Original article

Is there a correlation between simulated operations, urodynamics (vlpp) and urethral mobility?

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Abstract. *Introduction*: The diagnosis of stress urinary incontinence is based on history and physical examination and, if necessary, could be associated with additional tests especially the urodynamic. The Integral Theory, developed a new way to evaluate patients with stress urinary incontinence, known as 'Simulated Operations'. These techniques are maneuvers performed during the stress test (cough), to identify the defects of the urethral support elements that cause incontinence. *Objectives*: 1. To establish a correlation between simulated operations with the *Valsalva leak point pressure* (urodynamics)*;* 2. To correlate the simulated operations with the result of the Q-tip test; 3. To correlate intensity of symptoms with simulated operations through the pad test. *Material and Methods:* From May 2012 to February 2015 82 women with stress urinary incontinence were evaluated. All patients underwent simulated operations that consisted of four maneuvers during the cough test observing if there was urinary leakage during the maneuvers. For the maneuver 1, the atraumatic clamp was applied unilaterally at the pubourethral ligament insertion on the inferior border of the pubis (simulating the plication of the pubourethral ligament). In the maneuver 2, a clamp was used to plicate the vaginal mucosa at the level of the midurethra (simulate the plication of the urethropelvic ligament). In the 3rd maneuver, the index finger is placed in the suburethral region without tension. The 4th maneuver is the same maneuver 3 *with* tension. The Q-tip test has been used for evaluation of urethral mobility and the one-hour pad test to measure the severity of urinary leakage. The simulated operations were compared with the values of *Valsalva leak point pressure*, Q-tip test and pad test. *Results:* When performing the maneuvers 1, 2 and 3, most patients did not have urinary leakage. There was a significant association between *Valsalva leak point pressure* and the cessation of stress urinary incontinence with the maneuvers 1, 2 e 3 ($p = 0.008$, OR 0.965; $p = 0.0140$, OR 0.953; $p = 0.0002$, OR 0.949, respectivamente às manobras 1, 2 e 3, com IC 95%). During the maneuver 4, no patient presented had leak urine. The Q-tip test was statistically significant with maneuvers 2, 3 and 4. The pad test did not show statistical correlation with the simulated operations. *Conclusion:* The simulated operations demonstrated correlation with *Valsalva leak point pressure* and urethral mobility. Their use in clinical practice is recommended.

Keywords: Stress urinary incontinence; Simulated operations; Urodynamic study; Valsalva leak; Point pressure; Q-tip test; Pad test.

INTRODUCTION

Urinary incontinence (UI) is a frequent health problem among women[1] that affects quality of life and restricts social life because of the physical discomfort and embarrassment it causes. The International Continence Society (ICS) defines stress UI (SUI) as involuntary urine leakage during physical effort, sneezing, or coughing[2]. Approximately 12-55% of women will suffer from UI at some point during their lives[3]. Approximately 50% of all patients with UI present with SUI as the predominant or only symptom[4].

The diagnostic tests that assess SUI vary in complexity, from the urinary stress test to video urodynamic testing[5]. The Q-tip test helps to identify patients with urethral hypermobility, and urodynamic testing (which has improved the identification of voiding dysfunctions) has become a frequent test among patients with UI.

With proposal of the Integral Theory in the 1990s, a new concept was developed to explain and understand the various disorders of the pelvic floor and how they develop into voiding dysfunctions. According to this theory, pelvic organ prolapse and abnormal urinary and pelvic symptoms are primarily caused by the laxity of the vaginal connective tissue or supporting ligaments[6]. These structures are assessed during a physical examination using simulated operations (SOs) in which ligament defects are evaluated, either directly with a finger or with the help of a haemostatic clamp[7] with four different manoeuvres while the patients cough. Petros initially showed the importance of ligament integrity and, consequently, of the ligament-supporting tissues with regard to maintaining continence through two SO manoeuvres; most patients presented with interruption of urine loss after lateral compression of the urethra (which mimics the function of the pubourethral ligament) and the remaining patients did so after suburethral plication (which mimics urethropelvic support or hammock)[7].

