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ORIGINAL ARTICLE

Comparison of air-filled and water-filled catheters for use in cystometric assessment

Wei Sheng [1] · Ruth Kirschner-Hermanns [1,2]

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Abstract

Introduction and hypothesis To determine whether pressure readings measured with air-filled catheter (AFC) and water-filled catheter (WFC) systems are equivalent during cystometric assessment, especially in case of pressure measurements at Valsalva manoeuvres and coughs.

Methods Twenty-five subjects were recruited. The commercially available 7-Fr TDOC AFC, which simultaneously reads water and air pressures in the bladder and rectum, was used to compare filling and voiding data recordings. Data were compared using paired *t*-tests, Bland-Altman plots and linear correlation methods, respectively.

Results Pressure readings measured by the two systems showed a good correlation at Valsalva manoeuvres [$R^2 = 0.988$, 0.968 for vesical pressure (Pves) and abdominal pressure (Pabd), respectively] and at coughs ($R^2 = 0.972$, 0.943 for Pves and Pabd, respectively). There was a statistically significant difference between the two different measurement modalities at coughs ($p < 0.01$), initial resting pressure ($p < 0.01$) and the maximum pressure at detrusor overactivity ($p < 0.01$). This indicated that the difference between the two measurement modalities during Valsalva manoeuvres could reach up to 5.2 cmH_2O and 8.1 cmH_2O in Pves and Pabd measurements, respectively. During coughs, the difference could reach up to 20 cmH_2O and 19.5 cmH_2O in Pves and Pabd measurements, respectively.

Conclusions Pressure recordings from AFC and WFC systems appear to be interchangeable for some urodynamics parameters such as Pves at Valsalva manoeuvres if the baseline pressure is compensated, but not for fast-changing pressure signals such as coughs. This has to be considered when pressures are being taken with the AFC.

Keywords Air-filled catheter · Water-filled catheter · Urodynamics · Comparison study

Introduction

The air-filled catheter (AFC) has already gained popularity in some areas and countries despite the lack of strong scientific evidence for their use in urodynamics (UDS) studies. Compared with the water-filled catheter (WFC), this popularity might derive from some intrinsic advantages of the AFC, e.g., the omnidirectional detection of pressure, reduction in movement artefacts (due to the weightless air column vs. weighted water column), lack of air bubble interference and ease of set-up/use (according to our experience) [1]. However, the WFC measurement system is still the gold standard, and all the guidelines have been made based on this system. Some researchers have tried to look into the equivalency of these two measurement modalities. Currently, there are three clinically published peer-reviewed articles comparing pressure recordings measured with AFCs and WFCs in cystometric evaluations [2–4]. In two of these articles, the authors reported a similar study design with the use of two simultaneous catheters assessing vesical pressure (Pves) and two simultaneous catheters assessing abdominal pressure (Pabd) [2, 3]. This might have resulted in interference between catheters during measurement. Moreover, the presence of two catheters in the urethra might affect pressure measurements at voiding. The International Continence Society (ICS)

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✉ Wei Sheng
shengwei0708@gmail.com

[1] Department of Urology/Neuro-Urology, University Clinic, Rheinische Friedrich-Wilhelms-Universität Bonn, Bonn, Germany

[2] Neuro-Urology, Neurological Rehabilitation Center, Godeshoehe, Bonn, Germany

recommends that the urethral catheter should be as thin as possible [5]. Therefore, the aim of this study was to assess the equivalence of pressure readings measured by AFC and WFC systems during UDS studies using a single dual-lumen catheter that records air and water pressures simultaneously, especially during Valsalva manoeuvres and coughs [4].

Materials and methods

Patient enrolment

This study was performed at the department of neuro-urology in a neurological rehabilitation centre. Protocols were approved by the local ethics committee, and all patients signed an informed consent form. Patients were recruited through UDS referrals. Patients of both genders (≥ 21 years old) scheduled for UDS were included. Patients with lower urinary tract infection, urethral stricture disease or a suprapubic catheter in place were excluded. Patients with asymptomatic bacteriuria were not excluded. Pregnancy was also an exclusion criterion.

