



INDIAN
CONTINENCE
FOUNDATION

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EDITORIAL

Preservation of Urinary Continence is one of the predominant urological concerns globally and this explains the surfeit of exclusive for a and societies dealing with all facets of the issue.

The formation of the Indian Continence Foundation in 1998 reinforces this trend and affords a platform for purposeful interaction between professionals and groups interested in this critical area. ICF News Letter is evidently designed to catalyse this interaction and disseminate the current strategic concepts related to urinary incontinence.

The current issue has many useful materials which should interest consultants as well as postgraduates. One such insertion is Dr. Nitin Kekres's "Urodynamic Equipment – What to Buy". He evaluates the currently available Urodynamic equipments and succinctly separates grain from chaff. This paper will certainly help those who contemplate setting up Urodynamic infrastructure in making the right choice without being overwhelmed by marketing strategies. 'Good Urodynamic Practice' and 'Outcome Measures in BPH' are other papers in this issue packed with useful and practical information.

I have no doubt that the inaugural issue will positively impact and influence those interested in Urinary incontinence and allied areas.

K. Sasidharan
Manipal

"GOOD URODYNAMIC PRACTICE, GUP"

Werner Schafer, Aachen

(Urodynamic studies are important in the evaluation of voiding dysfunction and incontinence. Unless the equipment, study protocol and reporting terminology are standardised, this tool is likely to confound rather than assist the physician. This article is adapted from a draft for standardisation prepared for the International Continence Society - Editors)

Good Urodynamics Practice comprises three main elements:

1. Careful indication and selection of test parameters and procedures.
2. Precise measurement with data quality control and complete documentation
3. Accurate analysis and critical reporting of results.

General Ideas and Aims:

Traditionally, dysfunction of the urinary tract has been deduced from investigations of symptoms and morphological / anatomical changes, assumed to be closely related to or even responsible for storage and voiding dysfunction. Urodynamics allows direct assessment of lower urinary tract function by measurement of relevant physiological parameters. However, the first step is to formulate from a careful history, physical examination and standard urological investigations the "urodynamic question". Bladder diary and repeated free uroflowmetry with determination of post-void residual volume provide important information to define the "urodynamic question" as specific as possible.

Bladder diary (frequency / volume chart)

A record documenting voided volumes with time, fluid intake, and other information such as urgency or urine loss is most helpful. Ambulatory flowmeters may enhance such a documentation. A time period of at least two days to a week is recommended.

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Derived parameters are bladder capacity or typical volume voided, voiding frequency, day / night diuresis, are important values for plausibility control of subsequent urodynamic studies.

Then the aim of clinical urodynamics is to reproduce symptoms under the condition of precise measurement in order to identify the underlying causes for the symptoms, to quantify the related pathophysiological parameters, and in this way objectify the dysfunction and understand the clinical problem and either confirm a diagnosis or give a new specifically urodynamic diagnosis. The measurement may be supplemented by imaging. (videourodynamics).

Urodynamics is not an investigation which can be completely automated with the current equipment, except a most simple urodynamic procedure such as uroflowmetry. Some of these problems are related to current equipment and may be solved by improved technology on the basis of a consensus on measurement, signal processing, quantification, documentation, and interpretation, as is approached by this ICS Standardization on GUP.

UROFLOWMETRY

Recommendation : Uroflowmetry is non-invasive and relatively inexpensive. Therefore it is suitable as a first line screening test for objectivation of storage and voiding LUTS in all patients. Adequate privacy and a “normal” desire to void should be assured. Patient’s perception of this specific voiding may be documented. The recording can be automated, but not (yet) the data analysis.

Except for definitely normal results, the reliable interpretation requires repeated measurements and a careful plausibility check with redundant information such as “frequency” and “volume voided” from symptom questionnaire and bladder diary. Proper verification of any automated flow analysis should be documented. Sonographic estimation of post-void residual volume will complete the assessment of voiding function.