In 2003, Petros investigated the anatomical origins and the clinical significance of the cough pressure transmission ratio (CTR; i.e., increased urethral pressure during coughing) by measuring it before and after unilateral midurethral anchoring. The CTR improved with urethral anchoring, which suggests that the connective tissue dysfunctions in patients with SUI are caused by ligament lesions and the laxity of the muscles that act on urethral closure[8].

Urodynamic testing is the most common type of test used to assess UI. Currently, the debate regarding the need to perform the test on patients with SUI symptoms is on-going[9]. More recently, the real importance of urodynamics in defining therapeutic procedures and establishing prognoses for patients with SUI is being questioned because it is not a predictor of success or failure for SUI surgery, and also, its high cost and invasive nature[9,10].

Performing SOs in association with a physical examination might contribute to a more precise SUI diagnosis. SOs exactly mimic what happens during midurethral sling surgery: where a tape is inserted in the exact positon of the pubourethral ligament to reinforce it as an anchoring point for the three opposite muscle vectors which activate urethral closure[6-8]. This study sought to correlate SOs with[1] other SUI diagnostic tests (i.e., urodynamics [Valsalva leak point pressure; VLPP] and the Q-tip test); and[2] the one-hour pad test.

MATERIALS AND METHODS

This prospective study compares SUI diagnostic and assessment methods.

The variables included a VLPP (urodynamic study performed according to ICS norms), simulated operation including four manoeuvres performed during the cough test with a haemostatic clamp to assess whether urine loss is stopped during the manoeuvre.

Manoeuvre 1. A haemostat clamp is unilaterally applied at the insertion of the pubourethral ligament in the inferior edge of the pubic bone, lateral to the paraurethral sulcus, to simulate the plication of the pubourethral ligament. Simultaneously, the patient is asked to cough. The test is considered positive when urine loss is interrupted during the abdominal effort manoeuvre (Figure 1).

Figure 1. – Manoeuvre 1: The application of a haemostatic clamp unilaterally at the insertion of the pubourethral ligament at the inferior edge of the pubic bone.

Manoeuvre 2. The suburethral region (mid-urethra) is plicated with the help of a clamp, simulating the plication of the urethropelvic ligament while the patient is asked to cough. The test is considered positive when loss of urine is interrupted during the abdominal effort manoeuvre (Figure 2).

Figure 2. – Manoeuvre 2: The plication of the suburethral region (mid urethra) with the help of a clamp simulating the plication of the urethropelvic ligament.

Manoeuvre 3. The mid-suburethral region is supported with the help of the index finger or a haemostatic clamp, while the patient is asked to cough. The test is considered positive when urine loss is interrupted during the abdominal effort manoeuvre (Figure 3).

Manoeuvre 4: The suburethral region is compressed with the help of the index finger (i.e., manoeuvre 3 with tension), while the patient is asked to cough. The test is considered positive when urine loss is interrupted during the abdominal effort manoeuvre.

Figure 3. – Manoeuvre 3: The support of the mid suburethral region with the help of the index finger or a haemostatic clamp.

Q-tip test: The Q-tip is introduced at level of the bladder neck, and its angular variation (measured in degrees) during the increase in abdominal pressure is assessed. A variation greater than 30º suggests urethral hypermobility[11].

Pad test (one hour): This test consists of placing a pad (of known weight). Next, the patient drinks 500 mL of water in 15 minutes. Over the next 30 minutes, the patients is instructed to walk around, ascend and descend stairs, sit down and stand up (10 times), cough hard (10 times), run in place for 1 minute, bend over to pick up an object (five times), and wash their hands in running water for 5 minutes. After one hour, the pad is weighed again[12,13].

All tests were performed when the patient expressed the urge to urinate or had a minimum bladder volume of 150 mL.

