

## WHAT HAS HEAD TO HEAD COMPARISON OF FLUID VERSUS AIR FILLED PRESSURE SYSTEMS DURING CLINICAL CYSTOMETRY AND PRESSURE FLOW MEASUREMENT LEARNT US?

### Hypothesis / aims of study

ICS-standard cystometry is performed with a fluid filled tubing system with external pressure sensors. The installing and measuring procedures are standardized, however there is operator dependency in the process and the system is intrinsically sensitive to patient movements, as a consequence of the external pressure sensors and tubes required for the test. An air filled catheter pressure recording system was developed to circumvent (erroneous) external pressure reference and to avoid artefacts resulting from (patient &) tubes movements. Contrary to the fluid filled system the air filled system measures the urodynamic pressures at the site of the catheter tip (inside the patient). This also requires careful operating, but patient movements cause lesser measurement artefacts. We have compared how both systems perform when used head to head during otherwise ICS standard cystometry.

### Study design, materials and methods

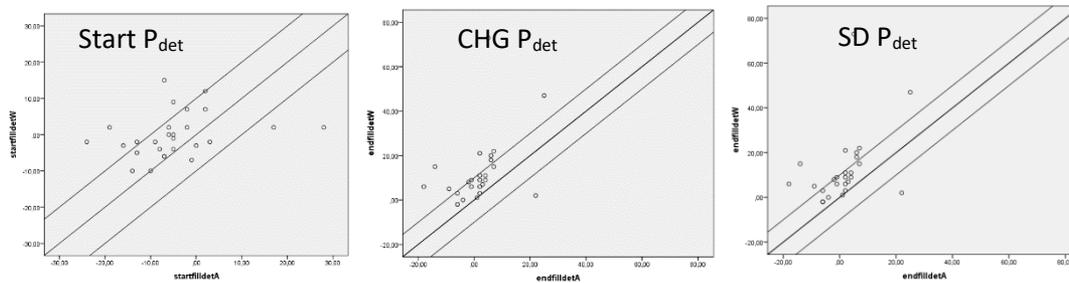
Forty patients with signs and or symptoms of LUT dysfunction were recruited, after IRB approval of the protocol and individual written informed consent. Men with intact saddle region sensation were excluded because of the double (2x7F side by side) catheterisation. Also women (or men) with a flowrate <15mL/s or with other (pre-urodynamic) signs of voiding dysfunction were not included.

Transurethral medium fill-rate simultaneous double system (fluid (FL) and air (A)) cystometry was performed in seated position when possible and supine when needed. Pressures at start (ST); first sensation (FS-FL or FS-A), at strong desire (SD), and during detrusor overactive contraction, in the patients that showed this feature (DO-FL or DO-A) are reported for intravesical (ves), abdominal (abd), and detrusor (det). Furthermore pressure peaks during cough, (CHG) strain (STR) and or voiding pressures (at-Qmax) were compared.

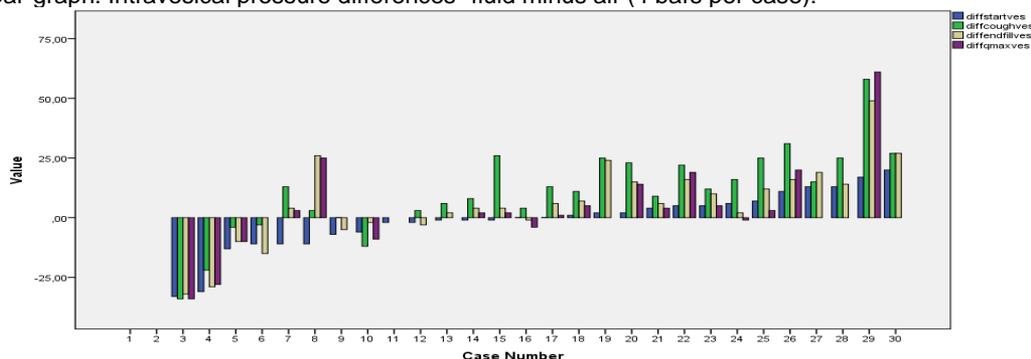
### Results

	Paired Differences		Sig. (2-tailed)
	Mean	Std. Deviation	
STvesFL - STvesA	-0,86	12,12	,711
STabdFL - STabdA	-11,40	27,47	,031
STdetFL - STdetA	9,86	29,48	,088
CHGvesFL - CHGvesA	11,11	17,97	,003
CHGabdFL - CHGabdA	-7,10	33,60	,265
CHGdetFL - CHGdetA	17,37	40,98	,037
STRvesFL - STRvesA	2,87	14,00	,441
STRabdFL - STRabdA	-8,88	15,65	,038
STRdetFL - STRdetA	10,54	10,21	,003
SDvesFL - SDvesA	6,15	16,76	,068
SDabdFL - SDabdA	-11,45	28,64	,040
SDdetFL - SDdetA	16,78	32,64	,013
QmaxvesFL - QmaxvesA	4,11	20,02	,383
QmaxabdFL - QmaxabdA	-18,05	29,38	,011
qmaxdetFL - qmaxdetA	21,84	38,86	,025

