Urol Res (2003) 31: 177–182
DOI 10.1007/s00240-003-0312-7

ORIGINAL ARTICLE

Johan J. M. Pel · Ron van Mastrigt

A flow rate cut-off value as a criterion for the accurate non-invasive measurement of bladder pressure using a condom-type catheter

Received: 27 August 2002 / Accepted: 20 March 2003 / Published online: 14 May 2003

Abstract We developed a condom-type catheter to non-invasively measure the bladder pressure during interruption of the flow rate. The aim of the present study was to establish a minimum flow rate value at which a reliable bladder pressure measurement can be made with this catheter. We reanalysed data from 43 patients who completed a pressure-flow study and a non-invasive test. The patients voided without straining. During the test, we simultaneously measured the bladder pressure (invasively) and the condom pressure (non-invasively). The pressure increase in the condom after interruption of the flow rate was analysed in 40 of the 43 patients. A plot of the difference between the bladder pressure and the maximum condom pressure as a function of the flow rate revealed that in 70% of the patients who voided with a maximum flow rate exceeding 5.4 ml/s, the condom pressure accurately reflected the bladder pressure (± 14 cmH_2O). We conclude that to accurately and non-invasively measure the bladder pressure with a condom-type catheter, the maximum flow rate should exceed 5.4 ml/s.

Keywords Non-invasive urodynamics · Isovolumetric pressure · Response time · Condom catheter · Flow rate

Introduction

At present, an invasive pressure flow study (PFS) is recommended for the diagnosis of bladder outlet obstruction in patients with lower urinary tract symptoms [3]. The invasiveness of this test, however, limits its scientific and clinical application, especially in patients with symptoms of benign prostatic hyperplasia. Over the last decade, methods have been developed to non-invasively measure bladder pressure and to avoid the risk of damaging or infecting the urethral wall. A review was published in which these techniques were described, including a technique based on a condom-type catheter [9]. This catheter consists of an incontinence condom connected to an outflow tube and pressure transducer. A pneumatic valve is fitted over the outflow tube. The condom is taped to the penis with Parafilm (laboratory film). When a patient voids through the condom and tube, the flow rate through the tube is (repeatedly) interrupted via a remotely controlled valve.

To accurately measure the bladder pressure in the condom, it is necessary that the condom is filled with urine and that the flow of urine through the urethra into the condom has completely stopped. In theory, the pressure in the condom then equals the bladder pressure when the bladder neck is open. When the flow rate of the patient is high, the condom quickly fills with urine upon interruption of the flow rate and repeated interruptions may be done in one voiding. However, when the flow rate is low, the filling of the condom is slow which makes it necessary to prolong the interruption of the flow rate. The extra time needed to pressurise the condom as a result of a low flow rate may increase the probability of detrusor inhibition/sphincter contraction.

The aim of the present study was to calculate a minimum flow rate value at which the condom is filled and pressurised quickly enough for a reliable pressure measurement. We reanalysed measurements from patients studied previously [6], in which we simultaneously measured the flow rate, the pressure in the condom with the condom-type catheter and the bladder pressure with an invasive catheter. The patients had a wide variety of symptoms but most had a reduced flow rate or were incontinent. Healthy volunteers and patients with dysfunctional voiding patterns or neurogenic bladder symptoms were not included. A pilot study on accurate, non-invasive bladder pressure measurements was published earlier [5]. This study comprised data on straining

J. J. M. Pel (✉) · R. van Mastrigt
Sector Furore, Department of Urology,
Room Ee1630, Erasmus MC,
3000 DR Rotterdam, The Netherlands
Tel.: +31-10-4087377
Fax: +31-10-4089451

and non-straining patients. In the patients who strained during voiding, negative pressure differences between the condom and bladder were found (sometimes down to -40 cmH_2O). The relatively high abdominal pressures were obviously not reflected in the pressure measured in the condom. Therefore, the present analysis was based only on patients who did not strain during voiding.

