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ORIGINAL ARTICLE

The negative predictive value of preoperative urodynamics for stress urinary incontinence following prolapse surgery

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Abstract

Introduction and hypothesis There is no consensus for the evaluation of stress urinary incontinence (SUI) in patients planning pelvic organ prolapse (POP) surgery. We sought to determine the negative predictive value (NPV) of prolapse reduction during preoperative urodynamics (UDS) for postoperative SUI.

Methods We performed a retrospective study of 322 women with preoperative UDS and subsequent POP surgery. Abstracted data included demographics, prolapse stage, prior prolapse or incontinence surgery, preoperative SUI complaint, prolapse reduction method, and length of follow-up. Any woman who reported SUI symptoms within 6 months from surgery was considered a diagnostic UDS failure. The NPV was calculated by dividing the number of patients who did not demonstrate SUI on UDS and had no postoperative SUI by the number of patients who did not demonstrate SUI on UDS.

Results Patient characteristics (age, race, parity, prolapse stage, prior surgery, and length of follow-up) were similar among those who had urodynamic-proven SUI and those who did not. The NPV of preoperative UDS for postoperative SUI in patients undergoing any POP repair was 97.9.0% [95% confidence interval (CI) 92.7–99.7%]. The NPV remained high in the subset of patients who underwent an apical suspension—98.6% (95% CI 92.7–100.0%)—as well as those without a preoperative SUI complaint—98.6% (95% CI 92.3–100.0%). In most patients (72.9%), a ring pessary with support combined with intraprocedural manipulation allowed for reliable stress testing.

Conclusions Our study supports using preoperative UDS as a screening tool to avoid unnecessary concomitant continence procedures. Further studies are needed to individualize patient preoperative assessment and surgical counseling.

Keywords Screening · Stress urinary incontinence · Urodynamics

Introduction

Stress urinary incontinence (SUI) has been shown to coexist in 63% of women with pelvic organ prolapse (POP) [1]. Some surgeons have advocated for a routine continence procedure at the time of advanced prolapse repair [2–4]. While this strategy reduces the number of patients with postoperative SUI, many patients undergo unnecessary procedures. This increases the risk of complications, such as voiding dysfunction, urinary tract infections (UTI), bladder perforation, or intraoperative blood loss [2, 4]. Currently, there is no consensus for the evaluation of SUI in patients planning prolapse surgery. At best, the American Urological Association (AUA) with the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) guidelines on adult urodynamics offer a grade C option, suggesting that "multichannel urodynamics with prolapse reduction may be used to assess for occult stress incontinence" [5].

To reduce unnecessary continence procedures, some have tried to identify predictors for postoperative SUI, such as focusing on preoperative urodynamic evaluation (UDS) [6, 7]. These studies have shown mixed results, with a significant limitation being an effective technique to reliably reduce the prolapse during stress testing [8]. Techniques for POP reduction during UDS include pessaries, Scopettes, ring forceps, and speculum posterior paddles. The variability in the anatomical nature of advanced POP precludes developing a single standard technique for prolapse reduction. Our group

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manipulates the reduction device (pessary, Scopette, speculum) to hold the urethra in as normal an anatomic position as possible while performing cystometrogram stress testing. The goal of this study was to determine the negative predictive value (NPV) of our prolapse reduction approach during preoperative UDS for postoperative SUI.

Materials and methods

The study protocol was approved by the University of Massachusetts Institutional Review Board. We performed a retrospective study of all women with preoperative UDS and subsequent prolapse surgery. We used Current Procedural Terminology (CPT®) codes and billing data to identify all patients older than 18 years of age between January 2011 and September 2014 with preoperative UDS and subsequent prolapse surgery, with or without a continence procedure. This includes codes 57,110, 57,120, 57,240, 57,250, 57,260, 57,265, 57,280, 57,282, 57,283, and 57,425 for POP surgery. At our institution, preoperative UDS is performed at the discretion of the attending surgeon. Some routinely perform preoperative UDS and others use it selectively. However, women with objective SUI on exam do not undergo UDS in the absence of another indication. We excluded patients who had no preoperative UDS, postoperative follow-up <5 weeks, underwent a posterior colporrhaphy alone (without concomitant anterior or apical repair), as well as those with missing or incomplete UDS with respect to SUI evaluation.

