Standing cough test for evaluation of post-prostatectomy incontinence: a pilot study

Allen F. Morey, MD, Nirmish Singla, MD, Maude Carmel, MD, Alexandra Klein, MD, Timothy J. Tausch, MD, Jordan Siegel, MD, Isamu Tachibana, MD, Jeremy Scott, MD

Department of Urology, University of Texas Southwestern Medical Center, Dallas, Texas, USA

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Introduction: *We implemented a standardized Standing Cough Test (SCT) for assessment of men with post-prostatectomy incontinence (PPI) and stratified results according to an objective clinical grading scale in an attempt to facilitate male anti-incontinence surgical procedure selection.*

Materials and methods: *SCT was routinely performed during the initial outpatient consultation for PPI. Incontinence severity was recorded based on a novel Male Stress Incontinence Grading Scale (MSIGS) to stratify PPI. Each patient was assigned an incontinence grade score of 0 through 4 during the SCT. Men with mild stress urinary incontinence (SUI) (grades 0-2) were offered sling surgery while those with heavier SUI (grades 3-4) were offered artificial urinary sphincter (AUS). MSIGS grade was correlated to preoperative patient-reported pads per day (PPD), and patient-reported outcomes of anti-incontinence surgery were assessed.*

Results: *Among 62 consecutive PPI patients, 20 (32%) were graded as mild based on SCT, while the majority (42/62, 68%) were graded as moderate-severe. Average time from prostatectomy to treatment was 6 years. MSIGS grade demonstrated a strong correlation with preoperative PPD (r = 0.74). Among the 53 patients who underwent surgery for PPI, 14 with mild SUI received a sling, while 39 (74%) more severe cases received an AUS. Patient-reported improvement was high overall in both groups (median 95%).*

Conclusion: *Most men with chronic PPI present for definitive treatment in a delayed manner after prostatectomy despite having severe incontinence. The SCT provides immediate, objective information about the severity of PPI which strongly correlates with patient-reported pads-per-day and may expedite anti-incontinence surgical procedure selection.*

Key Words: mid-urethral sling, post-prostatectomy incontinence, artificial urinary sphincter

Introduction

Post-prostatectomy incontinence (PPI) is one of the most bothersome sequelae of prostate cancer therapy. Surgical treatment is often required after failure of conservative measures such as a trial of pelvic floor muscle training exercises.[1,2] The most effective treatment strategies currently available involve placement of either a male sling or artificial urinary sphincter (AUS).[3]

Diagnostic strategies commonly implemented to ascertain the severity of PPI as a guide for treatment selection vary widely. Voiding diary,[4] validated questionnaires, and documentation of incontinence severity by number of pads per day (PPD) are commonly obtained during patient history to facilitate

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Address correspondence to Dr. Allen Morey, Department of Urology, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390-9110 USA

treatment decision-making.[5,6] For objective evaluation of stress urinary incontinence (SUI), pad weights have been recommended[7] along with ultrasonic post-void residual volumes to assess bladder emptying.[8] Cystoscopy is often conducted to evaluate integrity of the external urinary sphincter and bladder neck. Multichannel urodynamic testing have been advocated to provide further information about detrusor function and bladder contractility.[9] Valsalva abdominal leak point pressure measurement has also been suggested as an optimal method of evaluating sphincter weakness.[10]

Although these various diagnostic tests are often recommended, they tend to be costly, invasive, and time-consuming prior to male anti-incontinence surgery. We implemented a prospective, simplified protocol emphasizing the immediate physical demonstration of stress incontinence during the initial consultation based on a Standing Cough Test (SCT). We developed a urinary incontinence grading scale based on the severity of urinary leakage during initial office evaluation in an effort to distinguish mild cases, more appropriate for slings, from severe cases requiring AUS. We assessed the duration of time from prostatectomy to presentation in our male incontinence clinic among a large cohort of men with PPI.