Investigational set-ups

A single dual-lumen catheter (7-Fr dual-lumen single-sensor T-DOC® Air-filled™ Catheter, TDOC-7FS, Laborie Medical Technologies, Mississauga, ON, Canada) was used to assess vesical pressure for water (Pves-WFC) and air (Pves-AFC) systems. This single-catheter technique was also used to assess abdominal pressure using the water (Pabd-WFC) and air (Pabd-AFC) systems. Catheters were connected to a UDS device (Solar Silver, Medical Measurement Systems, Enschede, The Netherlands) to record measured pressure readings. The water-filling channel of the AFC was used as a bladder filler as well as the water pressure measurement channel. A three-way stopcock permitted dual functionality. A pressure cuff was used to maintain constant perfusion (2 ml/min) to prevent catheter blockage by faeces at the tip of the rectal catheter. Settings of the air-filled pressure measurement system were used according to the manufacturer's instructions. To assure correct and stable placement during the entire UDS investigation, vesical and rectal catheters were attached to the body surface with tape.

For both systems, Pves and Pabd were zeroed to atmospheric pressure. Water pressure transducers were located at the height of the patient's upper edge of the symphysis pubis. Filling cystometry was performed using body temperature (37°C) sterile saline (20–30 ml/min). During the filling phase, the water measurement channel for Pves-WFC was closed, while the pump channel was opened by turning the stopcock. When the infused saline volume reached 50 ml, 100 ml and every 100 ml thereafter, the pump was stopped. The stopcock was closed to the pump channel and opened to the Pves-WFC measurement channel. Then, the patients were asked to perform Valsalva manoeuvres and coughs consecutively (3 times for each). Air-filled measurement channels and Pabd-WFC measurement channels were opened to sensors and recording pressure readings throughout the study. During the voiding phase, the Pves-WFC measurement channel was always kept opened. All events were annotated, i.e., leaks, detrusor overactivity (DO; if any), coughs, Valsalva manoeuvres, first desire to void, strong desire to void, maximum cystometric capacity (MCC), permission to void, blood pressure and adverse events.

Before each UDS test, both rectal and vesical AFCs were calibrated using a column of distilled water at 0, 20 and 30 cmH_2O; WFC systems were calibrated by raising the catheters to a certain height. All UDS traces were screened and recorded by the head research nurse and the lead author to guarantee that only good quality signals were used for the comparison according to ICS-GUP [5].

Statistical analysis

Statistical analysis was performed using Medcalc statistical software version 15.6.1 (MedCalc Software bvba, Ostend, Belgium) and Microsoft Excel 2013. Sample size was calculated based on a previous pilot study [7], showing that 19 subjects were needed to give a power of 0.8 at 5% significance level for the main outcomes (Valsalva manoeuvre and cough measurements; G Power, Kiel, Germany).

It was assumed that baseline pressure values would be different between the WFC and AFC measurement systems (because of the different reference points used by the different technologies). A reasonable comparison of pressure readings can only be made between changes with respect to the baseline pressure value during movements such as Valsalva manoeuvres and coughs [6]. Hence, we subtracted the resting pressure value at each filled volume (i.e., 50 ml, 100 ml, 200 ml) from the peak pressure value during Valsalva manoeuvres and coughs. The same calculation was performed for maximum pressure at DO and at maximum voiding flow (Qmax). The "70% rule" as proposed by Sullivan was used to screen raw data during coughs, and the cough signal quality was evaluated by comparing the measured height of the cough spikes on Pabd and Pves traces as: grade A = a good cough signal (smaller spike 70–100% of the larger one); grade B = moderate cough signal (smaller spike 30–70% of the larger one); grade C = poor cough signal (smaller spike 0–30% of the larger spike). Grade A was deemed to be acceptable, grade B and C unacceptable [8]. Consequently, only grade A cough signals were included in our analysis. We used the same rule for the quality control at Valsalva manoeuvres. Correlations between the two methods at Valsalva manoeuvres and coughs were assessed by linear correlation plots. Paired sample *t*-tests were used for the comparison in all events. Bland-Altman plots were used to assess the equivalence between the two measurements for repeated data and single-measurement data [9, 10]. Results were presented as mean ± standard deviation (SD); $p < 0.05$ was considered statistically significant.

