

# Female Urology, Urodynamics, Incontinence, and Pelvic Floor Reconstructive Surgery

## Prospective Evaluation of Urodynamic Utility in a Subspecialty Tertiary Practice



Rena D. Malik, Deborah S. Hess, Maude E. Carmel, Gary E. Lemack, and Philippe E. Zimmern

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| <b>OBJECTIVE</b>  | To prospectively evaluate the utility of urodynamic evaluations (UDS) ordered in a tertiary referral center as part of a quality improvement project.   |
| <b>METHODS</b>    | Patients with UDS ordered by 3 subspecialty physicians were included. Physicians were surveyed when ordering UDS and at the post-UDS clinic visit to assess indications for UDS, pre- and post-UDS diagnosis, treatment plan, confidence level, and perceived helpfulness of UDS. UDS trained nurses conducting studies were surveyed on patient reported reproducibility of their symptoms and perceived difficulty of UDS.  |
| <b>RESULTS</b>    | From April 2017 to October 2017, 127 UDS were included of which 102 met study criteria. UDS were done for neurogenic (23%) and non-neurogenic lower urinary tract symptoms (76%). The majority were conducted for incontinence evaluation (79%), or after prior lower urinary tract surgery (33%). UDS nurses reported 90% of UDS fully or partially reproduced patient symptoms. Nurses found 18% of UDS difficult due to catheter malfunctions, physical limitations, and communication abilities. Post-UDS, providers found 97% of UDS interpretable. UDS resulted in a change in treatment plan in 78% of patients. On a Likert scale, mean pre-UDS confidence level was $2.9 \pm 0.8$ (range 0-5). This increased to $4.1 \pm 0.6$ post-UDS with 76% of evaluations having a change of at least 1 point. |
| <b>CONCLUSION</b> | UDS in a tertiary referral center result in change in patient treatment plans over three-fourths of the time with high rates of interpretability. UROLOGY 126: 59–64, 2019. © 2019 Elsevier Inc.  |

Multichannel urodynamic evaluations (UDS) are conducted to investigate the physiologic function of the lower urinary tract (LUT). They are utilized when the clinical diagnosis is not apparent after office evaluation and noninvasive measures, particularly for counseling or surgical planning prior to therapeutic intervention. UDS can be particularly helpful in populations where clinical symptoms are nonspecific and difficult to decipher, specifically in elderly females and neurogenic subpopulations.<sup>1</sup> Some argue that UDS are costly, time-consuming and conducted under variable circumstances which may not be representative of the true clinical scenario.

In a quality review, UDS was shown to be technically deficient or fail to answer the question for which the UDS was conducted in a third of patients.<sup>2</sup> Concerns regarding reproducibility and inter-rater reliability, particularly in detrusor overactivity or voiding dysfunction, have been noted.<sup>3-6</sup> However, others have found excellent inter-rater reliability with good urodynamic practices and strict quality control guidelines.<sup>7</sup>

The utility of UDS has come into question. In the VALUE trial, a randomized controlled trial assessing women with uncomplicated stress urinary incontinence (SUI) with or without UDS, it was found that UDS changed patient diagnoses and increased clinical confidence but did not significantly alter treatment plans or outcomes.<sup>8-10</sup> However, little contemporary data on the utilization and impact of UDS in a heterogeneous patient population exists.<sup>11-14</sup> In an effort to improve the quality of patient care, we sought to assess the use of UDS in our patient population and its impact on treatment plan and clinician confidence. We hypothesized that UDS conducted in a tertiary care center can result

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From the Division of Urology, Department of Surgery, University of Maryland School of Medicine, Baltimore, MD; and the Department of Urology, UT Southwestern Medical Center, Dallas, TX

Address correspondence to: Rena D. Malik, M.D., Division of Urology, Department of Surgery, University of Maryland School of Medicine, 29 S Greene St, Suite 500, Baltimore, MD 21201. E-mail: Rmalik@som.umaryland.edu

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in an increase in provider confidence and an alteration in management plan.

## MATERIALS AND METHODS

As a part of a quality improvement project, we reviewed the utility of UDS at our tertiary care center ordered by three Female Pelvic Medicine and Reconstructive Surgery (FPMRS) board-certified urologists. Institutional IRB exemption was obtained. Patients were excluded if they had UDS ordered by a non-FPMRS physician. The FPMRS provider ordering the study was asked to complete a pre-UDS Survey at the time of ordering the UDS. Without viewing their initial pretest responses, the FPMRS providers were later asked to complete a post-UDS survey at the time of the patients post-UDS clinic visit. Surveys were adapted from those utilized in the VALUE study to include a heterogeneous group of LUT diagnoses.<sup>15</sup> UDS-trained nurses were also asked to complete a survey at the time of the UDS to assess the reproducibility of the patient's symptoms, and the subjective difficulty of the study. The dates of studies, and clinic visits were documented on each survey. All responses were tallied by a neutral investigator (RM) that was not involved in the care of these patients. Our aims were twofold, first to determine nurse perceived difficulty with UDS and its relation to interpretability; second, whether the UDS findings would change the clinical diagnosis, the confidence level of the provider, or the treatment plan post-UDS.

### Pre-UDS

The pre-UDS questionnaire included free-text answers to the questions "What is the question you would like answered with the UDS?," "What is your pre-UDS diagnosis?" and "What is your pre-UDS treatment plan (based on clinical information?)." The free-text question answer was reviewed and classified into 6 categories which were not mutually exclusive. These were (1) to characterize incontinence mechanism, (2) history of prior surgical procedure, (3) neurogenic bladder, (4) suspected bladder outlet obstruction, (5) suspected voiding dysfunction and (6) other. Providers were asked the indication for UDS and selected from: (1) voiding LUTs, (2) storage LUTs, (3) SUI, (4) urge urinary incontinence, (5) mixed urinary incontinence (MUI), (6) neurogenic bladder, (7) benign prostatic hyperplasia, (8) pelvic organ prolapse to unmask occult SUI, and (9) other. These were not mutually exclusive. If unable to offer a treatment plan providers were asked why and given the following options: (1) UDS for surveillance of neurogenic bladder, (2) UDS for clarification of incontinence symptoms or (3) other. Providers were asked to rate their answer to: "Overall, how confident are you that you have made the best treatment plan for this subject," on a 5-point Likert scale from 1 (Not very confident <50%) to 5 Extremely Confident (≥95%).

### Nurse UDS

UDS-trained nurses were asked to complete a survey immediately after completion of the UDS. They routinely asked patients if they felt UDS reproduced their symptoms and documented it in the following question: "Did the UDS reproduce the patient's symptoms?" with options (a) fully reproduced, (b) partially reproduced, and (c) failed to reproduce. For asymptomatic patients undergoing UDS for surveillance, option (a) was selected. On a 5-point Likert scale from strongly disagree to strongly agree nurses were asked if they agreed with the

statement "This UDS was difficult to complete." If affirmative, they were asked "why?" with options: (a) The patient did not follow instructions, (b) the patient could not sit up due to physical limitations, (c) the voiding catheter fell out, (d) the rectal catheter fell out, (e) the EMG leads were not functioning properly, (f) the patient could not hold a large enough volume in their bladder, (g) the prolapse was difficult to reduce, and (h) other.

### UDS

UDS were completed using the International Continence Societies Good Urodynamic Practices standards using Laborie (Mississauga, Canada) urodynamic equipment.<sup>16</sup> Patients underwent free uroflowmetry to determine voided volume and maximum urine flow rate (Qmax). A 7 Fr. urethral catheter was inserted intravesically and a standard rectal balloon catheter placed into the rectum to obtain vesical and abdominal pressures, respectively. The urethral catheter was used to obtain a catheterized postvoid residual. Perineal surface electromyography pads were placed for assessment of urethral sphincter contraction and relaxation. Filling cystometry was completed using a fill-rate of 30-50 mL/min depending on the patient's clinical history. Detrusor pressure was calculated by subtracting abdominal pressure from vesical pressure. Patients were positioned in a seated position unless unable to sit due to neurologic comorbidities in which case, UDS studies were performed in supine position. UDS were interpreted by the FPMRS provider that ordered the study. Urodynamic diagnoses were defined according to International Continence Societies standards<sup>17</sup> including bladder outlet obstruction, stress urinary incontinence, detrusor under- and overactivity, and intrinsic sphincter deficiency.

