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Urodynamic protocol and central review of data for clinical trials in lower urinary tract dysfunction

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Introduction

Schafer *et al.* [1] showed, in a multicentre, multinational study of men with LUTS suggestive of benign prostatic obstruction (BPO), that many urodynamic traces were difficult or impossible to interpret. Subsequent experience with a standardized urodynamic protocol showed a great improvement in the standard of the urodynamics carried out. A standardized urodynamic protocol is now a prerequisite in all studies investigating lower urinary tract dysfunction. In multicentre trials, a central evaluation at a quality-control centre (QCC) further contributes to the value of the trial [2].

It is therefore of paramount importance that these data are of the highest possible quality to maximize the information available for analysis. In studies which use urodynamic endpoints, the use of a standardized urodynamic protocol with quality-control analysis of the tracings has become the norm. This protocol covers studies in both BPO and in storage dysfunction, i.e. either bladder overactivity (BOA, detrusor instability) or genuine stress incontinence (GSI). Methods, definitions and units conform to the standards recommended by the ICS, except where specifically noted [3].

Trials of treatments for BPO

There are several outcome measures in trials for the treatment for BPO, e.g. the maximum flow rate (Q_{max}) measured by uroflowmetry, or the detrusor pressure at maximum flow ($p_{det}Q_{max}$) and Q_{max} measured during pressure-flow studies (PFS). Q_{max} and $p_{det}Q_{max}$ are used in the assessment of the degree of obstruction and can be presented on an ICS nomogram (Fig. 1), and computed into a BOO index, (BOOI), equal to ($p_{det}Q_{max} - 2Q_{max}$) [4]. The inclusion of patients in trials is often based on Q_{max} and $p_{det}Q_{max}$, as they are used in the calculation of the BOOI: a BOOI of 20–70, representing mild to moderate obstruction, is one of the inclusion criteria in a recent BPO trial using an antimuscarinic drug to treat BOA.

The outcome measures for trials on storage dysfunction (GSI or detrusor instability) may include objective improvement in storage function (i.e. changes in bladder sensation), reduction in BOA, increased urethral competence, increased bladder capacity and improved compliance. In addition, any changes that may occur during voiding, the Q_{max}, $p_{det}Q_{max}$, volume voided and postvoid residual volume (PVR) will be recorded.

Initial submission of specimen traces to the QCC

When the decision is made to have a central review of urodynamic traces at a QCC, then each of the proposed participating centres should submit specimen traces for initial assessment. The inclusion of centres should be based on this assessment.

To eliminate as many problems as possible before the start of the study, prospective investigators should be asked to read the urodynamic brochure and submit five annotated urodynamic traces, including the storage and voiding phases, and five annotated urine flow traces for BPO trials. The urodynamic traces should be annotated (Fig. 2) with; the zero level for intravesical pressure (p_{ves}), intra-abdominal pressure (p_{abd}), p_{det}, urinary flow rate (Q) and volume (and with urethral pressure, p_{ura}, if urethral are measurements are included); the vertical scaling for p_{ves}, p_{abd}, p_{det}, Q and volume (and p_{ura} if urethral measurements included); the horizontal scaling of time (if the chart paper runs faster during the voiding phase this should be indicated); the investigator's urodynamic measurements and comments. The flow traces should be annotated with (Fig. 3): the zero level for flow; the vertical scaling of flow, e.g. the level for 25 mL/s; the horizontal scaling of time; and the investigator's opinion of Q_{max} and voided volume

Urodynamic studies

Clinical management depends on an accurate diagnosis; when investigating patients with lower urinary tract dysfunction appropriate attention must be paid to precise urodynamic technique. This section deals with setting up the urodynamic equipment and ensuring a good quality urodynamic test. The equipment required consists of a urine flow meter, urodynamic machine, an infusion pump and pressure measuring equipment.

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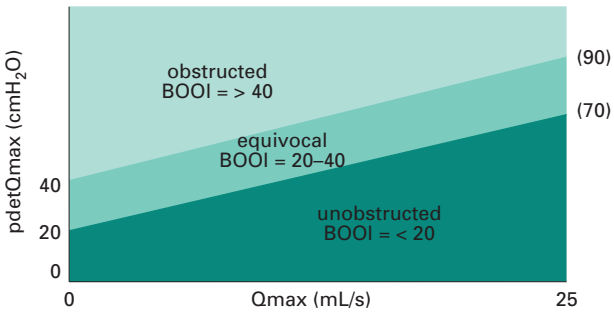

Fig. 1. The ICS pressure/flow nomogram using the BOOI [6]

Most commercially available flow meters are essentially accurate but require regular calibration, normally achieved by the constant-flow calibration device supplied by the manufacturer. However, if no device is supplied then a home-made system can be used (Fig. 4). The gate clamp can be adjusted, by trial and error, until it gives a constant flow of 10 mL/s. This is calculated by using a stop watch to measure the time taken for a defined volume of 100 mL to be collected by the flow meter. If the flow meter is not recording accurately, then the machine is adjusted according to the manual of instructions. If there are problems the manufacturer or agent should be contacted.

It is important that artefacts are excluded on urinary flow traces; in the example in Fig. 5 the flow meter indicates that the Q_{max} was 15 mL/s, but this is a 'spike' artefact and should be ignored. It has been shown that the flow rate estimated during the initial void of a male patient has a lower Q_{max} than those during the second and subsequent voids. In addition, the initial voided volume may be low. This phenomenon is probably caused by the patient's lack of familiarity with the clinic environment. Thus at the screening visit in any study the patient should provide two voids with voided volumes of >150 mL, with the higher Q_{max} used for inclusion/exclusion from the study (e.g. $\geqslant 12$ mL/s may be an exclusion criteria). A consistent PVR of >250 mL would exclude the patient from some studies; the PVR should be measured by ultrasonography after both flow tests. To prepare the patient for the flow tests the investigator can provide the patient with the following instructions. "*Try to come to the clinic with your bladder full, as this will mean a shorter time at the hospital. You may like to have one or two drinks within the hour before your appointment. The flow test takes 1–2 h; it will show how much urine your bladder holds and at what speed it empties. When your bladder feels full, you will be asked to pass water into a specially adapted toilet. This will be repeated once or twice. Each time, after you have passed urine, we will see how well you have emptied your bladder by using an ultrasound test.*"

Cystometry

To determine the bladder volume during filling cystometry, it is necessary to pump fluid (water or contrast media) into the bladder. Most pumps work on a peristaltic principle; some machines have an integral pump, which can be calibrated using the instructions in the urodynamic equipment manual. However, it is still wise to check the accuracy of the pump by assembling the infusion set and connecting its distal end to the filling catheter. The pump should then be started and the infusion rate checked using a stopwatch and a measuring cylinder. The pump should be set to deliver fluid at 10–60 mL/min, depending on the study.

