

DERIVATION OF A DIAGNOSTIC INDEX TO CLASSIFY BOO USING BLADDER PRESSURE AND FLOW MEASUREMENTS OBTAINED BY A NOVEL INTRA-URETHRAL DEVICE.

Hypothesis / aims of study

We hypothesized that a modified equation of Abrams-Griffiths could be constructed for use with data from a minimal invasive urethral device test. In this study, we present the rationale for the modified equation. Due to the fact that the modifications were previously performed on the equation itself, as to adequate minimal invasive variables to invasive results, the ICS nomogram was used as first conceived. We prospectively compared its performance to the classification by invasive PFS.

Study design, materials and methods

The urethral device is a cylindrical structure that adapts to the urethral meatus with its inner end going all the way to the navicular fossa with a lateral connection for a pressure transducer, and the distal end free for urinary flow. It consists of carbon-polyvinyl and silicon, making it light, not distensible and easy to sterilize. Immediately after conventional invasive urodynamics, bladder was filled up with the same volume of physiologic solution. The patients were submitted to a little upward pressure on the device against their urethra, for a tight connection, in order to avoid urinary leaks outside the device by a single examiner. The patient started a normal void and the examiner interrupted urinary flow through digital obstruction of the device's distal end 3 seconds later in order to permit a stream equalization. For each flow interruption cycle, respective p_{iso} on the plateau pressure and Q_{interr} were drawn. This was repeated for a minimum of 3 times and the average of the values were used.

These variables were compared using the Pearson's coefficient correlation test to their correspondent measures obtained through invasive urodynamics, which were p_{det} at Q_{max} and Q_{max} , respectively. This mathematical correlation was tested to determine substitute equivalents for an adapted Abrams-Griffiths equation worth for minimal invasive measures. We plotted on the graph the correspondent variables and observed a linear correlation between the minimal invasive Q_{interr} and invasive Q_{max} as well as a quadratic relationship between the pressures p_{iso} and p_{det} at Q_{max} .

Results

Fifty-one patients were referred to the laboratory by their clinicians due to LUTS complaints. They were drafted on their first visit during three months straight on the laboratory's schedule. The mean age was 64.8 ± 8.5 years. The prostate weight by digital rectal examination was of $39.2g \pm 18.8$, and the IPSS (international prostatic symptom score) was of 14 ± 6.9 . Among these men, 46 (90%) were suitable for analysis, 5 (10%) were excluded due to involuntary high amplitude detrusor contractions during the invasive test. Using invasive data, 21 (45.6%) were classified as obstructed, 15 (32.6%) as equivocal and 10 (21.7%) as unobstructed; a total of 25 (54.4%) of equivocal/unobstructed. Significant linear correlation was observed between invasive Q_{max} and minimal invasive Q_{interr} , $r = 0.558$, $p < 0.0001$ and a quadratic polynomial between invasive p_{det} at Q_{max} and minimal invasive p_{iso} . Thus, through simple linear regression for the urinary flow values and multiple linear regression for the pressure values, we found the numeric equivalents that substitute the variables. This was the final equation for classification of BOO using the urethral device test, and the result was denominated urethral device number (UD_n):

$$\text{Equation 4: } UD_n = 68.708 - 0.679 \times p_{iso} + 0.004 \times p_{iso}^2 - 1.254 \times Q_{interr}$$

The final result (UD_n) classified each patient as obstructed or equivocal/unobstructed, according to the ICS nomogram,¹⁰ which was not modified. This equation classified 27 (58.7%) of the patients as equivocal/unobstructed and 19 (41.3%) as obstructed. Sensitivity was 61.9%; specificity, 76%; PPV, 68.4%; NPV, 70.37%. Overall accuracy was 69.6%. (Table 1)

Table 1

Measurement	%	95% CI	n/total
Sensitivity	61.9	38.7 ; 81.1	19/21
Specificity	76.0	54.5 ; 89.8	19/25
Positive predictive value	68.4	43.5 ; 86.4	13/19
Negative predictive value	70.4	49.7 ; 85.5	19/27
Accuracy	69.6	54.1 ; 81.8	32/46

Interpretation of results

Measures obtained through the urethral device were comparable to the invasive correspondents and enabled the modification of the Abram-Griffiths original equation. The new formula can be applied to classify any other individual submitted to the urethral device test. Taking into account that data were obtained through different, though comparable, methods, it was necessary to adequate parameters to use the standard Abrams-Griffiths equation. The values of pressure and urinary flow measured minimally invasive partially correlated to the invasive measures. This happens because the minimal invasive method suffers external influences, such as urethral compliance, and abdominal pressure, which do not primarily affect the direct measures achieved through invasive urodynamics. In spite of using the same equation as a basis for minimal invasive classification of BOO, there was a mathematical grant, since the errors observed between the two methods were constant. This allowed for an equivalence represented by the new equation.

Concluding message

The urethral device test proved to be a promising substitute for invasive evaluation of men presenting with LUTS. Primary results presented good correlation to the gold standard method, even though there is still much to improve. It is an easily performed, acceptable method that may represent a reasonable option for BOO diagnosis in the near future.

Specify source of funding or grant	None
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes

<i>Specify Name of Ethics Committee</i>	Comitê de ética em Pesquisa UNICAMP / Sistema Nacional de Ética em Pesquisa
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes