

# A semi-automated programme for urodynamic diagnosis: preliminary report of a work in progress

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**Abstract:** A semi-automated computer diagnostic programme, titled *UDS ASSISTANT*, that can be used by physicians and medical professionals has been devised. The algorithms were developed basing on reference publications (ie, ICS standardization of terminology, ICI reports, Good urodynamic practice) and some urodynamic textbooks (Abrams' Urodynamics, Chapple's Urodynamics made easy, Nitti's Practical Urodynamics). The programme assists the examiner in making a urodynamic diagnosis from the data recorded during the examination. Data are currently entered manually by the examiner, but after a large-scale validation of the method, we don't exclude a totally automated diagnosis through a direct post-processing of the traces. The software may be an important diagnostic aid for those who are not particularly expert in urodynamics. Furthermore, basing the diagnosis on objective criteria of an algorithm sheet more than on subjective interpretation of traces, it may reduce the inter- and intra-observer variability that is one of the main restrain of current urodynamic investigation.

**Key words:** Urodynamics; Diagnostic software; Computer-assisted diagnosis.

## INTRODUCTION

In recent years the role of urodynamics in the assessment of lower urinary tract dysfunctions has become contentious.<sup>1,2</sup> Urodynamics is not an esoteric concept of limited applicability to be confined to the "ivory towers". Urodynamics may be questioned, but its basic principles are simple and in most cases it doesn't need complex mental efforts. However, some recent reports indicated that most of the time the personel carrying out urodynamics have little understanding of what the recordings mean.<sup>3,4</sup> The need of developing a urodynamics curriculum for urology residents has been recently addressed by some publications.<sup>5,6</sup> Indeed, in the Author's experience, there are instances of recordings still being sent to the equipment manufacturer for their interpretation! In cardiology the automatic interpretation of ECG is in use by at least 40 years and most of the electrocardiographs in current use are equipped with a diagnostic software with significant advantages for doctors and/or technicians who deal with more than hundred ECG tracings every day.<sup>7,8,9</sup> A urodynamic diagnostic software may be a useful tool to the beginners or where a doctor is not easily available, a situation quite common in a urodynamic lab. Furthermore, even among experts, interpretation of the tests is not always straightforward, resulting in a high intra- and inter-interpret variability. The rigid criteria of the diagnostic algorithms should reduce the subjective interpretation of the tracings thereby reducing the inter-observer and intra-observer variability.

## MATERIALS AND METHODS

The *UDS ASSISTANT* diagnostic software, developed by the second Author, is a Windows based program designed in Borland Delphi. The system acts as a black board in the sense that when faced with input data it gives an answer.<sup>10</sup> It's a unique file providing to install itself and generating all the service files. That means the software is able to recreate itself and all the files and parameters that could be accidentally deleted from the computer by the user. In addition the software checks automatically all the available update release. The software has been developed taking the criteria of ECG automated diagnosis programs as a model. In cardiology, the first automated ECG programs were developed in the 1970s, and improved in accuracy during the 1980s and 1990s. Today most currently commercial models incorporate these programs with significant improvement in relationship between user and the device. Technically, there is not much difference between an ECG and an urodynamic tracing (Fig. 1). In ECG the digital signal resulting from heart "electrical" activity are processed by a series of specialized algorithms to derive conclusions, interpretation and diagnosis. In *UDS-ASSISTANT* software "pressure" signal resulting from bladder and urethral activity and electrical signal resulting from pelvic floor muscle activity are processed through the most widely accepted algorithms developed in literature for the specific underlying pathology to make the more predictable diagnosis. Analyzed LUT dysfunctions include female and male incontinence, male

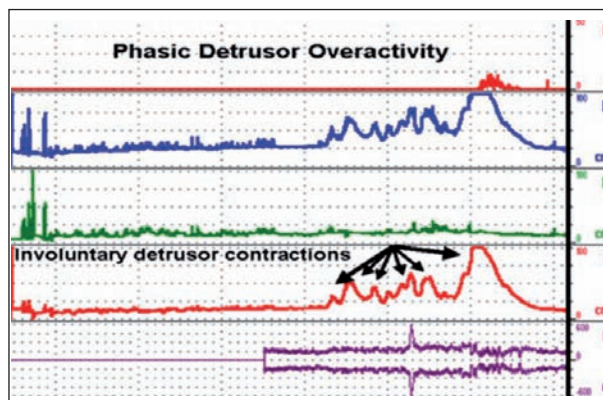
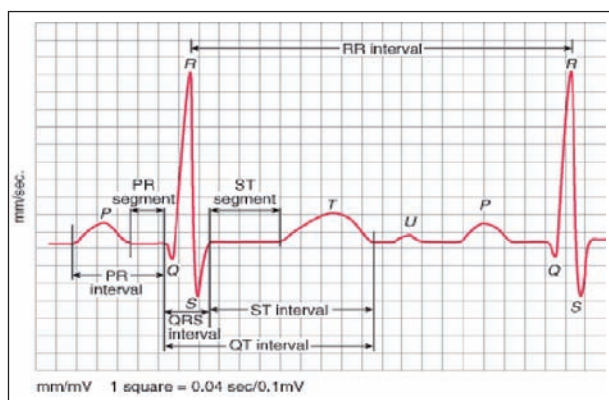


Figure 1. – "Electrical" spikes and segments of ECG, and "pressure" spikes ( involuntary contractions) and segments ( FSV, NDV, SDV, etc) of a cystometry trace.

