Good Urodynamic Practices: Uroflowmetry, Filling Cystometry, and Pressure-Flow Studies

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This is the first report of the International Continence Society (ICS) on the development of comprehensive guidelines for Good Urodynamic Practice for the measurement, quality control, and documentation of urodynamic investigations in both clinical and research environments. This report focuses on the most common urodynamics examinations; uroflowmetry, pressure recording during filling cystometry, and combined pressure–flow studies. The basic aspects of good urodynamic practice are discussed and a strategy for urodynamic measurement, equipment set-up and configuration, signal testing, plausibility controls, pattern recognition, and artifact correction are proposed. The problems of data analysis are mentioned only when they are relevant in the judgment of data quality. In general, recommendations are made for one specific technique. This does not imply that this technique is the only one possible. Rather, it means that this technique is well-established, and gives good results when used with the suggested standards of good urodynamic practice. *Neurourol. Urodynam. 21:261−274, 2002.* © 2002 Wiley-Liss, Inc.

Key words: urodynamics; standardisation; uroflowmetry; cystometry; pressure-flow studies

INTRODUCTION

A Good Urodynamic Practice comprises three main elements:

- A clear indication for and appropriate selection of, relevant test measurements and procedures
- Precise measurement with data quality control and complete documentation
- Accurate analysis and critical reporting of results

The aim of clinical urodynamics is to reproduce symptoms whilst making precise measurements in order to identify the underlying causes for the symptoms, and to quantify the related pathophysiological processes. By doing so, it should be possible to establish objectively the presence of a dysfunction and understand its clinical implications. Thus, we may either confirm a diagnosis or give a new, specifically urodynamic, diagnosis. The quantitative measurement may be supplemented by imaging (videourodynamics).

Urodynamic measurements cannot yet be completely automated, except for the most simple urodynamic procedure, uroflowmetry. This is not an inherent problem of the measurement itself, but is due to the current limitations of urodynamic equipment and the lack of a consensus on the precise method of measurement, signal processing, quantification, documentation, and interpretation. With the publication of this ICS Standardisation document on good urodynamic practice, it is expected that the necessary technological developments in automation will follow.

Urodynamics allows direct assessment of lower urinary tract (LUT) function by the measurement of relevant physiological parameters. The first step is to formulate the 'urodynamic question or questions' from a careful history, physical examination, and standard urological investigations. The patient's recordings of micturitions and symptoms on a frequency volume chart, and repeated free uroflowmetry with determination of post-void residual volume provide important

noninvasive, objective information that helps to define the specific 'urodynamic question' or questions, prior to invasive urodynamics such as filling cystometry and pressure-flow studies.

Recommendations for good urodynamic practice are bullet pointed, inset, and printed in bold.

RECORDING MICTURITIONS AND SYMPTOMS

A *Micturition Time Chart* records the time of each micturition. The usefulness of such a record is significantly enhanced when the voided volumes are recorded in a *Frequency Volume Chart*. The *Bladder Diary* adds to this the relevant symptoms and events such as urgency, pain, incontinence episodes, and pad usage. Recording for a minimum of 2 days is recommended. From the recordings, the average voided volume, voiding frequency, and if, the patient's time in bed is recorded, day/night urine production and nocturia can be determined. This information provides objective verification of the patient's symptoms, and furthermore, key values for plausibility control of subsequent urodynamic studies, for example, in order to prevent over-filling of the patient's bladder.

UROFLOWMETRY

Uroflowmetry is noninvasive and relatively inexpensive. Therefore, it is an indispensable, first-line screening test for most patients with suspected LUT dysfunction. Objective and quantitative information, which helps one to understand both storage and voiding symptoms are provided by this simple urodynamic measurement.

Adequate privacy should be provided and patients should be asked to void when they feel a "normal" desire to void. Patients should be asked if their voiding was representative of their usual voiding and their view should be documented. Automated data analysis must be verified by inspection of the flow curve, artifacts must be excluded, and verification must be documented. The results from uroflowmetry should be compared with the data from the patient's own recording on a frequency/volume chart. Sonographic estimation of post-void residual volume completes the noninvasive assessment of voiding function.

Normal Uroflow

Normal voiding occurs when the bladder outlet relaxes (is passive) and the detrusor contracts (is active). An easily distensible bladder outlet with a normal detrusor contraction results in a smooth arc-shaped flow rate curve with high amplitude. Any other shapes, such as curves that are flat, asymmetric, or have multiple peaks (fluctuating and/or intermittent), indicate abnormal voiding, but are not specific for it's cause.

It is assumed that it is normal for the mechanical properties of a relaxed outlet to be constant, and that the properties can be defined by the dependency of the cross-sectional area of the
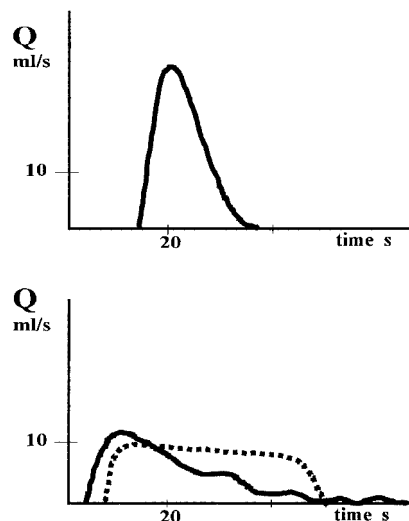

Fig. 1. Typical normal flow (**top**), constrictive flow (**bottom**, dotted line), compressive flow curve (**bottom**).

urethral lumen on the intraurethral pressure at the flow rate controlling zone (FRCZ). Typically, below the minimum urethral opening pressure (p_{muo}), the urethral lumen is closed. The lumen then opens widely with little additional pressure increase. With normal detrusor contractility and low intraurethral pressure, the normal flow curve is arc-shaped with a high maximum flowrate. (Fig. 1, top).

A normal flow curve is a smooth curve without any rapid changes in amplitude, because the shape of the flow curve is determined by the kinetics of the detrusor contraction, which arising from smooth muscle, does not show rapid variations. A decreased detrusor power and/or a constant increased urethral pressure will both result in a lower flowrate and a smooth flat flow curve. A constrictive obstruction (e.g., urethral stricture), with reduced lumen size results in a plateau-like flow curve. (Fig. 1, broken line).

A compressive obstruction with increased urethral opening pressure (e.g., benign prostatic obstruction) shows a flattened asymmetric flow curve with a slowly declining end part. (Fig. 1, bottom).

The same pattern may also originate from a weak detrusor in aging males and females. Fluctuations in detrusor contractility or abdominal straining, as well as variable outlet conditions, (e.g., intermittent sphincter activity) will lead to complex flow rate patterns.

Rapid changes in flowrate may have physiological or physical causes that owe to either changes in outlet resistance, for example, sphincter/pelvic floor contraction or relaxation, mechanical compression of the urethral lumen, or interference at the meatus, or to changes in driving energy, for example, abdominal straining. These intracorporeal causes lead to true flowrate changes. Rapid changes in flowrate may also be artifacts, when the flowrate signal is extracorporeally modified through interference between the stream and the collecting funnel, the flowmeter, movement of the stream across the

surface of the funnel, or patient movements. (see flow-curves in Figs. 3–8).

