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PATIENT BURDEN AND BLADDER OUTLET OBSTRUCTION EVALUATED BY A NOVEL NATURAL-FILLING TELEMETRIC PRESSURE-FLOW STUDY IN PATIENTS WITH LUTS/BPH

Hypothesis / aims of study

Pressure-flow study (PFS) has been regarded as the gold standard to diagnose BOO in patients with LUTS/BPH. However, urologists generally face several limitations in its application: the procedure is considered to be invasive and time-taking in nature. Moreover, it is usually performed in an open laboratory space and patients should wear pressure lines connected to the urodynamic machine during the procedure. Therefore, it not only causes significant discomfort of the patients but also does not guarantee the privacy. It also may not reflect actual voiding pattern since it is usually performed after non-physiological filling of the bladder during cystometry. To overcome these problems, several non-invasive methods of measurement has been designed, however, none of these has been universally accepted as a replacement of the standard PFS (S-PFS). In this study, we designed telemetric wireless PFS device to diagnose BOO, in an effort to provide patients with comfort and privacy. We also modified the S-PFS method so that the procedure can be performed without artificial filling of the bladder, i.e., with natural physiological-filling of urine. The telemetric device was designed to transmit real-time pressure and flow signals to the notebook computer. To our knowledge, this wireless natural-filling telemetric PFS (NFT-PFS) method has never been described previously. The purpose of this study was to evaluate the usefulness of the NFT-PFS and also was to assess the patient burden following the NFT-PFS procedure compared to those from S-PFS.

Study design, materials and methods:

A prospective study was performed in an outpatient basis between May 2007 and March 2008. Inclusion criteria included men whose age >50 and complaining LUTS/BPH without any neurological abnormality. Whole study procedure involved three steps: after obtaining informed consent, free flowmetry was done at the first visit day. Subsequently post-void residual volume was measured using ultrasound (Step 1: free flowmetry). The patient was instructed to visit the clinic again with holding urine for the next examination. At the next visit day, after ensuring the patient's bladder volume was >150ml using ultrasound, a standard urodynamic catheter for Pves and a rectal catheter for measuring Pabd were inserted in proper place, same as in the standard filling cystometry. Then, the patient was asked to void to the flowmeter alone in a private room while he wear the wireless transmitter in his waist. The signals from flow, Pabd and Pves were transmitted to the main receiver connected to the notebook computer outside the room in wireless manner (Step 2: NFT-PFS) (Fig. 1). Subsequent procedures including filling cystometry and S-PFS were performed in the ICS standardized fashion (Step 3: S-PFS). Immediately after each steps, the patients were asked to rate their experience on each steps of procedures in terms of pain, embarrassment, bother, boredom and return-to-the-test using visual analogue scale. The examiner also rated pain and patient compliance according to each study. Subjective items such as patient or examiner-rated burden and objective urodynamic parameters including time to complete the test, voided volume, Qmax, PdetQmax, BOO index (BOOI) and bladder contractility index (BCI) were compared among the three tests.

Results

58 patients with mean age of 64.6(±1.2, *SE*) were participated in this study. Their average prostate volume measured by transrectal ultrasound was 35.6(±2.4)ml. Mean IPSS symptom score and bother score were 16.5(±1.0) and 4.1(±0.2), respectively. Patients reported free flowmetry was better than any other two tests. Bother and embarrassment scores were not different between the S-PFS and NFT-PFS. However, NFT-PFS was superior in terms of pain and boredom score. Patients were more willing to return to the NFT-PFS test if necessary than to S-PFS. Examiner also rated that the patients were more tolerant to the NFT-PFS than S-PFS. Time to complete the test was significantly shorter in NFT-PFS than S-PFS. Qmax obtained in the NFT-PFS were not different from that in free flowmetry. In contrast, Qmax, PdetQmax and BCI from the S-PFS were significantly lower than that from NFT-PFS. However, BOOI was not significantly different between S-PFS and NFT-PFS (Table 1). BOOI and BCI were well correlated between the two studies (Pearson's correlation coefficient = 0.761, p <0.001; BCI: Pearson's correlation coefficient =0.680, p <0.001, respectively) (Fig. 2).