Materials and methods

We reanalysed data from a group of 43 patients who had completed an invasive and a non-invasive urodynamic test in an earlier study [6]. The patients were stratified in a group of non-obstructed and a group of equivocal and obstructed patients using the provisional ICS method for the definition of obstruction [3]. During the non-invasive test, the bladder pressure was measured using an incontinence condom (Rochester) guided over the invasive catheter, attached to the penis. At the beginning of our tests, we sometimes observed leakage from the condom. This was reduced to almost zero by securing the condom to the penis using two strips of laboratory film (3×15 cm). When this film is stretched, it becomes inelastic and thus increases the stiffness of the condom. A tube was connected to the outflow opening of the condom to guide the urine into a flow meter (Dantec). A pneumatic valve was fitted over this tube to interrupt the flow rate. After filling the bladder through the invasive catheter, this catheter was connected to a pressure transducer to measure the bladder pressure, $p_{bladder}$, simultaneously with the pressure in the condom, p_{condom}. The bladder pressure transducer was visually positioned at the same height as the pressure transducer of the external catheter (about 20 cmH_2O below the symphysis pubis). When comparing both pressures, we did not correct for height differences. The transducers were about 1 m apart. The investigator monitored the flow rate signal on a computer screen and interrupted the voiding when a stable value was established. After reaching a stable pressure reading, the valve was reopened and flow recommenced. When a new stable flow rate level was reached, another interruption was made. The total number of interruptions depended on the flow rate and voided volume, and was different in each patient. The flow rate value just prior to an interruption was called the interrupt flow rate, $Q_{interrupt}$.

From the flow rate and pressure signals measured in one voiding in each patient, we selected the highest condom pressure value, $p_{condom.max}$, the corresponding bladder pressure, and the interrupt flow rate value for further analysis. During each flow rate interruption, the condom inflated slightly. Opening the valve sometimes led to a flow rate overshoot, see for example Fig. 1 upper panel. When no reliable interrupt flow rate value could be selected due to this effect, the first interrupt flow rate value of the test was used in combination with a condom pressure value not measured during that interruption. Upon interruption of the flow rate, the condom filled with urine and the pressure in it increased. To describe this pressure increase with time, we fitted an exponential function to the condom pressure signal:

$$p_{fit} = p_{fit.max} \cdot \left(1 - e^{-\frac{t}{\tau}}\right) \quad (1)$$

In this formula, p_{fit} = the fitted condom pressure [cmH_2O], $p_{fit.max}$ = the maximum fitted pressure in the condom [cmH_2O], t is the time [s] and τ is the time constant that characterises the rate of pressurising the urethra and condom [s]. This time constant depends on the interrupt flow rate, $Q_{interrupt}$, the length and cross section of the urethra and the visco-elastic properties of the urethra, penis and condom.

Finally, the time necessary to reach 95% of the maximum pressure in the condom was calculated. This response time, $t_{95\%}$, is by definition three times the time constant τ. The reliability of the fit was calculated using the following equation:

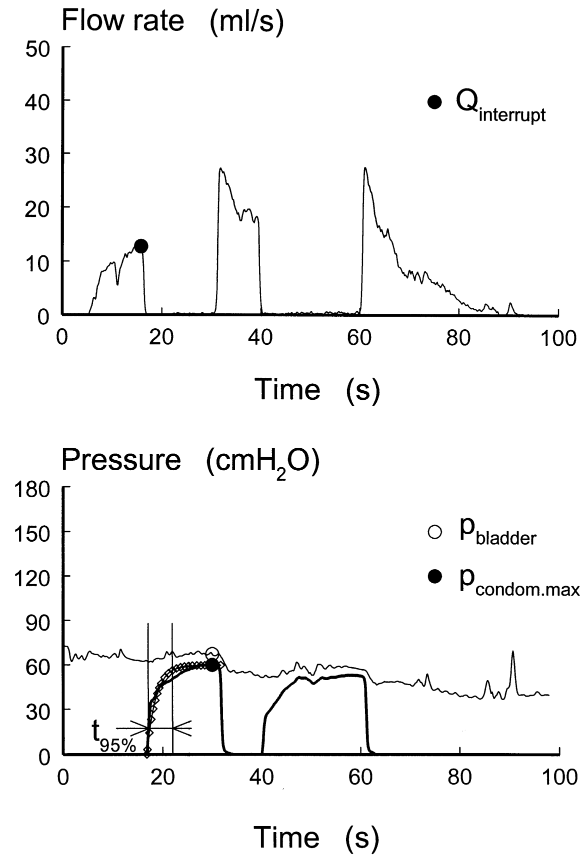

Fig. 1 The flow rate, *upper panel*, and the simultaneously measured bladder pressure, *lower panel*, (*thin line*; transurethral catheter) and condom pressure (*thick line*; condom-type catheter) in a non-obstructed patient. The maximum condom pressure and bladder pressure are low and correlate well. The interrupt flow rate is about 13 ml/s. An exponential function, p_{fit}, was fitted to the condom pressure signal (*diamonds*) to calculate the response time $t_{95\%}$ (see also Fig. 4)

