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A Critical Reappraisal of Cystometry in Neurogenic Bladder Diseases

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Summary. Repeated cystometry was performed over an eight hour period in 14 patients with detrusor hyperreflexia. Volumes at first contraction, and at bladder capacity and also bladder compliance showed significant differences within individual variances and an increase in standard deviation in relation to increase in mean value. Amplitude of contractions showed equal variances in all patients. After a logarithmic transformation of the measurements the volume at first bladder contraction showed a significant increase ($p < 0.02$) from the first to the second investigation performed an hour later. Determination of sample size in clinical trials using the pooled estimate of the standard deviations is discussed.

Key words: Detrusor hyperreflexia, Repeated cystometries, Intraindividual variation, Logarithmic transformation, Sample size.

Introduction

Voiding dysfunction is a frequent finding in neurological patients especially in patients with multiple sclerosis [3, 13]. To achieve optimal therapy cystometric controls are of major importance. Cystometric findings, such as changes in bladder compliance, appearance of detrusor hyperreflexia and capacity, are also used in objective assessment of the effect of treatment for neurogenic bladder dysfunction [1, 7, 12]. It is, however, still unclear how reproducible these parametres might be, and the degree of confidence which should be attached to the assessment of treatment.

In this study we determined the variation of the parameters measured during consecutive cystometry performed during an eight hour period upon patients with neurogenic bladder dysfunction.

Material and Methods

Urodynamic examination was performed in 6 men and 8 women (mean age 41 years ranging from 18 to 75 years) with detrusor hyperreflexia as defined by the International Continence Society [6]. The neurological diagnoses were: Multiple sclerosis in 6 patients, neoplasma cerebri in 2, traumatic paraplegia in 2, contusio cerebri in 2, spastic paraparesis in 1 and cerebral thrombosis in 1.

None of the patients had signs of urinary tract infection and non had been treated for bladder disturbances for at least three days prior to cystometry. None had been treated with an indwelling catheter.

Cystometry was performed transurethrally with the patient in a supine position using a balloon catheter and saline infusion. Bladder filling was started 5 min after catheterization and repeated 1, 3 and 8 h later. In three patients the last examination was not performed. Between examinations the catheter was kept open. Infusion was stopped when the resting bladder pressure had increased 10 cm H_2O, when the amplitude of detrusor hyperreflexia increased 100 cm H_2O, when the patient became incontinent or when maximal desire to void was achieved. In each case this bladder volume was defined as the bladder capacity. In addition the following parameters were recorded: Infused volume at first bladder contraction (VFC), the mean of the maximal pressure amplitudes of the first three detrusor hyperreflexia and the static bladder compliance defined as the bladder capacity divided by the difference in resting bladder pressure from the beginning to the end of infusion.

Statistics. Standard deviation (SD) and mean values of these parameters were calculated in each patient. A logarithmic transformation of the measurements was performed if SD varied directly as the mean [14]. Logarithms to base e was used. The individual variances obtained from the 14 patients were tested for homogeneity by the method described by Bartlett [5], using 5% limit of significance. Sample size N was calculated from the following equation for paired observation [9]

$$N = ((Z_{alfa} + Z_{beta})/(d/SD))^2$$

where Z_{alfa} is the standard normal deviate at the alfa significance level (e.g., $Z_{alfa} = 1.96$ for alfa = 0.05, two sided), Z_{beta} is the normal deviate at the probability of a type II error (i.e., $Z_{beta} = 0.841$ for beta = 20%), d is the mean difference in N paired observations and SD is the pooled estimate of the standard deviations obtained from the Bartlett test. Differences between the values obtained in the four examinations were analysed statistically by the paired t-test using 5% limit of significance.

