Reproducibility of Leak Point Pressure in Female Stress Urinary Incontinence

Eu Chang Hwang, Sun-Ouck Kim,* Dong Deuk Kwon

Purpose: To assess the reproducibility of the Valsalva leak point pressure (VLPP) based on urodynamics in females with stress urinary incontinence (SUI).

Materials and Methods: From October 2008 to December 2009, 65 consecutive women with urodynamically confirmed SUI underwent duplicate VLPP measurements. The intra-individual reproducibility of the VLPP recording obtained by one urologist was determined. The two observations were separated by a 10-min interval.

Results: The differences between the repeated measurements were not significant (initial vs. repeat VLPP, 84.8 ± 19.9 vs. 86.7 ± 20.3 cmH_2O; P = .094). Repeated VLPP measurements were reproducible. Defining intrinsic sphincter deficiency (ISD) as VLPP < 60 cmH_2O, the diagnosis of ISD changed between successive tests in three cases (from 55 to 89, 58 to 64, and 61 to 55 cmH_2O).

Conclusion: In female SUI, the VLPP is a reproducible method for evaluating urethral resistance. For VLPP < 90 cmH_2O, the diagnosis of ISD changed in repeated measurements in some patients; therefore, other clinical findings must be considered when deciding on a treatment method.

Keywords: urinary incontinence; stress; urodynamics; Valsalva maneuver; physiology; female; pressure.

INTRODUCTION

Continence of urine is maintained so long as the urethral pressure exceeds the bladder pressure, if the anatomy is intact. Traditionally, urologists have assessed the positive urethral pressure gradient at rest with the passive urethral pressure profile and under stress with the dynamic or cough urethral pressure profile. An alternative measurement of urethral resistance favored by urologists is the leak point pressure (LPP), which is the abdominal pressure at which the urethral resistance is overcome and fluid leakage is observed. Cough- or Valsalva-induced LPP is an important objective tool that is used routinely in the diagnosis of stress urinary incontinence (SUI) in urodynamics clinics. Valsalva leak point pressure (VLPP) has been used for evaluating urethral sphincter resistance in women with urinary incontinence that has been shown to be reproducible and to correlate with other measures of urethral resistance and the clinical severity of urinary incontinence.[1-3] VLPP has been promoted as a relatively simple test that can differentiate among SUI, bladder neck hypermobility, and intrinsic urethral sphincter deficiency (ISD). However, urodynamic techniques still have several major shortcomings in terms of reproducibility for predicting ISD or incontinence severity.[3] The reliability of a diagnostic test is dependent on the accuracy and reproducibility of the measurement tool, which can be determined by comparing the results of repeated examinations of the same subject. After assessing the reproducibility of the technique at maximum cystometric capacity with different catheter sizes, Bump and colleagues[3] demonstrated the reproducibility of VLPP in approximately 80% of adult women with SUI. Because VLPP is gaining more widespread acceptance as a clinically useful test for evaluating women with SUI, we studied the reproducibility of VLPP measured in females with SUI by comparing the results of two repeated cystometries.

MATERIALS AND METHODS

Study Population

From October 2008 to December 2009, 65 consecutive women with urodynamically confirmed SUI provoked by the Valsalva maneuver underwent duplicate VLPP measurements. All patients underwent a comprehensive assessment, including a clinical history evaluation, physical examination, and a multichannel urodynamic evaluation according to the standards of the International Continence Society.[4] Subjects were excluded, if they had a diagnosis of neurogenic disease possibly in-

Department of Urology, Chonnam National University Medical School, Gwangju, Korea.
*Correspondence: Department of Urology, Chonnam National University Hospital and Medical School 8, Hak-dong, Dong-gu, Gwangju #501-757, South Korea.
Tel: +82 62 2206702. Fax: +82 62 2271643. E-mail: seinsena@hanmail.net.
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Table 1. Baseline characteristics of the patients.

Characteristics	Values
No. of patients	65
Mean age (years)	51.5 ± 7.9
BMI (kg/m2)	25.6 ± 2.9
Hysterectomy, no (%)	3 (4.6)
Menopause, no (%)	42 (64.6)
Parity, mean ± SD	2.4 ± 1.7
Hormonal therapy, no (%)	8 (12.3)
Mean symptom duration, years (mean ± SD)	7.2 ± 6.1
Stamey grade, no (%)	
I	39 (60)
II	22 (33.8)
III	4 (6.2)
Initial VLPP (cmH2O)	
≤ 60	11
60 < VLPP ≤ 90	26
> 90	28

Abbreviations: BMI, body mass index; VLPP, Valsalva leak point pressure.

ducing neurogenic bladder, severe urogenital prolapse (Pelvic Organ Prolapse Quantification stages 2–4),[5] a history of anti-incontinence surgery or other surgeries that influence the urine stream, evidence of detrusor overactivity on filling cystometry, or if any LPP data measured using the urethral channel or visualization methods were missing.

