Int Urogynecol J (2008) 19:1631–1638
DOI 10.1007/s00192-008-0700-1

ORIGINAL ARTICLE

Quality of life after surgery for stress incontinence

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Received: 19 March 2008 / Accepted: 19 July 2008 / Published online: 6 August 2008

Abstract This study investigated changes in condition-specific quality of life (QOL) after surgery for stress urinary incontinence. Data from 655 women in a clinical trial comparing the Burch and fascial sling were examined. Improvement in QOL, measured with the Incontinence Impact Questionnaire (mean decrease 133.1; SD 109.8), was observed 6 months after surgery and persisted at 24 months. Women for whom surgery was successful (regardless of surgery type) had greater improvement in QOL (mean decrease 160.0; SD 103.9) than did women for whom surgery was not successful (mean decrease 113.6; SD 110.9; $p<0.0001$), although not statistically significant after adjusting for covariates. Multivariable analysis showed that QOL improvement was related to decreased urinary incontinence (UI) symptom bother, greater improvement in UI severity, younger age, Hispanic ethnicity, and receiving Burch surgery. Among sexually active women, worsening sexual function had a negative impact on QOL. Improved QOL was explained most by UI symptom improvement.

Keywords Quality of life · Surgery · Urinary incontinence

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Introduction

Urinary incontinence (UI) is a common condition with a recognized negative impact on general as well as condition-specific quality of life (QOL) [1, 2]. Quality of life has become increasingly important in patient care and as an outcome of randomized clinical trials for urinary incontinence [3]. The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) was a multicenter randomized clinical trial which compared the efficacy of the Burch colposuspension and fascial sling procedures in women with stress predominant urinary incontinence 2 years after surgery [4]. The trial showed that the autologous fascial sling resulted in a higher success rate compared to the Burch colposuspension but had more postoperative problems such as voiding dysfunction, urge incontinence, and urinary tract infections. We previously reported that a diminished QOL in these women before surgery was related to a greater frequency of stress UI symptoms,

increasing severity, greater symptom bother, prior UI surgery or treatment, and sexual dysfunction (if sexually active). We also found that current tobacco use, younger age, lower socioeconomic status, and Hispanic ethnicity [5] were associated with lower-incontinence-related QOL. The purpose of this study was to measure changes in UI-specific QOL at 24 months after surgery and to determine which factors (sociodemographic, clinical, surgical) predicted improvements in QOL.

Materials and methods

Women planning stress urinary incontinence (SUI) surgery were invited to participate in the trial. Eligibility requirements included documented pure or predominant SUI symptoms for at least 3 months, a positive standardized urinary stress test, and unobstructed voiding. Women (n= 655) 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. Concomitant procedures were allowed. Data were collected by interview and clinical examination preoperatively, at 6 weeks postoperatively, and at 3, 6, 12, 18, and 24 months postoperatively. Details of the study methods and primary results have been published previously [4, 6].

Measures

Quality of life was measured with the Incontinence Impact Questionnaire (IIQ) [7]. The IIQ was developed to measure the impact of UI on various activities, roles, and emotional states. The possible range of scores is 0 to 400, with a higher score indicating greater impact or worse quality of life. Change in QOL after surgery was calculated as baseline IIQ score−24-month IIQ score. A higher IIQ change score indicates a greater improvement in QOL.

Treatment factors considered in the analyses were the randomized surgical procedure, i.e., Burch colposuspension or autologous fascial sling, and whether the participant achieved overall treatment success 24 months postoperatively. Overall treatment success was defined as no self-reported SUI symptoms, negative 24-h pad test (defined as less than 15 g), negative 3-day diary, negative cough and Valsalva stress test standardized at 300 ml, and no retreatment for SUI (including behavioral, pharmacologic, or surgical therapies). A woman was considered a treatment failure if she failed any one of the outcome criteria listed previously.

