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Predictors of Treatment Failure 24 Months After Surgery For Stress Urinary Incontinence

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Abstract

Purpose—Identify baseline demographic and clinical factors associated with treatment failure after surgical treatment of stress urinary incontinence (SUI).

Materials & Methods—Data were obtained from 655 women randomized to Burch colposuspension or autologous rectus sling. Of those, 543 (83%) had stress failure status assessed at 24 months (269 Burch, 274 sling). Stress failure (n=261) was defined by any of the following: self-report of SUI by the Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire, positive stress test, or re-treatment for SUI. Non-stress failure (n=66) was defined as positive 24-hr pad test (>15 ml) or any incontinent episodes by 3-day voiding diary with none of the three criteria for stress failure. Subjects not meeting any failure criteria were considered a treatment success (n=185). Adjusting for surgical treatment group and clinical site, logistic regression models were developed to predict the probability of treatment failure.

Results—Severity of urge incontinence symptoms (p=0.041), prolapse stage (p=0.013), and being post-menopausal without hormone therapy (p=0.023) were significant predictors for stress failure. Odds of non-stress failure quadrupled for every 10-point increase in MESA urge score (OR:3.93,

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CI:1.45,10.65) and decreased over 2 times for every 10-point increase in stress score (OR:0.36, CI: 0.16,0.84). The associations of risk factors and failure remained similar regardless of surgical group.

Conclusion—Two years after surgery, risk factors for stress failure are similar after Burch and sling procedures and include greater baseline urge incontinence symptoms, more advanced prolapse, and menopausal not on HRT. Higher urge scores predicted failure by non stress-specific outcomes.

Keywords

Burch colpopexy; rectus facial sling; stress incontinence surgery; risk factors of failure

Introduction

Surgical treatment of stress urinary incontinence (SUI) in women offers relatively high success rates and immediate resolution of SUI symptoms. Failure rates for the most popular incontinence procedures vary depending on the criteria used to characterize urine loss and length of follow-up¹. Reported failure rates are as high as 74%¹ and may not be attributable to surgical technique alone². Little scientific data exist to guide surgeons and patients in determining the likelihood of surgical success for an individual woman, making it difficult for surgeons to effectively prepare patients for surgery. This is especially pertinent given the rapidly increasing, but understudied, surgical options for treating SUI. If we could identify which women were at risk for surgical failure, we may be able to modify treatments according to an individual woman's needs.

Proposed risk factors for surgical failures include patient demographics,³ history of previous pelvic or incontinence surgeries, physical examination parameters,⁴ urodynamic variables,⁵ and type of anesthesia.⁶ However, our ability to use these variables to predict which patients are at risk for failure is limited by the fact that the previous studies are inconsistent and most are retrospective, poorly designed, underpowered, or lack consistency in evaluation and follow-up.⁷ Many studies did not control for potentially confounding variables, or include a robust definition of failure including the use of both subjective and objective outcome measures to define cure.

The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) is a multisite randomized trial that compared treatment efficacy at 24 months between the Burch colposuspension and fascial sling procedures in women with stress predominant urinary incontinence (UI). The results of this clinical trial indicated that overall and stress specific success rates were higher in the group that received the sling than those that received the Burch procedures⁸. The purpose of this analysis and report was to identify baseline demographic and clinical variables associated with 24-month treatment failure in women undergoing surgical treatment in this randomized clinical trial.

Materials & Methods

Women planning SUI surgery were invited to participate in the trial. Eligibility requirements included documented pure or predominant SUI symptoms for at least three months and a positive standardized urinary stress test. Details of the study methods have been published previously⁹. All study procedures were approved by the institutional review board of each participating clinical center and the Biostatistical Coordinating Center with written informed consent obtained from all women prior to enrollment.

Women were randomized on the day of surgery in the operating room to receive a Burch colposuspension or an autologous rectus fascial sling. Key elements of the two surgical procedures were standardized across 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 pelvic prolapse surgery, abdominal and vaginal approaches for both pelvic prolapse repair and hysterectomy were permitted. However, surgeons were required to declare which concomitant procedures would be done prior to randomization.

Baseline assessment included a complete medical history, physical examination, urodynamic evaluation and patient survey. SUI treatment failure (stress failure) was defined as self-report of SUI by the MESA questionnaire (response of sometimes or often), positive stress test (leakage on examination during cough or valsalva at a standardized bladder volume of 300 mL), or retreatment for SUI (including behavioral, pharmacologic or surgical therapies). *The SUI treatment success* (stress success) group was divided into two subgroups: *non-SUI treatment failure* (non-stress failure), defined as positive 24-hr pad test (>15 ml) or any incontinent episodes by 3-day voiding diary in the absence of any of the three criteria for stress failure, and *total treatment success* for those subjects not meeting any failure criteria. Data were collected by interview and clinical examination pre-operatively, at 6 weeks post-operatively, and at 3, 6, 12, 18 and 24 months post-operatively. A woman could be defined as a treatment failure by retreatment any time post surgery and by the other criteria at any time after 6 months post-surgery.

