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Title: IS VALSALVA LEAK POINT PRESSURE A RELIABLE TEST?

	Negative VLPP	Positive VLPP
Mean measure differences (cm H ₂ O)	4.5	5.8
Limits of agreement (2DS) (cm H ₂ O)	± 26.4	± 41
ICC	0.904	0.921

Aims Of The Study:

The Valsalva Leak Point Pressure (VLPP) is a widely used diagnostic test in urogynaecological patients with severe Stress Urinary Incontinence (SUI). It is used to assess the intrinsic urethral sphincter and to decide the role of bladder neck hypermobility and intrinsic sphincter dysfunction in determining incontinence (1). The VLPP results would be crucial in determining the choice of surgery, which is strongly influenced by the intrinsic sphincter condition, but doubts still persist about its reliability (2-3). A test-retest study is an essential step to validate this diagnostic tool, and to show, as in any test, its results are reproducible and operator independent. In order to determine whether the VLPP results are reliable, reproducible and indicative of the same surgical option, a group of patients with various grades of SUI repeated the VLPP test with 2 different operators during one urodynamic session.

Methods:

53 consecutive patients with SUI underwent a full urogynaecological work up which included case history, clinical examination with assessment of pelvic floor dysfunction, supine stress test, multichannel cystometry with Pressure/Flow study, VLPP, Urethral Pressure Profile and endocavitary ultrasound of the lower urinary tract. During the urodynamic examination the VLPP was repeated at least twice, and at most four times, with patient in the supine position, with 200cc bladder volume; an 8 Fr catheter was used. A remote control device recorded the bladder pressure exactly when urine appeared at the external urinary meatus. If there was no urinary leakage the VLPP was considered negative and the maximum bladder pressure achieved during the Valsalva maneuver was registered. A cut-off of ≤ 60 cm H₂O was chosen to diagnose Intrinsic Sphincter Deficiency. The double blinded test was performed by two independent operators (the minimum time lapse before repeating the Valsalva maneuver was 5 minutes, and the maximum 35 minutes)

Statistical analysis

To assess reproducibility we used the Bland-Altman test, the coefficient of variation (CV), which repeats the variations around the means as percentages, and the intra-class correlation coefficient(ICC), which evaluates the operators' reclassification of patients.

Results:

203 VLPP tests were obtained in 53 patients. The VLPP was positive in 17 patients (32%) and negative in 41 (67%). The mean value of the negative VLPP was 93 cm H₂O (range 62 – 155) and the mean value of the positive VLPP was 68 cm H₂O (range 19 – 150).

Patients were then divided into two sub-group (VLPP negative and VLPP positive). Reproducibility of recording was assessed separately. 90% of the inter-operator difference fell between the 2 DS as predicted

by the Bland-Altman test. The mean CV was 9.9% in the VLPP negative patients and 13.7% in the VLPP positive patients. The table reports the results as difference in value, confidence intervals and ICC.

Conclusions:

The statistical analysis shows urinary leakage occurs at an almost constant bladder pressure. The lower the VLPP the more the results overlap, showing the leakage at low bladder pressure is a sign of severe deficit, which persists and is visible at retest. The retest made us reformulate diagnosis in only one patients because VLPP were 60, 60, 65 and 90 cm H₂O respectively. As soon as leakage takes place, the patient stops the Valsalva manouvre and the straining remains constant. When the VLPP is negative bladder pressure is more variable and depends on the degree of straining the patient does during each Valsalva manouvre. If there is no leakage the patient continues bearing down, often with non continuous, irregular pattern which results in different pressure

Therefore, if the test conditions are standardized- catheter size, bladder volume, patient's position, manouvre to elicit pressure – the VLPP appears to be reliable and to yield reproducible results.

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