From May 2012 to February 2015, 82 women presenting with SUI as the primary symptom were selected from the Female Urology Clinic of the Unicamp Clinics Hospital. The women were diagnosed at their initial physical examination using the cough test. Of these patients, 50 underwent SO manoeuvres 1 and 2, and 82 patients underwent all four manoeuvres. All patients underwent the urodynamic study, the Q-tip test, and the pad test.

The patients included in this study agreed to participate and signed the Informed Consent Form (Annex 1). The Ethics and Research Committee of the Faculty of Medical Sciences of Unicamp (Comitê de Ética e Pesquisa da Faculdade de Ciências Médicas da Unicamp - CEP-FCM-Unicamp; registration number 02291012.5.0000.540) approved this study.

Patients who did not lose urine during stress manoeuvres as well as those with stage III or IV anterior wall prolapse were excluded from the study.

Statistical analyses

An exploratory data analysis was performed using frequencies and descriptive statistics. The Mann-Whitney U test was used to compare manoeuvres and quantitative variables. A logistic regression analysis was used to analyse the relationship between the manoeuvres and the factors under study. The significance level adopted was 5%.

Results

Of the 82 women assessed, 50 underwent manoeuvres 1 and 2, and all women underwent manoeuvres 3 and 4. Of the patients who underwent manoeuvres 1 and 2, 35 (70%) did not present urine loss after manoeuvre 1, and 45 (90%) had interrupted urine loss after manoeuvre 2. Of the 82 women assessed using manoeuvres 3 and 4, 61 (74.39%) had interrupted urine loss with manoeuvre 3. All 21 patients who needed a compressive manoeuvre (manoeuvre 4) had interrupted urine loss.

The analysis of the variables age, VLPP, Q-tip test, and pad test with regard to manoeuvre 1 showed a significant association between the manoeuvre and VLPP because the patients who had interrupted urine loss had VLPP values higher than those who maintained SUI during the test, $p = 0.008$ (OR = 0.965, 95% CIs = 0.941-0.989). The mean VLPP was 118.7 cmH_2O in the group that had stopped urine loss with manoeuvre 1 and 80.53 cmH_2O in the group that maintained UI during the manoeuvre (Table 1).

Each one-unit reduction in the VLPP value increased the risk of losing urine during manoeuvre 1 by 4%.

The Q-tip and pad tests were not significantly associated with manoeuvre 1.

TABLE 1. Comparison between manoeuvre 1 and the variables under study (n = 50).

Variable	Mean	Median	Standard Deviation	Min	Max	P-value
Age						
No loss	55.57	57.00	11.27	32.00	75.00	0.7536
Loss	55.20	54.00	7.26	46.00	70.00	
VLPP						
No loss	118.7	126.00	33.13	74.00	202.00	**0.0008**
Loss	80.53	73.00	27.17	36.00	169.00	
Pad test						
No loss	28.63	13.00	17.53	0.00	130.00	0.7424
Loss	38.87	12.00	40.89	4.00	176.00	
Q-tip test (in º)						
No loss	22.94	25.00	13.89	0.00	55.00	0.2177
Loss	17.27	15.00	8.79	0.00	35.00	

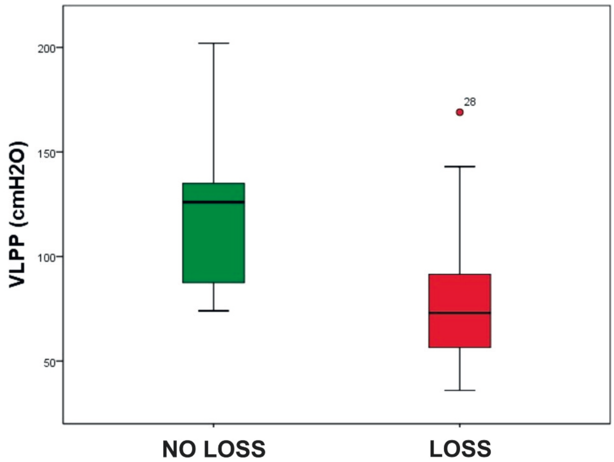

Figure 4. – VLPP relation among patients who don't have loss of urine and that kept the urinary loss.

