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ORIGINAL CONTRIBUTION

Normal Ranges of Variability for Urodynamic Studies of Neurogenic Bladders in Spinal Cord Injury

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Abstract

Background/Objective: Urodynamic studies are conducted on a regular basis to evaluate changes in bladder function after spinal cord injury. Often, differences in urodynamic parameters exist from one study or one year to the next. The objective of this study was to provide reference ranges for "normal" variability in urodynamic parameters that can be considered as "no real change" from one study to the next.

Design: Retrospective chart review.

Methods: Fifty consecutive individuals with spinal cord injury had 2 trials (trial 1 and trial 2) of urodynamic studies done 5 minutes apart, and the following data were collected: maximum cystometric capacity, opening pressure, maximum detrusor pressure, volume voided, and postvoid residual. The corresponding data were compared, and the frequency distribution for the change between consecutive studies was plotted. Because there is no standard, variability ranges for 5th to 95th, 10th to 90th, and 25th to 75th percentiles were calculated to give health care providers more choices.

Results: Ranges of variability are as follows in the following format (urodynamic parameter; mean value; +, maximum increase; −, maximum decrease)—5th to 95th percentile: cystometric capacity (234.63 mL, +213.50 mL, −158.05 mL); opening pressure (54.56 cmH_2O, +30 cmH_2O, −18.00 cmH_2O); maximum detrusor pressure (60.82 cmH_2O, +17.35 cmH_2O, −27.80 cmH_2O); volume voided (122.20 mL, +177.25 mL, −176.00 mL); postvoid residual (176.06 mL, +197.25 mL, −118.00 mL); 10th to 90th percentile: cystometric capacity (234.63 mL, +126.40 mL, −74.60 mL); opening pressure (54.56 cmH_2O, +13.70 cmH_2O, −12.00 cmH_2O); maximum detrusor pressure (60.82 cmH_2O, +10.00 cmH_2O, −20.00 cmH_2O); volume voided (122.20 mL, +105.60 mL, −82.00 mL); postvoid residual (176.06 mL, +131.00 mL, −86.00 mL); 25th to 75th percentile: cystometric capacity (234.63 mL, +72.00 mL, −27.00 mL); opening pressure (54.56 cmH_2O, +4.00 cmH_2O, −9.50 cmH_2O; maximum detrusor pressure (60.82 cmH_2O, +4.00 cmH_2O, −10.00 cmH_2O); volume voided (122.20 mL, +50.00 mL, −30.00 mL); postvoid residual (176.06 mL, +50.00 mL, −30.00 mL).

Conclusions: Urodynamic studies have variability. Knowing these ranges of variability can be helpful in determining whether differences between filling trial 1 and filling trial 2 in a single study or year-to-year changes in urodynamic studies are significant or simply the normal variability of the urodynamic study.

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Key Words: Spinal cord injuries; Urodynamics; Neurogenic bladder

INTRODUCTION

Urodynamic studies are an extremely important part of the urological evaluation in those with spinal cord injury (SCI) (1–5). They are the "gold standard" for evaluating bladder and sphincter function and for documenting the effectiveness of new drugs or other treatment modalities (1,6). Urodynamic studies are recommended to be

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conducted on a regular basis after SCI. Continuing to evaluate lower urinary tract function is essential to prevent upper and lower tract complications in patients with SCI. However, frequently there are differences in one or more urodynamic parameters from one study to the next or from one year to the next. Health care providers are faced with a dilemma regarding whether these are true changes requiring intervention or simply normal variability in urodynamic parameters.

There are several studies that support both short-term and long-term reproducibility of urodynamic studies (7–11). However, there have been no studies specifically evaluating and documenting the variability of urodynamic tests. The importance of knowing the normal variability of urodynamic studies is shown with the following patient.