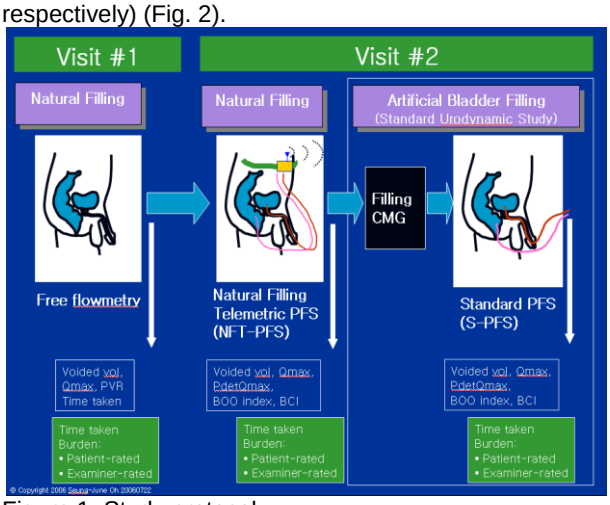

Figure 1. Study protocol

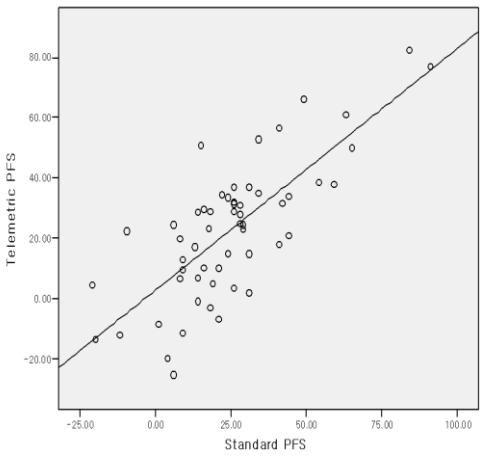

Figure 2. Correlation of BOO index

Table. Patient demographics and urodynamic results

	Free flowmetry (p-value)	Telemetric PFS	Standard PFS (p-value)
Voided volume (ml)	286.1 ± 25.5 (p=0.511)	300.7 ± 25.5	352.0 ± 20.9 (p<0.001)
Qmax (ml/sec)	14.9 ± 0.9 (p=0.952)	14.9 ± 1.2	9.8 ± 0.6 (p<0.001)
PVR (ml)	50.0 ± 15.7 (p=0.016)	91.9 ± 13.9	128.1 ± 13.4 (p=0.005)
PdetQmax (cmH2O)	NA	50.8 ± 2.4	44.4 ± 2.4 (p=0.001)
Popen (cmH2O)	NA	44.6 ± 3.1	45.1 ± 2.6 (p=0.820)
Pclose (cmH2O)	NA	26.4 ± 1.7	27.3 ± 1.7 (p=0.559)
slope	NA	2.3 ± 0.2	3.2 ± 0.3 (p=0.033)
BOOI	NA	22.8 ± 3.1	24.9 ± 2.9 (p=0.328)
BCI	NA	120.7 ± 5.4	93.2 ± 3.3 (p<0.001)
Patient-rated (PR) pain*	0.15 ± 0.11 (p<0.001)	3.15 ± 0.25	3.72 ± 0.29 (p=0.028)
PR embarrassment*	0.44 ± 0.18 (p<0.001)	1.81 ± 0.30	2.05 ± 0.30 (p=0.066)
PR bother*	0.06 ± 0.04 (p=0.001)	0.76 ± 0.21	0.89 ± 0.22 (p=0.515)
PR boredom*	0.26 ± 0.16 (p<0.001)	1.33 ± 0.27	3.00 ± 0.36 (p<0.001)
PR return-to-the-test*	9.33 ± 0.25 (p=0.009)	8.19 ± 0.41	7.52 ± 0.45 (p=0.025)
Time to complete test (min)	4.05 ± 0.37 (p<0.001)	12.93 ± 0.86	25.95 ± 0.93 (p<0.001)
Examiner-rated (ER) pain*	0.04 ± 0.04 (p<0.001)	2.63 ± 0.19	3.46 ± 0.21 (p<0.001)
ER compliance*	9.72 ± 0.11 (p<0.001)	7.81 ± 0.21	7.27 ± 0.25 (p<0.001)

Mean ± *SE*; p-value by paired t-test with Telemetric PFS; *10-point visual analogue scale

Interpretation of results

There were significant differences in the outcome parameters between the S-PFS and NFT-PFS. S-PFS was subsequently performed following the filling cystometry, therefore, S-PFS is considered to be done under the influence of artificial, non-physiological, rapid filling of the urinary bladder. Since we used the same 6 Fr calibre of the urodynamic catheter, we believe the filling rate is the main factor causing the difference between the two PFS results. Further study is warranted to prove this point. Bother and embarrassment scores were not different between the S-PFS and NFT-PFS in this study. This might be due to the sequence of the procedure. Catheters for Pves and Pabd were inserted just before NFT-PFS while thereafter no further reinsertion of the catheters was necessary for the S-PFS. This might have caused significant favour for the S-PFS in terms of the two aspects of patient rating. Since NFT-PFS can provide better study environment to patients and needs shorter time for completion, it can be applied to the LUTS/BPH patients instantaneously in office basis with ease. A new BOO normogram for natural filling condition should be established before widespread application of NTF-PFS in the clinical practice.

Concluding message

The objective parameters from this novel NTF-PFS method was proved to be well correlated with the standard PFS and may reduce patient burden secondary to the PFS. The time taken to perform NFT-PFS was shorter than that of S-PFS.

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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	**Institutional Review Board of the Seoul National University Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**