Materials and methods

Under an IRB approved protocol, we prospectively evaluated a consecutive series of men referred for treatment of SUI between September 2014 and July 2015. Only those with untreated post-prostatectomy SUI (PPI) were included in this dataset. Patients having mixed incontinence, neurogenic bladder, prior anti-incontinence surgical therapy, or stress incontinence due to causes other than radical prostatectomy were excluded from this analysis.

All patients underwent a SCT in order to physically demonstrate and document the severity of urinary leakage during initial office consultation. Verbal confirmation was obtained that patients had not voided for at least 60 minutes prior to examination. Examination of the urethral meatus was conducted by two examiners while the patient completed a series of four forceful coughs. Towels were held several inches from the meatus during coughs to collect any urinary leakage, which was then graded by examiner consensus according to a standardized Male Stress Incontinence Grading Scale (MSIGS), Table 1 and Video on line.

Patient-reported PPD and body mass index (BMI) were recorded and correlated to MSIGS scores among all patients examined. For those who progressed to surgical therapy, outcomes at 6 weeks and 3 months postoperatively were correlated to surgical treatment type and MSIGS score. Patient-reported outcome measures included a disease-specific Patient Global Index of Improvement (PGI-I) score[11] and an overall percentage of improvement. Other clinical data recorded included patient age, history of radiation, and determination of the time interval from radical prostatectomy to the performance of anti-incontinence surgery.

TABLE 1. **Male Stress Incontinence Grading Scale (MSIGS)**

Grade	Definition	Proposed management
0	Leakage reported in history but not demonstrable on exam	Sling
1	Delayed drops only	Sling
2	Early drops, no stream	Sling
3	Drops initially, delayed stream	AUS
4	Early and persistent stream	AUS

AUS = artificial urinary sphincter

Anti-incontinence surgery was performed using a standardized technique by the senior surgeon in all cases. Men with mild incontinence (MSIGS grades 0-2) had the AdVance sling (American Medical Systems, Minnetonka, MN, USA) placed, while those with heavier degrees of leakage (MSIGS grades 3-4) underwent AUS placement (AMS 800 series, American Medical Systems, Minnetonka, MN, USA) with cuff placement performed via a perineal incision. Patient-reported improvement was compared between the treatment groups, as was the percentage of men who would recommend their specific treatment type to others with a similar condition. Chi-square and correlational analyses were performed using SPSS version 19.0 (IBM, Armonk, NY, USA).

Results

A total of 62 men underwent MSIGS testing during initial clinical consultation for PPI from September 2014 to July 2015. Remarkably, the average duration from radical prostatectomy to initial anti-incontinence surgery in this series was 6.0 years (range 1-22 years) despite the finding that the majority (42/62, 68%) were graded as moderate-severe [10 (16%) grade 3, 32 (52%) grade 4]. The other 20 (32%) were graded as mild

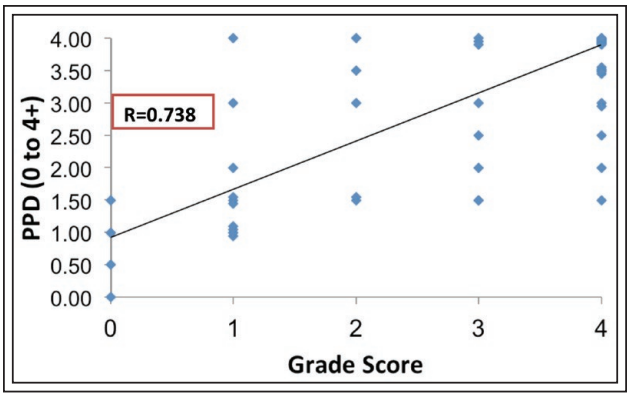

Figure 1. Strong correlation between patient-reported pads per day (PPD) and MSIGS grade score.