A 26-year-old man with a C5-C6 American Spinal Injury Association SCI who managed his bladder with reflex voiding came in for his routine annual checkup. Urodynamic testing revealed a postvoid residual (PVR) of 175 mL, which represented an 85-mL increase from the previous year's value of 90 mL. What was the significance of this increase, and how should it have affected subsequent treatment? It was possible that this 85-mL increase fell within a normal variability of the urodynamic test itself and was therefore not significant. It was also possible, however, that an 85-mL increase was outside the range of variability for the urodynamic test and represented a true change in bladder and/or sphincter function. If this were a true change, it would require closer monitoring or intervention.

The objective of this study was to provide reference ranges for "normal" variability in urodynamic parameters. Interpretation of urodynamic results and decisions to intervene are ultimately the decision of the health care provider, but ranges of variability can assist in the clinical interpretation of year-to-year changes in urodynamic studies.

METHODS

Retrospective chart review was conducted on 50 consecutive out-patients at Kessler Institute for Rehabilitation as part of an Institutional Review Board–approved project. Subjects included patients with either traumatic or nontraumatic SCIs who had had 2 filling and voiding urodynamic studies within 5 minutes. Individuals with neurogenic bladders due to other causes, such as stroke or brain injury, were excluded. Only patients whose studies involved 2 test trials were included; those with just 1 trial were excluded. None of the subjects were in spinal shock. Subjects were either free of urinary tract infection or had been treated just before testing. Written consent for urodynamic testing was obtained from all subjects before testing.

All urodynamic studies were conducted in the same manner, with the same equipment, and by a single physician and his urology staff. The equipment used was a 6-channel Life Tech system with a Janus computer system (Medtronics ALS, Tonsbakken 16-18, DK-2740 Skovlunden, Denmark). The subjects were placed in the lithotomy or sitting position. Before testing, their bladders were emptied by catheterization, using a 10F catheter for men and an 8F catheter for women. Each study involved 2 separate trials of bladder filling, 5 minutes apart (trials 1 and 2). The bladder was filled with sterile water at a constant infusion rate of 60 mL/s. If any of the following events occurred, the filling process was stopped: contraction and emptying of the bladder, attainment of maximum cystometric capacity (with a rise in the compliance curve), sense of urinary urgency, or elevation in blood pressure caused by autonomic dysreflexia. The bladder was emptied to determine the PVR volume, and the second trial (trial 2) was started 5 minutes later. The same study protocol was used for both trials. In subjects with a history of autonomic dysreflexia or whose neurologic level of injury was T6 or above, blood pressure was monitored closely during testing.

The following urodynamic parameters were measured during the filling and voiding phases in 2 trials, 5 minutes apart (trials 1 and 2): filling phase, maximum cystometric capacity (mL); voiding phase, opening pressure (cmH_2O); maximum detrusor pressure (cmH_2O), volume voided (mL); and PVR (mL).

If a parameter was measured during 1 trial but not the other, it was not considered for analysis. The corresponding data from the 2 trials were compared. For each parameter, the measured change between the 2 trials for each subject was calculated, and the frequency distribution curve for the changes among all 50 patients was plotted. A value of 0 represented no change between trials 1 and 2; a negative value signified a decrease in a particular parameter; and a positive value signified an increase in the parameter between the 2 trials. The mean measured values for each parameter in both trials 1 and 2 were calculated, as well as 3 percentile ranges for changes between trials 1 and 2. Because there are no established clinically significant ranges for changes in urodynamic parameters, 3 percentile ranges, 5% to 95%, 10% to 90%, and 25% to 75%, were determined to allow clinicians to work with the particular range of "normal variability" with which they feel most comfortable.