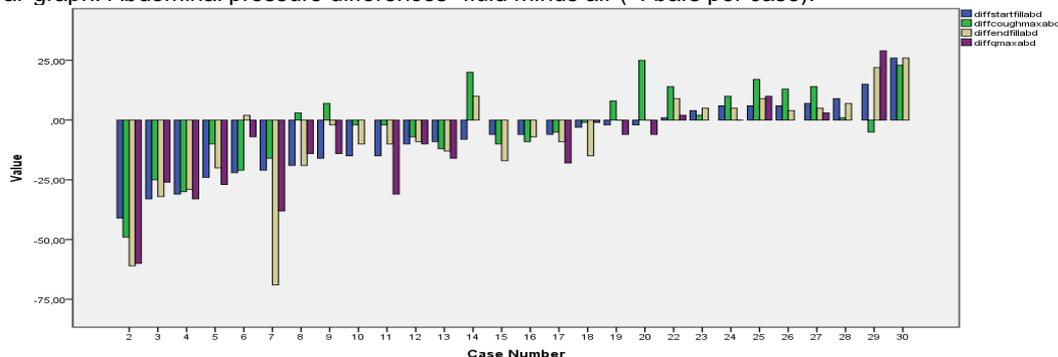
Paired mean pressure differences between the two systems (FL vs A) were small and not statistically significant. The st.dev. exceeded 10cmH<sub>2</sub>O. In 75% of the pressures the differences were <15cmH<sub>2</sub>O. Some scatterplots of Pdet FL (Y-axis) - A (X-axis) are shown for relevant pressure events, including the <> 10cmH<sub>2</sub>O range. Two bar-graphs show the differences in registered pressure (FL minus A) in 'ves' and 'abd', ranked from the largest negative pressure difference (FL>A) (left) to the largest positive difference (FL<A) in pressure at the start of cystometry.



Bar-graph: Intravesical pressure differences- fluid minus air (4 bars per case):



Bar-graph: Abdominal pressure differences- fluid minus air (4 bars per case):



### Interpretation of results

The mean differences between fluid and air filled systems are small but with a large standard deviation. In 25% of each measurement some of the differences were  $>15\text{cmH}_2\text{O}$ . The bar-graphs demonstrate however that the pressure-differences between FL and A at ST –CGH -SD &  $Q_{\text{max}}$  have been carried forward throughout the entire study in the majority of cases. Note e.g. an exception on this in the intravesical pressures bar-graph (see top graph) case 8: where the ST difference is negative and the other 3 differences (SD and  $Q_{\text{max}}$ ) are  $\approx 25\text{cmH}_2\text{O}$  positive; and also case 29 where the positive Pves difference at the start is much smaller than at the other 3 landmarks. Similarly in the lower graph; case 7 shows an outlier (negative) difference between FL and A in abdominal SD pressure. This suggests that the precision of both systems is comparable, apart from exceptions in both directions, but that intrinsic offset differences, in both directions, are a predominant source of the differences. It should be confirmed whether abdominal pressure (difference) is lesser inconsistent per test and whether the intravesical is lesser reliable at the start of cystometry, since the other 3 pressure landmarks seem to associate better.

### Concluding message

Mean differences between fluid and air filled measurement systems for urodynamic testing are small. If analysed per test however, the two systems may differ in the pressures 'produced'. Differences in 'zero', especially at the start of the (FL) cystometry are relevant. In the majority of measurements the difference between the fluid and the air filled system can be regarded as intrinsic 'offset' difference, that does not significantly affect the pressure pattern obtained.

### References

1. Rosier PF, de la Rosette JJ, Koldewijn EL, Debruyne FM, Wijkstra H. Variability of pressure-flow analysis parameters in repeated cystometry in patients with benign prostatic hyperplasia. *J Urol.* 1995 May;153(5):1520-5. PubMed PMID: 7536260.
2. Rosier PF, Schaefer W, Lose G, Goldman HB, Guralnick M, Eustice S, Dickinson T, Hashim H. International Continence Society Good Urodynamic Practices and Terms 2016: Urodynamics, uroflowmetry, cystometry, and pressure-flow study. *Neurourol Urodyn.* 2016 Dec 5. doi: 10.1002/nau.23124. Epub ahead of print Review. PubMed PMID: 27917521
3. Abrams P, Damaser MS, Niblett P, Rosier PF, Toozs-Hobson P, Hosker G, Kightley R, Gammie A. Air filled, including "air-charged," catheters in urodynamic studies: does the evidence justify their use? *Neurourol Urodyn.* 2016 Aug 31. doi: 10.1002/nau.23108. Epub ahead of print Review. PubMed PMID: 27580083.

### Disclosures

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