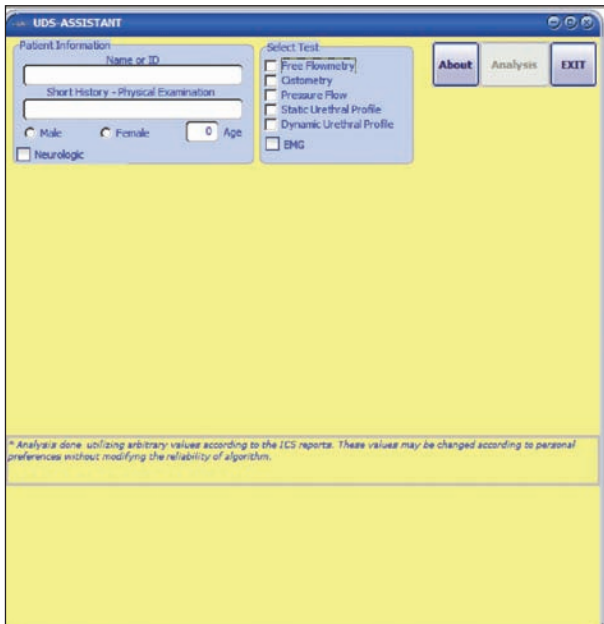


Figure 2. – The display of the software.

and female obstruction, urgency, neurogenic bladder and voiding disorders in pediatric age. Algorithms have been realized utilizing the statements and recommendations of the most authoritative Guidelines on urodynamics:

1. ICS (*International Continence Society*) Reports<sup>11,12</sup>
2. IUGA/ICS Joint Report on the Terminology for Female Pelvic Floor Dysfunction<sup>13</sup>
3. ICCS (*International Childrens Continence Society*) Terminology Document<sup>14</sup>
4. ICI (*International Consultation on Incontinence*) Reports<sup>15-18</sup>
5. Good Urodynamic Practice<sup>19</sup>

In addition three basic textbooks of urodynamics have been consulted:

1. Abrams: Urodynamics<sup>20</sup>
2. Nitti: Pratical Urodynamics<sup>21</sup>
3. Chapple: Urodynamics made easy<sup>22</sup>

In situations poorly defined by the literature, the choice of reference values was made on personal experience. The figure 2 shows the software display.

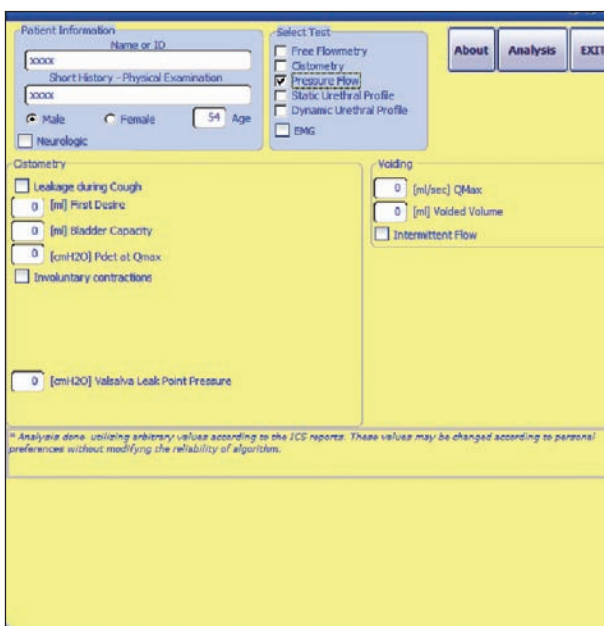


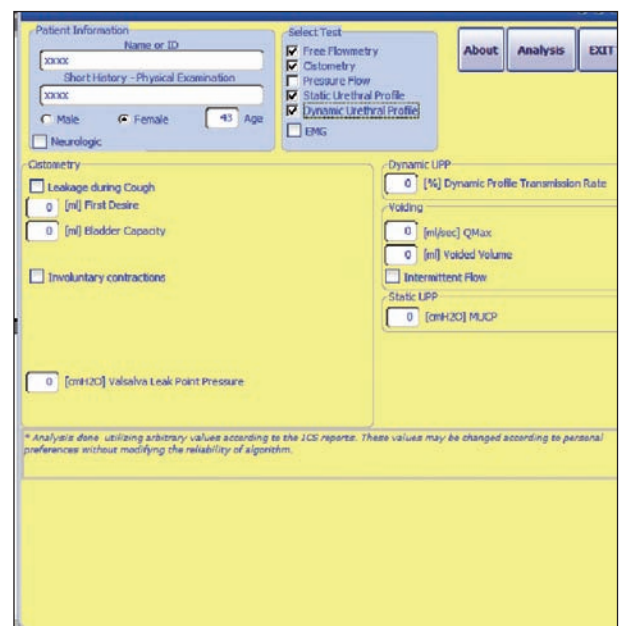
Figure 3. – Single test and pressure/flow analysis.

On the left, the ID of the patient including age, sex and a short clinical history is indicated. On the right, the list of urodynamic tests. To facilitate office urodynamics, the analysis has been devised both for single tests and for pressure/ flow studies. Once selected the test, a series of boxes to be filled out with data of the traces is displayed (Fig. 3). Likely ECG signals that are conditioned at starting of the procedure to remove noise, correct base level variations etc, a quality control procedure is accomplished by UDS-software at the beginning of pressure/flow study asking the examiner to check the proper strain gauges calibration by verifying that the difference between Pabd and Pves should no greater than 6 cm H2O (Fig. 4). A specific box identifies the neurologic patient, likewise ECG in patient with cardiac pacemaker. Urodynamics in neurologic patient has some special features including terminology that is different from that used in the non-neurologic patient (Fig. 5). After filling the boxes with the requested values, a click on the analysis button activate the display of the report that includes row data on the top, and the results of automated interpretation below (Fig. 6). Below we report the rationale of diagnostic algorithms utilized in the analysis of each test.