Accuracy of Uroflowmeters

Uroflowmetry measures the flow rate of the external urinary stream as volume per unit time in milliliters per second, (ml/s). The ICS Technical Report [Rowon et al., 1984] made technical recommendations with respect to uroflowmetry, but did not compare different flowmeters by specific testing. There are, however, differences in the accuracy and precision of the flow rate signals that depend on the type of flowmeter, on internal signal processing, and on the proper use and calibration of the flowmeter. The desired and actual accuracy of uroflowmetry should be assessed in relation to the potential information that could be obtained from the urinary stream compared to the information actually abstracted for clinical and research purposes. Some relevant aspects of the physiological and physical information contained in the urinary stream are outlined here.

The desired clinical accuracy may differ from the technical accuracy of a flow meter. The ICS Technical report recommended the following standards: a range of 0–50 ml/s for Q_{max}, and 0–1,000 ml for voided volume, maximum time constant of 0.75 s; an accuracy of $\pm 5\%$ relative to full scale, although a calibration curve representing the percentage error over the entire range of measurement should be made available. However, technical specifications from the manufacturers are rare and often not in accordance with ICS recommendations: this situation should be rectified.

Furthermore, as most flowmeters are mass flow meters (e.g., a weight transducer or rotating disk), variations in the specific gravity of the fluid will have a direct influence on the measured flow rate. For example, urine of high concentration may increase apparent flow rate by 3%. With X-ray medium, the flow rate may be overestimated by as much as 10%. These effects should be corrected by calibration software.

Thus, since the overall accuracy of flow rate signals will not be better than $\pm 5\%$, it would not be meaningful to report a maximum flow rate to a resolution better than a full milliliter per second (ml/s). Under carefully controlled research conditions, a better resolution may be possible by flowmeter calibration and instrument selection. However, such improvements in resolution may not be required for routine clinical applications. The dynamic properties of most flowmeters will be good enough for free uroflowmetry. When pressure flow data are analyzed, however, the limitation in signal dynamics should be taken into account because they will be different for pressure than for flow. Flow signals have a much slower response, and are less accurate than pressure signals.

Problems in Urine Flow Rate Measurement

The problems in measurement, as well as the information that can be abstracted from the flow rate signal are rather different for free uroflowmetry compared to combined pressure/flow recordings.

In free uroflowmetry, the shape of the flow curve may suggest specific types of abnormality, but reliable, specific, and detailed information about the cause for abnormal voiding cannot be derived from a flow curve alone. Only when uroflowmetry is combined with intravesical and abdominal pressure recordings does it become possible, from the pressure–flow relationship, to analyze separately the contributions of detrusor contractility and bladder outlet function to the overall voiding pattern. (Figs. 3–8)

Urine flow rate measurement is affected by a number of important factors.

Detrusor Contractility

As the voiding function reflects the interaction between the relaxed outlet and the contracting detrusor, variation of both will affect the flow. For steady outflow conditions, all variations in flowrate are related to changes in detrusor activity alone. The detrusor contraction strength varies neurogenically and myogenically, and can cause significant variability in urine flow rate measurements. (Fig. 5).

Bladder Outflow Resistance

If detrusor, contractility is constant, then changes in outflow resistance will lead to changes in flow rate, for example, in patients with detrusor–sphincter dyssynergia (Figs. 3, 7, 8).

Bladder Volume

As the bladder volume increases and the detrusor muscle fibers become more stretched, there is an increase in the potential bladder power and work associated with a contraction. This is most pronounced in the range from empty up to 150–250 ml bladder filling volume. It appears that at volumes higher than 400–500 ml, the detrusor may become overstretched and contractility may decrease again. Therefore, Q_{max} is physiologically dependent on the bladder volume. This dependency will vary between individuals and with the type and degree of pathology, for example, in constrictive obstruction, Q_{max} is almost independent of volume, and in compressive obstruction, the dependency becomes weaker with increasingly obstructed outlet conditions and lower flow rate.

Technical Considerations

The flow rate signal is influenced by the technique of measurement and by signal processing. The external urinary stream should reach the flowmeter unaltered and with minimal delay. However, any funnel or collecting device, as well as the flowmeter, will inevitably introduce modifications to

the flow rate recording. Physically, the external urinary stream breaks into drops not far from the meatus. This fine structure of the stream has a high frequency, which can be assessed by drop spectrometry, and contains interesting information. For standard uroflowmetry, however, such high frequencies should be eliminated by signal processing.

For free uroflowmetry, all intracorporeal modulations of the flow rate are physiological artifacts and should be minimized, for example by asking the patient to relax and not to strain. Nevertheless, certain dynamic patterns of intracorporeal modulations can provide information about functional obstruction, for example, typical patterns of the detrusor–sphincter dyssynergia, or abnormal straining. This information may be lost by excessive filtering or during analog to digital A/D conversion with a filter speed of less than 10 Hz. The precise interpretation of dynamic variations in the flow rate signal is only possible when the flow rate is viewed together with the simultaneously recorded pressure signals. Thus, only in combined pressure–flow recordings can the details of the flow signal be fully understood.

For the determination of the 'true' maximum flow rate value, particularly during free flow, such high frequency signal variations are more likely to be misleading, and consequently they should be suppressed electronically.

Recommendations for Uroflowmetry

In order to facilitate the recording of urine flow rate and pattern recognition of flow curves, it is recommended that graphical scaling should be standardized as follows:

- one millimeter should equal 1 s on the x-axis and 1 ml/s and 10 ml voided volume on the y-axis.

With respect to the technical accuracy of uroflowmeters, it is meaningful for routine clinical measurements to read flowrate values only to the nearest full ml/s and volumes to the nearest 10 ml.

In order to make electronically-read Q_{max} values more reliable, comparable, and clinically useful, we recommend internal electronic smoothing of the flow rate curve. It is recommended that:

- a sliding average over 2 s should be used to remove positive and negative spike artifacts.

If curves are smoothed by hand, the same concept should be applied. That is, when reading Q_{max} graphically, the line should be smoothed by eye into a continuous curve so that in each period of 2 s, there are no rapid changes. Such a smoothed, clinically-meaningful maximum free flow Q_{max} will be different (lower) from the peak value in the flow rate recording of electronic instruments currently available. (see Figs. 2, 5, 6, 8).

It is recommended that:

- only flow rate values, which have been 'smoothed', either electronically or manually, should be reported.

If a maximum flow value is determined electronically by simple signal peak detection without the recommended electronic smoothing, it should be labeled differently, $Q_{max.raw}$. Such raw data has meaning only if a detailed specification of the type of flowmeter used is given.

The interpretation of any dynamic variation (signal patterns) in free flow will rely on personal experience, can be only descriptive, and in general will remain speculative.

For the documentation of the results of uroflowmetry, the following recommendations are made:

- Maximum (smoothed) urine flow rate should be rounded to the nearest whole number (a recording of 10.25 ml/s would be recorded as 10 ml/s);
- Voided volume and post void residual volume should be rounded to the nearest 10 ml (a recording of a voided volume of 342 ml would be recorded as 340 ml);
- The maximum flow rate should always be documented together with voided volume and post void residual volume using a standard format: VOID: Maximum Flow Rate/ Volume Voided/Post Void Residual Volume.

For example, the automatically detected flows, $Q_{max.raw}$, are 16.6 and 21.3 ml/s with voided volumes 86 and 182 ml, respectively. The smoothed Q_{max} values are 8 and 17 ml/s and should be reported with voided volumes of 90 and 180, respectively, and the estimated residuals as VOID1 = 8/90/0 and VOID2 = 17/180/20 (see Figs. 2, 5, 6).

The adoption of these standards will aid the interpretation of uroflowmetry results. If data are not available, then a hyphen should be used, for example, if only the voided volume is known, VOID:—/340/—or if the voided volume was missing, VOID: 10/—/90.

