Guidelines on Urodynamic Equipment Performance

W6, 29 August 2011 09:00 - 12:00

Start	End	Topic	Speakers
09:00	09:15	The Guidelines workplan and structure	• Andrew Gammie
09:15	09:30	Discussion	All
09:30	09:40	Measurements and functions required	• Becky Clarkson
09:40	10:00	Discussion	All
10:00	10:10	Technologies for signal acquisition and processing	• Michael Drinnan
10:10	10:30	Discussion	All
10:30	11:00	Break	None
11:00	11:10	Benchmarking equipment performance	• Ron van Mastrigt
11:10	11:40	Discussion	All
11:40	11:45	Summary and way forward	• Andrew Gammie
11:45	12:00	Discussion	All

Aims of course/workshop

The ICS report on Urodynamic Equipment (Rowan et al.) was published in 1987. Since then, technology has changed substantially and the ICS has published Good Urodynamic Practices in 2002. The ICS Standardisation Steering Committee has therefore been applied to for a commission to revise of the 1987 report. This workshop will present a new draft document for discussion and involve as wide an audience as possible. It is felt that industrial and clinical workers together will be able to produce a practical benchmark against which to assess current equipment and new technologies. The workshop will therefore include short presentations of the report with interactive discussions following each.

Educational Objectives

Urodynamics equipment constitutes an essential part of the clinical evaluation of patients. The ICS is the relevant body to give clinicians guidance on that equipment, yet its technical report is over 20 years old and is therefore not helpful to the modern user. An update is therefore more than overdue. In order to develop an update, the working party feel that a committee production alone is insufficient. A wider consultation with stakeholders is required, to include for instance the companies that actually manufacture the equipment. A workshop in the format of a discussion meeting was proved effective in San Francisco in 2009 and we therefore propose another of similar format. An ICS meeting is the obvious point to gather all stakeholders together. An inclusive, widely accepted guideline on the performance of urodynamic equipment will be a powerful tool in enabling clinical staff to deliver quality urodynamic services.

Guidelines on Urodynamic Equipment Performance

ICS workshop 6 handout
0900-1200 Monday 29th August 2011

This workshop aims to develop consensus amongst users, scientists and manufacturers on the content of a new ICS guideline on urodynamic equipment. An outline of the proposed content is below, in note form, with a view to inviting discussion on the day and contributions to content.

The working group comprises the following ICS members: Andrew Gammie (Chair), Becky Clarkson, Chris Constantinou, Margot Damaser, Michael Drinnan, Derek Griffiths, Peter Rosier, Werner Schaefer, Ron Van Mastrigt.

Aim of the guideline

- summarise clinical performance requirements for urodynamic equipment (flow, pressure and EMG)
- relate these to specification and feature requirements
- develop technical specification ranges or limits from these requirements
- assess whether features can be classified as 'necessary' or are additional
- propose a set of tests / requirements for assessment of systems

1. Introduction

Previous paper (Rowan, 1986: "Urodynamic Equipment: Technical Aspects")
Accuracy may exceed clinical need.
New technologies need benchmarks for assessment
Method / process of document development
Structure and rationale of guideline – deal with common issues and real sources of error
Tables included to summarise clinical requirements and benchmarking tests
Basic requirements of a urodynamic system – document limited to features of normal systems.

2. Measurements

Precision vs. accuracy.
Non-computer methods, e.g. chart recorders
Rationale for recommendations, include references to signal bandwidths and accuracy.
Principle is to consider normal clinical test-retest variability as boundary, so instrumentation will not affect clinical diagnosis.
Analog to digital conversion (issues of relating digital resolution to clinical need)
Note different interpretative methods will require possibly different information

- Dynamic range should be at least 2x maximum physiological range;
- Sampling rate should be at least 5x bandwidth;
- Noise / sampling resolution 10x better than required accuracy from transducer (empirical rule of 10)
- Note too there will be a maximum accuracy specification recommended

2.1. Uroflowmetry and voided volume

Clinical requirements
Accuracy, Range, Linearity and hysteresis, Frequency response, Temperature dependence, Clinical importance of displaying artefacts, registering minimum flow, voiding time. Test-retest variability.

Measurement parameter and issues

Definition and brief description of measurement principles and physical sources of error: e.g. funnel effects, wag, delay

Technologies

Limitations and difficulties of each method: weight transducer, spinning disc

Comparison of: technology, one-off cost, measurand, bandwidth, artefacts, delays, hygiene, typical use.

Signal processing

Differentiation (volumetric) vs. integration (mass flow).

Amplification and filtering.

Automated removal of artefacts.

Automated measurement of Q_{max}.

Calibration

Benchmarking

Testing hysteresis, linearity, frequency response, temperature dependence

Funnel design issues

2.2. Abdominal pressure

Clinical requirements

Accuracy, Range, Linearity and hysteresis, Frequency response, Temperature dependence. Test-retest variability.

Measurement parameter and issues

Definition and brief description of measurement principle. Explain hydrostatic pressure and artefacts. Possibility of vaginal, stoma, rectal measurement.