RESULTS

The 50 consecutive subjects who met the inclusion criteria consisted of 40 men and 10 women with paraplegia or tetraplegia. The age range was 17 to 69 years. The majority had traumatic SCIs, except for 3 subjects: one with multiple sclerosis, one with a spinal cord tumor, and one with transverse myelitis. There were 29 subjects with complete SCI and 21 with incomplete injuries, as defined by the American Spinal Injury Association (12). Neurologic level of injury ranged from C2 to L2. The subjects used various urinary drainage methods (Table 1), including intermittent catheterization

(n = 14), indwelling Foley catheter (n = 11), suprapubic catheter (n = 7), reflex voiding (n = 15), and voluntary voiding (n = 3). For purposes of describing the type of bladder management (but not in any of the variability analysis), 1 person was counted twice because he used both intermittent catheterization and reflex voiding. Subjects used various medications for bladder management, including oxybutynin (n = 16), tolterodine (n = 19), terazosin (n = 10), propantheline (n = 3), tamsulosin (n = 3), and bethanechol (n = 1).

Our subject group included 50 consecutive individuals coming in for bladder testing, regardless of bladder management method. This provided a representative sampling of a typical SCI patient population one would encounter in a urodynamics center rather than a homogeneous patient population.

The 50 subjects were analyzed for maximum detrusor pressure, voided volume, PVR, and maximum cystometric capacity. All who used reflex voiding for bladder management voided during both trials 1 and 2, allowing analysis of opening pressures. Those using other types of management methods (eg, intermittent catheterization, indwelling Foley catheter, or suprapubic catheter) either did not void during trial 1 or 2 (n = 11) or did not void at all (n = 4). Therefore, only 35 of the 50 subjects were included in the analysis of opening pressure. Subjects not included in the opening pressure analysis did provide measurements for the other parameters.

For each parameter (total cystometric capacity, opening pressure, maximum pressure, volume voided, and PVR), the measured change between the 2 trials for each subject was calculated, and the frequency distribution curve for the change was plotted. Tables 2 through 4 summarize the mean measured urodynamic value for both trials 1 and 2, as well as the 5% to 95%, 10% to 90%, and 25% to 75% ranges for measured changes between trials 1 and 2 for each parameter. Each range gives the maximum increase or decrease in a urodynamic parameter that falls within the normal variability of the urodynamic study. These percentile ranges can be interpreted as reference ranges for normal variability in a urodynamic parameter between one study and another, or in other words, "no real change."

Table 1. Bladder Management Methods

Bladder Management	No. of Subjects
Intermittent catheterization	14
Indwelling Foley catheter	11
Suprapubic catheter	7
Reflex voiding	15
Voluntary voiding	3

DISCUSSION

Urodynamic studies are used routinely to evaluate bladder function after SCI (1–5). They are the "gold standard" for evaluating bladder and sphincter function and for documenting the effectiveness of new drugs or other treatment modalities (1,6). Another important application of urodynamic studies is the detection of silent autonomic dysreflexia (13). Urodynamic studies are an important component of a comprehensive assessment of the lower and upper urinary tract in conjunction with other modalities such as cystoscopy, renal ultrasound, and renal nuclear medicine scan.

Several studies have been done to evaluate the reproducibility of urodynamic studies. Most of the studies were performed on patients without SCI. The largest trial was a prospective, multicenter trial including 216 men with lower tract symptoms caused by benign prostatic hypertrophy (7). The study evaluated the test–retest reliability of several urodynamic parameters during 3 voids and found no significant changes in various parameters, including maximum flow rate, volume voided, and residual volume.

Three other prospective trials of urodynamic reproducibility were conducted in healthy women (8–10). These studies examined the short-term (2 months) and long-term (mean, 26.3 months) reproducibility of urodynamic studies in healthy women, as well as short-term reproducibility in postmenopausal women. Each study involved 10 to 12 subjects, and the studies evaluated parameters such as empty bladder pressure, first sensation pressure, first sensation volume, maximum capacity pressure, maximum capacity volume, compliance, opening pressure, maximum flow rate, voided volume, and detrusor contraction time. All 3 studies showed good short- and long-term reproducibility for the urodynamic studies.