The urodynamic assessments will require the machine to present individual traces giving information on p_{ves}, p_{abd}, p_{det} ($p_{ves} - p_{abd}$) and Q. Most machines produce both

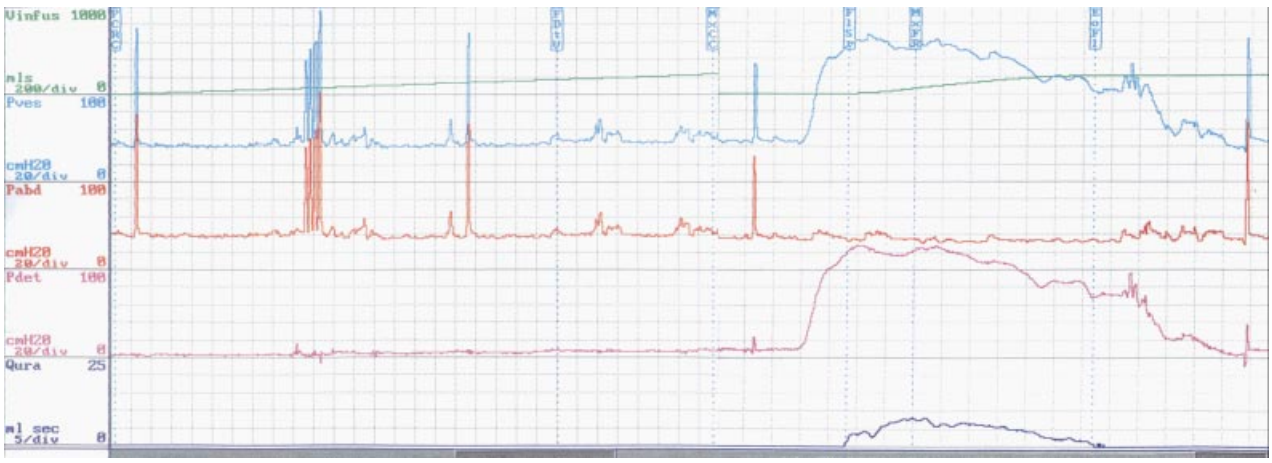

Fig. 2. The annotation of traces: each trace should show zero and full-scale deflection for flow rate, pressure and volume. The patient should be asked to cough at the start of filling, every minute during filling and before and after voiding to check transmission of pressure, First desire to void, maximum cystometric capacity and maximum flow rate should also be indicated on the trace.

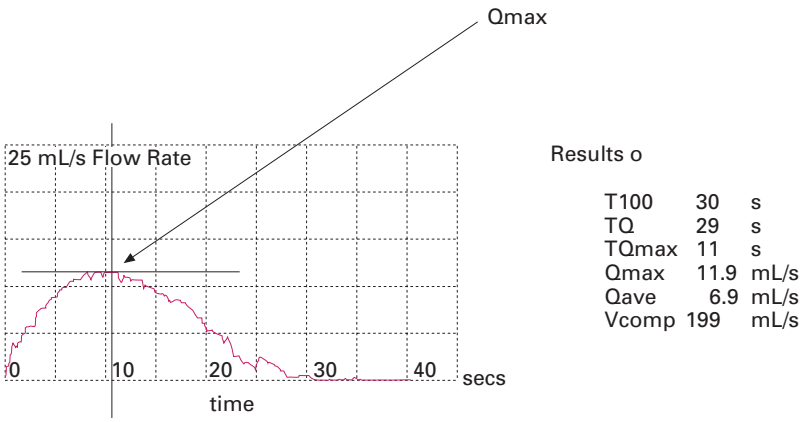

Fig. 3. Annotation of a flow rate trace: each trace should show zero and full-scale deflection for flow rate and the time scale on the horizontal axis.

a chart with the four traces displayed and a digital display for each measurement. For the detailed calibration of the machine the manual for the individual apparatus should be consulted. Both p_{ves} and p_{abd} are measured using transducers that convert a pressure wave in water into an electrical signal; p_{det} is then calculated electronically within the machine by subtracting p_{abd} from p_{ves}. Pressure can be measured by external transducers connected by fluid-filled manometer lines to the catheters within the patient, or with solid-state catheter-tip transducers (where the transducer is mounted on the catheter).

Urodynamic investigation

There are three fundamental and vital steps to setting up the equipment in fluid-filled systems: (i) preparing and priming the transducers, transducer domes and connecting tubes; (ii) checking the calibration of the transducers (the transducer should be calibrated by the service engineer, unless the operator is confident in his/her ability); (iii) setting the zero and establishing the pressure reference level.

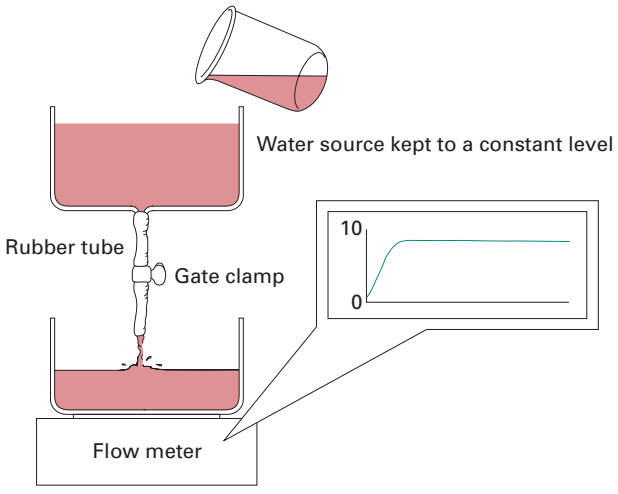

Fig. 4. Home-made calibration equipment for a urine flow meter.

