AUA/SUFU Guideline

ADULT URODYNAMICS: AUA/SUFU GUIDELINE

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Purpose: This guideline is intended to review the literature regarding the use of urodynamic testing in common lower urinary tract symptoms (LUTS) conditions. It presents the principles of application and technique to guide the clinician in the role of urodynamics in complex LUTS disorders. As urodynamics is only one part of the comprehensive evaluation of LUTS, the findings of this guideline are intended to assist the clinician in the appropriate selection of urodynamic tests following an appropriate evaluation and symptom characterization.

Methods: A systematic review of the literature using the MEDLINE® and EMBASE databases (search dates January 1, 1990 to March 10, 2011) was conducted to identify peer-reviewed publications relevant to the use of urodynamic tests for diagnosis, prognosis, guidance of clinical management decisions and improvement of patient outcomes in patients with various urologic conditions. The review yielded an evidence base of 393 studies after application of inclusion/exclusion criteria. These publications were used to inform the statements presented in the guideline as Standards, Recommendations or Options. When sufficient evidence existed, the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate) or C (low). In the absence of sufficient evidence, additional information is provided as Clinical Principles and Expert Opinion.

Guideline Statements

Stress Urinary Incontinence (SUI)/Prolapse

1. Clinicians who are making the diagnosis of urodynamic stress incontinence should assess urethral function. (*Recommendation*; Evidence Strength: *Grade C*)

2. Surgeons considering invasive therapy in patients with SUI should assess post-void residual (PVR) urine volume. *(Expert Opinion)*

3. Clinicians may perform multi-channel urodynamics in patients with both symptoms and physical findings of stress incontinence who are considering invasive, potentially morbid or irreversible treatments. (*Option*; Evidence Strength: *Grade C*)

4. Clinicians should perform repeat stress testing with the urethral catheter removed in patients suspected of having SUI who do not demonstrate this finding with the catheter in place during urodynamic testing. (*Recommendation*; Evidence Strength: *Grade C*)

5. Clinicians should perform stress testing with reduction of the prolapse in women with high grade pelvic organ prolapse (POP) but without the symptom of SUI. Multi-channel urodynamics with prolapse reduction may be used to assess for occult stress incontinence and detrusor dysfunction in these women with associated LUTS. (*Option*; Evidence Strength: *Grade C*)

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Overactive Bladder (OAB), Urgency Urinary Incontinence (UUI), Mixed Incontinence

6. Clinicians may perform multi-channel filling cystometry when it is important to determine if altered compliance, detrusor overactivity or other urodynamic abnormalities are present (or not) in patients with urgency incontinence in whom invasive, potentially morbid or irreversible treatments are considered. (*Option;* Evidence Strength: *Grade C)*

7. Clinicians may perform pressure flow studies (PFS) in patients with urgency incontinence after bladder outlet procedures to evaluate for bladder outlet obstruction*. (Expert Opinion)*

8. Clinicians should counsel patients with urgency incontinence and mixed incontinence that the absence of detrusor overactivity (DO) on a single urodynamic study does not exclude it as a causative agent for their symptoms*. (Clinical Principle)*

Neurogenic Bladder (NGB)

9. Clinicians should perform PVR assessment, either as part of a complete urodynamic study or separately, during the initial urological evaluation of patients with relevant neurological conditions (e.g., spinal cord injury and myelomeningocele) and as part of ongoing follow-up when appropriate. (*Standard;* Evidence Strength: *Grade B*)

10. Clinicians should perform a complex cystometrogram (CMG) during initial urological evaluation of patients with relevant neurological conditions with or without symptoms and as part of ongoing follow-up when appropriate. In patients with other neurological diseases, physicians may consider CMG as an option in the urological evaluation of patients with LUTS. (*Recommendation*; Evidence Strength: *Grade C*)

11. Clinicians should perform pressure flow analysis during the initial urological evaluation of patients with relevant neurological conditions with or without symptoms and as part of ongoing follow-up when appropriate, in patients with other neurologic disease and elevated PVR or in patients with persistent symptoms. (*Recommendation*, Evidence Strength: *Grade C)*

12. When available, clinicians may perform fluoroscopy at the time of urodynamics (videourodynamics) in patients with relevant neurologic disease at risk for neurogenic bladder, in patients with other neurologic disease and elevated PVR or in patients with urinary symptoms. (*Recommendation*; Evidence Strength: *Grade C*)

13. Clinicians should perform electromyography (EMG) in combination with CMG with or without PFS in patients with relevant neurologic disease at risk for neurogenic bladder, in patients with other neurologic disease and elevated PVR or in patients with urinary symptoms. (*Recommendation*; Evidence Strength: *Grade C*)

LUTS

14. Clinicians may perform PVR in patients with LUTS as a safety measure to rule out significant urinary retention both initially and during follow up. *(Clinical Principle)*

15. Uroflow may be used by clinicians in the initial and ongoing evaluation of male patients with LUTS when an abnormality of voiding/emptying is suggested. (*Recommendation*; Evidence Strength: *Grade C)*

16. Clinicians may perform multi-channel filling cystometry when it is important to determine if DO or other abnormalities of bladder filling/urine storage are present in patients with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (*Expert Opinion*)

17. Clinicians should perform PFS in men when it is important to determine if *urodynamic* obstruction is present in men with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (*Standard*: Evidence Strength: *Grade B)*

18. Clinicians may perform PFS in women when it is important to determine if obstruction is present. (*Option*; Evidence Quality: *Grade C)*

19. Clinicians may perform videourodynamics in properly selected patients to localize the level of obstruction, particularly for the diagnosis of primary bladder neck obstruction. *(Expert Opinion)*

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INTRODUCTION

Purpose

Lower urinary tract symptoms (LUTS), which include urinary incontinence, are a common and significant source of impaired quality of life and comorbidity in large numbers of adults and children. Commonly, patients presenting with LUTS have overlapping symptoms and conditions, making an isolated or homogeneous source of symptoms rare. Clinicians evaluating these disorders collectively utilize history, physical examination, questionnaires and pad testing data in the evaluation of symptoms.

Urodynamics (UDS) is the dynamic study of the transport, storage and evacuation of urine. UDS is an interactive diagnostic study of the lower urinary tract composed of a number of tests that can be used to obtain functional information about urine storage and emptying. Physical examination and endoscopic evaluation are integral in determining the etiology of complex LUTS. However, urinary symptoms and physical findings often do not adequately predict the pathophysiology of LUTS. Following these assessments, *urodynamic questions* (*What is the information I need to obtain from UDS?* and *What is the most appropriate UDS technique to obtain these results?*) may be formulated, and subsequent completion of the most appropriate UDS test(s) often aid in diagnosis. The main goal of UDS is to reproduce the patients' symptoms and determine the cause of these symptoms by urodynamic measurements or observations. Furthermore, some conditions have minimal or no symptoms, yet urodynamic testing may be appropriate (e.g., certain neurological disorders). However, the current literature is deficient in Level-1 evidence, which could elucidate the precise indications for urodynamic testing. Many would agree that conservative, empiric, non-invasive treatment of LUTS without urodynamic testing is an appropriate practice.

This guideline is intended to review the literature regarding the use of urodynamic testing in common LUT conditions and present the clinician with principles of application and technique. As UDS is only one part of the comprehensive evaluation of LUTS, these findings are intended to assist the clinician in the appropriate selection of urodynamic tests following an appropriate evaluation and symptom characterization. At this point, the clinician may utilize the principles in these guidelines to formulate urodynamic questions and select the appropriate urodynamic tests. The literature is inconclusive and "pure" symptomatalogy is rare; therefore, this guideline will not specify whether UDS testing should be done routinely in SUI or LUTS. The intent of this guideline is to identify concurrent factors and conditions in these patients and make recommendations regarding appropriate urodynamic techniques in these settings.

Methodology

A systematic review was conducted to identify published articles relevant to the use of UDS in patients with various urologic conditions, disorders and symptoms. Literature searches were performed on English-language publications using the MEDLINE® and EMBASE databases from January 1, 1990 to March 10, 2011 using the terms "urodynamics," "stress incontinence," "mixed incontinence," "urge incontinence," "lower urinary tract dysfunction," "LUTS," "LUTD" as well as key words related to pelvic organ prolapse, and various neurological diseases and key words capturing the various urodynamic tests known to be used in patients suspected or known to have these conditions. For certain questions, the searches only covered studies published between January 1, 2000 and March 10, 2011. The latter includes questions relating to utility of cystometry for stress/urgency incontinence/mixed incontinence, LUTS or pelvic organ prolapse, utility of EMG for LUTS or pelvic organ prolapse and utility of any combination of urodynamic tests for stress/urgency/mixed incontinence or pelvic organ prolapse. Studies published after March 10, 2011 were not included as part of the evidence base considered by the Panel from which evidence-based guideline statements (Standards, Recommendations, Options) were derived. Data from studies published after the literature search cut-off will be incorporated into the next version of this guideline.

