ORIGINAL ARTICLE

Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence

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ABSTRACT

BACKGROUND

Many surgical procedures are available for women with urinary stress incontinence, yet few randomized clinical trials have been conducted to provide a basis for treatment recommendations.

METHODS

We performed a multicenter, randomized clinical trial comparing two procedures — the pubovaginal sling, using autologous rectus fascia, and the Burch colposuspension — among women with stress incontinence. Women were eligible for the study if they had predominant symptoms associated with the condition, a positive stress test, and urethral hypermobility. The primary outcomes were success in terms of overall urinary-incontinence measures, which required a negative pad test, no urinary incontinence (as recorded in a 3-day diary), a negative cough and Valsalva stress test, no self-reported symptoms, and no retreatment for the condition, and success in terms of measures of stress incontinence specifically, which required only the latter three criteria. We also assessed postoperative urge incontinence, voiding dysfunction, and adverse events.

RESULTS

A total of 655 women were randomly assigned to study groups: 326 to undergo the sling procedure and 329 to undergo the Burch procedure; 520 women (79%) completed the outcome assessment. At 24 months, success rates were higher for women who underwent the sling procedure than for those who underwent the Burch procedure, for both the overall category of success (47% vs. 38%, $P=0.01$) and the category specific to stress incontinence (66% vs. 49%, $P<0.001$). However, more women who underwent the sling procedure had urinary tract infections, difficulty voiding, and postoperative urge incontinence.

CONCLUSIONS

The autologous fascial sling results in a higher rate of successful treatment of stress incontinence but also greater morbidity than the Burch colposuspension. (ClinicalTrials.gov number, NCT00064662.)

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Urinary incontinence affects an estimated 15 to 50% of women,[1,2] resulting in a significant medical, social, and economic burden.[1] In 1995 dollars, the annual direct costs of incontinence in the United States were estimated to be more than $16 billion.[3] Among women with incontinence, 50 to 80% are identified as having stress incontinence,[4] or involuntary leakage of urine resulting from physical exertion or sneezing and coughing.[5] Although the initial treatment of stress incontinence is often nonsurgical (behavioral therapy, pelvic-floor exercises, or incontinence devices), surgical treatment is considered for patients who are bothered by persistent symptoms. An estimated 4 to 10% of women in the United States undergo surgery intended to restore continence,[6] and this rate has increased steadily during the past 20 years.[7,8]

Many surgical procedures have been described for women with stress incontinence, yet few randomized clinical trials have been conducted to provide a basis for treatment recommendations. The fascial-sling procedure and Burch colposuspension are two well-established procedures with reported cure rates of 70 to 85% at 5 to 8 years.[9,10] In the Burch modified colposuspension,[11] the anterior vaginal wall is suspended (at the level of the bladder neck) with permanent sutures tied to the iliopectineal ligament (Fig. 1A). In the autologous sling procedure,[12] a harvested strip of rectus fascia is placed transvaginally at the level of the proximal urethra. The fascial strip is secured superiorly to the rectus fascia with permanent sutures (Fig. 1B). Although it has been suggested that the sling procedure may result in higher cure rates, this advantage may be offset by increased obstructive complications, such as voiding dysfunction and urge incontinence.[13,14] We conducted a multicenter, randomized surgical trial, the Stress Incontinence Surgical Treatment Efficacy Trial, to compare the efficacy and safety of the sling and Burch procedures 24 months after surgery.

METHODS

PATIENTS AND STUDY DESIGN

Women who were planning to undergo stress-incontinence surgery were invited to participate in the trial. 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 methods have been published previously.[15] All study procedures were approved by the institutional review board at each participating clinical center, and written consent was obtained from all women before enrollment. Randomization was performed in the operating room after anesthesia induction with the use of a permuted-block randomization schedule with stratification according to clinical site. The patients were aware of study-group assignments postoperatively. An independent data and safety monitoring board oversaw the progress, interim results, and safety of the study.

Formal interim time-to-event analyses of the primary outcome of overall success were planned for three time points, with the use of an O'Brien–Fleming stopping boundary, and were conducted when 19%, 44%, and 76% of failures had occurred. Although the test statistic at the third analysis crossed the stopping boundary in favor of the sling procedure, the protocol did not require stopping the trial when the boundary was crossed, and the data and safety monitoring board recommended that the study continue. No adjustment was made for these analyses.

Definitions of clinical terms, urodynamic nomenclature, and methods of evaluation of patients were uniform across all sites and in accordance with recommendations from the standardization committees of the International Continence Society.[5,16] Key elements of the two surgical procedures were standardized among all participating surgeons and included the use of preoperative antibiotics, skin-incision length, number and type of Burch sutures, fascial-sling length and width, and cystoscopic evaluation of the bladder. Because these procedures are frequently performed in conjunction with surgery for pelvic prolapse, abdominal and vaginal approaches for both pelvic prolapse repair and hysterectomy were permitted. However, surgeons were required to declare before randomization which concomitant procedures would be performed.

The two primary outcomes were composite measures of success in terms of overall urinary-incontinence measures and of stress-incontinence measures specifically. Overall treatment success was defined as no self-reported symptoms of urinary incontinence, an increase of less than 15 g in pad weight during a 24-hour pad test, no incontinence episodes recorded in a 3-day diary, a negative urinary stress test (no leakage noted on

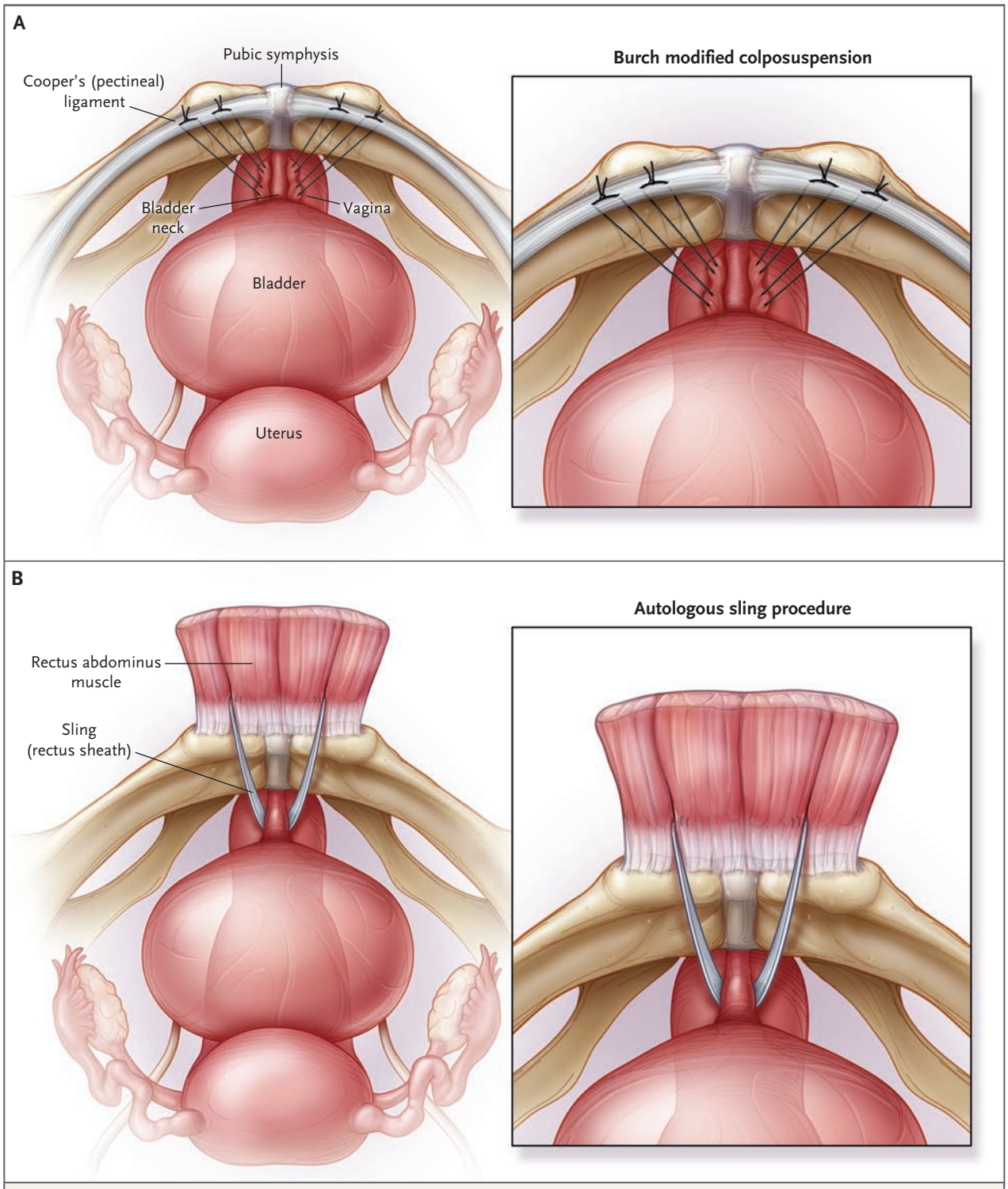

Figure 1. Burch Modified Colposuspension and Autologous Sling Procedure.

