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MULTIPLE HOME UROFLOWMETRY – A BETTER OUTCOME MEASURE?

Hypothesis / aims of study

Maximum urine flow rate (Q_{max}) is commonly used to assess the success of treatment for suspected bladder outlet obstruction (BOO). Generally, Q_{max} is measured once before treatment and once after. In a clinical trial, this is sufficient to demonstrate the *net* effect of the therapy under test [1]. Random intrasubject variation is reduced by averaging over large sample sizes, allowing small increases in Q_{max} to be detected overall. However, this relatively large intrasubject variation in Q_{max} may mask treatment induced change in an individual. We propose that by making multiple measurements of Q_{max} before and after treatment on each subject, we can demonstrate benefit at an individual level. We have developed a simple, electronic urine flowmeter designed for home use over 1-2 weeks. The flowmeter acts as an electronic voiding diary and records the full uroflowmetry trace of each void. Being extremely inexpensive in comparison to currently available electronic home flowmeters, it could viably be provided to all patients who undergo treatment.

Study design, materials and methods

18 patients with suspected BOO used our home flowmeter for one week before and one week after a course of α-blockers. Each patient also performed a single clinic flow test before and after the medication. Data from the home flowmeter were downloaded to a computer and purpose-made software used to produce a flow trace and calculate Q_{max} for each void. Each flow trace was checked visually.

Results

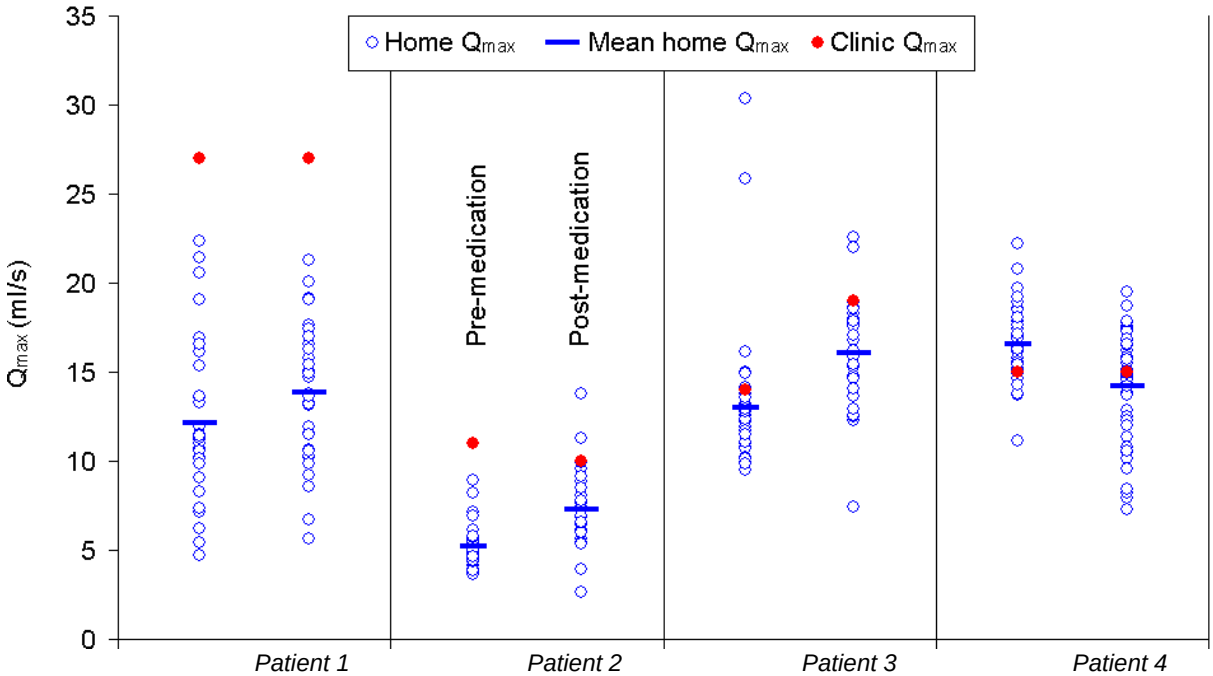
Clinic Q_{max}: 8 patients showed a post-medication increase, 3 did not change, 7 decreased, mean change = 1.1ml/s. Home mean Q_{max}: A total of 578 pre-medication (mean 32) and 536 post-medication (mean 30) flow measurements were available for analysis. 14 patients showed a post-medication increase (6 statistically significant), 4 decreased (1 statistically significant), mean change = 0.9ml/s. Clinic and home data are summarised in Table 1.

Table *1*. Change in clinic Q_{max} and home mean Q_{max} for all 18 patients.

	Patient	Δ clinic Q_{max}	Δ home mean Q_{max}	*P* *	Patient	Δ clinic Q_{max}	Δ home mean Q_{max}	*P* *
See Figure 1	1	0	1.7	0.1	10	-9	0.3	0.7
	2	-1	2.0	**<0.001**	11	-1	-0.7	0.5
	3	5	3.1	**0.002**	12	3	-0.6	0.4
	4	0	-2.4	**<0.001**	13	-2	1.0	**0.02**
	5	0	0.7	0.3	14	2	0.7	0.5
	6	4	1.3	**0.001**	15	6	-0.2	0.6
	7	5	1.0	0.3	16	-1	2.0	**<0.001**
	8	-2	1.3	0.3	17	5	3.1	**0.002**
	9	3	0.8	0.3	18	3	0.2	0.8

* *Unpaired t-test, bold text indicates statistical significance at the 95% level.*

Figure 1. Data for 4 patients. For each patient, pre-medication data are shown on the left and post-medication data on the right, as indicated for Patient 2.



Patient 1
Pre- and post-medication clinic Q_{max} values are clearly extremely unrepresentative, perhaps owing to an overly full bladder.

Patient 2
Clinic values are high compared to home values and show a decrease in Q_{max} whereas home data show a significant increase.

Patient 3
Agreement between home and clinic evaluation, although clinic Q_{max} values are high compared to home values.

Patient 4
Clinic values are representative but show no change in Q_{max} whereas home data show a significant decrease.

Interpretation of results

A plot of pre- and post-medication home flowmeter data, as in Figure 1, enables quick, visual evaluation of the improvement or decline in Q_{max}. For 6 patients, home measurements show a significant increase in mean Q_{max}; for 3 of these, clinic measurements indicate a decrease. Patient 2, shown in Figure 1, is an example of this. For 8 of the 18 patients, home measurements disagree with clinic measurements in the sign of the change. This lack of agreement between clinic and home evaluation of Q_{max} is disconcerting, although not surprising given the variability of single measurements.

Concluding message

Assessing treatment success in an individual with suspected BOO can be difficult due to the lack of an adequate gold standard. It may be argued that alleviation of symptoms is more important than an increased flow rate and indeed symptom scores are considered to be the primary outcome measure. However, objective assessment is also important to verify the intended physiological effect of the treatment. Therefore, symptom evaluation *and* uroflowmetry are recommended at regular intervals for the follow up of treatment in an individual [2], but comparison between single flows is meaningless. Multiple home uroflowmetry enables us to state with confidence how the patient's mean Q_{max} has changed, perhaps making it a suitable candidate for the gold standard of objective treatment assessment. Similarly, obtaining multiple flows during a clinical trial decreases the sample size required to detect the effect due to treatment.

References

1. J Urol (1995); 153: 99-103
2. Euro Urol (2001); 40: 256-264

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Newcastle and North Tyneside 1 Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**