### Male flowmetry

The International Continence Society has standardized certain objective measurements to be recorded during uroflow measurement, including flow pattern, voided volume, maximum flow rate ( $Q_{max}$ ), voiding time, and time to maximum flow . However, flow pattern,  $Q_{max}$ , and volume voided generally are regarded to be the most clinically useful for both screening and following patients. Because uroflow is partly dependent on volume voided, uroflowmetry nomograms are useful in distinguishing normal from abnormal flow rates. Since males show a significant decline in flow rate with age, the software utilizes Siroky nomogram for men under 55, and Bristol nomogram for men over 55.<sup>23,24,25</sup>

Voided volume should be at least 150ml and preferably 200 ml. For voided volume lower than 150 ml (correspondingly less in children: 50 to 100 ml) a warning indicate the voiding pattern has to be interpreted with caution for possible erroneous result due to inadequate voided volume and suggest to repeat the test. Intermittent flow may be due to abdominal straining to overcome a BOO or may indicate a



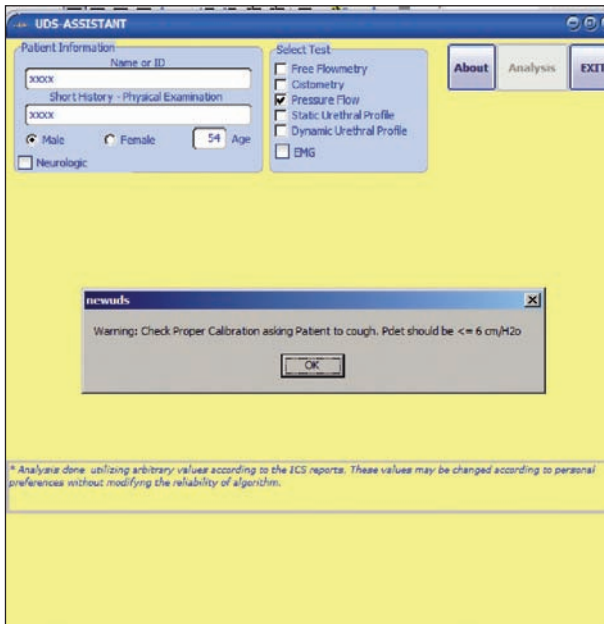


Figure 4. – Quality control procedure before starting pressure/flow study.

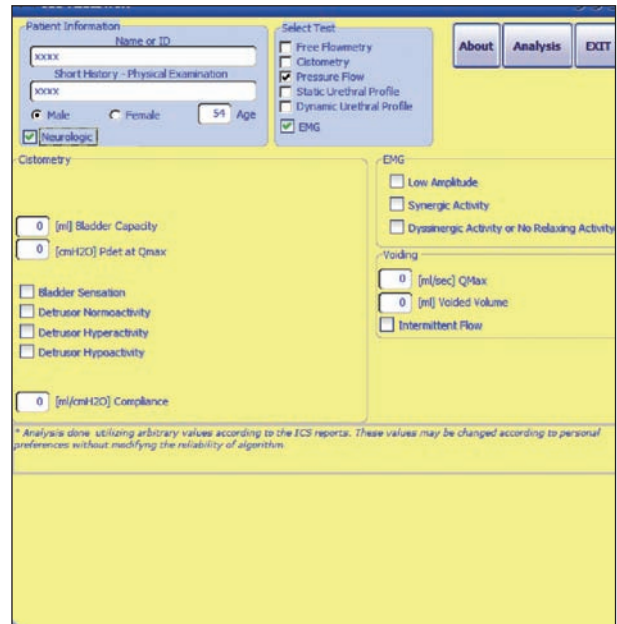


Figure 5. – Pressure/flow study in neurologic patient.

poorly contractile detrusor or a dysfunctional voiding in pediatric age or in younger adults. With an intermittent flow, a second warning indicate the need of a pressure/flow study for a better definition of the finding. In adults the free flowmetry predictive value is also reported, in order to reduce the need of pressure/flow study according to Limm and Abrams: if the Qmax is below 10 ml/s the chance of the patient to have a bladder outlet obstruction is 90%; if the Qmax is 10 ml/s to 15 ml/s the incidence of obstruction falls to 71%; if the Qmax is over 15 ml/s the chance of obstruction is 50% (high pressure/high flow system).<sup>26</sup>

*Female flowmetry*

Unlikely male, female doesn't show statistically significant variations in urine flow rate with respect to age, parity or first versus repeated voiding. The 10th centile of the Liverpool Nomogram for the maximum urine flow rate has been considered to be the most useful discriminant for a final urodynamic diagnosis of voiding difficulties in females.<sup>27</sup>

*Uroflowmetry in pediatric age*

Urine flowmetry together with ultrasound assessment of residual urine is by far the most common procedure in pediatric urodynamic practice. The results of the examination decide whether the child requires an invasive urodynamic investigation. Two aspects are particularly significant in a child flow curve: maximum flow and the shape of the curve.

