CLINICAL ARTICLE

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Head-to-head comparison of pressures during full cystometry, with clinical as well as in-depth signal-analysis, of air-filled catheters versus the ICS-standard water-filled catheters

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Abstract

Aims: To compare in vivo differences of two catheter systems for urodynamics to further discover their measurement properties.

Methods: Side-by-side catheterization with two catheters for intravesical and abdominal pressure during full cystometry in 36 prospectively recruited patients with analysis of mean and absolute differences at urodynamic events and post hoc in-depth signal analysis comparing the full pressure traces of both systems.

Results: The mean pressure differences at urodynamic events between air-filled and water-filled systems are small, however, with a large variation, without a systematic difference. The majority of the intersystem differences are significantly larger than $5 \, cmH_2O$. Further analysis showed that urodynamic event pressure differences of both systems at the start of the test were carried forward throughout the remainder of the test without subsequent or additional tendency to differ. Post hoc whole test signal analysis with pressures equalized from the first sample shows high cross-correlation (>0.981) between the pressure signals per location (rectum and bladder) per test and almost zero-time shift ($<0.05 \, s$) of all cystometry pressure samples.

Conclusions: We confirm earlier studies that showed random differences at events between air-filled and water-filled pressures during clinical urodynamic testing and confirm that these are intrinsic but not systematic—and still incompletely explained—offset-baseline differences. We determined on closer full measurement analysis after equalizing, that both systems are similar in displaying urodynamic pressure variations and amplitudes. We also confirm that both systems require awareness of intrinsic measurement properties during urodynamic testing and especially may necessitate adjustment of pressure offsets into a quantitative diagnosis of a urodynamic test.

1 | INTRODUCTION

International Continence Society (ICS)-standard cystometry is performed with a water-filled (WF) tubing system with external pressure sensors.[1,2] Installation and measurement procedures are standardized but depend on the skills of the operator. Furthermore, the WF system is intrinsically sensitive to patient movements and position, due to the external tubing and pressure sensors required for the test.[3] An air-filled (AF) catheter pressure recording system was developed,[4] at a time when microcatheter tip sensors were also evolving,[5] with the ability to bypass errors in external pressure referencing and to avoid artifacts resulting from patient and tubes movements. One AF system, developed from an intrauterine pressure monitoring system, was later commercialized (Tdoc® "air-charged") and initially evaluated for urethral pressure profile[6] in a comparison with microtip sensor catheters.[7] Later studies were evaluating the AF catheters in bench studies and also during cystometry, by intermittently using the fill channel of the AF intravesical catheter for comparative water-pressure recording.[8–10] Contrary to the WF system the AF system (and micro(tip) sensors) measures the urodynamic pressures directly at the catheter tip (inside the patient) and a recent study showed that this results in intrinsic but random differences in the displayed pressures.[11] Apart from this, imperfections may occur with the AF system as well, as can be observed in one publication with unexplainably flat traces on some of the graphs and apparently damped responses to patient movements.[12] The initially meager evidence for the AF catheters has raised concerns about too hasty clinical introduction of a new system, specific[13] but also in general.[14] Although as stated here above, the standard-ICS system can also be considered prone to imperfections.[3]

The demand for a better-structured introduction of new techniques in surgery is relatively new[15] and training and clinical quality management of urodynamics is scanty.[16] Reliable and reproducible measurement of physiological data is, however, critical in any clinical test and urodynamic testing is no exception.

Precise pressure measurement is relevant, but a large part of the urodynamic diagnosis is, on the other hand, based on qualitative pattern recognition. In addition, unavoidable artifacts, for example, patient movement, rectal activity, catheter position differences in the body, affect precision and detrusor (subtracted) pressure. Pattern recognition and interpretation of the measured pressures and the detrusor pressure require cognitive assistance to correct the artifacts before a diagnosis is made qualitatively but also for quantitative elements, for example, for detrusor pressure-flow analysis or leak point

pressures. The term cognitive assistance was never introduced in urodynamics, but earlier for prostate imaging.[17] However this becomes relevant when the quality of measuring and relevance of test-test variation in urodynamics are discussed. With the term cognitive assistance, we support the belief that urodynamic quality depends on clinical, practical, and interpretation skills, in addition to the technical quality of the equipment.[14] Cognitive assistance is, however, implicitly, introduced already since the initial good urodynamic practice where signal quality, pressure balance, and reference to zero are summarized.[1] Pressure pattern recognition (qualitative and cognitive assistance) is used to diagnose detrusor overactivity, reduced compliance, rectal contractions, and detrusor voiding contraction-pattern, but also to recognize, for example, tube knocks, flushes, straining, coughing, and so forth.[1,2] Quantitative analysis is relevant for grading leak point pressures, bladder outflow obstruction, and detrusor voiding contraction,[18] but is impossible without qualitative analysis of measuring quality and should therefore use cognitive assistance. WF system (or AF) immediate test-retest quantitative values for most of these are not available, however, are, based on one study, estimated $\approx 10\,mH_2O$.[19] Interobserver qualitative analysis variation is presumably large.[16]

To add more evidence for measurement techniques in urodynamics, we obtained the Institutional (Ethical) Board Review permission to prospectively recruit patients for the investigator-initiated single center prospective study reported here, comparing both catheter systems with two urodynamic catheters side-by-side with the aim to better understand their measurement properties (see Figure 1). The study was registered and initiated in January 2014; (clinical trials.gov: NCT02030340) with recruitment beginning in November 2014. The study data quality was monitored and verified.[20] We report prospective full cystometry, head-to-head comparison of water-filled versus air-filled catheters.
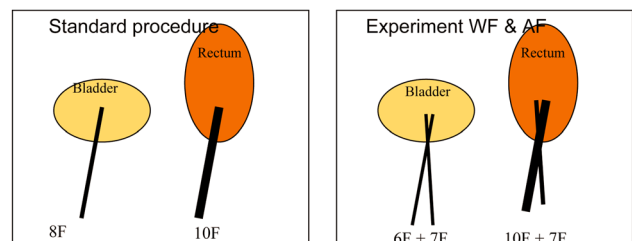

FIGURE 1 Our standard water-filled catheters (WF) cystometry (left-hand side) and the experimental WF + AF) cystometry (right hand side) with side-by-side catheters; AF catheters are both 7F

2 | MATERIALS AND METHODS

Adult patients with signs and or symptoms of lower urinary tract (LUT) dysfunction and clinical indication for UDI were recruited, after institutional review board (IRB) approval of the protocol and individual written informed consent.

Men with intact sensation in the saddle area were excluded at the request of the IRB to avoid any chance of additional patient discomfort from the dual (6F(WF) + 7F(AF) side by side see Figure 1) transurethral catheterization. Women (or men) with a flow rate less than 15 ml/s or with other (pre-UDI) signs of potential voiding (micturition) dysfunction were excluded. However, patients on clean intermittent self-catheterization were allowed. Very unfit patients (ASA > 2) were excluded and symptomatic UTI was a contraindication for UDI as per usual guidelines.

With the knowledge available at the time of the study design, predominantly the initial bench study,[7] we decided to power the study, with 36 patients tests and, as the primary outcome a systematic difference in the abdominal and intravesical pressures at urodynamic events (UE, see below) of more than $5 \, cmH_2O$ on Bland Altmann analysis, within a 95% confidence interval.[21] While designing the protocol we considered that a (systematic) difference of more than $5 \, cmH_2O$ between the two systems would be of potential clinical relevance especially when it would affect detrusor pressure, for quantitative diagnosis.

Transurethral medium fill-rate cystometry was performed in a seated position during the entire test in every patient, with a continuously measuring double system (AF + WF: see Figure 2A). An Andromeda-Ellipse modular urodynamics system (Medizinische Systeme GmbH Taufkirchen/Potzham) was used and all pressure channels were sampled with 20 Hz without any (additional) filtering or smoothing for graphic display or further analysis (see below). The catheters were inserted, not attached to each other, simultaneously with the top ends side by side; transurethral, until urine leaked out the fill channel and, into the rectum ≈10 cm past the anal sphincter. The external pressure sensors of the WF system were set to zero (in the device and program) when opened to atmosphere[1] and were flushed after insertion. Setting zero and a subsequent flush are visible in both (upper traces) pressures of Figure 2A occurring in the first minute. The AF catheter balloons were squeezed before insertion and also set to zero and charged, in accordance with the manual, when inside the bladder or rectum, also visible in traces 4 and 5 of Figure 2A. Catheters were taped close to their orifice of insertion and the tubes taped on the leg. Filling then started usually after the cough test. No attempt was made in any pressure trace to further influence the pressures (even when outside the expected range) other than extra flushing or zero checking. Room temperature saline solution bladder filling was done via the double lumen WF-catheter. Bladder fill sensations were assessed according to the standard.[2]

Pressures at start (ST; ST-AF and ST-WF); first sensation (FS-WF and FS-AF), at strong desire (SD-AF and SD-WF), and during detrusor overactive contraction (DO), of the patients that show this feature (DO-WF and DO-AF), are displayed in Table 1. These UEs were our primary outcomes for intravesical (ves), abdominal (abd), as well as for detrusor (det). Furthermore, pressure peak maximum during cough, (CHG-AF and WF), strain (STR-AF and WF), and voiding pressures (at-Qmax), for the patients able to void, are compared using Pearson correlations and t-tests.

While we analyzed our study results and discussed them with the other researchers who presented their (subsequently published[10,11]) data we found that our primary outcomes largely duplicated the results of these studies and we subsequently decided to add an in-depth signal analysis to better understand the differences and similarities between the two systems. For this post hoc whole test signal analysis, we transferred all urodynamic pressure traces to the engineering signal analysis programs of MATLAB®Simulink® with the aim to compare not only the pressures at UEs but all (20 Hz) pressure samples of the entire cystometry of every included patient (Figure 2B) for a precise sample to sample analysis.

3 | RESULTS

Forty-one patients were recruited, eight male and 33 females, with a mean age of 53.2 year (range 20–83 years). Nineteen patients (46%) had neurogenic LUTD; Table 2 provides diagnoses and also whether data could be included, nine patients were included with incomplete data. No patient had UTI after the test or any immediate or later sign of urethral, bladder anal, or rectal trauma. In five out of the first eight patients and in one later test we encountered technical difficulties with the software that had to display the extra channels, these measurements were not digitally analyzed due to being only on paper—the backup system. We were allowed to recruit (max 6) patients to replace for technical errors and therefore we included 41 patients to have 36 evaluable tests. Two (female) patients reported some discomfort while the urethral catheters were inserted and were only studied with a double rectal catheter. One intravesical and two abdominal AF catheters displayed initial pressures far above expected values and were not included in the analysis because they would have been replaced in the

routine clinical setting. One intravesical WF catheter was kinked, (pressure channel blocked) inside the bladder and pressures were damped the first 50% of the cystometry, catheter manipulation or reinsertion could have corrected this in clinical routine, data, before the catheter had unfolded, was also not included 17 (female) patients

