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Noninvasive Urodynamic Evaluation

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The longevity of the world's population is increasing, and among male patients, complaints of lower urinary tract symptoms (LUTS) are growing. Testing to diagnose LUTS and to differentiate between the various causes should be quick, easy, cheap, specific, not too bothersome for the patient, and noninvasive or minimally so. Urodynamic evaluation is the gold standard for diagnosing bladder outlet obstruction (BOO) but presents some inconveniences such as embarrassment, pain, and dysuria; furthermore, 19% of cases experience urinary retention, macroscopic hematuria, or urinary tract infection. A greater number of resources in the diagnostic armamentarium could increase the opportunity for selecting less invasive tests. A number of groups have risen to this challenge and have formulated and developed ideas and technologies to improve noninvasive methods to diagnosis BOO. These techniques start with flowmetry, an increase in the interest of ultrasound, and finally the performance of urodynamic evaluation without a urethral catheter. Flowmetry is not sufficient for confirming a diagnosis of BOO. Ultrasound of the prostate and the bladder can help to assess BOO noninvasively in all men and can be useful for evaluating the value of BOO at assessment and during treatment of benign prostatic hyperplasia patients in the future. The great advantages of noninvasive urodynamics are as follows: minimal discomfort, minimal risk of urinary tract infection, and low cost. This method can be repeated many times, permitting the evaluation of obstruction during clinical treatment. A urethral connector should be used to diagnose BOO, in evaluation for surgery, and in screening for treatment. In the future, noninvasive urodynamics can be used to identify patients with BOO to initiate early medical treatment and evaluate the results. This approach permits the possibility of performing surgery before detrusor damage occurs.

Keywords: Urodynamics; Bladder neck obstruction; Urination disorders; Urethra; Equipment and suppplies

INTRODUCTION

The longevity of the world's population is increasing, and in male patients, so are the complaints of lower urinary tract symptoms (LUTS). How does one evaluate these patients? Testing to diagnose LUTS and to differentiate between the various causes should be quick, easy, cheap, specific, not too bothersome for the patient, and noninvasive or minimally so [1].

Conventional urodynamic evaluation consists of registering vesical and abdominal pressures during the filling phase and include the flow during the voiding phase, which is invasive, time-consuming, and expensive [2]. Nowadays, urodynamic evaluation is the gold standard for diagnosing bladder outlet obstruction (BOO), but presents some inconveniences such as embarrassment, pain, and dysuria and with 19% of cases experiencing urinary retention, macroscopic hematuria, or urinary tract infection [3]. A greater number of resources in the diagnostic armamentarium could increase the opportunity for selecting less invasive tests on a patient by patient basis. For instance, in cases in which urodynamic studies would not provide the necessary benefit to overcome the risks of the study, less invasive tests might provide the confirmatory information needed to indicate treatment. The idea is not to replace but to provide alternatives to urodynamics that might better suit the needs of some patients and health care systems. These techniques might feasibly lend themselves to different environments, such

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as mobile and remote clinics. Overall, innovation in health care is how we expand our knowledge, refine practices, and provide better service.

A number of groups have risen to this challenge and have formulated and developed ideas and technologies to improve noninvasive methods to diagnosis BOO. These techniques start with flowmetry, increased interest in ultrasound, and finally the performance of urodynamic evaluation without a urethral catheter.

FLOWMETRY

Flowmetry is the simplest urodynamic test. The equipment is uncomplicated and cheap. Flow is defined by the fluid expelled from the urethra per unit of time. The flow is the result of the contraction of detrusor muscles against urethral resistance. Thus, slow flow can be due to lower detrusor contraction or to increased urethral resistance. By contrast, normal flow can be due to normal detrusor contraction and urethral resistance or to increased contraction of the detrusor and increased urethral resistance. In conclusion, flowmetry is not sufficient for confirming a diagnosis of BOO.

ULTRASOUND

Research has been done to evaluate the contribution of ultrasound to identifying patients with BOO. Methods such as the measurement of detrusor wall thickness (DWT), intravesical prostatic protrusion (IPP), and ultrasound-estimated bladder weight (UEBW) are available. To measure the DWT, it is necessary to use a high-frequency transducer (7.5 MHz) and enlarge by approximately 10× the image of the bladder wall (Fig. 1). The detrusor muscle presents a hypoechogenic image. All parts of the bladder wall have the same thickness [4]. The measurement of the bladder wall should be at least 250 mL in the bladder [5]. The threshold value for BOO is >2 mm [5]. The sonographic measurements of DWT are an accurate alternative for pressure-flow measurements to assess the presence of BOO. DWT measurements show a higher diagnostic power than do measurements of maximum flow rate (Qmax), average flow rate (Qave), postvoid residual urine, or prostate volume. DWT can help to assess BOO noninvasively in all men and can be useful for the evaluation of BOO at assessment and during treatment of BPH patients [5].

