

COMPARISON OF NOVEL HOUSEHOLD UROFLOWMETER ON CLINICAL TRIAL

Hypothesis / aims of study

to design a novel uroflowmetry monitoring system, and compare it with traditional methods.

Uroflowmetry is noninvasive, which can be used for testing patients with various urinary dysfunctions like bladder outlet obstruction (BOO). It is a widely used filtering instrument having great clinical value. Recently, with the requirement of urology department development and influence of aging phenomenon, traditional uroflowmetry is facing huge challenges. Community healthcare and household healthcare are calling for more convenient, portable test devices. Therefore, we designed a novel uroflowmetry collecting device based on the Remote & Mobile Voiding Diary Monitoring System, and compare it with traditional uroflowmeters in clinical use.

Study design, materials and methods

The Voiding Diary Monitoring system can remotely trace and record urination and uroflowmetry by automatically collecting voiding information from LUTS patients through collectors, urine conducting apparatus, wireless communication technology, mobile device, computer analysis and drawing, and data storage technology, etc. The novel uroflowmetry device (see Fig. 1) applies weighting sensor, which is made of stainless stupalith. The user put the urine cup on the sensor. The system can automatically perform uroflowmetry when the user is voiding into the cup (see Fig. 2). Female users can adopt urine conducting apparatus (see Fig. 3) to void in stand-up. The test results are stored in the build-in E2Rom of the sensor, and can be transmitted to the smart cell phone (see Fig. 4) via Bluetooth of the electronic scale timely or periodically. The smart cell phone can then send the data to the control center (see Fig. 5) in hospital through GPRS/CDMA/3G for remote monitoring.



Figure1. Collector



Figure 2. Urine collection cup



Figure 3
Urine conducting apparatus



Figure 4
Intelligent cell phone



Figure 5
Control center

38 outpatients who have LUTS are tested simultaneously with the system and LABORIE Spindle View TM uroflowmeter. Among them, there are 22 male patients and 16 female patients respectively, ranging from 21 to 37 years old, with an average age of 25.5. 19 patients are tested once, 19 patients are tested twice, equaling to 57 tests.

Comparison: Put the sensor with cup on LABORIE Spindle View TM uroflowmeter, and reset the readout of uroflowmeter (see Fig. 6). The user voids urine into the cup on the portable sensor, thus the uroflowmeter designed by us can test the same voiding with LABORIE uroflowmeter, facilitating the comparison of the data. Comparative data include voided volume, which is the volume voiding through urine tract. Qmax refers to the maximum uroflowmetry. Qave refers to the result dividing voided volume by voiding time. Voiding time refers to the voiding duration. Qmax time refers to the time needed for achieving the maximum uroflowmetry.

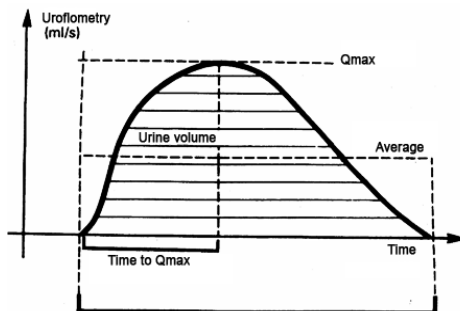


Figure 6 Location of the two uroflowmeters

We apply statistical software SPSS13.0 to analyze the data, and display the data with $\bar{x} \pm s$. Inspect and analyze the data measured with two different uroflowmeters. If $P < 0.05$, the difference has statistical significance.

Results

The system can accurately collect and analyze voiding time, uroflowmetry, voided volume, and automatically provide uroflowmetry parameters. The difference between the system and LABORIE Spindle View TM uroflowmeter on Qmax, Qave and voided volume is insignificant in statistics.

The uroflowmetry are tested 57 times all together among 38 outpatients. Table 1 describes the result comparison of two testing devices, and Figure 7 shows the comparative chart of the two testing methods.

Table 1 Comparison of the parameters measured with two uroflowmeters

Method	Qmax	Qave	Voided volume
LABORIE uroflowmeter	13.58±8.70	5.97±4.47	266.22±186.83
Electronic uroflowmeter	13.64±8.66	5.53±4.18	265.99±186.43
P	>0.05	>0.05	>0.05

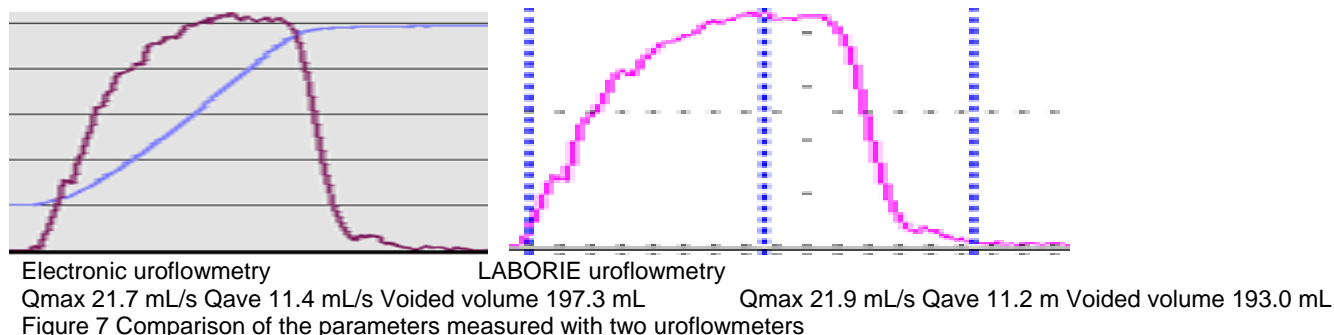


Figure 7 Comparison of the parameters measured with two uroflowmeters

Concluding message

In the era of aging population, the demands of LUTS patients (bladder outlet obstruction especially) for uroflowmetry are increasing.

Remote & Mobile Voiding Diary Monitoring System is a novel LUTS monitoring system featuring accurate, reliable, real-time, convenient and easy to management. It is as noninvasive, reliable as traditional methods. Its portable feature facilitates application out of hospitals. It can also record voiding diaries. It is the first uroflowmetry device in China. It complies with standard of ICS with regard to signal accuracy. It makes no difference with the counterpart of LABORIE in performance.

References

1. Guess HA, Arrighi HM, Metter EJ, et al, Cumulative prevalence of prostatism matches the autopsy prevalence of benign prostatic hyperplasia, Prostate 1990; 17: 241-246.
2. 1. Guan Zhichen, Yang Yong, Diagnosis of Voiding Dysfunction, Wu Jieping Urology 2004: Shandong Science & Technology Press, p1249-1294
3. 2. Guan Zhichen, Remote & Mobile Voiding Diary Development and 20 Cases of Young Voiding Report, Journal of Peking University (Health Sciences), 2010, Vol. 42, No. 4, p476-479.

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	the one in Peking University Shenzhen Hospital
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes