# NEW METHOD FOR A MINIMALLY INVASIVE URODYNAMIC ASSESSMENT IN MEN

# Hypothesis / aims of study

Urodynamic studies are considered the gold standard to diagnose bladder outlet obstruction. Several arguments favor the performance of urodynamic evaluation prior to surgery. However, the procedure is invasive, expensive and time-consuming. The purpose of this study was to evaluate a new minimal invasive urodynamic assessment model and compare the results with those of conventional urodynamic evaluation. Study design, materials and methods

Fifty consecutive male patients with complaints of LUTS were included in this study. The mean age was 62 (ranged from 34 to 82).

All patients underwent conventional and minimal invasive urodynamic studies. The minimal invasive urodynamic evaluation was done using a urethral device specially designs to be adapted to the urethral meatus and fossa navicularis, had a side opening to connect the pressure transducer and the other end free for the release of urine/saline solution (Fig.1). The patient was instructed on how to introduce the device in the fossa navicularis and gently presses it to avoid loss of urine.

During voiding, the patient was oriented to interrupt the flow with a digital maneuver that simply blocked the end (region 3) of the urethral device. Interrupted urine flow (Qinter) and isometric bladder pressure (Piso) were registered using this technique.

Since noninvasive urodynamic assessment is a method based on continuous variables (pressure and flow), a classification function was developed. This function is based on logistic regression.

All the enrolled patients were evaluated by both methods. The Abrams-Griffiths method was taken as the golden standard. We tried to find a function of minimal invasive data to approximate (i.e. to classify) as close as possible to the golden standard classification.

All computations were done with SAS (SAS Institute, Cary, NC), version 8.2.

### <u>Results</u>

The significance level for a null hypothesis was p=0.049. In the conventional urodynamic study, 21 patients were classified obstructed, 20 equivocal and nine normal according the Abrams-Griffiths number.

The urethral devices used in the minimal invasive urodynamic evaluation did not cause pain during the procedure. Leakage occurred between the urethra and the device in two cases, which required the exam to be repeated.

The significance levels of Piso and Qinter parameters were p=0.007 and p=0.008 respectively. Using the highest estimated probability-grouping model, sensitivity was 67% and specificity was 79%. When individuals classified as obstructed (if the corresponding probability was more than 50%) were compared with the Abrams-Griffiths number diagnosis, it was observed that of 21 patients with obstruction, 13 were identified by the noninvasive method.

In order to check if abdominal pressure could have an influence on the results, the statistical analysis was repeated using the following parameters: Piso, Pabd and Qinter.

A comparison between the conventional assessment and minimal invasive (using the parameters Piso, Pabd, Qinter) in relation to the results of the obstructed patients are as follows: of the 21 patients who presented obstruction, the noninvasive urodynamic assessment identified 14 who were really obstructed. It was observed that when Pabd was added to the statistical analysis, one more patient was identified as obstructed. Interpretation of results

The pressure that has to be applied against the urethra so that urine loss is avoided is enough to keep it well inserted and does not cause pain. The probability of a urinary infection due to the use of the urethral device is low because it is introduced only up to the fossa navicularis. Other techniques of non-invasive urodynamic evaluation have troubles reported like elasticity in the condom catheter and different types of material and size of the penile cuff may registered a higher isometric pressure (1,2). These inconveniences were not observed in the urethral device, although we considered this technique minimally invasive.

The results obtained using the urethral device to diagnose BOO revealed 67% sensitivity and 79% specificity. These results were similar to those reported by other authors, in which the condom catheter noninvasive urodynamic assessment was used to correctly diagnose 77% of the patients who presented obstruction (3). It is important to underscore the fact that 25.3% of the patients in that study were excluded from the analysis due to problems such as urine loss between the condom and penis (thirteen), faulty records (three), discomfort (two) and the inability to urinate (one patient). None of the patients using the urethral device were excluded because of technical problems. Concluding message

The urethral device proved to be simple and easy to use. The minimal invasive method was able to detect the most patients with bladder outlet obstruction, thus the conventional urodynamic assessment can be avoided, reducing its morbidity as well as costs.

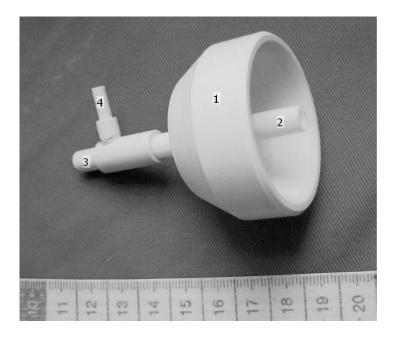
#### <u>References</u>

1 - J. Urol (2004) 171: 12-19.

2 - J. Urol (2001) 166: 2545-49.

3 - Neurourol Urodyn (2002) 21: 117-25.

Figure 1 – Urethral device 1 – the patient holds the device 2 – part of the device introduced into the urethra 3 – outlet for urine. 4 – connection for pressure transducer.



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HUMAN SUBJECTS: This study was approved by the Comissão Nacional de Ética em Pesquisa - CONEP and followed the Declaration of Helsinki Informed consent was obtained from the patients.