Non-invasive urodynamic measurements: towards clinical practice

Aims of course/workshop
What if you could get urodynamic information without doing invasive urodynamics? How about more information than from uroflowmetry, non-invasively? In this workshop we aim to present some of the newest non-invasive technologies and techniques which offer some of the important information usually yielded from invasive urodynamic studies. We will discuss how their diagnostic value compares to urodynamic studies, and to what extent they can be implemented in the clinical environment. Techniques which may become clinically useful in future will also be discussed. We welcome discussion with clinicians about realistic strategies to integrate these novel technologies into clinical practice.

Educational Objectives
The workshop will present a number of non-invasive urodynamic techniques which have been presented in the literature and workshop attendees will obtain a basic understanding of the principles behind these techniques. The clinical merit will be discussed, from those in routine clinical usage to experimental techniques whose clinical usefulness is, as yet, theoretical. The extent to which these techniques can be used instead of invasive urodynamics, or for obtaining information additional to uroflowmetry will be discussed, and the impact of this on diagnosis of the causes of LUTS. New techniques will be presented. This workshop will aim to educate about non-invasive urodynamic technologies and how they might be integrated into a clinical environment, and will foster discussion between clinicians and researchers in order to generate ideas and strategies for development of useful and practical clinical tools for clinician and patient.
Workshop 14

Non-invasive urodynamic measurements: towards clinical practice

Speakers: Clive Griffiths, PhD, Freeman Hospital, Newcastle upon Tyne, UK

Ron van Mastroigt, PhD, Erasmus Medical Centre, Rotterdam, Netherlands

Carlos D’Ancon, MD, Universidade Estadual de Campinas, Campinas, Brazil

Hideo Ozawa, MD, PhD, Kawasaki Medical University, Okayama, Japan

Chair: Becky Clarkson, PhD, University of Pittsburgh, Pittsburgh, USA
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Introduction

The purpose of a urodynamic test is to reproduce the lower urinary tract symptoms experienced in order to establish the pathophysiological mechanism and therefore confirm a diagnosis. This test, along with evaluation of the patient’s history and voiding habits is the most comprehensive method of making a diagnosis of the causes of LUTS. Urodynamic studies, however, are expensive, time-consuming, and may cause some discomfort and morbidity to the patient. In certain cases, this is acceptable. However, it would be useful if, in more ‘routine’ cases, diagnoses could be made with less invasive techniques.

A greater number of resources in the diagnostic armamentarium will increase the scope for selecting less invasive tests on a patient by patient basis. For instance, in cases where urodynamic studies might not provide the necessary benefit to overcome the risks of the study, less invasive tests might provide the confirmatory information to indicate treatment. Conversely non-invasive tests might reduce the number of urodynamic studies in borderline cases.

Ideally, development of less invasive tests would reduce the burden and expense of full urodynamic investigations, reduce the discomfort and risk to the patient, but still provide some relevant and useful information to improve diagnosis. The idea is not to replace, but to provide alternatives to urodynamics that might better suit the needs of some patients (and healthcare systems). These techniques might feasibly lend themselves to different environments, such as mobile and remote clinics. Overall, innovation in healthcare is how we expand our knowledge, refine practices and provide a better service.

A number of groups have risen to this challenge and have formulated and developed ideas and technologies which will enable familiar urodynamic parameters to be measured in a non-invasive way. From the conventional pressure/flow measurements of the condom catheter, cuff, and urethral device tests to the more abstracted measured of urine velocity using Doppler ultrasound and frequency spectrum of perineal noise, many different approaches have been taken. Currently, each of these technologies is in a differing stage of development, from the initial testing phase to the commercially available.

In this workshop we will discuss some of the more prominent methods of non-invasive urodynamic measurements requiring some level of technology differing from standard urodynamic equipment. The concepts and development of these techniques will be discussed by the speakers followed by some discussion on how to facilitate integration of such technologies into clinical practice.
Non-invasive measurement of bladder pressure and assessment of outlet obstruction in men using controlled inflation of a penile cuff

C J Griffiths, M J Drinnan, W A Robson, S McIntosh, C Harding, R S Pickard, P D Ramsden

Freeman Hospital, Newcastle upon Tyne, UK.

1. Basic principle
The basic principle of the test is shown below. When flow is underway, detected automatically, the cuff is inflated at 10 cmH₂O per second until flow is interrupted. At this point cuff pressure is taken to be equal to bladder pressure (isovolumetric). For the method to work, a number of underlying assumptions must hold true:

- Transmission of cuff pressure to the penile urethra.
- Urethra must remain open when flow is interrupted.
- Bladder contraction must not be inhibited by the interruption.

The first part of the presentation covers the scientific evidence supporting these assumptions (refs 1-5).

2. Application
The cuff is inflated until flow is interrupted or a safety limit of 200 cm H₂O is reached and then rapidly deflated. The cycle can be repeated several times during a void, as shown on the printout below (from the CT3000 device, Mediplus Ltd, UK). Plots of flow v cuff pressure help to identify interruption pressure. The highest obtained is used for assessment of obstruction (see below).
3. Diagnosis of obstruction

The next step is how the cuff interruption pressure is used to help diagnose bladder outlet obstruction. The principle is based on the ICS nomogram for the assessment of bladder outlet obstruction, but with two corrections:

- An offset of 40 cmH₂O to compensate for the inclusion of abdominal pressure and the height difference between the cuff and bladder.
- An increase in the slope to allow for the pressure rise between full flow and isovolumetric bladder pressure (which is proportional to flow rate).
For non-invasive data, the upper left region in figure 3 is obstructed; the lower right not obstructed; and shaded areas are uncertain. Symbols indicate diagnosis by invasive test and ICS nomogram (ref 6).

4. Prediction of outcome from surgery
Finally results are presented for a prospective study demonstrating how well classification of obstruction using the new technique predicted the outcome from surgery (ref 7).
Selected references


2. Transmission of penile cuff pressure to the penile urethra. Journal of Urology 2001; 166: 2545-2549


7. Predicting the outcome of prostatectomy using noninvasive bladder pressure and urine flow measurements. European Urology 2007; 52: 186-192
The condom catheter method for noninvasively measuring the isovolumetric bladder pressure and its application in a longitudinal study on 1020 healthy males.

Also some remarks on the perineal noise recording method and on how to compare the efficacy of methods for noninvasively diagnosing bladder outlet obstruction.

R. van Mastrigt, sector Furore (Physics of the Urinary Tract), Erasmus MC, Rotterdam.

From 1995 onwards, different noninvasive methods for diagnosing Bladder Outlet Obstruction (BOO) have been proposed. In 2006 an overview has been presented in a monothematic issue of the deceased journal “Urodinamica” which has been preserved at:


At the workshop the condom catheter method [1-8] will be shortly summarized, and its application in a longitudinal study on 1020 healthy volunteers to uncover the response of the urinary bladder to age related bladder outlet obstruction. The perineal noise recording method [9-12] will also be shortly discussed. Soon after the introduction of noninvasive methods calls for a nomination of the best method have been heard. Unfortunately a true comparison of these methods is multidimensional and can therefore not be completely rational. The most recent comparison attempt [13] nominates Doppler ultrasound measurement as best single method to noninvasively diagnose BOO on the basis of a likelihood ratio calculated for a test population of 22 patients (with caution).

We would like to suggest to base comparisons of tests for BOO on the Area under the Receiver Operator Curve (AUC), as this parameter is independent of the cutoff values used for the tests. For a test of the condom catheter method in a small population of 46 patients, we found an extremely high value of AUC. This was caused by the distribution of patients in the test population. It follows that for a valid comparison, the patient distributions used should be benchmarked. For that purpose the AUC of the maximum free flow rate can be used, as it can be calculated analytically for a homogenous patient distribution [14]. It would therefore seem that the difference of the AUC of a certain test and the AUC of the maximum free flowrate in the same population of patients is a distribution free parameter for comparing the efficacy of tests for diagnosing BOO.
References


Non-invasive Urodynamics – Urethral Connector

Carlos Arturo Levi D’Ancona, Professor and Chairman of Division of Urology, Universidade Estadual de Campinas, Campinas, SP – Brazil

Introduction
The urodynamics evaluation is an important diagnostic tool for the symptoms of the lower urinary tract. These symptoms are frequent in men over 60 years old and are related, principally to benign obstruction of the prostate [1].

