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Patient Satisfaction with Stress Incontinence Surgery

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Abstract

Aims—To identify predictors and correlates of patient satisfaction 24 months after Burch colpopexy or autologous fascial sling for treatment of stress urinary incontinence (SUI).

Methods—Participants were the 655 randomized subjects in the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER). Variables potentially associated with satisfaction were tested in bivariate analysis, including demographics, baseline clinical characteristics of incontinence, and outcomes on validated subjective and objective measures. Satisfaction with treatment was defined as a response of “completely satisfied” or “mostly satisfied” on the Patient Satisfaction Questionnaire (PSQ) at 24 months. Variables significantly related to satisfaction were entered into multivariable regression models to test their independent association with satisfaction.

Results—At 24 months post-surgery, 480 (73%) participants completed the PSQ. Mean ($\pm$ SD) age of the sample was 52 ($\pm$ 10) years and 77% were white. Most (82%) were completely or mostly satisfied with their surgery related to urine leakage. In the final multivariable model, patient satisfaction was associated with greater reduction in SUI symptoms (from baseline to 24 months; OR=1.17, 95% CI:1.10, 1.24) and greater reductions in symptom distress (OR=1.16; CI: 1.08, 1.24). Lower odds of satisfaction were associated with greater urge incontinence symptoms at baseline (OR=0.09, CI:0.04, 0.22), detrusor overactivity at 24 months (OR=0.29, CI:0.12, 0.69), and a positive stress test at 24 months (OR=0.45, CI:0.22, 0.91).

Conclusions—Stress incontinent women who also have urge incontinence symptoms may benefit from additional preoperative counseling to set realistic expectations about potential surgical outcomes or proactive treatment of urge incontinence symptoms to minimize their post-operative impact.

Keywords

patient outcomes assessment; patient satisfaction; surgery; urinary incontinence

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Introduction

Stress urinary incontinence (SUI) is a condition that is known to have significant social, economic and psychological consequences. Evidence-based treatment options for SUI include surgery, which is widely used. However, surgical success rates vary considerably, depending on how outcomes are measured and how success is defined.(1) Early studies of treatment for urinary incontinence focused on objective outcome measures, including urodynamic parameters, pad tests, or cough stress tests. Over time, symptom assessment, including the number of incontinence episodes on bladder diary and symptom questionnaires were included. Most recently, the patient's perspective, including patient satisfaction, has been recognized increasingly as an important dimension of outcome assessment. Formal approaches to patient-reported outcomes have received growing recognition, and patient satisfaction in particular has emerged as an important quality indicator.(2-4)

Although some studies have found modest to very good correlation between patient-reported outcomes and objective testing, (5,6) others have found a weak correlation.(7-9) Patient satisfaction is generally associated with reduction in incontinence episodes or frequency.(10) However, many patients who are not completely dry are satisfied, while in contrast, some who are completely dry are not entirely satisfied. Even though surgery can reduce episodes of stress incontinence, it may introduce other undesirable sequelae that may ultimately affect satisfaction with treatment (e.g., de novo urge urinary incontinence, urinary retention and prolonged urinary catheter drainage, and lower urinary tract or gastrointestinal injury). Thus, there appear to be multiple factors that enter into a patient's global impression of her satisfaction with treatment, including personal characteristics, expectations, baseline characteristics of her incontinence, complications of surgery, and various outcomes of her treatment for stress incontinence.

In recent literature, predictors of therapeutic failure have been identified and include greater baseline urge incontinence scores and symptoms, more advanced prolapse, and menopause without hormone replacement therapy.(11) Less is known about what factors might contribute to patient satisfaction with outcomes of surgical treatment for SUI, particularly in the long term. Knowing what achieves satisfaction and what defines success from both a patient and clinician standpoint would allow us to counsel patients more effectively regarding potential outcomes and to prepare them with appropriate expectations of surgery. Thus, the goal of this paper was to identify predictors and correlates of patient satisfaction as measured by subjective and objective instruments at 24 months following SUI surgery in a large cohort of well-characterized women.