Potential variables thought to affect or be associated with treatment failure included *sociodemographic characteristics* (age, race/ethnicity, occupational score, education, marital status, household annual income); *medical/surgical history* (body mass index, vaginal parity, prior UI surgery, prior pelvic prolapse surgery, hysterectomy, menopausal status/hormone replacement treatment (HRT), diabetes, smoking status); *characteristics of UI* (self-reported frequency of stress and urge incontinence symptoms¹⁰, quantity of urine leakage on a 24-hour pad test, number of incontinence episodes on a 3-day voiding diary, symptom bother and incontinence-related quality of life); *physical examination findings* (urethral hypermobility measured by the Q-tip test, pelvic floor muscle strength, and pelvic organ prolapse). Self-reported UI was quantified by the stress and urge subscale scores from the Medical, Epidemiological and Social Aspects of Aging (MESA) questionnaire.¹⁰ Finally, because concomitant surgery might affect the outcome of the study surgery, an indicator (yes/no) of concomitant surgery was included.

To identify predictors of stress and non-stress treatment failure, bivariate logistic regression models were fit modeling the probability of stress-specific failure and non-stress failure as a function of each covariate separately, adjusting for treatment group (Burch and sling) and site. Both continuous and categorical predictors were considered. Odds ratios (ORs) and 95% confidence intervals (CIs) described the associations between clinical parameters and the outcomes. Based on significance at the 0.05 level from the bivariate logistic regression models and clinical relevance, multivariable logistic regression models were fit for each defined outcome. To assess whether the relationships between the predictors and failure were similar for each of the treatment groups, interaction terms between each predictor and treatment were considered. Interaction terms between significant main effects were also tested for inclusion in the multivariable models. Hosmer-Lemeshow goodness of fit tests were calculated to assess the fit of the models. A 5% two-sided significance level was used for all statistical testing. Analyses were performed using SAS Version 9.1 (SAS Institute, Inc. Cary, NC).

Results

Of the 655 subjects, 543 (83%) completed the stress failure assessment at 24 months. 261 patients met stress failure criteria and 282 did not. Table 1 compares the women who met the

stress specific criteria for success and failure. The bivariate and multivariable analyses for stress failure are presented in Table 2. No statistically significant interactions between the covariates and treatment group were found for stress failure, implying that the relationships between each covariate and stress failure were similar for the Burch and sling groups. The multivariable models to predict stress failure were fit including treatment group, site and the following covariates: age, occupational score, body mass index, stress score, urge score, vaginal deliveries, prior surgery for urinary incontinence, menopausal status/HRT and prolapse stage.

The covariates that continued to demonstrate a statistically significant relationship to 24-month stress failure included: urge score, menopausal without HRT and prolapse stage. Specifically, for each 10-unit increase in the urge score, odds of stress failure were 1.84 times greater. The odds of stress failure differed in the post-menopausal women depending on whether they were taking HRT or not. Compared to pre-menopausal women, menopausal patients not taking HRT had approximately 1.5 times the odds of stress failure, whereas post-menopausal women taking HRT had a lower odds of stress failure. The odds of stress failure for women with stage 3/4 prolapse were approximately 2.5 times greater than that of women with stage 0/1 prolapse. As in the bivariate analyses, no interactions between covariates and treatment group were statistically significant, nor were the interactions between main effects. The goodness-of-fit test did not reveal that the model fit was inadequate ($p = 0.27$).

Of the 282 stress successes, 66 patients met non-stress failure criteria, 185 patients demonstrated no failure criteria and were considered total treatment successes, and 31 patients could not be classified due to missing information (Figure 1). Table 3 compares the women who met the non-stress failure criteria and those considered total treatment success. Table 4 presents the bivariate and multivariable analyses of non-stress failure in this group. The covariates that continued to demonstrate a statistically significant relationship to 24-month non-stress failure included the MESA urge and stress scores. The urge score demonstrated a positive relationship with non-stress failure, while the stress score demonstrated an inverse relationship. For each 10-point increase in the urge score, the odds of non-stress failure approximately quadrupled, while for every 10-point increase in stress score, the odds of non-stress failure decreased by over two. No interactions were statistically significant, and the goodness-of-fit test indicated reasonable model fit ($p = 0.96$).