The conventional urodynamic evaluation consists of registering vesical and abdominal pressures during the filling phase and including flow during the voiding phase, which is invasive, time consuming and expensive [2]. Over the past two decades, two alternative methods for measuring the vesical pressure in minimal invasive manner have been developed, in conjunction with the urinary flow (non-invasive) has made possible the detection of infravesical obstruction. These methods consist of devices called condom catheter and penile cuff [3,4,5,6]. A third alternative method had been developed at UNICAMP, which uses a device called urethral connector [7].

Development
The results of the device have already been published and present a sensitiveness of 67% and specificity of 79% [7]. The initial model consisted only of a device to which the transducer was connected and the interruption of the flow was done by the patient himself [Fig.1].

![Figure 1 – Urethral connector: A – connection to the urethra, B – connection to the transducer, C – local of obstruction of the flow.](image-url)

With the objective to facilitate the realization of this study, modifications of the urethral connector were proposed. In a previous study, the development of support instrumentation was presented, to be used with the urethral connector [8]. The system is composed of a pressure transducer, an electrical isolation enlargement board (National
Instruments NI USB-6215) and registered software at Labview® and with these it was possible to test new models (Fig.2).

Figure 2 – Diagram for the development of modifications of the urethral connector.

After various tests, it was possible to develop Version II of the urethral connector where the transducer is attached to the connector (Fig.3).

Figure 3 – Urethral connector version II. A – The part inserted into the patient’s urethra. B – Attachment and support for the transducer and wire.

Graph of the vesical pressure registered during a clinical exam with the urethral connector II. The arrows indicate the approximated movement in which the individual is instructed to close the exit of the device (Fig. 4). Note that the pressure slowly increases until it reaches the approximated static value, corresponding to the isovolumetric vesical pressure. Afterwards, the end of the connector is freed, permitting urination to continue. The
stopping of the flow is done several times during the urination, for periods of 2-3 seconds, which permits, with greater accuracy the vesical pressure.

For the comparison of two methods, conventional and connector, the vesical pressure at maximal flow and maximal vesical pressure in non-invasive method were used. These measurements are good indicators of bladder contractile activity. Figure 5 shows the comparison of vesical pressure registered with the two methods. The linear regression resulted in: angular coefficient of 2.00 +/- 0.49, \( r^2 = 0.8016 \), with a confidence interval of 95% of 0.6190 to 3.381. The Pearson value of \( r \) for correlation was 0.8953.

New studies are being done in order to refine the connector to join the transducer and the apparatus for interruption of the flow of the same device (Fig. 6).
Discussion

The procedure for occlusion of the flow was not adopted suddenly using the urethral connector to avoid hydraulic shock. In a previous study, lab simulations showed that abrupt occlusion could cause a rapid and significant increase of the pressure [9]. In all the exams, a behavior similar to that presented in Figure 4 was observed, with a gradual increase of pressure until a static regime value was reached, which corresponded to the isometric vesical pressure. According to the patients, a closing time of 2 to 3 seconds was not long enough to cause any discomfort and this has already been verified by other methods that there is no contraction inhibition of the detrusor during a brief interruption of the flow [10].

When the registered vesical pressure values of the urethral connector are compared to the conventional urodynamic method, the curve was presented [Figure 5]. The conventional method registers the pressure of a free flow, while the connector measures the value during an interrupted flow. Thus, although the pressures adopted for each method reflect the contractile activity of the detrusor, its values are not necessarily identical. However, a linear correlation between the measured pressures is observed, which shows the sensitiveness of the connector when registering the vesical pressure.

With the relationship of the fact that the flows registered using both methods are not different, it is indicative that the connector does not cause an increase of resistance of the urinary flow, and the necessary interruptions for measuring the vesical pressure do not significantly alter the parameters evaluated.