In the Burch procedure (Panel A), permanent sutures are placed in the anterior vaginal wall at the level of the bladder neck and proximal urethra and are then sutured to the iliopectineal ligament. In the autologous sling procedure (Panel B), a strip of rectus fascia is harvested, and permanent sutures are placed at its two ends. The sling is placed beneath the proximal urethra through a vaginal incision. The two ends of the sling are passed behind the pubic bone to the anterior abdominal wall, where they are secured, either to each other or to the rectus fascia.

examination during cough and Valsalva maneuvers at a standardized bladder volume of 300 ml), and no retreatment for urinary incontinence (including behavioral, pharmacologic, and surgical therapies). Since the study surgeries are intended to correct symptoms of stress incontinence without necessarily improving concomitant urge incontinence and the voiding diary and pad test do not differentiate between urge-incontinence and stress-incontinence events, the definition of success specific to stress incontinence was limited to no self-reported symptoms of stress incontinence, a negative stress test, and no retreatment for stress incontinence.

Data were collected preoperatively and postoperatively at 6 weeks and at 3, 6, 12, 18, and 24 months by means of interview and clinical examination. Baseline measures included sociodemographic characteristics; risk factors for urinary incontinence, including a high body-mass index, a history of vaginal childbirth, and previous surgery for urinary incontinence; quality of life specific to urinary incontinence[17]; clinical characteristics of urinary incontinence, including current behavioral or pharmacologic therapy, self-reported urinary-incontinence symptoms on a validated questionnaire distinguishing stress leakage from urge leakage,[18] quantity of urine leakage on a pad test,[19] and the number of incontinence episodes as recorded in a 3-day voiding diary[20]; findings on physical examination, including urethral hypermobility as measured by the Q-tip test[21] and pelvic-organ prolapse[22]; and urodynamic evaluation, including the presence of urodynamic stress incontinence and detrusor-overactivity incontinence.

The principal investigator at each site reported adverse events to the adverse-events committee, which comprised four investigators who were unaware of site-specific information. In certain cases, the descriptive details of the adverse event may have made it possible to discern the randomized surgical procedure. All adverse events were assigned a severity code according to a modified version of the classification system developed by Dindo and colleagues.[23] This system, which has been validated for use among surgical patients, classifies the severity of an event into one of four levels on the basis of the clinical measures taken to treat that event.

Postoperative urge incontinence was defined as treatment of clinically diagnosed new-onset or persistent urge incontinence after the 6-week follow-up visit. Adequacy of voiding was assessed and categorized dichotomously at hospital discharge and again 6 weeks after surgery. Voiding dysfunction was defined by the need for surgical revision to facilitate bladder emptying or the use of any type of catheter after the 6-week visit.

Patient satisfaction was assessed at 24 months with the question "How satisfied or dissatisfied are you with the result of bladder surgery related to urine leakage?" Patients rated their overall satisfaction, choosing one of five options that ranged from "completely satisfied" to "completely dissatisfied." Patients who answered that they were either "completely satisfied" or "mostly satisfied" were classified as being satisfied with the outcome.

STATISTICAL ANALYSIS

We calculated that 260 women per group would provide a power of 80% to detect a 12% difference between study groups (60% vs. 72%) with the use of a two-sided alternative hypothesis at a significance level of 5%. To allow for attrition and missed visits, we recruited a total of 655 women. Treatment success was assessed at follow-up visits every 6 months. If a treatment failed between scheduled visits, it was considered to have failed at the next visit. Data for women whose treatment was not known to have failed but who had not completed all assessments at the 24-month visit were censored at the last visit on which all failure assessments were complete.

For both outcome measures, we compared the success rates in the two groups at 24 months with the use of time-to-event methods for interval censored data.[24] We used Kaplan–Meier product-limit analysis to estimate the success rates at 24 months in the two groups and compared the treatment-failure distributions in the two groups, controlling for stratification by clinical site, with the use of the log-rank test. To determine whether concomitant surgery might have had an effect on the results, we tested the interaction between treatment group and concomitant surgery with the use of the Weibull accelerated failure-time model. All analyses were carried out with SAS statistical software, version 9.2 (SAS Institute).

RESULTS

PATIENTS

From February 2002 to June 2004, we screened 2405 women for trial eligibility (Fig. 2). Of these women, 556 were ineligible, 1193 declined to

participate or withdrew consent, and 1 died before randomization. A total of 655 women were randomly assigned to a study procedure: 326 to undergo the sling procedure and 329 to undergo the Burch procedure. One woman did not undergo the assigned treatment (Burch procedure), and four women were found to be ineligible after randomization (one assigned to the sling procedure and three assigned to the Burch procedure). A total of 520 women (79%) — 265 in the sling group (81%) and 255 in the Burch group (78%) — either were assessed for treatment success at the 24-month visit or were deemed to have had a treatment failure before that visit.

Women in the two surgical groups were similar in demographic, anthropometric, clinical, and urodynamic-study characteristics (Table 1). The frequency of previous surgery for urinary incontinence was similar in the two groups (13% in the sling group and 15% in the Burch group). The rates of concomitant surgery for pelvic prolapse (including anterior and posterior vaginal repairs, apical suspension procedures, and hysterectomy) were also similar in the two groups (55% in the sling group and 48% in the Burch group). The sling and Burch groups had similar estimated blood loss during the procedure (229 ml and 238 ml, respectively) and similar operative times (136 minutes and 138 minutes, respectively).

