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ORIGINAL ARTICLE

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Is the leak point pressure alone an accurate indicator of intrinsic sphincteric deficiency?

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Abstract The aim of this study was to determine the characteristics of women who meet the criteria for intrinsic sphincteric deficiency (ISD) on maximum urethral closure pressure (MUCP) but not on leak point pressure (LPP) measurement. We performed a cross-sectional chart review of every patient who underwent multichannel, microtransducer urodynamic testing in our center between 1994 and 1996 ($n = 423$). From this population we culled a sub-population of women who fit into one of the following two groups: women with no evidence of ISD on MUCP or LPP and women with evidence of ISD on MUCP only. Logistic regression was used to identify independent predictors of group membership. Increasing age (> 60.5 years) and a positive supine empty stress test were the only independent predictors of membership in the group of women with ISD on MUCP only. Knowledge of these risk factors may help clinicians in choosing appropriate pre-operative testing.

Keywords Intrinsic sphincteric deficiency · Leak point pressure · Maximum urethral closure pressure · Urodynamics

Abbreviations ISD: Intrinsic sphincteric deficiency · LPP: Leak point pressure · MUCP: Maximum urethral closure pressure

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Introduction

Intrinsic sphincteric deficiency (ISD) denotes an "intrinsic malfunction of the urethral sphincter itself," according to recommendations of the Urodynamic Society [1]. Although no single, definitive criterion for ISD exists, the two most commonly accepted objective measures used to diagnose this condition are the leak point pressure (LPP) and the maximum urethral closure pressure (MUCP).

McGuire et al. have asserted that the abdominal LPP correlates with severity of incontinence better than static measures of intraurethral pressure, specifically the MUCP [2]. But is the LPP, by itself, an accurate indicator of ISD? This question is important because many of the studies that have analyzed risk factors for the failure of anti-incontinence procedures have used a MUCP ≤ 20 cm H_2O as the criteria for defining an intrinsically weak urethral sphincter [3, 4, 5].

Many articles have been written regarding the lack of correlation between the LPP and the MUCP [6, 7], but no studies have looked at the characteristics of women who meet the criteria for ISD on MUCP but not on LPP. While the correlation between LPP and MUCP is poor, we assume that most women with a LPP > 60 cm H_2O will have a MUCP > 20 cm H_2O. Our goal is to determine the characteristics of women who are the exception to this rule, i.e., those with a MUCP < 20 cm H_2O whose diagnosis of ISD would be missed if only the LPP were assessed. Since a failure to diagnose ISD could affect patient counseling and treatment, we wish to see in whom the chance for this type of missed diagnosis is most likely.

Materials and methods

This is a cross-sectional study in which the urodynamic findings of every patient who underwent multichannel, microtransducer urodynamic testing in our Continence

Center between 1994 and 1996 were reviewed, regardless of pre-study diagnosis. We also collected non-identifying demographic, physical examination, and medical history data on all subjects. Approval for this study was granted by the Human Studies Committee at the University of Louisville. Urodynamic techniques and measurements, terms, and diagnostic criteria conform to the recommendations of the International Continence Society [8] unless specifically stated.

A Laborie (Williston, VT, USA) multi-channel urodynamic system recorded measurements from 8F Millar micro-tip catheters. A medium-fill (100 ml/min) retrograde cystometrogram was performed in the sitting position with room temperature normal saline. The LPP was obtained with a bladder volume of 150 ml by asking the patient to perform a Valsalva maneuver until urine loss was directly observed. If urine loss was not noted with Valsalva, the patient was asked to cough. This process was repeated to verify the initial finding. The lowest intravesical pressure found to produce urine loss minus the resting vesical pressure was recorded as the LPP. We excluded subjects who were unable to generate an intra-abdominal pressure >60 cm H_2O or who did not leak.

The MUCP was obtained by subtracting the intravesical pressure at maximum cystometric capacity from the maximal urethral pressure measured during the urethral closure pressure profile by withdrawing the laterally directed proximal sensor of the catheter from the bladder to the external urethral meatus. This process was repeated a second time, and the largest value was recorded as the MUCP.

