The Effect of Urodynamic Testing on Clinical Diagnosis, Treatment Plan and Outcomes in Women Undergoing Stress Urinary Incontinence Surgery

Larry T. Sirls,* Holly E. Richter,† Heather J. Litman, Kimberly Kenton, Gary E. Lemack,‡ Emily S. Lukacz,§ Stephen R. Kraus,‖ Howard B. Goldman,¶ Alison Weidner,** Leslie Rickey,†† Peggy Norton, Halina M. Zyczynski‡‡ and John W. Kusek for the Urinary Incontinence Treatment Network

From the William Beaumont Hospital (LTS), Royal Oak, Michigan, University of Alabama at Birmingham (HER), Birmingham, Alabama, New England Research Institutes (HJL), Watertown, Massachusetts, Loyola University (KK), Chicago, Illinois, University of Texas Southwestern Medical Center (GEL), Dallas and University of Texas at San Antonio (SRK), San Antonio, Texas, University of California-San Diego (ESL), San Diego, California, Cleveland Clinic (HBG), Cleveland, Ohio, Duke University (AW), Durham, North Carolina, University of Maryland Baltimore (LR), Baltimore and National Institutes of Health (JWK), Bethesda, Maryland, University of Utah (PN), Salt Lake City, Utah, and University of Pittsburgh, Magee-Womens Hospital (HMZ), Pittsburgh, Pennsylvania

Abbreviations and Acronyms

BMI = body mass index
ISD = intrinsic sphincter deficiency
MUCP = maximum urethral closure pressure
MUS = mid urethral sling
OAB = overactive bladder
OE = office evaluation
PVR = post-void residual urine
RMUS = retropubic MUS
SUI = stress urinary incontinence
TMUS = transobturator MUS
UDS = urodynamic study
UI = urinary incontinence
USI = urodynamic stress incontinence
VLPP = Valsalva leak point pressure

Purpose: We evaluated the influence of preoperative urodynamic studies on diagnoses, global treatment plans and outcomes in women treated with surgery for uncomplicated stress predominant urinary incontinence.

Materials and Methods: We performed a secondary analysis from a multicenter, randomized trial of the value of preoperative urodynamic studies. Physicians provided diagnoses before and after urodynamic studies and global treatment plans, defined as proceeding with surgery, surgery type, surgical modification and nonoperative therapy. Treatment plan changes and surgical outcomes between office evaluation and office evaluation plus urodynamic studies were compared by the McNemar test.

Results: Of 315 subjects randomized to urodynamic studies after office evaluation 294 had evaluable data. Urodynamic studies changed the office evaluation diagnoses in 167 women (56.8%), decreasing the diagnoses of overactive bladder-wet (41.6% to 25.2%, $p < 0.001$), overactive bladder-dry (31.4% to 20.8%, $p = 0.002$) and intrinsic sphincter deficiency (19.4% to 12.6%, $p = 0.003$) but increasing the diagnosis of voiding dysfunction (2.2% to 11.9%, $p < 0.001$). After urodynamic studies physicians canceled surgery in 4 of 294 women (1.4%), changed the incontinence procedure in 13 (4.4%) and planned to modify mid urethral sling tension (more or less obstructive) in 20 women (6.8%). Nonoperative treatment plans changed in 40 of 294 women (14%). Urodynamic study driven treatment plan changes were not associated with treatment success (OR 0.96, 95% CI 0.41, 2.25, $p = 0.92$) but they were associated with increased postoperative treatment for urge urinary incontinence (OR 3.23, 95% CI 1.46, 7.14, $p = 0.004$).

Conclusions: Urodynamic studies significantly changed clinical diagnoses but infrequently changed the global treatment plan or influenced surgeon decision to cancel, change or modify surgical plans. Global treatment plan changes were associated with increased treatment for postoperative urgency urinary incontinence.

