Published in final edited form as:

Obstet Gynecol. 2016 February ; 127(2): 348–352. doi:10.1097/AOG.0000000000001243.

Vaginal Swab Test Compared With the Urethral Q-tip Test for Urethral Mobility Measurement: A Randomized Controlled Trial

Isuzu Meyer, M.D.,

Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, Alabama

Jeff M Szychowski, Ph.D.,

Department of Biostatistics, University of Alabama at Birmingham, Birmingham, Alabama

Jana D Illston, M.D.,

Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, Alabama

Alison M Parden, MD, and

Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, Alabama

Holly E Richter, Ph.D., M.D.

Division of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, Alabama

Abstract

Objective—To assess whether a vaginal cotton-tipped swab is equivalent to the standard Q-tip test regarding urethral mobility. Secondly, to examine whether both tests agree in hypermobility diagnosis, discomfort level, and patients' preference.

Methods—In this randomized cross-over trial, women with stress urinary incontinence without prolapse beyond the hymen were randomized to undergo either a vaginal or urethral mobility test first followed by the alternate approach. The primary outcome was the difference in rotation angle, from resting to maximum strain, between tests. The equivalence margin was $\pm 10^\circ$. The secondary outcome was agreement in hypermobility diagnosis using two definitions, #1 maximum straining angle of 30° from the horizontal plane, #2 rotation angle 30° . Discomfort was assessed using 0-10 visual analog scale. Using 90% power assuming a standard deviation of 20° , 36 and 139 patients were needed for 10° and 5° equivalence margins, respectively.

Results—From January 2014 to March 2015, 140 women were randomized. The mean difference between the two tests was 5.1° (95% confidence interval 3.2 - 6.9°), meeting the

Corresponding Author: Isuzu Meyer, MD, Division of Urogynecology and Reconstructive Surgery, University of Alabama at Birmingham, 1700 6th Avenue South, Suite 10382, Birmingham, AL 35233, Phone: (205) 934-1704, Fax: (205) 975-8893, imeyer@uabmc.edu.

Presented at PFD Week 2015 (the American Urogynecologic Society Annual Scientific Meeting), October 13-16, 2015, Seattle, WA, and presented as a poster at the International Continence Society Annual Meeting, October 8, 2015, Montreal, Canada.

Financial Disclosure: The other authors did not report any potential conflicts of interest.

predefined equivalence criteria. In the hypermobility diagnosis, the urethral and vaginal tests had no disagreement using the definition #1 ($p=0.23$) whereas the two tests disagreed using definition #2 ($p=0.03$). The urethral approach had a higher discomfort level ($p<0.001$). The majority preferred the vaginal test (68% preferred vaginal, 32% no preference).

Conclusion—The vaginal swab test is equivalent to the standard Q-tip test in measuring urethral mobility with less discomfort and is preferred by patients.

Introduction

Urethral hypermobility is commonly present in women with stress urinary incontinence (SUI). It occurs when proximal urethral support is compromised, causing descensus of urethrovesical junction with increased abdominal pressure. The standard Q-tip test is the most common method to quantify the extent of urethrovesical support defects by measuring urethral mobility, first described by Crystle et al.¹ The urethra is considered hypermobile when a straining angle is 30° or greater. Test results may influence decision making on the type of anti-incontinence procedure to be performed.

The standard Q-tip test has inherent limitations. The test is performed by inserting a rigid cotton-tip swab into the urethra to the level of urethrovesical junction, potentially causing significant discomfort. Many providers do not feel comfortable performing the test due to the perception of invasiveness or may find the test difficult depending on their level of training and background. There is also a theoretical risk of urinary tract infection.

As the urethral supporting structures are interconnected with the vagina, the rotation of the anterior vaginal wall theoretically represents the degree of urethral rotation. Vaginal placement of a cotton-tipped swab would be a simpler and less invasive alternative method compared to the urethral Q-tip test. Our primary aim was to assess whether the vaginal cotton-tipped swab test is equivalent to the standard Q-tip test in measuring urethral mobility. Secondary aims were to examine whether both tests agree in the diagnosis of urethral hypermobility, assess discomfort with each test, and determine patients' preferred method.

