

VALIDATION OF SONOUROFLOWMETRY FOR ELECTRONIC RECORDING OF LOWER URINARY TRACT SYMPTOMS IN MEN

Hypothesis / aims of study

Etiology of lower urinary tract symptoms (LUTS) is multifactorial; therefore more precise phenotyping of patients will likely prove beneficial. A number of new instruments have been developed to evaluate bladder sensation, storage, voiding, and postmicturition symptoms and their impact on quality of life (QoL). Urinary diaries (micturition charts, frequency volume charts, and bladder diaries) have proven to be beneficial in assessing LUTS, however they have not achieved widespread acceptance. A likely reason is that pen and paper diaries are labor intensive for both patient (need to carry a pen and paper and record each event) and doctor (need to transfer, summarize, and analyze the data). These limitations could be addressed using an electronic diary, which would automate the recording and analysis of data, expediting the process and improving its accuracy, also making it more cost effective.

Hypothesis: A web based technology will allow patients to record every micturition and urgency episode in real time using a wireless phone. This novel method will be as accurate and facilitate better compliance when compared to the currently used pen and paper voiding diary.

Study design, materials and methods

SUF records the sound generated from the urine stream striking the water in a toilet bowl. This generates a sonourogram (sound file), which resembles the standard uroflowmetry recording. The degree of urgency is recorded by pressing 1-5 on the key pad, which corresponds to a 5-point urgency scale. Urgency is recorded immediately following micturition or whenever experiencing urgency without bladder emptying. A dedicated server runs a program, which automatically processes incoming data. All data recorded from an individual is stored prospectively, in separate files, on a secure website. Each record is associated with a time stamp, providing information on urinary frequency. (Figure)

	ID	Date Time	Flow Time (s)	Avg Flow Rate	Max Flow Rate	Time to Max Flow (s)	Vol.	Urgency (1-5)
	1761	2014-01-07 07:15:36	24	201	471	4	3893.56	1
	1759	2014-01-06 21:30:17	22	131	391	11	2273.44	1
	1750	2014-01-06 06:50:19	26	281	495	4	5796.98	1
	1748	2014-01-05 21:16:05	27	190	439	9	4078.95	1
	1743	2014-01-05 08:59:13	25	258	527	9	5111.58	1

A pen and pencil micturition chart was used to record baseline parameters (voiding urgency and frequency). QoL was evaluated using the International Prostate Symptom Score (IPSS) Questionnaire, and two standardized questions: Quality of Life due to Urinary Symptoms (QoL US) and Patient Perception of Bladder Condition (PPBC).

Twenty nine men, average age 67.8 years (range 49 – 80), which presented to the urology clinic with LUTS, were included in the study. Patients were asked to record every micturition and degree of urgency using SUF for a period of 3 days. They were then asked to record their frequency of micturition and the degree of urgency using a pen and paper micturition chart (MC) for an equal number of days. Subsequently, the efficacy of recording LUTS with each method was analyzed and compared. The content validity of SUF (did the instrument make sense to patient) was assessed at the conclusion of the study by a one-on-one interview by a specialized research nurse. Patients were asked to state their preference for SUF or MC and disclose the number of events they forgot to or could not record. The construct validity (relationship between recorded data and underlying theories) was evaluated based on the correlation of symptoms recorded with SUF or MC and QoL measures.

Results

Twenty five patients successfully completed the 3 day trial using MC and 27 using SUF. There were no statistically significant differences found in the micturition frequency ($p=0.24$), average number ($p=0.97$), and degree ($p=0.48$) of urgency episodes, between the two methods. When queried about their preference, 13 (44.83%) patients preferred SUF, while 16 (55.17%) preferred MC. In the group of patients that completed the 3 day trial, successfully using at least one of the two methods, 24.14% reported

that they forgot to report at least one episode of urgency using the MC, versus 17.24% using SUF, 17.24% could but forgot to record at least one micturition using MC versus 6.9% using SUF, and 13.79% could not record at least one micturition using MC, versus 27.59% using SUF. None of these differences reached statistical significance. Statistically significant correlations between the number of urgency episodes and average degree of urgency recorded versus IPSS, using SUF, and between micturition frequency and average degree of urgency versus IPSS, using MC were documented. In addition, statistically significant correlations were found between micturition frequency and QoL US, using MC, and between the degree of urgency and PPBC, using MC.

Interpretation of results

In this study population, recording symptoms with SUF did not prove to be preferable compared to MC, however SUF provided the same level of accuracy with increased adherence to the study protocol. All participants were able to reliably record LUTS using SUF and none of them reported difficulty with using the new device. Recording symptoms with SUF provided the same level of accuracy with better adherence to the study protocol.

Concluding message

SUF proved feasible to record LUTS in real time. The results from this study were compared to previously published evidence, suggesting that more severe LUTS are associated with a lower score on the health related QoL questionnaires. In addition to recording LUTS, ongoing studies are being done to measure flow parameters and voided volume. With the rapidly increasing use of mobile devices, and development of technologies such as electronic urinary diaries and app-based standardized questionnaires, instruments such as SUF could become the standard method for the management of LUTS.

Disclosures

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