*Maximum flow (Qmax)*

In studies of normal children a linear correlation has been found between the square of maximum flow (Qmax) and voided volume. If the square of Qmax (ml per second<sup>2</sup>) is equal to or exceeds voided volume in ml, the recorded maximum flow is most probably within the normal range.<sup>28</sup>

Mean Qmax is higher in girls than in boys probably due to girls' shorter urethra. Recently nomograms in centile forms have been reported both for girls and boys under 14 yrs of age for a wide range of voided volume.<sup>29</sup> These nomograms have been utilized in our software for automated analysis of flow in children.

*Flow curve shape*

A child with organic outlet tract obstruction often has a low amplitude flow curve, that is a plateau-shaped curve. Similarly this may be the case when there is a tonic sphincter contraction during voiding. However, more commonly sphincter overactivity during voiding is seen as sharp peaks and troughs in the flow curve, that is labelled as an irregular or "staccato" flow curve. With a "staccato" flow curve a warning indicate the possibility of dysfunctional voiding inviting the examiner to proceed to a pressure/flow study with patch EMG.

*Residual urine*

Measurement of post-void residual urine is the current complement of uroflowmetry for evaluating voiding dysfunction. However, threshold values delineating what constitutes an abnormal PVR are poorly defined. The pro-

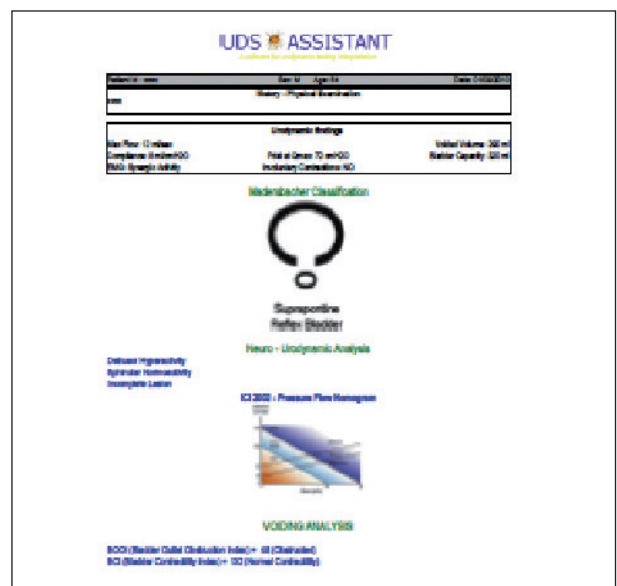


Figure 6. – Sample of a final diagnostic report in neurogenic patient.



gramme take into account only large PVRs (> 200ml) with a warning indicating that values greater than 200 ml may be associated with an increased risk of urinary retention, upper urinary tract dilation and renal insufficiency.<sup>30,31</sup>

#### Cystometry

Cystometry is mostly interpretative. The investigator should approach cystometry with a clear principle in mind, namely that "the role of urodynamics is to reproduce the patient symptoms". This means there should be a continuous dialogue between the investigator and the patient through the examen. This concept is particularly important when assessing the sensation the patient experience during cystometry.<sup>32,33</sup> Bladder storage function should be assessed in terms of bladder sensation, detrusor activity, bladder compliance and bladder capacity. Furthermore the urethra should be assessed in term of competency through cough (urodynamic stress incontinence) and strain (Valsalva leak point pressure). The failure to store urine during the filling phase may be either a result of an abnormal (overactive or oversensitive) detrusor or an abnormal (i.e. too weak) sphincter complex. In mixed incontinence the two situations coexist.

The software analysis considers the following data: FSF (first sensation of filling); cystometric capacity; involuntary detrusor contractions spontaneous or on provocation; compliance, expressed as increase in bladder volume per centimetre of water increase in pressure (ml/ cm H2O). In the normal bladder the change in pressure from empty to full should be less than 10 cm H2O giving a figure for normal compliance of greater than 40 ml/cm H2O; urine leakage through the external meatus during cough; VLPP at 200 ml of filling.<sup>34</sup>

Overactive bladder is diagnosed in presence of significant detrusor overactivity, subjectively observed by the examiner. There has been considerable confusion over the objective definition of DO with some investigators labelling patients as having DO if there is an increase of pdet greater than 15 cm H2O during filling. However, the ICS standardization document of 1988 made it clear that DO is characterised by phasic contractions (pressure rise and fall) without specifying a minimum change in pdet. Waves of an amplitude of less than 5 cm H2O are difficult to detect using most modern urodynamic equipments.<sup>35</sup> However, it is undoubtedly true that low pressure DO waves (5 cm H2O – 15 cm H2O) can produce troublesome symptoms of urgency particularly in women. Bladder hypersensitivity is diagnosed in presence of an early first sensation of filling and an early first sensation to void (usually < 100ml) which persist into normal and strong desire without concomitant phasic detrusor contractions. Bladder capacity is less than 250ml Reduced compliance is diagnosed when the pressure at cystometric capacity is greater than 10 cm H2O. Urodynamic stress incontinence is diagnosed when urine leak from the external meatus is observed when the patient raises her intra-abdominal pressure in the absence of a detrusor contraction. IDS is diagnosed when VLPP at 200 ml of filling is lower than 60 cmH2O. A VLPP greater than 90 cm H2O is usually associated with pure urethral hypermobility. VLPP values between 60 and 90 cm H2O form a grey area in which hypermobility and ISD usually coexist. If the patient does not leak a bladder cause for the leakage should be considered. The two stressors (cough and Valsalva) differ physiologically with regard to the rate and nature of the rise in pressure. Although higher abdominal pressures can be achieved with cough, the Valsalva LPP is better controlled and less variable.<sup>36</sup> Generally, cough LPP is used for patients who do not leak during Valsalva LPP measure-

ment. The programme takes into account both values.

