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ORIGINAL ARTICLE

A prospective study investigating the diagnostic agreement between urodynamics and dynamic cystoscopy in women presenting with mixed urinary incontinence

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Abstract

Introduction and hypothesis Patient history is often insufficient to identify type of urinary incontinence (UI). Multichannel urodynamic testing (UDS) is often used to clarify the diagnosis. Dynamic cystoscopy (DC) is a novel approach for testing bladder function. The primary objective of this study was to investigate the diagnostic agreement of UDS and DC in evaluating women with mixed urinary incontinence (MUI).

Methods Women presenting with MUI were approached for enrollment if UDS and DC were planned for further investigation. Investigators were blinded to history and comparative test results. McNemar's test and kappa coefficient were calculated to assess agreement between UDS and DC. Receiver operating characteristic (ROC) analysis was used to explore the best possible filling sensation cutoffs for DC that would best predict the filling sensation cutoffs from UDS.

Results Sixty participants were included, of whom, four were excluded for protocol violation. For the primary outcome measure of agreement, UDS and DC were concordant in 44/56 of stress urinary incontinence (SUI) cases (79%) with a $\kappa = 0.54$ and in 43/56 of urinary urge incontinence (UUI) cases (77%) with a $\kappa = 0.54$, indicating moderate, nearly substantial agreement. ROC analysis identified the best prediction of DC first urge to void as 148 cm^3, strong urge 215 cm^3, and maximum capacity at 246 cm^3. These parameters were used to compare UDS UUI to DC UUI and resulted in a $\kappa = 0.61$ ($p = 0.37$), indicating substantial agreement.

Conclusions When compared with UDS, DC shows moderate agreement for detection of SUI and substantial agreement for detection of UUI.

Keywords Cystoscopy · Stress urinary incontinence · Urgency urinary incontinence · Urinary incontinence · Urodynamics

Abbreviations

UDS	Urodynamic testing
DC	Dynamic cystoscopy
MUI	Mixed urinary incontinence
ROC	Receiver operating characteristic
SUI	Stress urinary incontinence
UUI	Urge urinary incontinence
ICS	International Continence Society
DO	Detrusor overactivity
UU	Urinary urgency
OAB	Overactive bladder
UTI	Urinary tract infection
POP-Q	Pelvic Organ Prolapse Quantification
PVR	Postvoid residual
MCC	Maximum cystometric capacity
IUGA	International urogynecological association
ISD	Intrinsic sphincter deficiency
MUCP	Maximum urethral closure pressure

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QUID Questionnaire for urinary incontinence diagnosis
SUDS Subjective Units of Distress Scale

Introduction

The International Continence Society (ICS) defines urinary incontinence as the complaint of any involuntary leakage of urine [1, 2]. Urinary incontinence is generally classified as stress (SUI), urge (UUI), mixed (MUI), and other rare types [2]. Determining type of incontinence is important, as it guides treatment and predicts its expected success and complications [3]. Patient symptoms are important in assessing urinary incontinence; however, they may be unreliable in distinguishing between the different types [3]. Multichannel urodynamic testing (UDS) is widely used to clarify the diagnosis and is considered the gold standard for assessing incontinence [3, 4]. MUI is a traditional indication for UDS, as the test commonly reclassifies clinical diagnoses and potentially identifies patients at risk for poor prognosis and surgical failure [4].

The primary goal of testing in MUI is to objectively reproduce patient symptoms by evaluating the storage phase of the bladder during cystometry [5]. Demonstration of detrusor overactivity (DO) and/or decreased bladder sensation thresholds is indicative of urinary urgency (UU) and UUI, whereas urinary leakage with increased intra-abdominal pressure in the absence of DO is a sign of SUI [4, 5]. As a gold standard, however, UDS is a lengthy test with a limited detection rate, particularly for overactive bladder (OAB) [4, 5]. For example, UDS may fail to identify DO in up to 46% of women with symptoms of OAB, as it may not be able to capture it at that specific point in time [4, 6]. For women with SUI symptoms, a cough leak is not seen in up to 15% of women during UDS [4, 7]. This discrepancy between symptoms and UDS testing may present a real clinical challenge to patient treatment.

Dynamic cystoscopy (DC) is a novel approach for testing bladder physiology and has been routinely used at this study's institution in women with symptoms of MUI. Currently, there is no reported literature on the comparison between UDS and DC as a single tool for evaluating incontinence. During direct-observed bladder filling, the woman is asked about filling sensations, as at UDS, and the bladder is inspected for changes consistent with DO. SUI is tested for at the completion of the procedure. With respect to the storage phase, DC gathers the same information as UDS, with the exception of urethral pressures. DC has the added advantage of direct visualization of the bladder for pathology.