Materials and Methods

Design and Participants

Data for this study were obtained from participants in the Stress Incontinence Surgery Trial (SISTEr), a multicenter, randomized clinical trial that compared the Burch colposuspension and the autologous rectus fascial sling procedures. Details of the trial design and methods and results have been reported.(12,13) The SISTEr trial was reviewed and approved by the Institutional Review Boards at all participating centers (See appendix for participating centers). All women provided written informed research consent prior to study participation.

Measure of Patient Satisfaction

Patient satisfaction, the dependent variable, was measured 24-months following surgery by asking women to respond to the following question, "How satisfied or dissatisfied are you with the result of bladder surgery related to urine leakage?" Women responded based on a 5-point Likert-type scale as 1 (completely dissatisfied), 2 (mostly dissatisfied), 3 (neutral), 4

(mostly satisfied), or 5 (completely satisfied). For data analysis purposes, we created a dichotomous response variable (“dissatisfied” versus “satisfied”) with “completely dissatisfied”, “mostly dissatisfied” and “neutral” responses combined to define “treatment dissatisfaction”, and “mostly satisfied” and “completely satisfied” responses combined to define “treatment satisfaction.”

Independent Variables

Factors hypothesized to predict treatment satisfaction included demographic characteristics, medical and UI treatment history including self-rated health, physical examination findings, type and severity of UI symptoms, UI symptom-related distress, quality of life, and patient expectations of surgery. Demographic characteristics recorded at baseline included age, ethnicity, and socioeconomic status. Socioeconomic status was measured using the Powers-Terrie Occupational Status Score.⁽¹⁴⁾ This measure bases occupational status on educational requirements and expected salary. Scores range from 0-100, with higher scores indicating greater status.

Medical history, self-rated health, body mass index (BMI; kg/m²), and pelvic organ prolapse examination findings were recorded at baseline only. Medical history variables included self-reported diagnosis of diabetes, smoking status, current estrogen use, and prior treatments/surgery for UI. Self-rated health was determined using the Health Utilities Index measure of overall health ranging from 1 (excellent) to 5 (poor).⁽¹⁵⁾ Pelvic organ prolapse was assessed with the Pelvic Organ Prolapse Quantification (POP-Q) System.

Expectations of surgery were obtained preoperatively by asking women to rate how much improvement in urine leakage they expected following their recovery from surgery. Women were asked to rate their expectation based on a 5-point Likert-type scale as 1 (no better), 2 (slightly better), 3 (somewhat better), 4 (much better), or 5 (completely better).

The Medical, Epidemiologic, and Social Aspects of Aging Questionnaire (MESA) was administered at baseline and at 24 months post-surgery to assess treatment outcomes.⁽¹⁶⁾ The MESA questionnaire includes 9 stress UI symptom and 6 urge UI symptom items. Responses to stress and urge items were summed to obtain a stress (ranging from 0 to 27) and urge symptom score (ranging from 0 to 18). A higher MESA symptom score indicates greater UI symptoms.

The 3-day bladder diary, 24-hr pad test, provocative stress test, and urodynamic testing were administered to further characterize urinary symptoms and symptom severity. The 3-day bladder diary captured voiding frequency, nocturia (≥ 2 voids/night), and number of UI episodes over each 24 hour period.⁽¹⁷⁾ The standardized 24-hr pad test quantified amount of involuntary urine loss (grams). A provocative stress test at a standardized bladder volume (300 ml) confirmed urine leakage from the urethra while the patient was asked to cough or Valsalva. Urodynamic evaluation verified the presence of urodynamic stress urinary incontinence and/or detrusor-overactivity. In addition, voiding parameters including uroflow and voiding pressures were assessed.

Changes in urinary symptom distress and condition-specific quality of life from baseline to 24 months post-surgery were identified as other study outcomes with the potential to impact patient satisfaction. The Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ) were administered to measure distress related to urinary symptoms and impact on quality of life, including activities, roles, and emotions, respectively.⁽¹⁸⁾ The UDI includes three symptom subscales: Irritative, Obstructive/Discomfort, and Stress. The IIQ measures impact of UI across four domains: Physical Activity, Travel, Social Relationships, and Emotional Health.

Complications encountered during the 24-month follow-up were also considered as potential predictors of patient satisfaction. Of particular interest were the need for surgical retreatment and voiding dysfunction. Voiding dysfunction was defined as time to resume normal voiding > 6-weeks, post-operatively.