### Post-UDS

Following the VALUE trial protocol, providers did not review their pre-UDS questionnaires prior to completing post-UDS questionnaires.<sup>8</sup> Providers were asked to answer the following with free-text answers: (1) "What is your post-UDS diagnosis?" and (2) "What is your post-UDS treatment plan?" They assessed their confidence in an identical fashion to the pre-UDS survey. They were asked to respond yes or no if the UDS was interpretable and if it was difficult to interpret. If affirmative they were asked the reason as (1) the intubated flow varied from the nonintubated flow, (2) there was a technical error in the study, (3) patient was unable to void for the study, (4) UDS not representative of patient symptoms or (5) other. On a 5-point Likert scale providers were asked if they agreed with the statements: "UDS was helpful in guiding management of this patient's diagnosis" and "UDS increased my confidence in the treatment plan of this patient." If they felt it was helpful they were asked why with the following options: (a) it answered the UDS question asked, and/or it provided details about the patient's underlying, (b) voiding dysfunction, (c) bladder capacity, (d) detrusor function (altered compliance, DO, or underactivity), (e) provided details about the patient's outlet or (f) other.

### Data Analysis

The answers to the post-UDS free-text questions regarding diagnosis and treatment plan were compared to corresponding pre-UDS questions to assess for a change in diagnosis or treatment. The reason for a change in diagnosis was categorized into 1 of 4 areas including: (1) change in type of incontinence, (2) change in

expected detrusor function, (3) change in outlet function, and (4) presence or absence of suspected voiding dysfunction. The manner in which the treatment plan was changed was classified as: (1) pursue conservative management, (2) pharmacologic treatment, (3) procedure or surgical management, (4) modification to the surgical plan or (5) proceed with further testing.

### Statistical Analysis

Data was presented as means with standard deviation and percentages when appropriate. Fisher's exact test was used to assess for association between pre-UDS indications, questions, and provider confidence level with a positive change in treatment plan. Wilcoxon Signed Rank Test was used to compare the pre- and postconfidence level. A *P* value for significance was less than 0.05. Statistical analysis was performed using Stata 13.1 (Statacorp, College Station, TX).

## RESULTS

Between April to December 2017, 127 were included and completed pre-UDS surveys, of which 102 underwent UDS and attended a post-UDS visit. The mean age of patients undergoing UDS was  $62.5 \pm 13.8$  years and 83% were female. Mean interval time between the initial visit and UDS and post-UDS visit was  $36.8 \pm 20$  and  $44.3 \pm 20$  days, respectively. Indications for UDS are shown in Figure 1. Of patients whose indications included SUI, only 5 had SUI without another indication selected, of which, 4 had previous incontinence surgery and 1 had suspected detrusor underactivity.

Based on free-text responses, 68% of UDS were ordered to determine incontinence mechanisms. The next most common indication for UDS were a history of prior urologic intervention possibly impacting bladder or urethral function (33%) and/or a history of neurogenic bladder (23%). The majority (77%) of patients with a previous intervention had a SUI procedure and/or excision of a mid-urethral sling. Of those patients with neurogenic bladder, they were nearly half male (42%), 29% had Parkinsons disease, 25% had multiple sclerosis, and 13% had suprasacral spinal cord injury (Table 1).

### Nurse Perspective on UDS

Nurses reported that 90% of patients felt that the UDS fully or partially reproduced their symptoms. When conducting UDS, they found 18% to be subjectively difficult to conduct due to

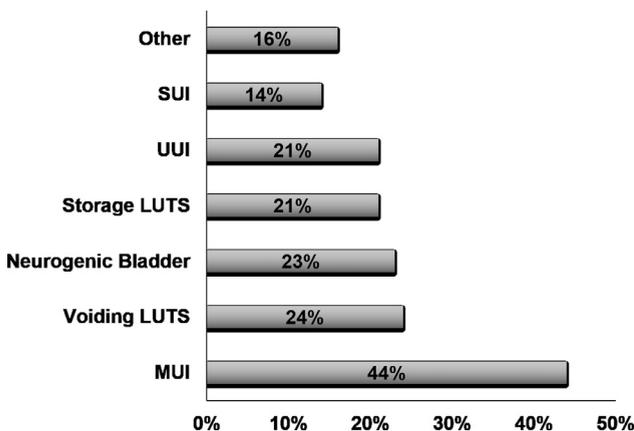


Figure 1. Provider reported indications for ordering UDS.