The primary aim of this study was to investigate the diagnostic agreement between DC and UDS for detecting SUI and UUI in women with a history of MUI requiring further clarification beyond that of history and physical examination.

Materials and methods

Study design, setting, and participants

This was a single-center, prospective, same-paired investigation conducted in the outpatient Pelvic Floor Clinic located within a tertiary care hospital in Calgary, Canada. The center has five academic consultant urogynecologists, and access is by medical referral for pelvic floor disorders. Recruitment for the study began in May 2015 and was completed by March 2016. The study received approval from the Conjoint Research Ethics Board at the University of Calgary.

Successive female patients meeting inclusion and exclusion criteria were approached for enrolment. Women were included if they were initially diagnosed in the office with MUI by participating urogynecologists and had both UDS and DC requested. With regard to MUI diagnosis, this referred to a clinical diagnosis of both SUI and UUI/UU in the same participant prior to any testing with UDS and DC. Thus, women with SUI-only or UUI/UU-only diagnoses were ineligible. Exclusion criteria were inability to provide consent, inability to read English and to complete the study questionnaires, age <18 years, and diagnosis other than MUI, including recurrent urinary tract infection (UTI), suspected bladder pain syndrome, suspected foreign body/neoplasm/fistula/diverticulum in the lower urinary tract, evaluation for urethral obstruction or hypotonic bladder and for gross or microscopic hematuria, testing for latent SUI, or solely for documenting incontinence prior to SUI surgery. Participants were asked to fill out a questionnaire on baseline demographic data and urinary symptoms. Immediately after each test, participants were asked to fill out an additional questionnaire measuring procedure acceptability scores [8]. UDS and DC were performed in random order. Pelvic examination was performed at the DC appointment and included the Pelvic Organ Prolapse Quantification (POP-Q) examination [2, 9]. Once recruitment was complete, a qualified physician blinded to patient history and DC results interpreted UDS data and provided final UDS diagnoses based on prespecified definitions. A different physician blinded to history and UDS results provided final DC diagnoses.

Testing protocol

All participants were investigated with the UDS system (Triton, Laborie Medical Tech., Canada) using a standardized protocol according to international standards [10]. DC was performed with a rigid cystoscope (27,005 BA, 30°, 4-mm telescope, Karl Storz) attached to the UDS pump and software. Prior to each test, the participant voided on a uroflow (to measure maximum flow rate and voided volume) and was then catheterized for a preprocedure postvoid residual (PVR). During the filling/cystometry portion of each test, volumes of instilled fluid at first urge to void, strong desire to void, and maximum cystometric capacity (MCC) were ascertained as per International Urogynecological Association/International Continence Society (IUGA/ICS) terminology [2]. Detrusor, vesical, and abdominal pressures were gathered during filling at UDS. Room-temperature normal saline was infused at a rate of 60 cm^3/min through a urodynamic catheter at UDS and through the scope at DC. During UDS, coughing and Valsalva were performed at 100 cm^3 and 300 cm^3, respectively, of instilled fluid and at MCC to test for SUI. During DC, cough and Valsalva were performed at MCC with the scope removed. Coexisting prolapse was reduced with a split speculum during cough/Valsalva. If no leaking was observed, the participant repeated cough/Valsalva while standing. For UDS, urethral profilometry to ascertain maximum urethral closure pressure (MUCP) and a pressure-flow study to measure detrusor pressure during voiding and maximum flow rate were performed. The profilometry was performed with a catheter pulley at a withdrawal rate of 5 mm/s and with saline perfusion at 5 ml/min [10]. The sensor was placed at the right lateral edge of the urethra. For cystoscopy, the bladder neck and midurethra were inspected for coaptation at MCC. Detrusor contractions were recorded. Cystoscopically visualized bladder abnormalities were recorded. For both, information was gathered on complications, UTI in the week following each test, protocol deviations, and procedure length. No incontinence or prolapse treatment was initiated between tests.

Variables and data sources

The primary outcome measure was the concordance between DC and UDS for detecting SUI and UUI in participants with MUI undergoing both tests. Methods, definitions, and units conform to the standards jointly recommended by the IUGA/ICS unless otherwise stated [1, 2].