The subjects were then separated into four groups based on their LPP and MUCP. The criteria for these groups are as follows: 1) subjects who met the criteria for ISD on both LPP and MUCP (which we defined as a LPP <60 cm H_2O and a MUCP <20 cm H_2O); 2) subjects who did not meet the criteria for ISD on LPP or MUCP; 3) subjects who met the criteria for ISD on LPP but not on MUCP; and 4) subjects who met the criteria for ISD on MUCP but not on LPP.

We then focused our analysis on the two groups necessary to answer our research question: those with no evidence of ISD (which we called Group A—MUCP >20 and LPP >60) and those with evidence of ISD on MUCP only (which we called Group B—MUCP <20 and LPP >60). We performed univariate analysis using the chi-square to test categorical variables and the *t*-test for continuous variables to compare characteristics between subjects in Groups A and B. Parsimonious logistic regression [9] (utilizing variables that showed a p value <0.05) was then performed to identify independent predictors of group membership.

Results

The demographics of our population are shown in Table 1. The break down of all subjects into the four urodynamic categories is shown in Fig. 1. This figure demonstrates that our initial assumption that most women with a LPP >60 cm H_2O will also have a MUCP >20 cm H_2O is correct. However, it also shows that a small percentage of women are exceptions to this rule. Of the 305 with a LPP >60 cm H_2O, 288 also had MUCP >20 cm H_2O and thus fell into Group A; however, 17 of the 305 had an MUCP <20 cm H_2O and thus fell into Group B.

Eighteen patient characteristics were compared between Groups A and B (Table 2). Statistically significant differences ($P<0.05$) were found during univariate analysis in the following six: age, maximum cotton swab deflection, change in cotton swab deflection with strain, positive supine empty stress test (defined as a loss of urine from the urethra viewed with the patient in the dorsal lithotomy position soon after emptying her bladder), urethrovesical junction hypermobility (maximum cotton swab deflection >30 deg or a change in deflection >30 deg), and the presence of an enterocele.

After adjusting for these significant predictors found during univariate analysis, only age and a positive supine empty stress test remained as independent predictors of group membership during logistic regression (Table 3). Only 6.1% of subjects in Group A had a positive supine empty stress test, compared with 25.0% positive in Group B ($P=0.02$). The mean age in Group A was 51.8 years and in Group B it was 67.9 years ($P<0.001$). When plotting a receiver operating characteristic curve (Fig. 2) comparing age in the two groups, 60.5 years of age was the cut-off value that best distinguished group membership. Using this age as a cut-off, membership in Group A versus Group B can be predicted with a sensitivity of 83.4% and a specificity of 75.3%.

Table 1 Total population demographics

Age	54.4 ± 13.1
Body mass index	30.5 ± 8.3
Parity	2.7 ± 1.9
Hormone replacement therapy	194 (49.9%)
Prior hysterectomy	235 (55.8%)
Prior incontinence surgery	114 (26.9%)