- If a flow/volume nomogram is used, this should be stated and referenced.

Uroflowmetry data from other than free flow, for example, measured in combination with intravesical pressure should be reported with an additional descriptive index, p, i.e., $Q_{max.p}$, for pressure–flow recording.

INVASIVE URODYNAMICS: FILLING CYSTOMETRY, PRESSURE–FLOW STUDY OF VOIDING

Introduction

Invasive urodynamic procedures should not be performed without clear indications and the formulation of specific urodynamic question(s). This process will usually be aided by the a priori completion of a frequency volume chart and free uroflowmetry. There are certain key recommendations, which will lead to the performance of a successful urodynamic study.

- A good urodynamic investigation should be performed interactively with the patient. It should be established by
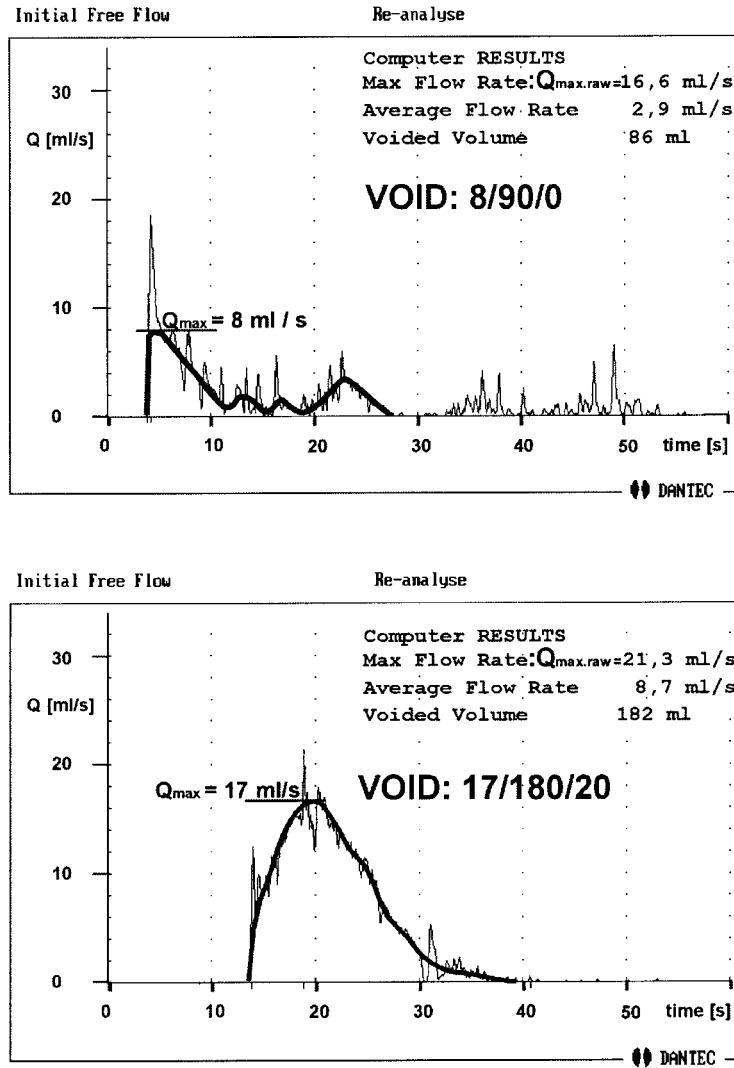
Fig. 2. Exclusion of artifactual spikes in the flow curve, $Q_{max.raw}$, and determination of a clinically relevant maximum flow rate, Q_{max}, by manual smoothing. The results from uroflowmetry should be reported in the standard format: $Q_{max}/V_{void}/V_{res}$.

discussion with the patient that the patient's symptoms have been reproduced during the test;

- There should be continuous and careful observation of the signals as they are collected, and the continuous assessment of the qualitative and quantitative plausibility of all signals;
- Artifacts should be avoided, and any artifacts that occur should be corrected immediately. It is always difficult and is often impossible to correct artifacts during a retrospective analysis. Furthermore, it is more time consuming than if the signals are continuously observed and tested at regular intervals and artifacts recognized during the urodynamic study and corrected.

At present, ambulatory urodynamic monitoring has to rely on retrospective quality control and artifact corrections. However, in principle, the same quality criteria apply for ambulatory urodynamic monitoring as for standard urody-

namics [van Waalwijk et al., 2000]. This makes a consensus on quality even more important, because only when such criteria are precisely defined can they be implemented in an "automated intelligent" ambulatory system.

Quality control relies on pattern recognition and a knowledge of normal values as well as prior identification of useful information obtained from noninvasive urodynamics and all other sources relevant for the urodynamic question. Thus, before invasive urodynamics, a frequency volume chart should be completed and multiple free flows should be evaluated. Useful information obtained from noninvasive testing includes typical voided volumes and post-void residual volumes as well as the expected values for Q_{max}. This information should be used for the control of subsequent invasive studies. Only by good preparation can it be assured that (a) the proper answers to the urodynamic questions will be obtained before the study is terminated and (b) necessary modifica-
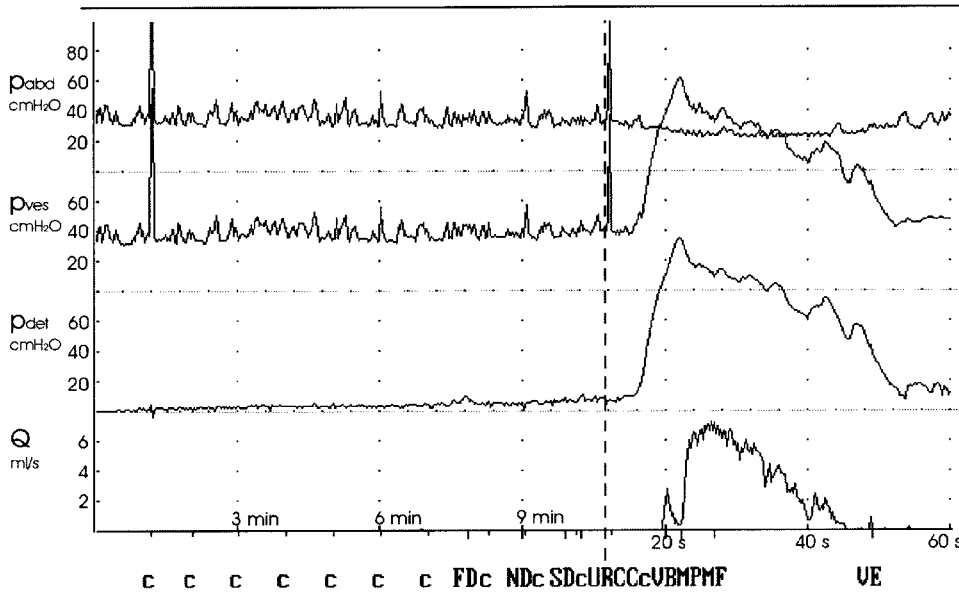
Fig. 3. Full recording of filling and voiding. Starting with initial values for p_{ves}, p_{abd} of 32 cmH$_2$O in the typical range for a standing patient with zero p_{det}; testing signal quality with a vigorous cough atbeginning, and regularly repeated (here less strong) coughs. Additionally, the pressure recordings show the typical pattern of a talking patient, while the p_{det} trace is unaffected; a weak contraction at first desire FD; another vigorous cough before voiding; beginning of flow shows dyssynergic sphincter activity as proven by decrease in flow with increase in p_{det}.

tions, additions, or repetitions of measurements will have been performed in order to derive the necessary information.

