Does Complicated Urinary Incontinence Necessitate Multi-Channel Urodynamic Testing?

Abstract

Objective: To compare long-term bladder function outcomes following mid-urethral sling surgery between women with complicated and uncomplicated urinary incontinence with and without pre-operative multichannel urodynamic testing (UDS).

Methods: Women undergoing a midurethral sling over the three years 2007 to 2010 were surveyed regarding treatment outcomes. Validated surveys were administered including the Incontinence Severity Index (ISI) at both pre-treatment and at telephone follow-up. Preoperative urodynamic testing was performed at the discretion of one of three surgeons who performed the surgery. Analysis of outcomes was conducted by performance of bladder testing and by if testing was indicated by published recommendations.

Results: There were 497 women who met inclusion criteria; however only 155 patients were left for analysis after exclusion criteria. There were few significant demographic differences between groups. Mean age at the time of the procedure was 57 years (range 33-90). Mean time since the surgery was 3.71 years (range 0.5-7.2 years). Patients both with and without concomitant prolapse surgery showed significant improvement in pre-operative ISI score. Based on published testing criteria, a nearly equal distribution of patients meeting criteria for testing did and did not have UDS performed yet differences in continence outcomes were not identified. In all cases there were no differences between subjects who had preoperative UDS for the study bladder outcomes.

Conclusion: Despite fulfilling published testing criteria recommending preoperative UDS continence outcomes following a mid-urethral sling surgery were not compromised when testing was omitted.

Keywords: Urinary; Incontinence; Urodynamics

Introduction

Urinary incontinence among women is a common condition with recent estimates citing the lifetime risk of undergoing surgery for stress urinary incontinence at 13.6% [1]. There are, however, other causes for urinary incontinence in women (e.g. urge urinary incontinence) that can arguably affect the success of stress incontinence surgery. How to best identify the etiology of urinary incontinence in any given woman has been a matter of debate with more recent scholarship calling into question the necessity of routine urodynamic testing among uncomplicated women presenting with stress-dominant urinary incontinence symptoms.

There are a fixed number of variables that determine the clinical utility of a diagnostic test. These variables include: (1) the test's pretest and posttest probability in predicting a given condition; (2) the rate probability differences for the condition change recommended interventions (e.g. if there is only 1 treatment option does having a “more sure” posttest probability matter?); (3) the difference between the benefits and harms of treatment; and (4) the potential harms of the test [2]. Each of these variables has been considered with respect to the question of whether multi-channel urodynamic testing has a role in the routine evaluation of the incontinent woman [2]. Of note, how the rate of probability differences for a given incontinence etiology to change treatment recommendations was addressed in two recent non-inferiority randomized trials both of which disfavored routine multi-channel urodynamic testing in the evaluation of an uncomplicated patient with stress urinary incontinence [3,4]. Both of these recent studies assessed the outcome of incontinence surgery (primarily midurethral sling procedures) one year following surgery [3,4].

The American College of Obstetricians and Gynecologists (ACOG) in collaboration with the American Urogynecologic Society (AUGS), recently published the committee opinion,
"Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment" [5]. In this opinion, steps were recommended to render insight as to whether a patient’s urinary incontinence problem is “complicated” or “uncomplicated.” This designation is intended to alert the clinician to settings where incontinence outcomes may be improved with testing or with referral to a specialist. The National Institute of Clinical Excellence (NICE) cited a similar distinction wherein a patient history of previous incontinence surgery or of voiding problems or a clinical suspicion of detrusor over activity, identifies a woman who may benefit from additional testing [6]. Notably some of these same criteria were used in the VALUE trial to exclude patient’s from study enrollment [3]. Both the ACOG and NICE recommendations acknowledge there will be women whose incontinence problem does not require multichannel urodynamic testing but caution there are settings where testing is advisable. However, depending on how strictly observed are the criteria for urodynamic testing, few women may actually avoid testing, and undermining the implicit goal in establish a distinction for testing. We present >1 year continence outcomes between women who did and did not receive pre-operative multi-channel urodynamic testing and who did and did not meet NICE criteria for urodynamic testing before a midurethral sling procedure. The aim of this study is to compare long-term midurethral sling surgery continence outcomes between cohorts defined by testing and by indication for testing. We hypothesize that even among women meeting criteria for testing, who possess a complicated incontinence problem; there will not be identified differences in bladder function when multi-channel urodynamic testing was omitted prior to the sling procedure.