Preclinical studies (e.g., animal models), pediatric studies, meeting abstracts, commentary, editorials, non-English language studies and studies of adults with urological conditions and symptoms other than those

noted above were excluded. Studies with less than 10 patients were excluded from further evaluation and thus data extraction given the unreliability of the statistical estimates and conclusions that could be derived from them. Studies that did not report data separately for males and females for certain patient populations (e.g., incontinence, pelvic organ prolapse and LUTS) were excluded. Review article references were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only non-redundant information.

Urodynamic Tests, Conditions and Outcomes Reviewed During this Process. This systematic review evaluated the following urodynamic tests: post-void residual, uroflowmetry, cystometry, pressure-flow studies, videourodynamics, EMG, urethral function tests (e.g., Valsalva leak point pressure (VLPP), urethral pressure profile) or any combination of the above. The target populations comprised adults with stress incontinence, mixed incontinence, urgency incontinence, LUTS, pelvic organ prolapse or neurogenic bladder. Outcomes of interest were grouped into four categories: diagnosis, prognosis, clinical management decisions or patient outcomes. Any outcome measure that could be classified in one of these categories was considered acceptable for review. A total of 393 studies met the inclusion criteria and addressed some combination of urodynamic tests, target populations and diagnostic categories noted above. Relevant data from these studies were extracted and summarized in evidence tables which comprise part of the full evidence report (available upon request).

Quality of Studies and Determination of Evidence Strength. Quality of individual studies was rated as high, moderate or low based on instruments tailored to specific study designs. Randomized controlled trials (RCTs) were assessed using the Cochrane Risk of Bias tool.[1] Conventional diagnostic cohort studies, diagnostic case-control studies or diagnostic case series that presented data on diagnostic test characteristics were evaluated using the QUADAS tool [2] that evaluates the quality of diagnostic accuracy studies. Cohort studies with a comparison of interest were evaluated with the Drug Effectiveness Review Project instrument.[3] As there

is no widely agreed upon quality assessment tool for case series that do not present data on diagnostic test characteristics, the quality of individual case series was not formally assessed with an instrument. Instead, these studies were labeled as low quality due to their study design.

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design, individual study quality, consistency of findings across studies, adequacy of sample sizes and the generalizability of samples, settings and treatments for the purposes of the guideline. The AUA categorizes body of evidence strength as Grade A (well-conducted RCTs or exceptionally strong observational studies), Grade B (RCTs with some weaknesses of procedure or generalizability or generally strong observational studies) or Grade C (observational studies that are inconsistent, have small sample sizes or have other problems that potentially confound interpretation of data). As most of the available evidence consisted of low quality case series, the majority of evidence was considered Grade C.

AUA Nomenclature: Linking Statement Type to Evidence Strength. The AUA nomenclature system explicitly links statement type to body of evidence strength and the Panel's judgment regarding the balance between benefits and risks/burdens.[4] *Standards* are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade A or Grade B evidence. *Recommendations* are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade C evidence. *Options* are non-directive statements that leave the decision to take an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears relatively equal or unclear; the decision is based on full consideration of the patient's prior clinical history, current quality of life, preferences and values. *Options* may be supported by Grade A, B, or C evidence.

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To formulate evidence-based statements, the Panel used BRIDGE-Wiz (Building Recommendations In a Developer's Guideline Editor), a software application that employs natural language to create and populate a template for guideline statements. It limits verb choices, promotes active voice and incorporates decidability and executability checks to ensure creation of statements that are actionable by end users.[5]

In some instances, the review revealed insufficient publications to address certain questions from an evidence basis; therefore, some statements are provided as *Clinical Principles* or as *Expert Opinion* with consensus achieved using a modified Delphi technique if differences of opinion emerged.[6] A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge and judgment for which there may be no evidence.

Limitations of the Literature. The Panel proceeded with full awareness of the limitations of the urodynamics literature. These limitations include: poorly-defined or heterogeneous patient groups, small sample sizes, lack of studies with diagnostically accurate data, lack of controlled studies with patient outcome data and the use of a variety of outcome measures. Overall, these difficulties precluded use of meta-analytic procedures or other quantitative analyses. Instead, narrative syntheses were used to summarize the evidence for the questions of interest.

Peer Review. This document was submitted for peer review to 84 urologists and other healthcare professionals, and 39 provided input. After the final revisions were made, based upon the peer review process, the document was submitted to and approved by the Practice Guidelines Committee (PGC) and the Board of Directors of the American Urological Association (AUA). Peer review comments are available upon request.

Background

Description of tests. The urodynamic tests considered by the panel for this guideline are described below. All urodynamic tests and related nomenclature are consistent with International Continence Society (ICS) terminology where applicable.

Post-void residual (PVR) is the volume of urine left in the bladder at the completion of micturition. This can be measured by ultrasound or catheterization.

Uroflowmetry is the measurement of the rate of urine flow over time.

Cystometry is the method by which the pressure/volume relationship of the bladder is measured during bladder filling. Measurements obtained during cystometry include bladder sensations, compliance, bladder capacity and the presence or absence of detrusor overactivity (DO).

Electromyography (EMG) is the study of the electronic potentials produced by the depolarization of muscle membranes. In most UDS tests, EMG measurement of the striated sphincteric muscles of the perineum is done to evaluate possible abnormalities of perineal muscle function that are often associated with lower urinary tract symptoms and dysfunction.

Pressure flow studies (PFS) measure the relationship between pressure in the bladder and urine flow rate during bladder emptying.

Videourodynamic studies (VUDS) include the addition of simultaneous imaging (usually fluoroscopy) during cystometry and/or PFS.

Abdominal leak point pressure (ALPP) or Valsalva leak point pressure (VLPP) is a measurement of urethral function or outlet competence and is the intravesical pressure at which urine leakage occurs due to increased abdominal pressure in the absence of a detrusor contraction.

Urethral pressure profile is the continuous measurement of the fluid pressure needed to just open a closed urethra.

Maximum urethral closure pressure (MUCP) is the maximum difference between the urethral pressure and the intravesical pressure.

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Utility in clinical practice. The utility of UDS in clinical practice is not well-defined and, as noted earlier, level-1 evidence regarding universal indications for UDS is scant. The conduction of well-designed RCTs is challenged by lower levels of evidence and expert opinion that strongly suggests clinical utility and, more importantly, the potential risks of implementing empiric therapies without complete evaluation. Low pressure storage of urine is necessary in order to protect the upper urinary tracts and complete evacuation of urine in the appropriate setting is important. A number of conditions can affect and disrupt proper LUT function. Under these circumstances, UDS can offer objective measurements of bladder and urethral function to elucidate the diagnosis and guide treatment.

Given the current status of the literature, it is essential that, prior to proceeding with an invasive UDS study, the clinician has a clear question and indication for performing the test as well as an intention to utilize information gleaned from the study to guide therapy. The UDS study should be tailored to answer specific questions and should be interpreted in the context of the specific patient's history and presentation. Two clear categories of patients who may benefit from UDS studies include: (1) those in whom information beyond that obtained by a history, physical examination and basic tests is necessary in order to make an accurate diagnosis and direct therapeutic decisions, and (2) those whose LUT condition may have the potential to cause deleterious and irreversible effects on the upper urinary tracts. Marked functional and anatomic abnormalities can be present even in the absence of concomitant proportionate symptoms, particularly in patients with neurologic disease.

In general, the clinical utility of UDS has been nicely summarized for the following situations: (1) to identify factors contributing to LUT dysfunction and assess their relevance, (2) to predict the consequences of LUT dysfunction on the upper tracts, (3) to predict the consequences and outcomes of therapeutic intervention, (4) to confirm and/or understand the effects of interventional techniques and (5) to investigate the reasons for failure of a treatment or treatments.[7]

In clinical practice, the role of invasive UDS testing is not clearly defined. Urologists generally accept that conservative or empiric, non-invasive treatments may be instituted without urodynamic testing. Many types of urodynamic testing require urethral catheterization and include cystometry, PFS and VUDS including urethral function testing. Such testing subjects patients to risks of urethral instrumentation including infection, urethral trauma and pain. Thus, the clinician must weigh whether urodynamic tests offer additional diagnostic benefit beyond symptom assessment, physical examination and other diagnostic testing. Uroflowmetry and ultrasound PVR may be appropriate non-invasive tests given the clinical scenario and the options for treatment. In the evaluation and treatment of LUTS, the literature is scarce and inconsistent with data to elucidate the optimal role of urodynamics in guiding therapy. Whether such testing can improve outcomes with any intervention, including specific surgical procedures, or may improve overall surgical outcomes in uncomplicated patients is not clear. In more complicated/complex individuals with LUTS, there may be a role for various types of UDS testing in order to exclude complicating factors and potentially guiding therapy.