An observed leak at any bladder volume with cough or Valsalva was considered positive for SUI [2]. At DC, markers for UU/UUI were the presence of DO (visual detection of blanching/tension in trabeculation or a contraction of the bladder). At UDS, UU/UUI were defined by an isolated rise in detrusor and vesical pressure > 5 cm H_20 associated with urgency (with or without leaking) or increased bladder sensations during filling (one or more of the following present: first desire to void <150 cm^3, strong desire to void <250 cm^3, MCC <300 cm^3) [11, 12].

Several secondary outcome measures were examined, including identification of voiding dysfunction and intrinsic sphincter deficiency (ISD). Suspected voiding dysfunction was defined as either void >200 cm^3 on uroflow with maximum flow rate < 20 cm^3/s and residual volume > 100 cm^3, or MCC > 500 cm^3 without an urge to void [11]. UDS exclusively looked at confirmed voiding dysfunction. No standard definitions for confirmed voiding dysfunction exist, but for the purpose of this study, it was defined as maximum flow rate < 12 cm^3/min with a detrusor pressure < 15 cm H_2O on the pressure-flow component [13]. ISD was defined as lack of midurethral coaptation or open bladder neck on cystoscopy and mean urethral closure pressure (MUCP) ≤20 cm H_2O on UDS [14, 15]. DC exclusively reported urologic pathology. Complications for both tests were noted (symptomatic vasovagal episodes, gross hematuria after test, UTI, and other). UTI was defined as culture >1 × 106 cfu/l with symptoms of dysuria, hematuria, suprapubic discomfort, or new/worsening frequency within 1 week of testing [16]. Procedure time was compared.

Urinary symptoms at enrolment were assessed by the validated six-item Questionnaire for Urinary Incontinence Diagnosis (QUID) [17]. Patient acceptability scores after each test were measured using the Subjective Units of Distress Scale (SUDS) [8].

Study size

The kappa coefficient was the primary statistic used to assess agreement between DC and UDS for detecting SUI and UUI in women with a history of MUI [18]. Based on literature findings in patients presenting with MUI for UDS, the diagnosis was reclassified to either SUI-only or UUI-only cases approximately 70% of the time [4, 5]. The chosen sample size was based on a confidence interval (CI) for kappa that would show at least moderate agreement [19]. Therefore, 60 participants would allow reporting of a kappa coefficient of 0.7 with a 95% CI width of 0.4 (0.5–0.9) [20].

Statistical methods

All data were analyzed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). Descriptive statistics were calculated for patient demographics, with means and standard deviations (SD) for parametric continuous variables, medians, and interquartile ranges (IQR) for nonparametric continuous variables and frequencies and proportions for categorical variables. McNemar's test was used to compare agreement between DC and UDS for each diagnosis of SUI only, UUI only, and MUI separately, as these were categorical variables (present/absent). For the primary outcome, McNemar's test and the kappa coefficient with 95% CI were calculated to assess agreement in detecting any SUI and any UUI separately. Secondary outcomes of the SUDS scale and test length were compared using the paired *t* test, as mean differences between DC and UDS for these measures were normally distributed. Wilcoxon signed-rank test was used to compare nonparametric data. Receiver operating characteristic (ROC) analysis was used to explore the best possible filling sensation cutoffs for DC that would best predict the filling sensation cutoffs from the UDS. Sensitivity and specificity of DC were calculated both before and after ROC analysis.

Results

In total, 60 successive participants meeting inclusion and exclusion criteria were recruited. Four were excluded from analysis as a result of protocol deviations (2 took an anticholinergic prior to one test but not the other, 1 did not show for UDS, and 1 had a primary indication to rule out voiding dysfunction despite having MUI symptoms). Therefore, 56 (93%) participants were followed until completion of both DC and UDS. Interval between the two tests varied from 0 (DC and UDS performed on same day) to 159 (mean 26.5) days. Baseline characteristics are presented in Table 1.

Final diagnoses based on tests are presented in Table 2. The primary outcome measure of detection concordance is presented in Table 3. The kappa coefficient of 0.54 is indicative of moderate, nearly substantial, agreement [19].