The effective practice of urodynamics requires: (a) a theoretical understanding of the underlying physics of the measurement, (b) practical experience with urodynamic equipment and procedures, (c) an understanding of how to assure quality control of urodynamic signals, and (d) the ability to analyze critically the results of the measurements. Because urodynamics deals largely with mechanical measurements such as pressure and volume and their related changes in time, and
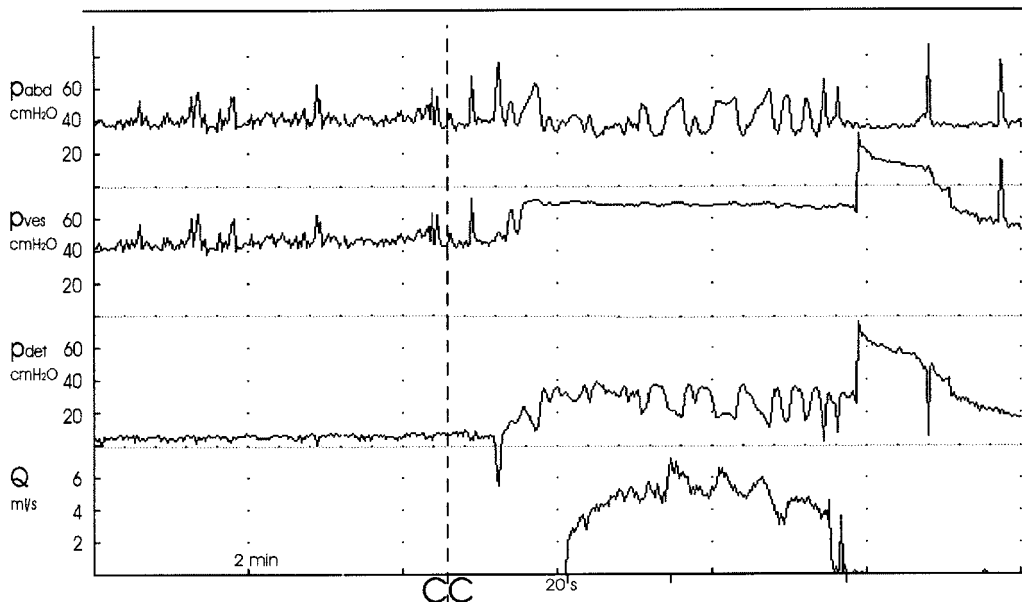

Fig. 4. Good recording quality until cystometric capacity CC is reached; at second cough before voding the intravesical signal is lost (no response in p_{ves}, negative spike in p_{det}). Dead p_{ves} — signal during voiding, which is "live" again only at second cough after voiding. Thus, pressure–flow study is lost. Careful observation of signals would have made it possible to interrupt the study immediately when signal failed and correct this problem before voiding starts.
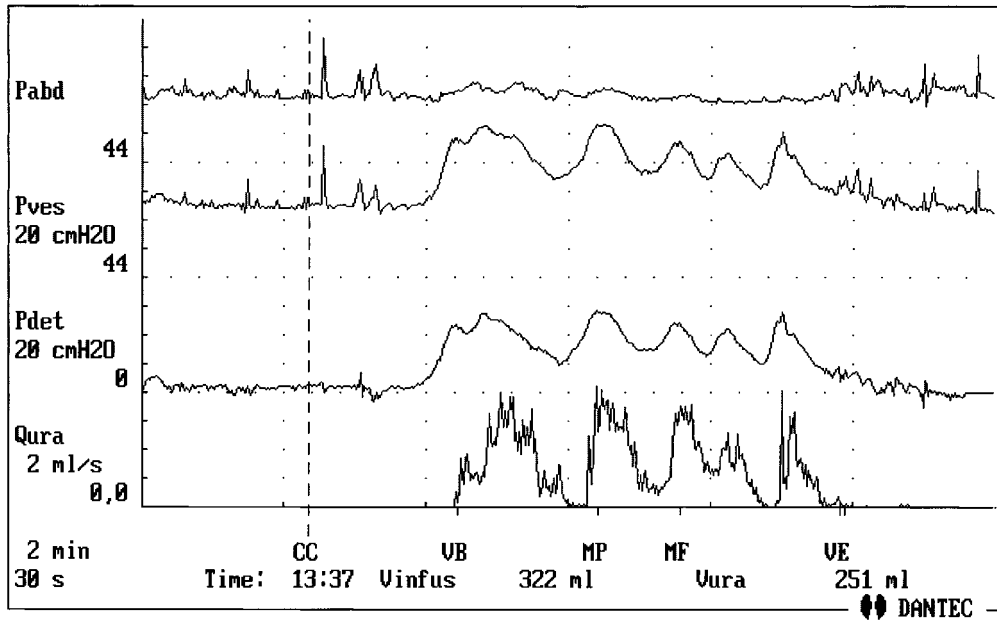
Fig. 5. Variable flowrate due to varying detrusor contraction strength. VOID: 7/250/70.

because many analytical models use mechanical concepts such as resistance to flow or contraction power, it is essential that the nature of these measurements and concepts, in particular for pressure and flowrate, are understood. Therefore, in addition to a comprehensive understanding of anatomy and physiology, some basic knowledge of biomechanics and physics is required.

The quality control of urodynamic measurements must be approached on a holistic basis. Different types and levels of data quality and plausibility control should be used: (a) on a physical and technical level, (b) on a biomechanical level, and (c) on a pathophysiological clinical level. A common problem in urodynamics is that clinicians often proceed immediately to a clinical interpretation, i.e., to level c without a critical analysis of the potential pathophysiological information content, without considering the plausibility of the signals (level a), without considering the biomechanical context of the measurements (level b), and without taking into account the physical properties of the
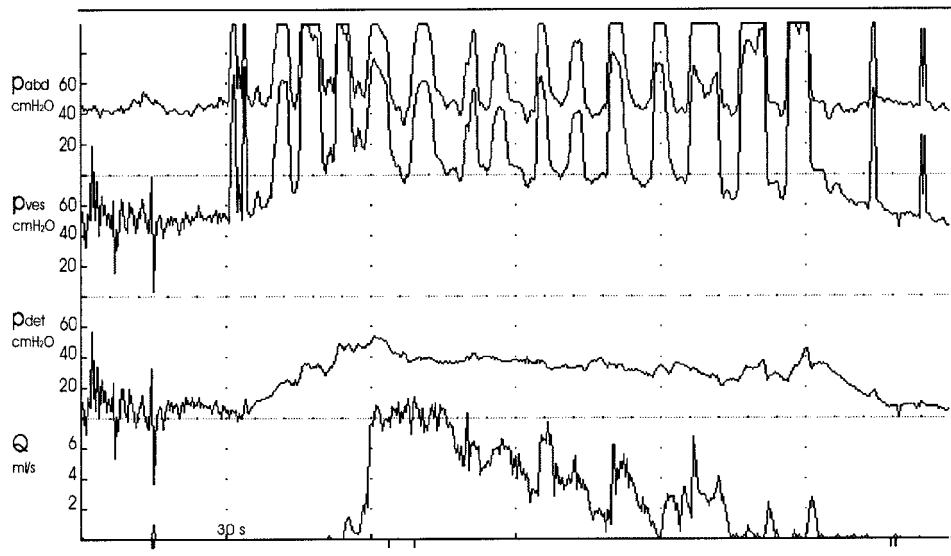