Results

Patient characteristics

Twenty-five patients (9 male and 16 female) with a mean age of 43.3 years (range 21–62 years) were recruited from April to August 2016. Of the 25 patients recruited, 16 were investigated in the sitting position and 9 in the reclined position. The UDS diagnoses were as follows: five patients with neurogenic detrusor overactivity (NDO), six with neurogenic underactivity, three with bladder hypersensitivity, two with idiopathic detrusor underactivity, three with idiopathic detrusor overactivity, four with both NDO and detrusor sphincter dyssynergia (DSD) and two who did not show any pathological findings during UDS studies.

Quality control

One patient presented an episode of high blood pressure with autonomic dysreflexia, and the infusion pump was therefore stopped at 335 ml before maximum capacity was reached. Data from this UDS study were included in the analysis. Four tests were excluded: in two cases, poor abdominal pressure measurements for unknown reasons for both systems were obtained; one test was excluded because active signals of Pabd-AFC measurement were lost halfway; one test was excluded because there were consistent low Pabd measurements in the WFC system during Valsalva manoeuvres and coughs. All these issues could not be settled by either adjusting the catheter position or flushing the catheter. Ultimately, 21 patients were included in our analysis.

Two hundred fifty and 301 raw data pairs were collected for the pressure measurement of Valsalva manoeuvres and coughs, respectively. After quality control using the "70% rule", 213 (85.5%) and 225 (90%) data showed good quality (grade A) in the WFC and AFC systems during Valsalva pressure measurement. Meanwhile, 205 (68.1%) and 282 (93.7%) data were grade A in the WFC and AFC measurement systems during coughs (Table 1). Finally, 204 and 190 data pairs were used for comparison at Valsalva manoeuvres and coughs, respectively. An example of a complete trace is shown in Fig. 1.

Comparative outcomes

Correlations of pressure readings between AFC and WFC systems at Valsalva manoeuvres and coughs are presented in Fig. 2. Strong correlations were observed between the two methods in Pves (R^2 = 0.988 for Valsalva, R^2 = 0.972 for coughs) and Pabd (R^2 = 0.968 for Valsalva, R^2 = 0.943 for coughs) measurement during Valsalva manoeuvres and coughs. There were no statistically significant differences between the two measurements at Valsalva manoeuvres (Table 2). However, significant differences were shown in all parameters at coughs ($p < 0.01$; Table 2). It showed that the paired difference in Pves and Pabd measurement could be up to 5.2 cmH_2O and 8.1 cmH_2O at Valsalva manoeuvres, respectively (Fig. 3), whereas in Pves and Pabd measurement it could reach up to 20 cmH_2O and 19.5 cmH_2O at coughs, respectively (Fig. 3).

Table 1 Quality control for Valsalva manoeuvres and coughs. Grade A, smaller peak pressure > 0.7 larger; grade B, smaller peak pressure > 0.3 and < 0.7 larger; grade C, smaller peak pressure < 0.3 larger. WFC, water-filled catheter; AFC, air-filled catheter

Quality control	Valsalva manoeuvre		Cough	
	WFCs	AFCs	WFCs	AFCs
All (*n*)	250	250	301	301
Grade A (%)	213 (85.2%)	225 (90%)	205 (68.1%)	282 (93.7%)
Grade B (%)	35 (14%)	21 (8.4%)	81(26.9%)	17 (5.6%)
Grade C (%)	2 (0.8%)	4 (1.6%)	15(5%)	2 (0.7%)

Other UDS events showed that there were no statistically significant differences between the two approaches when Pdet recordings were compared using paired *t*-tests, except for the comparison at initial resting pressure ($p < 0.01$) and at maximum pressure at DO ($p < 0.01$; Table 3). The Bland-Altman plots indicated that baseline Pdet could reach up to 18 cmH_2O for a given patient. Results are shown in the supplementary figure.