Materials and Methods

The study was conducted at a single academic medical center following approval by the Committee for the Protection of Human Subjects.

Target Population

All women who underwent a midurethral sling (MUS) procedure over the three years between January 1, 2007 and December 31, 2010 were eligible to participate. The CPT code 57288 was used to identify eligible patients within the hospital electronic medical record (EMR). One of three surgeons with a Female Pelvic Medicine and Reconstructive Surgery specialty practiced implanted the MUS that were either the American Medical Systems (Minnetonka, MN) Monarc™ device or the Caldera Medical (Agoura Hills, CA) Desara™ device.

Protocol

All patients were seen by 1 of 3 physicians using a standardized template-based assessment that was documented in the electronic medical record (EMR). The template included sections on International Continence Society (ICS) voiding symptoms as well as assessments of stress and urge urinary incontinence symptoms. In addition all patients completed Internet based general and condition-specific health surveys (Integrated Survey SystemTM, Dynamic Clinical Systems, and Hanover, NH). The results of these surveys were published within the hospital EMR. These surveys included the Urinary Distress Inventory (UDI) and the Sandvik Incontinence Severity Index (ISI). The decision to perform or not perform multichannel urodynamic testing was per the operating surgeon. All patients who did not undergo multichannel urodynamic testing demonstrated urethral urine leakage with stress maneuvers during office examination. In general testing was only done among women who did not document urine leakage during office examination and/or who had elevated post void residual volumes. The protocols for performance of the multichannel urodynamic testing have been described previously [7]. The procedure for performing the transobturatar sling across the three surgeons was per standard practice having all been trained by the same surgeon (JW).

Patients identified by the CPT code, having undergone a MUS, were contacted by phone and following agreement to participate, completed a phone survey conducted by trained interviewers using a script. In addition to the UDI and ISI surveys other surveys included: Patient Global Impression Improvement/Severity (PGI-I, PGI-S); and, 3 Incontinence Questions (3IQ). Details regarding the properties of all surveys used in this study are published elsewhere [8]. Subject responses were recorded on the study datashet and combined with matched demographic and clinical data extracted from the EMR that included the date of procedure, whether urodynamics testing was performed and pre-treatment continence survey scores.

Statistical Methods

The study population was divided into groups dependent on whether they had urodynamic testing or if they met National Institute of Clinical Excellence (NICE) criteria for pre-operative urodynamic testing (UDS) (previous surgery, clinical suspicion of detrusor over activity or voiding dysfunction). Standard definitions were used for these conditions, which were extracted from the EMR. All statistical analyses were done using JMP 11.1.0 (SAS Institute, Cary, NC) running on a MacBook Pro (Apple Computer, Cupertino, CA).

Results

Study Population

From January 1, 2007 to December 31, 2010, a total of 497 patients had undergone a midurethral sling by one of three FPMRS physicians; 3 patients had died, 151 (30%) patients phones were disconnected or did not reply to phone messages, 188 (38%) declined to participate leaving 155 patients for analysis (Figure 1). Comparing the study population to non-participating patients identified some differences. More patients of surgeon 2 did not participate in the study while fewer patients of surgeon 1 did not participate in the study. Participating patients were slightly older (61.4 years vs. 58.8 years; p=0.02). From the available data for non-participating patients there were no differences identified for prior incontinence surgery (p=0.28), clinical suspicion of detrusor over activity (p=0.73), or voiding dysfunction (p=0.41) relative to the study population. Among study subjects, 122 (83%) reported no history of a prior incontinence surgery, 73 (51%) had documentation in the clinical record of symptoms consistent with urinary urgency or frequency with or without incontinence, and 60 (42%) reported aberrant ICS voiding symptoms.
Table 1: Preoperative study outcomes among subjects who underwent a mid-urethral sling surgery and who did and did not undergo preoperative urodynamic testing.

