Evaluation of the clinical value of a simple flowmeter in the management of male lower urinary tract symptoms

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INTRODUCTION

Electronic uroflowmetry is often described as the single most useful and best objective means of discriminating between normal and abnormal voiding in men [1-3]. It is anticipated that ‘elderly’ people will come to constitute one quarter to one third of the population [4,5] of whom as many as 50% will have moderate to severe voiding problems [6-8]. This will have considerable bearing on the costs involved, including

What’s known on the subject? and What does the study add?
Electronic uroflowmetry reasonably predicts the likelihood of bladder outlet obstruction (BOO) and risk of AUR. This low-cost device, Uflowmeter™, allows men to perform uroflowmetry at home with ease and the results are compatible with that of electronic uroflowmetry. It can also estimate risk of AUR and the need for TURP to relieve LUTS.

OBJECTIVE

To show the clinical value of a simple flowmeter, which has been devised to measure uroflow on an ordinal scale (<10, 10–15, 15–19 and >19 mL/s) at home, for the management of male lower urinary tract symptoms (LUTS).

PATIENTS AND METHODS

A total of 186 men with LUTS were enrolled in the study.

The mean (range) follow-up was 220 (68–431) days. The men’s mean (range) age was 65.5 (46–83) years, mean (range) maximum urinary flow rate (Qmax) 12.8 (4.3–39.5) mL/s, mean (range) voided volume 294.8 (151–686) mL; mean (range) postvoid residual urine volume (PVR) 50 (0–303) mL and mean (range) International Prostate Symptom Score (IPSS) 13.5 (1–31).

The men underwent electronic uroflowmetry (‘clinic uroflowmetry’) and completed an IPSS questionnaire in the clinic. They then conducted 10 measurements with the device at home (‘home uroflowmetry’). The uroflowmetry and IPSS questionnaire were repeated 2 weeks later.

Quadratically weighted Kappa analysis (κ) of the home uroflowmetry vs. clinic uroflowmetry, and of the sensitivity and specificity of the home uroflowmetry values to correspond to the mean Qmax of clinic uroflowmetry (<10, 10–15, 15–19 and >19 mL/s) was performed. Similar analyses were performed for the IPSS.

Kaplan–Meier analysis was performed to evaluate whether home uroflowmetry was able to prognosticate acute urinary retention (AUR) or the need for transurethral resection of the prostate (TURP).

RESULTS

The home uroflowmetry values (κ = 0.84, 95% confidence interval [CI]: 0.78–0.90) were superior to the IPSS (κ = 0.083; 95% CI: 0.0–0.173) in correlating with the mean Qmax of clinic uroflowmetry.

Home uroflowmetry was most sensitive in identifying a mean Qmax of >19 mL/s (sensitivity: 0.99; 95% CI:0.97–1.00) and most specific in identifying a mean Qmax of <10 mL/s (specificity: 0.90; 95% CI:0.83–0.94).

The home uroflowmetry works best in ruling out a mean Qmax of <19 mL/s (diagnostic odds ratio [DOR] = 349.3; 95% CI:40.24–3037.7), followed by a mean Qmax of <15 mL/s (DOR = 91.02; 95% CI:31.23–265.23) and a mean Qmax of <10 mL/s (DOR = 32.04; 95% CI:14.0–73.19).

Men with a home uroflowmetry value ≤10 mL/s were more likely (n = 6; 8.8%) than those with a home uroflowmetry value >10 mL/s (n = 2; 1.7%) to develop AUR or require TURP (log-rank test: P = 0.017; hazard ratio:5.61[95% CI:1.10–28.64]). The IPSS failed to display the same discriminative capability.

CONCLUSION

Home uroflowmetry using this simple device is a satisfactory estimation of clinic uroflowmetry using an electronic flowmeter and can predict the significant progression of male LUTS.