All these studies were performed in subjects without SCI. Another study examined the reproducibility of urodynamics specifically in individuals with SCI (11). It evaluated the short-term reproducibility of urodynamic parameters such as bladder volume at first sensation, maximum cystometric capacity, presence of uninhibited contractions, opening pressure, maximum detrusor pressure, duration of bladder contraction, volume voided, and PVR volume in 50 patients with SCI. The study found statistically significant short-term reproducibility of all 8 of the urodynamic parameters evaluated.

These studies support the reproducibility of urodynamic studies. However, there are no studies that report ranges of normal variability of those urodynamic parameters from one study to the next. This is important to know because health care providers are sometimes faced with a dilemma in deciding whether a change in a urodynamic parameter from one study or one year to the next is a real change or not. This study provides variability reference ranges to help health care providers

Table 2. Percentile Reference Range 5th to 95th for Normal Variability in Urodynamic Parameters Between 2 Studies (Trials 1 and 2)

Urodynamic Parameter	Mean Urodynamic Value for Trial 1	Mean Urodynamic Value for Trial 2	5% to 95% Range for Differences Between Trial 1 and Trial 2 Within Normal Variability
Cystometric capacity	234.63 mL	255.77 mL	−158.05 mL decrease; +213.50 mL increase
Opening pressure	54.56 cmH_2O	51.91 cmH_2O	−18.00 cmH_2O decrease; +30.00 cmH_2O increase
Maximum detrusor pressure	60.82 cmH_2O	58.86 cmH_2O	−27.80 cmH_2O decrease; +17.35 cmH_2O increase
Volume voided	122.20 mL	132.17 mL	−176.00 mL decrease; +177.25 mL increase
Postvoid residual	176.06 mL	185.80 mL	−118.00 mL decrease; +197.25 mL increase

decide whether a difference in a urodynamic parameter from one study to the next is a true change.

Our group of subjects included 50 consecutive individuals coming in for bladder testing. Rather than using strict inclusion criteria to select a homogenous group, we purposely evaluated individuals with different bladder management methods (Table 1), different causes for SCI, and different levels and completeness of injury. We feel our group is a representative sampling of a typical SCI patient population one would encounter in a urodynamics center and is therefore a more realistic population on which to perform variability studies. It is possible, however, that a particular group of individuals with the same method of bladder management or very similar voiding pictures will have significantly different mean urodynamic values (eg, bladder capacity or pressures) than those of our group of subjects. In that case, the normal variability ranges for that group of patients would likely be different than those determined in this study.

This study examined the short-term variability of urodynamic tests, comparing differences between 2 trials conducted 5 minutes apart. One question may be the

Table 3. Percentile Reference Range 10th to 90th for Normal Variability in Urodynamic Parameters Between 2 Studies (Trials 1 and 2)

Urodynamic Parameter	Mean Urodynamic Value for Trial 1	Mean Urodynamic Value for Trial 2	10% to 90% Range for Differences Between Trial 1 and Trial 2 Within Normal Variability
Cystometric capacity	234.63 mL	255.77 mL	−74.60 mL decrease; +126.40 mL increase
Opening pressure	54.56 cmH_2O	51.91 cmH_2O	−12.00 cmH_2O decrease; +13.70 cmH_2O increase
Maximum detrusor pressure	60.82 cmH_2O	58.86 cmH_2O	−20.00 cmH_2O decrease; +10.00 cmH_2O increase
Volume voided	122.20 mL	132.17 mL	−82.00 mL decrease; +105.60 mL increase
Postvoid residual	176.06 mL	185.80 mL	−86.00 mL decrease; +131.00 mL increase

Table 4. Percentile Reference Range 25th to 75th for Normal Variability in Urodynamic Parameters Between 2 Studies (Trials 1 and 2)