Description of Conditions. LUTS is a term utilized to represent a multifactorial constellation of nonspecific symptoms that affects both bladder filling and urine storage. Filling LUTS include urinary frequency, urgency, incontinence and nocturia. Incontinence is discussed separately from "LUTS" in this document. Voiding LUTS include slow stream, hesitancy, intermittency, incomplete bladder emptying and post-void or terminal dribbling. LUTS is considered by some to represent the symptom complex previously referred to as "prostatism," (benign prostatic hyperplasia (BPH), enlarged prostate) and indeed is more commonly, albeit not exclusively, applied to male symptoms. For the purposes of this document, LUTS is applicable to both men and women and encompasses symptoms related to and often occurring secondary to a degree of outlet obstruction whether it be due to prostatic enlargement or a previous anti-incontinence procedure. Also important is the not-so-infrequent situation in which irritative LUTS may co-exist with obstructive LUTS and may cloud the assessment, thereby making diagnosis

difficult.

Stress urinary incontinence (SUI) exists as a symptom, sign and condition. The observation of SUI during urodynamics (urodynamic SUI) is defined as the finding of involuntary leakage during filling cystometry associated with increased intra-abdominal pressure in the absence of a detrusor contraction. The symptom of SUI is the *complaint* of involuntary loss of urine on effort or physical exertion (e.g., sporting activities) or on sneezing or coughing. This is to be differentiated from the sign of SUI, which is the *observation* of involuntary leakage from the urethra synchronous with effort or physical exertion or on sneezing or coughing.[7]

SUI may co-exist in the setting of pelvic organ prolapse (POP). POP is a condition occurring exclusively in females and is defined as the descent of one or more of the anterior vaginal wall, posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar after hysterectomy).[7] Occult SUI is defined as stress incontinence observed only after the reduction of co-existent prolapse. A significant proportion of women with high grade POP who do not have the symptom of SUI will be found to have occult SUI.

Overactive bladder (OAB), urgency urinary incontinence (UUI) and mixed urinary incontinence are symptom complexes that include a component of urinary urgency with or without incontinence in the absence of infection or other pathology. Urgency is the sudden uncontrollable desire to void that is difficult to defer and may or may not be associated with urinary incontinence. Mixed incontinence is the combination of SUI and urge incontinence (see below). OAB is defined as a syndrome in which several of the storage-related LUTS coexist with urgency being the principal and essential parameter. By definition, at least one parameter must exist in addition to the urgency in order to diagnose OAB. Patients will often describe urinary frequency with low-volume voids. Nocturia is a more variable part of the OAB complex and usually has a multifactorial etiology. Patients with nocturia as a primary symptom that significantly affects quality of life require separate investigation as to cause and treatment and are beyond

the scope of this guideline.

While OAB is a symptom-based diagnosis, DO is a urodynamic diagnosis characterized by an involuntary detrusor contraction during the filling phase of cystometry, which only occurs in a portion of patients with OAB. Although DO is often associated with OAB since its symptoms overlap those of the OAB diagnosis, the terms are not interchangeable, and DO is not required to make the diagnosis of OAB.

There are several theories regarding the pathophysiology of OAB and DO, and it is theorized that not all patients with symptoms of urinary urgency share the same pathophysiology. The neurogenic hypothesis attributes DO to nerve-mediated excitation of the detrusor muscle. The myogenic hypothesis suggests that uninhibited contractions occur as a result of spontaneous excitation within the bladder smooth muscle and propagation of these impulses through the bladder wall. Contributions of the urothelial cells and the afferent pathways have also been explored extensively and continue to be the subject of much scholarly activity. The afferent Aδ-fibers are thought to convey bladder filling information and respond to passive bladder distention and active detrusor contractions. The C-fibers respond to noxious chemical irritation or thermal stimuli. Inappropriately high activity of any of these fibers may contribute to OAB.

Neurogenic Bladder (NGB) refers to the disturbance of normal bladder function as a result of neurologic disease. Many neurologic conditions can be associated with NGB; however, the more commonly known conditions of which urologists and lower urinary tract specialists should be particularly aware include: spinal cord injury (SCI), multiple sclerosis, Parkinson's disease, stroke/cerebrovascular accident, traumatic brain injury, myelomeningocele (MMC), brain or spinal cord tumor, transverse myelitis, back or spine disease (including herniated disk, cauda equina syndrome), diabetes, peripheral nerve injury and other lower motor neuron diseases. Neurogenic bladder dysfunction can include problems of bladder storage (including ability to maintain continence) as well as bladder emptying and also introduces the concern of NGB-induced damage to the upper genitourinary (GU) tracts as a result of

sustained elevation in storage pressures. Damage to the upper tracts can include hydronephrosis and hydroureter, vesico-ureteral reflux, reflux nephropathy, urinary tract infections (UTI) and pyelonephritis. In addition, infectious complications can arise from NGB induced alterations in storage and emptying.

An additional concern specific to patients with NGB is the possible presence of autonomic dysreflexia (AD). AD is usually limited to SCI (T6 level and above) and is considered an exaggerated sympathetic response to afferent visceral or painful stimulation, which can have severe and life threatening consequences. Symptoms of AD include flushing, sweating above the level of injury, headache, severe hypertension and reflex bradycardia that can ultimately be lethal due to intracranial hemorrhage if not recognized or treated appropriately.[8] Typical triggers of AD include bladder distention, bowel distention, instrumentation of the lower urinary or GI tract as well as any neurologic noxious stimuli below the level of the SCI. The GU tract instrumentation needed to perform UDS along with the necessary bladder distention are both well-known culprits for triggering AD. For this reason, the specialist who performs UDS on patients who are at risk of AD must be prepared to monitor, promptly detect and initiate rapid treatment in the event AD occurs.

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GUIDELINE STATEMENTS

SUI/Prolapse

Guideline Statement 1.

Clinicians who are making the diagnosis of urodynamic stress incontinence should assess urethral function. (*Recommendation*; Evidence Strength: *Grade C*)

Urethral function should be assessed when invasive UDS testing is performed for the assessment of SUI. During invasive UDS testing, the clinical tools necessary for assessment of urethral function (e.g., intravesical catheter) are already in place and, in patients with urodynamic SUI, a quantitative assessment such as VLPP should be performed synchronously with the demonstration of urodynamic SUI. Although the clinical utility of such a measurement is controversial, it may provide useful information in certain situations.

Although not a universal finding, poor urethral function, as suggested by lower cough leak point pressure (CLPP), VLPP/ALPP,[9-16] and/or MUCP[11,17-21] tends to predict less optimal outcomes with some types of therapy. Some clinicians may utilize information about urethral function obtained from an invasive UDS exam to guide surgical treatment decisions. In such situations, an assessment of urethral function such as VLPP testing has clinical value and should be performed. For example, some clinical data suggest that certain anti-incontinence surgical procedures may have inferior outcomes in patients with low VLPP and/or low MUCP.[22, 23] In such cases, urethral function testing will potentially influence the choice of surgery.

While CLPP has been reported to be superior in demonstrating urodynamic SUI as compared to VLPP/ALPP,[24] both maneuvers can easily be performed to provide maximal information during routine invasive UDS.

Guideline Statement 2.

Surgeons considering invasive therapy in patients with SUI should assess PVR urine volume. (*Expert Opinion*)

Prior to performing invasive therapy for the treatment of SUI, clinicians should assess PVR urine volume.

Although most studies have not demonstrated a clear association between PVR and treatment outcomes, PVR assessment is important for several reasons.

PVR assessment, particularly if the PVR is elevated, can provide valuable information to the clinician and patients during consideration of treatment options. An elevated PVR is suggestive of detrusor underactivity, bladder outlet obstruction (BOO) or a combination of both. The exact clinical definition of "elevated" PVR volume remains unclear as does the optimal method of measurement (e.g., catheter, ultrasound). Nevertheless, patients with elevated preoperative PVR may be at an increased risk for transient or permanent postoperative voiding difficulties following urethral bulking injection therapy or SUI surgery. Additionally, postoperative urinary retention is not well defined, particularly regarding the volume and timing of urination in the postoperative period. Individuals who chronically carry an elevated residual volume or remain in chronic urinary retention are at increased risk of sequelae related to incomplete emptying such as ongoing voiding dysfunction, stone disease and recurrent UTIs.[25]

Assessment of postoperative PVR can be helpful in evaluating new onset postoperative voiding dysfunction, and, ideally, a preoperative PVR should be available for comparison. For example, if patients present with new obstructive or OAB symptoms after anti-incontinence surgery that are suggestive of BOO, an elevated PVR (as compared to the preoperative value) may be one of the findings that supports such a diagnosis. Although de novo postoperative BOO may not be associated with an elevated PVR in all cases, this finding can be helpful in directing further diagnostic testing and/or treatment.

