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COMPARISON OF TEST-TO-TEST VARIABILITY IN FLOW PARAMETERS RECORDED WITH A WIRELESS-BASED ACOUSTIC SYSTEM WITH THAT OF STANDARD UROFLOWMETRY.

Hypothesis / aims of study

Uroflowmetry suffers from significant test-to-test variability in an individual's test results [1]. This is likely a result of unnatural circumstances in a clinic, where patients must urinate on demand instead of when they are physiologically ready. To address this limitation, we have developed sonouroflow (SUF), an automated portable testing tool that allows recording of the urinary flow rate under physiological conditions. In addition SUF allows for objective prospective recording of lower urinary tract symptoms (LUTS). Here, we compare test-to-test variability of sonourograms – processed SUF audio signals converted into a flow curve – with that of standard uroflowmetry.

Study design, materials and methods

The SUF system uses wireless and web technologies to digitally capture, analyze and store urinary flow data and LUTS. It measures the intensity (amplitude) of the recorded sound derived from the acoustic emissions associated with urination, resulting from the impact of a urine stream onto an air-water interface. The data are recorded in real time using a conventional cellular phone. The recorded sound is transformed into a flow curve representing the amplitude of the audio signal versus time corresponding to the strength and duration of the urinary flow. Symptoms, including voiding frequency and nocturia, are recorded automatically and stored with an associated time stamp. The degree of urgency and the presence or absence of urge incontinence is recorded manually by the patient at the end of urinary flow recording by entering an urgency score. This is accomplished by pressing a number from 1 to 5 on the phone key pad corresponding to the five point Urgency Rating Scale [2]. Records of multiple tests are stored in a prospective manner, providing a voiding record of each patient (Figure).

Four consecutive micturitions recorded by a single study participant as displayed on the password-protected web site.

In this comparative study 32 adult male were asked to record their urinary flow rate using both conventional uroflowmetry and the SUF system. Flow parameters were first recorded using the Dantec Urodyn 1000 flowmeter at pre-set times, thus mimicking outpatient clinic appointments. Volunteers subsequently recorded urinations at home using SUF. Test-to-test

Click to Enlarge	Date	Flow Time (s)	Average Flow Rate(*)	Maximum Flow Rate (*)	Time to Maximum Flow(s)	Urgency (1-5)	Interval (h:m)
	2008-11-13 15:56:17	20	188	439	6	1	4:17
	2008-11-13 11:39:17	30	259	527	18	1	1:15
	2008-11-13 10:24:17	35	246	527	11	1	1:21
	2008-11-13 09:02:34	27	211	455	9	1	0:0

variability was compared between the two data sets. Flow time, average flow rate, maximum flow rate and time to maximum flow rate were compared. The University of Vermont Institutional Review Board approved this study and informed consent has been obtained from each participant.

Results

The coefficient of variation for values obtained by SUF was significantly lower for voiding time ($p < 0.001$) and significantly higher for average flow rate ($p = 0.009$); maximum flow rate and time to maximum flow rate were not significantly different between the two testing methods. A box-and-whiskers analysis was applied to display the differences in variability between the data sets for two methods for each individual participant. In 62% of study subjects, test-to-test variability for voiding time was lower for SUF than for standard uroflowmetry; in 43.8% of subjects, the variability in maximum flow rate values was lower for SUF; and in 56% of subjects, the variability in time to maximum flow rate values was lower for SUF. Ten subjects with the highest standard deviation with respect to voiding time values and the four subjects with highest standard deviation with respect to maximum flow values all occurred in the data set obtained by standard uroflowmetry.

Interpretation of results

SUF, in its current form, is equivalent to conventional uroflowmetry in its capacity to identify hesitancy, intermittency, and weak or irregular urinary stream. Test-to-test variability in voiding time obtained from SUF is significantly lower than that recorded using standard uroflowmetry. The variability in values for maximum flow rate and time to maximum flow rate obtained from SUF and uroflowmetry was comparable. Overall, parameters obtained from SUF were more consistent, with all extreme variations occurring in the uroflowmetry group. It is reasonable to expect the difference in test-to-test variability between the two methods to be even greater in patients suffering from lower urinary tract dysfunction, for whom urgency makes delaying urination difficult.

Concluding message

At this stage of development, SUF captures maximum and average urinary flow rates in relative, not absolute, values. The system in its current form could be used to monitor changes in flow parameters in a single patient. SUF could prove useful for monitoring disease progression or as a follow-up tool to evaluate treatment outcome. Ongoing studies seek to correlate sound parameters with flow-rate parameters expressed in millilitres per second. Identification of a suitable algorithm for extracting flow parameters with a sufficient degree of accuracy will allow for calculation of voided volume.

References

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2. European Agency for Evaluation of Medicinal Products CfPMP. Note for guidance on the clinical investigation of medicinal products for the treatment of urinary incontinence in women. 2001

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Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of Vermont Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**