Discussion

Since its launch, the AFC has generated great interest in the field of UDS studies. Three clinical studies have been conducted comparing cystometric pressure readings between AFC and WFC systems. Digesu et al. [1] used AFCs and WFCs to simultaneously compare Pves, Pabd and Pdet in 20 women. It was shown that pressure measurements from AFCs were overall higher than those from WFCs. They concluded that the two technologies were not interchangeable. However, Gammie et al. [2] showed that pressure recordings obtained with AFCs and WFCs were not significantly different during filling and at maximum flow during voiding, but pressure values differed up to 10 cmH_2O. In their settings, potential interactions between two catheters in the urethra may have influenced their results. In a recently published article, Timothy et al. used the "single catheter" technology [4]. Pressure readings were recorded with WFC and AFC systems

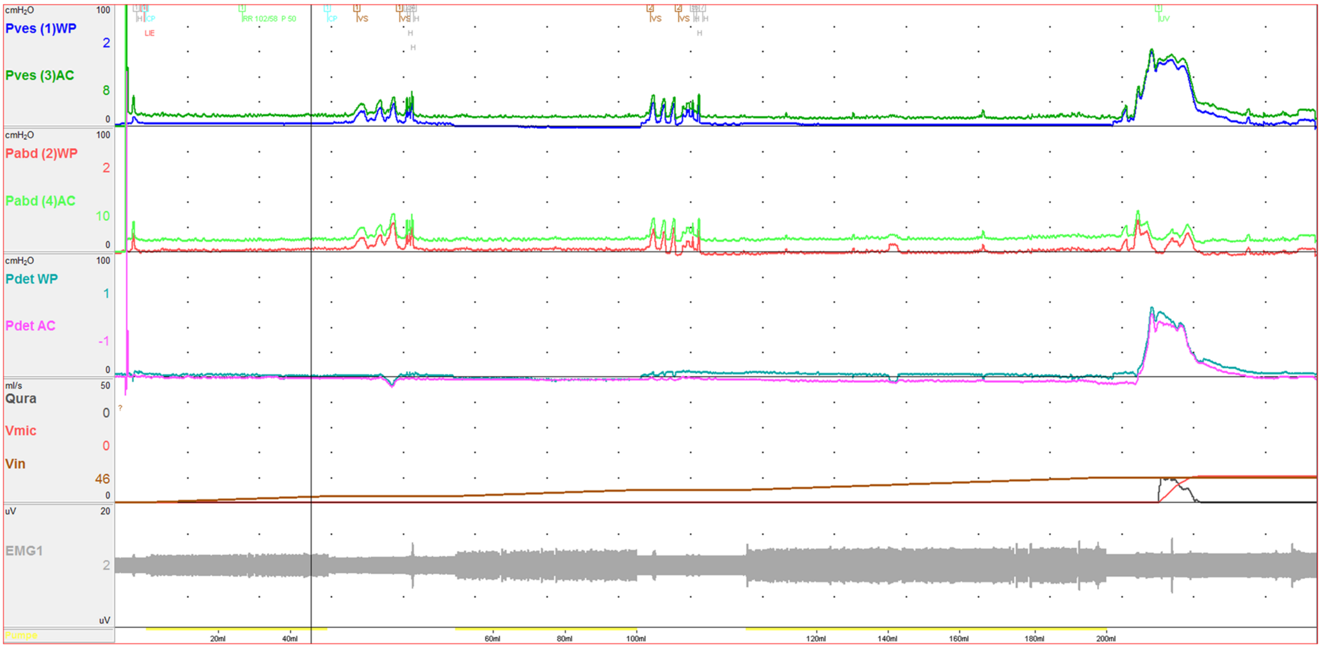

Fig. 1 Sample of the urodynamic test with simultaneous AFC and WFC measurements. Blue and red lines represent vesical pressure and abdominal pressure for the water-filled system, respectively. Dark green and light green represent vesical pressure and abdominal pressure for the air-filled system, respectively. During the filling phase, the Pves-WFC channel was closed using a three-way stopcock until Valsalva manoeuvres and coughs