were able to void during the test, allowing us to obtain data from voiding phase in addition to cystometry data. One male and two female patients had large leak volume DO incontinence and two men had (post radical prostatectomy) SUI incontinence; two female patients voided without the flowmeter switched on; we included the
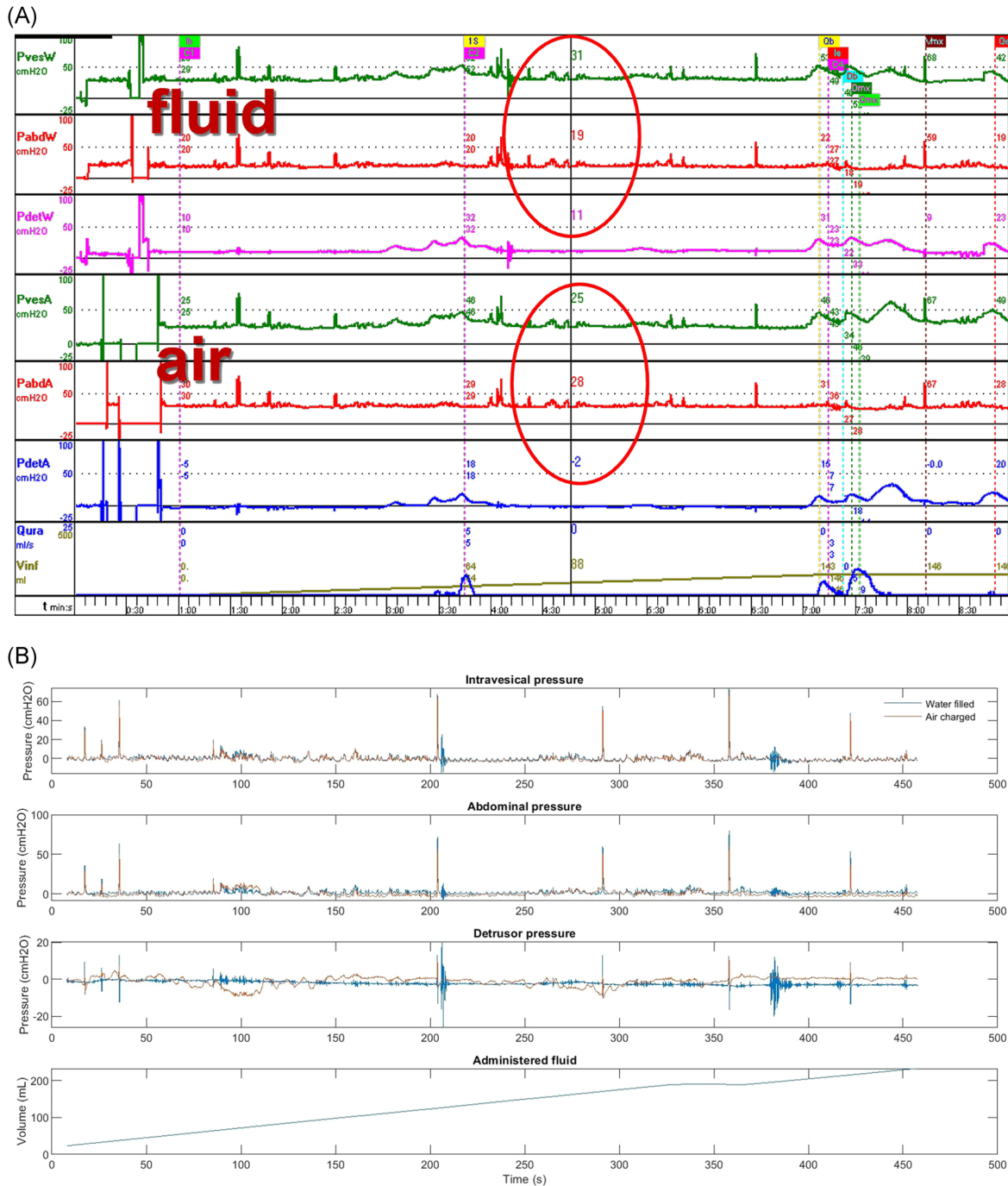

FIGURE 2 (A) Cystometry with simultaneous water-filled and air-filled pressure recording from top to bottom: PvesW(ater); PabdW(ater); PdetW(ater); PvesA(ir); PabdA(ir); PdetA(ir); Vinf(used); Qura (flowrate) and incontinence in this case; and time in min:s. Full scale vertical for all pressures is 100 cmH$_2$O. (B) Cystometry with the WF (blue) and the AF pressures over-projected for 20 Hz signal analysis (saline fill volume on bottom trace). Note that the vertical axes scales differ per pressure. Note the tube knock artifacts in the WF system. Note also that small differences in the intravesical and abdominal pressures add-up in the detrusor pressure (e.g., at 100 ml, 150 ml, and after 370 ml)

pressures during large leak-volume incontinence as if they were pressures during voiding in Table 1. One (transurethral) WF catheter was expelled during voiding and an AF catheter in another patient.

3.1 | Initial per-protocol primary study outcomes

Mean values per pressure and the differences between the UE pressures are shown in Table 1: Mean intravesical (ves) pressure at start (ST) of cystometry in the WF system: STves-WF, is 29.1 cmH$_2$O with an *SD* of 11.0 cmH$_2$O. Mean STves (at the identical moment) with the AF system is 30.1 cmH$_2$O (*SD* 9.4 cmH$_2$O) and the difference between STves-WF and STves-AF is −0.8 cmH$_2$O. The pressures show a weak and insignificant correlation (*r* = .352) and the mean difference in pressures is statistically not significant: *t*-test *p* = .711. The difference at the start of the cystometry in the abdominal pressures STabd-WF (28.4 cmH$_2$O) versus STabd-AF (39.8 cmH$_2$O) is −11.4 cmH$_2$O (*SD* 27.5 cmH$_2$O) and is statistically significant (*p* = .031) without correlation (*r* = .174). The majority (9) of the mean differences in the (12) UE pressures between WF and AF are larger than 5 cmH$_2$O (our primary outcome) and 4/12 are even more than 10 cmH$_2$O which is larger than an earlier reported clinical test-retest variation[19] although the majority of values are within the typical range.[22] We note that 50% (6/12) of the pressures shows a good and significant correlation between both systems and 5/12 shows differences that are statistically significant. We can, however, not uncover a specific pattern in these mean differences, the intravesical or the abdominal pressure seems identically prone to variance, however, the AF catheters tend to show higher pressures in the rectum, with the high proportion of negative mean differences, as observed earlier.[23] The Bland and Altman plots in Figure 3A–C support that the intrasystem differences are large with wide limits of agreement, but without proportional bias.