$$\text{fiterror} = \frac{\sum_{i=1}^{N} \text{abs}|p_{condom}(i) - p_{fit}(i)|}{\sum_{i=1}^{N} p_{condom}(i)} \quad (2)$$

with i the sample number and N the total number of samples in the fitted part of the condom pressure signal. Curves with a fit error > 0.02 were excluded from this part of the analysis.

The summarising data were not normally distributed but skewed. Therefore, percentiles were calculated to divide the observations into groups of equal size, with the 50th percentile equal to the median value. To calculate a minimum flow rate value, above which the condom pressure accurately represented the bladder pressure, we plotted the difference between the bladder pressure and the maximum condom pressure, $p_{bladder}$-$p_{condom.max}$, against the interrupt flow rate, $Q_{interrupt}$. The median value of the pressure differences was chosen as the middle value of a reliability interval. The borders of this interval were chosen at -4.0 cmH_2O and 23.8 cmH_2O (10th and 70th percentiles, respectively). This means that the interval contained 20% of the measurements with a difference between bladder and condom pressure higher than the median value, and 40% of the measurements with less than the median value. A flow rate cut-off value was calculated on the basis of the percentage of patients in the reliability interval.

Results

The condom-type catheter was used to measure pressure non-invasively in 43 patients. According to the ICS-nomogram, the standard PFS study showed that 13 patients were non-obstructed, ten were equivocal and 20 patients were obstructed. Figure 1 shows an example of a measurement using the condom-type catheter in a patient who was classified as non-obstructed according to the ICS nomogram. The upper panel shows the flow rate and the lower panel the simultaneously measured bladder pressure and condom pressure. Upon flow rate interruption, the condom filled with urine and the pressure increased to a maximum value. The interrupt flow rate was about 13 ml/s. During this interruption the highest pressure in the condom (~63 cmH_2O) was measured. This corresponded well with the simultaneously measured bladder pressure (~70 cmH_2O). In the lower panel, we also plotted the curve fitted to the condom pressure signal, p_{fit}, and the response time, $t_{95\%}$ (see equation 1). In three patients, the response time was not calculated because of a fit error > 0.02 (see equation 2). Figure 2 shows a measurement in an obstructed patient. Here, the interrupt flow rate was about 7 ml/s and the highest pressure in the condom, measured during the second interruption, again corresponded well with the bladder pressure (both values ~135 cmH_2O). Note that both values were much higher than those measured in the non-obstructed patient in Fig. 1. Figure 3 shows less agreement between the condom pressure (~120 cmH_2O) and the bladder pressure (~160 cmH_2O). This measurement was also made in an obstructed patient, but the $Q_{interrupt}$ of this patient of about 4 ml/s was lower than that measured in Fig. 2. Upon interruption of the flow rate, the pressure in the condom increased slowly. Then the pressure in the condom temporarily decreased. This may have resulted from a retraction of the glans of the penis in the condom or sudden expansion of the urethra. The newly freed space in the condom or urethra first needed to be filled with urine again. At reopening of the valve, the pressure difference between the bladder and condom was about 40 cmH_2O. The pressure rise in the condom did not fit equation 1 well (fit error > 0.02), and was thus one of three that were excluded when calculating the average response time, $t_{95\%}$.

