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The Accuracy of Portable Ultrasound Bladder Scanner Measurements of Postvoid Residual Volume in Women With Pelvic Organ Prolapse

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Objectives: The purpose of this study was to evaluate the accuracy of portable bladder scanner postvoid residual (PVR) volume measurements in patients with pelvic organ prolapse. A secondary goal was to determine whether covariates such as bladder volume and stage of prolapse affect bladder scanner accuracy.

Study Design: Complex urodynamic studies were performed on 70 patients with stage II or greater prolapse. Complex urodynamic studies included measurement of maximum bladder capacity (MBC) as well as measurement of PVR by urethral catheterization before, and following, complex filling cystometry. For each catheterized PVR, a corresponding bladder scanner measurement was obtained; the primary outcome was the difference between these measurements. In addition, bladder scanner measurements of MBC were compared with MBC by urodynamic pump. Measurements were compared by paired t test. Linear regression was used to assess association between covariates and bladder scanner error.

Results: There was no significant difference between catheter and bladder scanner PVR at the initial (mean difference, 5.94 mL; 95% confidence interval [CI], -3.8 to 15.7) or final (mean difference, 1.37 mL; 95% CI, -10.9 to 13.6) measurements. Maximum bladder capacity measurements by bladder scanner were significantly smaller than catheterized measurements (mean difference, -21.3 mL; 95% CI, -40.3 to -2.3). Stage III/IV prolapse was associated with increased bladder scanner error (P = 0.03).

Conclusions: The portable bladder scanner accurately measures PVR in patients with pelvic organ prolapse and could be considered as an alternative to catheterized assessment. However, stage III/IV prolapse is associated with increased bladder scanner error, which should be considered when determining appropriate candidates for bladder scanner PVR assessment.

Key Words: postvoid residual volume, pelvic organ prolapse, portable bladder scanner

(Female Pelvic Med Reconstr Surg 2019;25: 388–391)

P elvic floor disorders, including pelvic organ prolapse (POP), urinary incontinence, fecal incontinence, and other bladder filling and emptying abnormalities affect nearly 25% of women in the United States. Up to 11% choose to undergo surgical intervention.^{1,2} These conditions frequently coexist, and it is common for women presenting with symptoms of POP to also report urinary symptoms.³ For this reason, evaluation of bladder emptying

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DOI: 10.1097/SPV.0000000000000565

by measurement of postvoid residual (PVR) volume is recommended in the initial work up for pelvic floor disorders.^{4,5}

Historically, PVR was assessed by urethral catheterization. However, bladder ultrasound has become more popular in recent decades, as it is an effective and noninvasive alternative method for determining PVR. Since it was first described in 1967, the use of a portable ultrasound for measuring PVR has been validated by numerous studies and has reduced the need for urethral catheterization.^{6,7} In 1988, Roehrborn and Peters suggested that ultrasound should be the criterion standard for determining PVR given that it is accurate, noninvasive, and avoids potential complications that can result from urethral catheterization.8 Subsequently, determination of PVR with a portable bladder scanner became accepted as a reliable and accurate method, regardless of patient age, sex, diagnosis, or technician experience.

As technology has advanced, bladder scanners have become more sophisticated. Current models are often portable, automated, and provide real-time prescan imaging. These advances have resulted in enhanced accuracy and reduced variability of results, regardless of operator experience. 10-13 Despite these advances, there are instances in which bladder scanners are unable to provide an accurate measurement of PVR. The presence of altered anatomy, specifically ovarian cysts, renal cysts, and bladder diverticulum, has been reported causes of inaccurate PVR determination by bladder scanner. ^{14–20} Pelvic organ prolapse also causes alterations to normal pelvic anatomy and therefore could similarly lead to inaccurate bladder scanner measurements. To date, no prior studies have evaluated the accuracy of the portable bladder scanner in patients with POP.

The purpose of this study was to determine the accuracy of portable bladder scanners in the assessment of PVR in women with POP. We hypothesized that bladder scanner measurements in patients with more advanced stages of prolapse would be less accurate than bladder scanner measurements in patients with lesser stage prolapse.