Discussion

Two years after surgery, risk factors for recurrent or persistent SUI were similar in women undergoing Burch colposuspension and autologous rectus fascial sling procedures. In contrast to previous studies, this randomized controlled trial did not find a significant impact of many commonly reported “risk factors,” such as age, BMI, prior UI surgery, prior hysterectomy and diabetes mellitus, on continence outcomes¹¹⁻¹⁵.

The major finding in this study is that patients with higher urge scores demonstrated higher stress specific failure as well as overall failure. Therefore, it seems possible that urge symptoms are not merely a reflection of more urge incontinence episodes, but are associated with persistent or recurrent stress incontinence. In women with mixed incontinence, the underlying pathophysiology may be that the urge symptoms serve as a surrogate or manifestation of an intrinsic deficiency of the urethral sphincter from more advanced neuromuscular dysfunction, which may not be easily cured with continence surgery. Chaliha et al¹⁶ demonstrated that the normally observed increase in urethral pressure with bladder filling was not observed in patients with detrusor overactivity. This may suggest a primary urethral dysfunction in patients with urge incontinence symptoms.

Women with stage 3 or 4 prolapse were 2.5 times more likely than women without prolapse to have persistent or recurrent SUI. Advanced prolapse could be a manifestation of more extensive damage to the pelvic floor musculofascial support, its innervation, or its ultrastructural composition of elastin and collagen¹⁷. This finding is consistent with the observation of Daneshgari et al¹⁵ who found that pelvic organ prolapse and concomitant rectocele repair increased the risk of recurrent SUI. The finding that Burch and sling outcomes are worse in women with advanced pelvic organ prolapse cannot necessarily be extrapolated to other continence surgeries. Certainly, for the mid-urethral sling procedures, caution is recommended when quoting outcomes based on trials that exclude women with prolapse until more evidence becomes available in this group of women.

The results of this study contribute to the controversy over the relationship between estrogen status and continence. Contrary to others^{15,18}, our data indicate that menopausal women not taking HRT were twice as likely to experience persistent or recurrent SUI after surgery compared to those taking HRT. These data are typically confounded by difficulty in assuring the duration of use as well as dosage and specific hormonal replacement regimens used. HRT may correct the hypoestrogenism associated with atrophic, thinner tissue and improve neuromuscular function as shown in animal models in which gonadal steroids had important neuro-regenerative effects on peripheral motor nerves^{19,20}.

Our study findings are strengthened by our study design, a multi-center randomized trial with diverse surgeons from both urology and urogynecology, which contributes to the study's generalizability and limits potential biases. In addition, we had clearly defined and validated objective and subjective outcome measures and good follow-up for a 2-year period. Our conclusions are limited by the lack of information on the urodynamic studies done at 2 years, which will be reported in a separate paper.

Conclusion

In summary, patients with higher urge scores demonstrated higher stress specific failure as well as overall failure 2 years after surgery for stress predominant UI. Risk factors for persistent or recurrent SUI after a Burch or sling procedure are similar 2 years after surgery. These risk factors are potentially modifiable by separately addressing and treating concomitant pelvic floor disorders, such as urge incontinence, advanced prolapse, and/or hormone therapy. These observations might assist in counseling patients regarding the long-term efficacy of these 2 surgical procedures and discussing reasonable expectations, and proactively addressing the modifiable risk factors of urge incontinence and need for hormone replacement therapy.