Statistical Analysis

Data were pooled and satisfaction for all participants analyzed as one group. Potential predictors were explored in bivariate analyses to determine their relationship to patient satisfaction. Variables significantly related in bivariate analyses were entered into multivariable regression models to test their independent association with satisfaction. Treatment group (Burch vs. sling) and clinical site were entered into each model tested.

In the multivariable modeling, we included all variables that reached statistical significance ($p < 0.05$) in bivariate modeling. All subscales of the IIQ, UDI (stress UI, irritative and obstructive) and MESA (stress and urge UI) were also examined in the final model. Because the response variable (satisfaction) was missing information for many women, a sensitivity analysis was performed by fitting the final model assuming all women with missing information were satisfied and then assuming all these women were dissatisfied.

Results

A total of 655 women were randomized in the SISTER trial. Of these, 480 (73%) completed the patient satisfaction question at 24 months post surgery. Characteristics of this sample are shown in Table I. Most participants were white (77%) and had a mean ($\pm$ SD) age of 52 (± 10) years. Most (82%) were completely or mostly satisfied with the outcome of surgery related to urine leakage, while 18% were not. More subjects who received the fascial sling procedure than who received the Burch procedure (86.4% vs. 78.5%; $p=0.02$) were satisfied with the outcome of surgery.

Results of the bivariate analyses to examine associations between subject characteristics and satisfaction with treatment, controlling for treatment group and site, are presented in Table II. Higher odds of patient satisfaction with surgery was associated with higher baseline self-assessment of overall health, higher expectations of treatment success, the presence of urodynamic stress incontinence at baseline, and greater improvement on several outcome measures, including frequency of incontinence episodes, amount of urine loss, stress and urge incontinence symptoms, symptom distress (UDI), and quality of life impact of incontinence (IIQ) in several areas of life. Patient satisfaction with surgery was less likely with increased age, greater urge UI symptoms (MESA urge score) at baseline, presence of nocturia (at baseline and 24 months), urge incontinence (at baseline and 24 months), detrusor overactivity at 24 months, urodynamic stress incontinence at 24 months, positive stress test at 24 months, and surgical retreatment.

In the final multivariable model (Table III), patient satisfaction with treatment outcome was associated with greater reduction in symptom distress (total UDI score from baseline to 24 months) and greater reduction in stress UI symptoms (MESA stress score). Lower odds of satisfaction were associated with greater urge UI symptoms (MESA urge score) at baseline, detrusor overactivity at 24 months, and a positive stress test at 24 months (indicating surgical failure). Women who received the fascial sling procedure had slightly higher odds of satisfaction with treatment outcome than did women who received the Burch procedure, although it did not reach statistical significance ($p = 0.18$). This final model fits the data well (Hosmer-Lemeshow test for lack of fit not rejected, $p = 0.27$).

Because 166 women did not complete the form in which satisfaction was assessed, a sensitivity analysis was performed to ascertain how robust the findings were. When assuming all the women missing the satisfaction information were not satisfied, results were similar. The same was true when assuming all women were satisfied.

Discussion

Patient satisfaction is influenced by multiple factors and is regarded as essential to meaningful outcome assessment following surgical treatment of this quality-of-life disorder. This study demonstrated, not surprisingly, that patient satisfaction was associated with most of the outcome measures examined in bivariate analyses. The two post-operative factors independently associated with dissatisfaction in the multi-variable model were a positive stress test and the presence of detrusor overactivity.

Among the several baseline variables examined as potential predictors, only the presence of preoperative urge incontinence symptoms was associated with post-operative dissatisfaction. Interestingly, prior analysis of this cohort found that greater preoperative urge incontinence symptoms was a risk factor for treatment failure based on objective parameters.(11) The fact that both objective and subjective outcomes were impacted by the presence of preoperative urge symptoms strongly supports the concept that surgeons take such symptoms into account when counseling patients about SUI cure, as well as satisfaction.