Abstracted data included age, race, parity, prolapse stage by compartment, prior prolapse or incontinence surgery, prior hysterectomy, procedures performed, preoperative complaint of SUI, postoperative complaint of SUI, and length of postoperative follow-up. Abstracted urodynamic data included the presence of SUI, reduction method (Scopette, pessary, speculum), volume at first leakage, and lowest leak-point pressure (LPP). Patients are routinely examined ~6 weeks after surgery, screened for SUI symptoms, and tested for SUI using a stress test with the patient in the supine position while performeing Valsalva and cough as provocative maneuvers. Occasionally, scheduling issues result in a postoperative visit a few days before 6 weeks, so we used 5 weeks as a lower limit for exclusion. Patients are asked to present with full bladders, but bladder volume is not routinely recorded. Surgeons also follow-up postoperative patients at 6 months and 1 year or as medically indicated.

Patients who reported any SUI symptoms within 6 months postoperatively were considered diagnostic failures, regardless of severity, whether or not they pursued treatment or SUI symptoms resolved on subsequent follow-up. We used this liberal definition because we had no validated questionnaires available for the study period. Furthermore, in the rare event that there was an isolated positive stress test postoperatively, it was clear from documentation that the practitioner clarified whether this was a noticeable symptom to the patient, and any positive response was counted as a diagnostic UDS failure. When a postoperative SUI complaint was reported, the chronological start date of symptoms was used, rather than the date of the clinic visit; e.g., a delayed postoperative visit at 7 months with SUI symptoms that started 6 weeks prior would be counted as a failure. All available postoperative visits were reviewed, since patients often return to clinic for other reasons, such as UTIs.

There is no consensus on when SUI becomes a new diagnosis versus a missed occult SUI when it occurs after prolapse surgery. It seems unrealistic to expect this test to reliably predict SUI that first appears 6 months after the repair. In our study, those whose symptoms started >6 months after prolapse surgery were considered to have de novo SUI and were not considered to be failures of UDS detection.

Multichannel UDS was performed with the patient in an upright birthing chair at a 60° angle using a Laborie system (Aquarius TT, Williston, VT, USA). All studies were performed or supervised by a single experienced licensed practical nurse, with urogynecology fellows variably present. Cystometrogram and pressure-flow studies were performed in all patients, while urethral pressure profiles and electromyography were performed at the discretion of the attending surgeon. An air-charged dual-sensor catheter (Laborie, Mississauga, Canada) was placed in the bladder and a water-charged dual-lumen balloon catheter (Laborie) in the rectum. Prolapse reduction was performed prior to the start of bladder filling. Bladders were filled with room-temperature sterile water at 50 ml/min.

In most patients, a ring pessary with support adequately reduced the prolapse. The operator selected a size that would best reduce the prolapse without being expelled or kinked and obstruct the urethra. For those whom a pessary failed to completely reduce the prolapse, either the posterior paddle of a speculum or a pair of Scopettes was used for reduction. During stress testing, the operator manipulated the pessary or other support device to maintain the urethra in as normal an anatomic position as possible. The operator avoided obstructing the urethra or overcorrecting the urethrovesical angle during stress testing. Stress testing included cough and Valsalva efforts and was performed at bladder volumes of 100, 200, 300, and 450 ml (or cystometric capacity). Once leakage was seen, testing at higher volumes was typically omitted. Leakage was assessed visually during provocative maneuvers. Leakage visualized at any volume was recorded as a positive diagnosis of SUI, regardless of LPP.

Patient characteristics were described with mean and standard deviation (SD) or frequency and percent. Comparisons between those who had and did not have urodynamically proven SUI were made using the chi-square or Fisher's exact test (if the cohort was <5) for categorical variables and Student's *t* test or Wilcoxon rank-sum test (if the distribution was not normal) for continuous variables. The diagnostic accuracy of preoperative UDS as a screening tool was assessed by computing the NPV. *P* values <0.05 were considered

statistically significant. All statistical analyses were performed using Stata/MP 14.2 (StataCorp.2015, Stata Statistical Software: Release 14, College Station, TX, USA).