Based on results of a baseline analysis of factors related to quality of life [5], five groups of other predictive factors were also considered. *Sociodemographic characteristics* included age, race–ethnicity, and occupational score using the Nam–Powers–Boyd Occupational Status Score [8]. The Nam–Powers score ranks occupations based on educational requirements and expected salary on a scale from 0 to 100, where a higher score indicates greater status. We used it as a proxy measure for socioeconomic status. *Health status and history* included the following baseline measures: body mass index, stage of pelvic prolapse (0–I, II, III–IV) [9], and smoking status (never, former, current). *Preoperative UI severity* was measured by quantity of urine leakage in grams on a 24-h pad test [10] at baseline and prior UI surgery (yes–no). *Postoperative change in UI symptoms* was measured by change from baseline to 24 months in self-reported frequency of stress and urge incontinence symptoms, measured by the Medical Epidemiologic and Social Aspects of Aging questionnaire [11]. Larger reductions in scores for the latter symptom indicate greater improvement in UI symptoms. *Postoperative voiding status* was categorized as no difficulty or voiding dysfunction, defined as either the need for surgical revision to improve voiding postoperatively as determined by the treatment physician or the need for catheterization due to voiding difficulties at any time after 6 weeks following surgery. *Postoperative change in UI symptom bother* from baseline to 24 months was measured by the Urogenital Distress Inventory [7]. For each symptom experienced, bother is rated on a scale from 0="not at all bothersome" to 3="greatly bothersome." Bother was computed as the average of the bother of the symptoms experienced; the total score ranged from 0 to 300. Larger reductions in scores indicate less symptom bother (improvement). *Postoperative change in sexual function* from baseline to 24 months was measured with the short form of the Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) [12]. The possible range of scores is 4 to 48, with a higher score indicating better sexual function. In this analysis, a negative change score indicates improved sexual function.

In preliminary analysis, we considered several other factors that might affect postoperative QOL, including: severity of the worst adverse event related to surgery, number of urinary tract infections experienced from baseline to the 24 month follow-up visit, any type of concomitant surgery, anal incontinence, hormone replacement therapy–menopausal status, Valsalva leak point pressure, and duration of incontinence prior to treatment. These factors were not statistically significant in preliminary analyses and therefore were not included in the final multivariable model.

Analysis

The primary interest of this analysis is change in QOL (IIQ) between the preoperative assessment at baseline and the

24-month assessment. QOL data were not available at 24 months for women who had surgical retreatment prior to 24 months (n=14) or otherwise did not provide 24-month data (n=166) because of a missed visit or not completing the QOL measure. Women with missing QOL data were not significantly different than those with complete data on important factors, including treatment outcome. We also determined that IIQ scores did not change appreciably between 6 and 24 months after surgery. Therefore, we decided that data from the last completed visit or the last visit before surgical retreatment could be used as surrogate information when the 24-month measure was missing. This resulted in an analytical sample of 609 women, excluding 46 women with no available surrogate information from a prior visit. Sensitivity analysis was performed to compare the results of the multivariable analysis described below on the 609 women with the 475 women having 24-month information.

First, we described the change in QOL from baseline to 24 months for all women. Then, we used linear regression to determine differences by surgical procedure (Burch, sling) and differences by treatment outcome (success, failure). Next, we used multivariable modeling to determine if improvement in QOL was moderated by factors related to QOL. Specifically, we used linear least-squares regression analysis with the change in IIQ score as the dependent variable, entering the explanatory variables in the following temporally ordered groups or stages: (1) treatment factors; (2) sociodemographic factors, (3) health status and history factors, (4) UI symptoms (preoperative and postoperative changes), and (5) change in UI symptom bother. We tested if each successive group of variables added information to explain the postoperative change in QOL by using likelihood ratio tests. The amount (percentage) of variability in the change in QOL (IIQ score) from baseline to 24 months that is explained by all of the variables in the model is indicated by the value of R^2.The sample for the multivariable model consisted of the 476 women with complete information for all covariates considered.