Age, BMI, and Parity are presented as mean ± standard deviation

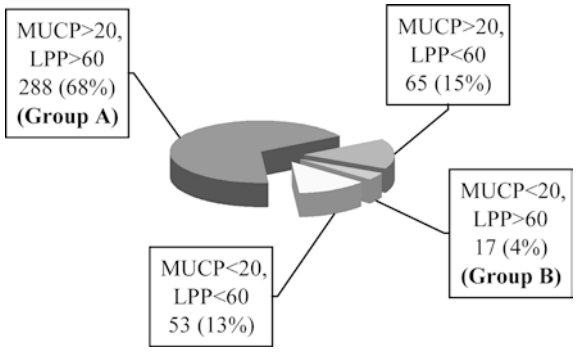

Fig. 1 Categorization of all subjects

Table 2 Univariate analysis comparing groups A and B

Variable	Group		Odds ratio	95% CI	*P*
	A	B			
Age	51.8 (12.4)	67.9 (7.2)	-	-	< .001
BMI	30.9 (8.1)	32.1 (6.8)	-	-	.574
Parity	2.7 (1.7)	2.5 (1.2)	-	-	.619
Pads/day	1.6 (2.1)	1.7 (1.4)	-	-	.891
Leaks/day	3.9 (4.4)	3.7 (3.6)	-	-	.895
Cotton swab max	57.4 (24.6)	37.3 (29.3)	-	-	.002
Cotton swab change	45.6 (21.4)	27.8 (20.4)	-	-	.001
Prior hysterectomy	48.3%	70.6%	2.57	(.88, 7.49)	.074
Prior incont surgery	21.9%	35.3%	1.94	(.69, 5.47)	.200
Wears pads	58.9%	76.9%	2.33	(.62, 8.74)	.198
HRT	46.2%	62.5%	1.94	(.69, 5.51)	.204
SST positive	31.4%	35.7%	1.21	(.39, 3.76)	.737
SEST positive	6.1%	25.0%	5.13	(1.48, 17.7)	.005
UVJ hypermobility	86.8%	60.0%	.228	(.077, .681)	.004
Rectocele	45.8%	35.5%	.647	(.23, 1.80)	.400
Cystocele	60.7%	41.2%	.454	(.17, 1.23)	.112
Vault prolapse	38.3%	43.8%	1.26	(.45, 3.48)	.661
Enterocele	19.5%	41.2%	2.90	(1.05, 7.98)	.033

First seven variables presented as mean ± standard deviation. *BMI* body mass index, *Incont* incontinence, *HRT* hormone replacement therapy, *SST* standing stress test, *SEST* supine empty stress test, *UVJ* urethrovesical junction, *CI* confidence interval

Table 3 Parsimonious multivariate logistic regression comparing groups A and B

Variable	Beta	*P*	95% CI for beta
Age	1.14	< .001	(1.06, 1.22)
SEST	6.63	.023	(1.29, 34.0)
UVJ hypermobility	.636	.671	(.079, 5.13)
Cotton swab change	.995	.827	(.952, 1.04)
Cotton swab max	.991	.640	(.953, 1.03)
Enterocele	1.93	.345	(.492, 7.58)

SEST supine empty stress test, *UVJ* urethrovesical junction, *CI* confidence interval

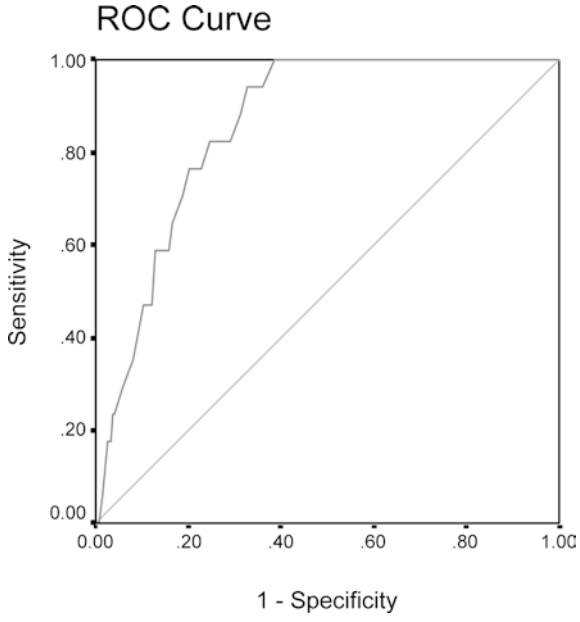

Fig. 2 Receiver operating characteristic curve of age in predicting membership in Group A versus B

Discussion

Many specialists in the fields of urology and urogynecology believe that identifying the presence or absence of ISD pre-operatively is of key importance in selecting the appropriate approach to surgical correction of female urinary incontinence [10, 11, 12]. Although measuring LPPs alone may be sufficient to make this diagnosis in certain instances, at other times it may not. This study provides information that may be helpful in identifying women in whom this single measurement may be insufficient. The diagnosis of ISD may be missed in women over the age of 60 and in those with a positive supine empty stress test without the benefit of a valid measure of MUCP.

A recent study has shown that fiber optic urodynamic systems do not reliably measure urethral closure pressures as compared to the gold standard of microtransducer catheters [13]. With this new technology, the presence or absence of ISD is therefore being determined by LPP measurements alone. Fiber optic systems are being used frequently because they are much less expensive than the microtransducer systems. As a result, the diagnosis of ISD may be being missed in some women who are preparing to undergo anti-incontinence surgery. Given that fiber optic urodynamic systems do not provide a valid measure of MUCP, practitioners who use MUCP values to make clinical decisions should use microtransducer urodynamic catheter technology in patients >60 years of age and/or with a positive supine empty stress test.

Some may argue that in the era of minimally invasive slings (such as tension-free vaginal tape) this argument is moot because this treatment is appropriate for both patients with and without ISD. However, a recent review of incontinence procedures showed that even with the drastic rise in sling cases in the late 1990s, the age-adjusted rate of retropubic suspensions showed no significant trend over time [14]. Furthermore, a recent prospective Scandinavian study of tension-free vaginal tape shows that failure rates are twice as high in patients

with MUCP < 20 cm H_2O as they are in those with MUCP > 20 cm H_2O [15]. Our study suggests that pre-operative urodynamics that do not include valid measure of MUCP may miss the diagnosis of ISD in some patients. Whether this diagnosis affects one's choice of procedure or pre-operative counseling on success rates, knowledge of its presence is valuable nonetheless.

Both advanced age and a positive supine empty stress test are known to be associated with the diagnosis of ISD. In a secondary analysis of our data (not reported in our results section) we found the supine empty stress test to be positive in a large proportion, 21.7%, of patients with the other disparity in the urodynamic criteria for ISD, MUCP > 20 cm H_2O and LPP < 60 cm H_2O. This was especially true of women over 60 years of age; in this urodynamic group 31.8% had a positive supine empty stress test. However, while we found the supine empty stress test to be highly specific, we did not find it to be as sensitive or predictive of the urodynamic diagnosis of ISD as previous studies [16, 17]. We do not recommend that it be used as a substitute for urodynamic testing.

This study has a number of limitations. It is a retrospective study and there were a relatively small number of subjects who met the criteria for Group B. However, the total *N* of this study (423) is larger than most published articles investigating urodynamic testing; and the relatively small adjustment in patient management that we suggest probably does not warrant the time and expense associated with a prospective study. Finally, the external validity of these findings must be considered. Our LPP values were measured at a bladder volume of 150 ml. Urodynamic centers that measure the LPP at higher volumes such as 300 ml may be more sensitive at detecting cases of ISD because the LPP tends to decrease as bladder volumes increase [18]. These centers may see less of a discrepancy in the diagnosis of ISD between MUCP and LPP measurements than we found in our study.

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Editorial comment

Valsalva leak point pressures and maximum urethral closure pressures are two different tests that can be used to evaluate and quantify urethral sphincteric function. The authors performed a cross-sectional study to determine the characteristics of women whose diagnosis of ISD would be missed based on an abnormal MUCP defined as < 20 cm H_2O if only a LPP was assessed. They found that of 305 patients with a normal LPP defined as > 60 cm H_2O, 288 patients also had a normal MUCP (Group A) compared to 17 patients who had an abnormal MUCP (Group B). In comparing 18 patients characteristics, they found that age greater than 60 years and a positive supine empty stress test were independent risk factors for membership in Group B. It is known that both MUCP and LPP are fraught with variables making each difficult to standardize and validate. One could question whether a MUCP with a cutoff < 20 cm can truly be used to define ISD. This brings up a related criticism described as a limitation by the authors—mainly that LPP were measured only at a bladder volume of 150 cc. Perhaps if the measurements were repeated at a larger bladder volume, there would have been an even greater correlation between MUCP and LPP. More needs to be done in the future to better standardize tests used to evaluate urethral function. As the authors mentioned, however, with the success of suburethal slings for all types of stress incontinence, perhaps this is a moot point.