Table 1. Demographics of neurogenic patients undergoing UDS (n = 24)

|                                |         |
|--------------------------------|---------|
| Gender                         |         |
| Female                         | 14 (58) |
| Diagnosis                      |         |
| Parkinsons disease             | 7 (29)  |
| Multiple sclerosis             | 6 (25)  |
| Suprasacral spinal cord injury | 3 (13)  |
| Lumbar disk disease            | 2 (8)   |
| Other                          | 6 (25)  |
| Indication for UDS             |         |
| Incomplete emptying            | 8 (33)  |
| Incontinence                   | 11 (46) |
| Surveillance                   | 2 (8)   |
| Treatment plan changed         | 16 (67) |
| Medical treatment              | 6 (25)  |
| SPT                            | 1 (4)   |
| CIC                            | 4 (17)  |
| Surgery for outlet             | 2 (8)   |
| Onabotulinum toxin injection   | 1 (4)   |
| Watchful waiting               | 2 (8)   |

vesical or rectal catheters falling out prior to completion of the UDS (28%), physical limitations of the patient (22%), difficulties communicating with the patient (17%), difficulties reducing a large pelvic organ prolapse (11%), or other (22%).

### Subjective Outcomes—Interpretability, Confidence, and Perceived Helpfulness

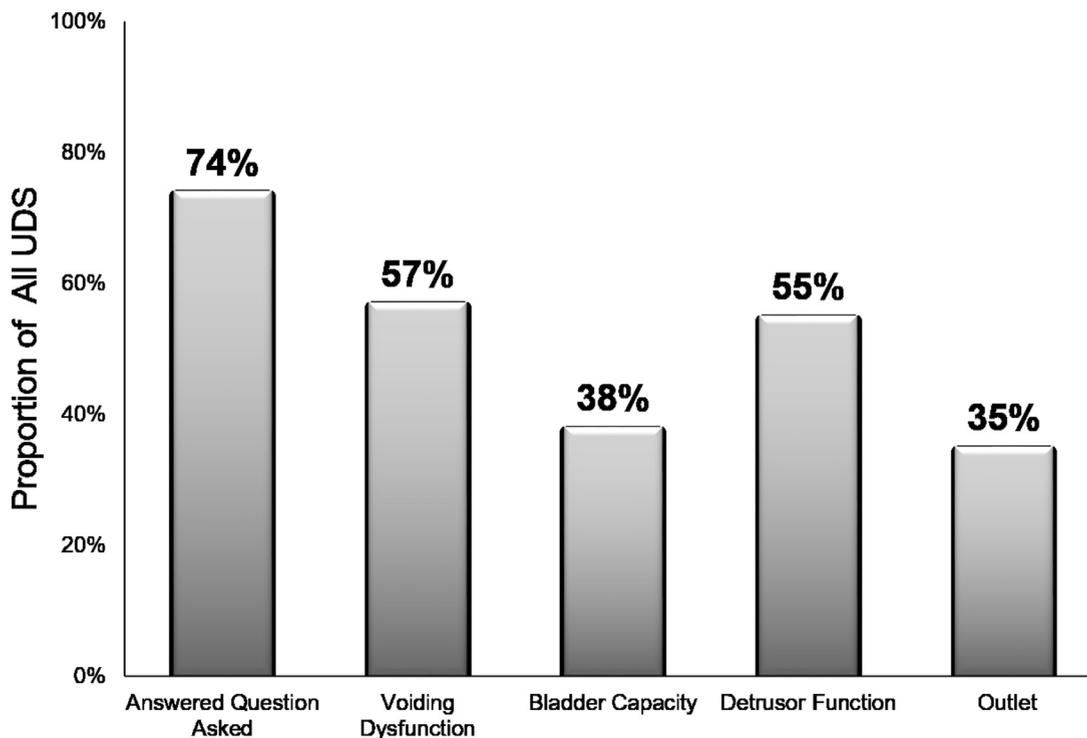
Nearly all UDS conducted (97%) were considered to be interpretable by providers. Of those that were interpretable, 10% were considered difficult to interpret due to patients being unable to void, inconsistent intubated and nonintubated flow results, technical error or UDS findings not representative of patient symptoms. Given the low number of studies that were considered uninterpretable, an association with nurse perceived difficulty was not conducted.