#### Pressure/flow studies

Conventional urodynamics is able to provide information on both filling and voiding phases of micturition cycle. This is achieved by measuring bladder and abdominal pressure with real-time computational determination of detrusor pressure by using the formula  $p_{det} = p_{ves} - p_{abd}$ . The accurate measurement of pdet is entirely dependent on the accuracy with which pabd and pves are measured. The 2002 ICS report says that after derivation, pdet is 0 cm H2O to 6 cm H2O in 80% of cases. As previously said, before starting the pressure/flow study, quality control is ensured by a warning that ask the examiner to check that pdet is under 6 cm H2O. The pressure-flow relation is much better defined in men than in women. In male patients the diagnosis of BOO is made by plotting the maximum flow rate (Qmax) against detrusor pressure at Qmax (pdet Qmax) into the ICS nomogram which is derived from Abrams-Griffiths, LPURR and URA nomograms.<sup>37</sup> BOO is also calculated without reference to nomogram utilizing the equation: BOOI (Bladder Outlet Obstruction Index) =  $p_{det}Q_{max} - 2 Q_{max}$

If the BOOI is greater than 40 then BOO exist; if it is below 40 then no definite BOO exists. Under 20 patient is unobstructed. In addition the software analyzes the detrusor contractility utilizing the equation: BCI (Bladder Contraction Index) =  $p_{det}Q_{max} - 5 Q_{max}$

A BCI of greater than 150 suggests strong contractility, whereas less than 100 is poor. BCI 100-150 is the normal range. The definitions and nomograms that are used to describe BOO in men do not apply to women, since men and women have unique micturitional characteristics. There is a distinct lack of consensus relating to the use of urodynamic assessment in the interpretation of voiding dysfunction in women. There are universally accepted nomograms for men with outflow obstruction<sup>38,39</sup> but there remain various different urodynamic criteria for women.<sup>40-44</sup> Recent attempts have been made to simplify and clarify them, such as the nomogram proposed by Blaivas and Groutz in 2000.<sup>45</sup> but standardization is still awaited. Nevertheless, voiding phase of female patient is analyzed through the Groutz-Blaivas nomogram. The nomogram includes 4 zones: unobstruction, mild, moderate, severe obstruction BOO is defined as free Qmax < 12 ml/s combined with pdet Qmax > 20 cm H2O. In according to the Authors, given the difficulty in performing uroflowmetry with a catheter in place and the fact that there was a significantly higher flow rate in the same woman without the catheter, we chose to use a non-invasive flow rate in the nomogram. Also, because they found no statistical difference in pdetQmax in obstructed versus unobstructed patients, we choose pdetmax as the pressure parameter. This enables analysis also in patients with urinary retention. Unlike male, detrusor contraction strength is not assessed in women. However, since an inadequately contracting detrusor may be related to post-operative voiding problems, the addition of pressure/ velocity plots described by van Mastrigt and Griffiths<sup>46</sup> and provided by some urodynamic equipments may be worthwhile.

#### Female static & dynamic profilometry

Urethral function tests represent a dark area of urodynamics.<sup>47</sup> Urethral hypermobility and intrinsic sphincteric deficiency probably falls in a bell-shaped distribution across stress incontinence populations; so that most cases of stress incontinence have some degree of both types of pathology.<sup>48</sup> Static and dynamic profilometry are the cur-

rent urodynamic tests to assess both intrinsic urethral tone and the urethral support.

#### Static profilometry

Static profilometry assess the functional status of the urethra by measuring the pressure throughout the urethral length.<sup>49</sup> Proponents believe it gives an indication of the severity of SUI and usually equate a maximal urethral closure pressure (MUCP) below 20 cmH<sub>2</sub>O, with ISD. Values greater than 20 cm H<sub>2</sub>O but lower than the hypothetical normal MUCP may indicate a hypofunctional urethra.<sup>50</sup> MUCP in female is closely dependent on age and decreases by 15 cm H<sub>2</sub>O per decade starting from 90 cm H<sub>2</sub>O at 25 yrs.<sup>51,52</sup> This concept is summarized in a simple formula, proposed by the SIFUD (*Societe Francophone d'Urodynamique*) several years ago, to calculate the theoretical normal MUCP of each woman.

$$MUCP = 110 \text{ minus age}$$

Example: a woman of 72 yrs should have a theoretical MUCP of: 110-72=38 cmH<sub>2</sub>O

The values between 20 and 38 cmH<sub>2</sub>O indicate a possible "hypofunctional" urethra

The values under 20 cm H<sub>2</sub>O indicate a possible ISD

#### Dynamic Profilometry

In women with a normal mechanism of support, increases in abdominal pressure during coughing are transmitted to the proximal three quarters of the urethra with urethral pressures exceeding intravesical pressures. The lack of such pressure transmission to the urethra indicates a poor supporting mechanism. The PTR (Pressure Transmission Ratio) is calculated as follow: PTR = urethral pressure rise during stress maneuvers/intravesical pressure rise x 100. The PTR in normal women tend to be greater than 90. Values under 90% are diagnosed as defect in support. A pressure transmission ratio value less than 90% in the proximal half of the dynamic profile had a sensitivity of 97%, a specificity of 56%, an abnormal predictive value of 53%, and a normal predictive value of 97%.<sup>53</sup>