Next, to investigate whether sexual function added information to explain postoperative change in QOL, we recomputed the final regression main effects model described above, adding the measure of sexual function (PISQ-12). The sample for this analysis consisted of the 255 women who were sexually active both preoperatively and at 24 months and who had complete data.

The outcome in these models is the change in IIQ score from baseline to 24 months. Larger increases in score (positive regression coefficients) indicate increased improvement in QOL at 24 months compared with baseline, whereas negative coefficients represent decreased (less) improvement in QOL. With the exception of the PISQ, larger reductions in scores of other measures (e.g., for stress UI symptoms, urge UI symptoms, symptom bother) from baseline to 24 months indicate greater improvement. Standardized slope coefficients ("standardized b") are reported so that the relative importance of the explanatory variables can be assessed; the relative size of the coefficients indicates how much of the variability in change in QOL from baseline is explained by that factor in relation to the other factors in the model. All analyses were computed using SAS statistical software (SAS Institute, Inc. Cary, NC, USA).

Results

Sample

The 655 women in the SISTEr study were predominantly white, middle-age (average 52 years), and socioeconomically diverse (Table 1). Over half reported prior treatment for UI, reported any anal incontinence, and demonstrated some degree of pelvic organ prolapse. The mean and median body mass index was 30, indicating that the sample was generally overweight. Characteristics of the 476 women included in these analyses were similar to that of the full sample of 655 women (data not shown).

Postoperative change in quality of life

Overall, QOL improved at 24 months compared with baseline, as indicated by a reduction of 133.1 (SD 109.8) points in the IIQ score (shown graphically in Fig. 1). The largest improvement in QOL occurred between the preoperative assessment and the 6-month postoperative visit, with little change between 6 and 24 months. This pattern is the same for both surgical groups. In a simple model not controlling for other factors, this improvement was similar (p=0.52) for women who received the Burch procedure (mean decrease 136.1; SD 112.1) and women who received the sling procedure (mean decrease 130.3; SD 107.7). However, after adjusting for covariates (Table 2), the improvement in QOL was significantly greater for those receiving the Burch procedure compared to the sling procedure (p=0.033). Among those women who achieved surgical success as defined for this trial, improvement in QOL (mean decrease 160.0; SD 103.9) at 24 months was significantly greater compared to women who did not achieve success (mean decrease 113.6; SD 110.9; $p<$ 0.0001), but this difference did not remain after controlling for additional variables (Table 2).

The results of the multivariable models are presented for all women in Table 2 and for sexually active women in Table 3. Each successive group of variables entered into the model explains significantly more of the change in IIQ

Table 1 Demographic and clinical characteristics of women (n=655)

Covariates		Number	Percentage	Mean (SD)
Treatment factors				
Surgical group	Burch	329	50.2	
	Sling	326	49.8	
Overall treatment outcome	Success	185	35.6	
	Failure	335	64.4	
Sociodemographic				
Age (years)		655		51.89 (10.29)
SES		641		56.88 (24.57)
Ethnicity	Hispanic	72	11.0	
	Non-Hispanic white	480	73.4	
	Non-Hispanic black	44	6.7	
	Non-Hispanic other	58	8.9	
Health status and history				
Body mass index (kg/m^2)		650		30.01 (6.13)
Stage of pelvic prolapse	0–1	162	24.7	
	II	387	59.1	
	III–IV	106	16.2	
Any anal incontinence	Yes	331	50.5	
	No	324	49.5	
Smoking status	Never	355	54.2	
	Former	207	31.6	
	Current	93	14.2	
Preop UI severity				
Quantity of urine leakage: 24-h pad test (baseline)		645		43.53 (79.40)
Prior UI treatment–surgery	Yes	338	51.6	
	No	317	48.4	
Postop change in UI symptoms				
Stress UI symptoms[a]		595		16.23 (6.48)
Urge UI symptoms[a]		595		3.93 (4.26)
Postop UI symptom bother				
Change in UDI[a]		607		111.36 (60.89)
Postop sexual function				
Change[a] in sexual function (PISQ) of those sexually active		367		−4.56 (6.35)