Key Words: urinary bladder, overactive; urinary incontinence, stress; diagnosis; urodynamics; suburethral slings

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* Correspondence: Department Urology, William Beaumont Hospital, Royal Oak, Michigan 48073 (telephone: 248-336-3388; FAX: 248-336-3190; e-mail: lsirls@mac.com).
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Urodynamic studies are often performed before SUI surgery despite the absence of data that these findings alter surgical plans or improve outcomes. A Cochrane Review concluded that UDS may change clinical decision making but there is insufficient evidence that UDS leads to better clinical outcomes.[1]

Organizations, including the International Urogynecological Association guidelines for research and practice and the Royal College of Obstetricians and Gynaecologists, recommend UDS before surgery for SUI. However, the National Institute for Health and Clinical Excellence in the United Kingdom stated that UDS is not routinely recommended before surgery in women with a clearly defined clinical diagnosis of pure SUI.[2] Some called this report unwise, noting that only 5% of patients with UI have pure SUI and a quarter have other urodynamic diagnoses.[3] However, 80% of Dutch gynecologists and urologists would operate on a patient with a positive stress test regardless of UDS findings and only 9% indicated that they may change the sling type based on urethral pressure measures.[4]

The ValUE (Value of Urodynamic Evaluation) study provided 12-month outcomes in women with uncomplicated stress predominant UI planning surgery and showed that women with OE alone had noninferior outcomes compared to those undergoing OE plus UDS.[5] In this secondary analysis of the ValUE trial we report on the subgroup of women randomized to UDS after OE to evaluate the effect of UDS on clinical diagnoses, global treatment plans and patient outcomes.

METHODS

Study

Design and oversight. ValUE was a multicenter, randomized trial of 630 women. Its design and methods were reported previously.[6] Briefly, women underwent a standardized OE (provocative stress test, PVR and urine dipstick), after which surgeons provided a diagnosis, a global treatment plan, including any of proceeding with surgery, defining type of surgery, or proceeding with or adding a nonoperative treatment plan (pharmacotherapy, pelvic floor physical therapy or other) and any planned modifications to surgery (tension more obstructive or less obstructive). Women randomized to UDS had data reviewed by the surgeon, who again defined a global treatment plan that may have modified any component of the original plan. Surgeons reported which UDS finding changed the global treatment plan. After surgery they reported whether the surgery was performed, the procedure was changed and/or the procedure was modified.

In this study we evaluated whether UDS changed clinical decision making in the selection/performance of SUI surgery and the addition of nonoperative treatment, and whether these changes altered the primary outcome, postoperative voiding dysfunction or urgency UI. A successful outcome was defined as a 70% decrease in the UDI (Urogenital Distress Inventory)[7] score from baseline to 12 months and a PGI (Patient Global Impression)-Improvement[8] score of very much better or much better at 12 months.[5]

Briefly, ValUE inclusion criterion included patient age 21 years or greater, minimum 3-month history of SUI, a MESA (Medical, Epidemiologic and Social Aspects of Aging) SUI score greater than the urgency UI score,[9] a positive stress test at any volume, PVR less than 150 ml and a desire for SUI surgery. Exclusion criteria included previous UI surgery, pelvic radiation, pelvic surgery within the last 3 months and anterior or apical pelvic organ prolapse 1 cm or greater. All participants provided written informed consent. Institutional review board approval was obtained at each site.

Procedures and measures. After OE investigators completed a clinical diagnosis. Treatment plan subjects randomized to UDS underwent noninvasive uroflow, filling cystometry with absolute or relative VLPP and/or maximum MUCP, and pressure flow study. UDS data and interpretation were recorded on a separate form using International Continence Society definitions.[10] Suspected ISD was self-defined by the surgeon. Subsequently, UDS investigators completed another clinical diagnosis and global treatment plan, indicating whether UDS influenced their treatment plan and, if so, which UDS components influenced the plan.

The variables selected a priori for potential association with clinical diagnosis change were demographic (age and race), medical/surgery factors (BMI, UI duration, parity, menopausal/hormone replacement therapy status and prior pelvic surgery), physical examination (urethral hypermobility and PVR) and UDS event categories of filling phase (maximum cystometric capacity and detrusor overactivity), urethral function measures (VLPP and MUCP), voiding phase (free uroflow, and pressure flow data and patterns) and absent USI.