in 50 women. Valsalva manoeuvres, coughs and other UDS events were evaluated. However, the "single catheter" technology was only applied to compare Pves recordings between the two catheter systems. Comparison data about Pabd recordings were not presented. Hence, Pdet values between catheter systems were not compared. Compared with previous studies, our study included patients from both genders with 9/25 being male. Because the study was conducted in a neurological rehabilitation centre, most patients (15/25) had neurogenic bladder dysfunctions.

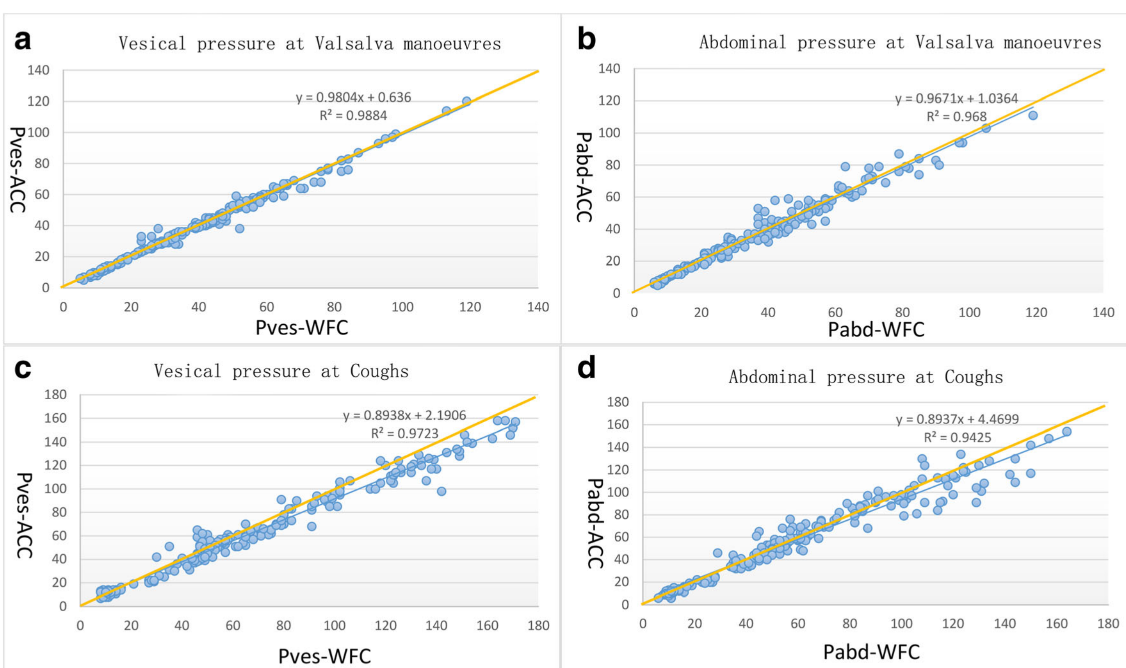

Fig. 2 **a** Correlation of Pves-AFC and Pves-WFC at Valsalva manoeuvres. **b** Correlation of Pabd-AFC and Pabd-WFC at Valsalva manoeuvres. **c** Correlation of Pves-AFC and Pves-WFC at coughs. **d** Correlation of Pabd-AFC and Pabd-WFC at coughs. Yellow line represents X = Y

Table 2 Comparison between two measurement modalities in Pves, Pabd and Pdet values at Valsalva manoeuvres and coughs. Pves, vesical pressure; Pabd, abdominal pressure; Pdet, detrusor pressure