Further observation taught us that also in our study the pressure differences were carried forward throughout the measurement as observed earlier.[11] In each graph and both systems most of the UE differences were almost identical to the differences at the start of the measurement.

3.2 | Post hoc whole test data signal analysis

The observation that the differences between the two systems are systematic and related to the first pressure after zeroing made us decide to perform a post hoc whole test analysis. With this, we wanted to test the hypothesis that baseline differences are the predominant reason for the observed differences in all UE pressures.

The digitally stored pressure graphs were transferred to signal analysis software and signal analysis was done after equalizing the initial pressures to exclude the differences that we observed to be systematic The equalizing (=removing of baseline differences) allowed us to judge and compare intrinsic measurement properties of both systems as an element of precision of measurement.

Of all measurements, 27 were complete for both WF, AF, P$_{abd}$, and P$_{ves}$ and available in digital form, 17 included a voluntary voiding. Before this signal analysis we have also removed the zeroing artifacts (in WF and in AF): see the zero pressures displayed in the first 50 s of cystometry graph in Figure 2A; a technique similar to[26] and the WF flush pressure peaks (as seen in the first minute of the graph in Figure 2B) and the WF tube knock artifacts (see tube knocks in Figure 2B at 4:00 min after the cough peaks) that are intrinsically impossible to be measured in the AF.

This analysis shows (see Table 3) that the cross-correlation of the pressure channels (per location P$_{abd}$ or P$_{ves}$) of both systems (WF and AF) is high: between 0.981 and 0.998 for P$_{ves}$ and between 0.982 and 0.998 for P$_{abd}$. The average time shift (measured over the full urodynamic studies) for optimum correlation in P$_{ves}$ is 0 s (−0.05 to 0 s) and in P$_{abd}$ −0.05 s (−0.05 to 0 s)[24] which is less than the intersample time of the urodynamic system, this implies that the AF system generally does not respond faster or slower than the WF. We have not observed any time-related deviation (drift) between the two systems.

Because we observed that the highest pressures cause the largest differences (see Figure 4), we specifically analyze coughs. Sixty-eight coughs were isolated from all cystometries and analyzed for peak pressures, time shift, and area under the curve.

3.3 | Post hoc analysis cough pressures

The WF cough pressures have a higher amplitude (intravesical 58.7 vs. 51.0 cmH$_2$O and abdominal 54.0 vs. 49.4 cmH$_2$O; both *p* = .000) and shorter duration (ves: 0.28 s vs. 31 s. and abd: 0.27 s vs. 0.31; both *p* = .000). The area under the—cough pressure—curve is not different. Figure 5 shows representative examples of a single and a double cough in detail (baselines 3.5 and 5 s). Within the WF system and during a cough the P$_{abd}$ is delayed to P$_{ves}$, causing a sinusoid in the P$_{det}$. The AF signals are (more) synchronous for P$_{abd}$ and P$_{ves}$, but both slower, when compared with the WF intravesical pressure. In the P$_{det}$, the deviation from the baseline is the highest in the WF,

TABLE 1 Descriptive statistics and analysis of mean differences between water-filled (WF) and air-filled (AF) pressures at the urodynamic events during cystometry and pressure-flow study

Descriptive statistics and analysis of differences between WF and AF pressures at the urodynamic events							
	N	Min	Max	Mean	*SD*	Mean diff (*SD*)	Correlation	*t*-test *p*
STves-WF	29	1	50	29.1	11.7	−0.8 (12.2)	.352	.711
STves-AF	29	10	51	30.1	9.4			
STabd-WF	30	6	47	28.4	11.6	−11.4 (27.5)	.174	.031
STabd-AF	30	2	170	39.8	27.0			
CHGves-WF	28	37	162	92.4	35.9	11.1 (18.0)	.871**	.003
CHGves-AF	28	22	153	81.5	34.0			
CHGabd-WF	29	33	158	81.9	36.3	−7.1 (33.6)	.630**	.265
CHGabd-AF	29	38	224	89.0	41.1			
STRves-WF	16	17	169	77.2	42.2	2.9 (14.0)	.960**	.441
STRves-AF	15	37	145	76.6	33.6			
STRabd-WF	16	8	160	66.9	39.9	−8.9 (15.7)	.924**	.038
STRabd-AF	16	38	144	75.8	33.2			
DOves-WF	8	27	52	57.1	20.8	10.9 (6.1)	.962**	.003
DOves-AF	7	19	77	50.6	21.1			
DOabd-WF	8	11	52	30.0	14.0	−9.7 (18.9)	.307	.188
DOabd-AF	8	23	73	39.7	17.6			
ENDves-WF	29	4	96	44.9	19.2	6.2 (16.8)	.563**	.068
ENDves-AF	29	3	53	30.7	14.5			
ENDabd-WF	28	17	97	38.8	15.9	−11.5 (28.6)	.039	.040
ENDabd-AF	29	21	149	42.1	25.3			
VOIDves-WF	22	19	95	58.3	20.2	3.5 (18.3)	.628**	.380
VOIDves-AF	22	17	92	54.7	22.0			
VOIDabd-WF	25	−4	80	39.7	20.1	−9.3 (22.4)	.411*	.059
VOIDabd-AF	23	20	88	49.7	21.2			
Descriptive statistics and analysis of differences between WF and AF pressures at urodynamic events that were not listed in the initial protocol.								
	N	Min	Max	Mean	*SD*	Mean diff (*SD*)	Correlation	*t*-test *p*
FSves-WF	38	4	66	35.0	13.3	3.6 (13.0)	.529**	.107
FSves-AF	38	2	62	31.5	13.1			
FSabd-WF	40	3	52	31.3	11.6	−3.9 (15.4)	.198	.124
FSabd-AF	39	2	79	35.1	12.5			
FSdet-WF	38	−13	32	3.4	10.2	6.3 (15.6)	.033	.026
FSdet-AF	37	−53	19	−3.7	12.2			
SDves-WF	38	2	69	40.1	14.6	4.5 (17.0)	.363	.120
SDves-AF	37	2	87	35.8	15.0			
SDabd-WF	39	3	60	33.4	11.7	−1.6 (15.7)	.142	.540
SDabd-AF	38	−3	78	34.9	12.2			

