Factors leading to surgical failure at two years. Stress-specific incontinence includes the results for repeat incontinence surgery and positive standardized stress test. Self-reported stress urinary incontinence leakage of urine involved a response of sometimes or often to any of the 6 questions from the stress incontinence subscale of the Medical, Epidemiological, and Social Aspects of Aging questionnaire. In the Burch retropubic urethropexy group, 45 patients completed the 2-year follow-up assessment and 1 other patient had interim retreatment before the 2-year point. ICIQ, International Consultation on Incontinence Questionnaire, Short Form.

Table 1

Baseline Demographic Characteristics, Clinical Characteristics, Urodynamic Findings, and Concomitant Procedures of the 113 Trial Participants

Characteristics ^a	Burch (n=56)	Midurethral Sling (n=57)	P Value ^b
Age at operation, mean (SD), y	56 (10)	56 (11)	.91
BMI, mean (SD), kg/m ²	28.3 (4.8)	28.1 (5.3)	.78
White race ^c	56 (100.0)	55 (96.5)	.50
Education level			.63
High school	15 (26.8)	17 (30.9)	
>High school	41 (73.2)	38 (69.1)	
Not documented	0	2	
Parity			.41
0	0 (0.0)	1 (1.8)	
1	4 (7.1)	2 (3.5)	
2	22 (39.3)	17 (29.8)	
3	30 (53.6)	37 (64.9)	
Menopausal	37 (66.1)	34 (59.6)	.48
Smoking history	13 (23.2)	11 (19.3)	.61
Prior incontinence surgery	4 (7.1)	4 (7.0)	.99
Preoperative diagnosis			.99
Occult	11 (19.6)	11 (19.3)	
SUI	13 (23.2)	14 (24.6)	
Mixed	32 (57.1)	32 (56.1)	
OABq, symptom severity score ^d , mean (SD)	38 (23)	41 (24)	.51
OABq, HRQL ^e score, mean (SD)	67 (24)	67 (21)	.92
Prolapse stage			.99
II	26 (46.4)	26 (45.6)	
III	21 (37.5)	22 (38.6)	
IV	4 (7.1)	5 (8.8)	
Unknown	5 (8.9)	4 (7.0)	
Type of urodynamics			.99
Not done	2 (3.6)	1 (1.8)	
Simple	10 (17.9)	11 (19.3)	
Complex	44 (78.6)	45 (78.9)	
ISD ^f			.45
No	31 (75.6)	33 (82.5)	
Yes	10 (24.4)	7 (17.5)	
Unknown	3	5	
Detrusor contraction ^g			.11
No	36 (81.8)	41 (93.2)	
Yes	8 (18.2)	3 (6.8)	

Characteristics ^a	Burch (n=56)	Midurethral Sling (n=57)	P Value ^b
Unknown	0	1	
Additional procedure			.52
None	12 (21.4)	17 (29.8)	
Posterior repair	20 (35.7)	19 (33.3)	
TAH or SCH	11 (19.6)	13 (22.8)	
Posterior repair and TAH or SCH	13 (23.2)	8 (14.0)	
Estimated blood loss, median (IQR), mL	200 (150–300)	200 (150–300)	.73
Operative time, median (IQR), min	253 (219–284)	251 (218–281)	.70
Length of stay, median (IQR), d	3 (2–3)	3 (2–3)	.82
Voiding dysfunction ^h			.33
No	19 (33.9)	14 (25.5)	
Yes	37 (66.1)	41 (74.5)	
Unknown	0	2	

Abbreviations: BMI, body mass index; IQR, interquartile range; ISD, intrinsic sphincter deficiency; HRQL, health-related quality-of-life component of the bother component; OABq, Overactive Bladder Questionnaire, Short Form; SCH, supracervical hysterectomy; SUI, stress urinary incontinence; TAH, total abdominal hysterectomy.

^aValues are presented as number and percentage of patients unless specified otherwise.

^bBaseline variables were compared between the 2 groups with 2-sample *t* test for continuous variables, Wilcoxon rank-sum test for ordinal measures, and χ^2 test or Fisher exact test for categorical variables.

^cRace was based on patient self-report.

^dOABq symptom severity score ranges from 0 to 100, with higher scores representing greater symptom severity or bother.