Since nearly all patients with a positive stress test underwent concomitant continence procedures as part of their repairs (90.6%; 202 of 223), we did not calculate positive predictive value (PPV), sensitivity, or specificity for preoperative UDS. Performing an intervention in this cohort before the outcome is known precludes interpreting the UDS as a screening tool.

Results

Three hundred and sixty-nine patients were identified using CPT prolapse surgery codes, as shown in Fig. 1. Eighteen patients were excluded because they lacked preoperative UDS. Seventeen were excluded because they lacked postoperative follow-up >5 weeks. Five were excluded because the preoperative UDS was indeterminate with respect to evaluation for SUI. These patients had multiple uninhibited detrusor contractions with voluminous leakage that precluded adequate evaluation of SUI. Seven were excluded because they underwent an isolated posterior colporrhaphy without anterior or apical repairs. Of the 322 patients who met inclusion criteria, 223 (69.3%) demonstrated SUI on UDS and 99 (30.7%) did not. Two patients whose preoperative UDS tested negative for SUI still had slings placed because of their strong complaint of SUI. They were excluded from the NPV calculation because UDS cannot be interpreted as a screening tool in this scenario. Ninety-seven patients reported no SUI symptoms at any follow-up visit within 6 months following surgery, and only two patients reported SUI. This yielded an NPV of 97.9.0% [(95% confidence interval (CI) 92.7–99.7%] for preoperative UDS for postoperative SUI in patients undergoing any anterior and/or apical prolapse repair. Only two cases of postoperative SUI were missed by preoperative UDS. One resolved with physical therapy alone, and the other patient underwent a sling.

The prevalence of urodynamic SUI in the subset who had an apical suspension was 71.0%. The NPV of preoperative UDS for postoperative SUI in these patients was 98.6% (95% CI 92.7–100.0%). Furthermore, the NPV of those without a preoperative complaint of SUI was 98.6% (95% CI 92.3–100.0%). Interestingly, of the 148 patients who complained of SUI preoperatively, 29 (19.6%) had a negative UDS for occult SUI.

As shown in Table 1, there were various types of POP surgeries, and all were performed for stage ≥2 prolapse. Most underwent apical suspensions, with the majority being a sacrocolpopexy. Two patients underwent both a uterosacral and