	Number of paired data	WFC mean (SD) in cmH_20	AFC mean (SD) in cmH_20	Paired *t*-test *p* value
Maximum Pves at Valsalva	204	39.44 (23.34)	39.31 (23.02)	0.43
Maximum Pabd at Valsalva	204	38.11 (22.04)	37.93 (21.70)	0.51
Maximum Pdet at Valsalva	204	1.65 (3.39)	1.72 (3.85)	0.85
Maximum Pves at cough	190	69.65 (43.25)	64.59 (39.21)	< 0.01
Maximum Pabd at cough	190	63.01 (38.67)	60.71 (35.66)	< 0.01
Maximum Pdet at cough	190	6.83 (7.82)	3.89 (9.44)	< 0.01

Our primary goal was to assess the equivalence of pressure readings between WFC and AFC systems at Valsalva manoeuvres and coughs. After quality control, we found that > 85% of raw data had good quality (grade A) in Valsalva manoeuvres for both systems. In cough pressure tests, about 30% of raw data had moderate or even bad quality (grade B and C) in pressure measurements with the WFC system. When looking at specific pressure measurements, we found that Pabd-WFC readings were quite low in some subjects or some episodes of the measurement during coughs. It is assumed that the water orifice of the rectal catheter interacted with the rectal mucosa during fast movements in such cases. Even with the presence of continuous perfusion, this resulted in blockage or partial blockage of the orifice and was the root cause of the falsely low readings.

When looking at linear correlation plots (Fig. 3), strong correlations were observed between the two methods at Valsalva manoeuvres and coughs. It seems that they correlated even better at Valsalva manoeuvres than at coughs ($R^2 = 0.988$ vs. 0.972 at Pves, $R^2 = 0.968$ vs. 0.943 at Pabd). In cough tests, tracings from AFC systems showed damped response over Pves and Pabd measurement, especially in Pves measurement. The result conforms to that from bench testing published by Cooper and Awada [11, 12]. In their studies, they concluded that pressure measurements from AFCs appear to be overdamped when performing high-frequency (fast) movements. When results from paired *t*-tests were considered, no statistically significant differences were found at Valsalva manoeuvres ($p = 0.43$, $p = 0.51$ and $p = 0.85$ for Pves, Pabd and Pdet, respectively) between the two measurements. The