Table 1 Participant baseline characteristics

Characteristic	Participants ($n = 56$)
Age, mean (± SD)	56.8 (± 13.2)
BMI (kg/m^2), mean (± SD)	32.7 (± 7.2)
Ethnicity	
Caucasian	50 (89%)
Asian	3 (5%)
South American	2 (4%)
Aboriginal	1 (2%)
Gravidity, median (IQR)	3 (2–4)
No. vaginal deliveries, median (IQR)	2 (1.5–3)
No. cesarean sections	
0	46 (82%)
1	5 (9%)
≥2	5 (9%)
Menopausal	
Yes	37 (66%)
No	15 (27%)
Unsure	4 (7%)
Prior prolapse surgery	6 (11%)
Prior incontinence surgery	12 (21%)
Prior hysterectomy	21 (38%)
Current use of anticholinergic or beta-3 agonist	9 (16%)
QUID stress score (out of 15), mean (± SD)	8.7 (± 3.1)
QUID urge score (out of 15), mean (± SD)	9.8 (± 4)
Current smoking	9 (16%)
POP-Q	
Stage 0	10 (18%)
Stage 1	15 (27%)
Stage 2	28 (50%)
Stage 3	2 (4%)
Stage 4	1 (2%)

BMI body mass index, *QUID* Questionnaire for Urinary Incontinence Diagnosis, *POP-Q* Pelvic Organ Prolapse Quantification

Table 2 Final urodynamic and cystoscopic diagnoses of incontinence types

Diagnosis	UDS ($n = 56$)	DC ($n = 56$)	*P* value*
SUI only	18 (32%)	16 (29%)	0.593
UUI only	9 (16%)	14 (25%)	0.132
MUI	17 (31%)	19 (34%)	0.593

UDS urodynamics, *DC* dynamic cystoscopy, *SUI* stress urinary incontinence, *UUI* urge urinary incontinence, *MUI* mixed urinary incontinence

*McNemar's test

Reported sensations during filling were significantly lower at DC than UDS for all parameters (Table 4). Given this, post hoc ROC analysis identified the best UUI/UU prediction cutoffs for DC for first urge to void (148 cm^3), strong urge to void (215 cm^3), and MCC (246 cm^3). Using these parameters to compare UDS UUI/UU to DC UUI/UU resulted in a κ= 0.61, with McNemar's test of agreement $p = 0.37$, indicating substantial agreement [19]. The sensitivity and specificity of DC for UUI/UU were 88.5% (95% CI 69.9–97.6) and 66.7% (95% CI 47.2–82.7), respectively. After ROC analysis, adjustment of sensory cutoffs and sensitivity and specificity of DC for UUI/UU were 76.9% (95% CI 60.7–93.1) and 76.7% (95% CI 61.5–91.8), respectively. With regard to SUI, sensitivity and specificity were 82.9% (95% CI 66.4–93.4) and 71.4% (95% CI 47.8–88.7), respectively.

Of the 10 UUI/UU cases detected by DC only, nine were diagnosed exclusively because of one or more heightened bladder sensations. The remaining case was diagnosed because of spontaneous DO at MCC during DC despite normal sensations. For the three cases of UUI/UU detected by UDS only, one was due to heightened sensations, one solely due to DO, and one due to both. Ten participants were observed to have DO: four were seen on both tests, and three each on DC and UDS only. Abnormal sensations were present on at least

Table 3 Agreement between urodynamics and cystoscopy for stress (SUI) and urge (UUI) urinary incontinence

Results	SUI ($n = 56$)	UUI ($n = 56$)
Present on both tests	29 (52%)	23 (41%)
Present on cystoscopy only	6 (11%)*	10 (18%)
Present on urodynamics only	6 (11%)**	3 (5%)
Absent on both tests	15 (27%)	20 (36%)
McNemar's test *p* value	>0.999	0.052
Kappa coefficient (95% CI)	0.54 (0.32–0.77)	0.54 (0.33–0.75)

CI confidence interval, *MCC* maximum cystometric capacity

*Cough leak occurred at volume that surpassed cystoscopic MCC by mean 74.2 cm^3

**Cough leak occurred at volume that surpassed urodynamic MCC by mean 68.4 cm^3

Table 4 Reported volumes of filling sensations during urodynamics (UDS) and dynamic cystoscopy (DC)

Sensation	UDS	DC	*P* value*
First urge to void (cm^3), median (IQR)	207 (105–300)	160 (129–198)	0.004
Strong desire to void (cm^3), median (IQR)	289 (216–416)	289(216–416)	0.006
Maximum cystometric capacity (cm^3), median (IQR)	391 (311–500)	323 (246–389)	<0.001

IQR interquartile range

*Wilcoxon signed rank test

one test in seven of these participants. During DC evaluation of the urethra, six participants were thought to have lack of coaptation; one had urodynamic ISD. No other participant had MUCP ≤20 cm H_2O. Four of these six participants demonstrated SUI on one of the two tests. Results of the other secondary outcomes are presented in Table 5.