(i) The transducer includes a sterile dome which has to be filled with fluid to allow pressure to be transmitted. Figure 6a shows a typical arrangement of the transducer dome connected to two three-way taps, the tubing that connects to either the bladder or abdominal catheter, and a syringe. The syringe is used to flush sterile water through the system. The transducer can either be held horizontally or vertically. Before starting the investigation or checking the calibration, the system must be 'primed' (Fig. 6a), i.e. fluid is flushed from the syringe through the transducer and into the connecting tubes, ensuring that there are no air bubbles in the system.

(ii) A 100-cm measure is required to check the calibration of the pressure transducers. Tap **B** is opened as shown in Fig. 6b; the end of the manometer tube **C** is placed at the zero mark (ensuring that the tube is primed and that there are no air bubbles); the pressures are set to zero (on most machines there is an instruction to either zero or balance the transducers). The traces and digital value should read zero. The manometer tube is raised until the end **C** is at the level of the 100 cm mark; the traces and digital value should now read 100 cmH_2O (Fig. 6c). If this reading is incorrect, the service engineer should be consulted. After checking the calibration, the pressures are re-zeroed so that atmospheric pressure is being recorded from the side-arm **B**, allowing the zero and reference level to be set correctly (Fig. 6d).

(iii) The ICS has published a technical report which has established the convention that 'zero pressure is atmospheric pressure'. Zero is taken as the open end of the short side-arm of the three-way tap **B** attached to the transducer (Fig. 6d). The ICS has also defined a reference level for external transducers and fluid-filled catheters as the superior edge of the symphysis pubis. Hence it essential to level the transducers to this reference point. The short arm of the three-way tap **B** is the appropriate point, which must be on the same horizontal level as the

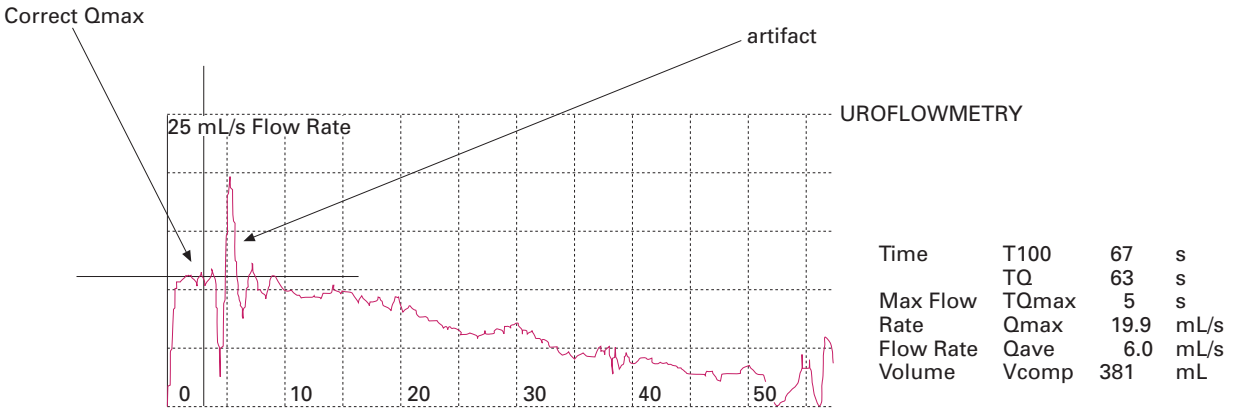

Fig. 5. The exclusion of artefact in a flow rate trace: a spike artefact read by the machine as 19.9 mL/s cannot be physiological. The estimated true Q_{max} is 11 mL/s at the intersection of the reader's vertical and horizontal lines.

upper edge of the symphysis pubis. Figures 6b,c show the position of the three-way taps during the urodynamic investigation. Tap **B** is rotated through 90° to allow pressure to be recorded from the patient to the transducer. If the position of the patient is changed during the investigation, for any reason, it is necessary to re-level the transducers.

Solid-state micro-tip catheters are calibrated by zeroing at atmospheric pressure and placing the catheter into a column of fluid to a depth of 100 cm; the trace and digital value should read 100 cmH_2O. Alternatively, insert the catheter into a pressure chamber, zero at atmospheric pressure, then increase the pressure in the chamber to 100 cmH_2O; the trace and digital value should then read 100 cmH_2O. If the calibration is incorrect the service engineer should be contacted. These transducers can be difficult to calibrate unless the operator is fully conversant with the technique. Catheter-mounted (solid-state) transducers have an integral reference level and are unaffected by positional changes.

Catheters and catheterization

The use of catheters will vary according to individual studies. In general, the bladder catheter used (to measure p_{ves}) should be a 6 F dual-channel catheter, which can remain in the urethra throughout the study. If insertion of a 6 F catheter proves too difficult for the size of the prostatic urethra, an 8 F catheter may be used. If an 8 F catheter is used for the first pressure-flow assessment, it should also be

