

Clinical Study

Bedside Cystometry as a Simple Alternative to Urodynamic Studies in Resource-Limited Settings in Diagnosing Pediatric Bladder Dysfunctions: A Single-Blinded Prospective Comparative Study

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Keywords

Bedside cystometry
Urinary bladder dysfunction
Urodynamic study

Abbreviations

BC - Bedside cystometry
CVP - Central venous pressure
EBC - Expected bladder capacity
OBC - Observed Bladder Capacity
PUV - Posterior Urethral Valve
UDS - Urodynamic study

Abstract

Background: Proper urodynamic evaluation of children is often limited by the cost, technical expertise and availability of the involved equipments. Bedside cystometry (BC) could be a useful alternative in the absence of facility for urodynamic study (UDS). In this study, the predictive value of BC is compared with that of the UDS in diagnosing functional abnormalities of the bladder in children.

Methods: This single-blinded prospective comparative study involved 30 children of age 4-18 years who were diagnosed with various urinary anomalies (e.g. posterior urethral valves, neurogenic bladder, bladder exstrophy and dysfunctional voiding). All of them underwent both BC and UDS. To mimic the resource-limited settings, BC was done using saline manometer and without rectal pressure monitoring.

Results: The overall sensitivity of BC was 92%, specificity was 100%, positive predictive value was 100% and negative predictive value was 95%. False-negative results were found in 8% of patients. Detrusor instability was detected by UDS and BC in 12 and 11 patients respectively. The observed differences between the two groups were not statistically significant. A high kappa value ($k = 0.93$) confirms a near-perfect agreement between the two diagnostic procedures.

Conclusion: BC could measure bladder volume and pressure as accurately as UDS. Therefore, it could be a valid, reliable, acceptable and cheap alternative to UDS in resource-limited settings where UDS facilities are not available.

INTRODUCTION

Urodynamic study (UDS) is an essential tool in the diagnosis of urinary bladder dysfunctions. UDS

evaluates both the static and dynamic elements of the bladder function. It is a sophisticated multi-channel study that consists of cystometry (filling

phase behavior of the urinary bladder), uroflowmetry (pressure-volume dynamics of voiding) and electromyography (study of the sphincter contractions). As it yields a wide range of information, it is considered to be the gold standard. However UDS requires complex and costly equipments that are not easily available in many resource-limited centers.

Although bedside cystometry (BC) is no match to UDS, it could be a simple yet valuable screening tool for the assessment of filling-phase behavior of the urinary bladder. Unlike UDS, it is done at bedside by a single-channel technique using simple and easily available materials in any hospital.⁽¹⁾ Most of the previous studies comparing BC and UDS have been done in adults, and there is a paucity of pediatric literature. The present study is intended to compare the predictive value of BC with that of standard UDS.

MATERIALS AND METHODS

Study Cohort

This single-blinded prospective comparative study was conducted in the department of pediatric surgery at a tertiary care center over a period of one year. Study cohort consists of 30 co-operative children aged 4-18 years who were diagnosed with posterior urethral valves (PUV), neurogenic bladder, vesical exstrophy or voiding dysfunction. All of them required assessment of bladder function as part of clinical management. Patients with urinary tract infections and those who could not be catheterized were excluded. Informed parental consent and child assent were obtained.

Study Design

All the study subjects underwent both BC and UDS in the same sitting. UDS was taken as the gold standard, against which BC was compared. BC was done in all but one before the UDS. Additional urological assessments such as urological imaging, blood biochemistry and urine culture were done as indicated.

Study Parameters

Demographic details, clinical history and physical examination findings were recorded for each of them. Subjective and objective variables were studied. Subjective variables included the filling volume and pressure at the first sensation of bladder filling, at the first desire to void and at the strong desire to void. Objective variables were pressure recordings at specified bladder volumes (e.g. 25%, 50%, 75% and 100% of the expected bladder capacity), bladder compliance and the presence or absence of detrusor instability. The bladder volume and pressure were also recorded at the time of any significant event such as cough.

Technical Standardization

Prior to the study, the rectum was emptied by administering bisacodyl suppository or sodium phosphate enema. At the outset, children were asked to empty the bladder on their own. Post-void residual volume was noted on catheterization. Privacy was ensured during the procedures. Koff's formula [30 x (age in years + 2) ml] was used to calculate the expected bladder capacity (EBC) for each patient.^(2,3) Pubic symphysis was taken as the reference point of manometer level and atmospheric pressure as the reference pressure in both UDS and BC.

