582

Almeida J[1], Watanabe R[1], Cohen D[1], D'Ancona C[1], Bassani J[1]
1. *Unicamp*

DEVICE AND METHOD FOR MINIMALLY INVASIVE URODYNAMIC ASSESSMENT IN MEN

Hypothesis / aims of study

More than 20% of men presenting lower urinary tract symptoms need prostate surgery. The decision on the treatment of these patients is usually taken with basis on the results of their urodynamic assessment. The conventional urodynamic test is not free of risk of complications (e.g. macroscopic hematuria, urinary tract infection), which are present in about 19% of the cases. In this study, we describe new improvements on a previously developed device for minimally invasive measurement of isometric bladder pressure.

Study design, materials and methods

The developed device, named urethral connector (UC), is made of polyvinyl carbon and polytetrafluoroethylene, and has now an adapter (a in Fig. 1A) provided with a conic tube designed to fit the urethral meatus and fossa navicularis and a built-in pressure transducer (b in Fig.1A, *Freescale* MPX2300DT1). Transducer calibration and dynamic bench-tests were performed with a setup in which pressure gradient was generated by gravity, and the reference pressure values were obtained by manometry. After a few seconds for continuous flow and pressure stabilization, the outlet of the UC was occluded, so that the steady-state static pressure could be recorded. To avoid hydraulic shock, occlusion was not instantaneous. The output voltage of the transducer was fed to a computer via NI USB-6215 interface (*National Instruments Inc.*), in which a *LabView*^{TM} program was used for data acquisition and processing. The UC was tested (immediately after the conventional urodynamic exam) in 8 patients, who signed the consent form. Patients were instructed to manually occlude and release urine flow through the UC. A t-test for paired comparisons was used to compare the pressure obtained with the UC with the conventional urodynamic method.

Results

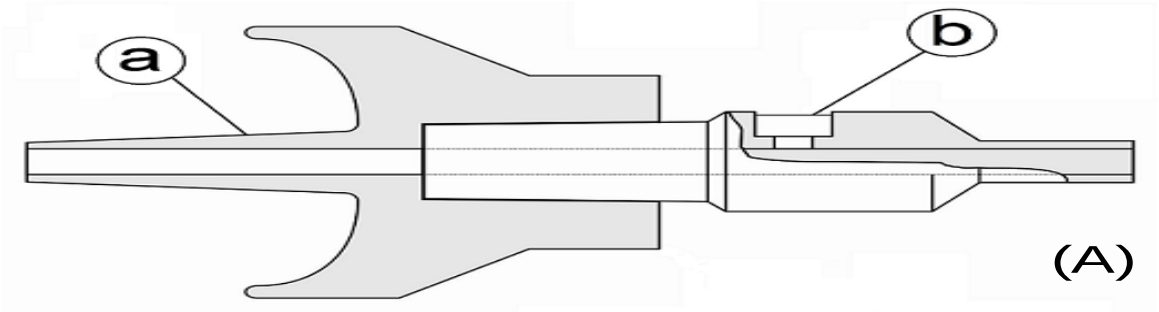
Bench-tests showed that the device responded linearly, and with high reproducibility, to the applied pressure. The steady-state pressure could be reliably measured in less than 400 ms after non-instantaneous UC occlusion, a period not long enough to cause much discomfort to the patient, but sufficiently long to avoid hydraulic shock (Fig.1B). About 75% of the patients considered the minimally invasive test as preferable to the conventional evaluation.

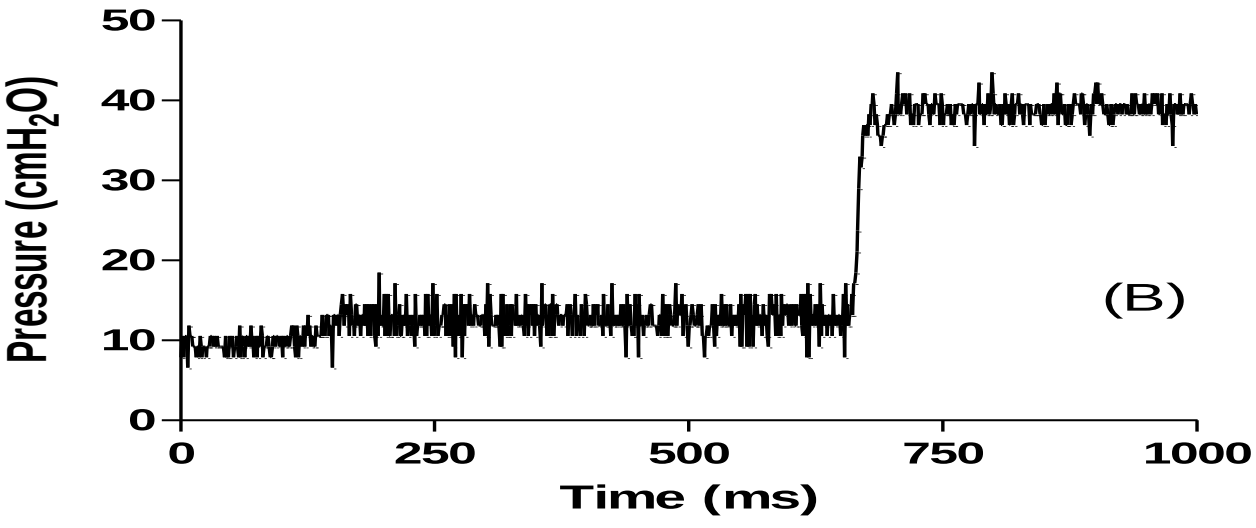
Interpretation of results

Preliminary clinical tests indicated that the new device is easy to use and allows shorter examination time. Patients referred no major discomfort. Although mean values of pressure were not statistically different with the two methods, present data were insufficient to allow reliable determination of correlation between them.

Concluding message

The UC performed well in bench-tests. Although more clinical testing is required, preliminary application indicated that the UC method is a convenient alternative to the conventional urodynamic test for measurement of static bladder pressure.





References

1. D'ANCONA CAL, BASSANI JWM, QUERNE FAO, CARVAL

HO J, OLIVEIRA RRM, NETTO Jr NR. New method for minimally invasive assessment in men with lower urinary tract symptoms. Urology, 71(1), p. 75-78, 2008
2. GOMMER ED, VANSPAUWEN TJA, MIKLOSI M, WEN JG, KINDER MV, JANKNEGT RA, van WAALWIJK, van DOORN ESC. Validity of a non-invasive determination of the isovolumetric bladder pressure during voiding in men with LUTS. Neurourology and Urodynamics, 18, p. 477-486, 1999
3. McINTOSH SL, DRINNAN MJ, GRIFFTHS CJ, ROBSON WA, RAMSDEN PD, PICKARD RS. (2004) Noninvasive assessment of bladder contractility in men. The Journal of Urology, 172, p. 1394-1398, 2004

Specify source of funding or grant	**This study was sponsored by the National Comission for the Development of Research, a governamental organ in Brazil**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethical Committe of UNICAMP - State University of Campinas - São Paulo - Brazil Registration Number: 1017/2008**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**