When performing manoeuvre 2, we observed that most patients did not lose urine. An association was found between VLPP and the interruption of urine loss using this manoeuvre because patients who had interrupted urine loss had higher VLPP values, $p = 0.0140$ (OR = 0.953, 95% CIs = 0.912-0.997). The mean VLPPs for patients who did not lose urine and those who remained incontinent during manoeuver 2 were 111.5 cmH_2O and 68.60 cmH_2O, respectively. With each one-unit reduction in VLPP, the probability of losing urine using manoeuvre 2 increased by 5% (Table 2).

The Q-tip test was significantly associated with manoeuvre 2 because patients with higher Q-tip angle variation were those who did not lose urine during the manoeuvre ($p = 0.0221$).

The pad test was not significantly associated with manoeuvre 2.

TABLE 2. Comparison between manoeuvre 2 and the variables under study (n = 50).

Variable	Mean	Median	Standard Deviation	Min	Max	P-value
Age						
No loss	55.16	55.00	10.35	32.00	75.00	0.1604
Loss	58.20	60.00	8.70	47.00	70.00	
VLPP						
No loss	111.5	104.0	38.97	47.00	202.00	0.0140
Loss	68.60	73.00	20.85	36.00	92.00	
Pad test						
No loss	28.96	13.00	34.71	0.00	130.00	0.4761
Loss	56.40	32.00	70.73	6.00	176.00	
Q-tip (in º)						
No loss	22.62	25.00	13.31	0.00	55.00	0.0221
Loss	8.80	8.00	7.66	0.00	18.00	

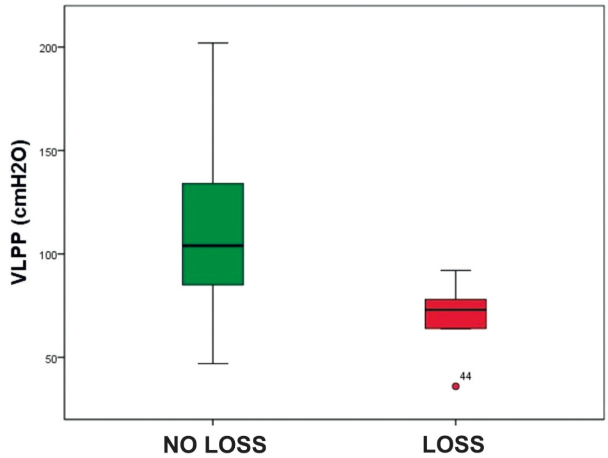

Figure 5. – VLPP relation among patients who don't have loss of urine and that kept the urinary loss.

When performing manoeuvre 3 (non-compressive suburethral support), we observed that patients who did not lose urine had higher VLPP values than those who continued to lose urine ($p = 0.0002$, OR = 0.949, 95% CIs = 0.899-1.003). The mean VLPPs for patients who did not lose urine with manoeuvre 3 and those who remained incontinent were 118 cmH_2O and 81 cmH_2O, respectively. Each one-unit increase in VLPP reduced the probability of losing urine using manoeuvre 3 by 3%.

The Q-tip test was significantly associated with manoeuvre 3 because patients who did not lose urine during the urethral support manoeuvre had a higher angle variation during effort than that of incontinent patients ($p = 0.0001$).

TABLE 3. Comparison between manoeuvre 3 and the variables under study (n = 82).