Although older women had lower odds of being satisfied with treatment in bivariate analysis, age was not significant in the presence of the other variables in the multi-variable model. In addition, patient satisfaction appears to be unrelated to ethnicity, socioeconomic status, smoking, estrogen use, BMI, or diabetes. A previous analysis in the same cohort identified several baseline measures that were associated with higher risk of surgical failure by objective parameters. Both greater prolapse stage and postmenopausal status were associated with increased risk of SUI surgical failure, but neither parameter seemed to affect patient satisfaction.

It is reasonable to hypothesize that variables that impact quality of life post-operatively might also be associated with patient satisfaction. Based on a previous analyses in the same cohort, Tennstedt and colleagues reported that younger age and Hispanic ethnicity were associated with greater improvement in quality of life.(19) However, neither variable had an impact on satisfaction in the present analysis.

It is difficult to compare our results with those of other surgical trials or case series, because many reports do not sufficiently describe the satisfaction measures that were used. However, surgical investigators in other fields have examined factors believed to affect patient satisfaction with treatment. For example, Sorlie and colleagues developed the Patient Satisfaction-Results and Quality (PS-RESKVA), a 39-item instrument with four subscales that assesses quality of contact with the nursing staff, quality of contact with the medical staff, adequate treatment information and global satisfaction with treatment.(20) This instrument was originally validated in Norway using a population of 482 patients admitted for elective urologic, cardiac or gastrointestinal surgery. They found that age, sex, and disease severity did not significantly affect global satisfaction scores. Other investigators have used this measure to assess outcomes in burn injury patients an average of 3.6 years after treatment and reported differences among the subscales, with overall higher scores on quality of contact with the nursing staff.(21) Despite the differences in this clinical condition, this work suggests that multiple aspects of care can affect satisfaction beyond treatment outcome alone.

This multi-center trial did not investigate some characteristics known to affect patient satisfaction with SUI surgery, including patient preparedness and goal achievement. (4,22,23) These domains are likely to interact with other determinants such as quality of information and quality of nursing. Thus, a broader viewpoint of the determinants of satisfaction may be necessary. Two conceptual models have been proposed for health care outcomes studies. The Quality Health Outcomes Model proposes that the effect of treatment on outcome measures is mediated by both structural and patient characteristics.(24) Based on their initial work, investigators recommend that research teams operationalize outcome measures so that they can best assess a broad range of measures known to affect satisfaction. However, the findings from our study are more consistent with the conceptual framework of Kane(25), which states that clinical and patient characteristic factors exert an effect on outcomes and that treatments act to alter those same clinical factors and therefore the outcomes of care. Further, although this trial recruited a broad population of women planning SUI surgery, it is not known whether women who volunteer to participate in research are inherently more likely to express satisfaction with treatment than non-participants.

Conclusions

Clinical care dictates that surgeons offer treatment only to those women who are expected to benefit from an intervention with an acceptable risk-benefit ratio. We recommend that the findings from this study be used by surgeons to help set realistic patient expectations about their surgical outcomes. In addition, since many women who undergo SUI surgery also have some urge incontinence or other urge symptoms, it is important that these be investigated credibly and appropriate treatment offered. Further research will be needed to determine whether a proactive approach such as peri-operative treatment of urge incontinence could improve patient-reported outcomes of surgery for SUI.

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Appendix

APPENDIX:

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Table I

Demographic and Clinical Characteristics (n=480)

Covariates	Number	Percentage	Mean (SD)
Demographic characteristics			
Age (years)	480		52 (10)
SES (occupational score)	469		57.9 (24.3)
Ethnicity			
Hispanic	51	10.6	
Non-Hispanic white	370	77.1	
Non-Hispanic black	25	5.2	
Non-Hispanic other	34	7.1	
Baseline incontinence characteristics			
Stress UI symptoms (MESA stress score)	480		19.4 (4.5)
Urge UI symptoms (MESA urge score)	480		6.6 (3.9)
Pad Test (grams)	473		41.0 (71.1)
Prior treatment/surgery for incontinence	261	54.4	
Medical history and physical			
Self assessment of overall health (n = 479)			
Excellent	109	22.8	
Very good	182	38.0	
Good	131	27.3	
Fair/poor	57	11.9	
Smoking status			
Never smoker	267	55.6	
Former smoker	155	32.3	
Current smoker	58	12.1	
Current estrogen/HRT use (n = 479)			
Yes	165	34.4	
No	183	38.2	
Pre-menopausal	131	27.4	
Diabetes	29	6.0	
Body mass index (kg/m ²)	478		29.8 (6.0)
Stage of pelvic prolapse			
0/I	103	21.5	
II	297	61.9	
III/IV	80	16.7	
Patient expectations of treatment outcome	477		4.3 (0.6)
Urodynamic stress incontinence (USI) at baseline (n = 470)	425	90.4	
USI at 24 months (n = 449)	76	16.9	