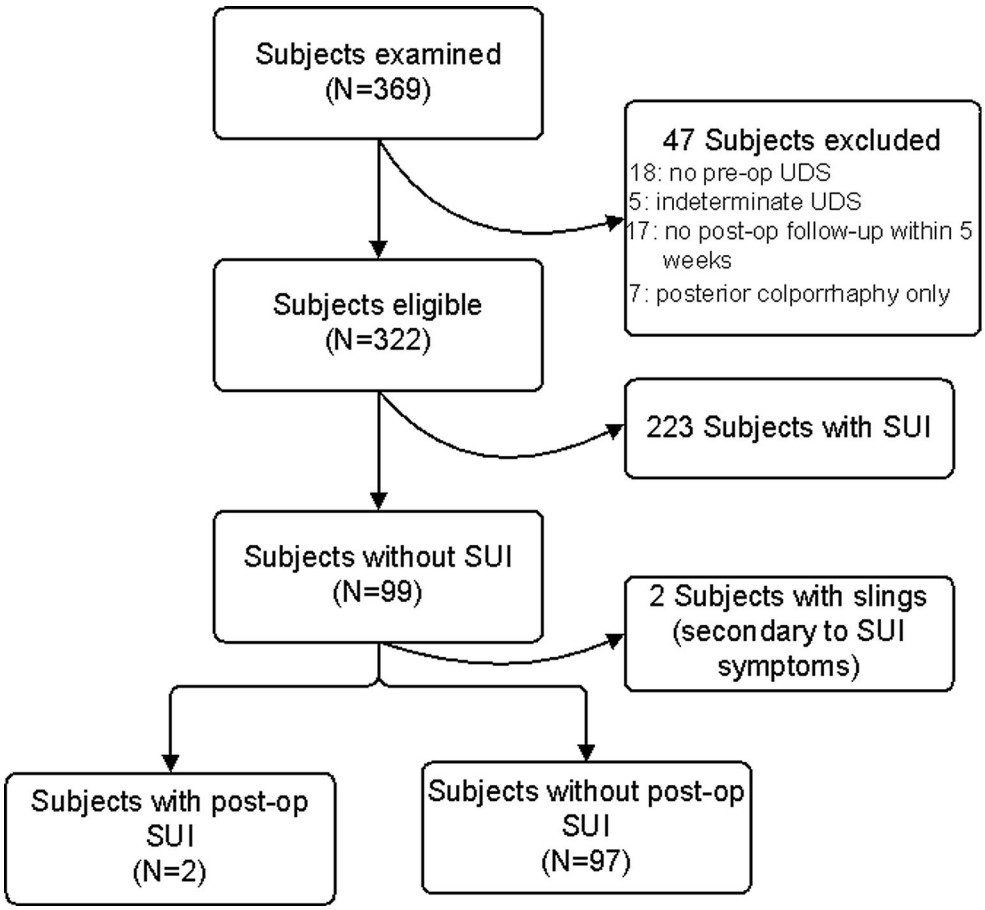

Fig. 1 Patient flowchart. *UDS* urodynamics, *SUI* stress urinary incontinence

Table 1 Surgeries

Variable Surgery	Number
Apical suspension[a]	258
Sacrocolpopexy	175
Uterosacral ligament suspension	40
Sacrospinous ligament suspension	45
Colpocleisis	21
Anterior colporrhaphy[b]	43
Continence procedures	204
Retropubic midurethral sling	195
Burch urethropexy	8
Periurethral bulking injections	1

[a] Two patients underwent both a uterosacral and sacrospinous ligament repair secondary to deficient ligaments on one side

[b] Without concomitant apical suspension or obliterative procedures

sacrospinous ligament repair during their surgery secondary to deficient ligaments on one side. Other procedures included colpocleisis and anterior colporrhaphies alone. Two hundred and four (63.4%) patients underwent a continence procedure at the time of POP repair. These included 195 midurethral slings, eight Burch urethropexies, and one periurethral bulking injection.

As shown in Table 2, patient characteristics were similar among those who had UDS-proven SUI and those who did not. There was no statistical difference in the subset of those who underwent an apical suspension. This included age, race, parity, prolapse stage, prior surgery (prolapse or incontinence), and length of follow-up. Patients had a median follow-up of 5 months (range 1–59 months).

In most patients (72.9%), a ring pessary with support adequately reduced the prolapse. Less frequently, a scopette (24.3%), posterior paddle of a Grave's speculum, or a combination (2.8%) was required to achieve optimal urethral positioning. In the remaining 32 patients, the method of prolapse reduction was not documented. The NPV for the cohort of those who had a pessary for prolapse reduction was 98.5% (95% CI 92.0–100.0%). The NPV of the other methods could not be calculated because there were no diagnostic failures (zero cell) or the number was too small.

Discussion

It is frustrating to patients and surgeons alike when surgery is performed to correct advanced POP and patients experience SUI postoperatively. This can result in a second trip to the operating room. However, universal concomitant continence surgery may result in a significant number of unnecessary procedures, which come with risks including urethral obstruction and graft erosion if mesh is used. A technique that can reliably identify patients who can avoid a continence procedure would be of great value. A predictive nomogram (with an online calculator) for individualized preoperative risk assessment for SUI after vaginal POP surgery has been created from the Outcomes Following Vaginal Prolapse Repair and Midurethral Sling data set, with external validation from the Colpopexy and Urinary Reduction Efforts trial (CARE) data set [9]. It found that a positive prolapse-reduction stress test had "limited predictive utility," with a concordance index of 0.54. This result was weaker than experts' predictions or variables such as age, body mass index (BMI), and even diabetes, although it was included as one of the seven predictors in the study's final model. Likewise, the sensitivity of the CARE trial's preoperative reduction stress testing for postoperative SUI was only 17–39% [8].