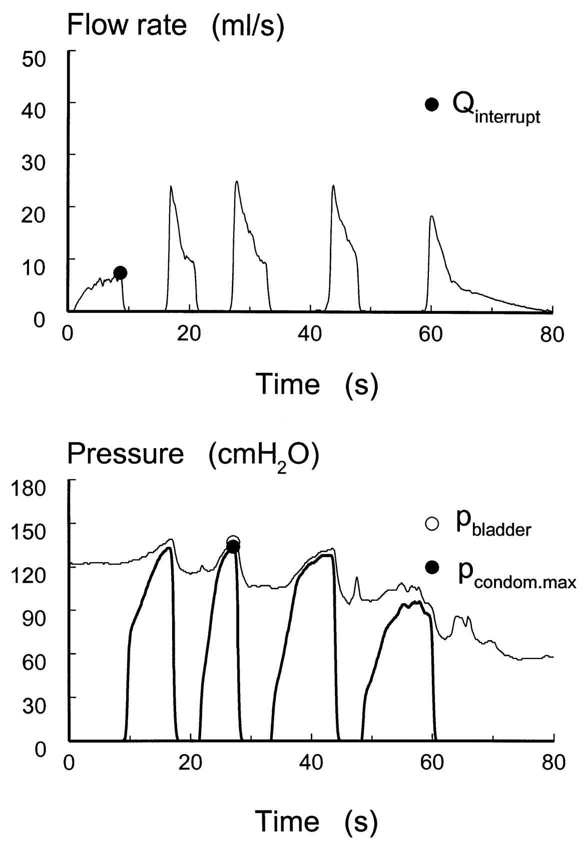

Fig. 2 The flow rate, *upper panel*, and the simultaneously measured bladder pressure, *lower panel*, (*thin line*; transurethral catheter) and condom pressure (*thick line*; condom-type catheter) in an obstructed patient. The maximum condom pressure and bladder pressure are high and correlate well. The interrupt flow rate is about 8 ml/s

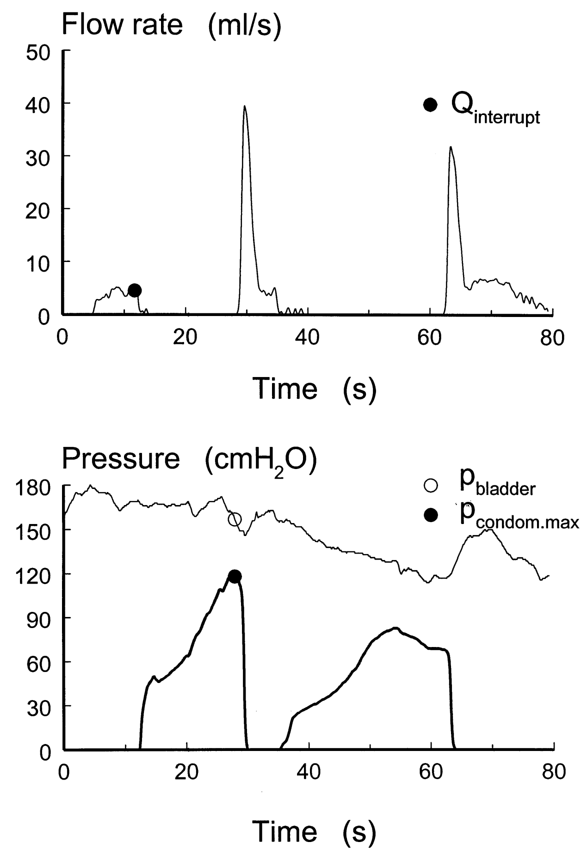

Fig. 3 The flow rate, *upper panel*, and the simultaneously measured bladder pressure, *lower panel*, (*thin line*; transurethral catheter) and condom pressure (*thick line*; condom-type catheter) in an obstructed patient. The maximum condom pressure and bladder pressure are high and do not correlate well. The interrupt flow rate is about 4 ml/s