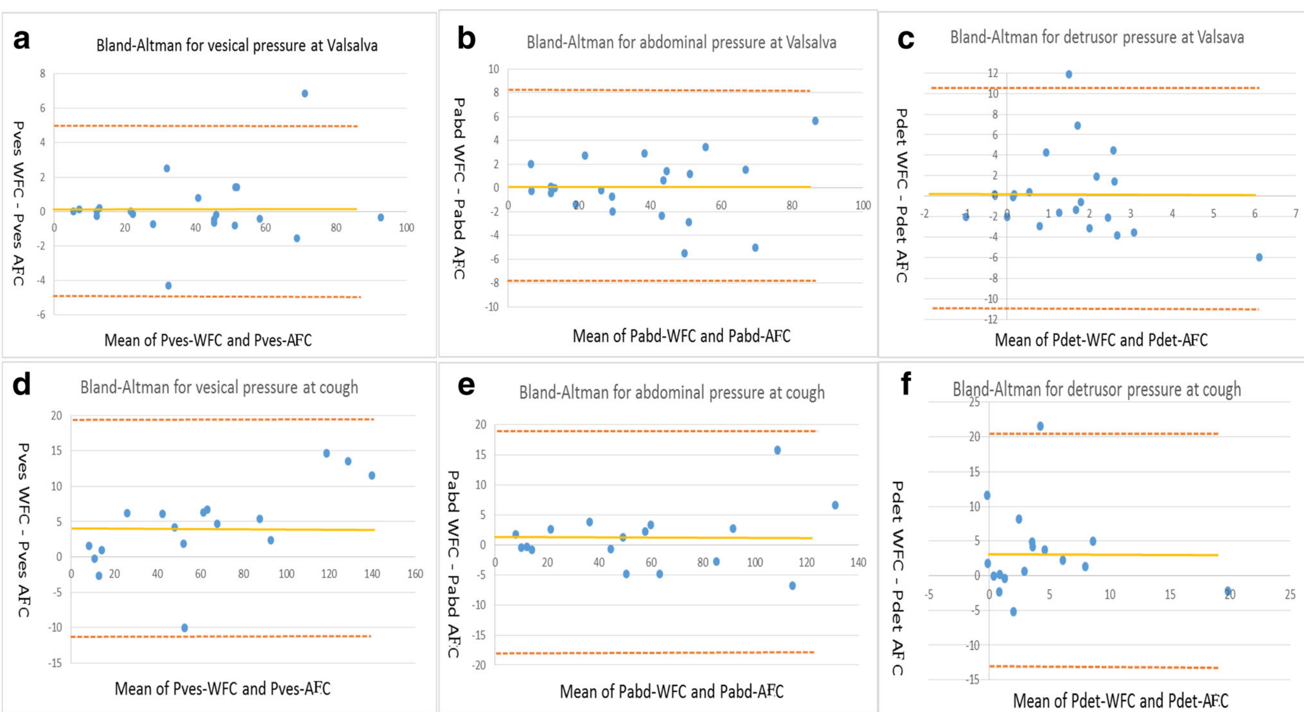

Fig. 3 Bland-Altman plots for repeated measurements per subject at Valsalva manoeuvres and coughs. Yellow line represents the average pressure value of difference. Red lines represent the limits of agreement (LOAs). **a** The 95% LoAs are –4.9 to 5.2 cmH_2O (0.16 ± 2.58). **b** The 95% LoAs are –8.0 to 8.1 cmH_2O (0.04 ± 4.09). **c** The 95% LoAs are –10.6 to 10.4 cmH_2O (4.93 ± 7.30). **d** The 95% LoAs are –11.4 to 20.0 cmH_2O (4.30 ± 8.00). **e** The 95% LoAs are –17.3 to 19.5 cmH_2O (1.08 ± 9.40). **f** The 95% LoAs are –13.7 to 20.1 cmH_2O (3.22 ± 8.62)

Table 3 Comparison between two measurement modalities, in Pdet values, at different points of the urodynamics test. DO, detrusor overactivity; Qmax, maximum flow

Recording point at which Pdet read	Number of paired data	WFC mean (SD) in cmH_20	AFC mean (SD) in cmH_20	Paired *t*-test *p* value
Resting,50 ml volume	21	0.86 (2.76)	–1.29 (4.74)	0.08
Resting,100ml volume	20	2.05 (3.03)	–0.85 (5.40)	0.06
Resting,200ml volume	17	2.65 (3.77)	0.94 (5.85)	0.32
Resting,300ml volume	14	3.14 (3.32)	–0.50 (5.89)	0.07
Maximum cystometric capacity	21	4.05 (4.04)	0.76 (5.78)	0.06
Pressure at Qmax	18	38.28 (27.28)	39.00 (28.02)	0.60
Maximum pressure at DO	22	40.05 (29.81)	37.45 (30.47)	< 0.01
Initial resting pressure	21	1.10 (2.77)	–2.67 (5.23)	<0.01
Resting pressure after voiding	10	4.00 (4.06)	2.80 (7.13)	0.49

average pressure values were almost identical between the two measurements at Valsalva manoeuvres (Table 2). On the contrary, there were significant differences between measurements at coughs (all $p < 0.01$ for Pves, Pabd and Pdet, respectively). Mean pressure values seemed to be higher in the WFC measurement than those in the AFC measurement (Table 2). In another clinical report from Gammie et al., a significant difference between the two methods at Valsalva manoeuvres ($p < 0.001$) was detected. The mean value of Pdet-WFC was higher than the one measured with AFCs. In contrast, there was no statistically significant difference between the two measurement modalities at coughs ($p = 0.22$) [3]. Varied results between studies may be due to different study designs and settings.

When Bland-Altman plots were performed, obvious discrepancies between the two approaches were identified. The differences could reach up to 5.2 cmH_2O and 8.1 cmH_2O in Pves and Pabd measurements at Valsalva manoeuvres and up to 20 cmH_2O and 19.5 cmH_2O in Pves and Pabd measurements at coughs. The results are in accordance with those from previous studies, which indicated that pressure readings from AFC and WFC systems were not absolutely interchangeable [2, 3]. However, a 5.2 cmH_2O pressure difference in Pves measurement between AFC and WFC systems at Valsalva manoeuvres appears to be clinically acceptable.