Fig. 6. The first part of the traces shows typical bi-phasic movement artifacts. The two coughs before voiding prove good recording quality. The typical picture of a unobstructed voiding: a weak detrusor contraction with p_{det} of 40 cmH$_2$O and a Q_{max} of 9 ml/s is supported by vigorous straining, which causes some variability in flow (VOID: 9/380/100).
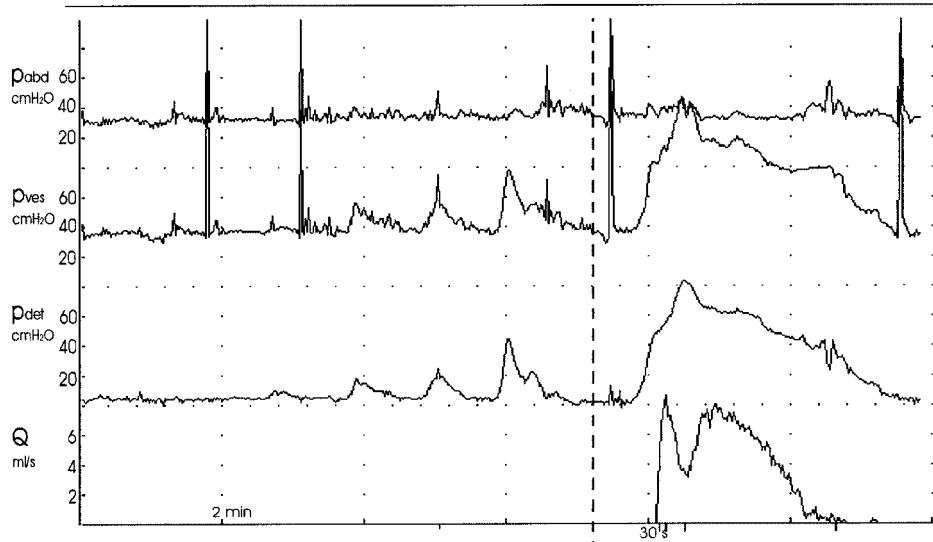
Fig. 7. A good recording showing the typical pattern of increasing detrusor overactivity and a dyssynergic event during voiding.

parameters, technical limitations, and accuracy of the signals. Therefore, it is recommended that:

- Invasive urodynamics should not be performed without precise indications and well-defined 'urodynamic questions' that are to be answered by the results of the urodynamic study.

Measurement of Urine Flow Rate During Pressure–Flow Studies

The usefulness of the concept of a FRCZ for data analysis requires that the recorded pressure and flow rate signal be synchronized with respect to the FRCZ [Griffiths et al. 1997]. Normally, no measurable time delay will exist between
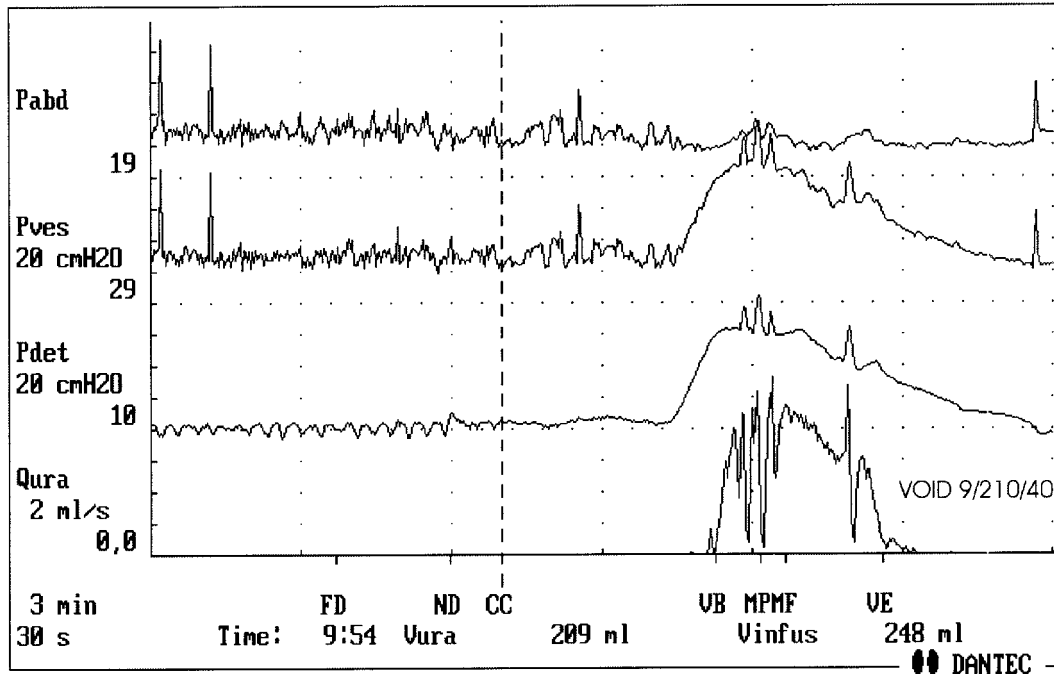

Fig. 8. High quality recordings allow detailed interpretation. The typical pattern of rectal activity becomes clearly visible in p_{det}. The flow artifacts can identified as dyssynergic events and manually corrected from $Q_{max.raw} = 11.2$ ml/s to $Q_{max} = 9$ ml/s.

the intravesical pressure signal and the actual flow at the FRCZ. However, a significant delay is to be expected for the typical urodynamic flow rate recorded extracorporeally. This delay will vary with anatomy, pathology, flow rate, and the set-up for measurement. Our understanding of the actual dynamics of flow rate changes is limited, and the relatively slow response of most flow meters may not be sufficient to match the dynamics of the much-faster pressure signal. The actual time difference may be from 0.5 to 2 s; the time delay between urethral closure and the end of any flow recording may be much longer, particularly in prostatic obstruction and terminal dribbling than between the opening of the urethra and the start of a flow rate signal. Therefore, we recommend the use of more descriptive terminology for synchronizing pressure and flow values, such as $p_{det.Qbeg}$ for the pressure at which flow begins instead of $p_{det.open}$, and $p_{det.Qend}$ when flow ends instead of $p_{det.close}$. The time delay correction needs to be considered when analyzing pressure flow studies [Griffiths et al. 1997].

In average, the maximum flow rate Q_{max} recorded during PF studies, ($Q_{max.p}$), is lower than during free flow (Q_{max}). This, however, is not due simply to a mechanical increase of outflow resistance by the intraurethral catheter, because such a difference is also found in suprapubic PF studies. A difference has also been reported between $Q_{max.p}$ during conventional and ambulatory urodynamics. This indicates more complex causes, possible psychogenic, but also physiologic, for example, that a difference in detrusor contraction strength may be involved, and that the fast filling rate used in clinical studies may lead to reduced contractility. This could also explain the difference in results between conventional and ambulatory studies.

Measurement of Intravesical and Abdominal Pressure

- It is recommended that there is strict adherence to the ICS standardization of zero pressure and reference height. Only then can pressure recordings be compared between patients and centers.

Zero pressure and reference height are concepts which are often confused in urodynamics. For example, by use of the misleading term "zero reference height". As both are independent features of pressure, they must be considered separately, and both must follow recommended ICS methodology.

- Zero pressure is the surrounding atmospheric pressure.

Zero pressure is the value recorded when a transducer is open to the environment when disconnected from any tubes or catheters, or when the open end of a connected, fluid-filled tube is at the same vertical level as the transducer. Only then can a "set zero" or "balance" be performed.

- The reference height is defined as the upper edge of the symphysis pubis.

