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INTRODUCTION

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The sector Furore of the Erasmus MC develops new and non-invasive measurement methods to assess bladder function (2). Recently, an external condom catheter was developed to measure the bladder pressure non-invasively. This article presents an

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The sector Furore of the Erasmus MC develops new and non-invasive measurement methods to assess bladder function (2). Recently, an external condom catheter was developed to measure the bladder pressure non-invasively. This article presents an

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overview of the development of this condom-
type catheter. It was tested in a group of
healthy male volunteers and patients with
lower urinary tract symptoms (LUTS). The
results of these measurements clarify both the
merits and limitations of this new technique
for both practical and clinical application.

CONDOM-TYPE CATHETER

Development and validation

A previous study showed that, on the basis
of a combination of isovolumetric bladder
pressure and maximum flow rate, classifica-
tion of bladder outlet obstruction (BOO) is
possible (3). We developed an external con-
dom catheter to measure this pressure non-
invasively (4, 5). Instead of measuring the
pressure proximally of the urethra (using a
transurethral catheter positioned in the blad-
der), the pressure is measured distally of the
urethra (in the condom). This change of mea-
surement location reduces the risk of damag-
ing and infecting the bladder and urethral
wall. The catheter consists of an incontinence
condom connected to a tube, a valve and a
pressure transducer (Fig. 1). The tube drains
in a flow meter and the condom is adjusted to
the penis and taped with laboratory film to
increase its stiffness and to prevent leakage of
urine. During voiding of a volunteer or pa-
tient through the condom, the flow rate is in-
terrupted by closing the tube with the valve.
During this interruption, the condom is pres-
surised. A pressure transducer measures this
pressure in the condom, $p_{\text{condom}}$. In theory,
when the urethra is open, the maximum con-
dom pressure equals the isovolumetric blad-
der pressure. During this test, the pressure
and flow rate signals are displayed on a com-
puter screen. Parameters such as maximum
signal values were calculated automatically
from the signals using self-written Matlab®
programs.

The method was first tested in a group of
healthy volunteers (6). All were able to apply
the condom and the laboratory film correctly.
None of them showed inhibition of the flow
rate after a single interruption of the stream
so that more than one pressure reading can
be taken in one voiding. Figure 2 shows an
example of such a repeated pressure mea-
surement. Upon interruption of the flow rate
(top panel), the condom quickly filled with

![Figure 1 - The external condom catheter made to measure the blad-
der pressure non-invasively (figure reproduced with permission* - see
acknowledgements).]
urine and the pressure increased to a maximum value (middle panel). The flow rate just prior to the first interruption, ~27 ml/s, was called the interrupt flow rate, $Q_{\text{interrupt}}$. After the pressure reached a maximum value, the valve was opened to continue voiding. In this example, the condom pressure was measured three times. The highest condom pressure, $p_{\text{condom.max}}$, of 135 cmH$_2$O was measured during the second interruption. To test if this pressure depended on the bladder volume, we calculated the bladder volume during the interruption, $V_{\text{bladder}}$, as the difference between the total voided volume and the voided volume at $p_{\text{condom.max}}$ (lowest panel). On average, we found that the condom pressure values measured depended significantly on the bladder volume. The highest condom pressure was found at approximately 52% of the maximum bladder volume. As bladder volumes strongly differ between individuals, repeated interruptions in one voiding are necessary to correct the condom pressures for the volume dependence.