#### Male profilometry

Male profilometry has limited clinical relevance as a diagnostic tool for bladder outlet obstruction, because it doesn't reflect the dynamic behaviour of the urethra during micturition. Conversely, it may be used to evaluate the degree of sphincter lesion after radical prostatectomy and to follow spontaneous recovery. Several papers reports the multifactorial origin of incontinence after radical prostatectomy: ISD is present in 2/3 of cases, sphincter and bladder dysfunction coexist in 1/3, isolated bladder dysfunction is less 10%, while BOO due to anastomotic stricture is present in 2.7-20% of the cases.<sup>54-58</sup> Quantification of sphincteric damage became important after the introduction of sling surgery in alternative to AUS, since sling surgery appears to be efficacious only in mild to moderate cases of incontinence. There are controversies about the assessment of sphincteric function after radical prostatectomy. Although VLPP has not been shown to correlate with severity of incontinence.<sup>59</sup> MUCP appears to be a more useful measurement in the post-RP population. MUCP in incontinent patients has been reported significantly lower than in continent patients.<sup>60</sup> Basing mostly on personal experience, the software algorithm describes three incontinent sub-groups:

1. MUCP between 60 and 80 cm H<sub>2</sub>O suggesting a mild sphincteric weakness.
2. MUCP between 40 and 60 cm H<sub>2</sub>O suggesting a moder-

ate sphincteric weakness.

3. MUCP under 40 cm H<sub>2</sub>O suggesting a severe sphincteric weakness.

#### Urethral profilometry and dysfunctional voiding

The ICS has defined dysfunctional voiding as an intermittent and / or fluctuating flow rate due to involuntary intermittent contractions of peri-urethral striated muscle during voiding in neurologically normal patients. In male the pattern, that has been called also "pseudodyssinergia" seems to account for 35% of bladder outlet obstruction especially in young adults.<sup>61</sup> In female dysfunctional voiding is quite common in painful bladder and related pelvic floor syndromes.<sup>62</sup> Obviously, the "gold standard" for diagnosing the disorder is the pressure/flow study with EMG. Is not infrequent, however, to observe in office practice the performance of flowmetry followed by cystometry and urethral profilometry. In presence of an interrupted free flow and with an MUCP exceeding 10 cm H<sub>2</sub>O the normal age-dependent MUCP value in the female and a fixed value of 120 cmH<sub>2</sub>O in male, a pressure/flow study with EMG is warranted. The latter usually evidentiates a poor relaxing sphincter with mild – to moderate obstruction in female and equivocal obstruction with underactive detrusor in male.

#### Neurogenic bladder

Urodynamic diagnosis in neurogenic bladder follows special features (terminology, sensation, compliance) in a condition similar to ECG in the patient with a pacemaker. As previously said, the software provide a specific algorithm for neurogenic patient. Neurogenic bladder dysfunction may be due to: dysfunction of the detrusor, dysfunctions of the sphincter, and a combination of both

When one suspect neurogenic bladder, a pressure/flow study with EMG becomes mandatory. Two types of information can be obtained from EMG: a simple indication of muscle behaviour, the so-called kinesiological EMG, or an electrical correlation of muscle pathology.<sup>63</sup> During urodynamic investigation a kinesiological EMG is usually obtained. Sphincter activity may be: synergic, dyssinergic or non-relaxing and low-amplitude. Synergic activity indicates a progressive increase of EMG activity during filling of the bladder (guarding reflex) followed by by a timely relaxation of the pelvic floor during voiding. Dyssinergic or non-relaxing activity indicates an increase of EMG activity during voiding (sometimes the activity may result unmodified or "waxing and waning"). Low amplitude EMG indicates a reduced electrical activity both during filling and voiding phase. The finding may indicate a peripheral denervation of the muscle for which a neurophysiological approach, through a needle EMG and oscilloscope, is recommended in the final report. Correspondingly, detrusor function may be: normo-, hyper-, hypo-active. The patterns of detrusor- sphincter function reported in the boxes of the display identifies eight types of neurourodynamic diagnoses, according to Madersbacher: <sup>64</sup>

- supra-pontine reflex bladder (detrusor hyperactivity-synergic EMG activity)
- spinal reflex bladder (detrusor hyper activity-dyssinergic or non-relaxing EMG activity)
- sub-sacral lesion (detrusor hypoactivity-low amplitude EMG)
- lumbosacral lesion I (detrusor hyperactivity-low amplitude EMG)
- lumbosacral lesion II(detrusor hypoactivity-dyssinergic or non-relaxing EMG activity)
- intra-pelvic lesion I (detrusor hypoactivity-synergic EMG activity)

- intra-pelvic lesion II (detrusor normoactivity-dyssynergic or non-relaxing EMG activity)
- intra-pelvic lesion III (detrusor normoactivity-low amplitude EMG activity).

In addition to neurourodynamic diagnosis, voiding phase is analyzed through A-G nomogram in male and Grouz-Blaivas nomogram in female to evaluate the presence or absence of a mechanical obstruction. The absence or presence of sensation during filling account for a complete versus incomplete neurogenic lesion.