Covariates	Number	Percentage	Mean (SD)
Nocturia at baseline (≥ 2 voids/night)	230	47.9	
Nocturia at 24 months (n = 446)	162	36.3	
Presence of urge incontinence at baseline	387	80.6	
Presence of urge incontinence at 24 months (n = 478)	145	30.3	
Voiding dysfunction (n = 477)	38	8.0	
Number of days to return to normal voiding	477		11.3 (24.0)
Detrusor overactivity at baseline (n = 473)	42	8.9	
Detrusor overactivity at 24 months (n = 450)	41	9.1	
Positive stress test at 24 months or failure *	90	18.8	
Surgical retreatment	21	4.4	
Outcomes between baseline and 24 months (Baseline scores - 24 month scores)			
Reduction in incontinence episodes/day (3-day diary)	443		2.8 (3.3)
Reduction in frequency of voids (3-day diary)	443		1.4 (7.4)
Change in grams of involuntary urine loss (24-hour pad test)	417		27.2 (77.3)
Change in stress UI symptoms (MESA stress score)	478		16.3 (6.4)
Change in urge UI symptoms (MESA urge score)	478		4.0 (4.2)
Change in quality of life (IIQ score)	479		135.8 (106.8)
Change in symptom distress (total UDI score)	478		111.3 (58.6)
Change in irritative symptom distress (UDI - irritative subscore)	479		31.2 (28.0)
Change in obstructive symptom distress (UDI-obstructive subscore)	479		17.8 (21.3)
Change in stress UI symptom distress (UDI - stress subscore)	478		62.2 (30.5)

* Women who did not yet have a positive stress test were considered in the “no” category.

Table II

Bivariate models for predictors of satisfaction with treatment outcome controlling for site and Burch/sling treatment group

Covariate	Odds Ratio (95% CI)	p-value
Demographic characteristics		
Age (years) *	0.69 (0.54, 0.89)	0.003
SES (occupational score) *	1.04 (0.94, 1.16)	0.41
Ethnicity		0.34
Hispanic	1.83 (0.52, 6.44)	
Non-Hispanic white	0.78 (0.30, 2.06)	
Non-Hispanic black	0.60 (0.15, 2.39)	
Non-Hispanic other	1 Reference	
Baseline clinical characteristics		
Stress UI symptoms (MESA stress score) *	0.89 (0.52, 1.53)	0.68
Urge UI symptoms (MESA urge score) *	0.32 (0.17, 0.61)	<0.001
Pad Test (grams) *	1.01 (0.97, 1.05)	0.63
Prior treatment surgery for incontinence		0.20
Yes	0.72 (0.43, 1.19)	
No	1 Reference	
Nocturia at baseline (2 voids/night)		0.015
Yes	0.54 (0.33, 0.89)	
No	1 Reference	
Presence of urge incontinence at baseline		0.002
Yes	0.25 (0.11, 0.61)	
No	1 Reference	
Medical history and physical		
Self assessment of overall health		0.020
Excellent	3.69 (1.54, 8.81)	
Very good	2.78 (1.30, 5.98)	
Good	1.95 (0.92, 4.16)	
Fair/poor	1 Reference	
Smoking status		0.30
Never smoker	1 Reference	
Former smoker	0.77 (0.46, 1.31)	
Current smoker	1.59 (0.62, 4.08)	
Current estrogen/HRT use		0.28
Yes	0.80 (0.42, 1.53)	
No	0.61 (0.32, 1.14)	
Pre-menopausal	1 Reference	