<table>
<thead>
<tr>
<th>Overall Complicated per NICE Criteria</th>
<th>UDS (n=72, 46%)</th>
<th>No UDS (n=83, 54%)</th>
<th>p</th>
<th>UDS (n=59)</th>
<th>No UDS (n=51)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at time of surgery, years (mean, SD, range)</td>
<td>56.5 (12, 34-89)</td>
<td>57.1 (10.7, 32-79)</td>
<td>0.72</td>
<td>55.5 (11.9, 34-85)</td>
<td>58.8 (11, 32-79)</td>
<td>0.14</td>
</tr>
<tr>
<td>Surgeon</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>3</td>
<td>24</td>
<td>8</td>
<td>20</td>
<td>5</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>36</td>
<td>36</td>
<td>30</td>
<td>21</td>
<td></td>
<td></td>
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<tr>
<td>1</td>
<td>12</td>
<td>39</td>
<td>9</td>
<td>25</td>
<td></td>
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<tr>
<td>Surgery (n, %)*</td>
<td></td>
<td></td>
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<tr>
<td>Hysterectomy</td>
<td>20 (28%)</td>
<td>21 (27%)</td>
<td>19 (55%)</td>
<td>15 (44%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior vaginal wall procedure</td>
<td>28 (39%)</td>
<td>35 (42%)</td>
<td>26 (49%)</td>
<td>27 (51%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-anterior wall procedure</td>
<td>16 (22%)</td>
<td>18 (22%)</td>
<td>13 (50%)</td>
<td>13 (50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complicated per NICE criteria (n, %)</td>
<td>59 (54%)</td>
<td>51 (46%)</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative ISI (mean, SD, range)</td>
<td>n=61</td>
<td>n=65</td>
<td>n=49</td>
<td>n=47</td>
<td>n=50 (3.5, 0-12)</td>
<td>0.04</td>
</tr>
<tr>
<td>Preoperative UDI-6 (mean, SD, range)</td>
<td>n=31</td>
<td>n=52</td>
<td>n=27</td>
<td>n=41</td>
<td>43.2 (30.8, 12.5-95.8)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

SD: standard deviation; ISI: Incontinence Severity Index; UDI-6: Urinary Distress Inventory; PGI: Patient Global Impression – Change or Severity. Bold indicating p<0.05.

Relationships between Women who did and did not Receive Multi-Channel Urodynamic Testing

There were differences between surgeons as to whether UDS testing was performed. Surgeon 3 was significantly more likely to perform urodynamic testing than the other surgeons (Table 2), \( p<0.0001 \). All other pre or post-surgery parameters, including surgery performed (hysterectomy, anterior prolapse repair, non-anterior prolapse repair), were not different between women who did and did not have urodynamic testing (Tables 1 & 3).

Women who leaked urine at follow-up, per the 3IQ questions, had predominately urge leakage. Thirty percent of current urine leakers reported stress dominant leakage symptoms, 48\% reported urge dominant leakage, 12\% reported mixed leakage, and 7\% leakage without stress or urge symptoms. Nearly fifty percent of enrolled patients had multichannel urodynamic testing \((n=72, 46\%)\). These women tended to have a longer follow-up period by about 7 months than women who did not have urodynamic testing \((p=0.04, \text{Table 3})\). Pre-treatment UDI-6 scores were also higher among women who had urodynamic testing although which items on the UDI-6 drove that higher overall score cannot be determined. Informing this deficit, women who had urodynamic testing were more likely to have been suspected to have detrusor over activity \((0.04)\) although overall there was only a trend between performance of urodynamic testing and a clinical suspicion of detrusor over activity \((p=0.07)\). There was no relationship between patient reported voiding symptoms and whether urodynamic testing was performed. Women with a history of a prior incontinence surgery were not more likely to have urodynamic testing \((p=0.91)\).

