

Accuracy of CaptiFlow™ portable home flow measuring device and its use as a diagnostic tool in the management of LUTS – a randomised cross over study

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Hypothesis / aims of study

A single clinic uroflow has limited power to diagnose obstruction, in part, because of known variance of up to 25%. The concept of a “true maximum flow” is therefore naive and a range of normal values for any individual is to be expected. However the logistics of establishing this by means of multiple clinic flows would be prohibitive in clinical practice. CaptiFlow™ is a simple, cheap, single use home measurement device to allow men to measure their own maximum flow rate. This study was initiated to investigate the relative diagnostic accuracy of 3 CaptiFlow™ measurements, and clinic uroflow, when compared to the mean of a series of 12 digital flow rates (Digiflow), in order to establish whether CaptiFlow™ could have a role in the management of male lower urinary tract symptoms (LUTS).

Study design, materials and methods

- Prospective, multi centre, crossover, randomised trial.
- Males with bothersome LUTS suggestive of BPH.
- 4 sites (UK, The Netherlands, Poland and USA).
- All subjects’ urinary flow was measured with three different devices/methods. The standard clinic flow (Qclinic) was taken and subjects were given 12 single use CaptiFlow™ devices and a portable, digital urine flow measuring device, Urospec™, from Medispec Ltd.
- The subjects performed 24 voids, 12 with the CaptiFlow™ and 12 with the Urospec.
- The first 3 CaptiFlow™ readings were used for comparison and the remaining flows were used to test the repeatability of the test.
- Demographics, preference and safety information was collected for all subjects throughout the study.
- Informed consent was given by all subjects included in the study.

Results

- 68 subjects were recruited into the study of whom 57 yielded evaluable data.
- The CaptiFlow™ device measures the maximum flow rate on a categorized scale from 5-17 ml/s. The average of the first three CaptiFlow™ was used in the primary analysis.
- The table shows the comparison of flow values derived from each technique, categorized according to the values displayed on the CaptiFlow™ device.
- Both Qclinic and CaptiFlow™ tended to underestimate compared to the Digital flow ($p < 0.003$ Qclinic, $p < 0.0001$ CaptiFlow™), but Qclinic and CaptiFlow™ were found to be statistically the same ($p = 1$).
- From these data, CaptiFlow™ had a power of 92% to detect a 2 ml/s difference in flow and a 99% power to detect a 2.5 ml/s difference in flow rate versus Qclinic.
- 81% of subjects preferred to measure the flow at home, compared to 14% who preferred the clinic for flow measurement and 5% who did not answer the question.

Tables and figures

The table shows three sets of comparisons of flow rate categories by three different devices and the number of subjects for each comparison. Green boxes denote equivalence.

Device used	Qclinic vs. CaptiFlow mean of 3 measurements								Total
Qclinic Measurement – flow rate categories in ml/s	0-5	5-7	7-9	9-11	11-13	13-15	15-17	17-	
0-5									0
5-7						1			1
7-9		2	2	3		1			8
9-11		1	3	2			2	1	9
11-13		1	2	1	2	2			8
13-15		1		1	2		4	2	10
15-17					4	1	1	7	13
17-						3	1	3	7
Total	0	5	7	7	8	8	8	13	56