[a] Change scores calculated as baseline score−24-month score

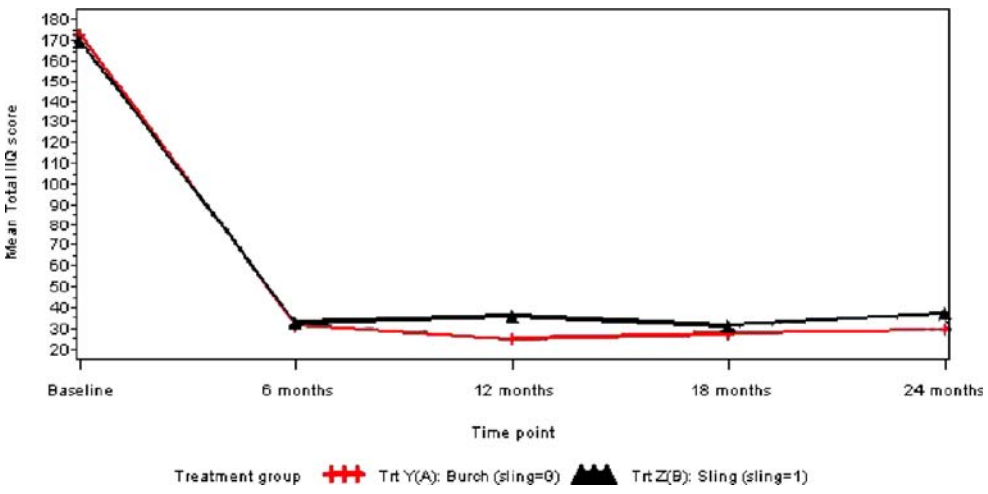

Fig. 1 Mean total IIQ scores vs time by treatment arm

Table 2 Factors related to the change in quality of life between baseline and 24 months in women with SUI (n=476 with complete information on all variables included)

Covariates		Standardized b[a]	p value
Treatment factors			
Surgical group	Burch	0.072	0.033
	Sling	Reference group	
Treatment outcome	Success	0.042	0.24
	Failure	Reference group	
Sociodemographic			
Age (years)		−0.095	0.006
SES		−0.040	0.26
Ethnicity	Hispanic	0.094	0.007
	Non-Hispanic black	−0.040	
	Non-Hispanic other	−0.040	
	Non-Hispanic white	Reference group	
Health status and history			
BMI (kg/m^2)		0.052	0.13
Stage of prolapse	0–I	0.047	0.26
	II	−0.010	
	III–IV	Reference group	
Anal incontinence	Yes	0.050	0.14
	No	Reference group	
Smoking status	Never smoker	−0.106	0.09
	Former smoker	−0.048	
	Current smoker	Reference group	
Preop UI severity			
Quantity of leakage (baseline pad weight)		0.117	<0.001
Prior UI treatment–surgery	Yes	0.103	0.002
	No	Reference group	
Postop change in UI symptoms			
Stress UI symptoms[b]		0.153	<0.001
Urge UI symptoms[b]		0.129	0.003
Postop voiding status			
No difficulty		0.076	0.024
Voiding dysfunction		Reference group	
Postop UI symptom bother			
Change in UDI[b]		0.415	<0.001
		R^2=0.53	

[a] Positive coefficients indicate larger changes (improvement) in QoL

[b] Change scores calculated as baseline score−24-month score

score (p<0.0001 for each likelihood ratio test). In Table 2, over half (53%) of the change in IIQ scores is explained by surgical group, age, ethnicity, smoking status, measures of UI severity, postoperative voiding status, and postoperative change in UI symptom bother. Reduction in bother of UI symptoms had the greatest effect on improving QOL after surgery, followed by reduction in stress and urge UI symptoms. Greater preoperative UI severity, as measured by prior UI treatment or surgery and greater pad weights, was related to greater postoperative improvement in QOL. As age increased, there was less improvement in QOL. In comparison to non-Hispanic white women, Hispanic women had the largest improvement in QOL, whereas women who were non-Hispanic black or another race reported the least improvement in QOL after surgery. Finally, women who experienced postoperative voiding dysfunction had less improvement in QOL after surgery than did women with no voiding problems.