For other UDS events, a statistically significant difference between methods was only seen at initial resting Pdet ($p < 0.01$) and maximum Pdet in case of detrusor overactivity ($p < 0.01$). The resting Pdet recordings from the WFC system were all positive, but negative for most resting Pdet recordings measured with the AFC system. Pdet recordings seem to be numerically bigger in the WFC system than those in the AFC system, except in the comparison of pressure at Qmax, in which the "changed pressure values" were compared. One plausible explanation was that, due to a usually relatively lower position of the rectal catheter, higher static pressure readings were registered rectally with AFCs than those vesically measured with AFCs. Hence, resting Pdet recordings could be negative in an AFC measurement [13]. This also suggests that the relative position between vesical and rectal catheters may play a significant role in baseline pressure readings in an AFC pressure measurement.

When other clinical events were assessed by Bland-Altman plots, the smallest pressure difference interval was detected at maximum Pdet in case of detrusor overactivity [95% limits of agreement (LOA), –3.2 up to 8.4 cmH_2O], whereas the biggest pressure difference interval was observed in the comparison of resting Pdet at MCC (95% LOA, –11.5–18 cmH_2O). This indicates that the difference between the two measurement modalities could reach up to 18 cmH_2O in resting Pdet measurement during UDS studies. Moreover, at the start of the infusion, the 95% LOA was –5.2 to 12.7 cmH_2O. This result is similar to that from Gammie et al., which stated that the pressure discrepancy can be a maximum of 10 cmH_2O between recordings of WFCs and AFCs at the start of the UDS measurement [3]. Therefore, when using the air-filled system for diagnoses or evaluations with the water-filled system's cut-off value being applied, the corresponding baseline compensation should be considered, as suggested by Gammie et al. [3].

Our study is not devoid of limitations. First and foremost, an open catheter with perfusion for Pabd measurement was used. Although a low flow rate continuous perfusion during UDS tests was used in case of blockage, we could not ensure the absence of an interaction between the catheter and the rectal mucosa during movements, which may have led to an increased number of outliers for Pabd-WFC measurement. However, we are convinced that only good quality data were included in our analysis by using the "70% rule" as described by Sullivan and also by repeated manual inspections. Second, our primary aim was to assess equivalence of pressure readings of WFC and AFC systems at Valsalva manoeuvres and coughs. Differences in diagnostics were not compared, so it is not completely clear how relevant the differences in pressure readings are for clinical purposes. However, according to our results, it can be speculated that when it comes to the diagnosis based on patterns, the two different systems might yield similar results. If the accurate value is needed, the diagnostic results can hardly be the same. Third, the sample size is a limiting factor for some comparisons, for instance, comparisons in baseline pressure readings at different filled volumes.

Conclusion

Pressure recordings from AFC and WFC systems appear to be interchangeable for some UDS parameters such as Pves during Valsalva manoeuvres if the baseline pressure is compensated, but not for fast-changing pressure signals such as coughs. This should be considered when AFC pressure measurements identical to WFC are needed. Further studies are still necessary to compare the diagnostics for both systems. However, based on our data, it seems that they may be interchangeable between the two different catheters for a diagnosis based on patterns, such as the diagnosis of urinary stress incontinence and detrusor overactivity. However, when accurate pressure values are needed, such as for diagnosis of bladder outlet obstruction and calculation of bladder compliance, they can hardly be equally beneficial.

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Compliance with ethical standards

Ethical Commission, Faculty of Medicine, Rheinische Friedrich-Wilhelms-Universität Bonn, ethical vote number: 395/15.

Informed consent Yes.

Conflicts of interest Ruth Kirschner-Hermanns received honoraria from Laborie Medical Technologies or Urodynamic Teaching and has been an invited speaker at Repha GmgH, Germany.

Wei Sheng has nothing to disclose.

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