Covariate	Odds Ratio (95% CI)	p-value
Diabetes		0.14
Yes	0.52 (0.22, 1.23)	
No	1 Reference	
Body mass index (kg/m) *	0.93 (0.62, 1.40)	0.73
Stage of pelvic prolapse		0.81
0/I	1 Reference	
II	0.92 (0.50, 1.69)	
III/IV	0.77 (0.34, 1.72)	
Patient expectations of treatment outcome	1.61 (1.07, 2.42)	0.021
Detrusor overactivity at baseline		0.95
Yes	1.03 (0.44, 2.38)	
No	1 Reference	
USI at baseline		0.014
Yes	2.71 (1.23, 6.00)	
No	1 Reference	
Number of days to return to normal voiding *	1.01 (0.90, 1.12)	0.89
Outcomes at 24 months		
USI at 24 months		<0.001
Yes	0.25 (0.14, 0.47)	
No	1 Reference	
Nocturia at 24 months		<0.001
Yes	0.37 (0.22, 0.63)	
No	1 Reference	
Presence of urge incontinence at 24 months		< 0.001
Yes	0.13 (0.08, 0.22)	
No	1 Reference	
Normal voiding		0.88
Later than 6 weeks post-op	0.93 (0.37, 2.34)	
At discharge or at 6 weeks	1 Reference	
Detrusor overactivity at 24 months		0.016
Yes	0.40 (0.19, 0.84)	
No	1 Reference	
Positive stress test at 24 months		<0.001
Yes	0.18 (0.11, 0.32)	
No	1 Reference	
Surgical retreatment		<0.001
Yes	0.19 (0.07, 0.51)	
No	1 Reference	
Outcomes: Change from baseline to 24 months		

Covariate	Odds Ratio (95% CI)	p-value
(baseline-24 months)		
Reduction in incontinence episodes (diary)	1.32 (1.15, 1.50)	<0.001
Reduction in involuntary urine loss (pad test) in grams *	1.22 (1.10, 1.36)	<0.001
Reduction in frequency of voids (diary)	1.03 (1.00, 1.07)	0.07
Reduction in stress UI symptoms (MESA stress score)	1.21 (1.15, 1.27)	<0.001
Reduction in urge UI symptoms (MESA urge score)	1.17 (1.09, 1.24)	<0.001
Change in quality of life (IIQ total score) *	1.08 (1.05, 1.11)	<0.001
Reduction in quality of life-activity (IIQ activity subscore) *	1.25 (1.14, 1.37)	<0.001
Reduction in quality of life-emotional (IIQ emotional subscore) *	1.32 (1.19, 1.46)	<0.001
Reduction in quality of life-social (IIQ social subscore) *	1.29 (1.15, 1.44)	<0.001
Reduction in quality of life-travel (IIQ travel subscore) *	1.25 (1.14, 1.37)	<0.001
Reduction in symptom distress (UDI total score) *	1.23 (1.17, 1.30)	<0.001
Reduction in irritative symptom distress (UDI - irritative subscore) *	1.30 (1.18, 1.44)	<0.001
Reduction in obstructive symptom distress (UDI- obstructive subscore) *	1.29 (1.12, 1.49)	<0.001
Reduction in stress UI symptom distress (UDI - stress subscore) *	1.40 (1.28, 1.53)	<0.001

*
per 10 units

Table III

Final multivariable logistic regression model to predict the odds of satisfaction with treatment outcome (n=448)

Variable	OR (95% CI)	p-value
Treatment group		0.18
Sling	1.55 (0.81, 2.95)	
Burch	1 Reference	
Urge UI symptoms at baseline (per 10 units on MESA urge score)	0.09 (0.04, 0.22)	<0.001
Detrusor overactivity at 24 months		0.005
Yes	0.29 (0.12, 0.69)	
No	1 Reference	
Reduction in symptom distress (total UDI score) from baseline to 24 months (10 unit change)	1.16 (1.08, 1.24)	<0.001
Reduction in stress UI symptoms (MESA stress score) from baseline to 24 months (10 unit change)	1.17 (1.10, 1.24)	<0.001
Positive stress test at 24 months		0.027
Positive (Failure)	0.45 (0.22, 0.91)	
Negative (Success)	1 Reference	