To identify a criterion for the accuracy of the pressure measured in the condom, we plotted $p_{bladder}–p_{condom.max}$ as a function of $Q_{interrupt}$ (see Fig. 4, upper panel). In four patients, the condom pressure was slightly higher than the bladder pressure. This was the result of a small difference in the height of the pressure transducers. In two patients, this pressure difference was more than 10 cmH_2O. Although not visible in the abdominal pressure traces, we think that these two patients strained slightly during the test. The median value of the pressure difference in the combined group of non-obstructed, equivocal and obstructed patients was 11.0 cmH_2O (50th percentile). The 25th and 75th percentiles were 3 cmH_2O and 26 cmH_2O. A reliability interval of –4.0–23.8 cmH_2O (10th and 70th percentiles, respectively; $\pm\sim14$ cmH_2O) was chosen. In total, 63% of the patients (27/43) fell inside of the reliability interval. In the lower panel, the inverse cumulative percentage of patients outside of this interval (16 cases) was plotted as a function of $Q_{interrupt}$. When this graph is read from right to left, every time a case falls outside of the reliability interval, this percentage increases with 100%/16 cases. At a flow rate value of less than 5.4 ml/s, we counted 50% of the patients outside the interval. This flow rate value was therefore chosen as a minimum flow rate at which the bladder pressure was still accurately measured in the condom. A total of 70% of the 27 patients with a flow rate exceeding 5.4 ml/s were in the reliability interval. Thus, in these patients, we found comparable pressures in the bladder and condom (pressure difference of ± 14 cmH_2O). In the remaining 16 patients with flow rates ≤ 5.4 ml/s, this percentage was decreased from 70% to 50%.

In Figure 5, we plotted for the non-obstructed (open circles), equivocal (plusses) and the obstructed patients (closed circles) the response time, $t_{95\%}$, against $Q_{interrupt}$, (see also Fig. 1). As mentioned, three cases were omitted from this analysis, leaving data for 40 patients. On average, it took 7.4 s (median value) to pressurise the urethra and condom (25th percentile = 5.1 s and 75th percentile = 12.3 s). The response time was rather high (t > 15 s) in four patients voiding with an interrupt flow rate higher than 7 ml/s. We think that as a result of the high condom pressures, the glans of the penis was pushed backwards in these measurements. Filling the volume with urine in the condom probably resulted in a delay in the pressure increase. As a result, the condom pressure rose slowly to its maximum value.

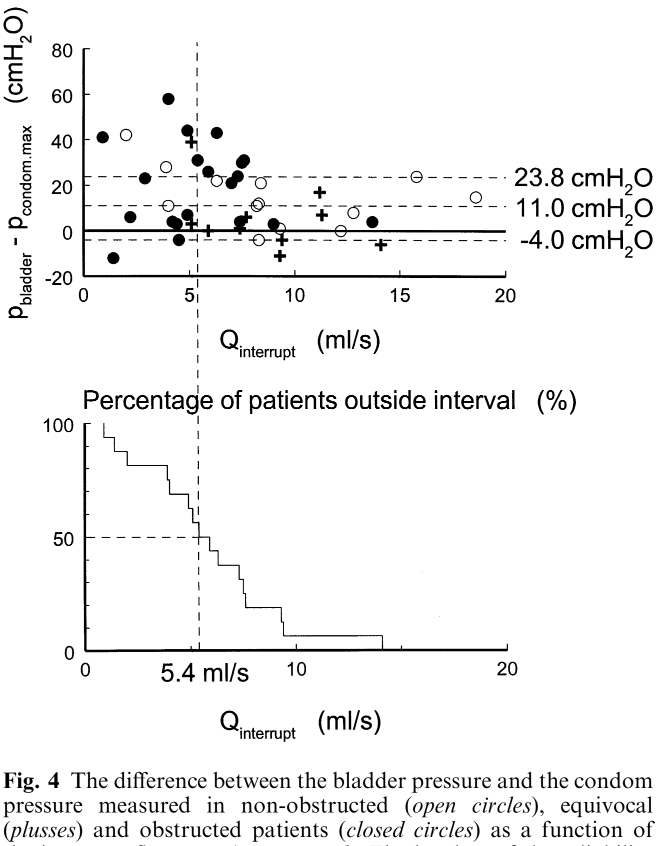

Fig. 4 The difference between the bladder pressure and the condom pressure measured in non-obstructed (*open circles*), equivocal (*plusses*) and obstructed patients (*closed circles*) as a function of the interrupt flow rate (*upper panel*). The borders of the reliability interval are the median value ± 14 cmH_2O. In the *lower panel*, the cumulative percentage of patients outside of this interval (counted from right to left) is plotted against the interrupt flow rate. From this plot, a flow rate cut-off value of 5.4 ml/s was derived