Materials and Methods

A prospective randomized crossover trial comparing the vaginal cotton-tipped swab test and the urethral Q-tip test for measuring urethral mobility was conducted at the University of Alabama at Birmingham. We hypothesized that the vaginal cotton-tipped swab test of urethral mobility would be equivalent to the traditional urethral Q-tip test. Women aged 21 years or older who presented with self-reported symptoms of SUI to the Urogynecology Care Clinic were recruited from January 2014 through March 2015. This trial did not include a drug, biologic or device, therefore did not meet the Food and Drug Administration Amendments Act Section 801 definition of an “applicable clinical trial.” Approval for this study was obtained from the institutional review board (X131203004), and written informed consent was obtained from all participants at enrollment. Eligibility requirements included a primary complaint of SUI and the most prolapsed vaginal point at the hymen or less.

Patients were excluded if they were pregnant, suspected urinary tract infection, or did not speak English.

Enrolled participants underwent both the vaginal cotton-tipped swab test and the urethral Q-tip test. The sequence of testing procedures was randomized in a 1:1 fashion, with half of the participants undergoing the vaginal test first, and the others undergoing the urethral test first. A sequentially numbered sealed envelope was selected to reveal the randomized testing sequence (computer generated) just prior to the testing procedures.

The vaginal test was performed by a cotton-tipped swab placed in the vagina 3cm proximal to the external urethral meatus in the midline (approximating the urethrovesical junction) at rest (Figure 1-A). The urethral Q-tip test was performed in the standard fashion; after application of 2% lidocaine jelly, a sterile cotton-tipped swab was inserted transurethally and withdrawn until resistance was met, representing the urethrovesical junction (Figure 1-B). For both testing procedures, the angles relative to the horizontal plane were measured at rest and with maximum straining using a goniometer. Each test was performed twice in the supine dorsal lithotomy position. After inserting a cotton-tipped swab, patients were asked to relax their pelvis each time prior to measuring the resting angle. Both tests were performed by the same examiner. All examiners were clinicians in the division of urogynecology at our institution. Upon completion of both tests, participants were asked to rate their discomfort level for each test using a 0-10 visual analog scale and to indicate which testing procedure they preferred. All medical records were reviewed for demographics including age, race, body mass index, smoking, parity, menopausal status, medical comorbidities, presence of urgency urinary incontinence, vaginal estrogen use, and prior pelvic surgeries.

The primary outcome was the difference in rotation angle, defined as a change from resting to the maximum straining angles (straining angle minus resting angle). The difference in the rotation angles between the two tests (the rotation angle of the urethral approach minus the rotation angle of the vaginal approach) was calculated. A 95% confidence interval (CI) was used to evaluate equivalence in rotation angle measurements between the two methods. We set a predetermined equivalence margin of $\pm 10^\circ$ for the two tests to be equivalent. We also planned an equivalence assessment with a $\pm 5^\circ$ margin.

For the secondary aims, hypermobility was defined using two criteria: #1: maximum straining angle of 30° or greater from the horizontal plane, the most widely accepted definition, or #2: rotation angle 30° or greater, the less common definition. Agreement in the diagnosis of urethral hypermobility between the two tests was assessed using each criterion.

The sample size was estimated to be 36 and 139 patients with an equivalence margin of $\pm 10^\circ$ and $\pm 5^\circ$, respectively, to provide 90% power assuming a standard deviation of 20° (based on pilot study data). Descriptive statistics and participant characteristics were compared by randomization sequence allotment. The two-sample t-test or Kruskal-Wallis test were used for quantitative measures, the chi-square test or Fisher's exact test were used for categorical measures, as appropriate. Mixed models were used to test for sequence effect. Equivalence of rotation angle measurements was tested with a 2-sided 95% CI.

Agreement of hypermobility assessment was based on McNemar's test. Correlation between the two tests was determined using the Pearson's correlation test. The Wilcoxon Signed-Rank test was used to compare the discomfort score between the two approaches. P-values of <0.05 were considered statistically significant. Analyses were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC).

Results

From January 2014 through March 2015, 140 participants were enrolled and randomly assigned to undergo either the standard urethral Q-tip test first (70 women) or the vaginal cotton-tipped swab test first (70 women). The mean age was similar between the two groups (56 ± 10 years for the urethral test first, 57 ± 13 years for the vaginal test first, $p=0.77$, Table 1). Of the demographic factors, the randomized sequences differed only by prior anterior and posterior repairs between the groups ($p=0.01$ for both, Table 1). Other demographic data are listed in Table 1.

For the primary outcome, the mean rotation angles were compared between the two tests. The mean rotation angle was $24 \pm 18^\circ$ for the standard Q-tip test and $18 \pm 16^\circ$ for the vaginal cotton-tipped swab test. No sequence effect was detected. The mean angle difference between the two tests was 5.1° with a 95% CI of 3.2 - 6.9° , thus meeting the predefined criteria for equivalence at a margin of $\pm 10^\circ$.

For the secondary aim, hypermobility was classified using two existing definitions; #1: a maximum straining angle of 30° or greater, and #2: rotation angle (a change from resting to maximum straining) 30° or greater. No disagreement was noted in the diagnosis of hypermobility between the urethral and vaginal tests using the maximum straining angle definition (#1 $p = 0.23$, Table 2), whereas statistically significant disagreement was noted with the rotation angle definition (#2 $p=0.03$, Table 2). In addition, a strong correlation was noted between the urethral and vaginal approaches using both definitions ($r_{\#1}=0.80$, $r_{\#2}=0.65$, both $p<0.001$, Table 2).

Participants reported a significantly higher median (range, Quartile 1-Quartile 3) discomfort level for the urethral test 3 (0-5) points compared to the vaginal approach 0 (0-0) points ($p<0.001$). Finally, 95 women (68%, 95% CI: 60-76%) preferred the vaginal approach, and 45 women (32%, 95% CI: 24-40%) had no preference. None preferred the urethral Q-tip test.

Discussion

The vaginal cotton-tipped swab test and the standard urethral Q-tip test were equivalent in measuring urethral mobility using an *a priori* $\pm 10^\circ$ equivalence margin. Further, the vaginal cotton swab test had less discomfort and was preferred over the urethral Q-tip test. The usefulness of the Q-tip test is the ability to measure the urethral rotation, which quantifies the extent of urethrovesical support defects, rather than to simply answer the dichotomous question of whether the urethra is hypermobile. Thus, this study aimed to compare the actual rotation of a cotton-tipped swab in the two separate orifices, the urethra versus vagina.

The 10° equivalence margin was chosen based on the original description of the Q-tip test. Crystle et al. reported that the rotation of a cotton-tipped swab greater than 20° from resting correlated with the urethral axis rotation indicative of urethrovesical support defects on bead chain cystourethrogram. They also estimated resting angles to be less than 10° relative to the horizontal plane assuming that a swab would not rotate in patients with no anatomical defects.¹ Since the original study, the currently accepted definition of hypermobility has been arbitrarily chosen with urethral rotation of 30° or greater. Given the assumption of resting angle <10°, there is up to a 10° difference between the original and the currently accepted definitions. Thus, we considered up to 10° as a reasonable difference where clinicians would feel comfortable choosing the alternative approach over the traditional test to assess urethral mobility.

In assessing the diagnosis of hypermobility, no disagreement was noted between the vaginal and urethral approaches using the most commonly accepted definition (maximum straining angle). However, the two methods disagreed using the less common definition (rotation angle). A further study should be considered to explore possible factors contributing to the disagreement in the diagnosis of hypermobility between the two tests.

Several methods have been explored to assess urethral mobility as an alternative to the urethral Q-tip test.²⁻⁵ The pelvic organ prolapse quantification (“POP-Q”) point Aa, corresponding to the urethrovesical crease in the anterior vaginal wall, has been evaluated in several studies. However, the reported correlations between the Q-tip test and point Aa were moderately strong at best (r : 0.35-0.54).³⁻⁵ Point Aa only measures the descensus of a single point in vaginal topography. Since the urethra is supported by the anterior vaginal wall and its surrounding musculo-connective tissue elements, the measurement of vaginal rotation could better capture the urethral rotation than using the single point Aa.