Assessment of PVR is generally safe and inexpensive but can be associated with several pitfalls. A single elevated PVR should not be considered a satisfactory assessment of bladder emptying ability. For example, a falsely elevated PVR may result from rapid diuresis or psychogenic inhibition (e.g., patient difficulty with emptying due to environmental factors), amongst other factors. Thus, an elevated PVR should be confirmed with a second measurement at a subsequent office

visit.

A PVR can be obtained in the office by bladder ultrasound or urethral catheterization. Ultrasound is less invasive and painful than catheterization and does not introduce the risk of infection or urethral trauma. However, portable office ultrasound bladder scanners have a measure of operator independence and can be inaccurate in several clinical circumstances including obesity, prior lower abdominal surgery, cystic pelvic pathology, pregnancy, peritoneal dialysis and in the setting of ascites.

Guideline Statement 3.

Clinicians may perform multi-channel urodynamics in patients with both symptoms and physical findings of stress incontinence who are considering invasive, potentially morbid or irreversible treatments. (*Option*; Evidence Strength: *Grade C*)

Multi-channel UDS are a preoperative option for patients considering surgical therapy for SUI. While urodynamic assessment may provide valuable information for some clinicians in stress incontinent patients who are considering definitive therapy, UDS are not absolutely necessary as a component of the preoperative evaluation in uncomplicated patients. In such patients (previously defined as one who has symptoms and signs of SUI with no relevant prior surgery, no neurological history or symptoms, no major health concerns and no other pelvic pathology (e.g., POP) or other LUTS such as frequency, urgency, UUI, or nocturia), direct observation of urinary leakage with coughing or straining on physical examination may provide an adequate urethral assessment. UDS can be considered an option in the evaluation of such patients.[26]

Information obtained from a multichannel UDS study may confirm or refute a diagnosis made based on history, physical examination and stress test alone. UDS may also facilitate specific treatment selection and provide important data that promotes full and accurate preoperative counseling of patients. Thus, prior to performing invasive, potentially morbid or irreversible treatment for SUI, clinicians may choose to obtain such

studies in selected patients, and they may be particularly helpful in complicated patients.

Multichannel UDS has not been shown to correlate with outcomes of various interventions for SUI.[27,28] However, UDS may alter the choice of therapy[27] or provide guidance in patient selection to minimize the incidence of some postoperative voiding symptoms.[28] With the addition of fluoroscopy to the UDS (VUDS), the reliability of the study for diagnosis of SUI and in assessing for concurrent conditions (e.g., BOO secondary to POP) may be enhanced.[29] Although the literature is mixed with regard to specific treatment selection based on UDS parameters, clinicians may need to adjust the treatment plans if the UDS studies suggest findings other than those which were expected based on history and physical examination alone, such as lack of SUI, DO or incomplete emptying.

Guideline Statement 4.

Clinicians should perform repeat stress testing with the urethral catheter removed in patients suspected of having SUI who do not demonstrate this finding with the catheter in place during urodynamic testing. (*Recommendation*; Evidence Strength: *Grade C*)

Patients who do not demonstrate SUI during Valsalva maneuvers or cough during urodynamics but who nevertheless complain of SUI symptoms *or* in whom SUI is suspected based on their history *or* in whom the presence of documented SUI would change their management, should have the urethral catheter removed and the Valsalva or cough testing repeated. A fundamental tenet of good urodynamic practice is to ensure that testing reproduces the patients' symptoms. If urodynamic testing does not demonstrate SUI in patients who complain of the symptom of SUI, it may not necessarily indicate that they do not have SUI, but may in fact suggest that the testing did not fully replicate symptoms.

Some patients with SUI demonstrated during physical examination will not have such findings during UDS with the urethral catheter in place.[30-32] Removal of the urethral catheter will allow demonstration or "unmasking" of SUI in many of these individuals with

repeat stress maneuvers. Over 50% of women with symptoms of SUI who do not demonstrate SUI with the urethral catheter in place will do so when it is removed.[30] One study found that 35% of men with post-prostatectomy incontinence did not demonstrate SUI until after catheter removal.[32] Removal of the urethral/intravesical catheter renders the measured LPP to be based on the true intraabdominal pressure, which in most cases should very closely approximate the intravesical pressure.

In patients for whom the urethral catheter is removed in order to make the diagnosis of urodynamic SUI, replacement of an uncontaminated urethral catheter should be considered to allow for completion of the pressure-flow (voiding) portion of the test. Additionally, the pressure-flow study may be completed and the bladder then re-filled to an acceptable volume. The catheter may then be removed and the LPP measured. The risks/harms of removing the catheter for LPP testing include loss of the ability to measure intravesical pressure at the time of stress leakage, the additional risk of UTI or trauma as a result of catheter removal and reinsertion and the additional time and potential expense if the catheter becomes contaminated.

Guideline Statement 5.

In women with high grade POP but without the symptom of SUI, clinicians should perform stress testing with reduction of the prolapse. Multi-channel urodynamics with prolapse reduction may be used to assess for occult stress incontinence and detrusor dysfunction in these women with associated LUTS. (***Option**; Evidence Strength: Grade C*)

Occult SUI is defined as stress incontinence observed only after the reduction of co-existent prolapse. A significant proportion of women with high grade POP who do not have the symptom of SUI will be found to have occult SUI.[33-37] If the presence of SUI would change the surgical treatment plan, stress testing with reduction of the prolapse to evaluate for occult SUI should be performed.[37-39] This can be done independently or during urodynamic testing. Prolapse can be reduced with a number of tools including but not

limited to a pessary, a ring forceps or a vaginal pack. Manual prolapse reduction during stress testing is not recommended as this will inaccurately assess VLPP. During such testing, the investigator should be aware that the instrument utilized for POP reduction may also obstruct the urethra creating a falsely elevated VLPP or prevent the demonstration of SUI.

Multi-channel UDS can also assess for the presence of detrusor dysfunction in women with high grade POP. Some patients with high grade POP may have an elevated PVR or be in urinary retention. UDS with the POP reduced may facilitate evaluation of detrusor function and thus determine if the elevated PVR/retention is due to detrusor underactivity, outlet obstruction or a combination of both. Invasive UDS may be performed both with and without reduction of the POP to evaluate bladder function. This may be helpful in the prediction of postoperative bladder function once the POP has been surgically repaired.[40,41]

Overactive Bladder (OAB), Urgency Urinary Incontinence (UUI), Mixed Incontinence

Guideline Statement 6.

Clinicians may perform multi-channel filling cystometry when it is important to determine if altered compliance, detrusor overactivity or other urodynamic abnormalities are present (or not) in patients with urgency incontinence in whom invasive, potentially morbid or irreversible treatments are considered. (***Option**; Evidence Strength: Grade C*)

Cystometry is the foundation in the assessment of urinary storage. When performing filling cystometry, a multi-channel subtracted pressure is preferred over a single-channel cystometrogram, which is subject to significant artifacts of abdominal pressure. In many uncomplicated cases, employing conservative treatments and empiric medical therapy for OAB without a urodynamic diagnosis is common and prudent practice. In patients with urinary urgency and/or urgency incontinence, filling cystometry, which provides subtracted pressure measurements, is the most accurate method in determining bladder pressure. In patients with urinary storage symptomatology, multi-

channel filling cystometry offers the most precise method of evaluating bladder storage pressures. The main urodynamic findings of OAB are DO (phasic and tonic) and increased filling sensation. DO is characterized by involuntary phasic rises in detrusor pressure during filling, which may be associated with urinary leakage. Tonic abnormalities of compliance are fortunately easier to measure and do appear on cystometry more readily. Compliance assessment is a very important measurement in patients with neurogenic conditions at risk for upper urinary tract complications as a result of high-pressure urinary storage. If significantly elevated storage pressures are encountered in these patients, treatments should be administered with the goal of lowering storage pressure in order to decrease the risk of upper and lower urinary tract decompensation. Increased filling sensation is determined by increasing sensations of bladder filling at low volumes in the absence of involuntary bladder contractions, which ultimately results in decreased functional bladder capacity in most cases. The patient communicates these sensations interactively with the clinician, and leakage is usually not present.