Technologies

Limitations and difficulties of measurement – what is actually measured by each method?

Include: water-filled catheter; air-filled catheter; catheter-tip transducer; fiberoptic transducer.

Comparison of: technology, one-off cost, disposability, external equipment required, bandwidth, artefacts, error due to height, hygiene & sterility, typical use. (for whole system, i.e. with catheters and connecting tubes)

Signal processing

Amplification and low-pass filtering vs. rapid pressure changes in e.g. cough pressure profile.

Physiological range -> dynamic range; signal bandwidth -> sampling rate, accuracy -> sampling resolution.

Calibration

Benchmarking

Testing hysteresis, linearity, frequency response, temperature dependence

2.3. Intravesical pressure

Clinical requirements

Accuracy, Range, Linearity and hysteresis, Frequency response, Temperature dependence. Test-retest variability.

Measurement parameter and issues

Definition and brief description of measurement principle.

Technologies

Limitations and difficulties of measurement

Include: water-filled catheter; air-filled catheter; catheter-tip transducer; fiberoptic transducer.

Comparison of: technology, one-off cost, disposability, external equipment required, bandwidth, artefacts, error due to height, hygiene & sterility, typical use. (for whole system, i.e. with catheters and connecting tubes)

Signal processing

Amplification and low-pass filtering vs. rapid pressure changes in e.g. cough pressure profile.
Physiological range -> dynamic range; signal bandwidth -> sampling rate, accuracy -> sampling resolution.

Calibration

Benchmarking

Testing hysteresis, linearity, frequency response, temperature dependence

2.4. Urethral pressure

Clinical requirements

Accuracy, Range, Linearity and hysteresis, Frequency response, Temperature dependence. Test-retest variability.

Measurement parameter and issues

Definition and brief description of measurement principles.

Technologies

Limitations and difficulties of measurement
Include: perfusion catheter; air-filled catheter; catheter-tip transducer; fiberoptic transducer
Comparison of: technology, one-off cost, disposability, external equipment required, water perfusion rate, bandwidth, artefacts, error due to height, hygiene & sterility, typical use. (for whole system, i.e. with catheters and connecting tubes)

Signal processing

Amplification and low-pass filtering vs. rapid pressure changes in e.g. cough pressure profile.
Physiological range -> dynamic range; signal bandwidth -> sampling rate, accuracy -> sampling resolution.

Calibration

Benchmarking

Testing hysteresis, linearity, frequency response, temperature dependence
Limitations of current test methods, need for research in this area.

2.5. EMG

Clinical requirements

Frequency range, muscle groups – what the information requirements actually are, esp. neurogenic

Measurement parameter and issues

Difficulties and relevance / irrelevance of signal

Technologies

Needle vs. surface electrodes. (but major on surface emg issues)
Limitations and difficulties of measurement
Input/output impedance, CMRR

Signal processing

Physiological range -> dynamic range; signal bandwidth -> sampling rate, accuracy -> sampling resolution.

Calibration

Benchmarking

Testing hysteresis, linearity, frequency response, temperature dependence

2.6. Filled volume

Clinical requirements

Accuracy, Range. Test-retest variability.

Measurement parameter and issues

Definition and brief description of measurement principles, use of filled, PVR, voided figures (volume balance consideration)

Technologies

Weight transducer, measurement from filling pump

Related issues (e.g. bag changes) and artefacts

Signal processing

Physiological range -> dynamic range; signal bandwidth -> sampling rate, accuracy -> sampling resolution.

Calibration

Benchmarking

Testing hysteresis, linearity, frequency response, temperature dependence

3. User interface and analysis

Clinical requirements

Ergonomics

Recording

- File type – ICS standard, ability to extract raw data in .txt or .csv, ability to integrate with eRecord-type software or PACS, plain viewer availability
- Patient information (privacy/encryption issues)
- Diagnostic information (residual volume etc)
- Backing up data

Display

- p_{det} calculation and display
- Ability to adjust screen resolution and printout to standard resolution (1cm=10s etc)
- Ability to mark events
- Integration of fluoroscopy

Analysis

- Guidance of automated analysis
- Automated calibration; zeroing of pressures; plotting of nomograms; quality control.
- Pressure/flow plots
- Bladder volume (calculation from infused/voided/residual)

Technologies

Limitations and issues of automation

Electrical safety

Evaluation

Benchmarking

4. Other methods of measurement

Non-pressure or research measurements (e.g. BWT, NIRS, perineal sound, penile cuff, UPR, URRP)
Also comment on ambulatory and leakage measurements
Mention intra-anal, urethral, catheter emg measurements
Comment on general application of benchmarking tests to these technologies and others as yet unknown

5. Summary

Draw together all the above – clinical requirements lead to technical recommendations.
Propose ways to make use of the document –assessing both current equipment and new technologies
Discuss possibility and tasks of specialist test centres
Highlight future needs for testing and acceptance

6. References

Rowan et al, 1986. J Med Eng Tech, 11(2); 57-64