Urodynamic Study

VLPP was measured with the patient in the lithotomy position on an urodynamic table, using a compact urodynamic device (Dantec Dynamics, Skovlunde, Denmark). The pressure transducers, zeroed at atmospheric pressure, were leveled at the upper edge of the symphysis pubis and connected to the intravesical and rectal catheter. A three-channel, fluid-filled 8 French (F) urethral cystometry catheter was used for every VLPP measurement. Residual urine was evacuated. Rectal pressure was measured with a water filled 8F balloon catheter. The bladder was filled with body temperature saline at 50 mL/min. A diagnosis of SUI was made, if the subject had symptoms of stress incontinence and there was direct visualization of urine leakage produced by stress without concurrently demonstrable detrusor activity during cystometry, after the bladder was filled to a volume of 250 mL. Each measurement was repeated twice, and the lowest value was selected for analysis.

Statistical Analysis

The intra-individual reproducibility of the VLPP recording was determined for one urologist with tests performed 10 min apart. The determination of test–retest reliability was made using the paired *t*-test, kappa agreement with Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 17.0. Results were considered statistically significant when the *P* value was < .05.

RESULTS

Patient Characteristics

The 65 subjects had a mean age of 51.5 ± 7.9 (range 31–72) years, mean parity of 2.4 ± 1.7 (range 0–7), and mean symptom duration of 7.2 ± 6.1 (range 1–31) years. Three subjects (4.6%) had undergone hysterectomies. The subjects were divided into three groups according to the initial VLPP parameters (cmH_2O): VLPP < 60, 60–90, and > 90 (**Table 1**).

Difference and Agreement between Test–Retest VLPP Values

The mean difference between the repeated measurements was –1.84 ± 8.76 and they did not differ significantly (**Figure**, *P* = .094). The agreement of test-retest VLPP values were excellent (kappa agreement value; 0.801, *P* = .001), however, defining ISD as VLPP < 60 cmH_2O, the diagnosis of ISD changed between successive tests in three cases as the measured VLPP changed from 55 to 89, 58 to 64, and 61 to 55 cmH_2O (**Table 2**).

DISCUSSION

This study demonstrates that repeated VLPP measure-

Table 2. Distribution of the initial and repeat VLPP measurements.

Variables	Initial VLPP (cmH_2O)		
	≤ 60	60 < VLPP ≤ 90	> 90
Repeat VLPP (cmH_2O)	≤ 60	9	1	0
	60 < VLPP ≤ 90	2	20	3
	90 >	0	5	25

Abbreviation: VLPP, Valsalva leak point pressure.
Kappa agreement value: 0.801 (*P* = .001).

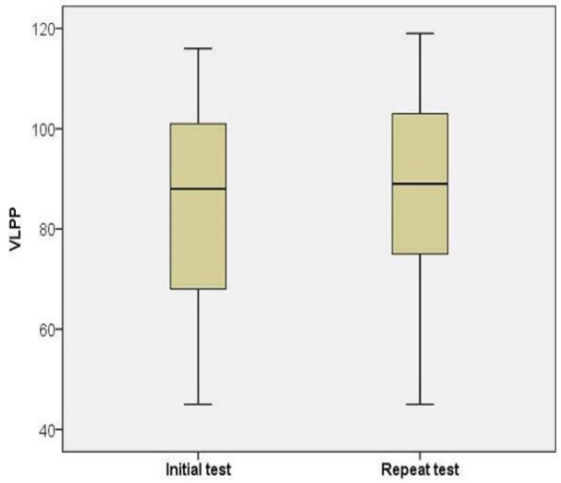

Figure. Reproducibility of the Valsalva leak point pressure (cmH_2O, VLPP) showing a boxplot of each VLPP measurement (initial vs. repeat VLPP, 84.8 ± 19.9 vs. 86.7 ± 20.3 cmH_2O; P = .094).

ments are reproducible in women with SUI, with excellent intra-individual agreement between consecutive measurements. However, we also found some variation in the diagnosis of ISD in a few cases. Defining ISD as VLPP < 60 cmH_2O, the diagnosis of ISD changed between the initial and repeat test. Despite the high reproducibility of VLPP, we suggest that repeated and careful measurement of VLPP is needed for an accurate diagnosis, and that other clinical findings must be considered when deciding on a treatment method for the VLPP range of 60–90 cmH_2O.