(Continues)

Descriptive statistics and analysis of differences between WF and AF pressures at urodynamic events that were not listed in the initial protocol.								
	N	Min	Max	Mean	*SD*	Mean diff (*SD*)	Correlation	*t*-test *p*
SDdet-WF	38	−23	33	6.0	11.5	3.9 (20.5)	.010	.264
SDdet-AF	36	−56	52	1.1	17.0			
DOdet-WF	13	−34	68	25.0	27.9	4.4 (28.6)	.336	.604
DOdet-AF	12	−2,00	58	21.8	19.1			
Voiddet-WF	23	−38,00	69	17.4	23.1	9 (26.2)	.408	.132
Voiddet-AF	22	−58.00	50	6.2	24.8			

*$p < .05$.

**$p < .000$.

the AF signal is smoother. Overall, the amplitude difference of the normalized signals, has a median of 6.8 (3.8–8.9) cmH_2O for P_{ves}, 6.0 (1.7–8.0) cmH_2O for P_{abd}, and 4.9 (1.2–9.7) cmH_2O for P_{det}. The cross-correlation for the coughs is between 0.990 and 0.997 for the WF and between 0.994 and 0.999 for AF. The time shift is between 0 s and −0.05 s between the systems, indicating that the AF signal is potentially one data sample slower than the WF signal. We consider that a delay of (less then) 5 ms is clinically not relevant. The average amplitude difference is 3.8 (1–7.0) cmH_2O in WF and 2.9 (0.6–6.1) cmH_2O in AF. There is no statistically significant difference between both systems regarding cough area under the curve (P_{ves} 25.2 cmH_2O*s WF vs. 24.7 cmH_2O*s AF (*t*-test p.30) and P_{abd} 25.0 cmH_2O*s vs. 26.1 cmH_2O*s; p.31).

The high cross-correlation of data samples of both systems per location (P_{ves} or P_{abd}) indicates that the signals are much overlapping after equalizing the two systems from the first relevant sample. The cross-correlation in the detrusor pressure is much lower, with a median of 0.720. This is explained by the fact that when P_{ves} and P_{abd} signals are subtracted to a derivative signal (P_{det}), an error in P_{ves} will add up to an error in P_{abd} certainly when the errors are in the opposite direction (see the example in Figure 2B). This is also observed in the UE P_{det} differences, obtained without equalizing the original pressures (Figure 3C), and accounts for WF as well as for AF and highlights that P_{det} (derivative) signals differ more than their originating signals.

There are pressure response differences between WF and AF urodynamic measurements. These differences exist apart from the already reported differences that result from baseline setting variations. Although the conclusion may also be that the WF system responds erroneously underdamped on fast pressure peaks, the AF

system responds, also in vitro, with damping. The peak pressure response intratest differences are, however, much smaller (in cmH_2O) than the baseline differences.

4 | DISCUSSION

In this prospective head-to-head comparison cystometry with AF catheters versus the ICS-standard WF catheters, we find on average small differences in mean pressures between the two systems but observe large ranges and standard deviations and wide limits of agreement of all the differences. The differences were random, unsystematic and, most of the tests have larger between test differences than expected as our primary outcome. The differences at the start of the cystometry persisted throughout the measurement and are referred to as baseline differences. After correction for the baseline differences (equalizing), we noted a high correlation between AF and WF of all 20 Hz pressure samples per location (abd or ves), which was lesser in the pressures more than 50 cmH_2O. Furthermore, (equalized samples) evaluation of the coughs separately shows that the AF produces little lower and longer cough peak amplitudes, in comparison with WF with a similar area under the curve. The (high) cross-correlation represents pressure pattern display (breathing, talking, movements, and rectal activity)—similarity for each channel in every test but is not identical to clinical uncovering and analysis of dysfunction—patterns and it is also not possible to extrapolate this to detrusor subtraction pressure patterns. Especially also the study cannot conclude on potential specific differences for pressure-flow measurements and or grading of voiding dysfunction and or of leak-point pressures. The "equalized similarity" is only partially relevant for clinical practice, because of the

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TABLE 2 Clinical information and inclusion of data

No	Sex	Diagnosis	Included	Complete*	Voided
1	M	PRP incontinence			
2	M	PRP incontinence			
3	M	Prostate/pelvic pain			
4	F	Recurrent(S)UI	X	X	X
5	F	DO-UI	X	X	X
6	F	Recurrent(S)UI	X	X	X
7	F	Recurrent(S)UI	X	X	X
8	F	Recurrent(S)UI	X	X	X
9	F	SCI (infarction)	X	X	
10	F	SUI	X		X
11	M	SCI (after Brindley explant)			
12	F	DO-UI	X	X	X
13	F	DO	X		X
14	F	DO-INCO	X	X	X
15	F	N-LUTD polyneuropathy	X	X	
16	F	N-LUTD tethered cord	X		X
17	F	N-LUTD SUI LMND	X	X	X
18	F	Recurrent (S)UI & pain	X	X	
19	M	MMC	X	X	
20	F	RUTI myelopathy	X	X	X
21	F	Recurrent SUI	X	X	X
22	M	N-LUTD caudal lesion	X	X	
23	F	Bladder Pain	X	X	
24	F	Recurrent (S)UI pain	X	X	X
25	F	RUTI & DO	X	X	X
26	F	N-LUTD Caudal lesion UTI's	X		
27	F	N-LUTD demyelinating disease, DO UI	X	X	
28	F	MMC	X	X	
29	F	Acontractile detr & UTI's (after SUI surgery)	X		
30	F	N-LUTD central-pontine	X	X	X
31	F	HSP DO UI	X	X	
32	F	SCI LMND	X	X	X
33	F	Acontractile detr & UTI's (after SUI surgery)	X	X	
34	F	Muscular dystrophia immobility	X		
35	F	MMC	X	X	X
36	F	Recurrent (DO)UI (after SUI surgery)	X	X	X
37	M	SCI LMND	X	X	