KEYWORDS
LUTS, uroflowmetry, Uflow-meter™ sensitivity, specificity, diagnostic odds ratio

Study Type – Diagnostic (exploratory cohort)
Level of Evidence 3b

INTRODUCTION

Electronic uroflowmetry is often described as the single most useful and best objective
investment in equipment, space needed and associated staff time, in carrying out uroflowmetry. As a result, a significant proportion of men with LUTS attributable to benign prostate enlargement (BPE) may not be able to undergo uroflowmetry in a timely manner. A simple low-cost flowmeter has recently been devised for male uroflowmetry on an ordinal scale at home so that this clinically important measurement can be acquired early in the diagnostic pathway of LUTS.

In the present study, we report the correlation between uroflowmetry of men using the novel device at home, ‘home uroflowmetry’ and that by formal uroflowmetry in the clinical setting, ‘clinical uroflowmetry’, and evaluate the value of the device in guiding the management of male LUTS.

PATIENTS AND METHODS

The novel device, the Uflow-meter™ (Medical Devices Technology International Ltd, MDTI, Wolverhampton, UK), is a low-cost, transparent plastic funnel-shaped device (Fig. 1) graduated into four compartments of different sizes: ‘CUP’, ‘TOP’, ‘MIDDLE’, and ‘BOTTOM’. There is a hole at the end of the BOTTOM compartment through which urine can pass to the exterior so that the volume of voided urine can be measured. To measure urinary flow, the patient holds the device vertically and then urinates into it. Owing to the difference between the rates of urine flowing into and out of the device, a column of urine starts to rise in the device. As the urinary column ascends further, the rate of the outflow will eventually match that of the inflow and the compartment reached by the peak fluid level will indicate the range (category) of maximum urinary flow rate (Qmax). A previous pilot study [8] showed that the category ‘BOTTOM’ satisfactorily indicates a steady flow of <10 mL/s, ‘MIDDLE’ 10–15 mL/s, ‘TOP’ 15–19 mL/s, and ‘CUP’ >19 mL/s.

CLINICAL EVALUATION STUDY

A previous pilot study [8] showed that most patients measured urinary flow at home ≥10 times only, despite being requested to perform more. We therefore considered the most frequently observed category of 10 home urinary flow measurements with the device (‘HomeUF’), to represent the usual urinary flow at home.

We performed a prospective, observational, institutional review board-approved study (two clinic visits, one home study and longitudinal follow-up of the participants) to correlate HomeUF with the mean Qmax measured by an electronic flowmeter in the clinic (Qmaxclinic), and to evaluate whether HomeUF is able to prognosticate the progression of severe LUTS, acute urinary retention (AUR), or the need for TURP. Where appropriate, mean Qmaxclinic is converted to an ordinal scale, ‘rankclinic’ (≥19 mL/s, 15–19 mL/s, 10–15 mL/s, and <10 mL/s), for comparison with HomeUF.

First clinic study

We enrolled men referred by family physicians to the urology clinic who had LUTS attributable to BPE for at least 4 weeks and were between the ages of 41 and 85 years into the study. The exclusion criteria were men who failed to (i) pass ≥150 mL urine during the uroflowmetry, (ii) stand during urination and (iii) comprehend the usage of the device. Men who had active UTIs, macroscopic haematuria, AUR, untreated prostate cancer, bladder cancer, a neuropathic bladder, upper limb disability, poor eyesight, or severe obesity that precluded the use of the device were also excluded.

At the clinic the IPSS questionnaire was completed, and uroflowmetry was performed using flow measurement by means of a weight transducer (Flowmaster; Medical Measurement Systems, Enschede, the Netherlands). The recommendations of the ICS to remove any obvious artifacts were strictly followed. The subjects were required to pass ≥150 mL urine during the uroflowmetry in their usual voiding pattern. Postvoid residual urine volume (PVR) was estimated using a transabdominal bladder scan (BladderScan® BVI 3000, Verathon Medical, Bothell, WA, USA). Once a participant had given informed consent, he was given one device, one measuring jug (to measure the voided volume of urine [VV]), and a voiding diary for the home study.