METHODS

This study was a prospective cohort study conducted at an academic female pelvic medicine and reconstructive surgery (FPMRS) subspecialty clinic. After approval by the University of Louisville Institutional Review Board, patients undergoing urodynamic studies (UDSs) before surgery for POP between September 2014 and April 2017 were offered enrollment. Women were eligible for enrollment if they spoke English, were at least 18 years of age, and had prolapse greater than or equal to stage II. Patients with congenital urogenital anomalies, chronic indwelling urinary catheters, history of recent urethral surgery, or known renal or ovarian cysts greater than 5 cm in diameter were excluded. All study participants underwent POP quantification system staging, performed by a licensed FPMRS subspecialist physician. Anterior, posterior, and apical prolapse were defined as prolapse arising from an individual anatomic compartment at a level 1 cm proximal to the hymenal ring or beyond. When prolapse was

TABLE 1. Patient Characteristics

Demographics		
Medical and Surgical History	n = 70	%
Patient age, y		
20–39	3	4.3
40–49	12	17.1
50–59	18	25.7
60–69	22	31.4
70–79	10	14.3
80–89	5	7.1
Race		
White	65	92.9
Black	3	4.3
Hispanic	1	1.4
Asian	1	1.4
BMI*	Mean = 29.79	SD = 6.62
Smoking status		
Nonsmoker	59	84.3
Former smoker	9	12.9
Current smoker	2	2.9
Medical comorbidities		
Heart disease	8	11.4
Hypertension	29	41.4
Diabetes mellitus	11	15.7
Neurologic disorder	6	8.6
Previous pelvic surgery		
Hysterectomy	28	40
Pelvic organ prolapse repair	18	25.7
Tubal ligation	13	18.6
Other prior abdominal surgery		
Upper abdomen	24	34.3
Lower abdomen	10	14.3

*n = 7 patients did not have BMI measurement.

noted in more than 1 compartment, staging was based on the leading edge. Patient characteristics such as age, body mass index (BMI), past medical, and surgical history were collected from the electronic medical record.

Before surgery for POP, appropriate patients undergoing preoperative assessment with UDSs in our clinic were offered participation in the study. After an informed consent process, UDS was conducted with reduction of prolapse with the goal of screening for occult stress incontinence. All UDSs were conducted by a medical assistant with 4 years of prior experience performing this study as part of routine care at our FPMRS practice. Multichannel UDSs were performed using a Laborie system and involved a free (noncatheterized) electronic uroflow, multichannel filling cystometry with 2 mm catheters in the urethra and vagina/rectum for multicompartment pressure measurement, and a pressure-flow voiding study with these catheters in place. During the filling phase of the study, the patient indicated when they could no longer voluntarily hold urine, and at this point, the fluid volume in the bladder (the maximum bladder capacity [MBC]) was measured by a urodynamics pump and recorded. If the patient had leaked or urinated part of the instilled volume before their indication that they were at bladder capacity, this leaked or urinated volume was measured by a scaled beaker and subtracted from the instilled volume to calculate the true volume in the bladder at MBC.

Measurement of PVR by urethral catheterization was performed immediately before filling cystometry portion of the UDS and after the patient had voided with urodynamics catheters in place (after the pressure-flow study). At these same 2 points in the test, before urethral catheterization, bladder volume was measured with a BioCon 700 portable bladder scanner, which was calibrated and maintained as per manufacturer recommendations. The ultrasound transducer was placed immediately superior to the pubic bone in the midline and directed toward the spine (posterior) at an angle between 0 and 60 degrees from the horizontal in an inferior direction. If readings suggested improper placement of the transducer, the nurse adjusted the transducer and repeated the measurement until the transducer ultrasound picture/reading indicated an image from the center of the bladder fluid.

In addition, bladder volume at MBC was measured with the bladder scanner. Bladder volume measurements obtained with the bladder scanner were then compared with their corresponding volumes measured by urethral catheterization before and after the test, as well as to the known infused volume at MBC.

The primary outcome was the difference between scanner PVR and catheterized PVR (scanner minus catheterized). Based on a prior study that found the clinically significant difference between bladder scanner and catheterized bladder volume measurements to be 30 mL with an assumed standard deviation of 71 mL (13), our sample size calculation determined that 70 patients were needed to detect a clinically significant difference with α of 0.05 and 80% power.

Descriptive statistics were used to assess all demographic characteristics. For the initial PVR, as well as the PVR measurement performed at the completion of UDSs, paired *t* test was used to calculate bladder scanner error, as defined as the difference between the bladder scanner measurement and the catheterized PVR volume (scanner PVR minus catheterized PVR). Bladder scanner error at MBC (bladder scanner measurement minus urodynamic pump estimate) was also calculated using paired *t* test. To assess the association between accuracy and potential predictors, analysis of variance was used to analyze the relationship of categorical variables to bladder scanner errors in the 2 PVR time points. Kendall correlation and linear regression were used to analyze the relationship of quantitative variables to bladder scanner error. Statistical analysis was performed using the R statistical software, version 3.3.1.