Uroflowmetry measures the flowrate of the external urinary stream by volume per unit time in millimeter

per second (ml/s). There are some recommendations from an ICS Technical Standard, but not to an extend that would allow to compare different flowmeters by some specific values. Therefore, we can only state that there are differences in the accuracy of the flowrate signals which depend on type of flowmeter, on internal signal processing, and on proper use and calibration. The actual and desirable accuracy of uroflowmetry should be viewed with respect to the potential information contained in the urinary stream and the information actually abstracted for clinic and research. Thus, we first will outline some relevant aspects of the physiological and physical information contained in the urinary stream.

Normal Uroflow :

Normal bladder voiding occurs when the bladder outlet relaxes (is passive) and the detrusor contracts (is active), so that the shape of the urinary flowrate curve reflects mainly the contractile performance of the detrusor.

At low intraurethral pressure level the normal flow curve is arc-shaped with a high flowrate. An increased urethral pressure level and / or a decreased detrusor power will both result in lower flowrate. A constrictive obstruction with reduced lumen size results in a plateau-like flow curve, i.e., shows rather constant flow values over most voiding time: a compressive obstruction with increased urethral opening pressure shows a flattened asymmetric flow curve with a slowly declining end part. Modulation of detrusor contractility and abdominal straining as well as variable outflow conditions, e.g. by sphincter activity, will lead to complex flowrate patterns. A normal flow curve is a smooth curve without any rapid changes in amplitude.

Recommendations :

Accurate reading of flowrate curves and even more so the recognition of patterns relies on the graphical scale. A time axis of 1 s per mm (or 1 mm per s) and an amplitude of 1 ml/s or 10 ml per mm are recommended. With respect to the technical accuracy of uroflowmeters it is not



meaningful to read values with a resolution of more than 0.5 ml/s for flowrate and of more than 10 ml for volumes, except in carefully controlled research studies.

Physiological Problems.

As the voiding function reflects the interaction between the relaxing outlet and the contracting detrusor, variation of both will affect the flow. For given outflow conditions all variation in flowrate are related to the detrusor alone. The detrusor contraction strength varies neurogenically and myogenically and can cause significant variability in uroflowmetry, so that at least all borderline cases require repeated measurements.

Within the low volume range, the maximum detrusor contraction power and work will increase with more pre-stretch of the detrusor by filling volume. This is most pronounced in the range up to 150-250 ml bladder filling volume. It appears that at filling volume higher than 400-500 ml the detrusor may be over-stretched and contractility decreases again. This will directly reflect on Qmax being physiologically dependent on the bladder filling volume. This dependency will vary interindividually and with type and degree of pathology: e.g. in constrictive obstruction Qmax is almost independent from volume, and in compressive obstruction the dependency becomes weaker with increasing obstruction.

URODYNAMIC EQUIPMENT – WHAT TO BUY?

Nitin Kekre

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CMCH, VELLORE.

Urodynamics has become an essential tool in modern urological practice. Its purpose is to define the pathophysiology of urological symptoms. This is necessary as the bladder has a very limited way of expressing its

pathology and has hence been aptly named as an “unreliable witness”. Urodynamic evaluation consists of a number of tests of varying degrees of complexity that can be performed individually, or in combinations depending upon the clinical problem. But properly performed urodynamic test is the single most important tool for an accurate diagnosis of disturbances of micturition.

The last decade has witnessed a “CHIP” revolution which has changed the composition of urodynamic equipment. Numerous commercially available urodynamic machines are in the market, and this produces a problem for the first time buyer. He is faced with several questions. Which is best machine? Do I need multichannel urodynamics? What about UP & EMG? Should I buy the multichannel video urodynamic etc., etc.? Unfortunately there is no simple answer to these questions. In my view complete multichannel video urodynamic is required in a managing complex tertiary neurological problems. For standard urological practice a simple subtracted two channel machine is more than enough. It gives the subtracted detrusor pressure reading. Similarly urethral pressure profile and EMG are not routinely helpful and have very limited clinical utility. Apart from these factors the cost of equipment is a crucial factor. The cost / benefit ratio also needs consideration.