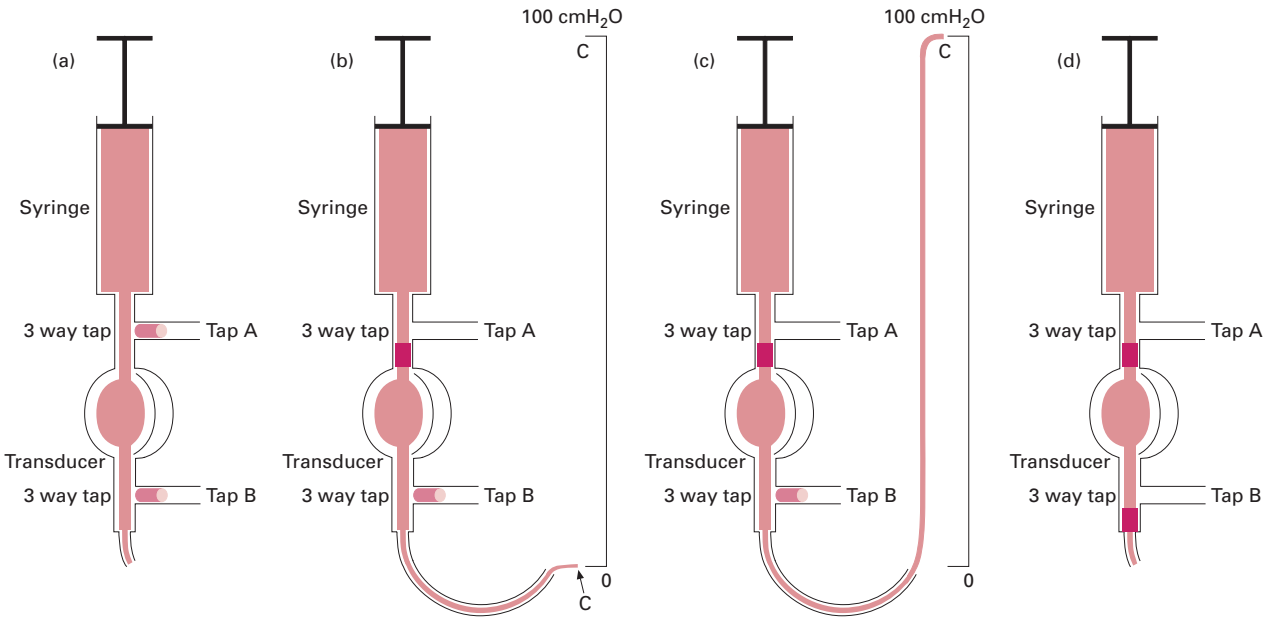

Fig. 6. **a,** Priming the pressure transducer and tubing/catheter to eliminate air bubbles and leaks. **b,** Calibrating the transducer: setting zero by placing the open end of the tubing/catheter at the zero point on a vertical 100 cm ruler and **c,** raising the open end of the tubing/catheter by 100 cm. **d,** Setting zero to atmospheric pressure via the side arm **B**.

used for all subsequent assessments in that patient [5]. For male catheterization, a local anaesthetic jelly or a lubricant jelly should be used to facilitate the passage of the catheter. The two-way catheter should be passed well into the bladder and fixed to the penis, leaving no gap between the external urinary meatus and the point at which tape **A/B** (Fig. 7) is attached to the catheter. The second piece of tape, **C/D**, should be applied to the shaft of the penis, ensuring that this does not obstruct the urethra. The key to success in fixing the urethral catheter is to be sure that there is no loop of catheter between the external urinary meatus and the point of tape fixation. If the above technique is used there should be few problems with the catheter being voided during the investigation. The same insertion technique is used for female catheterization; the catheter should be secured as closely as possible to the external urinary meatus to ensure that the catheter is not expelled during voiding.

The rectal catheter (to measure p_{abd}) has a small hole in the balloon to allow air and fluid to escape as the catheter is flushed through (Fig. 8a). The rectal catheter is passed through the anal canal into the rectum (in female patients it is possible to use the vagina to record abdominal pressure). The catheter should be advanced 10–15 cm from the anal verge to ensure that it is well within the rectal lumen. It is difficult to obtain good readings if the patient's rectum is full; hence, if during the rectal examination before urodynamics the rectum is noted to be full, then those patients should be asked to empty their bowels. As with the bladder catheters, to ensure fixation the catheter is attached as close as possible to the anal canal. Dry the anal verge to remove all lubricant fluid and attach with sticky tape so that as little catheter as possible is visible between the anus and the tape (Fig. 8b).

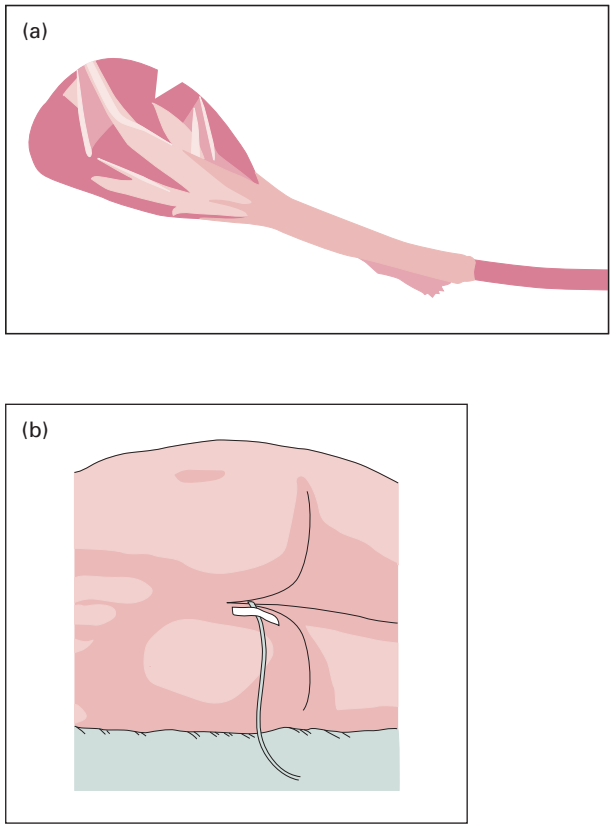

Fig. 8. a, The 'home-made' rectal catheter constructed from manometer tubing. A small cut is made in the balloon to allow excess fluid to escape. **b,** The rectal catheter should be taped as shown, as close as possible to the anal verge.