Discussion

The non-invasive condom catheter was developed to measure the isovolumetric bladder pressure. Upon flow rate interruption, the condom fills with urine and the pressure in it increases until equilibrium exists between the pressure in the bladder and in the condom. In theory, upon interruption of the flow rate, the shortening velocity of the bladder wall reduces to zero and the bladder contraction becomes isometric. The relation between the bladder pressure and shortening velocity of the bladder wall is described by a hyperbolic curve, known as the Hill equation [4]. Therefore, when the shortening velocity of the bladder wall decreases, the bladder pressure should increase. In a large number of

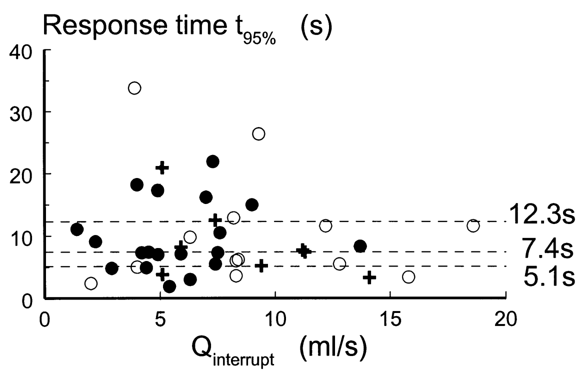

Fig. 5 The time needed to attain 95% of the maximum pressure in the condom was plotted against the interrupt flow rate in non-obstructed (*open circles*), equivocal (*plusses*) and the obstructed patients (*closed circles*). The median value of the response time was 7.4 s (see also Fig. 1)

patients (especially in non-obstructed and equivocal patients), we indeed observed an increase in bladder pressure upon flow rate interruption. However, especially in obstructed patients, we sometimes found pronounced differences between bladder and condom pressures. In most of these cases, no bladder pressure increase was seen upon flow rate interruption. In Fig. 1, a slight increase in bladder pressure upon flow rate interruption can be seen. The pressures are relatively small, which indicates that this patient voids with a weakly contracting bladder. In Fig. 2, the predicted increase in bladder pressure upon (repeated) interruption of the flow rate can clearly be seen. In Fig. 3, the filling time of the condom was, compared to Figs. 1 and 2, longer. Although the condom pressure reached quite a high value in Fig. 3, there still was a pressure difference of 40 cmH_2O between the bladder pressure and the condom pressure when the valve was reopened, resulting in an unreliable pressure reading in the condom. In this example, no bladder pressure increase was detected.

The aim of the present study was to calculate a minimum flow rate value as a predictor for a reliable pressure measurement in the condom. We found a cut-off flow rate value of 5.4 ml/s above which the condom pressure accurately reflected the bladder pressure (see Fig. 4). For accurate application of the condom-type catheter, first a free flow rate must be done to evaluate if a patient strains (intermittent voiding pattern) and if he voids at least 5.4 ml/s. The condom-type catheter is inaccurate in patients voiding less than 5.4 ml/s, and in these patients invasive urodynamics should be performed. On the other hand, the method is accurate in patients voiding more than 5.4 ml/s, which creates new opportunities for scientific research. For clinical application, it was shown that in 90% of the patients voiding even less than 5.4 ml/s (flow rates down to 4.5 ml/s) could be successfully classified as obstructed or non-obstructed [6].

The rate of filling and pressurising the urethra and condom depend on the flow rate value at interruption. The urethra is a distensible tube that expands when the pressure in it increases. The most distal part of the urethra, at which the condom was applied, was reinforced with laboratory film. The visco-elasticity of this part of the urethra was reduced due to this film. Therefore, the rate of pressurising the condom depended most on the visco-elastic properties of the proximal urethral wall. Equation 1 was fitted to the condom pressure signal to describe the filling of the condom. We found an average value for the time constant τ of $\sim$2.5 s (see equation 1), which means that after 2.5 s the pressure in the condom was about 63% of that in the bladder. It took an extra 4–5 s to completely fill and pressurise the urethra and condom to reach 95% of the bladder pressure ($t_{95\%}$ was 7.4 s). This finding underlines the necessity of carefully observing the pressure rise in the condom and not opening the valve when the pressure is still increasing in the condom. Slow pressurising of the proximal urethra should be taken into account when the flow rate is interrupted at the distal part of the urethra. In a study on the penile compression-release manoeuvre, it was reported that the flow rate change after the interruption depended on the magnitude of the isometric detrusor pressure. A compression time of 2–3 s was allowed in order to reach the isovolumetric state [8]. During this manoeuvre, no condom but only the proximal and a small part of the distal urethra needed to be completely pressurised. Our finding suggests that, on average, a delay time of 2–3 s might be too short a compression time to completely pressurise the proximal urethra to an isometric state. This could explain why the authors did not find significant differences in the penile compression release index observed in non-obstructed patients with normal contractility and those with impaired contractility.