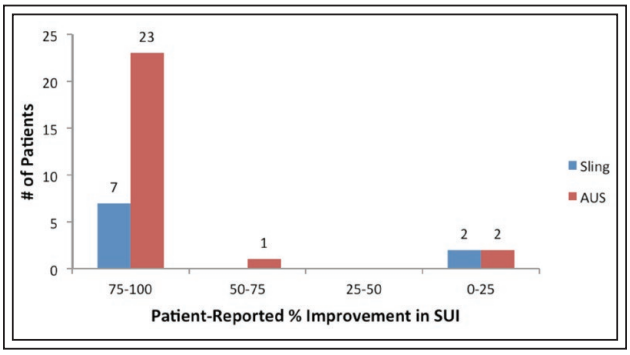

Figure 2. Patient-reported percentage of improvement in SUI following surgical intervention.

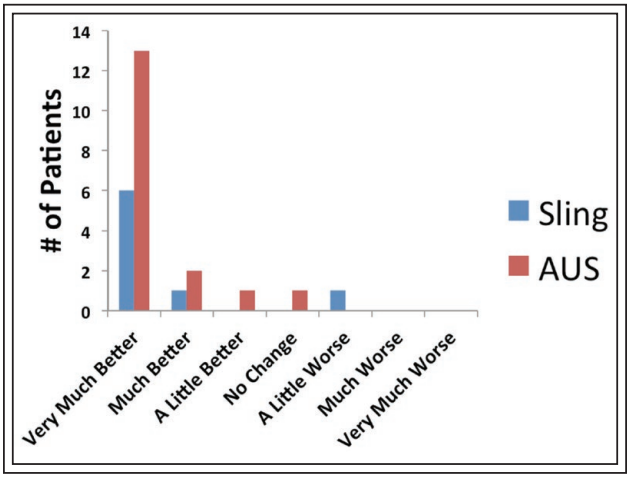

Figure 3. Results of PGI-I questionnaires, stratified by surgical treatment.

based on SCT [five (8%) grade 0, 10 (16%) grade 1, five (8%) grade 2] while. Overall, 53 patients underwent surgical intervention (14 AdVance male urethral sling surgery and 39 AUS placement), of which complete outcomes data were available for 35 men. Mean age (± standard deviation) was 70 ± 7 years (range 53-85) and was similar between the sling (mean 68 years) and AUS (mean 70 years) groups.

Of all 62 patients, MSIGS score correlated strongly with patient-reported PPD (r = 0.738, Figure 1). Patient-reported percentage of improvement was high following surgery (median 95% overall, Figure 2) and similar between AUS patients and AdVance sling patients (median 95% each). PGI-I scores similarly reflected a strong shift toward "very much better" in both AUS and sling groups, Figure 3. Only one patient, an 80-year-old man who underwent sling placement 22 years following prostatectomy, reported a negative PGI-I response of being "a little worse" after surgery. The percentage of men who would recommend their selected procedure to others with a similar condition was 91.4%, with similar rates for AUS (24/26, 92%) and AdVance sling (8/9, 89%, p = 0.62). No significant correlation was identified between BMI and the MSIGS grade score as seen in Figure 4.

We investigated further the outcomes of procedures performed on the 9 men with intermediate grades of leakage (2-3 PPD), in whom the surgical decision-making process is often more difficult than for patients with mild (0-1 PPD) or severe (≥ 4 PPD) PPI. Among the 7 with grade 3 incontinence on SCT, all received an AUS, and 85.7% (6/7) of these would recommend their selected procedure to others with a similar condition. Similarly, both grade 2 SUI patients received slings and stated they would recommend their selected treatment.

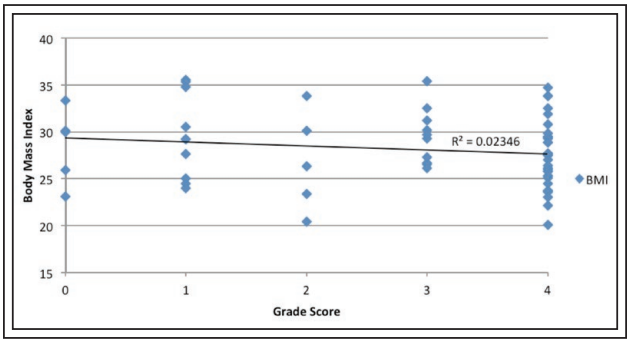

Figure 4. Correlation between body mass index (BMI) and MSIGS grade score.

