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URODYNAMIC QUALITY CONTROL: QUANTITATIVE PLAUSIBILITY CONTROL WITH TYPICAL VALUE RANGES

Aims of Study: Recently, a standardization report on "Good Urodynamic Practice, GUP", has been accepted by the ICS (Ref). This standard underlines the importance of data quality control, which relies on qualitative and quantitative plausibility control, and thus requires knowledge of typical values and patterns. However, it appears that the ICS GUP is based more on empirical data than on systematic research. Therefore, we have analyzed systematically urodynamic data to establish typical value ranges (TVR) for quantitative plausibility.

Material and Methods: 582 measurements from a quality controlled multicenter urodynamic study on males (mean 65.3 years) with lower urinary tract symptoms (LUTS) were re-analyzed. All measurements were done in standing or sitting position with 30 ml/min infusion rate following the ICS-GUP Standard, in particular correct zero and reference height had been enforced. All traces were carefully read independently by three investigators, and if necessary corrected for artifacts. On each trace, intravesical pressure (p_{ves}), intra-abdominal pressure (p_{abd}) and detrusor pressure (p_{det}) were read at beginning, i.e. before start of filling as initial resting pressure, at start and at end of filling without obvious muscular activity, and after voiding, respectively. Maximum cystometric capacity (MCC) and compliance here relates to comfortable filling as suitable for a voiding study. For each parameter, the mean value, standard deviation, median and various TVRs were calculated.

Results:

Initial filling	Mean±SD	Median	50%	80%	95%
p_{ves} (cmH_2O)	35.4 ±10.7	37	31~42	24~46	7~51
p_{det} (cmH_2O)	2.3±3.5	2	0~4	0~6	0~9
p_{abd} (cmH_2O)	33.1±10.9	35	28~39	20~44	5~49
End of filling					
p_{ves} (cmH_2O)	42.4±12.5	43	38~50	29~56	10~62
p_{det} (cmH_2O)	8.2±4.9	7	5~10	4~13	2~18
p_{abd} (cmH_2O)	34.2±12.3	36	30~41	20~47	2~51
V_{infus} [MCC](ml)	261.6±136.9	244	157~345	105~441	49~587
Compliance (ml/cmH_2O)	58.5±61.1	41.5	26.6~70.8	17.8~122.8	7~220

For the majority of patients TVRs for initial resting p_{ves} and p_{abd} were 31~42 cmH2O and 28~39 cmH2O, respectively; and for p_{det} it was 0~4 cmH2O with a mean of 2.3 cmH2O, i.e. very close to zero. The upper limits of 95% and 99% ranges for p_{det} were 9 and 13 cmH2O, respectively. However, the extreme values in the 95% and 99% ranges did reveal some artifactual measurements not recognize before. These were re-analyzed and corrected. Therefore we suggest $p_{det} \leq 10$cmH2O as upper limit of a realistic resting value. Typical errors related to initial resting pressures can be divided into three types: I) Normal initial resting p_{det}, but both p_{ves} and p_{abd} are wrong, due to wrong zero or wrong reference height; II) negative initial resting p_{det}, usually due to elevated p_{abd}; III) too high initial resting P_{det} (over 10 cmH2O). The incidences of I, II and III errors were 9.8%, 4.5% and 1.4% respectively. During filling, TVRs of MCC and compliance were 157~345 ml and 26.7~70.8 ml/cmH2O. During voiding, TVR of p_{abd} at relaxation was 25~38 cmH2O. A rare but relevant error with an incidence of 0.7% was a negative p_{abd} at pronounced relaxation during voiding, all starting from very low abdominal pressure possibly artifactual by itself. This leads to a misleading p_{det} value being higher than p_{ves}. At end of voiding, TVRs of p_{ves}, p_{abd} and p_{det} were 40~55 cmH2O, 30~41 cmH2O and 10~14 cmH2O, respectively. After voiding, usually p_{abd} showed little change and also p_{ves} and thus p_{det}, approached the pre-voiding levels within minutes. Other types of rare but relevant errors were: p_{ves} and p_{det} post-voiding on high level over a prolonged time. If the p_{det}-signal does not drop to pre-voiding level, then a cough test can distinguish between an elevated pressure due to a prolonged detrusor contraction (correct cough) or due to a blocked catheter (poor intravesical cough response). In few cases p_{ves} and p_{det} became negative, obviously then catheters had shifted or fallen out. These plausibility checks require that recording is not terminated before pressure signals have stabelized and final cough test is performed.