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References

1. Ward K, Hitlon P. on Behalf of the United Kingdom and Ireland Tension Free Vaginal Tape Trial Group. Prospective Multicentre Randomized Trial of Tension Free Vaginal Tape and Colposuspension as Primary Treatment for Stress Incontinence. *BMJ* 2002;325:67. [PubMed: 12114234]
2. Sand PK, Bowen LW, Ostergard DR, Nakanishi AM. Hysterectomy and prior incontinence surgery as risk factors for failed retropubic cystourethropey. *JRM* 1988;33:171.
3. Salin A, Conquy S, Elie C, Touboul C, Parra J, Zerbib M, et al. Identification of risk factors for voiding dysfunction following TVT placement. *European Urology* 2007;51:782. [PubMed: 17098355]
4. Meschia M, Pifarotti P, Gate U, Bertozzi R. Tension-free vaginal tape: analysis of risk factors for failure. *Int Urogynecol J* 2007;18:419.
5. Bowen LW, Sand PK, Ostergard DR, Franti CE. Unsuccessful Burch retropubic urethropey: A case-controlled urodynamic study. *Am J Obstet Gynecol* 1989;160:452. [PubMed: 2916634]
6. Deval B, Jeffry L, Al Najjar F, Soriano D, Darai E. Determinants of patient dissatisfaction after a tension-free vaginal tape procedure for urinary incontinence. *J Urol* 2002;167:2093. [PubMed: 11956447]
7. Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol* 1996;78:497. [PubMed: 8944504]
8. Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med* 2007;356:13.
9. Tennstedt S. Urinary Incontinence Treatment Network. Design of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER). *Urology* 2005;66:1213. [PubMed: 16360445]
10. Herzog AR, Diokno AC, Brown MB, Normolle DP, Brock BM. Two-year incidence, remission, and change patterns of urinary incontinence in noninstitutionalized older adults. *J Gerontol* 1990;45:M67. [PubMed: 2313045]
11. Stanton SL, Cardozo L, Williams JE, Ritchie D, Allan V. Clinical and urodynamic features of failed incontinence surgery in the female. *Obstet Gynecol* 1978;51:515. [PubMed: 652197]
12. Berglund AL, Eisemann M, Lalos A, Lalos O. Predictive factors of the outcome of primary surgical treatment of stress incontinence in women. *Scand J Urol Nephrol* 1997;31:49. [PubMed: 9060084]
13. Alcalay M, Monga A, Stanton SL. Burch colposuspension: a 10-20 year follow up. *Br J Obstet Gynaecol* 1995;102:740. [PubMed: 7547767]
14. Bowen LW, Sand PK, Ostergard DR, Franti CE. Unsuccessful Burch retropubic urethropey: a case-controlled urodynamic study. *Am J Obstet Gynecol* 1989;160:452. [PubMed: 2916634]
15. Daneshgari F, Moore C, Frinjari H, Babineau D. Patient related risk factors for recurrent stress urinary incontinence surgery in women treated at a tertiary care center. *J Urol* 2006;176:1493. [PubMed: 16952667]

16. Chaliha C, Digesu GA, Salvatore S, Khullar V, Athanasiou S. Changes in urethral resistance in the presence of detrusor activity. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;17:215. [PubMed: 16077996]
17. Karam JA, Vazquez DV, Lin VK, Zimmern PE. Elastin expression and elastic fibre width in the anterior vaginal wall of postmenopausal women with and without prolapse. *BJU International* 2007 May;100:346. [PubMed: 17532852]2006
18. Sun MJ, Ng SC, Tsui KP, Chang NE, Lin KC, Chen GD. Are there any predictors for failed Burch colposuspension? *Taiwan J Obstet Gynecol* 2006;45:33. [PubMed: 17272205]
19. Tanzer L, Jones KJ. Gonadal steroid regulation of hamster facial nerve regeneration: effects of dihydrotestosterone and estradiol. *Exp Neurol* 1997;146:258. [PubMed: 9225759]
20. Tetzlaff JE, Huppenbauer CB, Tanzer L, Alexander TD, Jones KJ. Motoneuron injury and repair: New perspectives on original gonadal steroids as neurotherapeutics. *J Mol Neurosci* 2006;28:53. [PubMed: 16632875]

Abbreviations

SUI	Stress Urinary Incontinence
MESA	Medical, Epidemiological & Social Aspects of Aging
UI	Urinary Incontinence
HRT	Hormone Replacement Therapy
OR	Odds Ratio
CI	Confidence Interval
UDI	Urogenital Distress Inventory
BMI	Body Mass Index
IIQ	Incontinence Impact Questionnaire
UDI	Urogenital Distress Inventory