In a group of patients with LUTS we tested how well the condom pressure reflected the bladder pressure (5). First, all patients underwent a standard pressure-flow study (PFS). On the basis of this test with catheters in the bladder and rectum, the patients were classified as non-obstructed, equivocal or obstructed using the provisional ICS method for definition of obstruction (1). Then, in a second procedure, the condom catheter was adjusted to the penis leaving the transurethral catheter in situ. After filling the bladder, the transurethral catheter was connected to a pressure transducer to measure the bladder pressure simultaneously with the condom pressure. Figure 3 shows an example, with the interrupted flow rate in the top panel and the simultaneously measured pressures in the lowest panel. The interrupt flow rate was about 7 ml/s. During the second interruption, the maximum pressures were measured and both correlated well (~135 cmH$_2$O). The difference in pressure $p_{\text{bladder}} - p_{\text{condom.max}}$ was plotted against the mean pressure $(p_{\text{bladder}} + p_{\text{condom.max}})/2$ for each patient (Fig. 4). The median value of the pressure difference was 11 cmH$_2$O (50th percentile). The borders of agreement were chosen at the 10th and 70th percentile. This means that the interval included 20% of the measurements with a dif-
difference between bladder and condom pressure higher than the median value and 40% of the measurements with less than the median value. The borderline values were -4.0 cmH$_2$O and 23.8 cmH$_2$O. On the basis of the invasive pressure-flow test, the patients were stratified in two groups: (1) a combined non-obstructed and equivocal group and (2) an obstructed group. It was found that the bladder and condom pressures correlated better in the combined group of non-obstructed and equivocal patients than in the group of obstructed patients. Still, the less accurate pressure readings in obstructed patients were on average higher than those measured in the combined group. This suggested that a classification of BOO on the basis of a combination of condom pressure and flow rate is possible. This will be further explored in the section on practical and clinical application.

Limitations and improvement

Patients and volunteers were asked not to strain during voiding. Despite this encouragement, some patients did. In a small group, we observed that in some cases the relatively high abdominal pressure was not reflected in the pressure measurement in the condom. Obviously, in these cases straining led to closure of the urethra which resulted in an unreliable pressure reading in the condom. We therefore concluded that this test could only be done in those patients who voided without straining. Furthermore, a too low flow rate at the moment of interruption prolongs the filling of the condom, which increases the risk of sphincter contraction or detrusor inhibition and thus an unreliable pressure reading in the condom. For a successful condom pressure measurement, it is therefore necessary that the condom is quickly filled and pressurised. The time necessary to reach the maximum condom pressure mainly depends

Figure 3 - The flow rate (top panel) and the simultaneously measured bladder pressure (thin line; transurethral catheter) and condom pressure (thick line) in an obstructed patient (lowest panel). The maximum bladder pressure and condom pressure are high and correlate well. The interrupt flow rate is about 8 ml/s (figure reproduced with permission*).

Figure 4 - Difference of the simultaneously measured bladder pressure and condom pressure in a combined group of non-obstructed and equivocal patients (white circles) and a group of obstructed patients (black circles) plotted as a function of the mean of both values (figure reproduced with permission*).
on the flow rate. We re-analysed the data of the group of patients in which the bladder and condom pressure were simultaneously measured to calculate a minimum flow rate value, above which the condom pressure accurately represented the bladder pressure (7). To this end, we re-plotted the data of Figure 4 as a function of Q_{interrupt} (Fig. 5, top panel). The lowest panel shows the inverse cumulative percentage of patients outside the borderlines as a function of Q_{interrupt}. When this graph is read from right to left, every time a case falls outside the reliability interval, this percentage increases. At a flow rate value less than 5.4 ml/s, 50% of the patients are outside the interval. This flow rate value was therefore chosen as a cut-off flow rate value above which the condom pressure accurately reflects the bladder pressure.

As mentioned above, the condom needs to be quickly filled and pressurised for an accurate pressure reading. It would be more efficient and accurate if (re)filling of the condom could be reduced. To achieve this, we developed a variable outflow resistance catheter (8). It consists of an incontinence condom connected to a set of three outflow tubes and a pressure transducer (Fig. 6). Remotely-controlled pneumatic valves are used to interrupt the flow of urine through each tube. This new condom-type catheter was designed to maintain a small pressure in the condom during voiding, called a preload (9). Figure 7 shows that when voiding starts (top panel), the catheter is set to a small outflow resistance (lowest panel). As a result, the condom partly fills with urine and the pressure in it increases to a preload value (middle panel). Superimposed on this preload, repeated isovolumetric pressure measurements are done by closing all tubes. When after each measurement the preload outflow resistance is restored, the condom remains partly filled with urine, which reduces its filling time during the next interruption. A second advantage of the preload is that it enables the investigator to monitor a sphincter contraction (a sudden drop in condom pressure) or detrusor inhibition (a gradual decrease of the pressure) and even the bladder volume dependence.