Compliance of bladder was assessed by measuring intra-vesical volume and pressure at two standard points as per the recommendations of the International Continence Society.^(4,5) Bladder compliance was expressed as the ratio of change in bladder volume against the corresponding change in bladder pressure till the time of strong desire to void.

Protocol of Urodynamic Study

An independent resident trainee, who was blinded to the findings of BC, performed UDS as per the prescribed standard methodology.^(4,5) Laborie™ urodynamic machine - version 6 (Laborie Medical Technologies Corp, New Hampshire, USA) was

used. Software incorporated in this multi-channel equipment automatically calculated the detrusor pressure from intra-abdominal and intra-vesical pressures and continuously displayed these 3 values in real-time.

Before starting the study, intactness of all the tube connections were checked using cough response test. Air bubbles were removed from all the tubes. Transducers were calibrated by zero balancing at the level of the pubic symphysis.

Endpoints of filling were defined as follows: (a) Strong urge to void and inability to hold urine further (b) Uncomfortable bladder sensation (c) Uncontrolled voiding during the study (d) Persisting bladder pressure >40 cmH₂O (e) Infused volume >150 % of EBC (f) Rate of leakage more than the rate of infusion.

Protocol of Bedside Cystometry

BC was performed by the principal investigator (the first author). Children were asked to void at the outset and the force of stream (qualitative) and volume of urine (quantitative) were recorded. With aseptic precautions, two sterile 5 Fr infant-feeding tubes were simultaneously inserted into the bladder through the urethra or through any other conduit such as the Mitrofanoff channel. Care was taken that the catheters were not too much inside the bladder, as this may irritate the detrusor or trigone. The amount of residual urine, if any, in the bladder was recorded. Both the tubes were fixed to the lower abdominal wall with an adhesive tape. One of the tubes was used to fill the bladder; the other served as monitoring channel connected to a manometer. Pediatric burette sets were used to fill the bladder with measured quantities of normal saline at an appropriate rate. Central venous pressure (CVP) manometer that is based on the level of water column was used to measure the pressure in cm H₂O. The same parameters as that of UDS were studied. A note was

made of any sudden wide fluctuation in pressure that is suggestive of bladder instability.

Monitoring of the rectal pressure was deliberately omitted in BC group in order to mimic the ground reality of resource-limited settings. (For further justification *vide infra*).

Statistical Analysis

Paired t-test or Mann-Whitney test was used for analyzing the quantitative data and chi-square test for the qualitative data. Agreement between BC and UDS was analyzed using Cohen's kappa statistics. P-value <0.05 was considered significant to disprove null hypothesis. Sensitivity, specificity and predictive value were also calculated for UDS and BC.

RESULTS

The mean age of patients (25 boys, 5 girls) was 9.4 years (SD 3.48; median 8.5 years). Among them 87% were aged 5-15 years. The mean EBC was 331 ml (range was wide due to the differences in the age of the patients). Table 1 summarizes the comparison of urodynamic values of UDS and BC. Detrusor instability was detected by UDS and BC in 12 and 11 patients respectively. The observed differences between the two groups were not statistically significant.

The overall sensitivity of BC was 92%, specificity was 100%, positive predictive value was 100% and negative predictive value was 95%. False-negative results were found in 8% of patients. The diagnostic accuracy of BC, taking UDS as the gold standard, was 97%. A high kappa value ($k = 0.93$) confirms a near-perfect agreement between the two diagnostic procedures.

DISCUSSION

Bladder dysfunction causes significant morbidity in many patients with PUV, neurogenic bladder, vesical exstrophy and dysfunctional voiding. It is

therefore important to have a periodic monitoring of the bladder condition in these patients. The pressure and volume characteristics of bladder are a measure of its functional status and overall

health. Often, these parameters guide us in specific management or intervention. Urodynamic study is now considered indispensable in the management of bladder malformations and dysfunctions.