Ensuring a high-quality recording from the patient

Before starting recording and after the patient is catheterized, both the bladder and rectal lines should be flushed once more, to ensure that all bubbles and leaks have been removed. The first quality-control test, the cough test, is used to ensure that there is a proper subtraction ($p_{ves} - p_{abd} = p_{det}$), as detrusor pressure change is fundamental to most urodynamic analyses. Before recording starts, the patient should be asked to cough and the p_{ves} and p_{abd} traces observed; there should be an equal rise in pressure during the patient's cough; the patient is then asked to cough at regular intervals

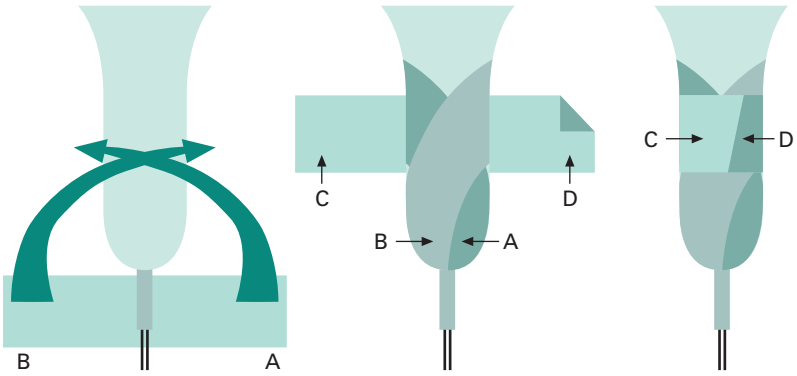

Fig. 7. Fixation of the double-lumen catheter in a male patient.

during the investigation. The patient should be asked to produce a cough that gives a deflection of ≈100 cmH_2O; this deflection should show a rapid increase to the peak and then a rapid fall, as shown in Fig. 9a. On the p_{det} line there may be a small biphasic peak, but this is not significant; what is crucial is that the height of the spikes on the p_{ves} and the p_{abd} lines are identical. If the spikes are not identical (Fig. 9b) then there may be bubbles or leaks, one or more of the catheters may be malpositioned, or there may be interference with the abdominal trace arising from faecal loading. All these points must be checked and the cough repeated until the proper pattern is observed.

Once the initial cough gives a good quality signal then the bladder can be filled; throughout bladder filling, the patient should be asked to cough every minute. If at any stage the quality deteriorates, then the investigation must be stopped and the cause of the poor pressure transmission investigated. Once the fault is corrected then filling can recommence.

After voiding, the patient must be asked to cough again to ensure that the catheters have not moved during micturition. Failure to show an equal transmission of pressure after voiding means that the results cannot be interpreted confidently and the investigation needs to be repeated.

Filling and voiding cystometry

If filling and voiding cystometry is to be used in men, then before any urodynamic study, free-flow rates should be measured. This allows the PFS voiding to be assessed by comparison with the free flow rates. The patient is asked to empty his/her bladder as completely as possible, and the free flow rate and volume voided are recorded. The patient is then catheterized. The urine is tested by dipstick; if the dipstick test indicates a possible abnormality, then a urine sample is submitted for culture and to assess bacterial sensitivities. The PVR can be assessed by draining residual urine after the initial void, but in some studies the protocol may demand that the PVR is measured by ultrasonography, but not removed.

The pressure lines are prepared by connecting them to the transducer, ensuring that the reference level is correct, zeroing at atmospheric pressure, priming the lines (leaving the three-way taps in the working position, Fig. 6b,c) and checking the empty resting pressures. As a guide, the empty resting pressure (p_{ves} and p_{abd}) should be 5–20 cmH_2O, if the patient is supine, 15–35 cmH_2O if sitting and 30–50 cmH_2O if standing (depending on obesity). Both p_{ves} and p_{abd} should be similar, with p_{det} in the range -5 to 10 cmH_2O.

Before starting the investigation, the patient should be asked to cough to ensure that there is equal transmission from p_{ves} and p_{abd}, and that the resting pressures are within the acceptable range. If they are not then all parts of the system need to be re-assessed; catheters should be examined to ensure they have remained in place, the pressure lines flushed to ensure there are no air bubbles in the system, zeroes and baselines re-checked, and if necessary, catheters and/or transducer domes changed. When all pressures are recording accurately, the urodynamics can commence, remembering that the system should not be re-zeroed once the pressure lines are primed, connected to the patient and recording.

The bladder is usually filled either with the patient seated (females) or standing (males). If the patient has mobility or physical problems, the bladder may be filled with the patient lying down. The filling rate should be 10–60 mL/min and the infused fluid, saline or contrast medium. If the bladder is very overactive it may be necessary to fill the bladder with the patient lying and to

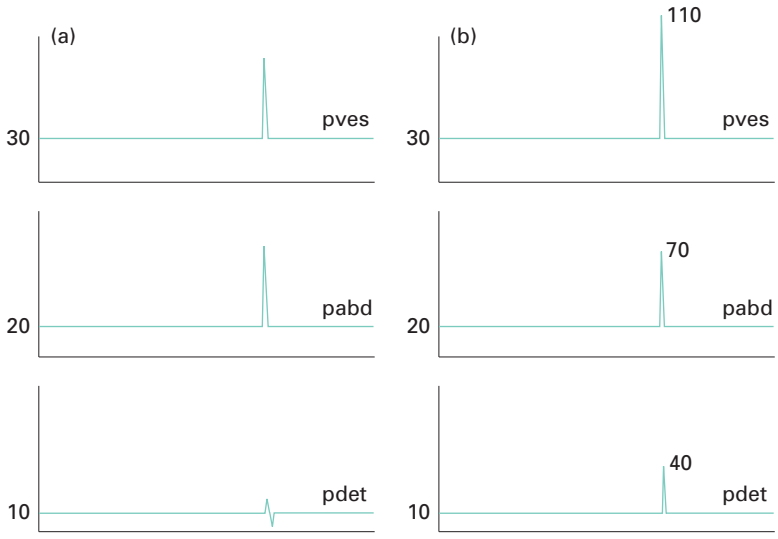

Fig. 9. a, Quality control: shows good subtraction of a single cough with a small (acceptable) artefact on the p_{det} trace. **b,** shows inadequate subtraction with a large cough artefact on p_{det}, which necessitates a check of the transducers and recording lines.

reduce the filling rate or even stop. If there is low compliance this may in part be due to filling too fast. Filling should be stopped for 2 min, when the pressure (p_{det}) stabilizes filling can recommence at a reduced rate. If the rate is changed or when the filling is stopped and restarted, there should be an indication on the trace. The patient must cough each minute and after voiding to ensure good quality control. The bladder is filled until the patient has a strong desire to void, but not over-full. The frequency-volume chart is a useful guide in determining the usual functional bladder capacity of the patient.