On a Likert scale, 87% of clinicians agreed or strongly agreed that UDS increased their confidence in the patient management plan on a scale of 1-5 of confidence in selecting the appropriate treatment plan from 1 to 5, providers had a mean pre-UDS confidence of  $2.9 \pm 0.8$  (median of 3) which increased to  $4.1 \pm 0.6$  (median of 4) on post-UDS (*P* < .001). A change in confidence level of 1 or higher point on the Likert scale post-UDS was documented by 78% of providers. Providers believed they were very or extremely confident that they had made the best treatment plan for the patient post-UDS 91% of the time (Supplemental Table 1).

Providers agreed or strongly agreed that UDS were helpful in 94% of the UDS completed. Reasons for which UDS were deemed helpful are seen in Figure 2. Most commonly they were subjectively helpful due to answering the question asked or providing details about underlying LUT function, specifically voiding dysfunction and detrusor function.

### Change in Diagnosis and Treatment Plan

After completion of UDS, providers changed the patient diagnosis in 74% of patients (Table 2). Most commonly, the diagnosis changed due to a change in the type of incontinence (47%) demonstrated compared to what was expected pre-UDS. Of those with altered incontinence, 15 (20%) had no demonstrable incontinence on exam, 20 (27%) had a change in the type of incontinence (ie, SUI to MUI or urge urinary incontinence).



**Figure 2.** Reasons providers found UDS subjectively helpful in determining a treatment plan.

Detrusor function was considered to be changed by the presence or absence of detrusor underactivity or overactivity when compared to pre-UDS diagnosis. The outlet was considered the cause for change of diagnosis in patients with unexpected bladder outlet obstruction or in patients whom bladder outlet obstruction was suspected but not observed on UDS.

In comparison to pre-UDS written treatment plan, 78% of providers changed their treatment plan after completion of UDS. Of which, 80% of plans were altered to pursue conservative management (39%), proceed with an invasive procedure and/or surgery (29%), or modify a pre-existing surgical plan (13%). None of the indications or question categories for UDS was predictive of a change in treatment plan. When evaluating our subset of patients with a sole indication of SUI or MUI for UDS, we found that three-fourths of patients with SUI proceeded to be managed with conservative management rather than an initially planned surgical intervention. In patients with MUI, 30% had no predetermined plan prior to UDS and were treated based on findings during the study, 35% changed their plan from a SUI procedure to conservative management, and 10% of patients changed treatment from third line overactive bladder therapy to a SUI procedure. Pre-UDS confidence level was also not significantly associated with a lack of change in treatment plan.

**Table 2.** Reason for diagnosis change post-UDS

| Reason                 | N (%)   |
|------------------------|---------|
| Change in incontinence | 35 (47) |
| Detrusor function      | 25 (33) |
| Outlet                 | 16 (21) |
| Voiding dysfunction    | 16 (21) |

## DISCUSSION

UDS are commonly used to help elucidate clinical diagnoses and construct treatment plans for patients with LUTs. While they have not been shown to alter the treatment plan in women with uncomplicated SUI their utility in a heterogeneous population of patients with LUTs is unclear.<sup>8</sup> Based on our prospective questionnaire based study, UDS done in a complex patient population are nearly always interpretable (97%) when performed by UDS trained nurses in a tertiary care center. In the large majority of UDS conducted, results increased provider confidence in the patient treatment plan (87%), resulted in a change in clinical diagnosis (74%), were subjectively helpful (94%) and altered the pre-UDS treatment plan (78%). Nurses reported that 90% of patients felt UDS fully or partially reproduced their symptoms while encountering occasional difficulties in completing the study.