LPP is a urodynamic measure of the abdominal pressure at which leakage starts during a sudden or sustained increase in abdominal pressure caused by a cough or Valsalva maneuver.[6] This value is believed to provide information about the presence of ISD and is used for predicting the surgical outcome in women with SUI.[7–9] Since the concept of ISD as an etiologic class of SUI was introduced, VLPP measurements have been used for the urodynamic determination of ISD.[10] The clinical usefulness of this measurement is that, it distinguishes between the two etiologies of SUI: anatomical causes and ISD. Despite the validity of the concept, the lack of a standardized methodology for measuring VLPP has created confusion among clinicians and has delayed the validation of the role of VLPP in outcome studies of the treatment of SUI. Urodynamic parameters need to be standardized for measuring VLPP include catheter size, calibrate the transducer to zero, patient position, bladder volume, type of stress, and timing of measurement.[11] Our present study is one of only a few studies that have assessed the reproducibility of the technique. Bump and colleagues[3] assessed the reproducibility of the technique to compare it to other measures of urethral resistance, and to assess the effects of methodological variation on measurement. They demonstrated that, VLPP was highly reproducible at the maximal cystometric capacity in approximately 80% of adult women with stress incontinence, so long as the catheter size was constant. Differences between two positive measurements using the same catheter are clinically and statistically non-significant.

Regarding the issue of reproducibility of urodynamic parameters in asymptomatic women, Sorensen[12] reported good to high reproducibility for urodynamic data measured on separate occasions within a 2-month period and found no significant change in variables with a small coefficient of variation. Sand and colleagues[13] studied 100 neurologically normal women with urinary incontinence in three repeated sessions, 1~2 weeks apart, and found a non-significant trend toward greater cystometric volume with each successive measurement. They showed 84% reproducibility of cystometrograms from the test–retest analysis.

Selected cut-off values of VLPP have been used worldwide for the diagnosis and determination of treatment methods in SUI based on results obtained by McGuire and colleagues[8] showing that a VLPP < 60 cmH_2O indicates the presence of significant ISD, a VLPP of 60 – 90 cmH_2O suggests a combination of urethral hypermobility and some component of ISD, and a VLPP > 90 cmH_2O suggests urethral hypermobility and minimal ISD. Since McGuire and colleagues[8,14] introduced the concept of VLPP in women with SUI in 1993, using videourodynamic studies as the urinary detection method, many authors have proposed several modifications of the method, including the use of a flowmeter, electronic detection with a microtip catheter, and visualization with or without stepwise increases in abdominal pressure.[3,15–18] However, there appears to be marked disparity in the values measured with these techniques for detecting the start of urinary leakage, even among values from a single patient.

To understand the issues related to VLPP measurement, it is important to clarify some of the terminology used in the literature. VLPP is also referred to as abdominal leak point pressure (ALPP) and stress leak point pressure (SLPP), both of which are the intravesical pressure measured during stress maneuvers. In some cases, cough has also been used for measuring VLPP, SLPP, and ALPP. Use of the Valsalva maneuver generates a slow sustained strain, whereas a cough creates a quick, sudden rise in intravesical pressure. However, Valsalva

and cough have been used interchangeably in descriptions of VLPP measurement. Bump and colleagues[3] reported a significantly higher cough LPP than VLPP. They attributed this to the finding, that reflex contraction of the external sphincter occurs during a cough and not while performing the Valsalva maneuver.[19] Another suggested issue is that the VLPP during a Valsalva maneuver facilitates pinpointing of the pressure at which leakage occurs versus a cough.

In this study, we measured VLPP at a bladder volume of 250 mL, as recommended by McGuire and colleagues[7] Several authors have reported progressive lowering of the VLPP with increasing bladder volume during filling in the same patients.[20,21] They suggested that during urodynamic studies, the observed VLPP depends on the detrusor pressure, the fluid used for the study, and the state of the other abdominal viscera. However, Petrou and Kollmorgen found that bladder volume did not statistically change the VLPP value.[22] Before using the VLPP in clinical practice, investigators should consider the effect of various variables on the value of VLPP. Further validation and standardization of the VLPP methodology will provide valuable information for its use in addressing the treatment outcome of SUI and in selecting the proper treatment for correcting SUI.

This study has some limitations. First, the number of patients included in the study were very few. Second, inter-individual reproducibility was not assessed. Third, we compared 2 measurements, made only 10 minutes apart, by a single urologist - thus potentially allowing bias from memory of the first measurement to affect the second measurement. Also, this study is without a control arm that should be investigated both in patients and healthy controls. Ideally, reproducibility should be tested and controlled by a replication study, which must be completely independent and generate identical findings known as commensurate results to clearly verify the results of the first study. Additionally, VLPP measuring device may have a design flaw and we have to consider the possibility of confounding bias conducting the reproducibility study.

However, few studies have examined the reproducibility of LPP. Therefore, despite these limitations, we believe that our study provides valuable information on the unnecessary use of repeated measurement of LPP, which is a time-consuming, uncomfortable, invasive procedure, in diagnosing incontinence severity in women.

CONCLUSIONS

VLPP is a reproducible method for evaluating the urethral resistance of women with SUI. Although, there is excellent agreement of test-retest VLPP measurement, for a VLPP in the range of 60–90 cmH_2O, the diagnosis of ISD might change with repeated measurements in a few subjects; therefore, other clinical findings must be considered when deciding on a treatment method for correcting SUI in these patients.

CONFLICT OF INTEREST

None declared.

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