The basic tool is a cystometrogram and uroflowmeter. They are the minimum essential feature of any urodynamic system.

UROFLOWMETER

It measures the flow of urine. Commercially available flow meters are based on following methods:

1. Weight transducer

Method	Mechanisms of Function	Advantages	Disadvantages
Weight	Measuring the weight of the collected fluid	Accurate irrespective of site of stream impact	Sensitive to mechanical disturbances. Density must be set.
Electronic Dip-Stick	The electrical capacitance of a dipstick mounted in the chamber changes as volume changes	Least expensive No mechanical parts	Relatively large variation in volume & flow rate calibration. Density must be set.
Rotating Disc	The voided urine is directed onto a Rotating disc. The power required to keep a rotating disc rotating at a constant rate is measured and is proportional to the mass flow rate of the fluid.	Accurate and reliable, insensitive to mechanical disturbances	Affected by site of stream impact

Cystometrogram (CMG) Equipment: Numerous CMG machines are available in India. Dantec, Weist, Laborie are all easily available. All of them provide the basic information and offer various other software packages. The modular concept of urodynamic machine is attractive as it offers the option of further development. Detailed discussions of individual machine is not within the scope of this article. But at the time of buying the issue of after sales service should be carefully addressed. I know of few machine which have never worked from the day of installation. Name and address of the manufacturers of Urodynamic equipment is provided in Table II

Manufacturer	Address	Equipment Available
C.R. Bard Inc.	Bard Urological Division C.R. Bard, Inc. Covington, GA 30209 Phone 800-526-4455	Fiber optic sensor 5 French sensor single, 10 French dual pressure flow, simple and complex CMG
Dantec Medical Inc.	777 corporate Drive Mahwah, NJ 07430 Phone 201-512-0066 Fax 201-512-0450	Flow simple and complex CMG, video-urodynamics ambulatory urodynamics
Laborie Medical Technologies Corp.	7 Green Tree Drive So. Burlington VT 05403 Phone 802-860-7230 Fax 802-860-1147	Flow, simple and complex, CMG Video-Urodynamics
Life-Tech, Inc.	PO Box 36221 Houston TX 77236-6221 Phone 713-495-9411 Fax 713-495-7960	Flow, simple and complex, CMG, Video-Urodynamics



Brown Medical Systems	19839 Buerkle Rd. White bear lake MN 55110 Phone 612-777-7900 Fax 612-777-7420	Flow, simple and complex CMG
(MMS) Medical Measurement Systems	1039 College Ave, Suite 8 Wheaton IL 60187 Phone 708-665-1336 Fax 708-665-1350	Flow simple and complex CMG, Video-Urodynamics ambulatory urodynamics
Surgitek	PO Box 40178 7504 RD Enschede Holland Phone 31 53 308 803 Fax 31 53 308 801	
	A Cabot Medical Company 3037 Mt. Pleasant St. Racine, WI 53404 Phone 414-639-7205 Fax 414-681-4038	Uroflow, simple and complex urodynamic video-urodynamic
Synetics Medical Inc.	1425 Greenway Drive Irving, TX 75038 Phone 214-518-0518 Fax 214-518-0080	Uroflow, simple and complex urodynamic video-urodynamic, UPP ambulatory urodynamic
F.M. Wiest USA Inc.	PO Box 637 690 Kinderkamack Rd. Orade11, NJ 07649-0637 Phone 201-262-4662 Fax 201-262-7626	Uroflow, simple and complex urodynamic Video-urodynamic. UPP ambulatory urodynamic

IN CONCLUSION: Uroflowmeter and multichannel CMG equipment would be sufficient for most of the urological problems. The cost, the type of practice and number of patients would influence the ultimate decision. The need for properly trained Urodynamicist / Technician is the ultimate key to a successful urodynamic evaluation. It is ultimately the man behind the machine and not the machine which is important.

2. Rotating disc
3. Electronic dip stick

All of them provide acceptable information. Dipstick flowmeters are comparatively cheaper. A comparison of these is provided in Table I.

