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# VALIDITY AND RELIABILITY OF A SIMPLE HOME UROFLOWMETRY DEVICE FOR REPEATED FLOW RATE MEASUREMENT.

## Hypothesis / aims of study

The urodynamic cause of lower urinary tract symptoms (LUTS) is best characterised by invasive pressure/flow studies (PFS) which reliably detect bladder outflow obstruction (BOO). Non-invasive methods of investigating LUTS such as uroflowmetry are more commonly used in clinical practice due to their ease of use and patient acceptability. Measurement of maximum flow rate (Q<sub>max</sub>) is considered to be diagnostically most useful but may be unreliable if measured on only one occasion<sup>1</sup>. The design of a simple, inexpensive portable uroflowmetry device would enable multiple measurements to be made by patients at home or could be used as a screening tool in primary care<sup>2</sup>. We aimed to evaluate the validity and reproducibility of measurement of Q<sub>max</sub> by a simple home flow device firstly by comparison with standard uroflowmetry and secondly by repeated use at home in men with LUTS.

#### Study design, materials and methods

A simple home uroflowmeter has been developed to measure Q<sub>max</sub>. This consists of a plastic cup with a funnel shaped column formed from 3 chambers. An aperture of diameter 4.6 mm is placed at the apex of the funnel. With the device held vertical, fluid poured into the cup will start to fill the funnel as well as flowing out through the aperture. With higher filling rates more fluid will be retained in the device and the fluid level will rise in the column. The aperture has been calibrated such that filling of the bottom, middle and top chambers of the column will correspond to input flows of <10, 10-15 and >15 ml s<sup>-1</sup> respectively, whilst a flow rate > 20 ml  $s^{-1}$  will start to fill the cup. The highest chamber reached by urine in the course of a void into device will therefore give an estimate of Q<sub>max</sub> for that void. Aperture



With ethical approval and informed consent we evaluated men who attended for uroflowmetry as part of their routine assessment for LUTS. In each subject, separate urine flow recordings were performed using a standard rotating disc flow meter and the home uroflowmetry funnel. For each void bladder volume was measured before and after micturition using ultrasound. Flows with voided volume < 150 ml were excluded from analysis. Men who took part in this initial study were also asked to use the uroflowmetry device at home twice daily for a seven day period and to record Q<sub>max</sub> and voided volume.

#### **Results.**

We recruited 38 men over a 5-month period (median age 64years; range 46-81 years), of whom 34 (89%) produced two consecutive flows with voided volume > 150 ml. The majority of men reported no difficulty using the device whilst 4 subjects were unable to take readings from the device themselves, most commonly because of obesity.

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Figure 1 compares measurements of  $Q_{max}$  obtained by the rotating disc and home uroflowmeter. Men whose voids remained within the bottom chamber had a mean (SD)  $Q_{max}$  using the rotating disc of 9 (2.4) ml s<sup>-1</sup>, whilst voids that reached the middle, top and cup had mean (SD) rotating disc  $Q_{max}$  of 14 (4.4) ml s<sup>-1</sup>, 19 (2.9) ml s<sup>-1</sup> and 28 (9.1) ml s<sup>-1</sup> respectively. For patients with a maximum flow rate < 15 ml s<sup>-1</sup> using the rotating disc, the home flow device had a positive predictive value (PPV) of 73% and negative predictive value (NPV) of 100%. For patients with a flow rate < 10 ml s<sup>-1</sup> using the rotating disc, the home device showed PPV of 86% and NPV 92%. After assigning flow rates obtained using the rotating disc to the same categories defined by the home device we estimated the degree of error between the  $Q_{max}$  readings obtained by the 2 devices (Figure 2). The statistical correlation between the values obtained on the two flow devices was analysed using the weighted Kappa statistic giving a value of 0.69.

Of the 7 men who recorded multiple flow rates at home using the device, 4 of 5 with an original rotating disc reading > 15 ml s<sup>-1</sup> had multiple correctly corresponding flows in the cup and top chamber. Home flow measurements obtained by the 2 men with a rotating disc measurement < 15 ml s<sup>-1</sup> were all correctly classified by observations in the bottom or middle chamber.

## Interpretation of results

A single measurement of  $Q_{max}$  using the home device shows good agreement with standard rotating disc data suggesting the calibration is valid. With a favourable body habitus, men are able to use the device successfully at home with little instruction. Using the two commonly applied thresholds of 15 and 10 ml s<sup>-1</sup> the home flow device performs well in terms of both repeatability and comparison with previous conventional measurement. In comparison to previous home uroflowmeters the present device is simple, cheap and amenable to mass production.

## Concluding message

We propose that this novel portable flow meter may be a useful tool to obtain multiple flows by men in their own homes. It appears to be easy to use and our results suggest that it may help to select those patients who would benefit from formal flow assessment in an outpatient setting.

Figure 1. Distribution of flow data.

Figure 2. Histogram showing interdevice error



#### References:

1. The value of multiple free-flow studies in men with lower urinary tract symptoms. BJU 1996: 77, 813-818.

2. Development of a low-cost flow meter to grade the maximum flow rate. Neurology and Urodynamics 2002: 21, 48-54.

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