Women in the sling group had 24-month cumulative rates of success that were significantly higher than those in the Burch group, with overall success rates of 47% versus 38% ($P=0.01$), and rates of success specific to stress incontinence of 66% versus 49% ($P<0.001$) by the log-rank test of equality of distributions with adjustment for site (Fig. 3). There was no clinically or statistically significant interaction effect of concomitant surgery and treatment group on either outcome ($P=0.74$ for overall success, and $P=0.84$ for success specific to stress incontinence).

The rate of occurrence of each component of the composite measure of success, as a percentage of patients with complete follow-up assessments, differed according to the treatment group (Fig. 4). These differences reflected the fact that the sling group had lower rates of reported symptoms related to stress incontinence, positive stress tests, and retreatment of stress incontinence than did the Burch group.

There was no significant difference between the sling and Burch groups in the percentage of patients who had serious adverse events (13% and 10%, respectively; $P=0.20$) (Table 2). However, surgical procedures to reduce voiding symptoms or improve urinary retention were performed exclusively in the sling group, in which 19 patients underwent 20 such procedures. Adverse events were more common in the sling group than in the Burch group (63% vs. 47%, $P<0.001$), with 415 events among 206 women in the sling group, as compared with 305 events among 156 women in the Burch group. This difference was due primarily to urinary tract infections; 157 women in the sling group (48%) had 305 events and 105 women in the Burch group (32%) had 203 events. When urinary tract infections were excluded, the rates of adverse events were similar in the two groups.

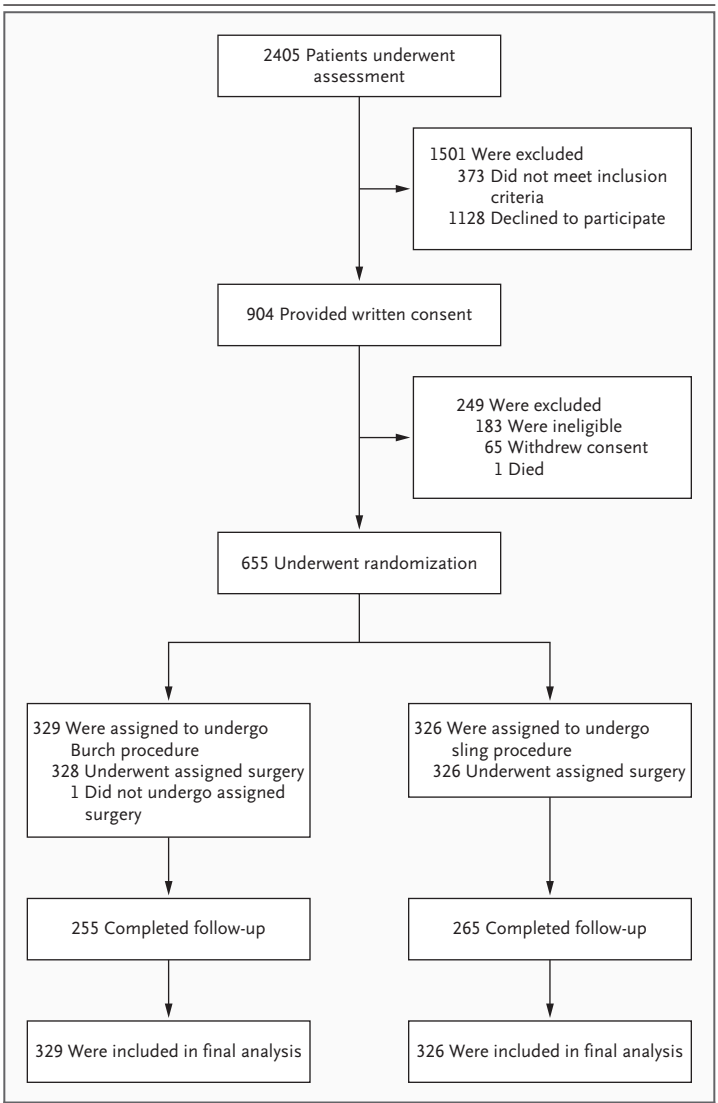

Figure 2. Enrollment and Outcomes.

Table 1. Selected Characteristics of the Patients.*

Variable	Burch Procedure (N=329)	Sling Procedure (N=326)	P Value
Demographic characteristics			
Age (yr)	52.2±10.5	51.6±10.1	0.47
Racial or ethnic group (%)†			0.04
Hispanic	9	13	
Non-Hispanic white	75	71	
Non-Hispanic black	5	9	
Non-Hispanic other	11	7	
Marital status (%)			0.56
Married or living with partner	69	67	
Not married	31	33	
Education (%)			0.79
High school or less	33	36	
Some training after high school	40	39	
College degree or more	27	25	
Household income (%)			0.65
<$20,000	21	17	
$20,000–49,999	29	31	
$50,000–79,999	21	21	
≥$80,000	29	31	
Risk factors			
Body-mass index	29.7±6.1	30.3±6.1	0.26
No. of vaginal deliveries (%)			0.14
0	8	10	
1–2	46	39	
≥3	46	51	
Previous incontinence surgery (%)	15	13	0.46
Smoking status (%)			0.04
Never smoked	59	49	
Former smoker	29	34	
Current smoker	12	17	
Hormone-replacement therapy (%)			0.66
Yes	35	32	
No	36	36	
No, premenopausal	29	32	

The distribution of time to return to normal voiding differed significantly between the two groups (P<0.001). At the time of hospital discharge, fewer patients in the sling group than in the Burch group had voiding with a residual volume of less than 100 ml (44% vs. 58%), and the difference persisted at 6 weeks (86% vs. 97%). Voiding dysfunction was more common in the sling group than in the Burch group (14% vs. 2%, P<0.001). More patients were treated for postoperative urge incontinence in the sling group than in the Burch group (87 patients [27%] vs. 65 patients [20%], P=0.04). The difference in urge incontinence was due to differences in the proportion of patients treated for persistent urge incontinence (79 patients in the sling group [24%] vs. 59 patients in the Burch group [18%]) rather than to differences in the proportion with new-onset urge incontinence (11 patients [3%] in both groups).

Treatment-satisfaction rates for the 480 subjects who answered the satisfaction question at 24 months were significantly higher in the sling

Table 1. (Continued.)

Variable	Burch Procedure (N=329)	Sling Procedure (N=326)	P Value
Clinical characteristics			
Quality of life‡			
Total score on Urogenital Distress Inventory	150.3±49.9	151.6±47.4	0.73
Total score on Incontinence Impact Questionnaire	173.2±99.2	169.7±103.4	0.66
Pad test weight (g)	42.4±61.2	44.7±94.3	0.71
Incontinence episodes per day (no.)	3.3±3.1	3.1±2.9	0.52
Urinary-incontinence symptom score§			
Stress score	19.5±4.5	19.2±4.7	0.37
Urge score	6.6±3.9	6.3±3.9	0.44
Prolapse stage (%)¶			
0 or 1	26	24	0.60
2	59	59	
3 or 4	15	17	
Q-tip test (degree)			
Resting angle	15.6±17.1	15.2±18.3	0.77
Straining angle	61.1±19.3	59.3±17.3	0.23
Difference between straining angle and resting angle	45.5±19.1	44.1±17.3	0.35
Urodynamic studies (%)			
Stress incontinence			0.64
Yes	89	89	
No	9	10	
Invalid study	2	1	
Valsalva leak point pressure‖			
≤60 cm of H_2O	4	3	0.46
Change of ≤60 cm of H_2O	22	20	0.54
Detrusor overactivity	11	7	0.10
Surgical characteristics			
Concomitant surgery (%)**			0.19
None	44	40	
Prolapse surgery with repair of anterior vaginal wall (with or without other repair)	17	23	
Prolapse surgery without repair of anterior vaginal wall (including posterior wall and apex)	31	32	
Other nonprolapse surgery††	8	6	

* Plus–minus values are means ±SD. Body-mass index is the weight in kilograms divided by the square of the height in meters. Percentages may not total 100 because of rounding.
† Racial or ethnic group was reported by the patients.
‡ Scores on the Urogenital Distress Inventory range from 0 to 300, with higher scores indicating greater distress. Scores on the Incontinence Impact Questionnaire range from 0 to 400, with higher scores indicating greater impact.[17]
§ Symptom scores are the sum of responses to nine questions regarding stress symptoms (with scores ranging from 0 to 27 and higher scores indicating greater severity) and six questions regarding urge symptoms (with scores ranging from 0 to 18 and higher scores indicating greater severity) adapted from the Medical, Epidemiological, and Social Aspects of Aging questionnaire.[18]
¶ Prolapse staging is based on the methods of the Pelvic Organ Prolapse Quantification system.[22]
‖ Valsalva leak point pressure refers to the vesical pressure at the time of leakage. The change in the Valsalva leak point pressure is the vesical pressure at the time of leakage minus the baseline vesical pressure.
** Concomitant prolapse repairs included repair of the anterior vaginal wall (anterior colporrhaphy and paravaginal repair), posterior colporrhaphy, apical suspension procedures (sacrospinous ligament suspension, uterosacral ligament suspension, and sacrocolpopexy), enterocele repair, and hysterectomy.
†† Other concomitant surgeries included anal-sphincter repair, tubal ligation, and abdominoplasty.

group than in the Burch group (86% vs. 78%, P=0.02).