What is the real application of this method? The study of non-invasive urodynamic evaluation has generated many studies; however, it has not been adopted in daily practice. It is difficult to interpret the results and it does not evaluate the phase of vesical filling and has a bit of an engineering characteristic. Since it is a non-invasive method it should be used...
in the first consultation of the patient, of course, when the symptoms first begin to present
themselves and not when it is time to schedule surgery. The exam most probably should be
between flowmetry and the conventional urodynamic study. A great advantage to using it is
that it can be repeated many times, permitting the evaluation of the obstruction during
clinical treatment.

Conclusion

The clinical studies showed the urethral connector had potential use as an
alternative method to the conventional urodynamic evaluation. The connector also showed
itself to be sufficiently sensitive to measure the isometric vesical pressure and do not alter
the results of the flowmetry.

Grants

To perform this study we had the support of the National Council of Scientific and
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Doppler ultrasound videourodynamics (D-VUDS)

Hideo Ozawa, MD, PhD, Assistant Professor of Urology, Atsushi Nagai, MD, PhD, Professor of Urology, Kawasaki Medical School, Hiromi Kumon, MD, PhD, Director and Professor of Urology, Okayama University Graduate School of Medicine and Dentistry and Pharmaceutical Science

1. Why Doppler ultrasound?

1) Pressure is not the only best parameter to measure the degree of bladder outlet obstruction (BOO).

The bladder outlet behaves physically as a distensible tube, two urodynamic variables of detrusor pressure and flow rate has been historically established. However the relation between the measured pressure and obstruction is not simple and straightforward\(^1\). Although a number of approaches to analysis of pressure flow studies were developed, all share the principle of catheter based pressure flow studies\(^2\). The catheter causes significant artifacts, including decreased flow rate and increased voiding pressure, altering and inhibiting the normal voiding reflex\(^3\).

2) Urinary velocity can be measured by Doppler ultrasonography without catheterization.

Recently Doppler ultrasonography has been used for evaluating flow velocities of blood flow. Normal urine doesn’t have blood cells so urine was thought not to produce Doppler effects\(^4\). However, our basic study confirmed that the decrease of pressure at high velocity (Bernoulli’s principle) caused dissolved gas to form micro-bubbles, which are detected by Doppler ultrasonography\(^5,6\). Normal urine at a flow rate of more than 1.0mL per second contains enough echo dense micro-bubbles to allow velocity measurement in the urethra.

Figure 1: Pressure flow study

![Image of a pressure flow study diagram]

- Decreased flow rate
- Increased voiding pressure
- Inhibit normal voiding reflex
- Risk of infection
- Not guarantee privacy

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using Doppler ultrasonography without contrast material. Therefore urethral catheterization can be avoided with the ultrasound urodynamic system.

Figure 2: Mechanism of Doppler effects from flowing urine

- Bernoulli’s principle
  Where the velocity of a fluid is high, the pressure of fluid becomes low.
- A fundamental of physical chemistry
  Dissolved gasses will be reformed into micro bubbles by a decrease in pressure.

3) Functional cross-sectional area (FCSA) of the prostatic urethra, which is directly correlated with BOO, can be obtained from velocity measured by Doppler sonography.

Using Doppler ultrasonography, flow velocity can be measured. Using a uroflowmeter, flow rate can be also measured. Flow rate divided by flow velocity in adequate phase represents the FCSA of the urethra at the point of measured velocity.
Figure 3: Significance of flow velocity during voiding

\[ Q = v \times A \]

\[ A = \frac{Q}{v} \]

The flow rate divided by flow velocity equals the functional cross-sectional area of the urethra, which may present a direct parameter of obstruction.

4) Clear Doppler signal was obtained from the urethra in a transperineal approach in the sitting position using the specially equipped lavatory chair.

A transabdominal approach cannot adequately visualize the urethra during voiding. Although transrectal approach is frequently used for the diagnosis of prostatic diseases, during voiding direct compression to the urethra is unavoidable. Moreover, these two approaches do not provide an angle facing the frontal plane of the urinary flow, which is the most suitable in detecting Doppler effects. A transperineal approach offers the ideal angle of detecting Doppler effects in the bladder neck and prostatic urethra.
2. Advantages of Doppler ultrasonography for urodynamics

1) Catheterization is not necessary.

2) Patients are not exposed to radiation.

3) Ultrasonography can be used in the voiding posture in contrast to CT and MRI in which patients need to void in the supine posture.

