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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

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 naïve 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
The study was a prospective multi-centre, cross-over, randomized trial in men with bothersome LUTS suggestive of benign prostatic obstruction, recruited from 4 sites in UK, Poland, The Netherlands 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 were instructed to perform 24 voids, 12 with the CaptiFlow™ and 12 with the Urospec, performed in randomised cross over order. The first 3 CaptiFlow™ readings were used for comparison whilst the remainder were used to establish the variance and 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.
The study had an 80% power to detect a clinically meaningful difference in flow (up to 2mls /s) estimated by Monte Carlo simulations.

Results
68 subjects were recruited into the study of whom 57 yielded evaluable data.

The CaptiFlow™ device measures the maximum flow rate on a categorised scale from 5-17 ml/s. The average of the first three CaptiFlow™ measurements is considered as the result of these measurements. The table below shows the comparison of flow values derived from each technique, categorised according to the values displayed on the CaptiFlow™ device. Both clinic flow and CaptiFlow™ tended to underestimate compared to Digiflow ($p<0.003$ 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.

83% of subjects preferred to measure the flow at home, compared to 16% who preferred the clinic for flow measurement and 1% who did not answer the question.

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		Captiflow (mean of 3 measurements) – flow rate categories in mls/sec								
		0-5	5-7	7-9	9-11	11-13	13-15	15-17	17-	Total
Clinic Measurement – flow rate categories in mls/sec	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 Clinic value. Binomial test 2 sided p value = 1.0

Device used		Digital flow (mean of all available measurements) – flow rate categories in mls/sec								
		0-5	5-7	7-9	9-11	11-13	13-15	15-17	17-	Total
flow rate categ	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 Clinic value. Binomial test 2 sided p value = 0.0029

	Device used	Digital flow (mean of all available measurements) – flow rate categories in mls/sec								
		0-5	5-7	7-9	9-11	11-13	13-15	15-17	17-	Total
Captiflow (mean of 3 measurements) – flow rate categories in mls/sec	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						1	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

Interpretation of results

Whilst CaptiFlow™ is only able to measure a flow rate of less than 17 mls 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 minimising 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 mls per second. Measuring the urine flow at home is significantly preferred by the patients.

Specify source of funding or grant	**Study was funded by Astratech AB, Molndal, Sweden**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinicaltrials.gov Reg NCT00710749**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**South West Research Ethics Committee granted MREC approval 08/H0206/32**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**