DISCUSSION

At 24 months, the pubovaginal fascial sling had significantly higher rates of success — both overall and specific to stress incontinence — than did the Burch colposuspension in women with predominant stress incontinence. These findings were not modified by performance of concomitant surgery for pelvic-organ prolapse. In addition, the frequency of surgical retreatment for stress incontinence was greater in the Burch group than in the sling group. Success rates declined steadily over the 2-year follow-up period, which confirmed previous observations[25,26] and underscored the need for long-term follow-up in these patients.

However, the higher success rates in the sling group were offset by higher rates of urinary tract infection, urge incontinence, voiding dysfunction, and the need for surgical revision to improve voiding. The increased efficacy and greater morbidity of the sling procedure confirm and quantify the results of previous systematic reviews[27-29] and may explain some of the reluctance in the past to use this procedure as a primary surgical treatment for stress incontinence.[14]

Our large, randomized surgical trial comparing the fascial-sling procedure with the Burch procedure had a robust 24-month follow-up with the use of standardized definitions, procedures, and methods of evaluation to assess a variety of outcome measures and comprehensive postoperative morbidity. The absence of such information to date has precluded rigorous assessment of surgical outcomes for this condition.[30,31] Reported success rates of surgery have varied widely.[27,28] Factors contributing to this variation have included the lack of standardized outcome measures, differences in the baseline characteristics of the study populations, and the length of follow-up.[32,33]

Success rates that are based on reporting by patients are consistently lower than those based on physician-reported measures.[34,35] Current research guidelines emphasize the importance of evaluating treatment efficacy with composite out-

Table 2. Adverse Events.*

Event	Burch Procedure (N=329)	Sling Procedure (N=326)	P Value†
	no. (%)		
Serious adverse events‡			
Patients with event	32 (10)	42 (13)	0.20
Total events	39	47	
Genitourinary	22	30	0.12
Ureteral injury	2	0	
Ureterovaginal fistula	1	0	
Incidental vaginotomy	1	0	
Incidental cystotomy	10	2	
Erosion of suture into bladder	1	0	
Recurrent cystitis, leading to diagnostic cystoscopy	5	6	
Pyelonephritis	1	1	
Catheter complication	1	1	
Voiding dysfunction leading to surgical revision	0	20	
Pelvic pain	0	2	0.25
Bleeding	3	1	0.62
Wound complication requiring surgical intervention	13	11	0.83
Gastrointestinal	1	1	1.00
Respiratory distress requiring intubation	0	1	0.50
Laryngospasm requiring reintubation	0	1	0.50

Table 2. (Continued.)

Event	Burch Procedure (N=329)	Sling Procedure (N=326)	P Value†
	no. (%)		
Adverse events§			
Patients with event	156 (47)	206 (63)	<0.001
Total events	305	415	
Genitourinary	203	305	<0.001
Cystitis	202	299	
Pyelonephritis	1	6	
Vascular or hematologic	5	9	0.29
Deep-vein thrombosis	0	1	
Bleeding	5	8	
Wound complication not requiring surgical intervention	69	71	0.69
Gastrointestinal	7	8	0.80
Pulmonary	10	9	1.00
Neurologic	6	5	1.00
Cardiovascular	0	2	0.25
Allergic (hives, itching)	0	2	0.25
Constitutional	3	0	0.25
Dermatologic (rash, erythema)	2	4	0.45

* The severity grade was determined by using a slightly modified version of the Dindo classification system,[23] which is based on the level of therapy required to treat an event: grade I, no pharmacologic, surgical, or radiologic intervention (allowed therapeutic regimens include antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy); grade II, pharmacologic treatment with drugs other than those allowed for grade I complications (including antibiotics, blood transfusions, and total parenteral nutrition); grade III, surgical, endoscopic, or radiologic intervention; grade IV, life-threatening complication requiring intensive care management; and grade V, death. Serious adverse events were defined as a severity of grade III, grade IV, or grade V; no grade V events occurred in either group.

† P values were calculated with the use of Fisher's exact test.

‡ Catheter complications included clot retention requiring cystoscopy (sling group, 1 patient) or a suprapubic tube stitched in place (Burch group, 1 patient). Wound complications requiring surgical intervention included incisional hernia (Burch, 5 patients; sling, 3), seroma or hematoma (Burch, 2; sling, 3), infection (Burch, 2; sling, 2), abscess (Burch, 1; sling, 1), and vaginal wound revision (Burch, 3; sling, 2). Gastrointestinal complications included 1 rectal injury (in the sling group) and 1 episode of constipation requiring surgical disimpaction (in the Burch group).