The study might demand that the leak-point pressure (LPP) is assessed during filling. This may be at a fixed volume, e.g. 200 mL (see below). If the patient is being assessed for incontinence, then it may be necessary to perform an exercise regimen at bladder capacity (depending on protocol), e.g. coughing when seated, and standing, walking, jumping and squatting/coughing (depending on mobility). Following this the patient voids, and is asked to cough after voiding to check that the catheters are in place and that pressures are recording accurately.

In many studies, and ideally in all investigations, a second fill/void cycle should be assessed. In this case, the bladder is not emptied after the first fill/void; the technique for the second fill and void should be identical to the first. At the end of the study, after voiding, the catheter is used to empty the bladder and the residual volume recorded.

Measurements during filling

Depending on the study, these comprise:

- The empty and full resting pressure (p_{det})
- The volume at the first desire to void, strong desire to void, urgency and bladder capacity; the maximum cystometric capacity is either the volume infused or the volume voided (plus any residual urine), whichever is the greater.
- The bladder capacity at the first unstable contraction (if any)
- The bladder volume at each leakage episode, the cause, i.e. BOA or GSI, and the volume leaked.
- The compliance, calculated as the volume infused divided by the change in pressure for the volume infused), e.g. if the volume infused = 400 mL, the empty resting pressure (p_{det}) is 5 cmH_2O, and the pressure at capacity (p_{det}) is 25 cmH_2O, then the compliance is $400/(25-5) = 20$ mL/cmH_2O.

Measurements during voiding

These comprise; Q_{max}, $p_{det}Q_{max}$, volume voided, residual urine and, if the protocol demands, p_{det}open and p_{det}min void. The BOOI (previously known as the Abrams–Griffiths number [4]) can be calculated from $p_{det}Q_{max} - 2Q_{max}$. Using the BOOI, patients can be categorized into one of three classes in the ICS nomogram [6], i.e. obstructed (BOOI $\geqslant 40$), slightly obstructed (BOOI 20–40) or unobstructed (BOOI $\leqslant 20$). The bladder contractility index (BCI) can also be calculated [4], where the BCI $= p_{det}Q_{max} + 5\ Q_{max}$. The BCI can be used to categorize bladder contractility into three classes [4], i.e. strong (BCI > 150), normal (BCI 100–150) or weak (BCI < 100). The bladder voiding efficiency percentage (BVE%) is then calculated as (volume voided $\times 100$)/maximum cystometric capacity [4].

Urethral function studies

The two common methods used to assess urethral function are urethral pressure profiles (UPPs) and leak-point pressures (LPPs) Traces can be obtained for both and should be annotated appropriately. For UPPs, the urethral closure pressure (UCP) depends on the subtraction of bladder pressure (p_{ves}) from urethral pressure (p_{ura}). The pressure recording used should indicate p_{ura}, p_{ves} and UCP. For LPPs, the exact time of leakage should be marked on the tracing and the pressure recording used should be indicated, i.e. p_{ves} for the Valsalva LPP (VLPP), p_{abd} for the abdominal LPP (ALPP) and p_{det} for the detrusor LPP (DLPP)

Urethral pressure profile catheters (using the Brown and Wickham technique) should be no larger then 10 F, with two opposed eye-holes 5 cm from the tip. A triple-lumen catheter, which allows the measurement of p_{ves} and p_{ura} and which also has a filling line, can be used. With microtip catheters, one or more transducers are mounted on the catheter, thus allowing p_{ves} and p_{ura} to be recorded simultaneously.

The UPPs are obtained with the patient supine; the bladder is empty or contains a standard volume, e.g. 100 or 200 mL. For the Brown and Wickham technique the UPP catheter is introduced and connected via a three-way tap to the infusion pump and transducer (Fig. 10). Fluid is flushed into the catheter from the transducer and the infusion pump set to 2 mL/min. The system should be checked for air bubbles and the patient asked to cough to ensure that there is good transmission of pressure. The catheter is then withdrawn at 1 mm/s; at least two successive measurements should be taken (two further profiles should be measured if the first two profiles differ by $> 10\%$).

Urethral pressure measurements

Variables measured for the female UPP (Fig. 11a) are the maximum urethral pressure (MUP), the maximum urethral closure pressure (MUCP, calculated

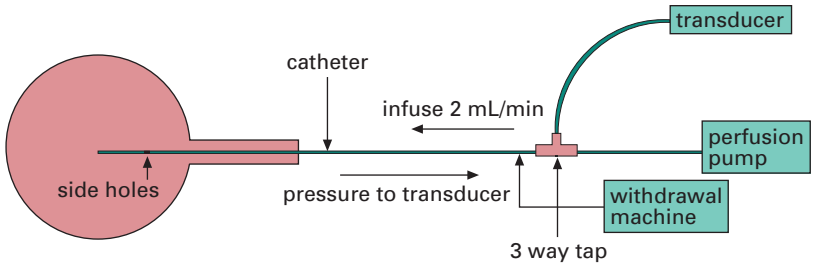

Fig. 10. The Brown and Wickham technique for urethral pressure profile measurements.

as MUP – p_{ves}), and the functional urethral length (FUL). For the male UPP (Fig. 11b), the measurements are MUP, MUCP and prostatic length (PL). The withdrawal speed and time scale must be recorded by the investigator.