The reference height is the level at which the transducers must be placed so that all urodynamic pressures have the same hydrostatic component. It is often argued that it does not make a difference for the most relevant parameter, p_{det}, if the same error is introduce to p_{ves} and p_{abd}, as they tend to cancel each other out. This is not an acceptable argument. The hydrostatic pressure is real and important, and inevitably plays a role in any intracorporeal pressure recording. Many important aspects of quality and plausibility control, such as typical resting value ranges at different patient position, are based on the proper recording of pressures, and will not apply if pressures are not recorded according to ICS standards. Also, it is only meaningful to subtract one pressure from the other, for example ($p_{ves} - p_{abd} = p_{det}$), when both are recorded to the same reference level.

Pressure Transducers

Urodynamic techniques were developed using external pressure transducers connected to the patient with fluid-filled lines, allowing easier compliance with the standards of correct zero and reference height. Catheter mounted pressure transducers, so-called microtip transducer catheters have become popular due to their apparent higher accuracy, better dynamic resolution, and their apparent independence from hydrostatic pressure. A catheter mounted pressure transducer is an advantage for dynamic recordings of urethral pressures during coughing (stress profiles) as well as for ambulatory urodynamics in mobile patients. Here only the application of catheter mounted pressure transducers for intravesical and abdominal pressure recordings will be discussed as urethral pressures are dealt with in a separate report [Lose et al., 2002].

All aspects of urodynamic pressure recording outlined in the preceeding section are valid and independent of transducer type. It is impossible to define the precise position of an intravesical and a rectal catheter mounted pressure transducers at to place them at any common level, and impossible to position them at the standard level of the upper boarder of the symphysis pubis. It has become popular to circumvent this problem by setting the catheter mounted pressure transducers to zero pressure when inside the body at the start of pressure recording. This, however, means that both the standard zero pressure as well the reference level are ignored, so that such recorded pressure cannot be compared between patients or centers. The fact is, the initial intravesical and abdominal resting pressures are real, are different between patients, and depend significantly on patient's position. Thus, there are significant potential errors; by ignoring the correct atmospheric zero pressure, an error of up to 50 cmH$_2$O, and as the reference height of the catheter mounted pressure transducers is usually undetermined, another potential error of 10 cmH$_2$O is possible for a full bladder can occur. In addition, when a study starts with zero abdominal pressure then the commonly observed abdominal pressure decrease at pelvic floor relaxation during voiding will evidently result in negative abdominal pressure values, and thus in p_{det} being higher than p_{ves}.

The same problems of apparent independence from the existing hydrostatic pressure also applies to air-filled catheters and/or connection tubings. Due to the absence of a water column between the balloon-covered opening on the catheter and the external transducer, the reference height in an air-filled system will refer to the position of the sensing balloon on the catheter and not to the external transducer.

- It is recommended that for intravesical and abdominal pressure recording external transducers connected to fluid-filled tubings and catheters be used. If microtip or air-filled catheters are used, any deviation from standard zero and reference level should be minimized and taken into account at the time of data analysis.

Urodynamic Catheters

Comparison between patients and urodynamic studies performed in different centers would be facilitated by the use of standard catheters. It is recommended that:

- For the measurement of intravesical pressure and for bladder filling, the standard catheter for routine urodynamics is a transurethral double-lumen catheter.

Only in small children and patients with severe constrictive obstruction (stricture) does suprapubic pressure recording have clear advantages. Intraurethral catheters should be as thin as possible, limited only by the practicality of insertion and by internal lumen sizes, which should be sufficiently large to avoid excessive damping of pressure transmission and to achieve the desired filling rate with standard pumps. A 6-Fr double lumen catheter is the smallest practical size at present.

The major advantage of a double lumen catheter is that the fill/void sequence can be repeated without the need for re-catheterization. Note that the use of a 6-Fr double lumen catheter can limit the infusion rate during cystometry to 20–30 ml/min, as a typical roller pump may not manage to transport a higher perfusion rate through such a small lumen. This can result in a incorrect filling volume being indicated by the machine, when the filling volume is calculated from the pump setting. For example, with a filling rate set at 60 ml/min and an actually achieved filling rate of 30 ml/min, the machine will show double the filling volume. Thus after voiding, a high calculated residual will occur. With some equipment, higher filling rates are possible; it is essential that any system should be critically tested to (a) measure the maximum filling rate that can be achieved by a particular catheter attached to an individual pump and (b) correct or calibrate the indicated infused volume.

The use of two separate tubes for filling and recording is less convenient. Removing the larger filling tube for voiding may appear to be an advantage because only a single small tube is left in the urethra. However, there are no data to suggest that, for example, in a compressive obstruction such as BPO, a 6-F catheter has detrimental influence on the pressure or flow data. There are, however, data suggesting that results from a single study may be misleading. A double lumen catheter facilitates a second fill/void study to establish reproducibility. Re-introduction of the separate filling tube for a repeated study is more invasive and complicated.

- The use of a rectal balloon catheter is recommended for the measurement of abdominal pressure, p_{abd}.

Although there are various methods for the successful recording of abdominal pressures, a flaccid, air-free balloon in the rectal ampulla gives a suitable signal for p_{abd} to determine a meaningful p_{det} when p_{ves} is measured synchronously ($p_{det} = p_{ves} - p_{abd}$). In females, vaginal recording may be more acceptable and provides comparable results. The recording of p_{abd} allows the measurement of any abdominal (i.e., perivesical) pressure component during changes in intravesical pressure. The role of the balloon is to maintain a small fluid volume at the catheter opening and to avoid fecal blockage, which can prevent or impair pressure transmission to the transducer. Additionally, as the rectal ampulla and the vagina are not homogeneously fluid filled spaces, the balloon prevents pressure artifacts arising from contact between the catheter opening and the wall tissue. The balloon serves this function best when it is filled only to 10–20% of its unstretched capacity. Overfilling and elastic distention of the balloon is the most common mistake in abdominal pressure recording. The resultant high balloon (not abdominal) pressure will produce a misleading pressure reading. Such an artificially-elevated balloon distention pressure can be avoided by making a small hole in the balloon, although this is unnecessary if the balloon is filled properly as described above. It is also possible to record reliable abdominal pressure with a very slowly perfused (<2 ml/min) open ended catheter. However, excessive fluid volume in the rectal ampulla may cause problems.

Equipment: Minimum Requirements for Filling Cystometry and Pressure–Flow Studies of Voiding

The ICS has not yet specified definite technical standards in respect of minimum requirements for filling cystometry and pressure flow studies beyond the ICS Technical Equipment Report [Rowan et al. 1997] and the appendix to the ICS document on pressure flow [Griffiths et al., 1997], where an data exchange software standard is recommended. Some further aspects will be discussed in more detail here.

Equipment Recommendations

The minimum recommended requirements for a urodynamic system are:

- three measurement channels, two for pressure and one for flow;
- a display (on printer and/or monitor) and secure storage of three pressures (p_{abd}, p_{ves}, p_{det},) and flow (Q) as tracings against time;

- infused volume and voided volume may be shown graphically or numerically;
- on-line display of pressures and flow, with adequate scale and resolution; scales must be clearly given on all axes; no information should be lost electronically when tracings go off-scale on display;
- possibilities to record standard information about sensation and additional comments (event recording).

Meaningful plausibility assessment and quality control is possible only when the measured and derived signals are displayed continuously as curves over time, without delay (in real time), as the examination proceeds. Each displayed curve and number should be labeled according to ICS standards with clear scaling of amplitudes and the time axis. The following sequential position of tracings is suggested: p_{abd} at the top, then p_{ves}, p_{det} and Q (see Figs. 3–8). It is least important when p_{abd} goes off-scale and is cut off (Fig. 6). Additional parameters such as EMG, bladder filling, and voided volumes can be displayed either as curves or digitally as numbers.