The visual urethral mobility examination subjectively assessed whether the urethral meatus rotates more or less than 30° from the horizontal plane. The reported correlation between the visual urethral mobility examination and the standard Q-tip test was not strong (r =0.47). The utility of the visual examination is limited as the authors suggested that the test should be performed by experienced providers to be a useful alternative to the Q-tip test.⁶ Imaging studies such as perineal ultrasound and voiding cystourethrogram have been also examined as an alternative to the Q-tip test; however, they are limited by their cost, availability, and special training required.^{7,8,9} The latter is also limited by radiation exposure (although low), contrast dye allergy, and potential infection risk.

Limitations exist in this study. First, this study excluded women with prolapse beyond the hymen, thus generalizability may be compromised. However, existing data have shown good correlation between urethral hypermobility and advanced prolapse, such as beyond the hymen (93-100%).^{3-5, 10} Second, the tests were performed only by urogynecologists. However, the vaginal test is easily performed by inserting a cotton-tipped swab into the vagina in the midline with no other special tasks required. Therefore, we do not expect significant differences in the results when performed by examiners such as generalists in obstetrics and gynecology or urology. Lastly, this is a single-center study. However, in order

to limit further bias, the data analysis was performed by a third party, independent from the division of urogynecology.

Strengths include that the urethral and vaginal tests were performed by the same examiner in each patient to avoid inter-observer differences, and four different examiners were involved in obtaining the urethral mobility measurements to increase generalizability. In addition, this study is unique by urethral hypermobility with two existing definitions.

The vaginal cotton-tipped swab test is less invasive technique and much preferred by women compared to the standard Q-tip test. Therefore, the vaginal approach should be considered as a reasonable alternative method when evaluating urethrovesical support in women with stress urinary incontinence.

Acknowledgments

Partially supported by the National Institutes of Diabetes and Digestive and Kidney Diseases, 2K24-DK068389 to HE Richter. For the remaining authors, none were declared.

Holly E Richter has received research grants from Pelvalon and has been a consultant for Pelvalon, Kimberly Clark, and Statking. She has received royalties from UpToDate.

The authors thank Lisa S Pair, CRNP, for her help with data collection.

References

1. Crystle CD, Charme LS, Copeland WE. Q-tip test in stress urinary incontinence. *Obstet Gynecol.* 1971; 38:313–5. [PubMed: 5105346]
2. Tapp K, Connolly A, Visco AG. Evaluation of Aa point and cotton-tipped swab test as predictors of urodynamic stress incontinence. *Obstet Gynecol.* 2005; 105:115–9. [PubMed: 15625151]
3. Mattison ME, Simsiman AJ, Menefee SA. Can urethral mobility be assessed using the pelvic organ prolapse quantification system? An analysis of the correlation between point Aa and Q-tip angle in varying stages of prolapse. *Urology.* 2006; 68:1005–8. [PubMed: 17095054]
4. Cogan SL, Weber AM, Hammel JP. Is urethral mobility really being assessed by the pelvic organ prolapse quantification (POP-Q) system? *Obstet Gynecol.* 2002; 99:473–6. [PubMed: 11864676]
5. Zyczynski HM, Lloyd LK, Kenton K, et al. Correlation of Q-tip values and point Aa in stress-incontinent women. *Obstet Gynecol.* 2007; 110:39–43. [PubMed: 17601894]
6. Robinson BL, Geller EJ, Parnell BA, et al. Diagnostic accuracy of visual urethral mobility exam versus Q-Tip test: a randomized crossover trial. *Am J Obstet Gynecol.* 2012; 206:528, e1–6. [PubMed: 22459346]
7. Dalpiaz O, Curti P. Role of perineal ultrasound in the evaluation of urinary stress incontinence and pelvic organ prolapse: a systematic review. *Neurourol Urodyn.* 2006; 25:301–6. discussion 307. [PubMed: 16688711]
8. Pirpiris A, Shek KL, Dietz HP. Urethral mobility and urinary incontinence. *Ultrasound Obstet Gynecol.* 2010; 36:507–11. [PubMed: 20503229]
9. Walsh LP, Zimmern PE, Pope N, et al. Comparison of the Q-tip test and voiding cystourethrogram to assess urethral hypermobility among women enrolled in a randomized clinical trial of surgery for stress urinary incontinence. *J Urol.* 2006; 176:646–9. discussion 650. [PubMed: 16813912]
10. Noblett K, Lane FL, Driskill CS. Does pelvic organ prolapse quantification exam predict urethral mobility in stages 0 and I prolapse? *Int Urogynecol J Pelvic Floor Dysfunct.* 2005; 16:268–71. [PubMed: 15856131]

Figure 1.

