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A NOVEL HANDHELD HOME-UROFLOWMETRY, P-FLOWDIARY®

Hypothesis / aims of study

A Simple screening tool for voiding dysfunction affecting daily life is expected in the era of aging society. The frequency volume chart (FVC) is a gold standard to check voiding patterns, but is difficult for the elderly to record for 3 consecutive days. Although uroflowmetry is useful for checking the voiding status, it can be performed only in medical facilities. The primary objective was to develop a handheld device which integrates FVC and uroflowmetry as a screening tool for lower urinary tract symptoms (LUTS) at home. Our project had two major tasks: first, the handheld device can precisely measure the urine flow at home, and, second, the device can analyze the large data to help physicians during their daily practices.

Study design, materials and methods

We developed a handheld device, P-Flowdiary®, which records time, voiding parameters including voided volume and flow rate using the gravimetric method, and voiding satisfaction (Fig. 1). The device consists of a disposable urine cup, a load cell and the circuit board on which microcomputer, clock, angle/ acceleration sensor, audio guidance, Bluetooth and SD card are mounted. Voiding satisfaction is recorded when a subject pushes the buttons which represent "good", "fairly good", "fairly bad" and "bad". The data stored in a SD card are analyzed using the dedicated software.

Results

The feasibility study was done in every participating institution. The first semester study focused on user-friendliness in 230 healthy volunteers. The use was acceptable to male volunteers, but not to female volunteers, especially elderly people. This problem was resolved by a dedicated portable chair. The noise caused by shaking and angle position was canceled using the sensors. The smoothing were achieved using software which calculated moving average and so on. We also revealed the accuracy equal with other uroflowmeters using gravimetric methods. P-Flowdiary® passed electrical safety test and Electro-Magnetic Compatibility test, and was approved for use as medical device of class 1. The dedicated software displayed the spread sheet of micturitions, the scatter plot of voided volume and maximum flow rate, and the time series of micturitions in different windows. Flow curves linking to the raw data were drawn when we clicked the data in other windows (Fig. 2). The color of dots in a scatter plot meant voiding satisfaction. A single record in a medical facility was also available like a conventional uroflowmeter. Flow curves and voiding parameters could be displayed on the tablet via Bluetooth.

Interpretation of results

The primary objective to develop a handheld device which integrates FVC and uroflowmetry was achieved. Also, the dedicated software could provide useful information of voiding status in every subjects. The significance of consecutive recordings of urinary flow is still obscure. Clinical trials are in operation to establish the novel concepts of urinary flow nomogram, diagnostic tool to clarify several types of voiding dysfunction and the assessment tool for therapeutic performance.

Concluding message

P-Flowdiary® is convenient and easy-to-use at home even in the elderly. We have proved the practical usefulness as a screening tool for voiding dysfunction, which provides better informed consent as well as assessment of therapeutic performance for every patient. However, the clinical usefulness of uroflowmetry and self-assessment of every urination is not clarified yet.



Fig 1. P-Flowdiary

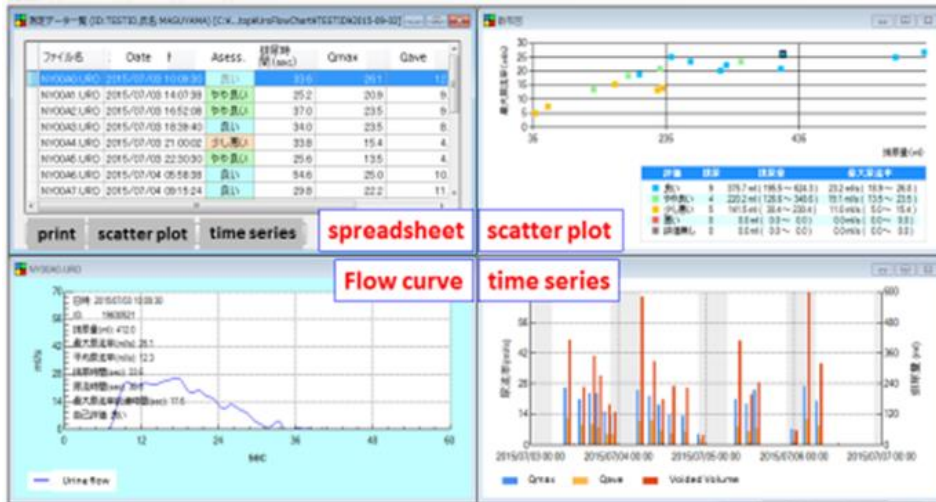


Fig. 2 Comprehensive voiding data at home

Disclosures

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