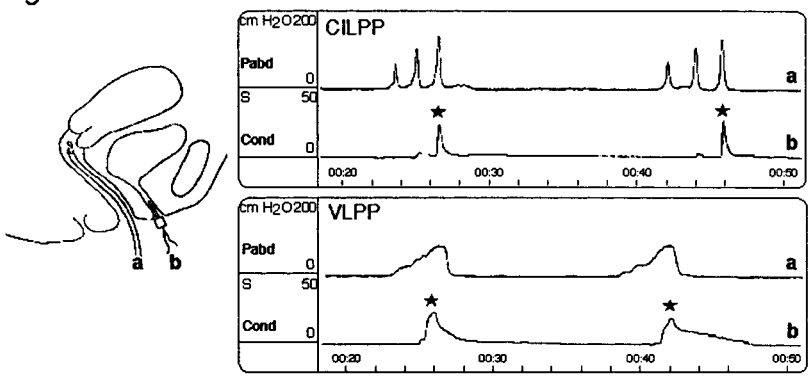
Figure 1



The practical set-up to determine CILPP and VLPP with the microtip catheter (a) placed in the vagina and the UEC-meter (b) in the urethra. Below are copies of leakage (★) and pressure recordings. Note the stepwise increase in cough strength. CILPP was defined as the mean of the lowest single pressure that produced leakage and the highest single pressure recorded without concomitant leakage. The lowest pressure producing leakage in a series of three Valsalva maneuvers defined the VLPP.

Results: CILPP verified leakage in 37/40 and 38/39 patients at 200 ml and at 90% of maximum bladder capacity, respectively. The corresponding figures for VLPP were 29/40 and 37/39. Thus at 200 ml, the *sensitivity* of CILPP was significantly higher than the sensitivity of VLPP.

At 200 ml, the *specificity* of CILPP was 0.73 (8/11) and the overall accuracy 0.88 (45/51). The corresponding figures for VLPP were 0.82 (9/11) and 0.75 (38/51). Increasing bladder volume to 90% of maximum capacity did not alter the specificity of either measure. Raising the volume did, however, increase the overall accuracy of both CILPP and VLPP to 0.92.

Mean *pressure levels* at leakage for CILPP were significantly lower at 90% of maximum bladder capacity than at 200 ml: 90.7 cm H_2O compared with 103.2 cm H_2O (p=0.0085). VLPP levels were significantly lower than mean CILPP levels at corresponding volumes, but there was no statistically significant difference between VLPP levels at 200 ml and 90% of bladder capacity: 72.5 cm H_2O and 68.6 cm H_2O respectively.

Conclusion: The sensitivity of CILPP is high over a wide range of bladder volumes whereas VLPP requires a large bladder volume to attain an acceptable detection rate. The specificity of CILPP and VLPP allows differentiation between patients with stress incontinence and controls.

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Title (type in CAPITAL LETTERS, leave one blank line before the text):
CLINICAL AND URODYNAMIC PATTERNS OF INTRINSIC SPHINCTER DEFICIENCY

Aims of the study

Patients with severe Genuine Stress Incontinence (GSI), a fixed urethra and no hypermobility, are ideal candidates for studying Intrinsic Sphincter Deficiency (ISD) as opposed to anatomic incontinence. We analyzed clinical data (age, previous uro-gynaecological surgery and/or hysterectomy, stress test, irritative symptoms and perineal testig) and urodynamic parameters (Valsava leak point pressure - VLPP, Maximum Urethral closure pressure - MUCP, the urethral functional length), in a group of patients with severe GSI and poor urethral mobility (pure ISD) and with moderate GSI and urethral hypermobility (pure anatomic GSI) in an attempt to identify specific ISD patterns (1-2-3),

METHODS

We recruited 87 consecutive patients with urodynamically demonstrated GSI. Each woman provided a standard urogynecologic based history, and underwent physical examination and full urodynamic testing. The VLPP and the MUCP were determined with 200 ml bladder volume, using an infusion pump and an 8 Fr catheter. VLPP was determined during a Valsalva manouvre. A MUCP ≤30 cm H20 and a VLPP ≤ 60 cm H20 were chosen as cut-off values. Poor or no urethral mobility was diagnosed with urethrocele ≤1 (HWS classification) associated with ultrasound cervicourethral displacement of ≤ 1 cm. Severity of incontinence was subjective (SEAPI-QMN classification). 38/87 pts had incontinence grade ≥ 2 and urethrocele ≤ 1 (pure ISD), 49/87 pts had incontinence grade = 1 and urethrocele ≥2 (pure anatomic GSI - no ISD)

Statistical analysis.For the logistic regression model, the disease status was used as binary dependent variable (48 pts with no ISD: disease status =0; 39 pts with pure ISD: disease status =1) and was correlated against these independent variables: age, previous uro-gynaecological surgery and/or hysterectomy, stress test, irritative symptoms, perineal testing, MUCP, VLPP and urethral functional length. The odds of having ISD were defined from odds ratio (OR) coefficients and 95% confidence interval (CI) using logistic regression.

To determine the odds ratios, a reduced model of stepwise logistic regression was produced, incorporating the same predictors, by backward conditional elimination that included only statistically significant potentially predictive variables. All statistical procedure were carried out in SPSS for Windows.

RESULTS

The multiple logistic analysis showed that only a low VLPP (below the cut off value) (r=0,314; p<0.0001), previous urogynecologycal surgery and/or hysterectomy (r=0.294; p<0.001) have a significant correlation with the presence of ISD. The correct estimate of this model was 81.9% for total subjects, 84.4% for subjects with disease status = 0 and 80% for subjects with disease status = 1. A stepwise logistic regression was used incorporating the VLPP value and the presence or absence of previous surgery. The low VLPP determines an odds ratio = 1.9 (CI 1.1-3); previous surgery determines an odds ratio = 2.1 (CI 13-3.4). When a low VLPP is associated with previous surgery the odds ratio is = 19 (7.1-50.7).

CONCLUSIONS

Logistical analysis of data from this series of patients shows only the VLPP and previous urogynaecological surgery and/or hysterectomy correlated with ISD. Low VLPP identifies 65% of cases while previous surgery detects 59%. When both variables are associated 89% of patients with ISD are identified.

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Title (type in CAPITAL LETTERS, leave one blank line before the text):
IS INTRINSIC SPHINCTER DEFICIENCY MULTIFACTORIAL? PART 1

Aims of the study

Two pathophysiologic mechanisms have been recognized as causing Genuine Stress Incontinence (GSI). The first, found mostly in patients with GSI, is a defect in the anatomic support of the urethrovesical junction. The second, commonly known as Intrinsic Sphincter Deficiency (ISD), causes incontinence through primary urethral and periurethral tissue abnormalities (1). This study compares two urodynamic parameters, the MUCP and the VLPP, with the severity of incontinence and poor prognostic factors, namely poor urethral mobility, age, previous urogynecologic surgery and/or hysterectomy, weight, number of pregnancies and hormone status, to see if the VLPP and/or the MUCP identify and quantify urethral sphincter function and diagnose ISD.

METHODS

We recruited 166 consecutive patients attending our urogynecologic center with urodynamically demonstrated Genuine Stress Incontinence. Each patient provided a standard urogynecologic history, and underwent physical examination and full urodynamic testing. The VLPP and the MUCP were determined with 200 ml bladder volume, using an infusion pump and an 8 Fr catheter. The VLPP was obtained during Valsalva maneuver. A MUCP ≤30 cm H20 and a VLPP ≤ 60 cm H20 were chosen as cut-off values. Poor or no urethral mobility was diagnosed with urethrocele ≤1 (HWS classification) associated with ultrasound cervicourethral displacement of ≤ 1 cm. Severity of incontinence was subjective (SEAPI-QMN classification). The Mann-Witney and Chi square tests were used for statistical analysis.