The following minimum technical specifications are recommended:

- Minimum accuracy should be ± 1 cmH$_2$O for pressure and $\pm 5\%$ full scale for flow and volume;
- Ranges of 0–250 cmH$_2$O, 0–25(50) ml/s, and 1,000 ml for pressure, flow, and volume, respectively;
- The software must ensure that no information for pressures up to 250 cmH$_2$O and for flow rates up to 50 ml/s is lost internally even when not displayed and that off-scale values are clearly identified;
- An analog/digital (A/D) frequency of 10 Hz per channel as the lower limit for pressure and flow;
- A higher frequency (minimum 20 kHz) is necessary for recording EMG;
- Calibration of all measurements should be possible.

The scalings should be kept unchanged as much as possible, because urodynamic data quality control is based on pattern recognition, and the recognition of patterns depend on scaling. Therefore, it is recommended that:

- During recording and for analysis, minimum scaling for pressure be of 50 cmH$_2$O per cm, for flow 10 ml/s per cm, and for the time axis 1 min/cm or 5 s/mm during filling and 2 s/mm during voiding.

To enable a retrospective judgment of the curves, urodynamic measurements should be documented as curves over time with comments and explanations. It is usually insufficient to document urodynamic measurements by a few numerical values alone. The same amplitude of scaling should be used for all documentation, although the time axis may be compressed. Only if there is no relevant information to be lost by reducing resolution, for example, during filling, the time scale can be compressed.

For a print-out, maximum full scale deflections of 200 cmH$_2$O, 50 ml/s, and 1,000 ml are sufficient for pressure, flow and volume, respectively. In most cases, half the maximum full scale will be sufficient to show all relevant parts of curves. Line resolution should be better than 0.10 mm.

During interventions, for example, interruption of bladder filling or manipulation of catheters, the continuation of both measurement and recording must always be possible.

On-line recording of comments should be possible, to complete the documentation.

Calibration of Equipment

The need to calibrate pressure transducers, flowmeters, and pumps cannot be stated; simply "yes" if there is a need or "no" there is not. The specification of the manufacturer should be studied. Two aspects must be considered: the intended accuracy of the system and the investigator's experience with the system. If a new system is installed or new transducers are being used, it is recommended that regular calibration be carried out. If experience with daily calibration shows that the potential error is small (e.g., <2 cmH$_2$O), then it will be sufficient to calibrate once a month. However, calibration should not be ignored and good urodynamic equipment makes it technically possible to perform a calibration. Calibration should not be confused with simple 'zero balancing', which is only one part of a calibration. In addition to setting the zero, it must possible to check and adjust the amplitudes of all measurement channels, i.e., to calibrate all signals.

Calibration of a flowmeter can be achieved by pouring a precisely measured volume at a constant flow into the flowmeter, typically 400 ml in 20–30 s (at 15–20 ml/s) and checking the recorded volume. Special constant-flowrate bottles are available for flow calibration. Similarly, one can test a pump by measuring the time to deliver a known volume, for example, 100 ml into a measuring cylinder. It is recommended that pump calibration be performed with the filling catheter connected. Such a pump calibration can only be as good as the cylinder used, which needs to have good resolution and be accurate. Some measuring beakers that are usually available in clinics are not accurate.

Pressure Signal Quality Control: Qualitative and Quantitative Plausibility

It is very important to observe and to test signals carefully and to correct any problems before starting the urodynamic study. If the signals are perfect at the beginning of the study, they usually remain so without the need for major intervention. If the signals are not perfect, remedial action must be taken. If a quality problem does not disappear at once, when filling commences, it will usually deteriorate further during the study.

Conscientious observation of the patient and of the signals, in particular p_{det}, during all parts of the study, together with

continuous signal testing, are the keys to high quality urody-namics. The first aim is to avoid artifacts and the second to correct the source of all artifacts immediately when they occur.

The following three criteria form the minimum recommen-dations for ensuring quality control of pressure recordings:

- Resting values for abdominal, intravesical, and detrusor pressure are in a typical range (see below);
- The abdominal and intravesical pressure signals are 'live', with minor variations caused by breathing or talking being similar for both signals; these variations should not appear in p_{det};
- Coughs are used (every I min. or, for example, 50 ml filled volume) to ensure that the abdominal and intravesical pres-sure signals respond equally. Coughs immediately before voiding and immediately after voiding should be included.

When standards are followed, i.e., with the transducer zeros set to atmospheric pressure, and the transducers placed at the level of the upper edge of the symphysis, a typical range for initial resting pressures values for p_{ves} and p_{abd} is (Schäfer, unpublished communications):

- supine 5–20 cmH$_2$O.
- sitting 15–40 cmH$_2$O.
- standing 30–50 cmH$_2$O.

Usually both recorded pressures are almost identical, so that the initial p_{det} is zero, or close to zero, 0–6 cmH$_2$O in 80% of cases and in rare cases up to 10 cmH$_2$O [Liao et al., 1999].

All initial pressure values should be verified and patients' position should be documented on the urodynamics trace.

All negative pressure values, except when caused by rectal activity, should be corrected immediately. It should always be kept in mind that p_{abd} is recorded not to know the actual rec-tal pressure, but to eliminate the impact of (abdominal) pres-sure changes on p_{ves}. The principal aim is to determine the detrusor pressure, p_{det}, which is the pressure in the bladder without the influence of abdominal pressure. Therefore, p_{det} cannot be negative.

By talking to the patient during the study, the proper dynamic response in the pressure signals can be observed and is "automatically" documented (see Figs. 3, 4, 8).

Problem Solving

If either detrusor or rectal contractions occur, the recorded pressures in p_{ves} and in p_{abd} will be different. Such changes can be identified and interpreted with sufficient accuracy and reliability only when the patient is observed and the relation between signal changes and patient sensation/activity are checked for plausibility and documented. Any pressure change caused by smooth muscle contractions will show a "smooth" pattern, (Figs. 5, 7, 8) i.e., there should be no rapid ("*stepwise*") changes (Fig. 4). If pressures increase or decrease step-wise, or with a constant slope over a long period of time,

a nonphysiological cause, such as catheter movement, should be considered.

If a sudden drop or increase occurs in either the p_{ves} or p_{abd} signal, the usual cause is the movement, blockage (Fig. 4), or disconnection of a catheter. When the patient changes posi-tion, sudden changes in resting values occur and are seen equally in both pressure signals. If p_{ves} (without change in p_{abd}) increases slowly—as typical for a low compliance blad-der—it is important to test for any other possible cause for a slow pressure increase. One cause could be a problem with the intravesical catheter measurement, for example, the hole for the pressure conducting lumen is slowly moving into the blad-der neck region. This should be assessed by asking the patient to cough, if there is no other apparent artifact. Furthermore, it is recommended that bladder filling is stopped, if the filling rate was above a physiological limit of 10 ml/min. If the value of p_{ves} drops after filling is stopped, it is likely that 'low com-pliance' was, at least in part, related to fast filling.

There are several common problems that must be solved before the study is started or when observed during a study:

Problem: Initial resting p_{det} is negative, for example, −5 cmH$_2$O Possible explanations:

- *because p_{abd} is too high*

  Solution: If p_{ves} is in the typical range, and both pressures are 'live', open the valve in the abdominal line and drain 1 or 2 drops from the rectal balloon filling volume. This will usually cause p_{abd} to fall to a proper value. If not, gently re-position the rectal balloon and/or make a small hole in the balloon.