^eOABq, HRQL score ranges from 0 to 100, with higher scores representing better health-related quality of life.

^fISD was defined as an abdominal leak point pressure <60 cm H₂O or a maximum urethral closure pressure <20 cm H₂O.

^gDetrusor contracting during the cystometry phase of the urodynamics examination. Results are based on those patients with complex urodynamics only.

^hVoiding dysfunction was defined as response of *somewhat* or worse using a 6-point Likert scale ranging from *not at all* to *a very great deal* to any of the following: "... the extent to which you were bothered by each of the following symptoms during the last 4 weeks: I feel like I do not completely empty my bladder, I need to spend more time on the toilet to feel that I completely empty the bladder, I need to void multiple times to empty the bladder, I have difficulty starting a urinary stream, or I have to push on the vagina to empty the bladder."

Adapted from Trabuco et al (5). Used with permission.

Table 2

Primary Outcome Analysis at 1 and 2 Years After Surgery

Outcome ^a	Burch (n=56)	Midurethral Sling (n=57)	Absolute Risk, Difference (95% CI)	NNT	P Value ^b
Overall continence at 1 y ^c					
ITT ^d	28.6 (16/56)	49.1 (28/57)	20.6 (3.0, 38.1)	4.9	.03
WPA ^e	34.0 (16/47)	54.9 (28/51)	20.9 (1.6, 40.1)	4.8	.04
Stress-specific continence at 1 y ^f					
ITT ^d	46.4 (26/56)	70.2 (40/57)	23.8 (6.1, 41.4)	4.2	.01
WPA ^e	55.3 (26/47)	78.4 (40/51)	23.1 (5.0, 41.3)	4.3	.01
Overall continence at 2 y ^c					
ITT ^d	32.1 (18/56)	47.4 (27/57)	15.2 (-2.6, 33.1)	6.6	.10
WPA ^e	39.1 (18/46)	56.3 (27/48)	17.1 (-2.8, 37.0)	5.8	.10
Stress-specific continence at 2 y ^f					
ITT ^d	44.6 (25/56)	70.2 (40/57)	25.5 (7.9, 43.2)	3.9	.006
WPA ^e	55.6 (25/45)	83.3 (40/48)	27.8 (9.8, 45.7)	3.6	.004

Abbreviations: ITT, intention-to-treat; NNT, number needed to treat; WPA, within-protocol analysis.

^aValues are presented as percentage and number of patients unless specified otherwise.

^bOutcomes were compared between the 2 groups using the χ^2 test.

^c*Overall continence* was defined as an International Consultation on Incontinence Questionnaire, Short Form, score of 0, a negative cough stress test, and no re-treatment for stress urinary incontinence.

^dAll randomly assigned patients were included in the ITT analysis, with those who did not return for follow-up considered not to be continent.

^eFor WPA, only patients with complete follow-up at 1 or 2 years, respectively, or who had interim re-treatment at or before the time period of interest.

^f*Stress-specific continence* was defined as a response of *never or rarely* to 6 questions from the stress-specific subdomain of the Medical, Epidemiological, and Social Aspects of Aging questionnaire, a negative cough stress test, and no reoperation for stress urinary incontinence.

Table 3

Secondary Outcomes at 2 Years After Surgery

Characteristics ^a	Burch (n=45)	Midurethral Sling (n=48)	P Value ^b
PGIS			.71
Normal/mild	39/42 (92.9)	39/44 (88.6)	
Moderate/severe	3/42 (7.1)	5/44 (11.4)	
Not reported	3	4	
Symptom improvement ^c			.26
0	0 (0.0)	0 (0.0)	
1	0 (0.0)	2 (4.4)	
2	1 (2.4)	0 (0.0)	
3	1 (2.4)	0 (0.0)	
4	0 (0.0)	1 (2.2)	
5	5 (11.9)	2 (4.4)	
6	0 (0.0)	4 (8.9)	
7	3 (7.1)	0 (0.0)	
8	4 (9.5)	1 (2.2)	
9	3 (7.1)	2 (4.4)	
10	25 (59.5)	33 (73.3)	
Not reported	3	3	
Median (IQR)	10 (8–10)	10 (9–10)	.26
Proportion reporting 10	25/42 (59.5)	33/45 (73.3)	.17
Treatment success ^d			.15
0	2 (4.8)	1 (2.2)	
1	0 (0.0)	0 (0.0)	
2	0 (0.0)	0 (0.0)	
3	1 (2.4)	1 (2.2)	
4	0 (0.0)	1 (2.2)	
5	3 (7.1)	0 (0.0)	
6	1 (2.4)	4 (8.9)	
7	1 (2.4)	0 (0.0)	
8	5 (11.9)	2 (4.4)	
9	4 (9.5)	2 (4.4)	
10	25 (59.5)	34 (75.6)	
Not reported	3	3	
Median (IQR)	10 (8–10)	10 (10–10)	.15
Proportion reporting 10	25/42 (59.5)	34/45 (75.6)	.11
ICIQ score ^e			.53
0 (none)	21 (46.7)	27 (56.3)	
1–5 (slight)	12 (26.7)	10 (20.8)	
6–12 (moderate)	10 (22.2)	5 (10.4)	