RESULTS Tables 1 and 2 illustrate the links between the cut-off values and urodynamic variables. Tables 3 and 4 illustrate MUCP, VLPP, severity of incontinence and poor prognostic factors.

	MUCP≤30cm 59/166pts	MUCP>30cm 107/166pts	
MUCP ♣	28.5cm (25-30)	58cm (45-67.5)	
VLPP≤60 cm	35/59 (59.3%)	20/107 (18.6%)	P⁺= 0.000
negative VLPP*	21/59 (35.5%)	73/107 (68.5%)	P⁺= 0.000
Cystomet. Capacity♣	374cc (350-401)	380cc (352-416)	P° = NS
U Funct. Length♣	2.1mm (1.9-3)	2.5mm (2-3)	P°= 0.03

TABLE 1: MUCP cut-off values

	VLPP≤60cm 55/166pts	VLPP>60cm 111/166pts	
MUCP♣	30.5cm (27-44)	55.5cm (37-65.2)	P° = 0.000
MCPU≤30cm	35/55 (63.6%)	24/111 (21.6%)	P⁺= 0.000
negative VLPP*	// //	94/111 (84.6%)	
Cystomet. Capacity♣	370cc (355-408)	383cc (350-412)	P° =NS
U Funct. Length♣	2.15mm (1.7-2.5)	2.5mm (2-3)	P°= 0.005

TABLE 2: VLPP cut-off value

♣ Interquartile range in brackets * no leakage with VLPP ° Mann-Whitney test
⁺ Chi square test

	MUCP≤30cm 59/166pts.	MUCP>30cm 107/166pts	
GRADE ≥ 2	38/59 (64.4%)	46/107 (42.9%)	P*= 0.01
DAILY PADS♣	2 (1-3.5)	1 (0-2)	P° = 0.03
URETHROC. ≤1	31/59 (52.5%)	40/107 (37.3%)	P*= NS
SURGERY(y/n)	28/59 (47.4%)	26/107 (24.2%)	P*= 0.004
AGE (y) ♣	62 (56-69)	53 (49-62)	P° = 0.000
MENOP.(y/n)	51/59 (86.4%)	61/107 (57.0%)	P*= 0.000
WEIGHT (kg)	70 (60-79)	65.5 (60-73.5)	P°= NS
PARITY (n°) ♣	2 (2-2)	2 (1-2)	P°= NS

TABLE 3:MUCP and prognostic factors

	VLPP≤60cm 55/166pts.	VLPP>60cm 111/166pts	
GRADE ≥ 2	42/55 (76.3%)	42/111 (37.8%)	P*= 0.001
DAILY PADS♣	2 (1-4)	1 (0-2)	P° = 0.000
URETHROC. ≤1	33/55 (60.0%)	38/111 (34.2%)	P*= 0.004
SURGERY(y/n)	26/55 (47.2%)	28/111 (25.2%)	P*= 0.006
AGE (y) ♣	60 (51-67)	56aa (49-64)	P°= NS
MENOP.(y/n)	41/55 (74.5%)	71/111 (63.9%)	P*= NS
WEIGHT (kg)	69.5 (59-78)	67 (60-74.5)	P°= NS
PARITY (n°) ♣	2 (1-2)	2 (2-3)	P°= NS

TABLE 4:VLPP and prognostic factors

♣ Interquartile range in brackets ° Mann-Whitney test * Chi square test

DISCUSSION

The high percentage of negative VLPP in our series may have been due to the technique we used. The gynecological position does not facilitate urinary leakage but is the most convenient for the doctor and the most comfortable for the patient. In most cases of positive VLPP the value was ≤ 60 cm H2O.VLPP was slightly more accurate than MUCP in predicting severity of incontinence. The most interesting point was that the two urodynamic tests did not identify the same population but all patients with a low VLPP or MUCP had more poor prognostic factors and more severe incontinence. This could be indicative of 2 different mechanisms generating ISD. We suggest a low VLPP or MUCP should make the physician strongly suspect ISD.