## RESULTS

One hundred urodynamic studies were retrospectively re-analyzed using the software. The diagnosis done by an urodynamicist was compared with that resulting from the software analysis. Data were inserted in the program blindly, for example, without knowing the diagnosis. Seventy-six exams were considered as routine investigation, while twenty-four were classified as a difficult cases. Difficult cases were considered male patients undergone several endoscopic operations (TUIP, TURP, re-do) for suspected bladder outlet obstruction and female patients undergone several anti-incontinence surgeries. Examiner skill was classified as high (expert urodynamicist), average (residents), poor (clinician not specifically involved in urodynamics). Only eighty-eight exams were eligible for re-analysis since twelve traces were discarded for technical inadequacy (poor calibration, infusion pump oscillations in UPP measurement, loss of detrusor line during voiding) in spite of examiner diagnosis. Diagnostic agreement between software and examiner diagnosis is reported in Table I. Overall, the correspondence between the two diagnoses was observed in 54.5% of the cases. Discrepancies were observed in 45.5% of the studies. As expected, diagnostic agreement was lower in complicated cases, mostly due to initial wrong diagnosis. Examiner skill was not a discriminating factor in resident diagnoses, probably because younger people strictly follow the available guidelines. In general, however, there was evidence of an unwillingness to follow existing standardization recommendations. In addition, poor facility with urodynamics was an important factor in the questionable diagnosis of the clinicians, since most of them had already planned an “unmodifiable surgical solution” despite the urodynamic traces. The best diagnostic agreement (90%) was seen in the sub-group of patients with neurogenic bladder dysfunction. Although in neurogenic bladder each individual patient may have a unique pattern of lower urinary tract dysfunction and require an individual management plan, the site of the lesion gives an indication of the likely pattern of the dysfunction. In this sub-group the only two discrepancies in diagnosis were seen during the spinal shock period, that software failed to recognize. In male LUTS diagnostic agreement was seen in 50% of the patients. Discrepancies were due mostly to missed diagnosis of detrusor underactivity (4/18: 22%) and poor-relaxing external sphincter (14 /18: 77%). In our opinion there is a tendency in the clinician to underestimate the problem of detrusor underactivity in favour of

bladder outlet obstruction, while the diagnosis of poor-relaxing spincter is almost never done. In female incontinence diagnostic agreement was seen in 37.5% of the cases. Discrepancies were present in the quantification of ISD (12/20: 60%) and in the diagnosis of bladder hypersensitivity (8/20: 40%), the latter being classified as overactive bladder in most of the cases. This was not surprising, since it is well known that both urethral function assessment and detrusor dysfunction evaluation are considered the “dark-grey zones” in current urodynamic investigation.

## DISCUSSION

Urodynamics is a series of more or less agreed-upon clinical tests to assess the function and dysfunction of lower urinary tract. According to this definition urodynamics is the only way of understanding why people are continent or incontinent. Urodynamics is the pivotal link between basic science on the one hand and the clinical reality on the other. Therefore it occupies a central place in the consultation. At present however there is a limited objective evidence for the clinical utility of urodynamics. According to Griffiths such a surprising conclusion could have, among others, at least two possible explanations:

1 any given symptom group have similar underlying pathophysiology requiring similar treatment, and so there is no need to differentiate them by urodynamics

2 current treatments are so non-specific and non-quantitative that underlying dysfunction is unimportant. Treatment works equally well or poorly in any case.

Beside these consideration, there is however a strong suspicion, based on expert opinion, that urodynamics is often done poorly, both in accomplishing the examination as well as in interpreting the traces. Recent experience from the central monitoring of multicentre studies<sup>65,66</sup> suggested that the quality of urodynamic results was often compromised because there is no quality control. In one large trial up to 38% of the traces were rejected during a central review.<sup>67</sup> Such high rates of rejection suggested that quality control was a problem in several urodynamic units, and this led to the development of the International Continence Society guidelines on Good Urodynamic Practice (ICS GUP). Furthermore, to improve this situation, the ICS tried to establish standards for proper training and certificate programs for urodynamics. In a competency-based approach to teaching UDS, five measurable components were defined: terminology and theory, setting up the study, running the study, interpreting the study, and reporting UDS.<sup>69</sup> Several papers have been published in the last years on quality control in urodynamics.<sup>68-71</sup> None of them however deal specifically with traces interpretation. Computer-aided diagnosis is a widely accepted procedure that supports the doctor’s interpretations, particularly if the experience and skill in a specific field is less than optimal. Many studies demonstrate that the use of computer software to partly or fully make a differential diagnosis improve the quality of care by reducing medical errors.<sup>72,73,74</sup> The urodynamic algorithm imitate the step-by-step reasoning that expert urodynamicists were assumed to use when they analyze the traces. This is particularly useful since often we tend to solve most of our problems using fast, intuitive judgments rather than the conscious, step-by-step deduction. It was particularly impressive to see that in some cases the software reported a diagnosis that was totally unexpected. After a re-evaluation of the patient the working diagnosis was modified. The display may be an useful track for a good urodynamic practice, since the examiner is forced to consider all significant aspects of the traces. Data are currently entered manually by the examiner, but a direct process of the traces, like the

TABLE I. – Diagnostic agreement between software and examiner diagnosis in 88 selected LUT dysfunctions.

LUT dysfunction	N° pts	Diagnostic agreement	%
Female incontinence	32	12/32	37.5
Male BOO	36	18/36	50
Neurogenic bladder	20	18/ 20	90
Overall	88	48/88	54.5



ECG stripe, is not technically difficult. The solution of “diagnostic machine”, however, would distort the current approach of the software, that is a structured guide to urodynamic tests. In urodynamics a basic principle often missed is that any urodynamic parameter must be “correctly” interpreted” and “intelligently” evaluated. That means that any incongruence of software urodynamic diagnosis with clinical picture should act as a red flag and imply a more detailed evaluation. Conversely, the overall reliability and significance of each urodynamic test in clinical practice has nothing to do with the software. We perfectly know that many tests have several shortcomings, but we assumed that they are the best in current use.