A better way of individualizing risk may be to ask: "Who does not need a continence procedure?" The CARE trial found a pooled NPV of 80% for all prolapse reduction methods (pessary, swabs, forceps, speculum, manual reduction) in the Burch group for preoperative UDS at 300 ml, with forceps having the highest NPV at 86% [8]. Each clinical site was assigned two prolapse reduction methods, which were the only ones used during preoperative UDS, with the goal of "reducing the prolapse to the extent expected by abdominal sacrocolpopexy" [8]. A subsequent study found an even higher NPV: Elser et al. performed a retrospective analysis on patients undergoing abdominal sacrocolpopexies [7]. They looked at 441 patients with preoperative UDS using swabs, speculum, or a pessary for reduction. Only those with UDS-diagnosed SUI (occult and nonoccult were analyzed together) had a concomitant continence procedure via Burch, retropubic sling, or transobturator sling. At the 6-week postoperative visit, of the 237 without SUI on UDS, 220 reported no incontinence. They did not differentiate SUI from urge incontinence, so assuming that all incontinence was SUI, we calculate that Elser et al. had at least a 92.8% NPV at the 6-week postoperative mark.

Our NPV of 97.9.0% correlates well with Elser et al's. findings. Ultimately, 322 patients underwent preoperative UDS, and 97 were spared incontinence procedures they did not need. Only one patient underwent additional surgery for SUI that was missed by UDS. Furthermore, the NPV of preoperative UDS remains very high in the subset of patients with apical suspensions, as well as when those that complained of SUI preoperatively were excluded. Our data supports the notion that UDS can be a reliable preoperative screening tool that identifies those who do not need an unnecessary procedure.

The NPV of a test is dependent on the prevalence of the condition in a population. A high prevalence increases the PPV and, conversely, decreases the NPV. The prevalence of urodynamic SUI in our cohort was 69.3%, which is higher than others have found [7, 8, 10, 11], making our finding more notable. A higher SUI prevalence underestimates our finding of the useful NPV of preoperative UDS. The CARE trial recruited women without preoperative symptoms of SUI and found a

Table 2 Patient characteristics

	Entire cohort			Apical suspension cohort		
	No urodynamic SUI (*N* = 97) *N* (%)	Urodynamic SUI (*N* = 223) *N* (%)	*P* value	No urodynamic SUI (*N* = 74) *N* (%)	Urodynamic SUI (*N* = 181) *N* (%)	*P* value
Age, mean (SD)	60.5 (12.2)	62.1 (12.5)	0.290	59.4 (11.3)	61.1 (12.0)	0.300
Race						
Caucasian	85 (88.5)	196 (89.9)	0.925	63 (86.3)	156 (88.6)	0.644
Black	1 (1.0)	2 (0.9)		1 (1.4)	2 (1.1)	
Asian	1 (1.0)	4 (1.8)		1 (1.4)	4 (2.3)	
Hispanic	8 (8.3)	13 (6.0)		8 (11.0)	11 (6.3)	
Other	1 (1.0)	3 (1.4)		0 (0.0)	3 (1.7)	
Parity						
0	1 (1.0)	5 (2.3)	0.827	1 (1.4)	3 (1.7)	0.868
1	9 (9.3)	21 (9.5)		7 (9.5)	17 (9.4)	
2	35 (36.1)	73 (32.9)		30 (40.5)	60 (33.1)	
3	22 (22.7)	62 (27.9)		18 (24.3)	52 (28.7)	
4+	30 (30.9)	61 (27.5)		18 (24.3)	49 (27.1)	
Prior prolapse surgery	16 (16.5)	25 (11.2)	0.194	10 (13.5)	23 (12.7)	0.862
Prior incontinence surgery	7 (7.2)	12 (5.4)[a]	0.523	5 (6.8)	9 (5.0)[a]	0.570
Midurethral sling	6 (6.2)	6 (2.7)		4 (4.1)	4 (2.2)	
Burch urethropexy	0 (0)	1 (0.4)		0 (0)	1 (0.6)	
MMK	0 (0)	3 (1.3)		0 (0)	2 (1.1)	
Pubovaginal sling	0 (0)	2 (0.9)		0 (0)	2 (1.1)	
Unknown	1 (1.0)	1 (0.4)		1 (1.0)	1 (0.6)	
Prolapse stage						
2	34 (35.1)	77 (34.5)	0.798	25 (33.8)	55 (30.4)	0.846
3	58 (59.8)	130 (58.3)		45 (60.8)	117 (64.6)	
4	5 (5.2)	16 (7.2)		4 (5.4)	9 (5.0)	
Length of follow-up (months), mean (SD)	4.0 (2.0–12.0)	5.0 (2.0–13.0)	0.605	4.0 (2.0–12.0)	5.0 (1.0–13.0)	0.950

