

VAGINAL Q-TIP URETHRAL MOBILITY MEASUREMENT AS AN ALTERNATIVE TO TRANSURETHRAL Q-TIP TEST

Hypothesis / aims of study

The Q-tip test assesses urethral hypermobility commonly present in women with stress urinary incontinence (SUI). Our primary aim is to assess whether equivalence exists between a new transvaginal Q-tip measurement (VQ) and the traditional urethral Q-tip test (UQ) for measuring angles of urethral hypermobility. We further examined whether both tests agree in the diagnosis of hypermobility, the discomfort level of each test, and determined the patients' preferred method. We hypothesized that VQ offers diagnostic equivalence for urethral hypermobility with less invasiveness, and thus preferred by women.

Study design, materials and methods

Women with predominant SUI and prolapse at hymen or less underwent both VQ and UQ testing. The testing sequence was randomized in a 1:1 fashion. A cotton swab was placed directly at the urethrovesical junction (UVJ) for the UQ; for the VQ, a Q-tip was placed 3cm proximal to the hymen (approximately at the UVJ) in the vagina. Each test was performed twice in the dorsal lithotomy position and mean measures determined. For the primary analysis, we set a predetermined equivalence margin of $\pm 10^\circ$ for the two tests to be clinically equivalent evaluating the 95% confidence interval (CI) for the mean difference between resting and straining angles. We also explored the data with a $\pm 5^\circ$ equivalence margin. Hypermobility was defined using two criteria: #1 maximum straining angle of $\geq 30^\circ$ from the horizontal plane (most widely accepted definition) or #2 a change between resting and straining angles $\geq 30^\circ$ (less common definition). Agreement in urethral hypermobility diagnosis between the two tests was assessed using each criterion. Subjects rated discomfort using a 10cm visual analog scale and chose their preferred test. The sample size was estimated to be 36 and 139 subjects with an equivalence margin of $\pm 10^\circ$ and $\pm 5^\circ$, respectively, to provide 90% power and assuming a standard deviation of 20° (based on pilot study data). Patient characteristics were compared by randomization sequence allotment. Mixed models were used to evaluate effects of sequence and carryover. Agreement of hypermobility assessment was based on McNemar's test. Correlation between the two tests was determined using the Pearson's correlation test. P-values of <0.05 were considered statistically significant.

Results

A total of 140 women were enrolled between 1/2014 and 3/2015. The mean age was 56 ± 12 . Of the demographic factors, the randomized sequences differed only by prior anterior and posterior repairs between the groups; neither were significantly associated with the primary outcome. No sequence or carryover effects were detected. The mean difference between UQ and VQ was 5.1° (95%CI 3.2-6.9, Table), thus met the predefined criteria for equivalence. However, the two tests did not meet the equivalence criteria at a margin of $\pm 5^\circ$. In addition, no significant disagreement was noted in the assessment of urethral hypermobility between the two tests using the more common definition maximum straining angle (#1 $p = 0.23$, Table), whereas statistically significant disagreement was noted using the less commonly used definition, a change between resting and straining angles (#2 $p = 0.03$, Table). A significant correlation (r) was noted between the two tests using both definitions (#1 $r = 0.80$, #2 $r = 0.65$, $p < 0.0001$ for both). The mean discomfort score was 3.5 ± 2.9 for UQ vs. 0.6 ± 1.4 for VQ ($p < 0.0001$). None preferred UQ, 67% preferred VQ, 32% reported no preference.

Interpretation of results

The transvaginal and urethral Q-tip measurements met the prespecified criteria for equivalence of $\pm 10^\circ$, however not at $\pm 5^\circ$. The transvaginal and urethral Q-tip tests agreed in the assessment of urethral hypermobility using the most widely accepted definition, a maximum straining angle of $\geq 30^\circ$ from the horizontal plane, with a significant correlation. The vaginal Q-tip test was preferred by the patients.

Concluding message

The transvaginal and urethral Q-tip tests are clinically equivalent for urethral hypermobility assessment at a $\pm 10^\circ$ equivalence margin. The transvaginal approach should be considered as a reasonable alternative to the traditional urethral Q-tip test, using the definition with a maximum straining angle $\geq 30^\circ$ from the horizontal plane. The vaginal Q-tip test is less invasive and much preferred by women.

Table: Assessment of Equivalence, Urethral Hypermobility, and Discomfort

Equivalence Assessment				
	UQ	VQ	UQ – VQ (95% CI)	
Angle* (degrees), mean $\pm$ SD	23.5 $\pm$ 18.0	18.4 $\pm$ 16.4	5.1 (3.2 – 6.9)	
Urethral Hypermobility Assessment				
Definition #1				P-value
UQ Positive	VQ Positive	69		
	VQ Negative	11		
UQ Negative	VQ Positive	6		
	VQ Negative	54		
		Correlation	0.80	0.23 <0.0001
Definition #2				
UQ Positive	VQ Positive	28		
	VQ Negative	15		
UQ Negative	VQ Positive	5		
	VQ Negative	92		
		Correlation	0.65	0.03 <0.0001
Discomfort Assessment				
Discomfort, mean $\pm$ SD	UQ	VQ		P-value
	3.5 $\pm$ 2.9	0.6 $\pm$ 1.4		<0.0001

*Angle = [maximum straining angle] – [resting angle]

UQ: Urethral Q-tip VQ: Vaginal Q-tip

Disclosures

Funding: Partially supported by the National Institute of Diabetes and Digestive and Kidney Diseases, 2K24-DK068389 to HE Richter. For the remaining authors, none were declared. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** The University of Alabama at Birmingham Institutional Review Board for Human Use (IRB) **Helsinki:** Yes **Informed Consent:** Yes