Conclusions: TVRs of urodynamic pressures are effective tools for quantitative plausibility. TVRs for the initial resting pressures before start of filling are sensitive and reliable indicator for correct set-up of measurement. Only the complete plausibility during filling and before and after voiding allow definite conclusions about measurement quality. Full application of such ICS GUP requires that TVRs are defined for other parameters and different patient groups. Such standardization has wide-ranging consequences for "accepted normal" values, which are often "personal" values of a specific investigator. The impact of TVRs can be easily demontrated when published figures in journals and text books are compared. In particular complex "normal" values such as e.g. for compliance are considerably influenced by non-standard measurements, individual rules used to read, and lacking control of data points.

Ref: Drafts ICS Standard "Good Urodynamic Practice", Yokohama 1997 and Jerusalem 1998

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URODYNAMIC QUALITY CONTROL: QUALITATIVE PLAUSIBILITY CONTROL WITH TYPICAL SIGNAL PATTERNS

Aims of Study: Recently, a standardization report on "Good Urodynamic Practice, GUP", has been accepted by the ICS (Ref) which underlines the importance of data quality control. Quality control relies on qualitative and quantitative plausibility control, and thus requires knowledge of typical values and patterns. However, it appears that the ICS standard is based more on empirical data than on systematic research. Therefore, we have analyzed systematically urodynamic data to identify and describe typical signal patterns (TSP) by amplitude and pressure gradients. We indicate the role and significance of them in quality control as a powerful tool for qualitative plausibility control

Material and Methods: 582 measurements from a quality control multicenter urodynamic study on males (mean age 65.3 years) with lower urinary tract symptoms (LUTS) were re-analyzed. Measurements were done in standing or sitting position with 30 ml/min infusion rate with simultaneous pressure recording through a 6F double lumen transurethral catheter for intravesical pressure (p_{ves}) and a 9F double lumen catheter with a flaccid balloon rectally for intra-abdominal pressure (p_{abd}). Detrusor pressure (p_{det}) was calculated electronically. All traces were carefully read independently by three investigators. Using manual graphical analysis, we identified signal patterns by typical amplitude, A, and typical pressure gradient, PG. The different types of signal patterns were compared among p_{ves}, p_{abd} and p_{det} tracings at beginning of filling, during filling, before, during and after voiding, respectively.

Results: The following classification into four TSP types appeared as a good compromise between the technical and the clinical aspects: I. fine structure (noise): small amplitude A<3cmH2O, various frequencies; II. minimal dynamic changes caused by breathing, talking, moving: A<5cmH2O, various frequencies; III. major changes due to cough tests: A>50cmH2O, PG>100cmH2O/s; IV: typical major changes due to muscular activity: detrusor instability (A>3cmH2O/PG=1-5cmH2O/s), rectal contractions (A=5-10cmH2O/PG=5-10cmH2O/s), unstable detrusor contractions (PG=5-15cmH2O/s), and straining (A>5cmH2O/PG=30cmH2O/s). We have listed only the positive gradient (i.e. rising pressure), but it is remarkable how symmetric most changes are, such as coughs, straining, unstable detrusor and rectal contractions. At beginning of and during filling, 91.8% and 98.3% of traces showed the identical fine structure and same minor changes between p_{ves} and p_{abd} tracings, respectively, so that the p_{det}-tracing was quiet. 92.3% and 98.5% of p_{ves}/p_{abd}-traces had equal or similar pressure changes at test-coughs. At beginning of filling, 2.2% traces showed rectal contractions. During filling, 8.3% traces showed straining, 17.4% rectal contractions, and 33.7% detrusor instability. Before voiding, 94.0% of p_{ves}/p_{abd}-traces had equal cough response. During voiding, 91.2% of traces showed same fine structure and minor changes on p_{ves} and p_{abd} tracings. 53.3% of traces showed straining, 2.1% rectal contractions and 15.3% a pronounced decrease in p_{abd} at initiation of flow interpreted as relaxation of pelvic floor. After voiding, 91.2% of traces had again the same fine structure in p_{ves} and p_{abd} tracings, and 87.5% had the equal cough response on p_{ves}/p_{abd}-tracings. When signal quality is good at beginning it usually remains stable or even improves during filling, When the patient is talking during filling a typical pattern occurs which allows continuous signal quality control with the same minor changes on p_{ves} and p_{abd} tracings. The p_{det} tracing should not show any fine structure and no minor changes. Test-coughs should be a standard in signal control. The different major changes can be easily recognized because of their distinct amplitudes and pressure gradients. Coughs and sneezing are very fast with high amplitude. Also the PG of straining is much faster than any contraction. Detrusor instability shows a wide variety of amplitude, where usually the PG and A are related, i.e. slow waves have low amplitudes. This also means that usually when a slow start of a detrusor contractions is observed, e.g. < 1cmH_2O/s, it will not reach a high amplitude. In this male patient group, instability was found in 34% and rectal contractions in 18%. Relaxation of pelvic floor during voiding is quite common in males with 15%.