The IPP measurement is performed in the sagittal plane with the use of transducer frequencies between 3 and 6 MHz (Fig. 2). The bladder should have at least 100 mL of urine for determining IPP. IPP is defined by the distance from the tip of the prostate's protrusion into the vesical lumen to the bladder neck measured in millimeters. IPP is divided into three stages: grade I, <5 mm; grade II, 5 to 10 mm; and grade III, >10 mm. IPP grade III reaches 80% sensitivity and 68% specificity for diagnosing BOO when compared with urodynamic evaluation [6].

Authors have calculated the UEBW from the measurement of BWT and bladder volume and found that a threshold value of 35 g best distinguishes the difference between obstructed and unobstructed bladders. However, other authors have evaluated patients with LUTS and found that UEBW did not present any individual correlation with LUTS or objective measurements of BOO [7].

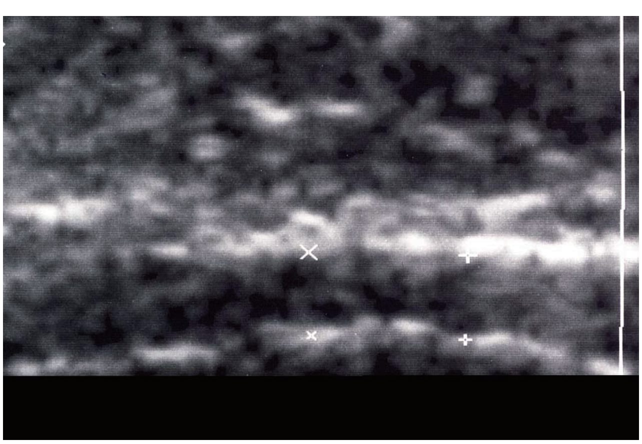

Fig. 1. Detrusor wall thickness: the hypoechogenic image is between the two crosses and the two X's.

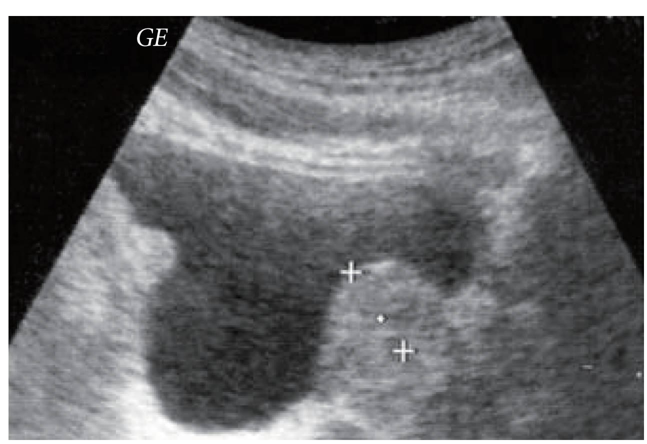

Fig. 2. Abdominal ultrasound demonstrating the intravesical protrusion of the prostate (between the two crosses).

NONINVASIVE URODYNAMIC EVALUATION

Schafer first described noninvasive urodynamics in 1994 when he used a condom catheter (Fig. 3) [8]. Later, McRae et al. [9] developed a cuff to obstruct the urine flow (Fig. 4). The principle of these tests is to interrupt the flow and measure the bladder pressure. The detrusor contraction is maintained and the urethral sphincters remain open and the column of fluid from the urethra to the bladder is sufficient to measure the bladder pressure (isometric pressure) (Fig. 5) [10].

In conjunction with the bioengineering department at Unicamp (University of Campinas), a new device consists of a urethral connector which is placed in the fossa navicularis was developed (Fig. 6). The measurements of the detrusor follow the same principles explained above. The results of the device have already been published [11]. The initial model consisted of only a device to which the transducer was connected and the interruption of the flow was done by the patient himself. The parameters analyzed were the isometric pressure and the interrupted flow. The mammograms utilized in conventional urodynamic evaluation are not applied in noninvasive urodynamics. Statistical analysis and logistic regression were used to develop a classification function. A receiver operating characteristic curve was constructed, which showed a sensitivity of 67% and specificity of 79%. A question then arose: Can the urethral connector promote urethral obstruction? A study was performed to compare the time flow, flow max, and volume between noninvasive and conventional urodynamics and the results showed no significant differences.