(Continues)

TABLE 2 (Continued)

No	Sex	Diagnosis	Included	Complete*	Voided
38	M	SCI DO (UMND)	X	X	X
39	M	DO RUTI	X		
40	M	MMC			
41	F	N-LUTD central	X	X	

Abbreviations: DO, detrusor overactivity; HSP, hereditary spastic paresis; MMC, meningomyelocele; N-LUTD, neurogenic lower urinary tract dysfunction; PRP, post radical prostatectomy; RUTI, recurrent urinary tract infection; SCI, spinal cord injury; SUI, stress urinary incontinence.

*Complete = vesical and intra-abdominal pressure evaluable with both systems.

predominance of the baseline differences. If a gold standard for urodynamic pressures had been available we would have been able to decide on precision (intrinsic measuring properties) as well as on accuracy (displaying "the truth"). We now assume, based on our post hoc analysis that both systems are similarly precise (or "capable") in showing intra bodily pressures, but also conclude and emphasize earlier statements[11,16,23] that both systems are probably also similarly inaccurate.

Our work confirms the results of earlier clinical studies regarding the UE pressures,[11,23] and adds in depth precision analyses with pressures equalized from the first sample after ICS-standard zero calibration of the systems to reference atmosphere pressure. The earlier study[11] has discussed the effects of position changes, but also the differences in pressure at UEs. While good quality signals test selection was done in that study, our results are very similar with regard to mean differences, standard deviations, and the limits of agreement of the diverse values. We confirm that baseline differences are random and remain relevant, and little changed, throughout the measurement.[11] This study[11] also introduces statements about software equalization (at test start) and or mathematical analysis (postprocessing). Our study confirms its relevance and could be a starting point for a discussion of structured cognitive assistance in standardizing the evaluation and reporting of urodynamic tests based on earlier presented principles.[1] Both (all) urodynamic systems should only be used, and the results should only be evaluated with thorough knowledge of the physiological background of lower urinary tract function. Albeit good precision of both systems, their inherent (inter and intrasystem) inaccuracy in the clinical setting necessitates careful attention. Urodynamic testing, as every clinical physiological measurement, requires quality control before and during the test and also requires standardized posttest cognitive assistance to arrive at a reliable diagnosis with regard to the quantitative as well as the qualitative elements. Education, training, systematic quality control, and consensus about (post-) processing of tests performed with any system are of utmost importance to ensure reliable urodynamic diagnosis and grading of dysfunction.

The additional (precision) differences, apart from the baseline (accuracy) differences between the systems, predominantly occur in fast and large amplitude pressure peaks with a higher but shorter peak in the AF, as predicted by the bench study.[8] The differences between the systems are not related to pressure drift in one or the other system.[9] The vast predominance of the pressure patterns was identical with a high cross-correlation and without any evidence for delayed response in the one versus the other. Nevertheless, also, small pressure differences quantitatively add up in the detrusor subtraction pressures when the differences are in the opposite direction although this study does not give arguments for the one system being intrinsically better than the other. Both, our study as the earlier,[11] have clearly shown very much larger limits of agreement when DO pressures or voiding pressures have been analyzed. Like the earlier study, we can also not find evidence in the graphs that recognition and uncovering of rectal activity, DO, or voiding contraction are significantly hindered or changed in the AF system when the WF system is taken as the reference. The only impression that we can share that we think is more or less systematic is that the (slow-wave low amplitude) rectal activity was slightly livelier (pronounced) displayed in the AF system, when present in some of the patients. We have not had the impression, also not in retrospect, that with cognitive assistance, (or mathematical correction, based on baseline pressures) one system would have led to a change of diagnosis when compared with the other, however, our study has not been designed to conclude this. We also are aware that with both systems we would normally have made corrections (catheter manipulations, reinsertion, and or replacement) during the test and or we would have done a second test because of the technical imperfections, in a small proportion of measurements.

Relevant differences between the currently evaluated systems importantly relate to measuring system set-up
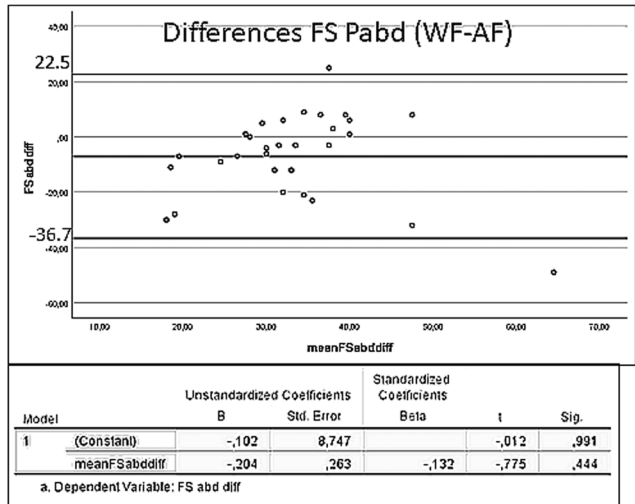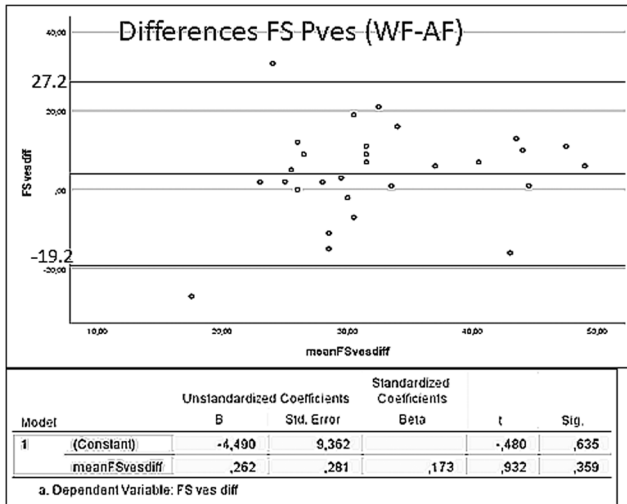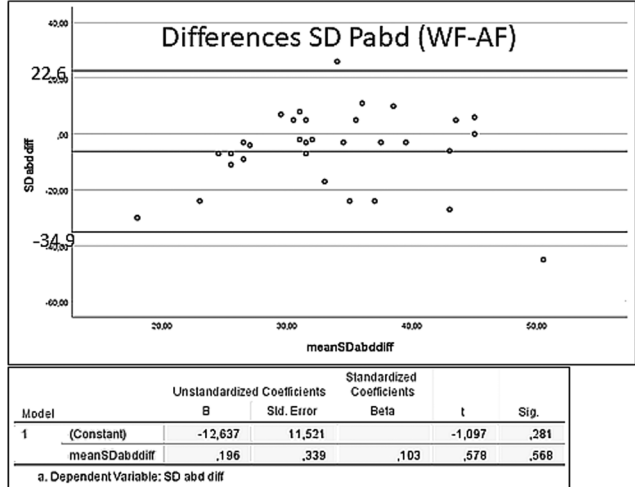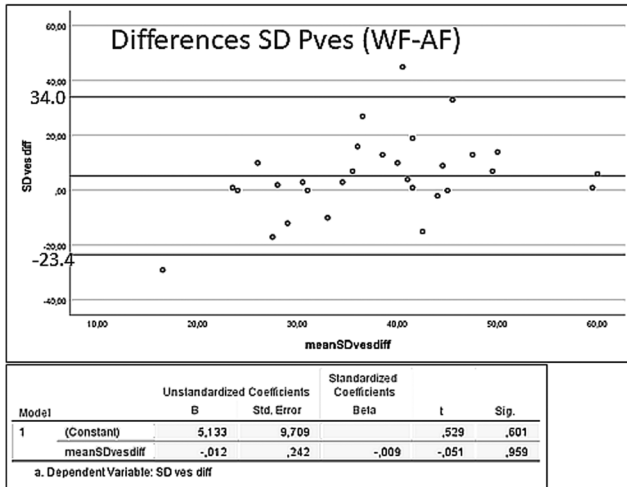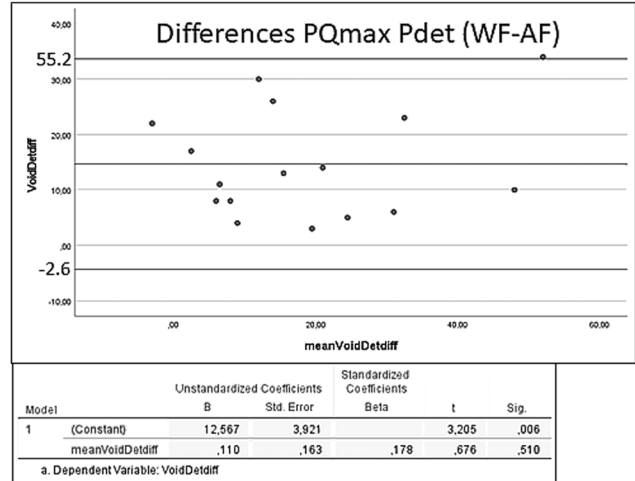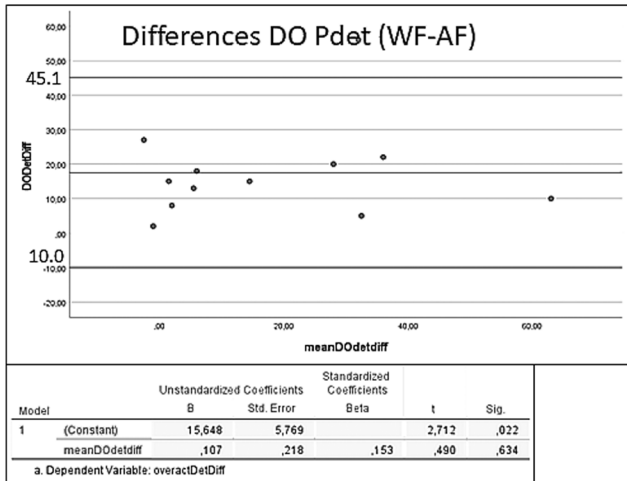
FIGURE 3 Bland and Altman graphs: (A) pressure differences at FS, (B) pressures at *SD* (C) pressures at DO and during voiding or DO-incontinence. Limits of an agreement are indicated, and the tables show the regression coefficients all test-test differences were not proportional. DO, DO, detrusor overactivity; FS, first sensation