Relationships between Women who did and did not Meet NICE Criteria for Urodynamic Testing

Despite no mindfulness of the NICE criteria for when to obtain multichannel urodynamic testing, a nearly equal distribution of patients who met these conservative criteria did and did not actually have testing done \((59 \text{ had urodynamic testing and } 51 \text{ did not})\) (Tables 1 & 3). Demonstrates that between these two groups there were no differences across the pre and postoperative metrics, including surgery performed (hysterectomy, anterior prolapse repair, non-anterior prolapse repair), with the exception that women who had testing possessed more leaky ISI scores. More than 40 months after the index surgery, there were no identified differences in ISI scores between women who met NICE criteria for bladder testing yet did not have it performed. Focusing on the matter of prior incontinence surgery as defining a "complicated" patient, no differences in ISI scores were identified between those with \((p=0.76)\) or without urodynamic testing \((p=0.51)\).

Relationships of Current Leakage to Pre-Surgery Bladder Function

The relationship between current bladder leakage and pre-surgery bladder function follows expected patterns. Women with a clinical suspicion for detrusor over activity, irrespective of confirmatory urodynamic findings, had higher (more incontinence) ISI scores at follow-up \((\text{ISI with clinical suspicion } 3.8, \text{ ISI without clinical suspicion } 1.6, p=0.0003)\). These women also reported at follow-up more frequency symptoms per the UDI-6 \((p=0.05)\). Women with dysfunctional voiding symptoms, irrespective of urodynamic findings, had worse ISI scores at follow-up \((\text{ISI with symptoms } 3.1, \text{ ISI without symptoms } 2.0, p=0.05)\). These same women with voiding problems at follow-up also scored higher on the voiding question for the UDI-6 \((p=0.03)\). A history of prior incontinence or prolapse surgery did not associate with current ISI leakage severity \((p=0.75)\). There was no difference in pre- or post-surgery ISI scores by surgeon (Table 3).
Table 2: Continence outcomes among subjects who underwent mid-urethral sling surgery and who did and did not undergo preoperative urodynamic testing by surgeon.

<table>
<thead>
<tr>
<th>Surgeon 1</th>
<th>Surgeon 2</th>
<th>Surgeon 3*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Op UDS</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>(n)</td>
<td>39</td>
<td>12</td>
</tr>
<tr>
<td>ISI Pre-Op</td>
<td>5.5</td>
<td>5.9</td>
</tr>
<tr>
<td>ISI Current</td>
<td>2.6</td>
<td>2.8</td>
</tr>
</tbody>
</table>

UDS: Urodynamic Testing; ISI: Incontinence Severity Index.
p<0.05 between surgeons for current or postoperative ISI scores with or without urodynamic testing. *Surgeon 3 was more likely to perform urodynamic testing p<0.0001.

Table 3: Postoperative study outcomes among subjects who underwent a mid-urethral sling surgery and who did and did not undergo preoperative urodynamic testing.