Variable	Mean	Median	Standard Deviation	Min	Max	P-value
Age						
No loss	55.64	55.00	11.18	31.00	75.00	0.0628
Loss	61.38	61.00	9.56	47.00	82.00	
VLPP						
No loss	115.32	118.0	37.41	46.00	202.00	0.0002
Loss	81.33	81.00	24.85	36.00	132.00	
Pad test (g)						
No loss	22.30	8.00	31.42	0.00	130.00	0.1888
Loss	31.43	20.00	38.78	1.00	176.00	
Q-tip (in º)						
No loss	23.33	25.00	13.23	0.00	55.00	0.0001
Loss	10.48	9.00	9.12	0.00	35.00	

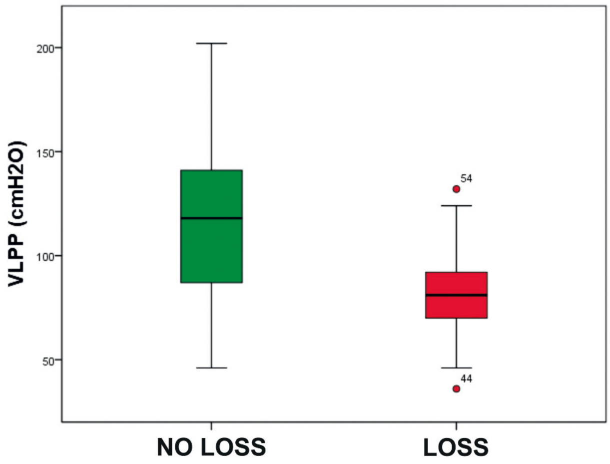

Figure 6. – VLPP relation among patients who don't have loss of urine and that kept the urinary loss.

TABLE 4. Comparison between the variables of patients who needed manoeuvre 4 to stop urine loss and those who did not lose urine using manoeuvres 1, 2, or 3 (n = 82).

	VLPP	Q-tip test	Pad test
Manoeuvre 1	p = 0.0012	p = 0.01745	p = 0.4064
Manoeuvre 2	p = 0.0197	p = 0.0279	p = 0.4064
Manoeuvre 3	p = 0.0002	p = 0.0001	p = 0.2832

No significant association was found between manoeuvre 3 and the pad test (Table 3).

During manoeuvre 4 (suburethral compression), no patient presented urine loss while coughing. A correlation was found between VLPP and the Q-tip test (Table 4).

DISCUSSION

While searching for less invasive SUI diagnostic methods, Petros developed SOs[7], which can often provide the information necessary to identify the type of UI via a physical examination because the specific ligament defects causing incontinence can be identified. In clinical practice, it is important to determine whether SUI is primarily caused by urethral hypermobility or a consequence of a deficiency in the intrinsic sphincter mechanism.

SOs have been previously described and tested[6,7]; however, the correlations between SOs and VLPP have never been discussed. VLPP values equal to or higher than 90 cmH_2O suggest urethral hypermobility, whereas those equal to or lower than 60 cmH_2O suggest intrinsic sphincter deficiency[14]; a VLPP between 60 and 90 cmH_2O is defined as a "grey area". In our study, SOs were compared with VLPP, the Q-tip test, and the pad test to assess the possible correlation between these SUI assessment tools. We performed an analysis of continuous data because the "grey area" of 60-90 cmH_20 includes numerous patients.

We observed correlations between all 4 manoeuvres and VLPP, showing that each increase in VLPP reduced the possibility of losing urine during the manoeuvres. Thus, SOs are a new, fast, and efficient way of assessing SUI. Furthermore, they are easy to perform in the physician's office. When performing an SO manoeuvre, it is possible to observe urethral mobility and estimate the severity of UI in patients who need manoeuvre 4 to interrupt urine loss. It is also possible to simulate the role of a sling surgery by performing suburethral support, thereby inferring the post-surgery result.

In 2011, a systematic review assessed the reclassification rate of the type of UI diagnosed via anamnesis with or without physical examination and after urodynamic testing. Only 9% of patients who had been diagnosed with SUI alone were reclassified as having mixed UI (MUI), and 7% were classified as suffering from detrusor hyperactivity. These changes suggest that unlike patients with MUI, the urodynamic testing of patients with SUI alone might not add much information to the clinical examination[15]. However, SOs complement a physical examination and improve clinical assessment accuracy using a simple and inexpensive approach.

