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PILOT STUDY USING A NOVEL ELECTRONIC URGENCY ASSESSMENT DEVICE TO MEASURE STORAGE PARAMETERS INCLUDING THE INTERVOID-INTERVAL IN HEALTHY VOLUNTEERS

Hypothesis / aims of study

Since the publication of the ICS standardisation of terminology of lower urinary tract function report (1), the pathological symptom of urgency has been recognised as the pivotal symptom in the overactive bladder syndrome. Urgency; "the complaint of a sudden compelling desire to pass urine which is difficult to defer" has always been difficult to measure objectively. We have therefore developed an electronic urgency assessment device that logs the onset of urgency and urinary incontinence to the nearest second and also records the volume and timing of each void. Using this data other storage parameters (warning time, refractory/urgency-free time and intervoid-interval) (2) can be derived and means of these parameters over the period of the assessment can be calculated by computer software. Such parameters have previously been impossible or difficult to measure. (3) The device is a small non-invasive unit which is easily carried in a purse or pocket. It has 3 colour coded buttons with which the subject can record events and a digital display to permit the recording of the voided volume.

This study was performed to trial the device in an asymptomatic population and to determine baseline values of storage parameters including the intervoid-interval. In addition the validity of the device was assessed by comparison with a paper frequency volume chart (FVC).

Study design, materials and methods

By use of posters we recruited volunteers with no current urological symptoms and no significant history of bladder disorders. Each volunteer was given a full explanation of how to use the electronic device and to accurately complete a FVC. The pathological symptom of urgency was explained in detail and clearly differentiated from the normal sensation of urge. None of the volunteers experienced urgency, therefore warning time and refractory time which are functions of urgency could not be measured in this group. At a time of their choosing each volunteer trialled the device for a continuous 72 hour period and simultaneously completed the FVC. Data from the electronic device was later downloaded to a personal computer. Each volunteer was questioned regarding any accidental button presses and any errors were removed from the data prior to analysis. Dedicated software calculated the means of the storage parameters measured over the period of the assessment and also calculated the mean 24-hour frequency and mean volume of each micturition.

Results

Table 1. Demographic Characteristics of Sample population (n=40)

Sex	Male	20
	Female	20
Age (years)	Mean	34.1, SD=12.03 (Range 20-61)
BMI (kg/m^2)	Mean	25.21, SD=4.96 (Range 18.3-41.8)

Table 2. Results from 72-hour assessment with electronic urgency assessment device

	Mean ±SD	*Range*	*Standard Error of mean*	*95% Confidence interval of the mean*
Average 24-hour frequency	6.19 ±1.82	3.7-11.3	0.29	5.61-6.78
Average volume per micturition, *millilitres*	275.60 ±115.66	37.5-604.2	18.23	238.64-312.62
Average intervoid-interval, *mins (n=40)*	245.38 ±67.47	126.4-379.8	10.67	223.80-266.96
Average intervoid-interval, (awake periods), *mins (n=125)*	208.13 ±79.10	67.5-484.3	7.08	194.22-222.23

Diagram 1. Scatter plot of average intervoid-interval versus average micturition volume

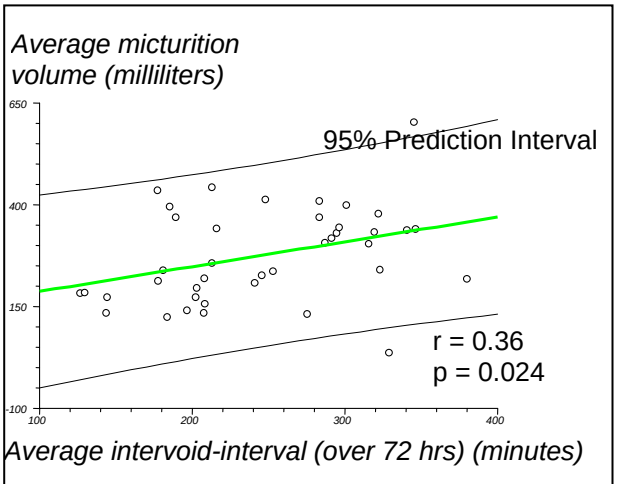
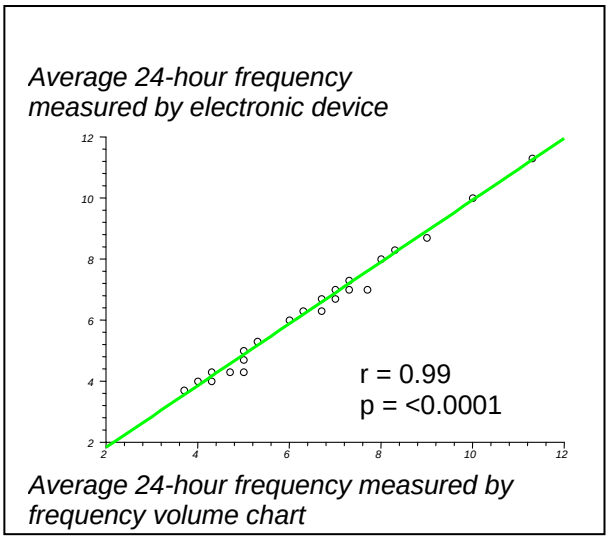


Diagram 2. Scatter plot of 24-hour frequency measured by FVC versus electronic device



Interpretation of results

This data demonstrates a baseline mean intervoid-interval of 245.38±67.47 minutes (including awake and sleep periods) and a lesser value of 208.13±79.10 minutes when calculated from awake periods in each subject only. A significant difference was demonstrated between these values (p=0.0083). This was anticipated as inclusion of sleep periods lengthens the intervoid interval since most volunteers did not experience nocturia. Only 12 (30%) volunteers had 1 or more nocturia episodes during the 72 hour assessment. Regression analysis (Diagram 1) shows a statistically significant correlation between average volume voided and average intervoid-interval (correlation coefficient(r)=0.36, p=0.024). However this correlation was not demonstrated when comparing voided volume to the awake intervoid interval (p=0.16). From our understanding of the voiding cycle as the intervoid-interval decreases, average volume voided would also be anticipated to decrease (assuming total urinary output is static) and this data confirms this assumption and demonstrates the ability of the device to measure the intervoid-interval.

The validity of the device was assessed by comparison with a standard FVC (Diagram 2). A statistically significant correlation (r= 0.99, p<0.0001) between average 24-hour frequency measured by these 2 tools was demonstrated with the electronic device having far greater precision in recording the timing of voids. At best an accurately completed FVC is precise to approximately 30 minutes. The electronic device is precise to the nearest second thereby allowing the calculation of time-dependent storage parameters such as the intervoid-interval.

Concluding message

The results of this initial small pilot confirms the hypothesis that intervoid-interval is related to volume voided based on the current concept of the voiding cycle. (2) Use of this device allows the accurate measurement of the intervoid-interval and will also allow the measurement of other storage parameters in those who suffer with urgency. Intervoid-interval has never previously been measured and this study gives an estimate of the normal value and range for this parameter. High validity of the device was also demonstrated when compared to the commonly used paper FVC but with much greater precision of measurement. This increased precision and ability to measure time related parameters makes this a more accurate assessment of the voiding cycle than a standard FVC, with many volunteers commenting on its ease of use. We believe this device can be used clinically to assess bladder dysfunction and will have particular utility in the objective assessment of therapies directed at storage disorders.

(1) Neurourol Urodyn (2002) 21:167-178
(2) BJU Int (2005) 95:335-340
(3)J Urol (2005) 173:1214-1218

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HUMAN SUBJECTS: This study was approved by the South Sheffield Research and Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.