Discussion

The SCT is a clinical evaluation tool described nearly 20 years ago by Kowalczyk et al as a method of determining whether one or two AUS cuffs should be installed.[12] Although we no longer perform tandem cuff AUS procedures, we have found the SCT to be a useful method to easily assess the severity of PPI for many years at our tertiary care institution. We are not aware of any other studies evaluating the SCT as a means of stratifying PPI patients over the past 20 years.

As a result of routinely performing the SCT in several hundred PPI patients over more than a decade in our subspecialty clinical practice, we have recognized several distinct patterns of leakage that can be commonly observed. The fundamental principle of the MSIGS is to ascertain whether leakage observed during the SCT is predominantly visible as drips or whether it deteriorates into a visible stream under stress. The MSIGS is an attempt to standardize those leakage patterns and correlate them with other patient-reported indicators of condition severity and clinical outcomes. We noted a strong concordance between MSIGS and patient-reported PPD regardless of body habitus, and choice of treatment (sling versus AUS) appeared to be facilitated using this grading scale. Favorable outcomes following incontinence procedures (both sling and AUS) were observed at postoperative follow up based on both self-reported improvement and a validated questionnaire (PGI-I).

Physical examination

While contemporary methods to evaluate the severity of PPI rely on some combination of history, PPD, pad weights, cystoscopy, and urodynamics, no gold standard currently exists. We feel the simple physical demonstration of urinary leakage during routine examination is important and is underemphasized. Our MSIGS offers several major advantages over other tests, including efficiency, objectivity, and cost-effectiveness. Grading scales based on physical examination have proven useful in various other urological and non-urological applications, such as pelvic organ prolapse,[13] hemorrhoids,[14] and joint sprains.[15] In 1973, Kaufman classified degrees of incontinence into three grades[16] but to our knowledge, this scale has been abandoned since then.

Physical examination is briefly mentioned for demonstration of incontinence in recent meta-analyses on evaluation of PPI, but without recommendations on how to incorporate physical exam findings into treatment decisions.[17-20] Thiel et al evaluated various urodynamic parameters including detrusor overactivity, low first sensation, low bladder compliance, and low bladder capacity as potential predictors for AUS outcomes in managing PPI, but none were predictive of successful outcomes nor correlated with patient-reported PPD usage.[21] Similarly, others have found no correlation of abdominal leak point pressure (ALPP) to severity of sphincter damage and SUI outcomes.[22] These results parallel those of the multicenter, randomized, noninferiority Value of Urodynamic Evaluation (VALUE) trial, which verified that urodynamic testing in a large cohort of women with uncomplicated, demonstrable SUI did not affect the outcome of surgical intervention.[23] Treatment success in the VALUE trial was notably defined by responses to PGI-I, as in our study, and the Urogenital Distress Inventory.

Surgical management

Although the AUS has remained the gold standard treatment for PPI since the 1970s,[24] the male urethral sling has emerged as a viable, less complex alternative treatment option that enables spontaneous voiding without hydraulic pump manipulation or circumferential urethral compression. Patients usually prefer a sling if given the choice, since it takes effect immediately and avoids a mechanical device prone to malfunction or revision.[25] While slings can be effective for management of mild to moderate PPI (grade B evidence), severe PPI is better managed with AUS (grade C evidence).[20,26] In our experience over the last several years, the failure rates of slings are minimized when the procedure is used more selectively. While placement of a male sling does not preclude AUS implantation at a later date for failed cases, we believe that appropriate initial preoperative stratification of patients to receive either sling or AUS is required to avoid the need to perform a second, more complex operation unnecessarily.

