Baseline Urodynamic Predictors of Treatment Failure 1 Year After Mid Urethral Sling Surgery

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Purpose: We determined whether baseline urodynamic study variables predict failure after mid urethral sling surgery.

Materials and Methods: Preoperative urodynamic study variables and postoperative continence status were analyzed in women participating in a randomized trial comparing retropubic to transobturator mid urethral sling. Objective failure was defined by positive standardized stress test, 15 ml or greater on 24-hour pad test, or re-treatment for stress urinary incontinence. Subjective failure criteria were self-reported stress symptoms, leakage on 3-day diary or re-treatment for stress urinary incontinence. Logistic regression was used to assess associations between covariates and failure controlling for treatment group and clinical variables. Receiver operator curves were constructed for relationships between objective failure and measures of urethral function.

Abbreviations and Acronyms

DO = detrusor overactivity
FUL = functional urethral length
MCC = maximum cystometric capacity
MUCP = maximum urethral closure pressure
MUS = mid urethral sling
NIF = noninstrumented uroflowmetry
Pabd = abdominal pressure
Pdet = detrusor pressure
PFS = pressure flow study
Pves = vesical pressure
PVR = post-void residual urine
Qmax = maximum flow
ROC = receiver operator curve
SUI = stress urinary incontinence
TOMUS = Trial of Mid Urethral Sling
USI = urodynamic stress incontinence
VLPP = Valsalva leak point pressure

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Results: Objective continence outcomes were available at 12 months for 565 of 597 (95%) women. Treatment failed in 260 women (245 by subjective criteria, 124 by objective criteria). No urodynamic variable was significantly associated with subjective failure on multivariate analysis. Valsalva leak point pressure, maximum urethral closure pressure and urodynamic stress incontinence were the only urodynamic variables consistently associated with objective failure on multivariate analysis. No specific cut point was determined for predicting failure for Valsalva leak point pressure or maximum urethral closure pressure by ROC. The lowest quartile (Valsalva leak point pressure less than 86 cm H_2O, maximum urethral closure pressure less than 45 cm H_2O) conferred an almost 2-fold increased odds of objective failure regardless of sling route (OR 2.23, 1.20–4.14 for Valsalva leak point pressure and OR 1.88, 1.04–3.41 for maximum urethral closure pressure).

Conclusions: Women with a Valsalva leak point pressure or maximum urethral closure pressure in the lowest quartile are nearly 2-fold more likely to experience stress urinary incontinence 1 year after transobturator or retropubic mid urethral sling.

Key Words: urinary incontinence, stress; urodynamics; surgical procedures, operative

URODYNAMIC testing is often performed before surgery for stress urinary incontinence to try to predict which women are at greater risk for failure, or to recommend 1 type of procedure over another. For many years in women with a MUCP less than 20 cm H_2O a sling procedure rather than a Burch colposuspension was recommended.[1] It is not known whether this measure or other urodynamic measures predict results of MUS surgeries. To date, smaller studies have resulted in mixed conclusions about whether the retropubic or transobturator approach has a greater failure risk in women with poor urethral function. In this planned secondary analysis of the TOMUS trial we determined whether certain preoperative urodynamic findings predict objective or subjective failure after MUS surgery.

MATERIALS AND METHODS

Methods[2] and primary results[3] for the TOMUS randomized equivalence trial comparing retropubic to transobturator mid urethral slings have been previously described. Eligible women had pure or predominant stress incontinence symptoms for at least 3 months, a positive urinary stress test at a bladder volume of 300 ml or less and were planning surgery. Institutional review board approval was obtained at all participating sites, and an independent data and safety monitoring board monitored the study.

Urodynamics

All patients underwent preoperative urodynamic testing according to International Continence Society Guidelines[4] and according to a standardized research protocol. The details and specifics of the NIF, filling cystometry and PFS have been previously published.[5]

Urethral Profilometry

The difference between the urodynamic protocol used in this TOMUS trial and our previously published urodynamic protocol[5] is that urethral profilometry was added and, therefore, a triple lumen (7Fr) catheter instead of a dual lumen (7Fr) catheter was used for testing. After NIF but before filling cystometry, urethral pressure profiles were performed with the patient in the supine position with perfusion[6] using a flow restrictor at 0.5 ml per minute. Three urethral pressure profile withdrawals at 1 mm per second were performed measuring FUL and MUCP, and the subject had to have at least 2 valid profilometries (FUL 50 mm or less) for MUCP/FUL data inclusion. The physicians who performed surgery in the trial were blinded to all the urodynamic measurements and results. The term delta is used when the urodynamic measure is the difference from baseline.

Primary outcomes of objective and subjective success status were assessed 12 months after randomization.[3] An objective failure was defined as a positive stress test, a positive pad test or re-treatment for stress incontinence. A subjective failure was defined as reported stress-type urinary incontinence symptoms sometimes or more often on the Medical Epidemiological and Social Aspects of Aging questionnaire,[7] leakage on a 3-day voiding diary or re-treatment for stress incontinence.

The 14 urodynamic measures investigated as continuous variables included VLPP, MUCP, FUL, first desire, strong desire, MCC, vesical compliance, detrusor compliance, NIF Qmax, PFS Qmax, delta PvesQmax, delta PabdQmax, delta PdetQmax and PVR after NIF. The 3 categorical urodynamic parameters investigated were urodynamic stress incontinence (yes/no), detrusor overactivity (yes/no) and the point at which the patient leaked (with Valsalva, with cough at MCC only or did not leak). Receiver operator curves were constructed for the relationships between objective failure and VLPP as well as MUCP. Outcomes for women with the lowest quartiles vs higher values for VLPP and MUCP were compared.

Logistic regression was used to assess the association between each proposed covariate and failure, controlling for treatment group. Models were fit separately for objective and subjective failure. Preliminary multivariable models including treatment group (regardless of significance) were constructed including any covariates with $p < 0.05$. To assess whether urodynamic variables were independently associated with outcome after controlling for clinical variables, in the final model we controlled for significant clinical variables that would be readily available to the clinician at the time of treatment planning (age and concomitant surgery). Because VLPP and MUCP

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