Method and measurement of leak point pressure (LPP)

In stress–incontinent patients, leak point pressure can be recorded as abdominal leak point pressure (ALPP) or valsalva leak point pressure (VLPP) depending on the aims of the study.

Abdominal leak point pressure (ALPP)

- The bladder is filled to 200 mL with the patient sitting.
- Only the abdominal catheter is left *in situ*.
- A valsalva manoeuvre is performed whilst the patient observes the abdominal pressure on the monitor or trace.
- The patient is asked to gradually increase the abdominal pressure whilst the investigator checks for leakage. The abdominal pressure at which leakage occurs is recorded and marked on the trace.
- The test is performed twice and the lowest pressure at which leakage occurs is taken as the Abdominal Leak Point Pressure (ALPP).

Valsalva Leak Point Pressure (VLPP)

- The bladder is filled to 200 mL, with the patient sitting.
- Using an aneroid pressure gauge, the patient makes a seal around the mouthpiece with her lips. She is asked to blow into the mouthpiece (while relaxing her pelvic floor) and increase the pressure to 10 mmHg while the clinician looks for urinary leakage.
- If leakage is not demonstrated at this level, the patient is asked to increase the reading to 20, 30 mmHg until leakage is observed. The pressure gauge helps to show the patient how to increase the abdominal pressure.
- If leakage does not occur, then the patient may be able to achieve higher pressures without blowing into the gauge. The patient is shown the recording representing p_{ves} on the trace or monitor (the digital reading may be used) and is asked to increase p_{ves} in increments of 20 cmH_2O, by straining, holding the pressure for 5 seconds.
- Alternatively, the patient can be asked to gradually increase p_{ves}, by straining: in this situation either video is required or the investigator must view the external meatus to precisely time leakage.

If, using any of these methods, leakage is not observed, the bladder is then filled in increment of 100 mL and the process is repeated, until capacity.

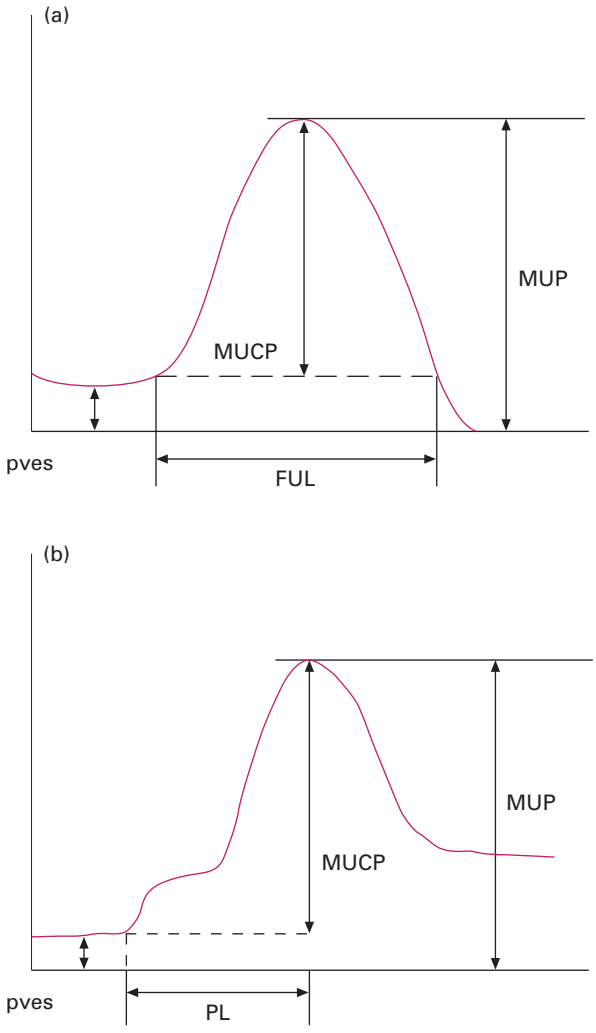

Fig. 11. a, Female and **b**, male urethral pressure profile measurements.

- The VLPP is the minimum increase in total bladder pressure pves that causes leakage in the absence of a detrusor contraction.
- The position of the patient must be noted, sitting up, semi recumbent etc.

Detrusor Leak Point Pressure (DLPP)

Detrusor leak point pressure (DLPP) has been used to assess urethral function in relation to bladder compliance in neurogenic patients. DLPP is the detrusor pressure at which leakage first occurs around a filling catheter. The position of all leak point pressures must be clearly indicated on the trace by the investigator.

Principles and procedure for the central review of urodynamic data

Investigator's procedure

Originals or copies (an original version should remain at the site) of traces will be sent to the central reviewer, for examination after each patient visit. Traces should not be faxed, as the quality is inadequate. Each trace should be identified by a study number, the investigator, a subject number (e.g. hospital number), visit date, visit number (1–10) and assessment number (e.g. first fill/void).

Urodynamic data forms should be completed, containing both the original results (generated by the urodynamic equipment) and corrected values resulting from a review of the traces by the original investigator. A copy of the form, together with the trace (or good-quality photocopy) should be sent to the QCC.

The examiner will review the trace and complete his/her part of the urodynamic data form (and enter the data onto a database if required). The completed form will be returned to the investigator for information and storage in the study file. All traces must contain the scaling on the *x*- and *y*-axis. Any problems/difficulties should be recorded and will be considered by the examiner.

There should be a short questionnaire (see Appendix) for all urodynamic studies, including urethral function studies, which all investigators must complete, giving details of any deviation from the study protocol and information on the position of the patient during filling, voiding and the UPPs. This should be attached to each trace that is sent for central review.

Urodynamic review

The following rules are typical for a central review of uroflowmetry. For traces with smooth curves with no significant artefacts affecting the Q_{max} values, the original value given by the free-flow equipment will be accepted as the result. Traces where the Q_{max} value is influenced by artefacts will be measured again using a ruler. The examiner will indicate the place on the curve where the Q_{max} value is measured by drawing vertical and horizontal lines on the free flow trace. The value is given to the nearest 1 mL/s (Fig. 5).