With the objective of facilitating the realization of this study, modifications of the urethral connector were proposed. In a previous study, the development of support instrumentation

Fig. 3. Condom catheter described by Schafer et al. [8].

Fig. 4. Penile cuff.

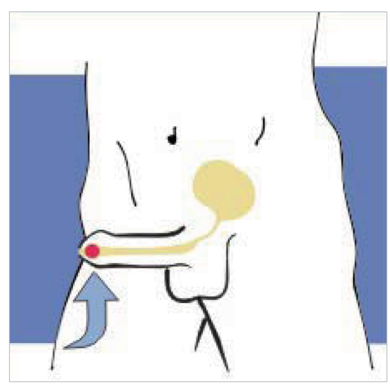

Fig. 5. The interruption of the flow maintains the detrusor contraction and the sphincter remains open.

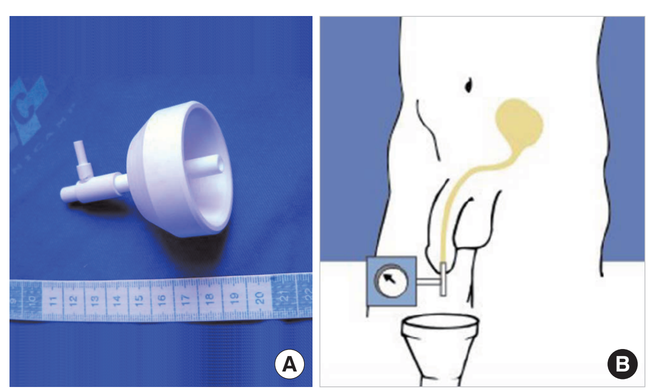

Fig. 6. (A) Urethral connector and (B) position of the urethral connector.

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was presented to be used with the urethral connector [8]. The system is composed of a pressure transducer, an electrical isolation enlargement board (National Instruments NI USB-6215), and registered software from LabVIEW (National Instruments, Austin, TX, USA). With these, it was possible to test new models (Fig. 7).

After various tests, Version II of the urethral connector was developed, in which the transducer is attached to the connector (Fig. 8).

A graph of the vesical pressure registered during a clinical exam with the urethral connector II is shown in Fig. 9. The arrows indicate the approximated movement in which the individual is instructed to close the exit of the device. Note that the pressure slowly increases until it reaches the approximated static value, corresponding to the isovolumetric vesical pressure. Afterwards, the end of the connector is freed, permitting urination to continue. The flow is stopped several times during voiding, for periods of 2 to 3 seconds, which permits greater accuracy of the vesical pressure.

For the comparison of two methods, conventional and connector, the vesical pressure at maximal flow and maximal vesical pressure with the noninvasive method were used. These measurements are good indicators of bladder contractile activity. Fig. 10 shows the comparison of vesical pressure registered by using the two methods. The linear regression resulted in an angular coefficient of 2.00±0.49, r^2=0.8016, with a 95% confidence interval of 0.6190 to 3.38l. The Pearson value of r for the correlation was 0.8953.

The procedure for occlusion of the flow by use of the urethral connector to avoid hydraulic shock was not adopted without

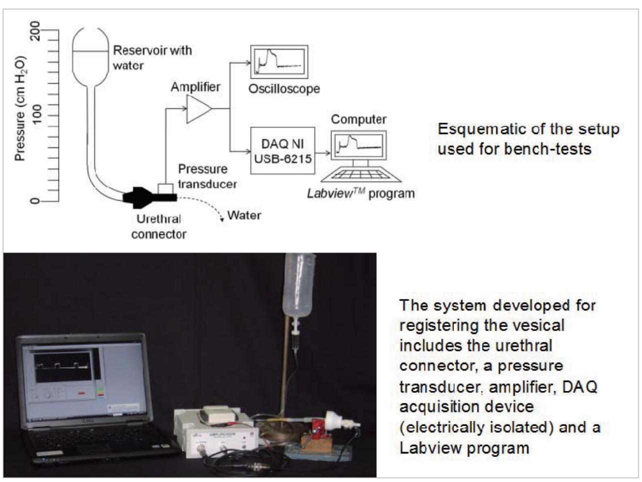

Fig. 7. Bench test for development and testing of the urethral connector.