In 2007, the UI Treatment Network (UITN) study reported that approximately 10% of women with a positive cough test who used an average of 3 pads/day did not show SUI in a urodynamic study[16]. That finding prompted a discussion of the role of urodynamics because urodynamics can fail to identify patients with typical symptoms of SUI. When using the Blaivas classification, type 0 UI corresponds to patients with SUI complaints who do not show urine loss on effort during video urodynamic testing[17]. This finding indicates that tests do not always reach maximum accuracy; however, when other tools with similar efficacy are available (e.g., SOs), it is possible to obtain a more accurate diagnosis.

Thus, SOs help clinicians to understand the structural defect that causes UI. If urine loss continues during manoeuvres 1, 2, and 3, then the patient likely suffers from severe incontinence, with the predominance of an intrinsic sphincter deficiency; the patient will most likely not have a satisfactory response to sling placement without tension. In contrast, if urine loss is interrupted during manoeuvres 1, 2, or 3, then the predominant defect causing SUI is likely urethral hypermobility.

By demonstrating the correlation between VLPP and SO, we showed that a physical examination plays an important role in simplifying the diagnosis and predicting the treatment outcomes of SUI.

CONCLUSIONS

SOs are easy to perform during physical examination and show a significant correlation with VLPP and the Q-tip test. The one-hour pad test was not correlated with SOs. The compressive manoeuvre characterised cases of severe UI, represented by the predominance of intrinsic sphincter deficiency. SOs improve the diagnosis of SUI in clinical practice and their use is recommended.

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Multidisciplinary commentary

Although this paper at first glance would appear be to be nothing more than esoteric to the majority of readers, the use of simulated operations is not new. The Trendelenburg test for varicose veins was first described in 1891 and quite simply uses a ligature around the thigh to compress the long saphenous vein and mimic the outcome of a high ligation at the sapheno-femoral junction. A positive test prevents the appearance of the varicosities on standing[1,2]. Medical students for centuries have been taught the benefit of pressure occlusion of the deep inguinal ring to diagnose hernia and predict outcome from herniorrhaphy.

In this very well described and elegant paper Tiecher et al. demonstrate techniques for interrupting urine loss in SUI and therefore predict the outcome of MUS surgery. Interestingly the findings correlate well with the results of mid-urethral sling (MUS) surgery when performed in well trained and expert hands[3]. The Integral Theory teaches that sling reinforces the pubourethral ligament and the apex of the MUS creates a rotation point around the apex of the sling upon which the three directional muscles forces act in order to prevent urine loss on coughing and straining. Manoeuvre-1 recreates the PUL and manouevre-2 recreates the external-urethral ligament (EUL) the importance of which are both critically detailed in the Integral Theory. The results in this paper would suggest that expert surgery would produce a 90% success rate for the MUS, exactly what was found in the 5 year study by Sivaslioglu 3.

As such the need for urodynamic testing is made obsolete. A good history followed by a careful examination, the basic tenets of good medicine, with the appropriate simulated operations is all that is need for a successful outcome for SUI surgery in well trained hands.

But there is an argument to take this further. The Integral Theory has shown the benefit of other ligament repair with the cure of other symptoms including urinary urgency, pelvic pain and ODS. Simulated operations could potentially be used in these circumstances.

In patients with urinary urgency the subject could allow the bladder to fill and at the point at which the urgency occurs could lie down and with a speculum carefully supporting the vaginal apex/posterior fornix would hopefully reduce the desire to urinate confirming the potential benefit to that patient of repairing the cardinal and uterosacral ligaments. Similarly patients with pelvic pain would experience a reduction in pain with a similar manoeuvre and pre- and post-test stroking of the introitus with a Q-tip could demonstrate benefit in vulvodynia.

For patients with ODS due to perineal descent, digital pressure on the perineum would improve subjective and possibly even objective ‘push’ and emptying by supporting the deep transverse perineal ligament. Concomitant support of the vaginal apex with a speculum and digital perineal pressure would do similar to those with ODS from apical descent, especially after hysterectomy.

This paper represents an exciting step forward in the management of patients with pelvic dysfunction, and as with all good research, opens far more doors than it could ever close.

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