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Title (type in CAPITAL LETTERS, leave one blank line before the text):
IS INTRINSIC SPHINCTER DEFICIENCY MULTIFACTORIAL? PART 2

AIMS OF THE STUDY

Intrinsic Sphincter Deficiency (ISD) causes incontinence through urethral and periurethral tissue abnormalities. It is usually associated with high grade incontinence and poor prognosis. Bladder neck hypermobility can coexist with ISD in women with GSI. Although subjective parameters such as history and physical examination are essential for diagnosing urethral dysfunction, urologists and gynecologists (1-2-3) are searching for an objective test to quantify urethral sphincter function and to diagnose ISD. This study compares the MUCP and the VLPP with grade of incontinence, age, previous urogynecologic surgery and/or hysterectomy and Urethral functional length in an attempt to see if the VLPP and/or the MUCP identify patients with ISD.

METHODS

We recruited 166 consecutive patients attending our urogynecologic center with urodynamically demonstrated Genuine Stress Incontinence. Each patient provided

a standard urogynecologic history, and underwent physical examination and full urodynamic testing. The VLPP and the MUCP were determined with 200 ml bladder volume, using an infusion pump and an 8 Fr catheter. The VLPP was obtained during Valsalva maneuver. A MUCP ≤30 cm H20 and a VLPP ≤ 60 cm H20 were chosen as cut-off values. Severity of incontinence was subjective (SEAPI-QMN classification). The Kruskal-Wallis and the Chi square tests were used for statistical analysis. Accuracy was calculated from 2 x 2 tables using standard formulas.

RESULTS

Table 1 demonstrates that accuracy, in terms of grade of incontinence, is slightly better with the VLPP than with the MUCP. Table 2 shows incontinence is more severe and the incidence of poor prognostic factors is increased in patients with one or two abnormalities.

	VLPP	MUCP
SENSITIVITY	83.8%	62.8%
SPECIFICITY	60.2%	52.1
POSITIVE PREDICTIVE VALUE	47.2%	40%
NEGATIVE PREDICTIVE VALUE	89.7%	3.4%
DIAGNOSTIC CAPACITY	67.3%	55.7%

TABLE 1 Accuracy of the VLPP and the MUCP

	AGE♣	GRADE≥2	n°PADS♣	SURGERY	U F L♣
Normal VLPP and MUCP (86 pts)	53.5yrs (48-62)	31/86 (36.0%)	1 (0-2)	21/86 (24.4%)	2.5mm (2-3)
Abnormal VLPP or MUCP (44 pts)	59yrs (51-67)	26/44 (59.0%)	2 (1-3)	15/44 (34.0%)	2.5mm (2-3)
Abnormal VLPP and MUCP (36 pts)	62yrs (56-67)	27/35 (77.1%)	2 (1-4)	21/35 (60.0%)	2 (1.5-2.5)
	P°= 0.001	P⁺= 0.000	P°= 0.003	P⁺= 0.000	P°= 0.003

TABLE 2 Poor prognostic factors, VLPP and MUCP
♣ median and interquartile range in brackets
° Kruskal-Wallis test ⁺ Chi square test

CONCLUSIONS

ISD, as described by the AHCPR, is a concept rather than a real diagnosis and, above all, does not indicate the method of diagnosis. Some authors have associated ISD with low urethral pressure and others with a low leak point pressure.

On the basis of our experience, because the results of the two urodynamic tests do not overlap and do not identify the same population, we can hypothesize that ISD has a multifactorial genesis and that a low MUCP or a low VLPP detects a different ISD pathogenetic mechanism.

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