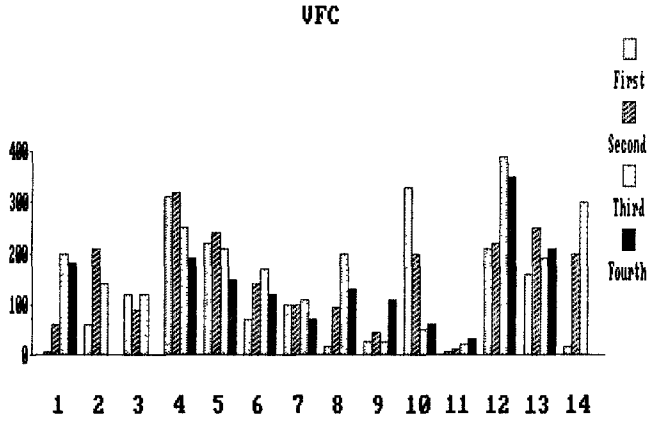

Fig. 1. Volume at first bladder contraction (VFC) in consecutive cystometries in 14 neurological patients

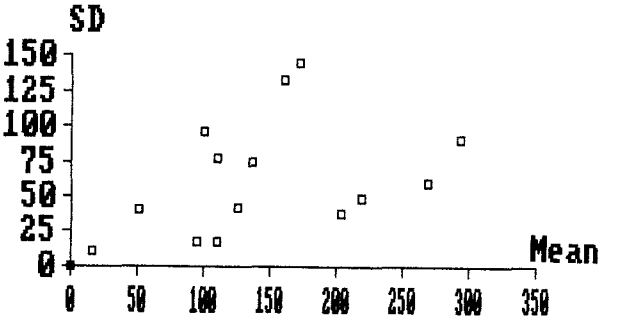

Fig. 3. Relation between standard deviation and mean value in volume at first bladder contraction in 14 neurological patients. A linear relation is observed

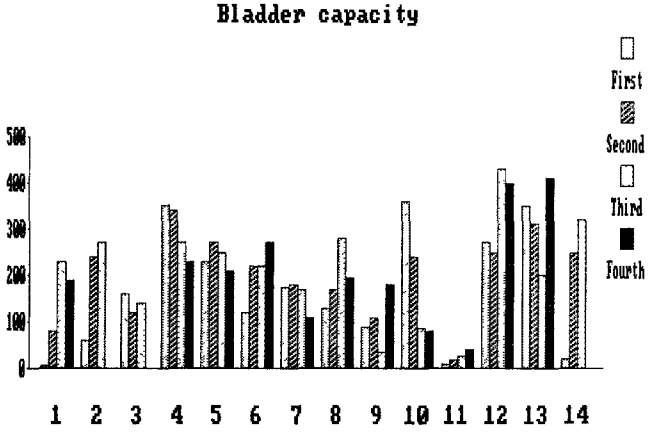

Fig. 2. Bladder capacity in consecutive cystometries in 14 neurological patients

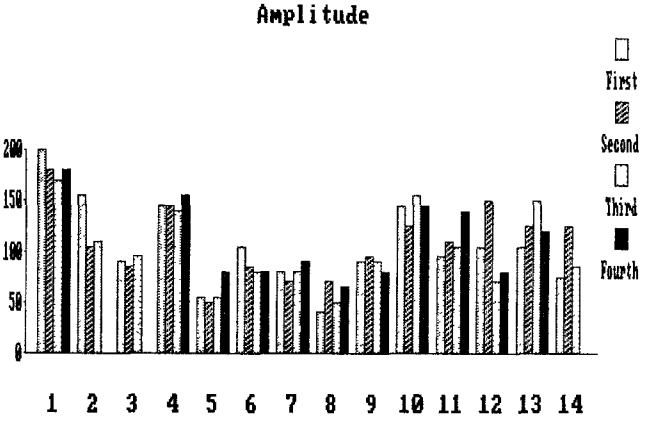

Fig. 4. Pressure amplitude of detrusor hyperreflexia in consecutive cystometries in 14 neurological patients

Table 1. Pooled estimate of the standard deviations (SD) of cystometric findings when using the original scale and after a logarithmic transformation of the measurements

	Original scale			Logarithmic transformed	
n	*n*	SD	Ba	SD	Ba
Volume at 1. bladder contraction	14	73	28[a]	0.82	16
Amplitude of contractions	14	18	20	0.17	9
Bladder capacity	14	86	24[a]	0.73	17
Bladder compliance	11	14	23[a]	0.39	6

Ba = Bartlett's test
[a] statistically significant at $p < 0.05$

Results

Detrusor hyperreflexia was reproduced in all examinations. Only in three patients did the first desire to void occurr before the onset of detrusor hyperreflexia. In the rest of the patients bladder sensation was only experienced with bladder contraction.