**PRACTICAL AND CLINICAL APPLICATION OF THE CONDOM-TYPE CATHETER**

The condom-type catheter may be used as a new classification tool to identify BOO in patients. To explore this possibility, we constructed a nomogram based on flow rate and condom pressure (10). The data of patients who first underwent an invasive pressure-flow test followed by a non-invasive test were re-analysed. Amongst five strategies, we test-
ed a classification on the basis of the maximum free flow rate, \(Q_{\text{max}}\) alone (strategy I) and a combination of maximum flow rate and maximum condom pressure (strategy II). The selected patient population for the non-invasive test had a wide variety of urological symptoms ranging from BOO to incontinence. We found that in this population, all patients voiding with a maximum flow rate smaller than 4.5 ml/s were obstructed and all those voiding with a maximum flow rate higher than 13.8 ml/s were non-obstructed. Thirty percent of the patients could be correctly classified. To classify BOO in the remaining 70% of the patients, measurement of bladder pressure is necessary. In the second strategy, we plotted for each patient \(P_{\text{condom,max}}\) versus \(Q_{\text{max}}\) (Fig. 8, top panel). Logistic regression was used to calculate separation lines between non-obstructed (white circles) and equivocal (plusses) and between equivocal and obstructed patients (black circles). In this way, 73% of all patients could be correctly classified. However, the equivocal zone was delineated by crossing lines, indicating that three independent classification zones cannot be constructed. We therefore attempted to join two classification zones. As the \(P_{\text{condom,max}}\) values measured in the equivocal and obstructed group were significantly higher than those in the non-obstructed group (Mann-Whitney U-test: \(p<0.05\)), we combined the equivocal patients with the obstructed patients. We re-calculated a separation line between this combined group of patients and the non-obstructed patients, and found that the overall success-rate was increased with 20% to 93% (Fig. 8, middle panel). A combination of both strategies results in a two-step approach: patients voiding with a \(Q_{\text{max}} < 4.5\) ml/s and \(Q_{\text{max}} > 13.8\) ml/s are classified by flow rate alone. The remaining patients are classified using a combination of maximum flow rate and a separately measured maximum condom pressure (Fig. 8, lowest panel). Using this strategy, 93% of our patients could be correctly classified non-invasively.

We evaluated the newly constructed non-invasive obstruction nomogram in a small group of 16 patients who underwent a Trans
Urethral Resection of the Prostate (TURP). The day before the TURP, each patient was asked to drink about half a litre of water to produce two separate voidings. We first measured the free flow rate to evaluate the urinary stream. Patients who severely strained during this test were not included in the study. Next the condom pressure was measured and evaluated. Both measurements

Figure 7 - An example of a measurement using the variable resistance catheter. The outflow resistance was step-wise increased to a preload resistance. As a result, the pressure in the condom increased to a preload. The flow rate was repeatedly interrupted to measure the maximum condom pressure and to test bladder volume dependence (figure reproduced with permission*).