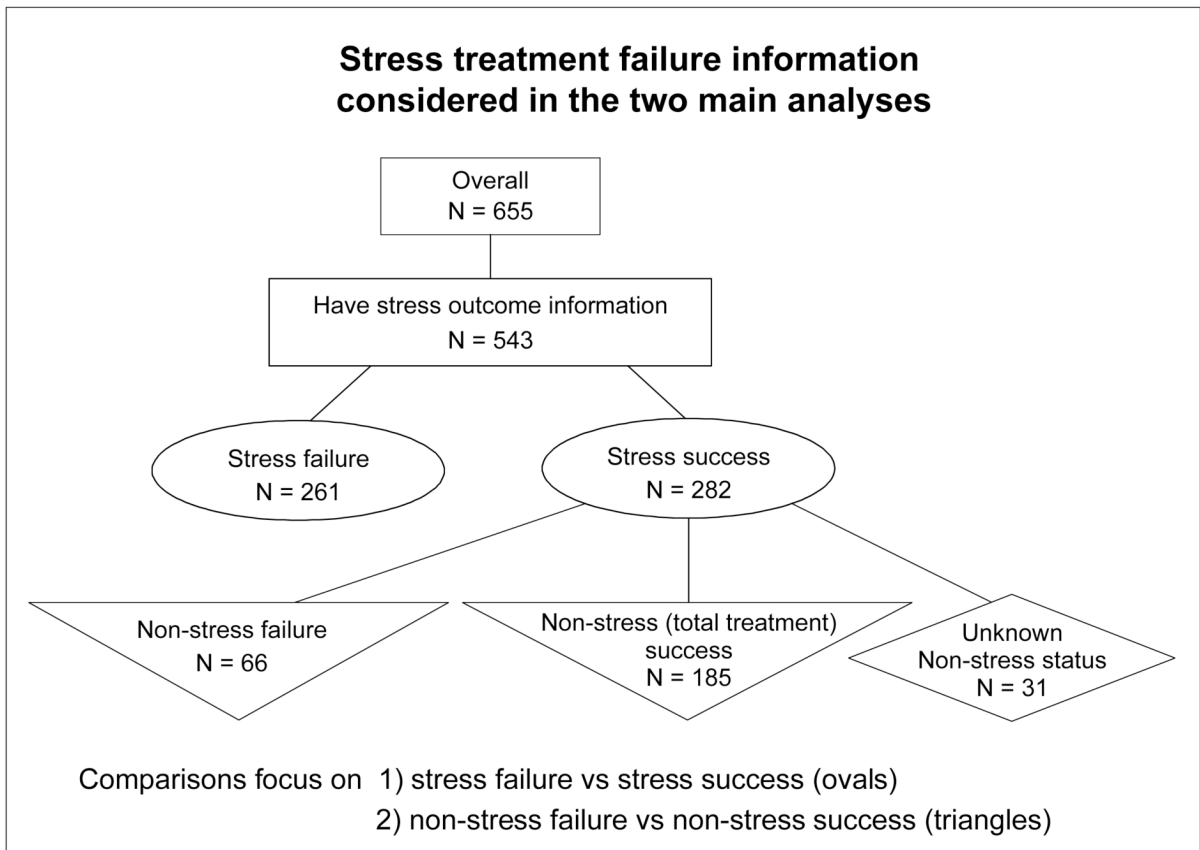


Figure 1.

Table 1
Selected Characteristics of Sample by Stress Success status (n=543)

Characteristics	Stress success (n=282)	Stress failure (n=261)
Demographic Characteristics		
Age — years: mean (s.d.)	51.4 (9.3)	54.0 (10.9)
Racial and ethnicity group — %:		
Hispanic	10	11
Non-Hispanic White	77	73
Non-Hispanic Black	6	7
Non-Hispanic Other	7	9
Marital status - %		
Married/living as married	69	68
Not married	31	32
Education — %:		
High School or less	31	39
Some post-HS training	37	39
Baccalaureate or more	32	22
Household Income — %:		
<\$20,000	16	23
\$20,000 - \$49,999	28	34
\$50,000 - \$79,999	21	20
\$80,000 +	35	23
Occupational Score: mean (s.d.)	59.9 (25.0)	54.5 (24.5)
Medical History		
BMI: [†] mean (s.d.)	29.5 (5.8)	30.4(6.4)
Vaginal Deliveries — %		
0	13	6
1-2	43	41
3+	44	53
Prior UI surgery — %	14	18
Prior Prolapse surgery — %:	1	3
Hysterectomy — %:	30	34
Menopausal Status/HRT Usage — %:		
HRT	37	33
No HRT	31	44
Pre-menopausal	32	23
Diabetes — %:	5	9
Smoking Status-%		
Never Smoked	56	55
Former Smoker	32	33
Current Smoker	12	12
Prolapse Stage [‡] — %:		
Stage 0/1	26	19

Characteristics	Stress success (n=282)	Stress failure (n=261)
Stage 2	62	59
Stage 3/4	12	22
Point Ba: mean (s.d.)	-0.70 (1.59)	-0.31 (1.94)
Point Bp: mean (s.d.)	-1.82 (1.33)	-1.53 (1.64)
Point Gh: mean (s.d.)	3.51 (1.19)	3.66 (1.21)
Brink Score: mean (s.d.)	9.23 (2.01)	8.65 (2.13)
Quality of Life		
Total UDI Score: ¹⁹ mean (s.d.)	146.0 (48.6)	157.9 (45.6)
Total IIQ Score: ¹⁹ mean (s.d.)	168.0 (101.0)	176.7 (99.3)
Clinical Characteristics		
Pad test weight — g: mean (s.d.)	41.7 (69.5)	46.3 (95.5)
Incontinence episodes/day: mean (s.d.)	3.2 (3.2)	3.2 (2.8)
Urinary Incontinence symptom score [§]		
Stress score: mean (s.d.)	19.0 (4.8)	19.9 (4.1)
Urge score: mean (s.d.)	5.9 (3.9)	7.4 (3.9)
Q-Tip test — degrees:		
Resting angle: mean (s.d.)	16.1 (18.1)	14.3 (16.4)
Straining angle: mean (s.d.)	61.6 (18.6)	59.0 (17.9)
Delta = straining – resting: mean (s.d.)	45.5 (18.3)	44.7 (18.8)
Concomitant Surgery - %		
None	44	38
Concomitant Pelvic Surgery: Prolapse repair: Anterior wall prolapse repair, +/- other repair OR	56	62
Prolapse repair: Other, no anterior wall prolapse repair (includes posterior wall, apex) OR		
Concomitant Other Surgery (no prolapse)		

* UI denotes urinary incontinence, UDI Urogenital Distress Inventory;²⁰ and IIQ Incontinence Impact Questionnaire.²⁰

[†] BMI, body mass index: weight (kg) relative to square of height (m²).