To further understand the larger impact of the Burch procedure compared to the fascial sling in explaining QOL improvement, we used models to predict change in IIQ score controlling for Burch–sling and just one other variable at a time. Not controlling for any variables, the model predicts an average improvement in QOL of 136 points for women in the Burch group and 130 points for women in the sling group—only a six-point difference between the two treatment groups. However, when controlling for differences in stress UI symptoms, the model now predicts an average improvement in QOL of 141 points for women in the Burch group and 121 points for women in the sling group—a 20-point difference (p=0.022). Thus, controlling for change in stress UI score in the model

Table 3 Factors related to the change in quality of life between baseline and 24 months among sexually active women with SUI (n=255 with complete information on all variables included)

Covariates		Standardized b[a]	p value
Treatment factors			
Surgical group	Burch	0.089	0.054
	Sling	Reference group	
Treatment outcome	Success	0.023	0.62
	Failure	Reference group	
Sociodemographic			
Age (years)		−0.007	0.89
SES (occupational class)		−0.098	0.037
Ethnicity	Hispanic	0.118	0.021
	Non-Hispanic black	−0.028	
	Non-Hispanic other	−0.055	
	Non-Hispanic white	Reference group	
Health status and history			
BMI (kg/m^2)		0.003	0.95
Stage of prolapse	0–1	0.063	0.60
	II	0.054	
	III–IV	Reference group	
Anal incontinence	Yes	0.069	0.13
	No	Reference group	
Smoking status	Never	−0.053	0.78
	Former	−0.034	
	Current	Reference group	
Preop UI severity			
Quantity of leakage (baseline pad weight)		0.089	0.054
Prior UI treatment–surgery	Yes	0.104	0.020
	No	Reference group	
Postop change in UI symptoms			
Stress UI symptoms[b]		0.114	0.050
Urge UI symptoms[b]		0.089	0.130
Postop voiding status			
No difficulty		0.117	0.010
Voiding dysfunction		Reference group	
Postop UI symptom bother			
Change in UDI[b]		0.402	<0.001
Postop sexual function			
Change[b] in PISQ (of those sexually active)		−0.182	<0.001
		R^2=0.58	

[a] Positive coefficients indicate larger changes (improvement) in QoL

[b] Change scores calculated as baseline score−24-month score

accentuates the improvement in QOL for women in the Burch group compared with women in the sling group. The model presented in Table 2 where many variables are controlled for reaches a similar conclusion, that is, a 133-point improvement in the Burch group compared with a 117-point improvement in the sling group—a 16-point difference.

We also investigated change in the IIQ subscale scores by treatment group. In models predicting differences in each IIQ subscale score, there was greater improvement in the travel subscale score (standardized beta=0.126, $p<$ 0.001) and modest but not significant improvement in the emotional (standardized beta=0.065, p=0.070) and social (standardized beta=0.062, p=0.086) subscales for women in the Burch group compared with women in the sling group.

Among women who are sexually active (Table 3), improvement in UI symptom bother had the greatest impact on improving QOL. Worsening of sexual function after surgery was associated with less improvement in QOL. As for the full sample, when controlling for all other factors in the model, sexually active women who were Hispanic and had no voiding problems after surgery, had decrease in stress UI symptoms, had prior UI treatment–surgery, and were of lower socioeconomic status reported more improvement in QOL. However, the effects of age and change in urge UI symptoms were not statistically significant in this model. Having the Burch procedure and preoperative

pad test weight were both marginally significant (p=0.054) in this model.

Sensitivity analyses comparing the results of the models in Tables 2 and 3 to models including only women with complete 24-month information revealed that results were comparable. While the regression coefficients in the final models changed slightly, the significance of nearly all variables remained consistent.