- *because p_{ves} is too low*

  Solution: This may be due to air bubbles trapped in the cathe-ter, the catheter not being in the bladder, or the catheter being blocked/kinked. Gently flush through the p_{ves} line (max. 10 ml). It is very important to flush slowly while obser-ving the pressure signal because pressures above 300 cmH$_2$O may damage the transducer. If this does not solve the pro-blem, add some more volume to the bladder via the filling lumen. If resistance to filling is high and it does not drain easily when opened, it will be necessary to check catheter position, and to re-position the catheter, if necessary.

Problem: Initial p_{det} too high, for example, 15 cmH$_2$O Possible explanations:

The key problem here is indicated by the measurement of 15 cmH$_2$O. The situation is different from the clear state-ment that 'p_{det} cannot be negative', as we do not have a defi-nite upper limit for the normal maximum 'resting' value for p_{det}. Thus, we can only follow the present guidelines that in most tests, in an empty bladder p_{det} is between 0–5 cmH$_2$O, and in some 90% it is between 0–10 cmH$_2$O. For any higher value, stringent plausibility checking must be applied. If the patient has no detrusor overactivity, a p_{det} of 15 cmH$_2$O is unlikely to be valid and there may be a signal problem. First

check, if p_{abd} and p_{ves} are in the expected ranges. For example, if in a standing patient, initial p_{ves} is 30 cmH₂O and p_{abd} is 15 cmH₂O, then by experience the value of p_{abd} is too low (because p_{abd} is too low). If in a supine patient p_{abd} is 10 cmH₂O and p_{ves} is 25 cmH₂O, then the value of p_{ves} is too high (because p_{ves} is too high). Check the zero balance and proper signal response to coughing for both signals.

- *because p_{abd} is too low*
  Solution to p_{abd} being too low: Very slowly flush the rectal balloon with 1 or 2 ml.
- *because p_{ves} is too high.*
  Solution to p_{ves} being too high: This problem can be related to a misplaced catheter, a kink in the catheter, or contact with the bladder wall in an empty bladder, which occludes the eyehole(s) of the catheter. Proceed according to the solution for p_{ves} being too high, in the first example above.

If no signal problem can be identified, the clinical study may be started, but the p_{det} signal deserves particular attention. If compliance is normal and the bladder normal at filling, then it is very important to record and check, for some period after the micturition, the post-voiding resting value of p_{det}. Only if an elevated p_{det} is perfectly reproducible for repeated filling and voiding studies can it be accepted. However, it is most likely that a high resting p_{det} will not be reproducible and will be corrected by the measures described above.

In summary, if any resting value or cough response does not fit the usual values or patterns, it should be corrected before bladder filling is started. If this is not possible, the signals must be observed even more carefully and every effort made to reveal the potential source of error or artifact during the study.

Retrospective Artifact Correction

In principle, a good p_{det} signal requires only that p_{ves} and p_{abd} show the same fine structure and quality of signals before filling, during filling, and after a voiding. (Figs. 3, 4, 7, 8) Both p_{ves} and p_{abd} must have the same zero and reference level. The most common mistake is to set *(balance)* the initial pressure values of p_{ves} and p_{abd} to zero with the catheters connected to the patient instead of setting zero to atmospheric pressure. This results in incorrect p_{ves} and p_{abd}. If this is done, urodynamic studies cannot be compared between centers and between patients. Although it may seem convenient and easy to start with a value of p_{det} as zero, this practice will lead to problems later in the test. As soon as pelvic floor relaxation occurs, which is particularly common during voiding, the value of p_{abd}, if starting at zero, becomes negative. With a negative p_{abd}, p_{det} will be higher than p_{ves}, a conceptually meaningless result. Furthermore, it will then be impossible to correct a negative p_{abd}. Cough tests at regular intervals, particularly before voiding and after voiding, document the dynamic response of the pressure channels and are fundamentally important.

A typical physiological artifact that can be easily recognized is a rectal contraction. Rectal contractions are usually of low amplitude and may or may not be felt by the patient (Fig. 8). The value of p_{abd} shows a phasic rise with no change in the p_{det} signal—a potentially confusing fall in p_{det} results from the electronic subtraction, but this is, of course, an artefact. Usually rectal contractions are relevant only because they may be misinterpreted as detrusor overactivity (Fig. 8): they have no relevance to voiding.

Biphasic spikes as a response to cough tests are another example of artifacts that are easy to correct. However, any other artifacts such as a signal which is nonresponding (dead), has stepwise changes in pressure, or has negative pressures, often cannot be corrected or can be corrected only with a lot of speculation about the underlying causes of the problem. Studies with such artefacts, should be repeated see the next section).

Retrospective corrections require the same strategies for plausibility control as during recording, but then they are much more difficult and less successful to perform.

A few common artifacts (e.g., rectal activity, biphasic spikes at cough tests, or insufficient p_{abd} response during straining) can be accepted during the study as they can be corrected retrospectively. Usually, this is easier to do manually than through a computerized system.

Urodynamic Computer Software

Computer applications should allow the easy use of even the most complicated analytical algorithms. However, most of the software offered by the urodynamic equipment industry is neither original nor validated. The software may, in fact, not do what the original developer(s) of the algorithm intended. Therefore, it is recommended that:

- When analytical urodynamic software is used to perform data analysis according to any published concept, the source of the software should be specified. It should also be clearly stated if the software has been validated, i.e., proven to provide results consistent with the algorithms to which the analyses are attributed.

STRATEGY FOR REPETITION OF URODYNAMIC TESTS

- It is recommended that a urodynamic test should be repeated if the initial test suggests an abnormality, leaves the cause of troublesome lower urinary tract symptoms unresolved, or if there are technical problems preventing proper analysis.

It may not be necessary, however, to repeat a study, which beyond any doubt, confirms the expected pathology, for example, detrusor overactivity which correlates with the patient's symptoms. However, if the study is inconclusive, then the

consequences of not finding a clear answer to the urodynamic question(s) should be considered. If an invasive therapy is planned, the urodynamics should be repeated. Therefore, it is necessary to analyze the signals during the study and document the study immediately upon its conclusion. Only then is it possible to be sure that the urodynamic study is of a quality that answers the urodynamic question and provides an understanding about the patient's clinical problem. Therefore, it is recommended that:

- The urodynamic findings and the interpretation of the results should be documented immediately after the study is finished, i.e., before the patient has left the urodynamic laboratory. Doing so allows for a second test if required.

The analysis of a good study is easy and straight-forward. Indeed, an easy analysis actually is the key criterion for good urodynamics. A good study is one that is easy to read and one from which a any experienced urodynamicist will abstract the same results and come to the same conclusions. For computerized analyses, high data quality is even more important than for manual graphical data analysis. Efforts to achieve urodynamic data of high quality during the study will produce great benefits at the time of data analysis. The future development of urodynamic equipment and software should force investigators to conduct proper on-line data quality control. Analysis of ambulatory studies will remain problematic, as it is less easy to conduct on-line assessment of quality, and analysis is time consuming. Hence, it will be necessary to ask the patient to return, on another occasion, should the investigation require repeating, for whatever reason.

CONCLUSIONS

This is the first report of the ICS Standardization committee of Good Urodynamic Practice. The authors are well aware that this is just a first step and many more will have to follow. Only the essential aspects are considered, but if these basic standards are followed, the quality of urodynamic studies will be significantly improved.

ACKNOWLEDGMENTS

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