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de Zeeuw S<sup>1</sup>, Kranse R<sup>1</sup>, van Mastrigt R<sup>1</sup>

1. Section Furore, Department of Urology, Erasmus MC, Room Ee 1630

# NON-INVASIVE URODYNAMIC PARAMETERS AS PREDICTOR VARIABLES FOR DEVELOPING VOIDING PROBLEMS

### Hypothesis / aims of study

In a longitudinal study of changes in bladder pressure secondary to benign prostatic enlargement, male volunteers repeatedly undergo a non-invasive urodynamic examination to measure bladder pressure using the condom catheter method. We studied if the urodynamic parameters measured can predict deterioration of the volunteers' lower urinary tract condition, leading to exclusion in the next study round. This is a first step towards our primary goal to non-invasively monitor and predict compensation or decompensation of the urinary bladder (if it exists).

#### Study design, materials and methods

Between 2001 and 2003 1020 male volunteers were included in a non-invasive longitudinal study [1]. Inclusion criteria were: age 38 to 77 years, the ability to continuously void in a standing position with a minimum flow rate of 5.4 ml/s, no history of any heart condition and no treatment or surgery of the lower urinary tract (LUT), and no other disease that could affect urinary bladder function. LUTS were not an exclusion criterium. Each volunteer will be investigated 3 times in 5 years. Each investigation consists of 3 voidings: once in a uroflowmeter to determine the maximum flow rate and twice through the condom catheter to measure the isovolumetric bladder pressure. Voiding through the condom catheter is repeatedly interrupted to measure the maximum pressure in the condom ( $P_{cond.max}$ ), which represents the maximum isovolumetric bladder pressure. Prostate volume is determined by transabdominal ultrasonography (Aloka SSD-900, 3.5 MHz probe). Urethral resistance (URR) was calculated as  $P_{cond.max} - 5.8^*Q_{max} - 36.4$  [2].

From the 963 male volunteers that underwent 2 successful condom measurements in the first round, 720 volunteers completed the second study round between 2004 and 2006 and 41 volunteers were excluded because they had surgical or medical interventions for the treatment of LUTS, had other diseases that could affect urinary bladder function or were under treatment by a urologist. The rest of the volunteers opted out, were excluded for other medical reasons, were deceased or did not respond to the invitation. The data from the first round were stratified into "included in the second round" (n=720) and "excluded in the second round for urological reasons" (n=41).

Data were expressed as median [Inter Quartile Range, IQR]. Differences between volunteers that were included and volunteers that were excluded in the second round were tested using the Mann-Whitney U test. Logistic regression was used to test which parameters contribute to the odds that a volunteer is excluded in the second round. The best fitting model was used to calculate the probability of such exclusion.

### **Results**

Table 1 shows the characteristics of the volunteers that were included in the second round and volunteers that were excluded in the second round as a result of voiding problems. Volunteers that were excluded were significantly older, had larger prostates, had a higher IPSS score, and a lower free flow rate and voided volume. The isovolumetric bladder pressure was the only tested parameter that was not significantly different between included or excluded volunteers (p=0.10 and p=0.08, respectively).

The most suitable logistic regression model contained age (OR=1.06, p<0.01), prostate volume (OR=1.03, p<0.01), IPSS score (OR=1.16, p<0.01) and  $P_{cond.max}$  (OR=1.01, p<0.05). This means for example that with each year of age the odds that an older volunteer will be excluded in the second round increases with 6% over that of a younger individual. The Hosmer and Lemeshow test was not significant (p>0.70) indicating a good fit of the model.  $Q_{max}$  and voided volume were left out of the model, because the associated OR's were not significant. URR was left out of the model because it is linearly related to  $Q_{max}$  and  $P_{cond.max}$ .

Table 1 Characteristics of volunteers			
		Included in second round	Excluded in second round
		(n=720)	(voiding problems, n=41)
Age		53 [16]	65 [12]*
Prostate volume (cm <sup>3</sup> )		30 [16]	49 [47]*
IPSS score		5 [6]	9 [8]*
Free voiding	V <sub>voided</sub> (ml)	300 [230]	240 [143]*
	Q <sub>max</sub> (ml/s)	16 [10]	11 [8]*
1 <sup>st</sup> condom	V <sub>voided</sub> (ml)	335 [215]	260 [122]*
measurement	P <sub>cond.max</sub> (cmH <sub>2</sub> O)	98 [39]	109 [58]
	URR	-34 [-68]	-2 [-68]*
2 <sup>nd</sup> condom	V <sub>voided</sub> (ml)	360 [165]	285 [150]*
measurement	P <sub>cond.max</sub> (cmH <sub>2</sub> O)	101 [39]	111 [54]
	URR	-32 [-72]	2 [-67]*

 $V_{voided}$  = voided volume,  $Q_{max}$  = maximum flow rate,  $P_{cond.max}$  = maximum condom pressure, URR = urethral resistance. \*p<0.05 Included in second round vs Excluded in second round.



With the logistic regression model the probability that a volunteer will be excluded in the second round can be predicted. Although there is overlap between both groups, the calculated probability for the group that was truly excluded was significantly higher than that for the group that was truly included (figure 1, p<0.01). Using a probability threshold of 0.05 (the a priori probability = 41 / (41+720)), sensitivity was 76% and specificity was 77%.

#### Interpretation of results

We constructed a logistic regression model from a number of non-invasive parameters measured in the first study round to predict the probability that a volunteer will be excluded from the second round due to voiding problems. The most suitable model included age, prostate size, symptom score and isovolumetric bladder pressure.

The predicted model does not allow us yet to decide if the bladder of the volunteer was in the compensating or decompensating phase (or if such phases truly exist). More information will be available after the completion of the third round, which started in November 2006, over a period of 5 years.



### Concluding message

The probability that a volunteer will develop voiding problems that will exclude him from the longitudinal study can be predicted by age, prostate size, IPSS score and isovolumetric bladder pressure with 76% certainty. This is a first step towards our primary goal to predict if the bladder of a patient with voiding problems is in the compensating or decompensating phase, which is important for correct therapeutically decisions.

#### **References**

- 1. Applicability and reproducibility of condom catheter method for measuring isovolumetric bladder pressure. Urology 63:56-60 (2004).
- 2. Development of a non-invasive strategy to classify bladder outlet obstruction in male patients with LUTS. Neurourol Urodyn 21:117-25 (2002).

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HUMAN SUBJECTS: This study was approved by the Medical Ethical Review Comittee Erasmus MC and followed the Declaration of Helsinki Informed consent was obtained from the patients.