Discussion

The SISTEr Trial is the only randomized controlled clinical trial which has compared the Burch colposuspension and the fascial sling procedures and provides a unique opportunity to evaluate which surgical, demographic, or clinical factors affect postoperative QOL. The major findings of our study were as follows: (1) the greatest improvement in QOL occurred during the first 6 months following surgery, and this improvement was maintained for 24 months; (2) improvement in QOL was related most strongly to decreases in UI symptom bother and in UI symptoms; and (3) the Burch procedure was associated with greater improvement in QOL. Similar conclusions were reached when we limited our study to women who were sexually active.

The Burch procedure was associated with greater improvement in QOL than was the fascial sling procedure after controlling for other variables, although this effect was less pronounced than the effect of the clinical incontinence factors. We previously reported that the fascial sling had greater surgical success as compared to the Burch urethropexy and that women who received the sling were more satisfied with the treatment outcome than women who received the Burch [4]. Although the fascial sling had a higher rate of treatment success, this sling procedure also had higher rates of urinary tract infections, difficult voiding, and postoperative urge incontinence. Perhaps this higher rate of voiding difficulty mitigated the higher rate of treatment success in a quality of life outcome assessment. That is, from the patient's perspective, being more dry is not the only factor that has an effect on UI-related quality of life. The change in the IIQ subscale scores suggests that the voiding difficulties following the sling procedure could interfere with travel and also contribute to patient perception that the incontinence problem is not fixed, thereby having an effect on emotional status.

However, improvement in UI symptoms is clearly the most important factor related to improvement in postoperative QOL compared to QOL before surgery. When all of the factors thought to affect postoperative QOL were considered together in a multivariable model, change in UI symptoms and associated bother were more important than the type of surgery and success of the surgery in explaining improvement in QOL. The definition of surgical success in this trial was conservative. Women could have experienced substantial and clinically meaningful improvement in incontinence episodes and symptom bother and still be defined as a surgical failure. Symptoms, symptom bother, and quality of life share the similarity of being patient perceptions as distinguished from objective outcomes such as leakage observed by stress test or pad test. The fact that symptom improvement is more important than objective measures of treatment success in affecting quality of life should be reassuring to most clinicians——if we improve patients' complaints, we will improve their QOL. This finding also underscores the importance of measuring patient-reported outcomes in clinical studies.

The SISTEr study has several strengths. This is one of the largest randomized controlled clinical trials investigating two traditional surgical procedures for stress urinary incontinence surgery. The SISTEr study population is ethnically and socioeconomically diverse. Multiple clinical and demographic factors were measured allowing for exploration of complex contributions to QOL. While 24-month outcomes are reported here, a wide variety of measurements including quality of life are continuing to be obtained from these women, allowing for long-term evaluation of the impact of these surgical procedures.

Subjects in the SISTEr trial were recruited from tertiary referral centers, and this may limit the generalizability of these findings. On a cautionary note, our findings cannot be generalized to the synthetic midurethral slings which may have different success rates and complications than the fascial sling. A limitation of the study is the high rate of concomitant prolapse repairs. Fifty-one percent of the study participants had a concomitant prolapse repair at the time of their incontinence procedure. While this was not considered to be a factor when comparing the success rates between the Burch and sling [5], concomitant prolapse surgery may be a factor when comparing postoperative changes in QOL. It is likely that successful prolapse surgery, like successful incontinence surgery, results in improved quality of life. We did not design this study to look at the impact of the concomitant prolapse surgery on the overall QOL.

In summary, we found that improvements in quality of life after stress incontinence surgery are significant and durable over 24 months. We also found that these improvements in quality of life are most associated with factors that the surgery is designed to improve, namely improving incontinence symptoms and symptom bother.

Acknowledgements This work was supported by cooperative agreements from the National Institute of Diabetes and Digestive and Kidney Diseases with additional support from the National Institute of Child Health and Human Development and the Office of Research on Women's Health, National Institutes of Health.

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Conflicts of interest None.

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