Home study

The enrolled men were instructed to pass urine ≥150 mL (measured with the measuring jug issued) into the Uflow-meter™ during their active time (excluding nocturia) at home once a day for 10 days in the 2 weeks after the first clinic. The time of voiding, VV and reading of each measurement were recorded. The HomeUF mean VV values were calculated for comparison with the mean rankclinic VV values.

Second clinic study

The enrolled men visited the clinic 2 weeks later to repeat the uroflowmetry, PVR, and IPSS questionnaire. The HomeUF was noted and confirmed with the clinic-staff. No additional therapy or change of therapy was offered to treat LUTS between the two clinic visits. After the second clinic visit, the men received either medical therapy or surgical therapy for their LUTS, as indicated by their clinical needs. The urologists had no knowledge of the home uroflowmetry results.

Prospective follow-up

The men were then followed for any development of AUR or need for surgical intervention for LUTS attributable to BPE, which signified significant LUTS progression.

Sample size calculation and data analyses

The agreement (as determined by the quadratically weighted Kappa statistic, κ) between HomeUF and rankclinic was evaluated, and the sensitivity, specificity and diagnostic odds ratio (DOR) of the HomeUF to detect a mean Qmaxclinic of ≤15 mL/s were calculated to evaluate the clinical value of HomeUF.

FIG. 1. Uflow-meter™ When in use, the device is held over a lavatory basin (or a container if the measurement of VV is required) and the patient urinates into the cup. The compartment reached by the peak level of the urine column indicates the rank of the micturition flow (BOTTOM compartment <10 mL/s, MIDDLE 10–15 mL/s, TOP 15–19 mL/s, and CUP >19 mL/s).
the device. The prevalence of the target disorder (mean Qmaxclinic ≤ 15 mL/s) was expected to be ≈ 60% [9]. The type I error (α) was set at 0.05 and the type II error (β) at 0.2.

According to the work of Sim and Wright [10] and Cantor [11], if the minimally acceptable lower limit of the 95% CI for κ (preliminarily reported as 0.60 [12]) is set at 0.5, then 165 subjects need to be recruited to test for κ. In the present study, the minimum acceptable lower limit of 95% CI for the sensitivity should not fall below 0.90, and thus the sample size required to estimate the sensitivity (expected to be 0.95) is 182, based on the calculation of Jones [13]. The lower limit of the 95% CI for the specificity should not fall below 0.50, and thus the sample size required to estimate the specificity (expected to be 0.60) is 154, based on the calculation of Flahault [14].

Thus, 182 patients were required for the study.

For comparison, κ was also determined for the agreement between rankclinic and the mean total IPPS scores (IPSS total < 8, 8 – 19, and >19); the mean score for question no. 5 of the IPSS (IPSSQ5 [0–1, 1–2, 2–3, and >3]) and the mean score of IPSS questions 1, 3, 5 and 6 on voiding (IPSS voiding [<4, 4–8, 8–12, and >12]).

For the group comparisons, the chi-squared test/Fisher’s exact test, anova and the Student paired t-test were used for the nominal data and continuous data bearing normal distribution, respectively. For continuous data not displaying a normal distribution, the Kruskal–Wallis test or Wilcoxon signed-rank test was used, where appropriate.

To determine whether fewer home urinary flow measurements suffice to reach the same agreement as that between HomeUF of 10-day measurements and rankclinic, the κ values between HomeUF of 1-day, 3-day, 5-day, 7-day, and 9-day measurements and rankclinic were calculated.

Kaplan–Meier analysis was used to evaluate the progression of LUTS attributable to BPE. Univariate analysis (log-rank test) was carried out to evaluate whether the lowest category of HomeUF (i.e. BOTTOM) and IPSS total >19 were of value in prognosticating AUR or surgical intervention for LUTS attributable to BPE.

A P value of <0.05 (two-tailed) was considered to indicate statistical significance. The PASW Statistics 18.0 (IBM SPSS Statistics) statistical package was used for the analysis.