§ Cystitis was defined as culture-proven bladder infection or, in the absence of a culture, clinical suspicion of a bladder infection that resulted in treatment. Wound complications not requiring surgical intervention included 2 sling exposures (visualization of the sling material in the vagina), incisional hernia (Burch group, 2; sling group, 1), superficial wound-edge separation (Burch, 10; sling, 5), seroma or hematoma (Burch, 13; sling, 11), infection (Burch, 31; sling, 21), and granulation tissue or stitch granulomas (Burch, 13; sling, 31). Gastrointestinal events included ileus (Burch, 5; sling, 2) and other complications (anal fissure, constipation, prolapsed hemorrhoids, nausea and vomiting, abdominal pain, rectal bleeding, and pseudomembranous colitis) (Burch, 2; sling, 6). Pulmonary events included atelectasis (Burch, 4; sling, 6), pneumonia (Burch, 2; sling, 1), pulmonary edema (Burch, 1; sling, 1), and other complications (anesthesia airway difficulty resulting in rescheduling of surgery, oversedation, upper respiratory infection) (Burch, 3; sling, 1). Neurologic complications included sciatica (Burch, 1; sling, 1), numbness or weakness or pain temporally related to surgery (Burch, 4; sling, 3), and vertigo or vestibular neuritis (Burch, 1; sling, 1). In the sling group, cardiovascular events included bradycardia treated in the recovery room (1) and junctional rhythm ruled out for myocardial infarction (1). In the Burch group, constitutional events included fever of unknown origin (2) and hypokalemia (1).

come measures that include both subjective and objective efficacy measures as well as an assessment of morbidity.[36-38] Success rates in our trial were low, as compared with those in previous studies.[9,10] This finding may be related to our use of composite outcome measures, resulting in a stricter definition of success. The substantial variation in failure rates among studies using single-component measures supports the use of composite outcome measures[32] and highlights the lack of concordance among several traditional measures.

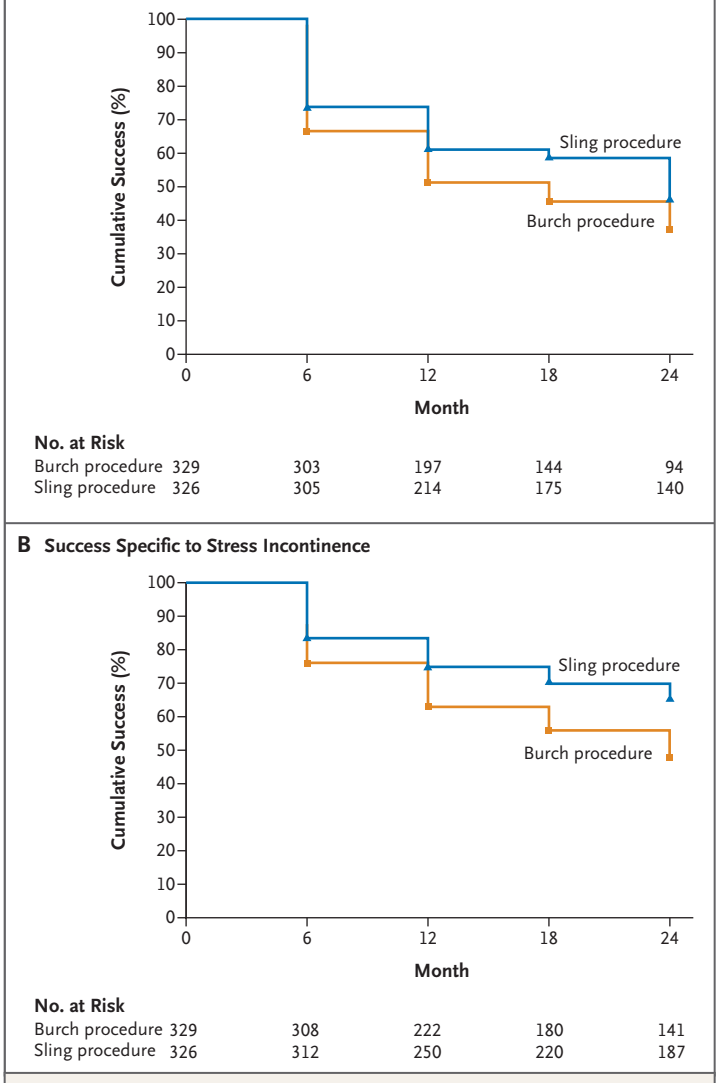

Figure 3. Kaplan–Meier Curves for Success of Surgical Treatment for Urinary Incontinence at 24 Months among All Patients.

Panel A shows the overall treatment success for urinary-incontinence measures (P=0.01), and Panel B shows success in terms of measures of stress incontinence specifically (P<0.001), with both comparisons based on the log-rank test of equality of distributions, with adjustment for site.

