

OUTCOMES AND COMPLICATIONS OF BURCH, FASCIAL, AND MIDURETHRAL SLINGS

Hypothesis / aims of study

The primary aims of this study are to report differences in 24-month outcomes, satisfaction, quality of life, and complications after midurethral slings and traditional, more invasive continence procedures (Burch and rectus fascial sling).

Study design, materials and methods

This is a planned ancillary analysis of two large multicentre comparative effectiveness trials comparing (1) rectus fascial sling and Burch colposuspension and (2) retropubic and transobturator midurethral sling (MUS) procedures for stress predominant urinary incontinence (SUI). Participants in both trials were recruited from 9 clinical sites across the United States and all were consented for surgical treatment of SUI. Inclusion and exclusion for the two populations differed slightly; however, similar data and outcomes were collected in both trials. Combining data from the two samples, we computed a propensity score analysis to aid in controlling for bias between the samples selected for the two studies. When the propensity quintile was controlled, associations of baseline covariates and study all became statistically non-significant indicating that the propensity score removed the bias between the samples in the measures studied. Propensity stratum was used in all analyses to control for differences in the study populations. We grouped retropubic and transobturator MUS in a single group the procedures were not found to be significantly different in primary trial.

Results

Participant age (52±10 vs 53±11) did not differ in the two trials. Participants in trial (1), Burch vs fascial sling, were more likely to have stage III/IV prolapse (16% vs 8%) and higher UDI (151±49 vs 135±46) and IIQ (171±101 vs 152±97) scores than those in trial (2) of MUS; although, these differences were not significant after controlling for propensity score.

Overall treatment failure was defined by objective criteria (positive stress test or positive pad test or retreatment) and subjective criteria (self-reported UI symptoms or leakage episodes recorded on diary or retreatment). The table below shows the frequency and percentage of overall treatment failure, each component of failure, satisfaction, and QOL by incontinence procedure. There was a significant difference in overall failure at 24 months amongst the 3 types of surgery (p=0.007). Overall failure rate between fascial and MUS was not different; however, overall failure after Burch was greater than after MUS (OR 1.69, 95% CI 1.20-2.36). When compared to women with MUS, the fascial sling cohort had similar rates of retreatment (OR=0.58, 95% CI 0.28-1.21) and MESA symptom scores (OR=0.49, 95% CI 0.62-1.20), however, they were less likely to fail by positive stress test (OR=0.49, 95% CI 0.32-0.76). Compared to the MUS group, women after the Burch procedure were more likely to seek retreatment for SUI (OR=1.81, 95% CI 1.03-3.18) and report UI symptoms (OR=1.40, 95% CI 1.02-1.92) but did not differ on the rate of positive stress test. Satisfaction and UDI scores did not differ amongst the 3 groups, but IIQ scores improved more after fascial sling than MUS (mean difference -12.4, 95% CI 3.0, 21.8).

Outcome Measure N(%) OR (95% CI)	Midurethral Slings N=498	Fascial Slings N=284	Burch N=274	P Value
Overall Failure	304 (57.6%) 1.00	156 (58.9%) 1.07 (0.77, 1.48)	179 (70.2%) 1.69 (1.20, 2.36)	0.007
Surgical Retreatment	29 (5.8%) 1.00	12 (4.2%) 0.58 (0.28, 1.21)	33 (12.0%) 1.81 (1.03, 3.18)	0.004
Pad Test	55 (11.1%) 1.00	36 (12.6%) 1.23 (0.75, 2.04)	38 (13.9%) 1.42 (0.88, 2.29)	0.35
Stress Test	128 (25.4%) 1.00	35 (12.3%) 0.49 (0.32, 0.76)	73 (26.3%) 1.19 (0.83, 1.71)	0.0004
Voiding Diary	240 (46.1%) 1.00	118 (41.0%) 0.85 (0.62, 1.17)	122 (43.9%) 0.93 (0.68, 1.27)	0.62
MESA Stress Symptoms	195 (38.1%) 1.00	101 (34.8%) 0.86 (0.62, 1.20)	129 (45.9%) 1.40 (1.02, 1.92)	0.02
Satisfaction	163 (35.3%) 1.00	83 (33.3%) 1.04 (0.73, 1.49)	73 (30.4%) 0.88 (0.62, 1.26)	0.67
UDI Mean (SD) Adjusted Mean Difference (95% CI)	30.6 (37.6) 0.0	37.4 (45.7) 5.0 (-0.8, 12.6)	38.1 (41.8) 6.4 (-0.2, 13.0)	0.10
IIQ Mean (SD) Adjusted Mean Difference (95% CI)	23.0 (50.4) 0.0	38.1 (72.5) 12.4 (3.0, 21.8)	30.1 (56.5) 3.4 (-5.4, 12.7)	0.03

When models were repeated including concomitant surgery, concomitant surgery was not associated with any outcomes nor did controlling for surgery change the associations of treatment group with outcomes.

Total percentage of SAE and AE did not differ significantly amongst the 4 treatment groups.

The Table below displays the number of unique patients with genitourinary complications by procedure.

	Burch	Fascial Sling	Retropubic MUS	Transobturator MUS
Serious adverse event	32	44	46	26
Adverse event	156	206	120	97
Cystotomy/bladder perforation	10	2	15	0
Voiding dysfunction requiring catheter or surgery	0	21	9	0
Cystitis	202	299	43	25

Interpretation of resulty

Two years after surgery, women with predominant SUI report similar satisfaction and symptom bother after Burch, fascial sling, and MUS. However, women undergoing Burch were more likely to meet our composite definition of treatment failure and were more likely to undergo retreatment for SUI. Although individual complications differed by procedure, overall complication rates were similar.

Concluding message

Continence outcomes 2 years after sling procedures (fascial or synthetic, midurethral) are similar and superior to those of Burch colposuspension with significantly fewer women seeking retreatment for SUI. The frequency and type of complications did not differ by continence procedure.

Disclosures

Funding: NIH NIDDK Urinary Incontinence Treatment Network **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Boards at clinical sites - Loyola, Maryland, Alabama, Utah, San Diego, Beaumont, San Antonio, Pittsburgh, Texas-Southwestern **Helsinki:** Yes **Informed Consent:** Yes