RESULTS

A flow diagram showing the design and conduct of the study is shown in Fig. 2. A total of 192 men were consecutively enrolled. Of these, 186 men (mean [50] age
whereas in 82% men, measurements were ranked HomeUF, distribution of the mean Qmax clinic values Box-plot diagrams (Fig. 3) show the category. for 16 (8.6%) men it was in the CUP 33 (17.7%) men it was in the TOP, and men it was in the MIDDLE category, for was in the BOTTOM category, for 69 (37.1%) HomeUF. For 68 (36.6%) men the HomeUF urinary flow measurements were ranked CI: 0.78 – 0.90). In contrast, IPPS total only subgroups. HomeUF was superior to the accurately categorized 0.28 (95% CI: 0.22 – 0.35) of mean Qmax clinic with the lowest 0.083 (95% CI: 0.000–0.173). Table 1 shows the sensitivity, specificity and DOR of HomeUF to indicate a mean Qmax clinic of <19 mL/s, 15–19 mL/s, 10–15 mL/s, and <10 mL/s in the clinic uroflowmetry. HomeUF was most sensitive in identifying a mean Qmax clinic of >19 mL/s (sensitivity: 0.99; 95% CI: 0.97–1.00) and most specific in the mean Qmax clinic of <10 mL/s (specificity: 0.90; 95% CI: 0.83–0.94). The overall diagnostic performance (i.e. the DOR) of HomeUF was best in ruling out a mean Qmax clinic of <19 mL/s (DOR: 349.3; 95% CI: 40.24–3037.7), followed by a mean Qmax clinic of <15 mL/s (DOR: 91.02; 95% CI: 31.23–265.23) and then a mean Qmax clinic of <10 mL/s (DOR: 32.04; 95% CI: 14.03–73.19).

In terms of the number of home urinary flow measurements required to give the best estimate of rank clinic, the χ values for one measurement, three measurements, five measurements, seven measurements, nine measurements and 10 measurements were 0.76, 0.79, 0.78, 0.80, 0.83 and 0.84, respectively, and the correct stratification of rank clinic were 0.65, 0.70, 0.67, 0.70, 0.72 and 0.74, respectively. From that we concluded that, nine or 10 home urinary flow measurements were needed to achieve good to perfect agreement (χ > 0.8) between HomeUF and rank clinic.

Eight (4.3%) men developed severe LUTS (six developed AUR and two required TURP for significant LUTS) during the mean follow-up period of 220 days. Figure 4 shows that subjects with a HomeUF limited to the BOTTOM category were more likely (n = 6; 8.8%) than those with a HomeUF higher than the BOTTOM category (n = 2; 1.7%) to develop AUR or require TURP for symptomatic LUTS (log-rank test: P = 0.017; hazard ratio 5.61 [95% CI: 1.10–28.64]).
None of the subjects with a HomeUF higher than MIDDLE category (n = 49) developed AUR or required TURP within the follow-up period. The IPSS failed to achieve the same discriminative capability (mean IPSS total ≤ 19 vs mean IPSS total > 19, log-rank test: P = 0.325)

**DISCUSSION**

The current study echoed the findings of others [15–17] that the symptomatology of LUTS is poorly correlated with the degree of BOO, of which the likelihood is still best predicted by electronic uroflowmetry [17–23]. However, a single clinic uroflowmetry reading may not be sufficiently representative and reliable to predict BOO [24–26]. This issue can be avoided by conducting multiple flow tests in clinics, which dramatically improves the diagnostic accuracy of voiding function [27]. Nonetheless, performing multiple tests in clinics is time-consuming and often difficult for both patient and clinician, especially if the patient cannot void in his usual pattern [27,28] or if the patient does not comply with repeating the uroflowmetry to finish the testing. Although the practice of home uroflowmetry with the provision of an electronic home uroflowmeter may address this problem, such a device is not widely available either in the primary care setting [28] or at the tertiary level of many urological services.