Our finding that the two procedures had similar success rates as measured by pad tests and voiding diaries may reflect the higher number of patients with symptoms of urge incontinence in the sling group, since these two measures cannot differentiate stress incontinence from urge incontinence. It is likely that we underestimated the rate of postoperative urge incontinence, since our definition was restricted to patients who received treatment for this condition. This factor may explain in part why only 3% of the patients in our trial had new-onset urge incontinence, a rate that is at the low end of the range reported by others.[29,39]

The higher rate of urinary tract infections reported in the sling group, as compared with the Burch group, may be related to a delayed return to adequate voiding and a prolonged need for catheterization in the sling group. Our definition of urinary tract infection did not require a positive urine culture, and it is possible that some patients received empirical antibiotic therapy for symptoms alone, leading us to overestimate the true incidence of postoperative urinary tract infection in either or both groups. For instance, the higher rate of urge incontinence identified in the sling group may have led to more false diagnoses of urinary tract infection in that group.

All the patients in our study received care in tertiary care centers, and the study population included only women with urethral hypermobility and pure or stress-predominant incontinence. Whether the results can be generalized to other groups of women is uncertain. Both the patients and the health care providers were aware of study-group assignments, and it is possible that bias affected the measurement of some outcomes.

Just over half the women underwent concomitant surgery for pelvic-organ prolapse, a proportion consistent with that in other studies.[8] Although we did not find any material differences in success rates on the basis of concomitant surgery, such procedures could potentially influence the number of adverse events identified in both groups.

The sling group also had higher satisfaction rates than did the Burch group, a difference that was consistent with the success rates. However, satisfaction rates were higher in both groups than were success rates, indicating that satisfaction was influenced by factors beyond the resolution of incontinence symptoms. Further analyses are needed to assess the relationships among the satisfaction reported by patients, improvement in the quality of life, and outcome measures described here.

New surgical procedures for stress incontinence continue to be introduced into clinical practice without evaluation of their efficacy and safety in well-designed, randomized clinical trials.[27,28] There has been a recent transition from

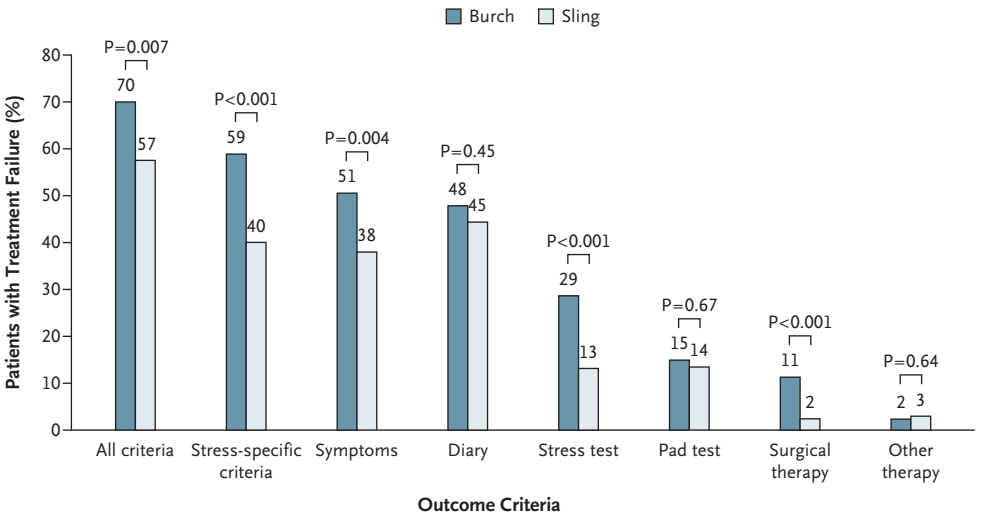

Figure 4. Proportion of Patients with Treatment Failure at 2 Years, According to Overall Composite Criteria, Composite Criteria Specific to Stress Incontinence, and Other Criteria.

Results are given for 520 patients — 255 who underwent the Burch procedure and 265 who underwent the sling procedure — for whom complete data were available at 24 months. P values are crude unadjusted comparisons of percentages.

the fascial sling and Burch procedure to the newer midurethral synthetic sling. A previous randomized surgical trial comparing the midurethral sling with the Burch procedure showed similar efficacy of the two procedures,[32,40] although that study has been criticized for being underpowered. No randomized trials have compared the midurethral sling with the autologous fascial sling. The relative frequency with which these procedures are performed in the United States is difficult to assess because they have identical procedural codes. Rigorous comparative trials are needed to assess the efficacy and safety of these novel surgical techniques as compared with the efficacy and safety of the procedures studied in our trial.

The number of women undergoing surgical therapy for stress incontinence is increasing, and this trend is likely to continue as the population ages. Our data show that the pubovaginal fascial sling has significantly higher efficacy than the Burch abdominal colposuspension at 24 months in women with predominant stress incontinence, but such success comes at the cost of more complications. Clinicians should discuss such tradeoffs when making recommendations to patients regarding the optimal procedure and should emphasize that complete resolution of incontinence symptoms after surgery is unlikely.

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APPENDIX

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