Characteristics ^a	Burch (n=45)	Midurethral Sling (n=48)	P Value ^b
13–18 (severe)	1 (2.2)	6 (12.5)	
19–21 (very severe)	1 (2.2)	0 (0.0)	
Patient satisfaction ^f	29/42 (69.0)	34/44 (77.3)	.39
Not reported	3	4	
Prolapse recurrence			
Anterior	1/38 (2.6)	2/41 (4.9)	.99
Apical	0/38 (0)	0/41 (0)	---
Voiding dysfunction ^g	8/44 (18.2)	9/44 (20.5)	.79
Increased postvoid residual ^h	0/39 (0)	0/41 (0)	---
Urgency incontinence ⁱ			
De novo symptoms	2/26 (7.7)	1/22 (4.5)	.99
Resolution of baseline symptoms	10/18 (55.6)	17/26 (65.4)	.51
Antimuscarinic medication use	11 (24.4)	13 (27.1)	.77

Abbreviations: ICIQ, International Consultation on Incontinence Questionnaire, Short Form; IQR, interquartile range; PGIS, Patient Global Impression of Severity.

^aValues are presented as number and percentage of patients unless specified otherwise.

^bSecondary outcomes were compared between the 2 groups using Wilcoxon rank-sum test for the measures with a visual analog scale and χ^2 test or Fisher exact test for categorical variables.

^cSymptom improvement assessed with the question “Compared to how you were before your recent surgery for urinary leakage, how are your urinary leakage symptoms now?” Responses ranged from 0 (much worse) to 10 (much better) in a visual analog scale.

^dTreatment success was evaluated using the question “In your opinion, how successful has your treatment for urinary leakage been?” Responses ranged from 0 (not at all successful) to 10 (very successful) in a visual analog scale.

^eICIQ scores ranged from 0 to 21, with higher scores representing more severe urinary leakage.

^fPatient satisfaction was based on response to the question “How satisfied or dissatisfied are you with the result of your surgery for urinary leakage?” Satisfaction was defined as a response of *completely satisfied* in a 5-point Likert scale ranging from *completely dissatisfied* to *completely satisfied*.

^gVoiding dysfunction was defined as response of *somewhat* or worse using a 6-point Likert scale ranging from *not at all* to *a very great deal* to any of the following: “... the extent to which you were bothered by each of the following symptoms during the last 4 weeks: I feel like I do not completely empty my bladder, I need to spend more time on the toilet to feel that I completely empty the bladder, I need to void multiple times to empty the bladder, I have difficulty starting a urinary stream, or I have to push on the vagina to empty the bladder.”

^hIncreased postvoid residual was defined as postvoid residual >150 mL.

ⁱDe novo and resolution of urgency incontinence were based on response to the question “How often do you get a sudden urge or desire to urinate that makes you want to stop what you are doing and rush to the bathroom but you do not get there in time (ie you leak urine or wet pads)?” from the Overactive Bladder Symptom questionnaire (Blaivas JG, Panagopoulos G, Weiss JP, Somaroo C. Validation of the overactive bladder symptom score. J Urol. 2007 Aug;178(2):543-7. Epub 2007 Jun 14). Patients were considered to have de novo urgency incontinence if their response changed from *never* or *rarely* at baseline to *a few times a month* or more at follow-up. Resolution of urgency incontinence was defined as a change from the response of *a few times a month* or more at baseline to a response of *never* or *rarely* at follow-up.