DRAFT MARCH 1997

Outcome measures in treatment of uncomplicated benign prostatic obstruction (BPO)

Introduction:

"Clinical benign prostatic hyperplasia (BPH)" is not a well defined condition, but comprehends entities of benign prostatic enlargement (BPE), lower

urinary tract symptoms (LUTS) and bladder outlet obstruction (BOO).

BPE is present in many elderly males. In itself it is without clinical importance, but it might cause LUTS and / or BOO. It is today well recognized that LUTS in the elderly male may be caused by a range of other conditions than BPE or BOO, and that only a weak correlation has been found between BPE and BOO.

Outcome measures therefore have to address all three components: BPE, LUTS and BOO. While LUTS often affect the patients' quality of life and BOO might affect patients' health by upper urinary tract damage and / or irreversible detrusor changes, BPE per se is less important as an outcome.



During the last decade many new treatments of “clinical BPH” have been introduced including invasive treatments like superficial or interstitial laser treatment, rectal or urethral heating of the prostate by microwaves, balloon dilatation, temporary or permanent stents and medical treatments like 5-alpha – reductase inhibitors and alfa-adrenoceptor-blocking agents. The efficacy of these treatments has been registered in many different ways e.g. by changes in: symptoms including symptom score, quality of life, urinary flow rate, residual urine volume, prostatic volume, voiding diary, pressure flow parameters, number of patients going into complete retention etc. The side effects and complications of treatments have also been assessed in many different ways leaving both the consumer (the patient) and the treating doctor without proper documentation. A major reason for this is, that there is no consensus on which parameters should be used to measure of treatment and further that the tools used to measure changes are often poorly described concerning reproducibility, validity, reliability, sensitivity, specificity and responsiveness.

The ICS report on “Standardization of outcome studies in patients with lower urinary tract dysfunction” gives the general principles, governing the present report, which analyses the tools used to describe the different aspects of uncomplicated “clinical BPH” and on that basis gives recommendations on how to measure outcome of treatment of uncomplicated “clinical BPH”.

Symptoms:

Lower urinary tract symptoms (LUTS) constitute the main indication for treatment of uncomplicated BPH. Scoring of the severity of symptoms is therefore necessary in order to quantitate the symptoms and their influence on the patients’ quality of life and register / monitor changes after treatment. Many symptom scores have been used in the evaluation of BPE. None of them have been designed to specifically measure outcomes of treatment. None is BPE or BPO specific. Some

symptom scores are self administered by the patient; others are filled in by the clinician. Finally individual symptoms may be considered separately to evaluate changes. If such a score is used reliability and validity data should be provided if available or their absence indicated.

1. American Urological Association (A.U.A.) symptom score.

The AUA score contains a symptom score, a condition specific Quality of Life score and a bothersomeness score.

It has a high reliability and validity although there are some concerns about validity in a study finding low or no correlation between symptom score and actually measured voiding parameters like frequency and weak stream.

2. The International Prostate Symptom Score (IPSS)

The IPSS is the same as the AUA symptom score and the condition specific Quality of Life score, but without the bothersomeness score.

3. The Danish Prostatic symptom Score (DAN-PSS-1)

The DAN-PSS-1 contains a symptom / symptom-bothersomeness part and a sexual question part. Only the first is validated (8). It has a high reliability and validity.

a. Comments.

A total of 24 question combining symptoms and bothersomeness of symptoms cause longer page lay-out, smaller type size and may be confusing, especially to aged patients. Therefore, usability among different populations and different socio-economic groups might be lower than that of the AUA score.

4. Bolognese symptom questionnaire for BPH

This score system contains a symptom score, a symptom bothersomeness score and global urination problems questionnaire.

It has a high reliability and validity. It has not been widely used.



5. Boyarsky score

The first symptom score published to assess LUTS in BPH. It has never been validated in its original form, and is normally used in a more or less modified form.

