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THE DYNAMIC URINE VIBRATION HALTER: A NEW OUTPATIENT AMBULATORY FLOWMETER

Hypothesis / aims of study

Uroflowmetry and urodynamics are integral diagnostic tools for quantifying lower urinary tract symptoms (LUTS), monitoring symptom progression, and conducting outcomes research. However, these tests generally require that patient be present in an outpatient facility. The Dynamic Urine Vibration Halter (DUVH) was developed in order to provide a non-invasive medical device for the diagnosis and monitoring of LUTS. It utilizes a design that enables regular home self-testing and enhances data collection and diagnostic material relating to patient symptoms.

Study design, materials and methods

The technology is based on measuring the flow characteristics *inside* the urethra. A removable, small, vibro-acoustic sensor is placed on the dorsal side of the penis at the time of urination (fig 1). The sensor is connected to a small portable recorder which stores captured data (fig 2). A dedicated software algorithm analyzes the recorded data and displays uroflowmetric findings (fig 3).

An IRB approved study was conducted at two outpatient urology centers. Study investigators instructed patients to urinate into weight-based uroflow meters while wearing the device. Patients were assisted with the device's use. Comparison of the parameters measured on a weight-based uroflow meter was made with those generated by the DUVH's proprietary algorithms. The flow curve was also compared between the weight-based uroflow meter and DUVH (fig 3). All of the uroflow parameters recorded by the DUVH (voided volume, maximum flow rate, voiding time, flow time, average flow rate) were compared with the weight-based uroflow meter using a paired student t-test.

Results

25 patients were recruited. Uroflowmetry data was collected from 24 patients. One patient was unable to void. 19/24 patients were able to record their voids simultaneously using the DUVH. One patient's intermittency caused an insufficient reading from the weight-based uroflow, but the DUVH recognized all parts of the void. The DUVH failed in 3 patients due to an insufficient signal recording to differentiate a void. The device failed in another patient who had a penile prosthesis. No statistical difference from parameters measured by the weight-based uroflow meter was noted as shown in table 1.

Interpretation of results

This preliminary study shows very promising results for the DUVH. The uroflow tracing for both the DUVH and the standard weight-based uroflow meter are nearly identical; the visual diagnostic impressions are the same. In addition, the quantitative measures showed a high degree of correlation. In unpublished studies comparing urodynamic diagnosis of obstruction with an algorithmically derived measure of the vibratory characteristics during flow there was an equally high correlation. This suggests that the DUVH may prove useful as an independent, non-invasive, quantitative measure of urethral obstruction and may be used as a metric for both initial diagnosis, clinical follow up and efficacy outcome studies.

Concluding message

The DUVH is a promising new technology for repeated outpatient uroflow monitoring that requires nothing more than a small disposable sensor placed on the dorsal side of the penis and an external recording device.

Table 1 – Parameter means and statistical differences

	Qmax (ml/s)	**Voided Volume (ml)**	**Voiding Time (s)**	**Qavg (ml/s)**	**Flow Time (s)**
DUVH	9.37 (5.04)	176.26 (145.33)	31.75 (13.48)	5.72 (3.45)	30.07 (12.67)
Flowmeter	9.53 (5.02)	187.63 (149.99)	30.16 (15.03)	6.26 (3.18)	28.26 (13.79)
p-value	0.92	0.81	0.73	0.61	0.68

Figure 1 – Vibro-acoustic sensor

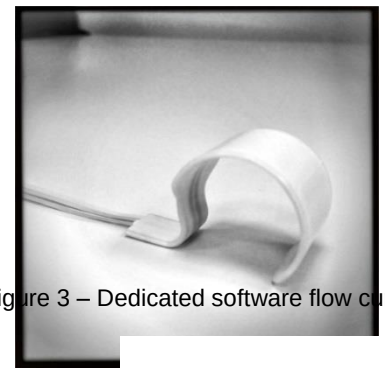

Figure 2 – Recorder

Figure 3 – Dedicated software flow curve output – example in comparison to traditional uroflow output

	Device	DUVH
Qmax	16	16.07
Qavg	10	10.46
Voiding Time	19	18.25
Flow time	19	18.5
Voided Volume	208	207

Disclosures
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