Discussion

This study showed diagnostic agreement between UDS and DC for SUI and UUI in participants with symptoms of MUI requiring further clarification, and thus the primary outcome was achieved. Taking into consideration that UDS is an imperfect gold standard, DC showed moderate agreement with UDS for SUI. Sensations to void were consistently reported earlier during DC and when this was adjusted for using ROC analysis, DC showed substantial agreement with UDS for UUI/UU and had the advantage of allowing direct visualization of the bladder and significantly shorter testing time. Participants accepted both procedures equally. To the authors' knowledge, this is the first study of this kind in more than two decades. Previous comparison studies are very scant and flawed by vague selection criteria, heterogeneous urogynecologic population (not just incontinence), and restrictive diagnostic criteria for both SUI and UUI [21, 22].

Strengths of this study were its prospective nature with same-patient comparison. In addition, results of UDS and DC were interpreted by blinded physicians. Precise instructions on study protocol were developed and disseminated. The two DC investigators practiced in conjunction to ensure consistency prior to study launch. Acceptability surveys were anonymous to limit response bias, and diagnostic criteria were strictly predefined to eliminate definition bias. Weaknesses of the study included the lack of follow-up information on treatment outcomes and, as such, UDS or DC could not be correlated with clinical outcomes. Interobserver variability or reproducibility of UDS and DC administration were not tested, and information was not collected on women who were approached for enrollment but declined to participate. Furthermore, the study was four participants short of calculated sample size and therefore slightly underpowered. Thus, the nonsignificant difference in SUI and UUI detection between UDS and DC can be considered a trend. However, this similarity in detection reflects the authors' experience in practice at the study institution.

Bladder storage and sensory symptoms were included in the definition of UUI/UU. The traditional definition refers to the presence of DO; however, patients with idiopathic OAB

Table 5 Comparison of secondary outcomes between dynamic cystoscopy (DC) and urodynamics (UDS)

Variable	DC (*n* = 56)	UDS (*n* = 56)	*P* value
Suspected voiding dysfunction	3[*]	4[*]	n/a
Confirmed voiding dysfunction	n/a	1[a]	n/a
Intravesical pathology	3[b]	n/a	n/a
Complications	2 gross hematuria	1 vasovagal	n/a
UTI	0	0	n/a
SUDS acceptance score[c], median (IQR)	20 (10–41)	20 (10–40)	0.476 [d]
Test length (min), median (IQR)	7 (5–9)	21.5 (20–25)	<0.001[d]

n/a not applicable, *UTI* urinary tract infection, *SUDS* Subjective Units of Distress Scale, *IQR* interquartile range

[*] No participant had suspected voiding dysfunction on both tests

[a] Patient had positive screen at UDS, negative screen at DC

[b] Biopsy confirmed: polypoid cystitis, inverted papilloma, cystitis cystica

[c] 0 no distress, 100 maximum distress

[d] Paired *t* test

have several etiologies, including a sensory component [23, 24]. We used volumes less than the lower limit of normal, as proposed by the Society of Obstetricians and Gynecologists of Canada [11]. The rate of agreement for UUI/UU was skewed by the fact that DC identified more cases than UDS. It is difficult to say whether this was overcall with DC versus improved sensitivity. The fact that DC volumes at defined sensations were significantly lower than UDS volumes favored false positivity, thus the reason for ROC analysis. Theoretically, this can be explained by the larger caliber of the cystoscope and its potential in causing urethral irritation and heightened sensation [25].

With respect to SUI, the level of agreement was moderate. Again, this was a reflection of six cases of positive cough/Valsalva stress test detected at DC only and vice versa. The maneuver of an attempted provoked leak with a retrofilled bladder was the same at both tests; thus, it makes sense that sensitivity would be similar. In fact, for both tests, the detection rate was 63%, which falls within the quoted SUI leak rate of 60–70% at UDS in MUI patients [3, 5].

Conclusion

In summary, this study showed moderate agreement for detecting SUI and substantial agreement for UUI/UU detection between DC and UDS. Upon closer examination, detection rates for SUI were equal. It must be kept in mind that the gold standard of UDS is an imperfect test against which DC in this study was measured. DC as a sole test for MUI patients would offer the benefit of direct visualization of bladder and urethra, physician presence during testing to allow correlation with patient symptoms, and shorter procedure time. Future considerations with regard to research for DC should focus on reproducibility of DC diagnosis and correlation to treatment plans, as well as posttreatment patient satisfaction. In conclusion, this study supports the hypothesis that cystoscopy can be elevated from being an anatomic investigation of the bladder and urethra to potentially a physiologic test similar to UDS in women with MUI.

Compliance with ethical standards

Conflicts of interest None.

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