Table 1. Comparison of urodynamic parameters with bedside cystometry

Study Parameter	UDS*	BC*	P - value
Subjective Parameters			
OBC (ml)	254 ± 194	265 ± 200	0.32
EBC/OBC (%)	80 ± 55	82 ± 59	0.73
Volume at first bladder sensation (ml)	22 ± 42	27 ± 53	0.18
Pressure at first bladder sensation (cm H ₂ O)	2 ± 4	2 ± 5	0.45
Volume at first desire to void (ml)	105 ± 90	111 ± 125	0.35
Pressure at first desire to void (cm H ₂ O)	8 ± 19	7 ± 15	0.32
Volume at strong desire to void (ml)	203 ± 165	214 ± 175	0.32
Pressure at strong desire to void (cm H ₂ O)	14 ± 28	16 ± 22	0.31
Objective Parameters			
Pressure at 25% EBC (cm H ₂ O)	4 ± 9	4 ± 6	0.23
Pressure at 50% EBC (cm H ₂ O)	8 ± 18	8 ± 13	0.48
Pressure at 75% EBC (cm H ₂ O)	12 ± 20	13 ± 20	0.32
Pressure at 100% EBC (cm H ₂ O)	19 ± 20	19 ± 20	0.50
Bladder Compliance	18.7 ± 30.1	16.5 ± 24.5	0.27

* Values as Mean ± 2 standard deviations. BC - Bedside cystometry, EBC - Expected bladder capacity, OBC - Observed bladder capacity, SD - Standard deviation, UDS - Urodynamic study

The cystometric techniques have evolved ever since 1882, when Mosso and Pellacani first used a water manometer to measure bladder pressure and recorded it on a smoked drum.⁽⁶⁾ Initially, simple methods were used; but with passage of time, accuracy and consistency of recordings improved with advancements in digital recording systems and transducers. Neale described the use of a CVP manometer as a simple tool of measuring bladder pressure.⁽⁷⁾

The modern-day UDS requires an elaborate, cumbersome and costly setup that is available only in a few tertiary-care hospitals. Single-use UDS catheters are costlier than the two infant

feeding tubes, pediatric burette set and CVP manometer used in BC. However, such low-cost alternatives are acceptable only if the diagnostic accuracy is not compromised. Previously published studies were mostly pertinent to adult females and geriatric patients.⁽⁸⁻¹²⁾ We could find only a single pediatric study of BC in spina bifida patients.⁽¹³⁾ There is a paucity of literature regarding this in the pediatric age group, although UDS has been widely used in them.^(14,15) Several authors have acknowledged the usefulness of single-channel urodynamics in the evaluation and treatment of urinary incontinence.⁽¹⁶⁻²³⁾

Bates, in 1970, showed the importance of differentiating between the gross intra-vesical pressure, the contribution of intra-abdominal pressure and the true detrusor pressure in judging the real pathophysiology.⁽²⁴⁾ It was after this publication, multi-channel cystometry became popular and developed to reach its present complexity.⁽²⁴⁾ Recently, Cherian et al found that the gross vesical pressure and detrusor pressure (vesical pressure minus intra-abdominal pressure) are comparably identical in children. They also noted several artifacts with the usage of additional rectal catheter in an already anxious child.^(25,26)

Subjective variables measured in this study need accurate active feedbacks communications from the patients regarding their subjective perceptions (e.g. sensation of filling, desire to void). The younger the child, the more difficult it will be to have this interaction. For this reason children younger than 4 years were not included in this study. The mean age of patients in this study was 9.4 years with a standard deviation of 3.5 years. Previously published studies involve mainly adults or geriatric patients.

Ouslander reported a sensitivity of 75%, a specificity of 78% and a positive predictive value of 85% for simple cystometry.⁽⁸⁾ Other workers have also confirmed similar outcomes with simple cystometry.^(9,12) Wheeler et al⁽¹⁰⁾ who compared simple water manometer cystometry with 4-channel electronic cystometry in females with voiding dysfunction found that the water manometer had an accuracy of 93% in detecting detrusor instability and had a good correlation of bladder volume with the 4-channel manometry.

Unlike multi-channel UDS machines, BC does not have software for automatic recording and storing of data. As they have to be done manually, the observer must be vigilant while performing BC. With practice this skill is acquired easily and the learning curve is not prolonged.

CONCLUSIONS

BC could measure the changes in bladder volume and pressure as accurately as UDS and could detect bladder instability with high sensitivity, specificity and accuracy. It therefore is a valid, reliable, acceptable, easy-to-perform and cost-effective alternative to UDS in resource-challenged settings without UDS facilities.

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