The volume at first bladder contraction (VFC) and the bladder capacity during the repeated examinations varied in some of the patients very little and in other patients by 2–300 ml, as shown in Fig. 1 and 2. This large variation was in some patients due to an increase in bladder volume during the study but the opposite pattern was also seen. A large variation was related to high mean values of VFC, as

Table 2. Cystometric findings in 4 consecutive investigations during the day (SD)

	n	1.	2.	3.	*n*	4.
Volume at 1. bladder contraction (ml)	14	118 (112)	155 (91)	169 (103)	11	145 (88)
Amplitude of contractions (cm H_2O)	14	106 (43)	109 (36)	102 (38)	11	110 (39)
Bladder capacity (ml)	14	166 (128)	185 (98)	209 (111)	11	210 (117)
Bladder compliance (ml/cm H_2O)	11	37 (19)	33 (20)	34 (14)	9	32 (20)

Table 3. Changes in logarithmic transformed measurementes in relation to the first cystometry

	2.	3.	4.
Volume at 1. bladder contraction (ml)	203%[a]	223%	197%
Amplitude of contractions (cm H_2O)	105%	98%	107%
Bladder capacity (ml)	155%	175%	162%
Bladder compliance (ml/cm H_2O)	116%	101%	121%

[a] statistically significant for $p < 0.02$)

shown in Fig. 3. Because of this linear relation between SD and mean a logarithmic transformation of the measurements was performed. In this way the 14 different variances were not significantly different, as shown in Table 1. The same was found for the bladder capacity.

The amplitude of contractions showed homogeneity of variances in all patients (Table 1 and Fig. 4) and standard deviation was not related to the mean value. Bladder compliance (ml/cm H_2O) was difficult to measure in 3 patients because of small bladder capacity. In the remainder values were above 20 ml/cm H_2O in all but one. A linear relation was seen between SD and mean of bladder compliance and homogeneity of variances were achieved after a logarithmic transformation (Table 1).

The pooled estimate of the standard deviations may be used to determine sample size in future clinical trials, when homogeneity of variances is observed. For instance, a two fold increase in the volume at first bladder contraction would require at least 9 patients, if the probability of a type II error is 20% and the level of significance is 5%. Using only the amplitude of the contractions 6 patients with an anticipated decrease in amplitude of 20 cm H_2O would be required.

Differences between the 4 examinations are shown in Table 2. When logarithmically transformed a significant increase in the volume at first bladder contraction from the first to the second investigation was observed, as shown in Table 3. Comparing other groups of measurements (2–4) no significant changes were seen.

Discussion

The logarithms of the measurements gave the optimal fit when 3 of the cystometric parameters were evaluated. This has also been described in patients without neurological diseases [10]. The last parameter, the amplitude of the detrusor hyperreflexia, showed no direct relation between the standard deviation and the mean of the measurements and only small changes were seen in consequtive examinations.

An increase in the VFC from the first to the second investigation was observed as in previous reports, using 1 or 10 minutes between investigations [4, 11]. This finding could be due to a distension of the bladder caused by the first bladder filling which reduced bladder excitability. It could also be explained both by an increased bladder excitability shortly after the catheter had been introduced and by increased patient acceptability. Finally it could be explained by an increased urine production during the first investigation since the bladder capacity was unchanged. However, the increase was small and when adjusted for the probability of an extreme result as a high number of groups are compared using the Bonferroni's method [2], the increase was not significant. But a larger pause (1/2–1 h) after introduction of the catheter could possibly reduce the large variation of the VFC.

No increase was observed in bladder capacity. In this study bladder capacity was estimated from the degree of pressure increase during detrusor hyperreflexia and maximal desire to void. In previous studies [4, 13], bladder filling was stopped during detrusor hyperreflexia allowing isometric contractions to take place. In this way the determination of bladder capacity is preferentially determined by the increase in the resting bladder pressure and a smaller variation might therefore be expected. In all patients the same type of cystometric finding was seen in all examinations. This has also been shown in patients with a constant state of disease when examinations were performed with an interval of months [8, 15]. But the parameters measured during cystometry, especially the VFC, showed a high degree of variation and using this parameter in evaluation of new pharmacological treatment requires a large number of patients. However, some of the variation shown in this study could be with normal limits or be due to reaction to the catheter. Evaluation of treatment should therefore be performed at the same time during the day as control examinations. In addition, using the VFC as a parameter for describing the severity of the bladder disturbances, more than one examination should be performed.

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