[‡] Prolapse staging is based on the methods of the Pelvic Organ Prolapse Quantification System.¹⁸

[§] UI Symptom scores: Total score on the Medical, Epidemiological and Social Aspects of Aging questionnaire.²² Response categories for each item 0 = “never” to 3 = “often.”

Table 2

Bivariate and Multivariable Associations of Potential Predictors of Stress Failures Controlling for Treatment Group (Burch, Sling): Odds ratios (95% confidence intervals and p-values (n=543))

Continuous predictors	Bivariate Analyses		Final Multivariable Analysis *	
	Adjusted Odds Ratio ** (95% CI)	p-value	Adjusted Odds Ratio ** (95% CI)	p-value
Age (10 year increase)	1.28 (1.08, 1.52)	0.005	1.12 (0.87, 1.44)	0.38
Occupational score (10 unit increase)	0.91 (0.85, 0.98)	0.011	0.94 (0.87, 1.02)	0.15
Body mass index	1.03 (1.00, 1.06)	0.061	1.01 (0.98, 1.05)	0.47
Point Ba	1.14 (1.03, 1.25)	0.013		
Point Bp	1.14 (1.01, 1.28)	0.036		
Point Gh	1.11 (0.96, 1.28)	0.17		
Brink Score	0.88 (0.81, 0.95)	0.002		
UDI Score (10 point increase)	1.06 (1.02, 1.10)	0.003		
IIQ Score (10 point increase)	1.01 (0.99, 1.03)	0.37		
Pad test weight (10 g increase)	1.01 (0.99, 1.03)	0.49		
Incontinence episodes/day	0.99 (0.93, 1.04)	0.62		
Stress score (10 point increase)	1.50 (1.02, 2.21)	0.039	1.24 (0.75, 2.05)	0.39
Urge score (10 point increase)	2.65 (1.69, 4.16)	<0.0001	1.84 (1.03, 3.30)	0.041
Resting angle (5° increase)	0.97 (0.92, 1.02)	0.23		
Straining angle (5° increase)	0.96 (0.91, 1.00)	0.068		
Delta (5° increase)	0.98 (0.94, 1.03)	0.49		
<hr/>				
Categorical predictors	Adjusted Odds Ratio *** (95% CI)	p-value		
<hr/>				
Ethnicity		0.59		
Hispanic	0.91 (0.41, 2.03)			
Non-Hispanic White	0.73 (0.39, 1.37)			
Non-Hispanic Black	1.00 (0.41, 2.46)			
Non-Hispanic Other	1 Reference			
Marital Status		0.71		
Married/living as married	0.93 (0.65, 1.35)			
Not married	1 Reference			
Education		0.025		
High School or less	1 Reference			
Some post-HS training	0.81 (0.54, 1.20)			
Baccalaureate or more	0.54 (0.35, 0.85)			
Household Income		0.015		
<\$20,000	1 Reference			
\$20,000 - \$49,999	0.84 (0.50, 1.41)			
\$50,000 - \$79,999	0.66 (0.37, 1.17)			

Continuous predictors	Bivariate Analyses		Final Multivariable Analysis *	
	Adjusted Odds Ratio ** (95% CI)	p-value	Adjusted Odds Ratio ** (95% CI)	p-value
\$80,000 +	0.45 (0.27, 0.77)			
Vaginal Deliveries		0.015		0.07
0	1 Reference		1 Reference	
1-2	1.94 (1.00, 3.77)		2.20 (1.03, 4.71)	
3+	2.55 (1.32, 4.93)		2.45 (1.13, 5.28)	
Prior UI surgery	1.30 (0.82, 2.08)	0.26	1.23 (0.73, 2.09)	0.44
Prior Prolapse surgery	2.11 (0.62, 7.20)	0.23		
Hysterectomy	1.16 (0.81, 1.68)	0.42		
Menopausal status/HRT		0.003		0.023
Yes	1.20 (0.77, 1.86)		0.94 (0.51, 1.75)	
No	2.03 (1.31, 3.14)		1.67 (0.96, 2.89)	
Pre-menopausal	1 Reference		1 Reference	
Diabetes	1.68 (0.85, 3.31)	0.14		
Smoking Status		0.92		
Never smoked	1 Reference			
Former smoker	1.08 (0.74, 1.57)			
Current smoker	1.07 (0.62, 1.85)			
Prolapse Stage		0.002		0.013
Stage 0/1	1 Reference		1 Reference	
Stage 2	1.30 (0.85, 1.99)		1.25 (0.77, 2.02)	
Stage 3/4	2.75 (1.56, 4.85)		2.64 (1.34, 5.21)	
Concomitant surgery	1.27 (0.89, 1.79)	0.18		

* In the multivariable analysis, clinical site is also controlled for.