SUI stress urinary incontinenc, SD standard deviation, MMK Marshall-Marchetti-Krantz

[a] One patient had both a midurethral sling and a pubovaginal sling

urodynamic SUI prevalence rate of 27% with prolapse reduction at 300 ml [8]. Elser et al. had a prevalence of urodynamic SUI of 46% in their cohort [7]. Smaller studies have also noted a prevalence well below our study findings: Sinha et al. found that 31% of clinically continent women had occult SUI on UDS (detected using a ring pessary) [10], and Chaikin et al. found that 58% of women had SUI unmasked with pessary prolapse reduction [11]. Our prevalence rate may be partially attributable to our liberal definition of SUI as being any stress incontinence at any volume. It is also possible that our technique artificially increased the rate of SUI by overcorrection of the urethrovesical angle.

We are unable to comment on PPV, sensitivity, or specificity of preoperative UDS using our prolapse reduction approach. These calculations include patients whose preoperative UDS tested positive for SUI, for which they likely underwent a continence procedure. An intervention prior to determination of the outcome precludes interpreting UDS as a screening tool.

There are several weaknesses in our study. The technique of placing the urethra in a "normal position" is subjective and difficult to reproduce. However, this is the nature of a functional study such as UDS. We are unaware of any objective technique that will reproducibly correct the urethra's position. However, anyone routinely caring for these patients can recognize when the urethra is in a reasonably normal anatomic position. Our definition appears to work and was easily taught to a licensed practical nurse and the three different fellows performing these studies. Furthermore, this highlights an interesting point regarding how POP reduction may affect urodynamic parameters, if at all. Our current study is limited in this respect, since we did not perform UDS with unreduced prolapse. Prior studies have suggested that there are no clinically significant differences in filling or pressure flow parameters, only maximum urethral closure pressures (which we rarely performed) [12].

Whether urodynamics with POP reduction are as sensitive as a clinical pelvic exam with POP reduction for occult SUI has not been investigated. A literature review by Roovers and Oelke in 2007 comment on this limitation, and we are not aware of any prospective studies that have investigated this comparison [13].

The lack of a validated questionnaire to assess for both preoperative and postoperative incontinence reflects our study's retrospective nature. While it is our practice to routinely assess postoperative patients for SUI, without prospective study protocols, it is possible we missed patients. For this reason, we chose a liberal definition to minimize missing patients with SUI and any patient who mentioned SUI symptoms postoperatively was considered a diagnostic UDS failure. This includes any patient who characterized it as rare, bothersome, used pads, tried any non-surgical intervention (physical therapy or pessary), or underwent surgical intervention. Additionally, there is a risk of underestimating postoperative SUI because our chart review is limited of our own institution, so patients who presented to providers outside of our electronic medical system would be missed. Finally, selection bias is possible but unlikely. During this period, only 18 patients underwent POP surgery without a preoperative UDS, as reflected in Fig. 1.

A notable strength of our study is its generalizability, albeit to a primarily Caucasian population. We included several types and routes of prolapse repairs, and the findings remain consistent among the subset of apical suspensions as well. Using the strategy of placing the urethra in a normal anatomic position during stress testing, we reliably identified a significant numberof patients who safely avoided a continence procedure without experiencing postoperative SUI.

In summary, our study supports using preoperative UDS as a screening tool to avoid unnecessary concomitant continence procedures. Further studies are needed to identify additional risk factors to facilitate tailoring a patient's preoperative assessment and surgical counseling.

Compliance with ethical standards

Conflicts of interest None.

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