4) Ultrasonography can guarantee patient privacy by using a specially equipped robotic manipulator.

5) Anatomical information of the lower urinary tract and surrounding structure can be obtained.

6) Doppler ultrasonography can be monitored real time with flow data and urethral movement.

7) Ultrasonography can be used at the patient’s convenience compared to CT and MRI which many departments need to use.
Table 1: Comparison among examinations for evaluating lower urinary tract function

<table>
<thead>
<tr>
<th></th>
<th>Doppler</th>
<th>PFS</th>
<th>VUDS</th>
<th>CT</th>
<th>MRI</th>
<th>Cuff</th>
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<tr>
<td>Absence of catheterization</td>
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<td>−</td>
<td>−</td>
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<tr>
<td>Safety from radiation exposure</td>
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<td>+</td>
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<td>Comfort of voiding posture</td>
<td>+</td>
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<td>Patient privacy</td>
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<tr>
<td>Anatomical information</td>
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<td>urethra</td>
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<td>movement of urethra</td>
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<td>Convenience of voiding time</td>
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<td>equipment available</td>
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3. Comparison to conventional pressure flow study (PFS)

Men who have various degrees of obstruction were compared along the parameters of both PFS and Doppler ultrasound urodynamic studies. Velocity ratio (VR=V₁/V₂) was the parameter having the best correlation with BOO parameter measured by PFS (Spearman’s rho=0.728; p<0.001), although A₁ (FCSA at the prostatic urethra) had a similar correlation (rho=-0.708; p=0.001). All men with VR exceeding 1.6 were in the obstructed group. Similarly, all men with below 1.0 were equivocal or unobstructed. This means that although flow was accelerated through the sphincter in the unobstructed group and equivocal group, flow-velocity was reduced through the sphincter in the obstructed group\(^{10}\).

Ding reported that the retest correlation using Spearman’s rho for VR in terms of intrarater and interrater reliability was 0.95 and 0.57, respectively; that for A₁ was 0.97 and 0.64, respectively\(^{11}\). This noninvasive urodynamics has better correlation with obstruction than the other noninvasive method using transabdominal ultrasound of the intravesical prostatic protrusion (IPP)\(^{12}\). We found that noninvasive velocity flow urodynamic evaluation based on Doppler ultrasound was viable to diagnose BOO with reasonable reliability\(^{13}\).

Although some of the analytical methods and the robotic arm related technology still need to be confirmed by larger-sample studies, these applications will become more attractive to the neurourologist.
4. Hurdle for developing the equipment for the practical use of clinical practice.
We demonstrated that flow velocity can be measured by Doppler ultrasonography which is promising for developing non-invasive urodynamic study. We thought that once the principle is accepted, ultrasound companies would develop non-invasive ultrasound equipment voluntarily. But they are underestimating the demand for non-invasive urodynamic machines. They supplied only ultrasound machine, however they have not modified the ultrasound equipment. Since we have got several grants, we cooperated with local engineers to produce remote control robotic manipulators and analytical computer programs with some success. Ideally it should be able to adjust to an adequate position before micturition. This aiming process is tough for a beginner at this examination. So urologists may still have difficulty conducting the procedure in their own practices. Modification in the ultrasound equipment might be mandatory.

For the development of urodynamic machine, reimbursement for urodynamic study in each country is important. If the reimbursement is higher, hospitals could afford to buy relatively expensive urodynamic machines. The companies would be able to develop urodynamic machines with new concepts relatively easily. Reimbursement for pressure flow study is much cheaper in Japan; approximately $70 than that in the other countries (USA $507, UK $625, Brazil $100 etc.)14. Further development of the Doppler urodynamic equipments is tough in Japan. After the earthquake struck north-eastern Japan this spring the situation is getting worse for us. Any members of ICS connected with any ultrasound machine company can develop non-invasive urodynamic equipment using Doppler technique.
References


14. Personal communications

Correspondence: Hideo Ozawa, MD, PhD

Department of Urology,
Kawasaki Medical University, Kawasaki Hospital,
2-1-80 Uchisange, Kita-ku
Okayama, 700-8505, Japan
E-mail: UrOzawa@gmail.com
The future of non-invasive technologies

Becky Clarkson, University of Pittsburgh, Pittsburgh, PA, USA

This section will be split into two categories: a round-up of techniques not covered by guest speakers in this workshop; and a discussion of how we can integrate these new tools into clinical practice and the common barriers that are faced.