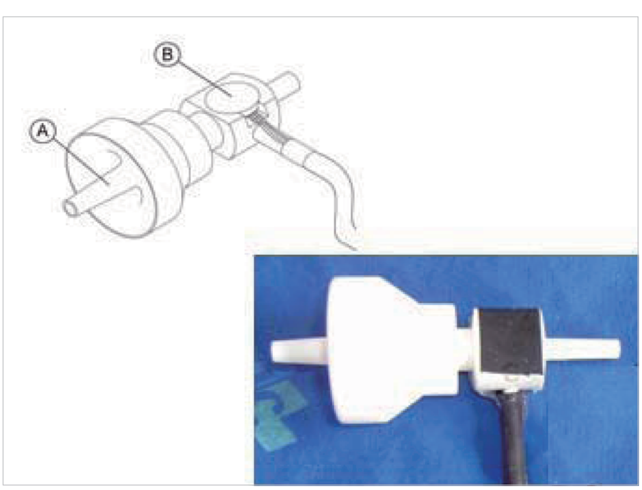

Fig. 8. Urethral connector, new version.

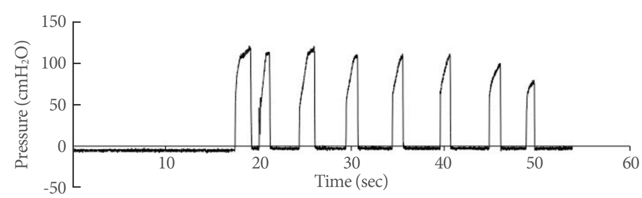

Fig. 9. Vesical pressure registered by the urethral connector during clinical evaluation. The arrows indicate the approximate moment at which the patient was instructed to close the device, permitting the determination of the pressure, which was, in this case, about 98 cmH_2O.

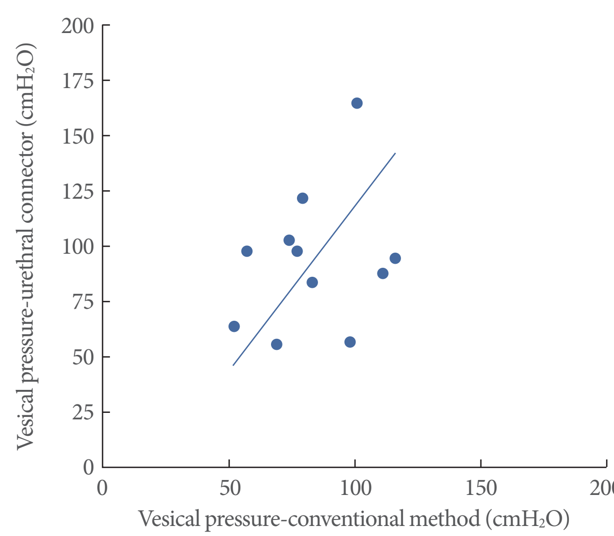

Fig. 10. Vesical pressure registered by the urethral connector method versus the conventional method.

reason. In a previous study, laboratory simulations showed that abrupt occlusion could cause a rapid and significant increase in the pressure. In all the exams, a similar behavior to that presented in Fig. 9 was observed, with a gradual increase of pressure until a static value was reached, which corresponded to the isometric vesical pressure. According to the patients, a closing time of 2 to 3 seconds was not long enough to cause any discomfort. This has already been verified by other methods showing that there is no contraction inhibition of the detrusor during a brief interruption of the flow [12]. The registered vesical pressure values of the urethral connector were compared with the conventional urodynamic method, and the curve can be seen in Fig. 10. The conventional method registers the pressure of a free flow, whereas the connector measures the value during an interrupted flow. Thus, although the pressures measured for each method reflect the contractile activity of the detrusor, the values are not necessarily identical. However, a linear correlation between the measured pressures is observed, which shows the sensitivity of the connector when registering the vesical pressure. Considering that the flows registered by use of both methods were not different, this suggests that the connector does not cause an increase of resistance of the urinary flow, and the necessary interruptions for measuring the vesical pressure do not significantly alter the parameters evaluated.

What is the real application of this method? The study of noninvasive urodynamic evaluation has generated much research; however, it has not been adopted in daily practice. It is difficult to interpret the results and it does not evaluate the phase of vesical filling and has a bit of an engineering characteristic.

Because it is a noninvasive method, it should be used in the first consultation with the patient, when the symptoms have first begun to appear and not when it is time to schedule surgery. The exam most probably should be placed between the flowmetry and the conventional urodynamic study.

The great advantages of using the urethral connector are as follows: minimal discomfort, minimal risk of urinary tract infection, and low cost. This method can be repeated many times, permitting the evaluation of obstruction during clinical treatment. Why should this device be used? The connector should be used to diagnose BOO, for the evaluation for surgery, and in screening for treatment. In the future, noninvasive urodynamics can be used to identify patients with BOO, start early medical treatment, and evaluate the results. The goal is to treat the patient before detrusor damage occurs.

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