Urodynamic Parameter	Mean Urodynamic Value for Trial 1	Mean Urodynamic Value for Trial 2	25% to 75% Range for Differences Between Trial 1 and Trial 2 Within Normal Variability
Cystometric capacity	234.63 mL	255.77 mL	−27.00 mL decrease; +72.00 mL increase
Opening pressure	54.56 cmH_2O	51.91 cmH_2O	−9.50 cmH_2O decrease; +4.00 cmH_2O increase
Maximum detrusor pressure	60.82 cmH_2O	58.86 cmH_2O	−10.00 cmH_2O decrease; +4.00 cmH_2O increase
Volume voided	122.20 mL	132.17 mL	−30.00 mL decrease; +50.00 mL increase
Postvoid residual	176.06 mL	185.80 mL	−30.00 mL decrease; +50.00 mL increase

applicability of short-term variability ranges when evaluating year-to-year changes in urodynamic studies. A limitation of this study is that we did not evaluate long-term variability in this cohort. The problem with examining year-to-year variability in urodynamic studies is that a large number of variables such as pharmacological interventions, hydration status, calibration methods, or neurological changes can occur between annual tests. These variables could cause large changes in urodynamic measurements, but they would be attributable to causes other than the normal variability of the urodynamic test. Therefore, we chose to look at short-term variability to eliminate these confounding variables and look specifically at ranges of variability of the urodynamic test itself. There is no established "gold standard" for the variability of urodynamic studies. It should be noted that, with a larger selected reference range, greater variability will be shown. We reported results as 3 separate ranges: the 5th to 95th percentile range, the 10th to 90th percentile range, and the 25th to 75th percentile range (Tables 2 through 4). We decided to include 3 ranges to provide health care providers with the option of using the range with which they feel comfortable when evaluating changes in urodynamic studies. If a health care provider prefers to use the narrowest range of normal ("no true change"), the 25th to 75th percentile range can be used as a reference. If another health care provider feels comfortable with a wider range of variability, the 5th to 95th percentile range can be used as a reference.

These ranges can be used as a tool as health care providers seek to interpret short-term urodynamic variability. This information is also helpful for evaluating year-to-year changes in urodynamic studies. In the long-term studies, it is particularly important to control as many variables as possible, such as hydration, equipment calibration, catheter size, fill rates, and patient position during the study. While the focus of this paper is on urodynamic variability, it is also important to note that, particularly after SCI, changes in spasticity due to a variety of causes can affect bladder and sphincter function. For example, if a person has constipation and undergoes a study, the constipation will likely affect sphincter function. While bowel issues are the most common cause, other potential causes of increased spasticity include acute urinary tract infection, pressure ulcer, ingrown toenail, or syrinx. Therefore, it is important to not just assume a change is caused by the bladder or sphincter but to also rule out other causes that may affect bladder and sphincter function.

Ultimately, it is up to the health care provider to interpret urodynamic results and to consider the entire clinical picture of the individual when drawing conclusions and making treatment decisions. If a change from one year to the next seems alarmingly large to a clinician despite falling within these ranges of "normal variability," immediate repeat urodynamics can be performed to further clarify the change.

While this study will help alert a health care provider to a change, future studies will help determine which of these changes are clinically significant even though they may or may not fall within a particular normal variability range. This study used a variety of individuals with various types of bladder management. Future studies may be done to determine if there are subtle differences of normal variability of various urodynamic parameters when evaluating specific variables such as level of injury and type of bladder management. Showing similar values in repeated urodynamic studies in a subset of patients would strengthen the significance of these findings.

CONCLUSION

The purpose of this study was to publish reference ranges of variability of urodynamic studies in those with neurogenic bladders. These ranges can be used as a guide by health care providers in determining whether changes from one urodynamic study to the next are significant or simply fall within the expected variability of the urodynamic study itself ("no true change"). If there is a question of whether the change is caused by some other problem, such as bowel issues, the problem can be addressed, and follow-up urodynamic studies can be performed.

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