6. Patient satisfaction

Symptom scores and to a certain degree also individual symptoms do not obviously capture the patho-physiological disease “clinical BPH”. To cover the whole field a universal subjective outcome classification might cover the concept better. It might be a simple grading of outcome as 1. much worse, 2. somewhat worse, 3. unchanged, 4. somewhat better, 5. Much better.

Little validation has been done of such scores.

DIRECT ANATOMICAL & PHYSIOLOGICAL MEASURES.

1. Prostate size and anatomy

Estimation of prostatic size and anatomy is performed to establish the diagnosis of BPE and as a therapeutical guidance if treatment is directed against changing prostatic size and / or anatomy. Prostate size correlates poorly or not at all to symptomatology, BOO and treatment outcome.

2. Digital rectal examination (DRE).

Although DRE may give a rough estimate of prostate size the reliability is poor.

3. Transrectal Ultrasound Scanning (TRUS).

Planimetric volumetry is often regarded as the gold standard for prostate volume determination, and excellent correlation between the planimetric volume and the absolute volume in cadavers has been demonstrated. Reliability is very good. Different methods and formulas to measure and calculate prostate volume from different axis of the prostate, are less accurate. Often simpler formular are used to calculate prostate volume from axial, sagittal and coronal diameters. The accuracy of these seem sufficient for daily clinical use. Transition zone volume and transition zone index may be a valuable supplement to wholegland volume determination. If treatment intends to

change prostate volume, measurements should be done before and after treatment. Timing of post treatment testing depends on mechanism of action of the modality.

The method used and its reliability and validity should be provided if available or their absence indicated.

4. Normal values

Prostate volume seems to change with age. This relation has been demonstrated by meta-analysis of studies with prostates obtained by autopsy, a study performed with ultrasound volume measurements on the patients for vasectomy and volunteers, and a community based study with ultrasound. As a significant overlap exists among prostate volume in LUTS and BOO it is at present difficult to estimate appropriate “normal values” for different populations and age groups.

5. Morphology

It has been reported that the anteroposterior diameter increases more than the transverse diameter with age and the shape of prostate becomes round by transverse section, although controversy exists.

Changes in microscopic features of glandular, muscle and connective tissue content in the gland might show to be relevant.

6. Infravesical obstruction

“Clinical BPH” has traditionally been synonymous with “obstructive BPH”. The only method to accurately assess BOO is pressure-flow studies with simultaneous recording of intra-abdominal pressure, intravesical pressure and urinary flow rate. As this is an invasive, time consuming procedure, it will probably never be adopted as a routine procedure in all patients with “clinical BPH”. It is however cornerstone in the assessment of outcome after treatments claiming to relieve BOO. Results should be presented as stated in the ICS standardization report on: pressure-flow studies of voiding, urethral resistance and urethral obstruction.

Methods used should be stated, reliability and validity data should be provided if available or their absence indicated.

ABOUT THE FOUNDATION

The Indian Continence Foundation (I.C.F.) is the Indian affiliate of the International Continence Society. It is constituted as a registered Trust with the following objectives:

- To create an awareness among members of the public about the problem of incontinence and incontinent people.
- To provide for the scientific care of incontinent persons through training of care-providers and family members in the same.
- To disseminate knowledge about the various incontinence aids, appliances & devices available to patients of incontinence
- To procure these for patients at concessional rates through interaction with manufacturers.
- To promote the latest medical developments in the field of incontinence among Doctors, Nurses and para-medical personnel.
- To provide a forum for patients and family

members to interact and solve social and emotional issues of mutual concern.

In order to fulfil these objectives, the foundation has an elaborate schedule of activities. Some of them are

- Newsletters on current developments on incontinence catering separately to Medical personnel.
- Workshops for Nurses & Care-providers to impart training in the care of incontinent patients.
- Public lectures, Seminars and interactive discussions on topics of relevant concern
- Establishment of a database of Incontinent patients with a view to evolving long-term policies for the prevention of Incontinence.

If you wish to be a part of this endeavour, please contact the President or Hon. Secretary of the foundation for a fact sheet and other details. Individuals, Organisations as well as Corporate bodies are welcome.

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