Figure 8 - The maximum condom pressure is plotted versus the maximum flow rate and non-obstructed (nobs; white circles), equivocal (eq; plusses) and obstructed patients (obs; black circles) are separated by classification lines calculated using logistic regression. In the middle panel, the combined obstructed and equivocal patients (white circles) are separated from non-obstructed patients (black circles). This classification results in a two-step approach (lowest panel): patients with a maximum flow rate <4.5 ml/s or >13.8 ml/s are classified by flow rate alone. The remaining patients are classified using a combination of maximum flow rate and a separately measured maximum condom pressure (figure reproduced with permission*).
were repeated six weeks after surgery in 9 of
the 16 patients. To visualise the urodynamic
changes after the TURP, we plotted for each
patient the maximum condom pressure ver-
sus the maximum free flow rate (Fig. 9, top
panel). A thin line connects the measure-
ments of the same patient before and after
TURP. In one patient - labelled (A) -, the flow
rate and the condom pressure remained the
same after the operation, implying that this
patient probably voided with a weakly con-
tracting bladder. A second patient - labelled
(B) - voided intermittently before the opera-
tion. After the operation, not only the flow
rate but also the condom pressure increased
enormously. This example illustrates that a
condom pressure measurement is not reliable
in the case of a patient who voids intermit-
tently. In the remaining patients, the maxi-
mum flow rate increased 160% on average.
The condom pressures were on average in-
creased with 20% after TURP. We did not ex-
pect to find this small increase, because the
detrusor was unaltered. We think that a bet-
ter pressure transmission between bladder and
condom existed because of the increased flow
rate, resulting in a higher condom pressure
after the operation.

In Figure 9 (lowest panel), the non-invasive
classification areas were added to the con-
dom pressure - flow rate plot. Eight of the 9
post-operative evaluations fell in the non-ob-
structed areas (nobs) and only 10 of the 16
successful pre-operative evaluations fell in
the obstructed areas (obs). The line separat-
ing the (obs) from the (nobs) seems to be de-
fining too high given that 6 of the 16 patients
before the TURP fell in the non-obstructed
areas. However, 4 of these 6 patients are near
the obstructed area border and showed im-
provement after the operation. As the non-
invasive evaluation is based on the ICS-
nomogram, our preliminary finding suggests
that some patients (invasively) diagnosed as
non-obstructed on the basis of the ICS-nomo-
gram might still benefit from surgical relief
of the prostate. The non-invasive nomogram
(as proposed) was derived from a small pop-
ulation studied in one centre (St. Franciscus
Gasthuis, Rotterdam, the Netherlands). For a
general application, a larger multi-centre
study is necessary to establish more definite
borderlines. Such a multi-centre study, in-
cluding three urodynamic centres in Rotter-
dam (Erasmus MC, Havenziekenhuis and St.
Franciscus Gasthuis) and one in Tilburg (St.
Elisabeth Hospital) is in preparation.

END OF CLASSICAL URODYNAMICS?

The results of measurements done in
healthy volunteers and patients with LUTS
show that if the free flow rate of the subject
exceeds 5.4 ml/s, straining is avoided and the flow of urine is continuous, then a reliable bladder pressure measurement can be done with the condom method. The following question may therefore be asked: can the condom method replace the classical, invasive urodynamics? It has been shown that the isovolumetric bladder pressure measured with the condom method can be used to classify BOO by combining it with a free flow rate. Therefore, in patients with a flow rate >5.4 ml/s this method can replace classical urodynamics to classify BOO. If the voiding symptoms are severe, i.e. voiding with a very poor flow rate or straining, invasive urodynamics is still the only tool to be used, although in severely obstructed patients measurement of free flow rate alone might suffice (11). Also for the assessment of bladder stability, compliance or dyssynergia, invasive urodynamics is presently the only choice. In addition, to replace classical urodynamics in a subgroup of patients, the non-invasive method may also widen the clinical application of urodynamics. An example is formed by patients treated for BOO for instance by TURP. Nowadays, an invasive pressure-flow study is not always done in these patients because of its morbidity. However, a poor flow rate could be the result of a weakly contracting bladder as well as BOO. Many patients undergo surgery without a urodynamic diagnosis to differentiate between both causes for voiding complaints. The condom method provides a patient-friendly alternative to investigate this group of patients. Moreover, the test could be repeated in almost all patients after the operation. Such a post treatment evaluation is rare, but essential for a clinical evaluation of alternative therapies.

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