Midline sagittal diagram of female pelvis demonstrating a cotton-tipped swab rotation (*curved arrow*) with valsalva (downward abdominal force on the pelvis, *straight arrow*) from the horizontal plane (*dashed line*). Cotton-tipped swab in the vagina, the vaginal swab test (**A**) and in the urethra, the standard urethral Q-tip test (**B**). This image was published in Black JM, Hawks JH. Medical-surgical nursing: clinical management for positive outcomes. 8th ed. St. Louis (MO): Saunders; 2009. Copyright © Elsevier 2009.

Table 1
Baseline Characteristics

Characteristic	UQ First (n=70)	VQ First (n=70)	P-value [§]
Age (years) *	56.0 ± 10.4	56.5 ± 12.9	0.77
Race [‡]			0.15
White	57 (81%)	62 (89%)	
Black	9 (13%)	8 (11%)	
Hispanic/Other	4 (6%)	0 (0%)	
BMI (kg/m ²) *	32.0 ± 7.2	30.4 ± 6.1	0.15
Smoking [‡]	15 (21%)	12 (17%)	0.52
Parity [‡]	2 (2 – 3)	2 (2 – 3)	0.11
Menopausal [‡]	52 (74%)	50 (71%)	0.70
Hypertension [‡]	33 (47%)	43 (61%)	0.09
Diabetes Mellitus [‡]	11 (16%)	7 (10%)	0.31
Asthma [‡]	10 (14%)	13 (19%)	0.49
Urge Urinary Incontinence [‡]	55 (79%)	48 (69%)	0.18
Vaginal estrogen therapy [‡]	25 (36%)	25 (36%)	>0.99
Prior Hysterectomy [‡]	45 (64%)	47 (67%)	0.72
Prior Incontinence Procedure [‡]	25 (36%)	26 (37%)	0.86
Retropubic MUS	17 (24%)	14 (20%)	0.54
Transobturator MUS	9 (13%)	13 (19%)	0.35
Pubovaginal	1 (1%)	0 (0%)	>0.99
Burch or MMK	1 (1%)	2 (3%)	>0.99
Anterior Repair [‡]	27 (39%)	13 (19%)	0.01
Mesh	2 (3%)	4 (6%)	0.68
Posterior Repair [‡]	20 (29%)	8 (11%)	0.01
Mesh	3 (4%)	3 (4%)	>0.99
Apical Repair [‡]	8 (11%)	5 (7%)	0.38
Mesh	3 (4%)	1 (1%)	0.94

* Mean ± standard deviation,

[‡] n (%),

[‡]median (Q1 – Q3)

[§]P values: the two sample t-test or Kruskal-Wallis test for quantitative measures, the chi-square test or Fisher's exact test for categorical measures, as appropriate

UQ, urethral Q-tip test; VQ, Vaginal cotton-tipped swab test; BMI, body mass index; MUS, midurethral sling; MMK, Marshall-Marchetti-Krantz

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table 2

Urethral Hypermobility Assessment

Definition #1: Maximum straining 30°				
Total N		N		P-value
UQ Positive	80	VQ Positive	69	0.23 *
		VQ Negative	11	
UQ Negative	60	VQ Positive	6	
		VQ Negative	54	
			Correlation	0.80
			<0.001 †	
Definition #2: Rotation angle 30°				
Total N		N		P-value
UQ Positive	43	VQ Positive	28	0.03 *
		VQ Negative	15	
UQ Negative	97	VQ Positive	5	
		VQ Negative	92	
			Correlation	0.65
			<0.001 †	

* McNemar's test,

† Pearson's correlation test

UQ, Urethral Q-tip test; VQ, Vaginal cotton-tipped swab test