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IMPROVEMENT IN QUALITY OF LIFE IN WOMEN AT TWO YEARS AFTER UNDERGOING THE BURCH COLPOSUSPENSION OR FASCIAL SLING PROCEDURE

Aims of Study:
Surgery, a common treatment for stress urinary incontinence (SUI), is expected both to relieve UI symptoms and improve health-related quality of life (HRQOL). This study investigated changes in incontinence-related quality of life (QOL) in 655 women in a clinical trial comparing the Burch and fascial sling for stress urinary incontinence (SUI). **Study Design, Material and Methods**: Data from 655 women (mean age 51.9 yrs, sd 10.3yrs) enrolled in a randomized clinical trial to compare the Burch retropubic urethropexy and autologous rectus fascial sling procedures were examined. HRQOL was measured with the Incontinence Impact Questionnaire (IIQ), a condition-specific measure of HRQOL that assesses the impact of UI on activities, roles, and emotional states. 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. First, we determined 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 (surgery type, surgical outcome), 2) sociodemographic factors (age, ethnicity, socioeconomic status), 3) health status and history factors (BMI, fecal incontinence, current smoking, stage of prolapse), 4) pre-operative UI severity (pad test weight, previous UI treatment), 5) post-operative change in stress UI and urge UI symptoms, 6) post-operative voiding status (no difficulty, voiding dysfunction [surgical revision, catheter use > 6wks post-op]) and 7) post-operative change in UI symptom bother (UDI). We tested if each successive group of variables added information to explain the post-operative 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 post-operative change in QOL, we recomputed the final regression main effects model described above, adding a measure of post-operative change in sexual function (PISQ-12). The sample for this analysis consisted of the 255 women who were sexually active both pre-operatively and at 24 months and who had complete data.

Results
Overall, the greatest improvement in QOL occurred within 6 months after surgery and was maintained through 24 months as indicated by a reduction of 133.1 (sd 109.8) points in the IIQ score. 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 other factors, the improvement in QOL was significantly greater for those receiving the Burch procedure compared to the sling procedure (p=0.033) (Table 1). 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 factors (Table 1). 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 post-operative 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 no post-operative voiding dysfunction had more improvement in QOL after surgery than did women with voiding problems. Results were similar in the model (not shown) focused on women who are sexually active. 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.

Table 1. Factors related to the change in quality of life between baseline and 24 months in women with SUI

Covariates	Standardized b*	p-value
Treatment Factors		
Surgical group: Burch (Ref: Sling)	0.072	0.033
Treatment Outcome: Success (Ref: Failure)	0.042	0.24
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	
(Ref: Non-Hispanic white)		
Health status and history		
BMI (kg/m^2)	0.052	0.13

Stage of prolapse: 0/1 (Ref: III/IV)	0.047	0.26
II (Ref: III/IV)	-0.010	
Anal incontinence: Yes	0.050	0.14
Smoking status: Never smoker (Ref: Current)	-0.106	0.09
Former smoker (Ref: Current)	-0.048	
Pre-op UI severity		
Quantity of leakage: baseline pad weight	0.117	<0.001
Prior UI treatment/surgery: Yes (Ref: No)	0.103	0.002
Post-op change in UI symptoms		
Stress UI symptoms**	0.153	<0.001
Urge UI symptoms**	0.129	0.003
Post-op voiding status		0.024
No difficulty (Ref: Voiding dysfunction)	0.076	
Post-op UI symptom bother		
Change in UDI**	0.415	<0.001
	R^2 = 0.53	

* Positive coefficients indicate larger changes (improvement) in QoL. For categorical variables, coefficients are compared with the reference group (listed in parentheses).
** Change scores calculated as baseline score – 24-month score

Interpretation of results

Following surgery for stress UI, improvement in QOL was related most strongly to decreases in UI symptom bother and in UI symptoms. When all of the factors thought to affect post-operative 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 (as defined in this trial) in explaining improvement in QOL.

Concluding message

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. This 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.

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Is this study registered in a public clinical trials registry?	**Yes**
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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**