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URODYNAMIC CHANGES 12 MONTHS AFTER RETROPUBIC AND TRANSOBTURATOR MIDURETHRAL SLINGS

Hypothesis / aims of study

To determine if changes in urodynamics (UDS) parameters after midurethral sling (MUS) differ between retropubic midurethral sling (RMUS) and transobturator midurethral sling (TMUS) procedures and whether they are associated with successful treatment outcomes.

Study design, materials and methods

The Trial of Midurethral slings (TOMUS)[1] was a prospective randomized equivalence trial conducted at 9 sites, comparing 12 month subjective and objective outcomes of RMUS and TMUS. 597 women were randomized to RMUS or TMUS and underwent standardized UDS[2] before and 12 months after surgery. UDS parameters are listed in table. Objective success included: negative 300 cc bladder stress test, negative 24 hour pad test and no stress urinary incontinence (SUI) retreatment. Subjective success included: no self report of SUI, no leaks on a 3 day voiding diary and no retreatment of SUI. Linear models were fit to assess change in UDS measures from baseline to 12 months by treatment group and success status. Contingency tables were constructed for categorical measures; chi-square tests were used to test for associations.

Results

Table: Comparison of changes in NIF, CMG, UPP & PFS after surgery by TMUS/RMUS arm

	TMUS					RMUS					Inter-action p-value*
	N	Pre	Post	Diff: Post–Pre	P	N	Pre	Post	Diff: Post–Pre	P	
NIF Qmax	226	25 (12)	20 (9)	-5 (14)	<0.001	212	25 (13)	20 (9)	-5 (12)	<0.001	0.88
Time to Qmax	226	14 (17)	13 (14)	-1 (18)	0.65	211	13 (15)	14 (21)	1 (23)	0.52	0.42
Void Volume	226	313 (138)	307 (108)	-6 (161)	0.56	214	311 (134)	313 (105)	2 (151)	0.82	0.57
PVR	197	21 (31)	25 (40)	3 (50)	0.34	186	23 (34)	33 (47)	10 (52)	0.009	0.21
1st sense	247	119 (83)	141 (85)	22 (102)	<0.001	247	115 (82)	142 (98)	27 (106)	<0.001	0.58
MCC	250	358 (121)	348 (110)	-10 (113)	0.16	249	349 (125)	357 (112)	9 (114)	0.24	0.07
MUCP	204	68 (31)	63 (31)	-6 (34)	0.02	211	67 (34)	60 (29)	-6 (32)	0.005	0.82
FUL	204	32 (8)	31 (7)	-1 (10)	0.33	211	31 (8)	31 (8)	0 (10)	0.85	0.41
Qmax	222	22 (11)	20 (9)	-2 (11)	0.005	226	22 (11)	19 (9)	-3 (11)	<0.001	0.28
Pdet@Qmax	137	18 (12)	21 (13)	3 (13)	0.01	124	18 (11)	23 (12)	5 (11)	<0.001	0.19

*The interaction test statistic tests the hypothesis that the difference between pre and post UDS data is the same in the RMUS and TMUS treatment arms.

No differences in UDS parameters between procedures were seen and no changes in UDS parameters correlated highly with either subjective or objective outcomes. Rates of denovo detrusor overactivity (DO) was similar between both procedures (p=.61) and no difference was seen in the rates of resolution of DO (p=.94).

Interpretation of results

After MUS, both maximum (Qmax) and average uroflow rates were decreased on noninvasive uroflow (NIF), sensations were delayed and maximum urethral closure pressure (MUCP) decreased with no change in urethral length, Qmax was deceased while Pdet@Qmax slightly increased. No differences in UDS parameters were seen between RMUS and TMUS procedures. No changes in UDS parameters correlated highly with either subjective or objective success.

Concluding message

MUS procedures were associated with decreased flow rates and minimal increases in voiding pressures contrary to what has been reported after fascial sling procedures[3] supporting the concept that these procedures are not obstructive. Interestingly, no changes in urethral closure pressures were seen. Changes in UDS parameters did not differ by treatment group and were not associated with MUS subjective or objective outcomes suggesting that cystometry and pressure flow analysis do not adequately assess the mechanism by which these procedures work.

References

1. Richter et al, N Engl J Med 2010;362:2066-76.
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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**NIDDK Data Safety Monitoring Board, IRB Approval obtained from all academic institutions where this trial took place**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**