The diagnosis of DO is not always made during UDS, even in those patients in whom it is known to exist, as it may be limited by technical factors or the suboptimal sensitivity and specificity of DO detection during sedentary filling cystometry. It is generally well accepted that patients with urgency incontinence often demonstrate DO on urodynamic evaluations, but do not uniformly have this finding. DO may also occur on urodynamics and not be well correlated with symptoms. Poor compliance may not be detected in cases of outlet incompetence. Thus, when patients have an incompetent outlet, compliance assessment should be accomplished after successful occlusion of the outlet. As such, urodynamic evaluation must always be considered within the context of symptoms and overall patient assessment.

UDS may have a role in the clinical circumstances in which conservative and drug therapies fail in patients who desire more invasive treatment options for OAB. Patients with OAB may have concomitant findings on UDS that affect the ultimate treatment decision. A patient with urgency incontinence may have concomitant urodynamic diagnoses of SUI or BOO. These factors must be taken into consideration when considering treatment options for refractory urgency incontinence, as their correction may greatly improve the symptoms related to urinary urgency.

In the setting of mixed urinary incontinence, UDS may contribute by aiding in symptom correlation. In addition, these studies assist by identifying and quantifying bladder and urethral abnormalities of urine storage. These studies are also useful to determine if other complicating factors are present that may affect treatment decisions. However, due to the multifactorial nature of mixed urinary incontinence, these tests may not precisely predict outcomes of treatment.[42-46]

Guideline Statement 7.

Clinicians may perform PFS in patients with urgency incontinence after bladder outlet procedures to evaluate for bladder outlet obstruction. *(Expert Opinion)*

Symptoms of bladder storage failure are a source of decreased patient satisfaction following treatment for SUI. It is imperative to determine the etiology of these symptoms as urinary obstruction, urethral injury, bladder injury and urethral erosion may present with storage symptoms. In addition to a comprehensive assessment and endoscopic examination, urodynamic testing may be useful. PVR volumes alone cannot diagnose outlet obstruction. The clinician should consider pressure flow testing to assess for BOO in patients with refractory urgency symptoms after a bladder outlet procedure. Although there is no urodynamic standard for obstruction and the classical "high pressure/low flow" pattern characteristic of male BOO may not be found in obstructed women, the finding of an elevated detrusor voiding pressure in association with low flow may suggest obstruction, particularly in the presence of new onset filling/storage or emptying symptoms after surgery. In patients found to be obstructed, sling incision or urethrolysis may be beneficial and is frequently associated with symptom resolution. In women with significant elevations in PVR, urinary retention or definite alterations in voiding symptoms following an anti-incontinence procedure, these findings strongly imply BOO, and urodynamics

may not be necessary before intervention.

Guideline Statement 8.

Clinicians should counsel patients with urgency incontinence and mixed incontinence that the absence of DO on a single urodynamic study does not exclude it as a causative agent for their symptoms*. (Clinical Principle)*

The technical reasons for the inability to elicit the finding of DO in certain individuals, whether spontaneous or provoked, are unclear. Thus, it is very important to attempt to replicate symptoms as precisely as possible. Despite this, UDS may not diagnose DO even in patients who are very symptomatic. Therefore, urodynamic findings should be interpreted in the context of the global assessment, including examination, diaries and residual urine as well as other pertinent information. Additionally, it is equally prudent in many cases to reserve urodynamic testing until after a failed empiric treatment or following consideration of a form of invasive therapy. In these situations, UDS is equally important in determining the presence or absence of other factors (e.g., SUI, BOO) that could influence treatment decisions.

Neurogenic Bladder (NGB)

Guideline Statement 9.

Clinicians should perform PVR assessment, either as part of complete urodynamic study or separately, during the initial urological evaluation of patients with relevant neurological conditions (such as spinal cord injury and myelomeningocele) and as part of ongoing follow-up when appropriate. (*Standard;* Evidence Strength: *Grade B*).

Patients with a variety of neurological conditions may develop bladder dysfunction either early in the course of the disease or as the disease progresses. In these patients, PVR is a useful tool for assessing the possibility of significant bladder and/or outlet dysfunction. In some cases such as SCI, the neurogenic bladder condition that ensues occurs abruptly, and after an initial period of stabilization

(spinal shock), the resultant bladder function tends to be fairly fixed. In other cases, there tends to be progression of bladder dysfunction as the disease progresses (e.g., multiple sclerosis (MS), Parkinson's disease (PD)), although there exists considerable variability. In some conditions, bladder dysfunction occurs early, often before other neurological sequelae (multiple systems atrophy). In many conditions, perhaps none more notable than cerebrovascular accident, the development of bladder dysfunction can be profound, but the additional presence of mobility disturbances often clouds the issue of those symptoms that are due to neurogenic bladder versus functional disturbances. Notably, patients with these conditions and others (e.g., MMC, cervical myelopathy, childhood history of posterior urethral valves, transverse myelitis, disc disease) may not have classic lower urinary tract symptoms. Therefore, evaluation with PVR assessment is appropriate both at the time of diagnosis and after to monitor for changes in bladder emptying ability periodically regardless of the symptoms or at the discretion of the physician. In addition to those mentioned, other systemic conditions/treatments may affect bladder function. Among those most commonly mentioned are diabetes mellitus, chronic alcohol use, AIDS and radical pelvic surgery.[47-52]

PVR assessment has been shown to influence treatment planning in a variety of neurological conditions. While the definition of elevated residual has varied (usually either a specific volume or proportion of overall bladder volume), the finding of elevated residual urine volume may influence decision making.[53-55] The implications of an elevated PVR in neurogenic voiding dysfunction include the development of UTI's, urosepsis, upper tract deterioration and stone disease. The implementation of intermittent catheterization or consideration for surgical intervention to reduce PVR may be appropriate once the cause of elevated residual is determined. In this regard, the use of PVR may serve as a useful screening tool in patients who have already undergone complete urodynamic testing to determine the need for re-assessment and/or change in bladder management.

Ultimately, PVR results alone may not be sufficient to make certain management decisions without additional information (e.g., bladder compliance or poor detrusor

contractility) obtained from a multichannel urodynamic study.

Guideline Statement 10.

Clinicians should perform a complex cystometrogram (CMG) during initial urological evaluation of patients with relevant neurological conditions with or without symptoms and as part of ongoing follow-up when appropriate. In patients with other neurologic diseases, physicians may consider CMG as an option in the urological evaluation of patients with LUTS. (*Recommendation*; Evidence Strength: *Grade C*)

Patients with a variety of neurological conditions can develop significant bladder dysfunction that may dramatically impact quality of life and renal function. While the interval of repeated CMG testing is debatable and often dependent on the findings of initial testing and/or patients' responses to initial interventions, CMG is recommended at the time of initial consultation (or after the spinal shock phase in the case of SCI) of patients for neurogenic bladder conditions due to SCI and MMC and others thought to be at risk for the development of renal impairment. Performance of a CMG in patients with these and other neurological conditions will give an accurate assessment of detrusor dysfunction[56] (e.g., neurogenic DO, hyporeflexia, areflexia, altered compliance) and may provide guidance as to appropriate management strategies.[57, 58] The maintenance of low intravesical pressures is a clinical tenet initially reported in MMC patients that has been adopted for other neurological conditions such as SCI. As such, CMG provides diagnostic, therapeutic and prognostic information in patients with SCI and MMC. The utility of CMG in other neurological conditions (e.g., MS, PD, and CVA) is less clear, specifically regarding preservation of renal function. However, CMG remains an option for the better evaluation of detrusor dysfunction in these disease processes and has been shown to accurately diagnose detrusor dysfunction in these subgroups.[50,59-64] Patients with neurological diseases such as MS, PD, and CVA who do not respond symptomatically to initial medical management or who develop voiding dysfunction/ impaired bladder emptying as a result of the disease

process or treatments for bladder dysfunction may benefit from CMG testing, which allows for better diagnostic acumen and appropriate therapeutic intervention.

The benefits of CMG must be weighed against the potential risks imposed especially in this population. While UDS typically carry risks of bleeding, discomfort and infection, the patient with NGB may be particularly prone to risk of infection due to the voiding disorder itself, which might be exacerbated by CMG. Perhaps more important is the concern of causing AD, which is well known in the NGB patient due to SCI and can be life threatening. The panel's consensus is that the clinician who performs CMG in the patient at risk for AD be adept in its detection and prompt management, including having necessary monitoring equipment and the ability to provide quick drainage and pharmacologic intervention when necessary.

Guideline Statement 11.