Our study indicates that UDS is a powerful tool which alters management in a complex patient population as seen in our tertiary referral center. While clinician confidence, perceived helpfulness and even interpretability are subjective outcomes, a change in patient diagnosis and/or treatment plan are objective measures that support the utility of UDS. We did not find any association of specific patient indications, questions for which UDS were ordered or provider pre-UDS confidence level with subsequent change in treatment plan. While drawbacks to UDS certainly exist, there is sufficient evidence to support their use in patients with appropriate indications.<sup>18</sup> Furthermore, when assessing

pain and embarrassment in patients undergoing UDS, UDS are generally well-tolerated.<sup>19,20</sup>

These results are similar to those previously published by Suskind et al, in which prospective pre- and post-UDS questionnaires were administered to 5 clinicians ordering UDS in 285 patients. Treatment plans were changed 43% of the time commonly due to changes involving surgery and alterations in pharmacologic treatment.<sup>20</sup> In comparison to our study cohort, their population was younger with a higher proportion of patients with neurogenic bladder. A unique feature of our study was evaluation of UDS-trained nurses experience as this has not been examined before. In addition, the ability of providers to respond with free-text offered flexibility in detailing the provider thought process and minimized bias in determining change in the post-UDS treatment plan.

In our practice, UDS are ordered following guidelines suggested by the American Urological Association and Society of Urodynamics, Female Pelvic Medicine and Reconstructive Surgery.<sup>21</sup> The population we see is unique to that of a tertiary referral center including patients with refractory LUTs, history of prior incontinence or pelvic surgery impacting the LUT, pelvic radiation, neurogenic bladder, or previous failed management of urinary incontinence or bladder outlet obstruction. This is divergent from the patient population evaluated in the VALUE trial and may be more representative of patients clinicians encounter and tend to evaluate using UDS. Our data suggests that UDS conducted in this appropriately selected population tends to provide high yield information which often guides subsequent treatment interventions.

Current review of UDS use in the United States finds that, in female Medicare populations, use of UDS increased by 29% from 2000 to 2010, most commonly in women with urinary incontinence in the eighth decade of life.<sup>12</sup> In an analysis of female patients with MUI undergoing surgical intervention from 2000 to 2011 the utilization of UDS increased to nearly 75% of patients prior to primary intervention and 63% prior to secondary intervention in a random sample of Medicare claims.<sup>13</sup> Correspondingly, a review of outpatient national claims data of adult women over 2000-2012 found an increase in UDS utilization rate per 10,000 person-years from 31.1 to 40.6 between 2000 to 2011 with a drop in 2012 to 27.6 per 10,000 person-years with a similar trend in men undergoing UDS.<sup>14,14</sup> This decline corresponds to the timing of the publication of the VALUE trial recommending against the use of UDS in uncomplicated SUI.<sup>8</sup> Furthermore, there was a notable change in Current Procedural Terminology coding and bundled payments for UDS in the 2010 calendar year resulting in declining reimbursements.<sup>22</sup> It is unclear how broad utilization has changed since 2012, however, we encourage the continued use of UDS in the abovementioned complex patients to help identify appropriate management plans.

Our institution is similar to others both in academic and private practice settings where specifically trained

UDS nurses perform UDS which are interpreted by the provider at a later date. Specifically our institution has dedicated UDS nurses who have been trained with specific procedure and annotation requirements as previously described by the Urinary Incontinence Training Network.<sup>23</sup> To our knowledge no previous study has included the perspective of the health care providers, other than physicians, conducting the study. Our study supports that well-trained personnel can nearly always conduct studies with interpretable results and minimal difficulty.

The results of our data should be interpreted in the context of its limitations. Our patient population is representative of patients typically seen in a subspecialty tertiary referral center which may not be generalizable to all clinical practices. We chose to include multiple indications for UDS to be representative of a typical UDS practice, which limits the statistical power of our analyses. Furthermore, while providers were blinded to their pre-UDS data there is an inherent bias in which one would select a study they ordered as helpful or noting an improvement in confidence. UDS were ordered and performed by FPMRS trained physicians, and may differ from studies ordered and performed by other non-FPMRS trained individuals. Lastly, we did not assess patient satisfaction or outcomes of treatment after UDS.

## CONCLUSION

In this quality improvement project following a previously tested approach adapted from the VALUE trial, UDS ordered for a complex patient population typically seen in a tertiary referral center are nearly always interpretable, subjectively helpful, and increase provider confidence in the management plan. UDS were reliably conducted by UDS-trained nurses and resulted in a change in clinical diagnosis and alteration in management plan in nearly 75% of patients.

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## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.urol.2019.01.004](https://doi.org/10.1016/j.urol.2019.01.004).

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