__Conclusions:__ TSP is a powerful tool for the qualitative plausibility and quality control. Combined with typical value ranges TVRs, the TSPs allow definitive judgment of the quality of a urodynamic investigation, and the clear identification of artifacts. The definite identification of the described typical signal patterns is an indispensable pre-condition for good urodynamic practice. The suggested definitions and classification of TSPs is another relevant step towards a genuine computer expert system for clinical urodynamic practice, which can only work on basis of a functioning automated real-time quality control.

Ref: Drafts ICS Standard "Good Urodynamic Practice", Yokohama 1997 and Jerusalem 1998

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THE VOLUME DEPENDENCE OF MAXIMUM FLOW RATES REVISITED

__Aims of study__

In a population of patients or healthy volunteers, maximum flow rates increase with the voided volume. Mechanically, there are two possible explanations for this phenomenon. Firstly, larger volumes will generally be voided by people with a larger bladder, i.e. consisting of more smooth muscle cells. The contraction velocity of a shortening muscle depends linearly on the number of cells that are in series in the muscle. Secondly, the volume change of a contracting sphere depends on the product of the wall shortening velocity and the 2/3 power of the volume. When flow rates are measured repeatedly in the same individual the first mechanism does not apply. But the second does. As it is known that in urinary bladder smooth muscle the (maximum) shortening velocity is independent of the stretched muscle length [1] it may be expected that in an individual flow rates increase with the 2/3 power of the volume. This is not the case. As early as in 1979 [2] evidence has been provided that in a single person, above a certain minimum voided volume, flow rates are independent of the voided volume, or even slightly decrease with increasing voided volume. The subject of the present study is the hypothesis that this discrepancy results from mechanical interaction between the cells in the bladder wall, i.e. that the frequently used 2/3 power law is not valid for the urinary bladder geometry.

__Methods__

Fresh, male pig bladders from the local slaughterhouse were suspended in a 2 liter organ bath containing Krebs solution. A double lumen catheter was inserted into the bladder via the prostatic urethra and connected to a pressure transducer and infusion pump. The bladder was stimulated to contract with 50 V pulses of alternating polarity with 5 ms duration at a repetition rate of 100 Hz. When maximum isometric pressure was developed the pump withdrew a small, preset volume of fluid from the bladder at a preset flow rate. The procedure was controlled by a PC, and is illustrated in Figure 1. The passive response to the flow rate enforced by the pump was also measured and used for

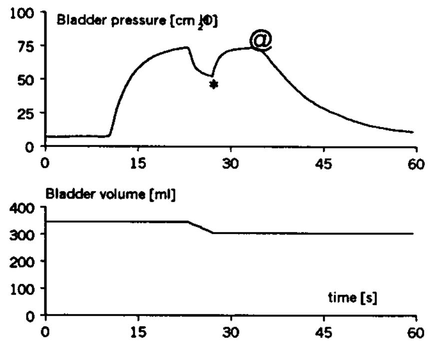

Fig.1. A stop test measurement in a pig urinary bladder in vitro.