<table>
<thead>
<tr>
<th>Overall Complicated per NICE Criteria</th>
<th>UDS (n=72, 46%)</th>
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<th>No UDS (n=51)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISI at follow-up (mean, SD, range)</td>
<td>2.7 (3.5, 0-12)</td>
<td>2.4 (3.4, 0-12)</td>
<td>0.56</td>
<td>2.9 (3.5, 0-12)</td>
<td>3.2 (3.9, 0-12)</td>
<td>0.64</td>
</tr>
<tr>
<td>UDI-6 at follow-up (mean, SD, range)</td>
<td>22.7 (23.9, 0-100)</td>
<td>18.1 (19.4, 0-79)</td>
<td>0.2</td>
<td>24 (24.9, 0-100)</td>
<td>22.3 (21.4, 0-79.2)</td>
<td>0.71</td>
</tr>
<tr>
<td>PGI Change at follow-up (mean, SD, range)</td>
<td>2.2 (1.6, 1-7)</td>
<td>2.3 (1.7, 1-7)</td>
<td>0.64</td>
<td>2.3 (1.6, 1-7)</td>
<td>2.7 (1.8, 1-7)</td>
<td>0.18</td>
</tr>
<tr>
<td>PGI Severity at follow-up (mean, SD, range)</td>
<td>1.8 (3.3, 1-4)</td>
<td>1.8 (0.9, 1-4)</td>
<td>0.93</td>
<td>1.8 (0.8, 1-4)</td>
<td>2.0 (0.9, 1-4)</td>
<td>0.19</td>
</tr>
</tbody>
</table>

SD: Standard Deviation; ISI: Incontinence Severity Index; UDI-6: Urinary Distress Inventory; PGI: Patient Global Impression – Change or Severity. Bold indicating p<0.05.

Discussion

Diagnostic testing renders value to a patient when it yields information that meaningfully informs the decision for treatment due to its predictive capacity in regard to treatment outcome. If a test has no merit in predicting a treatment outcome, the value of the test approaches zero since by definition, value (a measure of efficiency) is the quotient of outcome by cost. In our study, multichannel urodynamic testing did not render identified improvements in estimating the outcome of mid-urethral sling surgery even among women with complicated (those who by recognized authorities may benefit from additional testing) urinary incontinence thus affirming our study hypothesis.

It could be argued that subjects who had multichannel urodynamic testing and had findings that might diminish the outcome of stress incontinence surgery, were discouraged from pursing surgery. In this case, a “more well” population of tested patients artificially raises the post-treatment incontinence outcomes among the tested group perhaps to a level on par with “less well” patients who were not tested. Likewise, a surgeon’s sense of a patient health status may alone prompt testing with poor or intermediate results reinforcing a predetermined desire to believe surgery would not be benefit the patient incontinence problem. In response, patient’s who had no testing, yet possessed risk factors, may have had testing outcomes that would have mistakenly discouraged a surgical treatment that would otherwise prove helpful. Also if a surgeon’s sense of a patient’s health status, independent of testing results, is the driver of treatment recommendations, then ACOG’s recommendation to refer “complicated” patients to a specialist may have merit but multichannel urodynamic testing could be arguably omitted. In light of VALUE, VUSIS trials, together with our findings, it would seem that the choice to pursue multi-channel urodynamic testing before mid-urethral sling surgery should be made carefully and not as part of routine.

The VUSIS trial offers a unique perspective on the merits of multichannel urodynamic testing. Everyone in this trial had multichannel urodynamic testing. Over 90% of subjects had surgery and among these all were treated with a midurethral sling (retropubic or transobturator). Detrusor over activity was the only urodynamic finding that was independently associated with the risk of postoperative persistent urinary incontinence yet this finding was only identified in 6% of subjects. That said, still 82% of those subjects with detrusor over activity reported improved continence following midurethral sling surgery. Our study results are not that surprising in light of this sort of finding begging the question in whom should multichannel urodynamic testing ever be done in the setting of predominant symptoms of stress urinary incontinence? Given the design of the VUSIS trial, those settings where testing would

have seemed to render some valuable insight with regard to treatment
choice or outcome, no benefit was identified.