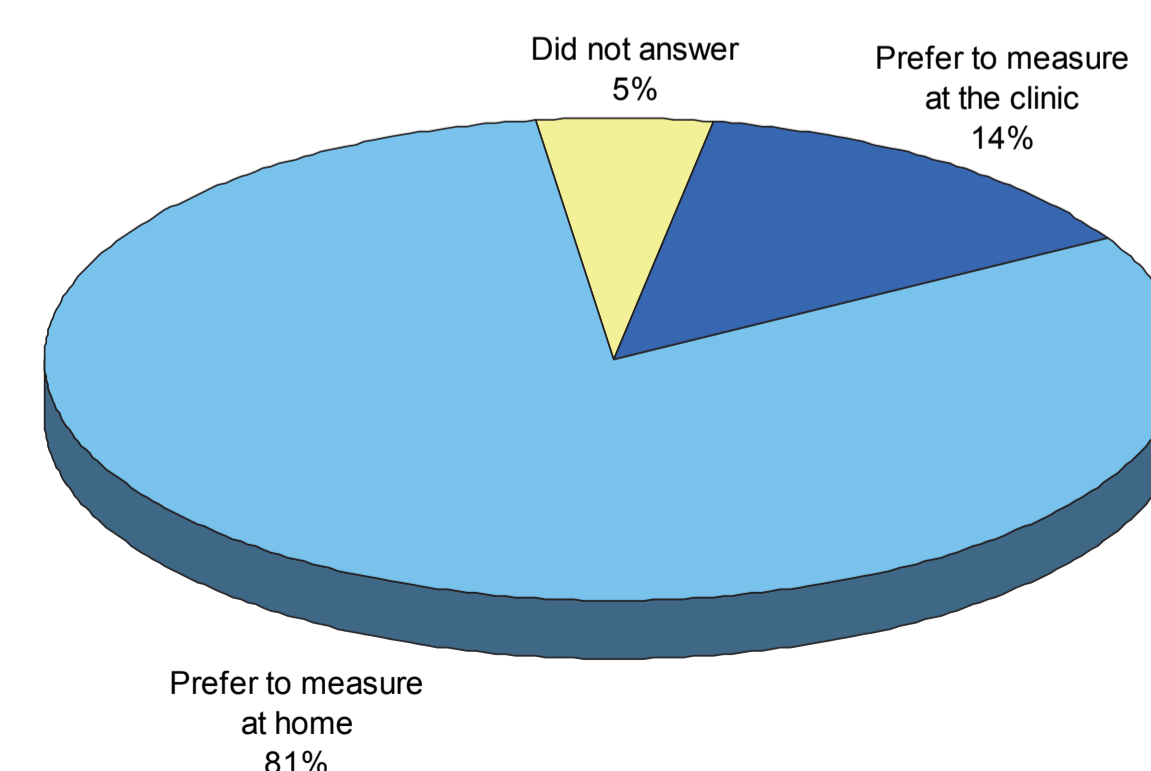
23 men had higher Captiflow value. 23 men had higher Qclinic. Binomial test 2 sided p value = 1.0

Device used	Qclinic vs. Digital flow								Total
Qclinic Measurement – flow rate categories in ml/s	0-5	5-7	7-9	9-11	11-13	13-15	15-17	17-	
0-5									0
5-7								1	1
7-9			1	1	3	2	1		8
9-11				2	3		2	1	8
11-13			1	2	2		3		8
13-15						2		5	7
15-17						2	6	4	12
17-							3	4	7
Total	0	0	2	5	8	6	15	15	51

26 men had higher Digital value. 8 men had higher Qclinic. Binomial test 2 sided p value = 0.0029

Device used	CaptiFlow mean of 3 measurements vs. Digital flow								Total
CaptiFlow (mean of 3 measurements) – flow rate categories in ml/s	0-5	5-7	7-9	9-11	11-13	13-15	15-17	17-	
0-5									0
5-7			2			2			4
7-9				4	3				7
9-11				1	3	2	1		7
11-13					1	1	3	1	6
13-15						1	5	2	8
15-17							3	4	8
17-					1		3	8	12
Total	0	0	2	5	8	7	15	15	52

5 men had higher Captiflow value. 33 men had higher Digital value. Binomial test 2 sided p value = <0.0001



CaptiFlow™



Captiflow device

The patient voids into an expanded plastic funnel and urine is collected in the bag; the side of which is marked to show voided volume and the maximum flow (within a categorise range) achieved. This portable device is self contained and fully disposable.

Interpretation of results

- Whilst CaptiFlow™ is only able to measure a flow rate of less than 17 ml/s per second, the average of three measurements offers a level of accuracy equivalent to a single clinic flow and so may prove to be useful in minimizing clinic visits whether during initial assessment or as part of follow up regime after interventions for LUTS.
- Whilst performing multiple digital flows demonstrates the range of flows achieved by an individual, it is doubtful whether the ability to measure this range adds clinical value.

Concluding message

Three home CaptiFlow™ measurements are as accurate as a single clinic flow in recording flow rates less than 17 ml/s per second. Measuring the urine flow at home is significantly preferred by the patients.

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