** Unless otherwise indicated in parentheses, odds ratios reported indicate the change in odds of stress failure for a one-unit change in the continuous predictor.

*** For the categorical predictors, odds ratios denote the change in the odds of stress failure compared to the referent group indicated (or not having the condition).

Table 3
Selected Characteristics of Women who met criteria for Stress success by non-Stress Success status (n=251)

Characteristics	Non-stress success (n=185)	Non-stress failure (n=66)
Demographic Characteristics		
Age — years: mean (s.d.)	51.6 (9.5)	51.5 (9.6)
Racial and ethnicity group — %:		
Hispanic	9	14
Non-Hispanic White	76	77
Non-Hispanic Black	7	4.5
Non-Hispanic Other	8	4.5
Marital status - %		
Married/living as married	70	68
Not married	30	32
Education — %:		
High School or less	34	20
Some post-HS training	36	39
Baccalaureate or more	30	41
Household Income — %:		
<\$20,000	15	18.5
\$20,000 - \$49,999	31	24
\$50,000 - \$79,999	19	18.5
\$80,000 +	35	39
Occupational Score: mean (s.d.)	59.5 (24.7)	61.7 (26.0)
Medical History		
BMI: [†] mean (s.d.)	29.2 (5.5)	30.7 (7.0)
Vaginal Deliveries — %		
0	14	9
1-2	44	39
3+	42	52
Prior UI surgery — %	12	20
Prior Prolapse surgery — %:	1	3
Hysterectomy — %:	26	32
Menopausal Status/HRT Usage — %:		
HRT	41	30
No HRT	26	38
Pre-menopausal	33	32
Diabetes — %:	4	5
Smoking Status-%		
Never Smoked	53	61
Former Smoker	35	27
Current Smoker	12	12
Prolapse Stage [‡] — %:		
Stage 0/1	24	27

Characteristics	Non-stress success (n=185)	Non-stress failure (n=66)
Stage 2	62	68
Stage 3/4	14	5
Point Ba: mean (s.d.)	-0.57 (1.68)	-1.02 (1.23)
Point Bp: mean (s.d.)	-1.76 (1.38)	-2.10 (1.10)
Point Gh: mean (s.d.)	3.50 (1.29)	3.42 (0.90)
Brink Score: mean (s.d.)	9.29 (2.04)	9.30 (1.84)
Quality of Life		
Total UDI Score: ¹⁹ mean (s.d.)	146.6 (50.0)	143.7 (47.6)
Total IIQ Score: ¹⁹ mean (s.d.)	166.6 (102.0)	171.2 (104.3)
Clinical Characteristics		
Pad test weight — g: mean (s.d.)	40.4 (71.0)	44.1 (62.8)
Incontinence episodes/day: mean (s.d.)	3.3 (3.2)	3.4 (3.7)
Urinary Incontinence symptom score [§]		
Stress score: mean (s.d.)	19.1 (4.8)	18.8 (4.8)
Urge score: mean (s.d.)	5.6 (4.0)	6.8 (3.6)
Q-Tip test — degrees:		
Resting angle: mean (s.d.)	16.0 (18.0)	15.1 (17.8)
Straining angle: mean (s.d.)	62.3 (19.6)	59.6 (17.0)
Delta = straining – resting: mean (s.d.)	46.3 (18.7)	44.5 (16.4)
Concomitant Surgery - %		
None	42	48
Concomitant Pelvic Surgery: Prolapse repair: Anterior wall prolapse repair, +/- other repair OR	58	52
Prolapse repair: Other, no anterior wall prolapse repair (includes posterior wall, apex) OR		
Concomitant Other Surgery (no prolapse)		

* UI denotes urinary incontinence, UDI Urogenital Distress Inventory;²⁰ and IIQ Incontinence Impact Questionnaire.²⁰

[†] BMI, body mass index: weight (kg) relative to square of height (m²).

[‡] Prolapse staging is based on the methods of the Pelvic Organ Prolapse Quantification System.¹⁸

[§] UI Symptom scores: Total score on the Medical, Epidemiological and Social Aspects of Aging questionnaire.²² Response categories for each item 0 = “never” to 3 = “often.”

Table 4

Bivariate and multivariable associations of potential predictors of “non-stress” failures controlling for treatment group (Burch, Sling): Odds Ratios (95% confidence intervals) and p-value

Continuous Predictor	Bivariate Analyses		Final Multivariable analysis *	
	Adjusted Odds Ratio ** (95% CI)	p-value	Adjusted Odds Ratio ** (95% CI)	p-value
Age (10 year increase)	1.00 (0.74, 1.34)	0.98	0.97 (0.62, 1.50)	0.88
Occupational score (10 unit increase)	1.04 (0.92, 1.16)	0.54	1.11 (0.97, 1.27)	0.12
Body mass index	1.04 (0.99, 1.09)	0.088	1.04 (0.98, 1.10)	0.23
Point Ba	0.82 (0.67, 1.00)	0.046		
Point Bp	0.79 (0.61, 1.03)	0.079		
Point Gh	0.94 (0.74, 1.20)	0.63		
Brink Score	1.00 (0.87, 1.16)	0.97		
UDI Score (10 point increase)	0.99 (0.93, 1.05)	0.70		
IIQ Score (10 point increase)	1.01 (0.98, 1.03)	0.73		
Pad test weight (10 g increase)	1.01 (0.97, 1.05)	0.70		
Incontinence episodes/day	1.01 (0.93, 1.10)	0.79		
Stress score (10 point increase)	0.88 (0.49, 1.59)	0.68	0.36 (0.16, 0.84)	0.017
Urge score (10 point increase)	2.18 (1.07, 4.48)	0.033	3.93 (1.45, 10.65)	0.007
Resting angle (5° increase)	0.99 (0.91, 1.07)	0.74		
Straining angle (5° increase)	0.96 (0.89, 1.04)	0.33		
Delta (5° increase)	0.97 (0.90, 1.05)	0.49		
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Categorical predictors	Adjusted Odds Ratio *** (95% CI)	p-value		
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Ethnicity		0.57		
Hispanic	2.54 (0.58, 11.23)			
Non-Hispanic White	1.74 (0.48, 6.30)			
Non-Hispanic Black	1.16 (0.19, 6.93)			
Non-Hispanic Other	1 Reference			
Marital Status		0.80		
Married/living as married	0.93 (0.51, 1.70)			
Not married	1 Reference			
Education		0.075		
High School or less	1 Reference			
Some post-HS training	1.88 (0.89, 3.99)			
Baccalaureate or more	2.39 (1.12, 5.08)			
Household Income		0.67		
<\$20,000	1 Reference			
\$20,000 - \$49,999	0.58 (0.23, 1.47)			
\$50,000 - \$79,999	0.72 (0.27, 1.94)			

Continuous Predictor	Bivariate Analyses		Final Multivariable analysis *	
	Adjusted Odds Ratio ^{***} (95% CI)	p-value	Adjusted Odds Ratio ^{**} (95% CI)	p-value
\$80,000 +	0.83 (0.35, 1.99)			
Vaginal Deliveries		0.35		0.21
0	1 Reference		1 Reference	
1-2	1.44 (0.53, 3.91)		1.99 (0.61, 6.43)	
3+	1.93 (0.73, 5.12)		2.78 (0.86, 8.95)	
Prior UI surgery	1.83 (0.86, 3.90)	0.11	1.88 (0.75, 4.67)	0.18
Prior Prolapse surgery	2.93 (0.40, 21.29)	0.29		
Hysterectomy	1.30 (0.71, 2.40)	0.40		
Menopausal status/HRT		0.15		0.57
Yes	0.80 (0.40, 1.60)		0.73 (0.27, 1.97)	
No	1.56 (0.78, 3.11)		1.13 (0.45, 2.85)	
Pre-menopausal	1 Reference		1 Reference	
Diabetes	1.21 (0.30, 4.84)	0.79		
Smoking Status		0.48		
Never smoked	1 Reference			
Former smoker	0.67 (0.35, 1.28)			
Current smoker	0.89 (0.36, 2.16)			
Prolapse Stage		0.14		0.13
Stage 0/1	1 Reference		1 Reference	
Stage 2	0.96 (0.50, 1.83)		0.87 (0.41, 1.86)	
Stage 3/4	0.28 (0.08, 1.05)		0.22 (0.05, 0.99)	
Concomitant surgery	0.76 (0.43, 1.34)	0.34		

* In the multivariable analysis, clinical site is also controlled for.

** Unless otherwise indicated in parentheses, odds ratios reported indicate the change in odds of non-stress failure for a one-unit change in the continuous predictor.

*** For the categorical predictors, odds ratios denote the change in the odds of non-stress failure compared to the referent group indicated (or not having the condition).