The device tested in the present study, despite its primitive appearance, may play an important role in this regard. It is designed to make multiple measurements of uroflow at home (provided that an adequate VV of urine is passed). Its diagnostic capability was evaluated in a cohort of male patients covering a wide range of ages, Qmax values and severity of LUTS.

Pridgeon et al. [12] showed, with a group of 46 men, that the same device can give a 100% positive predictive value and has a 100% sensitivity in diagnosing men with a urinary flow of ≤15 mL/s (as detected by an electronic flowmeter), but with a specificity of only 60.8%. In the present study, the corresponding sensitivity was 95% (95% CI: 91–98%) and the specificity was 81% (95% CI: 69–90%). The positive predictive value was 93% (95% CI: 87–96%) and the negative predictive value was 88% (95% CI: 75–95%).

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Instrument</th>
<th>Sensitivity (95% CI)</th>
<th>Specifity (95% CI)</th>
<th>Positive likelihood ratio (95% CI)</th>
<th>Negative likelihood ratio (95% CI)</th>
<th>DOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOMEURF</td>
<td>No higher than the TOP compartment</td>
<td>0.79 (0.68–0.87)</td>
<td>0.90 (0.83–0.94)</td>
<td>7.56 (4.34–13.09)</td>
<td>0.24 (0.15–0.37)</td>
<td>32.04 (14.03–73.19)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>No higher than the MIDDLE compartment</td>
<td>0.95 (0.86–1.00)</td>
<td>0.81 (0.69–0.89)</td>
<td>5.06 (2.89–8.88)</td>
<td>0.04 (0.03–0.12)</td>
<td>11.08 (4.92–26.25)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>No higher than the BOTTOM compartment</td>
<td>0.99 (0.97–1.00)</td>
<td>0.68 (0.59–0.77)</td>
<td>3.12 (1.48–5.34)</td>
<td>0.01 (0.00–0.04)</td>
<td>34.48 (13.01–97.99)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>Mean IPSS ≤ 8</td>
<td>0.51 (0.39–0.62)</td>
<td>0.77 (0.69–0.85)</td>
<td>2.33 (1.97–2.79)</td>
<td>0.04 (0.03–0.10)</td>
<td>6.33 (3.09–13.47)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>Mean IPSS &gt; 8</td>
<td>0.25 (0.17–0.37)</td>
<td>0.69 (0.60–0.78)</td>
<td>1.22 (0.96–1.54)</td>
<td>0.01 (0.00–0.05)</td>
<td>2.26 (1.89–2.69)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>Mean IPSS &gt; 12</td>
<td>0.49 (0.41–0.57)</td>
<td>0.74 (0.66–0.82)</td>
<td>1.85 (1.42–2.39)</td>
<td>0.04 (0.03–0.10)</td>
<td>4.34 (3.04–6.43)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>Mean IPSS &gt; 18</td>
<td>0.74 (0.67–0.80)</td>
<td>0.73 (0.65–0.82)</td>
<td>2.73 (2.05–3.62)</td>
<td>0.05 (0.04–0.15)</td>
<td>7.75 (4.26–13.81)</td>
</tr>
<tr>
<td>HOMEURF</td>
<td>Mean IPSS &gt; 24</td>
<td>0.95 (0.91–0.98)</td>
<td>0.81 (0.69–0.89)</td>
<td>5.06 (2.89–8.88)</td>
<td>0.04 (0.03–0.12)</td>
<td>11.08 (4.92–26.25)</td>
</tr>
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</table>

TABLE 1: Sensitivity, specificity and DOR of HOMEURF subgroups in identifying the various cut-off values of the mean Qmax clinic.
Caffarel et al. [25] postulated that in a small group study of 22 male volunteers, all of whom performed 24 measurements at home, the highest level of the urine column across multiple flows was actually limited to the same chamber in most circumstances (>90% of micturition). However, our initial pilot study [9] showed that none of the men with LUTS were prepared to perform such a large number of flow tests at home and the high number of measurements recommended (up to 24) may reduce compliance with its usage by patients, making the results difficult to interpret for healthcare professionals. Despite a smaller number of home urinary flow measurements, 82% of the total micturitions of home urinary flow in this study are categorized to the same rank, HomeUF, signifying that it is a reasonable measurement of choice of home urinary flow; however, at least nine measurements of home urinary flow must be performed in order to attain the highest agreement with the mean Qmax(rank clinic) measured in the clinic ($\kappa > 0.8$).