Traces with no automatic output from the free-flow equipment will be measured using a ruler, with the examiner adding indications as above. In case of doubt, only peaks that last for at least 2 s will be considered as true Q_{max} values. If the examiner decides that a certain trace cannot be properly examined because of poor readability or because it is not available for central review, the results will be excluded. Traces which for any reason are considered to be unreliable may be withdrawn by the examiner, the reason being stated. A completed central review form for each trace will be returned to the investigator for filing in the study file.

Cystometry procedure

The following measurements are usually those subject to central review, and all urodynamic traces will be measured again according to the grid on the paper or with a ruler by the examiner, who will indicate the position on the traces of the following measurements:

Filling cystometry: empty resting pressure (p_{det}), volume at first involuntary contraction, maximum cystometric capacity, pressure at maximum cystometric capacity (p_{det}), compliance, leakage volume caused by involuntary detrusor contraction, and/or GSI. If the empty resting pressure (p_{det}) is outside the range -5 to $+10$ cmH_2O the recording will be rejected unless there is a reasonable explanation. The volume at the start of the first involuntary contraction (the contraction must be $\geqslant 5$ cmH_2O) must be noted, whether this results in leakage or not. For consistency at central review, this will be the first involuntary contractions $\geqslant 5$ cmH_2O, measured as the increment above the empty resting pressure (p_{det}) and the volume at which this occurs will be either the volume infused or the volume voided plus residual urine, whichever is the greater.

The maximum cystometric capacity is the bladder volume when infusion is terminated, in response to the patient's experience of a 'strong desire to void' or 'urgent desire to void' or when further filling causes leakage and there is no further increase in cystometric capacity (stated as v_{cap}).

Voiding cystometry: According to the protocol, some or all the following measurements will be checked; Q_{max}, $p_{det}Q_{max}$, p_{det}open and p_{det}min void, and in men the BOOI, the BCI and the BVE%. Q_{max} will be measured according to the procedure for evaluating free-flow rates.

If the same Q_{max} is attained more than once, or if it is sustained for a period of time, then the point of $p_{det}Q_{max}$ is taken to be where the detrusor pressure has its lowest value for this flow rate [6]. A time delay of 0.5–1.0 s is assumed; this represents the time taken for urine to reach the flowmeter.

In controlled situations, pressures can be adjusted. Firstly, when the initial p_{det} (i.e. the p_{det} at the start of filling) is above or below the baseline all p_{det} measurements can be measured as an increment above the initial p_{det} reading (which must be in the range -5 to $+10$ cmH_2O). This means that if the initial p_{det} is $+5$ cmH_2O and the $p_{det}Q_{max}$ is 95 cmH_2O, $p_{det}Q_{max}$ would be corrected to 90 cmH_2O. This pragmatic decision ensures consistency of analysis technique, because p_{det} is totally dependent on the accurate recording of p_{ves} and p_{abd} which cannot be guaranteed. Secondly, if p_{abd} decreases during voiding and cannot be corrected, then p_{det} will be adjusted to take account of this.

Urethral pressure profiles

The readings will be taken from the reproducible profiles and therefore not the highest or lowest but the estimated mean of two similar profiles. The withdrawal speed and time scale must be indicated on the trace. The MUP will be measured from the baseline to the highest part of the curve, the MUCP as MUP $-$ p_{ves} and the urethral length as in Fig. 11a,b.

Leak point pressure

The ALPP and VLPP will be the minimum increase in p_{abd} and p_{ves}, respectively, to cause leakage; the LPPs must be clearly marked on the trace.

Ineligible recordings

Traces which for any reason are considered to be invalid may be withdrawn by the examiner with a reason stated. If a particular trace is withdrawn because of a problem during voiding, all voiding measurements will be considered invalid. Traces will be disqualified when: technical failures occur, e.g. if the catheters measuring either p_{ves} or p_{abd} are voided or displaced; traces go 'off scale' during voiding and cannot be interpreted; if there is no flow trace during voiding cystometry; if traces are of poor quality and/or if there is inadequate transmission of pressure, and are considered by the examiner to be unreadable. In cases where additional information is required, the central reviewer will contact the responsible investigator.

Final decisions

If there are large discrepancies among the assessment of the QCC, the final review and the investigator's assessment, the traces will be reviewed again, with the final judgement being given by the QCC.

Conclusions

A standard urodynamic protocol for any clinical trial that uses urodynamic measurements as either inclusion criteria or outcome measures, enhances the quality of the data obtained. The central review of urodynamic data by a QCC further enhances the value of the data by providing a single standard of interpretation. The overall quality of data in any trial can be further improved by selecting for participation only those centres whose traces submitted before the trial begins are of the highest quality. There are ethical issues around ensuring the highest quality of data, as it will reduce confidence intervals and thereby increase the power of the study, necessitating fewer participants.

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Appendix

Questionnaire

Was the protocol adhered to? Yes/No

If no, state reasons.....

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.....

Review of Cystometry Traces

What type of catheter was used? (specify)

Was the protocol infusion rate used? Yes/No

If NO state filling speed.....mL/min

Was more than one cystometry performed? .....(number)

What was the patient's position during filling cystometry?

	Fill 1	Fill 2
a	lying	lying
b	sitting	sitting
c	standing	standing

What was the patient's position during voiding cystometry?

	Fill 1	Fill 2
a	lying	lying
b	sitting	sitting
c	standing	standing

If the patient changed position during the cystometry study, e.g. the patient was filled lying and voided standing, was the height of the transducers adjusted to the level of the superior edge of the symphysis pubis? Yes/No

Review of urethral pressure profiles

Method: Brown and Wickham: Yes/No

Type of catheter .....

Microtip: Yes/No

Position: Lying/
Sitting

Review of Valsalva leak point pressure

Method: Pressure gauge Yes/No

Strain Yes/No

Position Lying
Semi-recumbent
Sitting

Bladder volume .....

Additional comments.....

.....

.....

Investigator..... Date.....