RESULTS

Seventy-nine women were enrolled in this study; 9 women were excluded owing to inability to complete the UDSs or for

TABLE 2. Characteristics of Pelvic Organ Prolapse

Stage of Pelvic Organ Prolapse		
Anatomic Locations of Prolapse	n = 70	%
Stage II	57	81.4
Stage III	10	14.3
Stage IV	3	4.3
Anterior only	10	14.3
Posterior only	16	22.9
Apical only	0	0
Anterior and posterior	17	24.3
Anterior and apical	9	12.9
Posterior and apical	1	1.4
Anterior, posterior, and apical	17	24.3

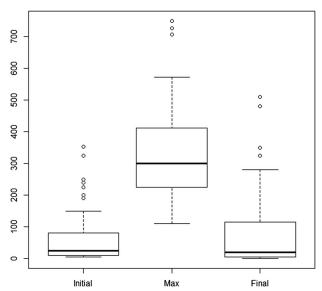


FIGURE 1. Box plot of catheterized bladder volumes (mL) at each point of measurement.

prolapse less than stage II, leaving 70 patients for analysis. The mean \pm SD age of study participants was 58 ± 12.8 years old, and mean \pm SD BMI was 29.8 ± 6.9 kg/m². Most patients (93%) were Caucasian (Table 1).

Anterior prolapse was noted in 76% of patients (n = 53), whereas 73% of patients (n = 51) had posterior prolapse. Apical prolapse was less common and only present in 39% of patients (Table 2). In patients with prolapse in more than 1 compartment, overall POP quantification system staging was based on the leading edge. Most women (81.4%) had stage II prolapse, whereas only 14.3% had stage III and 4.3% had stage IV.

The median initial and final catheterized PVR volumes were 25 mL (interquartile range [IQR], 11.25–80 mL) and 20 mL (IQR, 5–112.5 mL), respectively (Fig. 1). There was no significant difference between the bladder scanner and catheterized PVR either initially, before filling cystometry (mean difference, 5.94 mL; 95% CI, –3.8 to 15.7), or on final PVR after pressure flow study

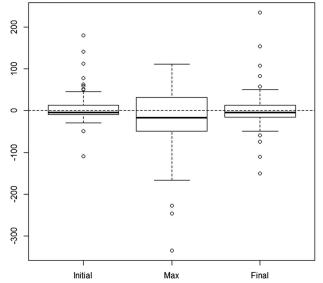


FIGURE 2. Box plot of difference (mL) between bladder scanner and catheterized measurements at each point of measurement.

TABLE 3. Effect of Bladder Volume on Raw Accuracy of Bladder Scanner Measurements

Catheter Volume	Predicted Error	95% Confid	ence Interval
10	9.8	-0.5	20.2
50	6.1	-3.3	15.4
100	1.3	-7	9.7
300	-14.5	-27.4	-7.7
600	-48.5	-66.3	-25.3

(mean difference, 1.37 mL; 95% CI, -10.9 to 13.6) (Fig. 2). For these measurements, there was no evidence that the absolute error of the bladder scanner exceeded the threshold of 30 mL, either initially (mean difference, 24.9 mL, P = 0.9022) or at the final measurement (mean difference, 28.8 mL, P = 0.5957).

The median MBC during the UDSs was 300 mL (IQR, 225–411 mL). For these measurements, the bladder scanner systematically underestimated catheterized bladder measurements (mean difference, -21.3 mL; 95% CI -40.3 to -2.3). At MBC, the mean absolute error was 57.3 mL, significantly larger than the threshold of 30 mL (P < 0.0001).

The impact of urine volume on bladder scanner accuracy was assessed with linear regression analysis, demonstrating an anticipated increase in bladder scanner error with increasing bladder volume (regression coefficient, 0.012; P < 0.001) (Table 3).

When anterior, posterior, and apical prolapse were independently considered as predictors of accuracy, no significant effect was noted between the anatomic location of prolapse and the accuracy of bladder scanner measurements (anterior, P=0.63; posterior, P=0.56; apical, P=0.93). This finding was consistent at all bladder volumes.