While surgical intervention for PPI is commonly postponed for at least 12 months to allow for spontaneous improvement following prostatectomy,[27] we noted a remarkable mean delay of 6 years from the time of prostatectomy to the time of anti-incontinence surgery. This suggests the obvious need for a more refined approach to the evaluation and management of men with PPI, which happens to be among the most bothersome complications of prostate cancer treatment.[28] Appropriate validated questionnaires to highlight patient bother from PPI appear to be either lacking or underutilized.

Due to logistical cost and time constraints in our high-volume clinic, as a general rule we have preferred careful history and physical examination in lieu of routine implementation of urodynamic assessment for

most uncomplicated male SUI cases. Invasive testing protocols involving urodynamics appear to be of limited value in straightforward, previously untreated PPI cases since these have not been shown to influence anti-incontinence surgical outcomes.[21-23] Furthermore, sophisticated urodynamic testing may not be readily available in the community urology practice setting. The MSIGS appears to show promise for determining the operative candidacy for sling versus AUS, since patient-reported PGI-I outcomes were outstanding for both the AUS and sling sub-cohorts.

Strengths and limitations

This pilot study indicates that the SCT provides meaningful information about the severity of leakage in PPI patients in an efficient manner. While the MSIGS appears to have value in stratifying PPI patients, this study does have several obvious limitations. This series reports a limited number of patients with relatively short follow up. The role of other patient comorbidities such as advanced age, cardiovascular disease, prior radiation, potency status, reoperative cases, or androgen deprivation is unknown. Perhaps results would have been as good or better if all patients had received an AUS, but we feel it is important to identify appropriate sling candidates to reduce unnecessary additional costs and surgical trauma.

While we requested patients not to void for at least 60 minutes prior to MSIGS classification, bladder volumes prior to Valsalva were not routinely recorded. We acknowledge that bladders containing higher volumes of urine may be more likely to leak versus those having lower volumes, and that the influence of bladder volume on MSIGS should be established via performing bladder scanning at the time of testing. Alternatively, MSIGS score could be evaluated after cystoscopy, when the bladder is filled to a standardized 300 cc volume to increase reproducibility, as in the VALUE trial.[23] Cough strength may be difficult to standardize across patients, and a quantitative evaluation of abdominal pressure generated may be useful. Although we demonstrated a strong correlation of MSIGS values with PPD (which has, in turn, been correlated strongly to pad weights),[29] we did not record pad weights in this series.

Despite these limitations, however, our pilot study presents a number of important strengths. The SCT was intentionally developed as a simple, rapid, office-based screening tool to be utilized by community urologists, allied health care professionals, or urological oncologists to immediately and objectively assess PPI severity in one clinic visit. These clinicians may not otherwise be equipped to conduct extensive evaluation of male incontinence, which likely explains our finding that many incontinent men persist for many years with this disabling condition prior to initial referral for definitive treatment. We continue to see men who have been reported to have "excellent" continence who are found be wearing pull-up diapers and have high grade SUI during the SCT. We also have seen patients who have been determined to have insignificant SUI after multiple invasive tests elsewhere, who have obvious high grade SUI on SCT. We suspect that use of the SCT with the MSIGS in the assessment of post-prostatectomy patients may help expedite appropriate referral for patients with slow or suboptimal return of continence.

Data was collected in a prospective fashion to reduce selection bias. Assignment of MSIGS grade was validated by the consensus of two independent observers, thereby reducing potential inter-rater variability and increasing reproducibility of the results. While further testing is needed to ascertain the role of an incontinence grading scale in the evaluation of PPI patients, this report suggests that the simple office-based strategy of incontinence grading during physical exam can provide a powerful, immediate addition to the current clinical armamentarium. Finally, we challenge the broader urological community to incorporate this simple test early in the evaluation of post-prostatectomy patients when continence concerns arise in hopes of preventing unwarranted treatment delays. Specifically, we encourage incontinence experts globally to elucidate the role of the SCT in male SUI and to investigate the relationship of MSIGS to traditional urodynamic parameters.

Conclusion

The SCT enables a rapid, non-invasive, objective assessment of PPI severity, which correlates strongly with patient-reported PPD and appears to facilitate anti-incontinence surgical procedure selection. □

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