The VALUE trial randomized “uncomplicated” patients to either basic
office assessment (BOA) or BOA plus multichannel urodynamic testing.
Exclusion criteria included no prior history of incontinence surgery or
recent history of prolapse surgery. Enrolled objects needed to have avoided
residual volume less than 150 mL and some urethral hypermobility but no
anterior wall prolapse or sufficient bulge >1 cm beyond the hymen. While our sample
size was small, a history of a prior incontinence surgery did not predict a
worse incontinence outcome following a transobturator sling procedure.
While the specifics of that prior incontinence surgery are not available
from our extracted data it is at least clear that this surgical history cannot
routinely recommend multichannel urodynamic testing. Our study also
included women who were in some cases additionally having a prolapse
repair. Indeed about 40% of women in our study had some sort of anterior
wall procedure yet not all of these women had preoperative testing nor
did this appear to make a difference in post-treatment ISI scores. If having
an anterior wall bulge sufficient enough to warrant repair did not predict
continence outcomes following midurethral sling surgery it is hard to understand
what meaning multichannel urodynamic testing imparted on the decision for surgery?

There are conceivably settings where multichannel urodynamic
testing appears to render patient value. For patients with a neurologic
disorder wherein there is a risk for upper tract injury there remains no
better way to test the bladder’s function. There are also settings where the
diagnostic picture is so unclear that multichannel urodynamic testing
may offer benefit. No one is recommending no bladder testing. Basic office
assessment can include office urodynamic testing among assessments of
voiding efficiency, infection, etc. The physician treating women with
urinary incontinence should be adept at understanding the limitations of
their clinical assessments and judiciously apply testing only in those
settings where the patient will reasonably find benefit.

Our study has limitations. Our study is retrospective, single-center, not
randomized, and characteristics of enrolled patients are not necessarily
uniform. Likewise, data recorded from an EMR can be categorized in
ways that can limit finer understandings of associations. In addition,
there were differences in how the surveys were administered before and
after surgery. Prior to surgery, an Internet-based survey tool was used
while after surgery, patient’s agreeing to participate in the study, were
administered the survey by phone. None of these issues, however, would
be necessarily expected to bias toward or against performing multi-
channel urodynamic testing although surgeon number 3, who contributed
fewer cases than surgeons 1 and 2, did preferentially perform this testing
without identified post-treatment continence effect. In regard to survey
administration technique, phone surveys would generally bias toward
more positive responses. This would tend to over-estimate the effect of
treatment yet our change in ISI was less than that reported in the VALUE
trial. Given the reported ISI scores among VALUE trial subjects prior to
surgery were higher than those in our study and with a wider difference in
these score post-surgery, this suggests our subjects had more incontinence
at follow-up. This is likely best explained by the differences in follow-
up time. To dismiss our study findings, acknowledging its limitations,
h owever, misses that our findings in some respects would not otherwise
be identified by already existing studies on this matter. Our findings argue
for investigating the real possibility defining the “uncomplicated” patient
with symptoms of stress urinary incontinence is likely broader than could
be justified from the existing literature.

In making a diagnosis the clinician is in essence estimating changing
probabilities altered as new information is collected from a patient.

In a sense, the effect of the basic office assessment is to enhance the
probability of identifying an incontinence condition that would be
meaningfully changed by performing a mid-urethral sling procedure. Any
diagnostic test is performed across the range of probabilities for a given
diagnosis, from so low as to “rule out” treatment efficacy, to so high as to
“rule in” direct treatment without need of additional clarifying diagnostic
information. Curiously, based on data collected with the VALUE trial,
Zimmern et al. [9] found clinician confidence improved with urodynamic
testing despite the fact this confidence had no clinical significance. This
study, interpreted in the light of the probability work performed in making
a diagnosis, would be like believing one’s horoscope altered the probability
estimates on being involved in an automobile accident. That diagnostic
confidence is improved with urodynamic testing could suggest physicians
fundamentally misunderstand the probabilistic nature of clinical diagnosis
[10]. It would seem that for at least the uncomplicated woman presenting
with predominate stress urinary incontinence symptoms, the basic office
assessment “rules in” the probability of a condition that will be positively
impacted by a mid-urethral sling. Future research could be directed at
expanding the population of women wherein the pre-test probabilities of
SUI are so high as to cross the treatment threshold and save unnecessary
testing. Our study suggests that such a population does exist.

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