When stage of prolapse was considered as an independent predictor of bladder scanner accuracy, the presence of either stage III or IV prolapse was associated with a significant increase in bladder scanner error when compared with measurements in women with stage II prolapse (regression coefficient, 18.1; P=0.03). No other medical or surgical covariates were found to have a significant effect on the accuracy of bladder scanner measurements (Table 4).

DISCUSSION

In this prospective cohort study comparing ultrasonographic bladder scanner PVR volume measurements to the criterion standard of catheterized PVR, we found that the accuracy of bladder

TABLE 4. Effect of Medical and Surgical Covariates on Raw Accuracy of Bladder Scanner Measurements

Covariate			
Prior Surgery	Regression Coefficient	P	
Prolapse stage >2	18.1	0.032	
Age	0.44	0.092	
Gravity	0.68	0.717	
Parity	0.88	0.648	
BMI	-0.04	0.940	
Hysterectomy	-2.41	0.731	
Lower abdomen	-6.14	0.533	
Upper abdomen	-1.32	0.858	
Prolapse repair	1.66	0.833	
Any surgery	4.11	0.582	

scanner measurement of bladder volume decreases with advancing stage of POP. In addition, accuracy of PVR measurements by bladder scanner in patients with POP is inversely related to bladder volume. Whereas measurements of PVR were accurate in patients with prolapse, bladder scanner measurements of MBC were less accurate. For all stages of prolapse, when bladder volumes are above 100 mL, the average error exceeds our threshold for clinical significance.

Our finding, that bladder scanner measurements are less accurate when measuring larger bladder volumes, is a known statistical phenomenon and was previously demonstrated to occur irrespective of the presence of POP.²¹ However, POP may also contribute to increased error by anatomic distortion of the bladder in an inferior direction, making accurate ultrasound assessment from the suprapubic transducer more difficult to obtain. Furthermore, the relationship between prolapse and increased error as the urine volume increases is likely compounded, as opposed to merely additive, as women with higher levels of prolapse tend to have larger residual from kinking of urethra associated with advancing prolapse stage. Likely, our findings result from a combination of statistical and anatomic factors, and further study is needed to better understand this relationship.

In practical terms, the fact that the bladder scanner is less accurate at MBC does not diminish its potential for use in PVR assessment, as our study shows that bladder scanner assessments of PVR are not significantly different than catheterized volumes. In addition, clinicians can be reasonably assured that a bladder scanner assessment of bladder volume in patients with POP is accurate within 30 mL if the measurement is less than 100 mL. In situations where bladder volume is measured to be greater than 100 mL by bladder scanner, the measurement could be verified by catheterization. Also, some clinicians may feel that, at larger bladder volumes, 30 mL no longer represents a clinically significant difference. In other words, although an error of 30 mL could represent a clinically significant difference between measurements of 10 mL and 40 mL, the difference between 570 mL and 600 mL could be of less clinical significance.

Finally, it is notable that our study did not demonstrate a correlation between BMI and bladder scanner accuracy. Although this may seem counterintuitive, a prior study using the same model of bladder scanner found similar results.²¹ This finding should, however, be interpreted with caution, as the mean BMI in our patient population was 29.79 kg/m² with a relatively low standard deviation ($\pm 6.62 \text{ kg/m}^2$). Therefore, we are not able to predict the effect that extreme elevations in BMI would have on bladder scanner accuracy.

Strengths of this study include its prospective nature and the ability to use each patient's bladder scanned measurements for comparison with those of the current criterion standard urethral catheterization. In addition, there was no risk for interoperator variability, as all measurements were performed by the same experienced medical assistant. Lastly, we obtained adequate power to determine that PVR error in bladder scanners did not reach a preset evidencebased verified threshold for clinical significance (30 mL).

Limitations of this study include a population largely comprised of patients with stage II prolapse. As more advanced stages of prolapse were encountered less frequently, unequal sample sizes could have influenced our finding that women with stage III or IV prolapse have less accuracy in bladder scanner measurements. Therefore, further study evaluating a larger sample of patients with stage III and IV prolapse is needed to better understand the extent of this relationship. Furthermore, this study is limited by the fact that this population is located in a tertiary care center in one region and may have characteristics that are not generalizable to all populations.

Overall, given the accuracy of portable 3-dimensional bladder scanner measurements of PVR in patients with POP and because of its potential to decrease patient discomfort and risk of catheterization, the results of our study suggest that its use should be considered as an alternative to urethral catheterization when measuring PVR in patients with POP.

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