



Background

Urodynamic investigation (UDI) is the gold standard to assess refractory lower urinary tract symptoms (LUTS). Water-filled systems (WFS) are the method of choice for UDI pressure measurements according to the International Continence Society (ICS). Air-filled systems (AFS) are widely used as convenient alternative to WFS, although it is unclear whether these systems produce comparable measurements.

Aim

To determine whether AFS provide comparable quality to WFS.

Methods

Design

• Randomized controlled non-inferiority trial (Clinicaltrials.gov: NCT04033770) performed at Balgrist University Hospital, Zurich, Switzerland from April 2021 to January 2022

Inclusion criteria

- Adults aged ≥ 18 years
- Refractory LUTS planned for UDI

Exclusion criteria

- Age <18 years, pregnancy, breast feeding, signs or symptoms for urinary tract infection, urinary diversion, anus-*praeter*, dementia, cognitive impairment

Procedures

- Randomization (N=490): WFS (N=244), AFS (N=246)
- Same-session repeated UDI
- Quality evaluation by urodynamic expert blinded to measurement system used
- Scoring system: Total maximum of 18 points (abdominal quality (9), vesical quality (8), detrusor quality (1)) with higher values indication a better UDI quality
- A follow-up telephone visit was conducted 7-14 days after UDI to evaluate adverse events

Outcomes

Primary outcome: Artefact susceptibility evaluated by a modified Bristol UTrAQ quality scoring scale¹. The non-inferiority margin was pre-specified as -2 points on the quality scoring scale (AFS-WFS).

Secondary outcomes: Typical UDI artefacts, UDI study lengths, adverse events within 7 - 14 days.

Results

Baseline characteristics were similar between groups (table 1). Inferiority of AFS could be rejected at the pre-specified non-inferiority margin (figure 1). In the subgroup analysis of vesical and rectal catheters, an inferiority of the air-filled system could also be rejected.

Typical artefacts consisted of repeated rectal contractions, poor pressure transmission during cough test at empty bladder and detrusor resting pressure outside of the physiological range at empty bladder (table 2).

Baseline resting pressures were significantly higher for AFS compared to WFS (vesical pressure WFS vs AFS: 19.8 ± 7.1 vs 26.1 ± 8.4 cmH₂O; abdominal pressure WFS vs AFS: 21.4 ± 7.6 vs 30.7 ± 9.2 cmH₂O, $p < 0.001$).

UDI installation time and examination time were similar between groups (installation time WFS vs AFS: 27 ± 7.6 vs 27.1 ± 7.9 min; examination time WFS vs AFS: 58.9 ± 16.4 vs 61.3 ± 25.2 , $p \geq 0.21$).

Except for self limiting pain adverse events did not differ significantly between groups (table 3).

Table 1: Baseline characteristics	WFS (N = 244) No. (%)	AFS (N = 246) No. (%)
Sex		
Female	102 (42)	92 (37)
Male	142 (58)	154 (63)
Locomotion		
Walking	180 (74)	182 (74)
Wheelchair	64 (26)	64 (26)
Main method of bladder emptying		
Spontaneous	131 (54)	127 (52)
Intermittent catheterization	66 (27)	85 (35)
Indwelling catheter	47 (19)	34 (14)
	median (Q1–Q3)	median (Q1–Q3)
Age - [years]	60 (47 - 74)	59 (48 - 69)
BMI - [kg/m²]	25.1 (22.6 - 28.9)	25 (22.2 - 28.4)
Charlson comorbidity index	3 (1 - 4)	3 (1 - 4)
Neurogenic Bowel Dysfunction Score (NBD)		
Total NBD Score	4 (1 - 9)	4 (1 - 9)
NBD General Satisfaction	7 (5 - 9)	8 (5 - 9)
Urinary Symptom Profile (USP)		
Stress Urinary Incontinence Score	0 (0 - 2)	0 (0 - 1)
Overactive Bladder Score	5 (2 - 9)	4 (2 - 8)
Low Stream Score	3 (1 - 9)	3 (1 - 9)

AFS=Air-filled system, BMI=Body mass index, UDI=Urodynamic investigation, WFS=Water-filled system.

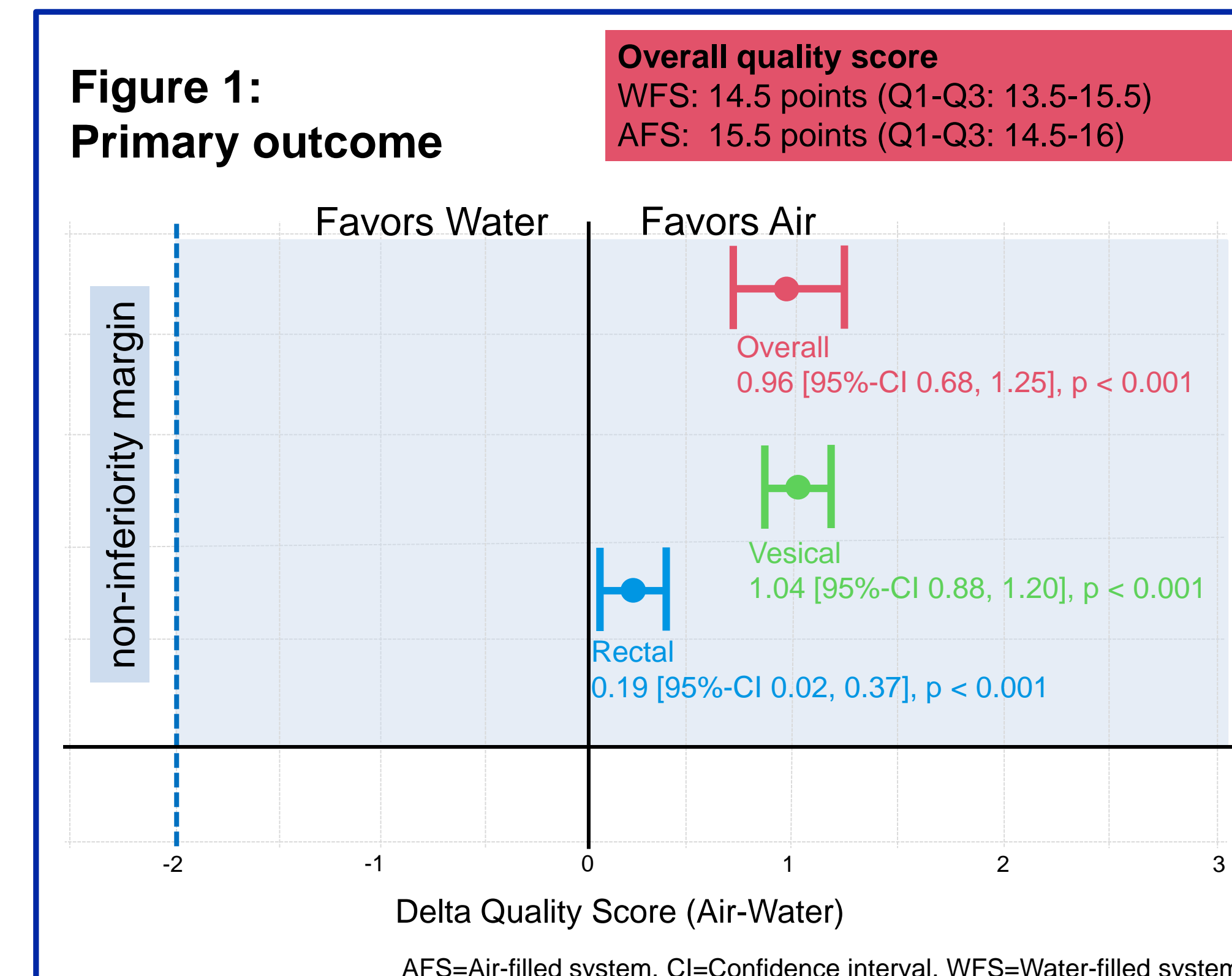


Table 2: Typical urodynamic investigation (UDI) artefacts		UDI 1			UDI 2		
		WFS (N = 244) No. (%)	AFS (N = 246) No. (%)	p	WFS (N = 244) No. (%)	AFS (N = 246) No. (%)	p
Relevant rectal contractions throughout UDI*	Pabd	138 (57)	166 (67)	0.013	160 (66)	180 (73)	0.103
	Pves	93 (38)	10 (4)	<0.001	145 (60)	19 (8)	<0.001
Bad cough quality at UDI start**	Pabd	11 (4)	17 (7)	0.252	16 (7)	24 (10)	0.21
Initial resting pressure out of physiological range***	Pdet	40 (16)	104 (42)	<0.001	37 (15)	107 (43)	<0.001

*A phasic rise in pabd of low amplitude with no effect on pves²; **Assessing transmission quality throughout UDI, characterized by a fast phasic pressure change in pves and pabd with a minimum peak height of 15 cmH₂O above resting pressure. No change in pdet²; ***Pressure at the start of UDI. For pves and pabd in supine position: 5–20 cmH₂O, sitting position: 15–40 cmH₂O, standing position: 30–50 cmH₂O. Pdet centered on zero (± 5 cmH₂O)². AFS=Air-filled system, pabd=Abdominal pressure, pdet=Detrusor pressure, pves=Vesical pressure, WFS=Water-filled system.

Table 3: Symptoms after UDI / adverse events	WFS (N = 244) No. (%)	AFS (N = 246) No. (%)	p
Urinary tract related pain	60 (25)	86 (35)	0.014
Gross hematuria	19 (8)	22 (9)	0.644
Increased urgency	48 (20)	42 (17)	0.458
De-novo incontinence	13 (27)	6 (14)	0.175 [†]
UTI within 7 days after UDI	17 (7)	11 (5)	0.234
Changes in stool characteristics	13 (5)	7 (3)	0.334

Pearson Chi-Square test was used to analyze categorical data ([†]Fisher's Exact test); AFS=Air-filled system, UDI=Urodynamic investigation, UTI=Urinary tract infection, WFS=Water-filled system.

Conclusions

Our results demonstrate that AFS are non-inferior to WFS regarding overall quality of urodynamic traces. However, both measurement systems have particular pitfalls that need to be known for problem solving during UDI and require awareness for accurate interpretation of UDI.

References: ¹Gammie A, Hashim H, Abrams P. Bristol UTrAQ: A proposed system for scoring the technical quality of urodynamic traces. *Neurourology and Urodynamics*. 2022;41:672-678. ²Hogan S, Gammie A, Abrams P. Urodynamic Features and Artefacts. *Neurourology and Urodynamics*. 2012;31:1104–1117.