TABLE 3 Signal analysis results

Cystometry ($n = 27$)	Intravesical pressure	Abdominal pressure	Detrusor pressure
Cross-correlation	0.995 [0.981–0.998]	0.993 [0.982–0.998]	0.720 [0.494–0.808]
Time shift (s)	0 [−0.05 to 0]	−0.05 [−0.05 to 0]	53.35 [−0.1 to 151.94]
Δ Mean (cmH$_2$O)	5.4 [0.3–12.3]	−7.1 [−13.8 to 5.9]	8.3 [4.8–12.7]
Δ FSF (cmH$_2$O)	4.0 [1.1–6.1]	2.1 [−1.2 to 4.4]	1.8 [0.9–4.1]
Δ SDV (cmH$_2$O)	6.4 [2.5–10.5]	3.6 [−1.6 to 7.4]	4.2 [1.1–6.2]
Pressure-flow study ($n = 17$)			
Cross-correlation	0.996 [0.992–0.998]	0.993 [0.981–0.998]	0.870 [0.596–0.966]
Time shift (s)	0 [0–0]	0 [−0.05 to 0]	−0.05 [−0.6 to 0]
Δ Max P$_{det}$ (cmH$_2$O)			12.3 [3.0–17.4]

Note: Comparison 20 Hz samples WF versus AF Values are presented as median [interquartile range], Δ = water-filled − air-filled.

Abbreviations: FSF, first sensation of filling; P$_{det}$, detrusor pressure; SDV, strong desire to void.
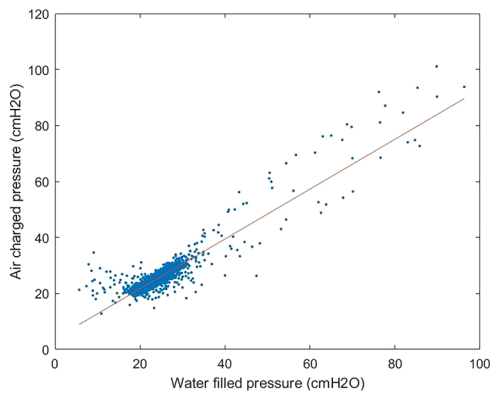

FIGURE 4 Scatterplot of cystometry P$_{ves}$ WF versus AF samples of Figure 2a; including the tube knock artifacts. Relatively large differences occur in the low (<10 cmH$_2$O) pressures (tube knocks) and the pressures >40 cmH$_2$O, including patients' moving and coughing. >98% of the 9.000 samples (per system) between 15 and 40 cmH$_2$O is close around the mean. AF, air-filled; WF, water-filled

and the zeroing procedure applied in both systems. Although this study has been single site and ICS standard practice, the results of urodynamics are in general also inherently sensitive to the fact that the body masses that rest on the pelvic cavity and are measured as pressures, are in-homogeneous and not fixed.[25] Even a technically perfect and infallible, fool-proof system for intracorporeal urodynamic measurement will not be 100% precise. We postulate that both systems have, despite similar precision a similar inherent risk of being inaccurate in clinical measurements. Both systems require similar cognitive assistance to incorporate intrinsic measurement properties and, especially necessitate awareness of baseline pressures and may require adjustment of pressure offsets when necessary, into quantitative (and specifically detrusor subtraction pressure) urodynamic analysis.
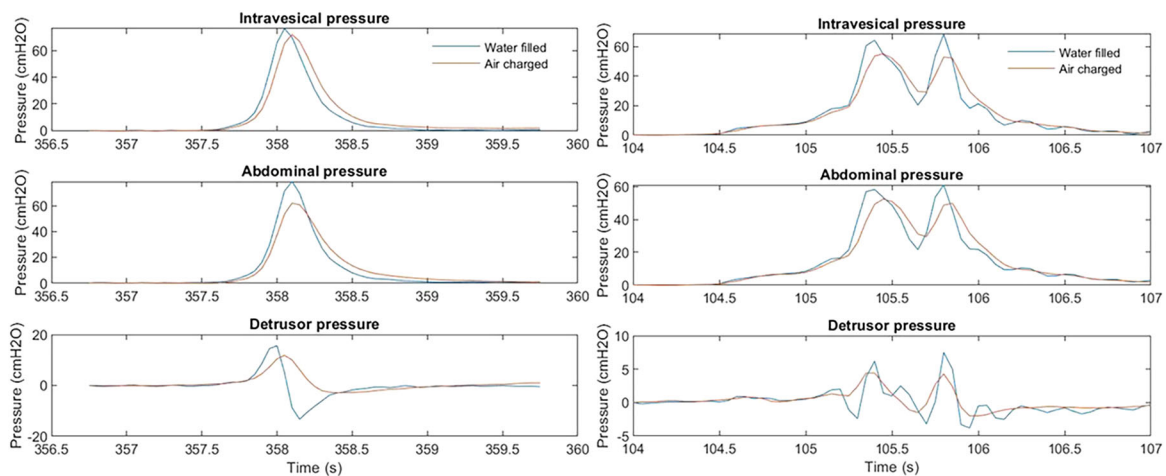

FIGURE 5 Examples of a single and a double cough in detail (baselines 3.5 and 5 s) with responses of each system per location and the resulting detrusor subtracted curves

5 | CONCLUSIONS

Head-to-head comparison of water-filled with air-filled urodynamic catheters shows small mean pressure differences but large and random absolute intersystem differences and wide limits of agreement between test pressure values. We observed that the differences are very much larger than the earlier benchmark result and also clinically relevant when not adjusted. We confirm earlier studies with these conclusions. Detailed signal analysis unveiled that both systems are equally precise when the baseline differences are eliminated, however, the air-filled system has an intrinsic delay of 0.05 s during high-pressure coughs and is slightly damped in comparison with the water-filled system.

We have additional and more specific than the earlier studies shown that the differences between water-filled and air-filled systems for urodynamics cannot primarily be attributed to the intrinsic measurement technique (precision) of the catheter systems.

CONFLICT OF INTERESTS
The authors declare that there are no conflict of interests.

DATA AVAILABILITY STATEMENT
Anonymized data file can be made available.

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