Other technologies
There are a number of other technologies available which have not been mentioned previously, which will be summarised here with the relevant reading material. These include:

Constant Low flow cuff device

This device utilises an inflatable penile cuff in a dynamic way to measure bladder pressure continuously throughout voiding. The premise of this technique is that the cuff inflates sufficiently to reduce flow to the very low rate of 2.5ml/s. The pressure in the cuff is then controlled via a feedback mechanism to keep flow constant at that rate. The pressure in the cuff is therefore not a single measure of interruption pressure (as with the interruption cuff test), but is a continuous measure of voiding pressure during the entire void.

This technique has just completed initial stage development and testing, with the result that the technique reliably measures voiding pressure in many subjects (1), see example in figure 1. Further development is underway and more trials are planned.

![Figure 1](image)

Figure 1, example of measurement of bladder pressure using the low flow cuff technique (cuff pressure in red compared to vesical pressure in blue)

Near infrared spectroscopy of the bladder

Near infrared spectroscopy (NIRS) is a non-invasive optical method of imaging blood flow up to a few centimetres below the surface of the skin. This technique has often been used in
the brain (2), but has also been used to quantify blood flow in muscle and has thus been applied to detrusor muscle (3). A number of studies (4-6) led to a commercial device ‘uroNIRS 2000’ (MMS International, Netherlands) being produced. While some studies have shown that using an algorithm including PVR, voided volume and flow rate with the NIRS data (4, 6) classified BOO well, a recent, independent study concluded that NIRS would not provide ‘substantial clinical usefulness’ (7). It has also been suggested that NIRS could be used to diagnose spontaneous detrusor contractions (DO) (8) during the storage phase.

**Ultrasound measurement of detrusor parameters**

A somewhat simple technique (in that it can be implemented using a standard U/S machine – BWT/DWT, or is already inbuilt into some bladder scanners – bladder weight) is measurement of bladder or detrusor wall thickness. There is some discussion as to whether the measurement of the bladder wall (detrusor plus adventitia, mucosa, etc) (9) or the detrusor alone is better (10, 11), but the general premise is that a thicker wall implies hypertrophy secondary to outlet obstruction. Such a technique requires an ultrasound system with 7.5MHz probe and ability to locate, zoom into and measure the bladder wall, and therefore requires no new technology. Normal values have been acquired (12) and those at differing bladder volumes (an important consideration). Studies on DWT have shown good sensitivity and specificity for diagnosing BOO (10), although the measurement route (transabdominal vs transvaginal (13)) is also of some discussion. A standardisation document for this technique has been proposed.

It has also been proposed that ultrasound estimated bladder weight (UEBW) might be a useful parameter in the assessment of BOO (14, 15). This feature is incorporated into some bladder scanners. UEBW has also been used to measure the severity of vesicoureteric reflux in children (16).

Bladder wall thickness/UEBW have been assessed for association with symptoms of OAB (17, 18), where it was found that higher UEBW and BWT were associated with UUI and DO in women. However, in a study of 180 subjects (men and women) with a range of different causes of LUTS, it was found that classification of OAB/BOO using BWT was very difficult (19).

**Home uroflowmetry (electronic voiding diaries)**

There are other related areas where an increase in technology can yield more useful information for the clinician. This includes such as repeat home uroflowmetry (20, 21). Information from voiding diaries can be very useful, and as technology improves repeat home uroflowmetry becomes realisable. Home flowmeters which double as electronic voiding diaries, recording flow, volume, and time of each void over a day-week period can give an insight into
the patient’s voiding habits which may not be well articulated or reproduced in a clinic. (See workshop 36B)

**Discussion**
The workshop will end with a discussion of the following points:

- Opinions from clinicians on the use of these technologies in clinical practice;

- Opinions from researchers/developers on how to get these technologies into mainstream clinical usage;

- What are the major barriers to getting new technologies into practice?
References / Further Reading