Clinicians should perform pressure flow analysis in patients with relevant neurologic disease with or without symptoms, or in patients with other neurologic disease and elevated PVR or urinary symptoms. (*Recommendation*, Evidence Strength: *Grade C*)

PFS are an appropriate component of the work-up of NGB. This is especially true for those patients thought to be at risk for or found to have elevated PVR, hydronephrosis, pyelonephritis, complicated UTIs and frequent episodes of AD. This study can accurately distinguish between BOO and detrusor hypocontractility/acontractility.[65,66] It is also valid for those patients who seek management for voiding disorders caused by NGB as a means to help delineate possible treatment options as well as monitor treatment outcomes.

Voiding disorders in this patient population can be caused by a variety of factors due to the NGB. Complicating matters even further is the possibility that "normal" pathophysiologic processes (e.g., BPH, OAB, incontinence) can often co-exist in the patient with NGB. Use of PFS for diagnostic purposes is especially pertinent in this population as the underlying neurologic

disease could impact or obscure patient symptomology.[61] The assessment of whether the voiding disorder is due to BOO versus weakened or absent detrusor function can be readily determined by PFS.[64,65] PFS was also reported to be beneficial in the assessment of LUTS when NGB was present along with co-existing OAB and/or diabetes.[67,68]

No relevant studies were identified either supporting or refuting the use of PFS for guiding clinical management or improving outcomes. However, the consensus amongst the panel is that PFS do have a role in this regard. Specifically, the panel concludes that PFS provide a more reliable identification of the voiding disorder, which can then direct specific treatment options and can be used for monitoring the treatment outcome. For example, in the patient with NGB, elevated PVR and frequent episodes of AD, the detection of detrusor external sphincter dyssynergia (DESD) using PFS, fluoroscopy and EMG might lead the clinician to implement better mechanisms of bladder drainage and treatments for the prevention of bladder contractions.

The benefits of PFS must be weighed against the potential risks imposed especially in this population. While UDS typically carry risks of bleeding, discomfort and infection, patients with NGB may be particularly prone to risk of infection, which might be exacerbated by PFS. Perhaps more important is the concern of causing AD, which is well known in the NGB patient due to SCI and can be life threatening. The panel's consensus is that the clinician who performs PFS in the patient at risk for AD be adept in its detection and prompt management, including having necessary monitoring equipment and the ability to provide quick drainage and pharmacologic intervention when necessary.

Guideline Statement 12.

When available, clinicians may perform fluoroscopy at the time of urodynamics (videourodynamics) in patients with relevant neurologic disease at risk for neurogenic bladder, or in patients with other neurologic disease and elevated PVR or urinary symptoms. (*Recommendation*; Evidence Strength: *Grade C*)

The use of simultaneous fluoroscopy with contrast-based UDS is an appropriate component in the urodynamic assessment of patients with NGB. The ability to assess the lower and upper urinary tract with simultaneous fluoroscopic imaging improves the clinician's ability to detect and understand underlying pathologies. Visual assessment aids clinicians in their ability to delineate specific sites of obstruction, identify the presence and grade of vesicoureteral reflux as well as the urodynamic parameters that are present at the time of reflux, identify anatomic and physical abnormalities of the bladder such as bladder diverticula, bladder outlet abnormalities, and bladder stones and provide a more accurate means to diagnose DESD, detrusor bladder neck dyssynergia, and specific conditions (e.g., primary bladder neck obstruction (PBNO) and dysfunctional voiding).

VUDS has been found to improve the diagnostic evaluation of patients with NGB. VUDS permits diagnosis of bladder neck abnormalities in patients with NGB due to a variety of different neurologic conditions and in some cases may help distinguish the etiology of NGB with respect to the underlying neurological disease.[50,69]

No relevant studies were found either supporting or refuting the use of VUDS to improve prognosis, clinical decision making or patient outcomes. Consensus amongst the panel confirmed that the addition of simultaneous fluoroscopy during CMG and PFS provided additional worthwhile information regarding the diagnosis beyond what either study alone could provide. Therefore, VUDS should be considered by the clinician when evaluating the patient with NGB. For example, in a patient with NGB, high PVR, urinary incontinence and hydronephrosis, the use of VUDS could delineate if vesicoureteral reflux was present and causing the hydronephrosis, if leakage was occurring due to storage problems or an incompetent outlet, whether obstruction was present or not and if so, specifically where the obstruction was localized and whether the obstruction was caused by DESD.

The benefits of VUDS must be weighed against the potential risks, especially in this population. The risks of infection, bleeding, discomfort and especially AD have

been previously mentioned. It is believed that these risks are more likely related to the other components of urodynamic testing, and the addition of fluoroscopic studies does not increase these risks. Although the radiation dosage of videourodynamic studies is low, radiation exposure is additive. These studies should be done in a manner which provides the desired clinical information at the lowest possible radiation dose to the patient.

Guideline Statement 13.

Clinicians should perform EMG in combination with CMG with or without PFS in patients with relevant neurologic disease at risk for neurogenic bladder, or in patients with other neurologic disease and elevated PVR or urinary symptoms. (*Recommendation*; Evidence Strength: *Grade C*)

Preservation of urinary tract integrity remains a primary goal in the long-term management of patients with neurogenic bladder. Patients presenting with abnormal compliance, DESD and hydronephrosis are at higher risk for developing deterioration of renal function. EMG testing is a useful modality to assist in the diagnosis of DESD,[50, 65, 70,71] which is characterized by involuntary contractions of the external sphincter during detrusor contraction. The most important information provided by the EMG is the determination of whether perineal contractions are coordinated or uncoordinated with detrusor contractions.[72-75] Knowledge of this condition is important, as management should be initiated to lower urinary storage pressures and assure adequate bladder emptying.[71]

The signal source for measurement of EMG activity is the activity of the external urethral sphincter, the external anal sphincter and the pelvic floor musculature. The two most commonly used sources of measurement are surface electrodes and concentric needle electrodes. Needle placement may be a significant source of discomfort for patients, and reproducibility may be an issue without significant operator experience. The surface electrode has the advantage of ease (reproducibility) of placement and patient comfort. Although the signal source is less specific, surface electrodes can provide a good quality signal if properly used. The practical application of EMG

involves determination of whether the perineal muscles are relaxed or contracting. The most important information provided by the EMG is the determination of whether perineal contractions are coordinated or uncoordinated with detrusor contractions.[71-74]

The major limitation of EMG testing is that this is a technically challenging, non-specific component of urodynamic testing. Artifacts are common, and interpretation of EMG requires close interaction between the clinician and the patient. The clinician must have a clear understanding of the history and any relevant physical findings. EMG alone rarely makes the diagnosis of an uncoordinated sphincter. The EMG diagnosis is taken into context with fluoroscopy, cystometry and flow rate in order to obtain the most accurate diagnosis.

LUTS

Guideline Statement 14.

Clinicians may perform PVR in patients with LUTS as a safety measure to rule out significant urinary retention both initially and during follow up. (*Clinical Principle*)

PVR may be elevated due to detrusor underactivity, BOO or a combination thereof. Thus, an elevated PVR is a non-specific indication of poor bladder emptying. For example, while men with LUTS and benign prostatic obstruction (BPO) may have an elevated PVR, an elevated PVR in isolation does not necessarily predict the presence of obstruction.[50,69] PVR alone cannot be used to differentiate between obstructed and non-obstructed patients. Furthermore, there is no agreed upon standard definition of exactly what constitutes an elevated PVR.

In general, urologists agree that in some patients an elevated PVR may be harmful. The potentially harmful impact of a large PVR has been derived from the experience in the pediatric population, the elderly, diabetics and neurogenic patients. It is not clear which patients with an elevated PVR and LUTS without any of these conditions are predisposed to harm. Furthermore, there are no relevant studies that have identified the usefulness of PVR for guiding clinical management,

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improving patient outcomes in patients with LUTS or predicting treatment outcomes in men and women.

The potential benefits of measuring PVR include the identification of patients with significant urinary retention and decreasing potential morbidity, including UTIs and upper tract damage. In such patients, the identification of an elevated PVR can facilitate selection and implementation of treatment as well as monitor treatment outcomes. While no conclusive evidence exists to support or refute the use of PVR to predict the outcome of LUTS treatment, it may be used on the basis of expert opinion as a safety measure to evaluate for significant urinary retention both initially and during subsequent monitoring.

The risks/harms of assessing PVR using catheterization are low and include UTI or urethral trauma. These risks can be eliminated with ultrasound determination of PVR. However, measurement of PVR may be associated with false positives and negatives and thus could lead to inappropriate treatment. Therefore, it is recommended that decisions not be based on a single measurement.