The better agreement between software and examiner diagnosis was observed in neurogenic patients except in spinal shock phase. During spinal shock, bladder filling is accompanied by an elevation of resistance in the bladder neck area, with a concomitant increase of pressure in the external sphincter zone but without a simultaneous increase of the electromyographic activity. These results indicate an increased sympathetic activity in the smooth muscle component of the entire urethra.<sup>75</sup> Analyzing only the detrusor and sphincter activity in a set-up of pressure/flow study despite the patient inability to void, the software fail to recognize this activity and the subsequent diagnosis is “sub-sacral lesion-complete”. A good accordance between software and examiner diagnosis was observed in male outlet obstruction. The wide use of nomograms makes highly reproducible the diagnosis of male outlet obstruction. A recent report indicated that urodynamics has good reproducibility when looking at the BOOI (bladder outlet obstruction index) and BCI (bladder contraction index), indicating that a second study is not necessary in most patients and one investigation is sufficient for an accurate diagnosis on which treatment options can be based.<sup>76</sup> However, classify the male patients with symptoms of lower urinary tract (LUT) dysfunction “only” on the basis of prostate enlargement is a limited view of the problem.

Results of a recent study indicated that LUTS in male can result from a complex interplay of pathophysiologic features that can include bladder dysfunction and bladder outlet dysfunction such as benign prostatic obstruction or poor relaxation of the urethral sphincter. About one third of men with LUTS who were older than 55 years of age had benign prostatic obstruction. Patients younger than 55 years old were more likely to have poor relaxation of the urethral sphincter as a likely cause of LUTS.<sup>61</sup> In clinical practice a poor relaxing sphincter is rarely acknowledged. A typical finding is that of a patient 55 years old undergone TUIP, TURP, and TURP re-do by different surgeons for a suspected bladder outlet obstruction due, in fact, to a poor relaxation of the urethral sphincter.

Most of conflicting results in female incontinence were related to the distinction between ISD and urethral hypermobility and to the assessment of combined detrusor dysfunction. Currently, there is no adequate consensus on how to diagnose SUI or categorize the disorder in terms of the two principal postulated pathophysiological mechanisms; intrinsic sphincter deficiency (ISD) and urethral hypermobility. These represent extremes of a spectrum, and coexist in the vast majority of patients. Recent reports indicate that mid-urethral sling may be equally effective in both conditions (77,78). However, it is clear from other reports that the appropriate diagnosis of SUI poses many challenges, both in the need to clarify the role of the relative components of ISD and hypermobility, which appear to exist across a spectrum, and to determine their influence on treatment outcome.<sup>79,80</sup>

Likewise, CMG is an essential part of the diagnostic evaluation of incontinent female, both in defining underlying pathophysiology of a mixed incontinence and directing treatment. In spite the ICS Revision of Terminology (2002) that abolished the distinction between sensory and motor urgency, recent evidence indicates urothelium as sensory function and sensory hypersensitivity may be causative of frequency and urgency unrelated to a detrusor overactivity.<sup>81,82</sup> The software make a clear distinction between hypersensitivity and OAB, but probably the latter should be further re-defined according to the type of detrusor contractions, for example phasic and terminal,<sup>83</sup> and warning time that may account for brain control.<sup>84</sup> Last but not least, the programme may have a role also among expert urodynamicist by reducing the inter- and intra-observer variability of urodynamic diagnosis. Urodynamics provide in essence a subjective interpretation of an objective evaluation. This account for short-long-term variability of urodynamic diagnoses and for inter-observer variability. Considerable efforts have been made in recent years to improve the standards and comparability of urodynamics worldwide.<sup>85,86,87</sup> In spite of rules and recommendations of ICS and other reference groups, it is interesting to see that experienced urodynamicists failed to agree on the interpretation of urodynamic recordings in several situations. Recently some reports on the development of an objective method to assess bladder filling sensation during cystometry have been published.<sup>88</sup> Likewise, extensive objective methods of assessment of urodynamic tracings are strongly warranted by several experts. The step-by-step analysis of the programme may be an useful tool for interpreting the traces utilizing the same criteria. A multicenter study is under way to verify this goal. As indicated in the title the software is a work in progress. Some modifications have been already planned. The most significant is the introduction of a range value instead a single value.

The range should include a test retest variation of 10-15% for various parameters (volume, pressure, or flow), which can be regarded as the physiological variation of UDS.<sup>89</sup>

Furthermore, values chosen according to the experience of the Author, mostly related to urethral hyper- and hypo-activity, should be verified by others. However, it is our belief that the values can be changed according to personal preferences without modify the reliability of the algorithm.

## CONCLUSION

Despite limitations, urodynamic studies remain the primary method of evaluating lower urinary tract complaints. Latest reports indicates urodynamic evaluations are fast becoming routine in the office environment (with only complicated cases referred to specialty centers) due to increasing demand of medical justification for surgical procedures.<sup>90</sup> The dictum “bladder is an unreliable witness” is now around 30 years old, but probably it’s time that urodynamics is no longer complicated or cumbersome. In this scenario, urodynamic diagnostic software promise to be an useful technical support to the examiner who seeks assistance in interpreting urodynamic testing results and applying this to their practice. In principle, the software does not add anything new but simply collect the data in a structured way to coin a correct diagnosis according to the literature. This approach has at least two advantages: the first is to improve the performance of the inexperienced urodynamicist, the second is to encourage the practice of urodynamics by making it easy.

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