One may argue that the device is not sufficiently precise to measure urinary flow on a small scale, nonetheless it is good enough to stratify urinary flow into different categories based on a few clinically important cut-off values of $\geq 19$ mL/s, $\geq 15$ mL/s, and $\geq 10$ mL/s (Table 1) as reflected by the remarkable DOR, which is able to represent the discriminatory capability of the test irrespective of the prevalence of the target disorder [29]. In their study of urinary flow using home uroflowmetry, Boci et al. [24] showed that the Qmax of $\sim 90\%$ of all home urinary flow measurements for men with a high BOO grade of 3–6 on the Schäfer classification [30] was $\leq 14$ mL/s, whereas only $\sim 6\%$ of all home urinary flow measurements for men with a low grade of BOO (Schäfer classification 1–2) were $< 10$ mL/s. In addition, men with a Qmax of $\leq 12$ mL/s are nearly four times as likely to develop AUR as those who have a Qmax of $> 12$ mL/s [31]. In fact, the follow-up observation in the present study showed that the subjects were more likely to develop AUR or undergo surgical intervention for their LUTS if their HomeUF was limited to the BOTTOM compartment of the flowmeter (predicting a mean Qmax$_{clinic}$ of $\leq 10$ mL/s in clinic uroflowmetry). In this context, the device may act as an effective screening tool in the triage process for men with LUTS, allowing them to be referred earlier to urological surgeons. It may be particularly effective for those who have a higher risk of developing AUR or more imminent require surgical therapy (e.g. their HomeUF is limited to the BOTTOM category).

As cost containment is always important in healthcare delivery and some urology clinics may face resource constraints in carrying out uroflowmetry, the home uroflowmetry device used in the present study could serve as a reasonable alternative tool in the evaluation of male LUTS; the device costs $\sim 6$ by bulk purchase whereas the local cost of uroflowmetry plus urological consultation amounts to $\sim 146$. Thus, it is affordable for most patients with LUTS and could be incorporated into the clinical practice of family physicians and nurse-led clinics as a screening tool in the treatment of male LUTS.

This device is not meant to, and indeed is unable to, replace formal pressure flow tests for the diagnosis of BOO in male patients with LUTS. The device is also not able to record the voiding flow pattern, which may be needed to diagnose conditions such as detrusor sphincter dsysynergia.

Furthermore, patients with morbid obesity, poor eyesight, and physical disability may not be able to use the device. Another limitation is that the subject must pass at least 150 mL of urine before the home uroflowmetry becomes informative. As with the limitation of formal uroflowmetry, the flowmeter is not able to distinguish between BOO and detrusor underactivity, especially in elderly men with voiding disorder [32], for whom a conventional pressure flow study may still have to be undertaken to confirm the disorder.

CONCLUSION

In conclusion, this device is easy to use and allows multiple measurements to be made by patients at home. Its measurement of urinary flow at home gives a robust estimation of the urinary flow measured by an electronic flowmeter in the clinic and can prognosticate the development of significant male LUTS. This information will certainly help clinicians in the decision-making process of the treatment algorithm of male LUTS.

CONFLICT OF INTEREST

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Abbreviations: Qmax, maximum urinary flow rate; PVR, postvoid residual urine volume; AUR, acute urinary retention; DOR, diagnostic odds ratios; HomeUF, 10 home urinary flow measurements; QmaxClinic, Qmax measured using the electronic flowmeter in the clinic; rankClinic, mean QmaxClinic converted to an ordinal scale; VV, voided volume of urine; IPSSTotal, total IPSS scores; IPSSQ5, score for question 5 of the IPSS; IPSSvoiding, IPSS scores for questions on voiding.