Guideline Statement 15

Uroflow may be used by clinicians in the initial and ongoing evaluation of male patients with LUTS that suggest an abnormality of voiding/ emptying. (*Recommendation*; Evidence Strength: *Grade C*)

Uroflow measurement is a non-invasive urodynamic assessment that provides an objective and quantitative indication of the integration of bladder function and the outlet. Like PVR, uroflowmetry is limited by its inability to distinguish between a low flow rate due to outlet obstruction, bladder underactivity or both. Significant abnormalities in uroflow are indicative of a dysfunction in the voiding phase of the micturition cycle. In addition, because uroflow is dependent on voided volume, there may be significant variability of measured uroflows in the same patient. In males different studies have shown variability in the diagnostic accuracy of uroflow for detecting BOO ranging from moderately high to low.[76-81] The reported variability may be due to the variety of Qmax

thresholds and reference standards used in the literature with no clear answer regarding the ideal threshold and reference standard.

Although the literature reviewed fails to specifically identify clinical scenarios when uroflowmetry is useful, the panel believes that this test has value in the evaluation of disorders of voiding, even if further testing is required to make a specific diagnosis. Uroflowmetry can also be used for monitoring treatment outcomes and correlating symptoms with objective findings. Risks/harms of uroflowmetry include false positives and negatives, which may lead to inappropriate treatment. Uroflow results should be interpreted in light of the potential effects of artifact. Clinicians should be aware that uroflow studies (both peak and mean) can be affected by the volume voided and the circumstances of the test. Serial uroflowmetry measurements which are consistent, similar and comparable provide the most valuable information for the clinician. Furthermore, uroflowmetry should ideally correlate with the patient's symptomatology.

Based on the current literature and the relative ease of measurement of uroflow, the panel supports the use of uroflowmetry in the initial diagnosis and follow-up of LUTS in men. The correlation of urinary symptoms and uroflow in women is not as well understood.

Guideline Statement 16.

Clinicians may perform multi-channel filling cystometry when it is important to determine if DO or other abnormalities of bladder filling/urine storage are present in patients with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (*Expert Opinion*)

The role of filling cystometry and the finding of DO in predicting treatment outcomes remain controversial. No relevant studies that met the inclusion criteria were identified regarding the usefulness of cystometry for guiding clinical management in patients with LUTS. For some conditions associated with LUTS (e.g., DO), cystometry is the diagnostic standard. However, cystometry often fails to explain symptoms,[82] and the reproducibility of finding DO from one study to another

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in the same patient can vary if the studies are performed consecutively[56] or on different days.[83] Many studies have attempted to use cystometry to help determine prognosis after various treatments for LUTS in men and women.[84-91] However, there is considerable variation in these studies with respect to the central thesis, and the findings revealed no apparent trends. Although the presence or absence of DO has not been shown to consistently predict specific treatment outcomes, the panel believes that there are instances when a particular treatment for LUTS might be chosen or avoided based on the presence of DO and, more importantly, impaired compliance. The panel felt that this could be particularly important when invasive or irreversible treatment is planned as it could aid in patient counseling. While there are no data to support or refute this recommendation, the panel believes that for many clinicians the presence of DO or impaired compliance remains an important piece of information in dictating treatment.

Guideline Statement 17.

**Clinicians should perform PFS in men when it is important to determine if *urodynamic* obstruction is present in men with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (*Standard*; Evidence Strength: *Grade B)*

BOO in men is a urodynamic diagnosis. This may or may not be associated with obstruction from benign prostatic enlargement. The voiding PFS is the current reference standard for the diagnosis of BOO in men. To be useable, a PFS study must be well performed with minimal artifacts.[92-94]

Many studies assessed the use of PFS to predict outcomes of men with LUTS treated with surgical procedures to reduce outlet resistance.[95-108] While the results of these studies showed variability regarding the ability of PFS to predict outcomes of surgical procedures to treat benign prostatic obstruction (BPO), the panel concluded that the preponderance of evidence suggests that a diagnosis of obstruction on a PFS predicts a better outcome from surgery than a diagnosis of no obstruction. Therefore, it can be recommended as part of the evaluation of LUTS in men.

The panel also believes that despite some limitations, PFS remain the only means of definitively establishing or ruling out the presence of BOO in men. However, it may not always be necessary to confirm urodynamic obstruction prior to proceeding with invasive therapy. Patients should also be made aware of the risks of PFS, which include hematuria, UTI and dysuria as well as some of the diagnostic pitfalls of the studies.

Guideline Statement 18.

**Clinicians may perform PFS in women when it is important to determine if obstruction is present. (*Recommendation*; Evidence Quality: *Grade C)*

The urodynamic diagnosis of obstruction in females is not as well established as in men. Various diagnostic criteria have been used to define obstruction.[109-114] One inherent problem with the diagnosis of female BOO is the number of conditions that may cause it and the lack of a highly prevalent condition, such as BPO in men, on which to base a nomogram. While definitions of female BOO vary, all studies have shown differences in pressure (higher in obstructed women) and flow rate (lower in obstructed women) though there tends to be tremendous overlap.

Another limitation of PFS in women is the lack of literature correlating PFS findings with outcomes. The only study that evaluated a treatment response in "obstructed women" was for urethral dilation, a procedure not advocated by many experts.[115] Other studies evaluating outcomes of stress incontinence surgery found no significant correlations. [116,117]

Based on the current body of evidence, the panel supports the use of PFS as an option in women for the evaluation of potential BOO, particularly if invasive treatment is planned. We realize that diagnostic criteria are not standardized, and this is an area for current and future research. However, as there is no consistent evidence that shows the lack of value of PFS, it should remain as part of the diagnostic armamentarium. In addition, the documentation of obstruction will likely influence treatment decisions, and PFS is a useful modality to aid in the diagnosis. Due to the limitations of PFS in women, the panel believes that the results of PFS should always be correlated with patient symptoms

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and other diagnostic tests to make the most accurate diagnosis of female BOO.

Guideline Statement 19.

Clinicians may perform videourodynamics in properly selected patients to localize the level of obstruction particularly for the diagnosis of primary bladder neck obstruction. *(Expert Opinion)*

In certain young men and women of all ages with suspected BOO, VUDS can be extremely useful in diagnosing PBNO. This disorder is characterized by a delay or failure of the bladder neck to open during a voluntary detrusor contraction. In young men and women without an obvious anatomic cause of obstruction like BPO in men or POP in women, VUDS can differentiate between functional causes of obstruction like PBNO and dysfunctional voiding. PBNO is a videourodynamic diagnosis whose hallmark is relatively high detrusor pressures in association with low flow and radiographic evidence of obstruction at the bladder neck with relaxation of the striated sphincter and no evidence of distal obstruction. Videourodynamic evaluation is the only diagnostic tool that can document pressure/flow parameters and localize functional obstruction of the bladder neck. To date, there are no studies comparing treatment of PBNO on men or women diagnosed with VUDS versus those who had treatment but no VUDS. Since the perceived standard of diagnosis is VUDS and the condition is relatively rare, it is unlikely that such studies will be done. Therefore, the panel feels that VUDS remains the standard test in which to diagnose PBNO and should be an option for any young male or for a female patient in whom the condition is suspected. The risks of VUDS include those related to the PFS study itself as well as those associated with radiation exposure.

Future Research

UDS is an interactive study that measures lower urinary tract function during urine storage and emptying. However, widespread variability in technique and interpretation of UDS leads to many unanswered questions. For most clinicians, common uncertainties include questions as to the optimal clinical conditions to perform urodynamic testing. Unfortunately, this review and others have found that definitive answers are elusive. Not only does variance in urodynamic testing limit the ability to answer some of these important questions, but we are severely limited by a variance in the practice and reporting of lower urinary tract disorders. To begin to answer these important questions, adherence to terminology and consistency in clinical practice is desperately needed. In this context, the panel cannot stress enough the importance of good urodynamic practice, which emphasizes formulating the urodynamic question, insuring that testing reproduces symptoms, accurately interpreting artifacts and reporting results in the context of the clinical scenario. Consistency and quality of urodynamic practice may ultimately facilitate answering some of these complex questions. As a result, the panel recommends that publishers and editors of manuscripts involving urodynamic studies strictly adhere to good urodynamic practice and terminology.

When performing urodynamic studies for the various clinical conditions reported in this guideline, the panel has recognized a number of important issues, which warrant future research:

SUI. Understanding urethral function is critical to elucidating the etiology of SUI. The current methods of assessing urethral function, including urethral pressure profilometry and VLPP testing, are imperfect and do not consistently correlate with treatment outcomes. There is an overlap between normal and abnormal values in urethral pressure profile as well as a lack of consensus regarding which method is the optimal test to determine urethral function. To date, there is a lack of a consistent, standardized method for performance of these tests as well as absolute normative values for these tests. Considerable investigation is needed to standardize the appropriate technique to assess urethral function. In addition, there is a lack of consistent data showing that existing tests predict outcomes with any given intervention for SUI. Further investigation is needed to determine if urethral function tests may accurately predict outcomes of surgical SUI treatment or assist in the appropriate selection of a surgical procedure.

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Future Research

As noted previously, the role and value of invasive UDS in the uncomplicated patient with SUI remains unclear. Prior groups have recommended such testing prior to surgical intervention in all patients with SUI.[118] This recommendation was made despite a lack of evidence that these tests improve overall outcomes, reduce postoperative morbidity (e.g., postoperative voiding dysfunction, de novo urgency or urgency incontinence, and urinary retention) or favorably impact choice of intervention in groups of uncomplicated patients with SUI undergoing preoperative UDS as compared to individuals who do not undergo preoperative UDS testing. In contrast, the American Urological Association SUI Guidelines Panel characterized UDS as optional in women with uncomplicated SUI.[26] Prospective RCTs comparing outcomes in patients undergoing preoperative UDS testing v. those not receiving such testing may be helpful in assessing the utility, safety and value of UDS testing in patients for whom a variety of treatment options exist . Investigation is needed to determine the optimal, cost-effective utilization of urodynamics prior to selection of surgical therapy.

NGB. In patients with NGB, restoring effective bladder emptying and maintenance of continence are only a part of the overall management. Disorders of compliance and high urinary storage pressures may lead to febrile UTI, urinary calculi and renal failure.[119] Thus, characterization of the anatomy and function of the lower urinary tract is important in patients with neurogenic disorders. At present, cystometry via catheterization is the predominant technique of measuring bladder function. In these patients at risk for UTI or AD, development of less invasive means of assessing bladder function is desirable. Further research is needed into alternative measurements of bladder function, such as further development of ultrasonic measurement of bladder wall thickness or assessing for BOO via external means.

The concept of high storage pressures and elevated detrusor LPP leading to upper tract deterioration has been reported in myelodysplastic patients with elevated detrusor LPP. It remains unclear whether similar storage pressures place patients with other neurogenic disorders at similar risk. At what point does decreased compliance really cause upper tract changes? Should the urodynamic assessment in these patients be similar? Clearly, in patients with neurogenic bladder, detrusor LPP warnings need to be assessed and validated in various neurological populations; this would facilitate development of treatment protocols. In addition, this may provide insight into another area of needed research – determining the optimal frequency of urodynamic follow-up in patients with "stable" neurogenic bladder. Lastly, it would be useful to identify specific circumstances when decreased compliance may predict a poor outcome for a specific modality of treatment.

VUDS is often utilized in patients with neurogenic bladder, assuming that the anatomic detail will provide additional anatomic information that is of value in treatment. It would be useful to validate the role of fluoroscopy during urodynamics in neurogenic (and other) populations. Although the radiation exposure (dosage) during VUDS is low, some clarification regarding frequency of testing and protocols to minimize radiation dosage in patients who are at risk of chronic exposure to radiography is needed.

Further study is clearly needed to clarify the role of UDS in predicting the outcomes of treatment. Can we stratify patients for the most appropriate therapy based on urodynamic findings?

Urgency and/or Urinary Urge Incontinence. OAB symptoms may occur as a result of increased bladder sensitivity or involuntary contractions of the bladder. This may result in symptoms of urinary urgency, frequency and/or urgency incontinence. UDS may often fail to identify abnormal contractions of the bladder in patients with urgency incontinence. In addition, measurements of urinary sensation are subjective and largely correlated with volume. In patients with urgency incontinence, more study is needed in performing cystometry. Further insight is needed into the optimal filling protocol that is most accurate in diagnosing DO. In addition, clarity is needed to determine if provocative studies should be performed to elicit DO and when those maneuvers are indicated. Lastly, more data are needed to stratify outcomes of treatment based on the presence or absence of DO. Measurement

of bladder sensation is largely subjective and does not strongly correlate with urinary urgency. Further study is needed in order to develop better methods of assessing bladder sensation and urinary urgency, perhaps quantified to severity. These measurements should be correlated to treatment outcomes.

In evaluating bladder storage disorders, research is needed to identify alternative methods of quantifying bladder sensation and storage pressures which are more reproducible. This would undoubtedly improve reliability and clinical relevance.

Data are mixed regarding the outcomes of SUI treatment in patients with urodynamic findings of DO or increased bladder sensation. Further insight is clearly needed to assess whether DO or increased bladder sensation is predictive of response to therapy. Does any risk vary with the different types of treatment or SUI surgery? Additionally, is the urodynamic finding of bladder storage abnormality associated with a higher risk of complications following SUI management? This information is needed to quantify the role of UDS prior to surgical management of SUI.

LUTS. Patients with various constellations of LUTS may undergo PVR or uroflow testing as non-invasive methods to screen for disorders of bladder emptying. Although very widely utilized in urologic practice, many questions remain regarding the utility of non-invasive testing methods. What is the optimal PVR volume to recommend treatment? Is volume alone adequate, or should treatment decisions be coupled with bladder pressure? In addition, how many PVR assessments should be measured to initiate therapy? If more than one measurement is thought optimal, what is the reproducibility of these measurements? Does elevated PVR predict treatment outcomes or complications? PVR is commonly utilized as the test to diagnose urinary retention. What should be defined as "significant" retention, and what is the optimal setting to recommend intervention? When utilizing uroflowmetry as a screening assessment of emptying, the volume voided is vitally important. Voided volumes of at least 150 ml have been reported to be necessary for the "accuracy" of the study. However, the real relationship between uroflowmetry and voided volume or bladder

capacity is poorly understood. Should uroflow be "standardized" to volume on a nomogram chart? This information is needed in order to enhance the clinical accuracy and relevance of uroflow as a screening study. In addition, as a commonly performed screening test, more data are clearly needed to determine if abnormal uroflow studies predict therapeutic outcomes or complications.

PFS are the "definitive" method to assess abnormalities of emptying. In men, the data are not conclusive that PFS predict outcomes of outlet reduction by "prostatectomy." Conclusive study is needed to determine if urodynamic evidence of obstruction is actually predictive of a more favorable outcome to treatment of outlet obstruction. What are the detrusor pressures that absolutely diagnose obstruction, and is there more than one measurement needed? In women, no clear consensus exists regarding the urodynamic criteria of obstruction; determination of such criteria is desirable. Can this be measured by pressure-flow alone, or is some element of video needed? In voiding disorders due to underactive detrusor function, investigation into which parameters actually constitute detrusor underactivity is desirable. Also, in voiding disorders in patients with underactive detrusor function, how can concomitant obstruction be diagnosed? In addition, the precise technique and role of EMG testing remains unclear. Future study regarding technique and correlation to treatments is needed to more adequately determine the role of EMG testing.

When evaluating disorders of emptying, VUDS can be valuable by providing anatomic detail of emptying. PBNO is a VUDS diagnosis and should be considered in young males and women. However, the exact indications for VUDS as opposed to PFS have not been well defined. Further insight is needed to identify patients who would benefit from VUDS.

AUA/SUFU Guideline

List of Abbreviations

List of Abbreviations

AD – Autonomic dysreflexia

ALPP – Abdominal leak point pressure

AUA – American Urological Association

BOO – Bladder outlet obstruction

BPH – Benign prostatic hyperplasia

BPO – Benign prostatic obstruction

CLPP – Cough leak point pressure

CMG – Cystometry/cystometrogram

CVA – Cerebrovascular accident

DESD – Detrusor external sphincter dyssynergia

DO – Detrusor overactivity

EMG – Electromyography

FDA – Food and Drug Administration

GU – Genitourinary

ICS – International Continence Society

LPP – Leak point pressure

LUT – Lower urinary tract

LUTS – Lower urinary tract symptoms

MMS – Myelomeningocele

MS – Multiple sclerosis

MUCP – Maximal urethral closure pressure

NGB – Neurogenic bladder

OAB – Overactive bladder

PBNO – Primary bladder neck obstruction

PCG – Practice guidelines committee

PD – Parkinson's disease

PFS – Pressure flow studies

POP – Pelvic organ prolapse

PVR – Post-void residual

RCT – Randomized controlled trial

SCI – Spinal cord injury

SUFU – Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction

SUI – Stress urinary incontinence

UDS – Urodynamics/urodynamic studies

UTI – Urinary tract infection

UUI – Urgency urinary incontinence

VLPP – Valsalva leak point pressure

VUDS – Videourodynamics/videourodynamic studies

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Conflict of Interest Disclosures

All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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This document was written by the Urodynamics Guidelines Panel of the AUA Education and Research, Inc., which was created in 2009. The PGC of the AUA selected the panel chair. Panel members were selected by the chair. Membership of the panel included urologists, nurses, and other clinicians with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the use of urodynamics.

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While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today, these evidence-based guideline statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines are not intended to provide legal advice about use and misuse of these substances.

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