In the present study, we found that for an accurate non-invasive pressure measurement, the free flow rate of the patient should exceed 5.4 ml/s. In this way, the condom can be filled and pressurised so quickly that the risk of sphincter contraction or detrusor inhibition is minimal. To further reduce this risk during a non-invasive measurement, we developed a variable outflow resistance catheter. Using this catheter, the outflow resistance can be increased step-wise to estimate the isovolumetric pressure in the condom without complete interruption of the flow rate. This new condom-type catheter can also be used to reduce the response time of the measurement by maintaining a low pressure in the condom, called a preload, during voiding [7]. When voiding starts, a small outflow resistance is selected to fill and partly stretch the condom with urine. As a result, the pressure in the condom increases to a preload value. Superimposed on this preload, an isovolumetric pressure measurement is done. After each measurement, the preload outflow resistance is restored. In that way, the condom remains filled with urine. We think that, using this modified procedure, a flow rate cut-off value of less than 5.4 ml/s could be feasible.

Conclusions

A condom-type catheter was developed to measure the bladder pressure non-invasively during the interruption of the flow rate. A flow rate which is too low at the moment of interruption unnecessarily prolongs the filling of the condom, which could cause premature sphincter closure or bladder inhibition. In the present study, we calculated a flow rate cut-off value to quantify this unreliability in the tested population. The bladder pressure was accurately ($\pm$14 cmH_2O) measured non-invasively in 70% of the patients who voided with a maximum flow rate exceeding 5.4 ml/s. We found a median response time of 7.4 s to reach 95% of the maximum pressure in the condom. Non-invasive classification on the basis of a combination of the maximum condom pressure and the maximum flow rate may still be done in patients voiding with smaller flow rates.

Acknowledgements This research was supported by the Technology Foundation STW, applied division of the Netherlands Organisation for Scientific Research (NWO) and the technology programme of the Ministry of Economic Affairs.

References

1. Altman DG (1999) Practical statistics for medical research. Chapman and Hall, Padstow
2. Griffiths CJ, Rix D, MacDonald A, Robson W, Kelly L, Reddy M, Drinnan MJ, Pickard RS, Ramsden PD (2000) Can non-invasive bladder measurements identify men with bladder outflow obstruction? Neurourol Urodynam 19: 429
3. Griffiths DJ, Höfner K, van Mastrigt R, Rollema HJ, Spangberg A, Gleason D (1997) Standardization of terminology of lower urinary tract function: pressure-flow studies of voiding, urethral resistance and urethral obstruction. Neurourol Urodynam 16: 1
4. Hill AV (1938) The heat of shortening and the dynamic constants of muscle. Proc R Soc London B 126: 136
5. Pel JJM, van Mastrigt R (1999) The accuracy of a non-invasive bladder pressure measurement with an external catheter. Neurourol Urodynam 18: 251.
6. Pel JJM, van Mastrigt R (2002) Development of a strategy to non-invasively classify bladder outlet obstruction in male patients with LUTS. Neurourol Urodynam 21: 117
7. Pel JJM, Spigt MG, Knottnerus JA, van Schayck CP, van Mastrigt R (2001) A modified procedure to non-invasively measure the bladder pressure: preloading the condom. Neurourol Urodynam 20: 386
8. Sullivan MP, Yalla SV (2000) Penile urethral compression-release manoeuvre as a non-invasive screening test for diagnosing prostatic obstruction. Neurourol Urodynam 19: 657
9. Van Mastrigt R, Pel JJM (1999) Further towards a non-invasive urodynamic diagnosis of infravesical obstruction. Urodynamica 9: 131