INTERNATIONAL SPINAL CORD INJURY

URODYNAMIC BASIC DATA SET (version 2.0)

The first version of the International Spinal Cord Injury Lower Urinary Tract Function Data Set was developed by Fin Biering-Sørensen, Michael Craggs, Michael Kennelly, Erik Schick, and Jean-Jacques Wyndaele.

The current revision of the International Spinal Cord Injury Urodynamic Basic Data Set was performed by Jürgen Pannek (chair), Michael Kennelly, Thomas M. Kessler, Todd Linsenmeyer, Jean-Jacques Wyndaele, and Fin Biering-Sørensen.

The International Spinal Cord Injury Lower Urinary Tract Function Basic Spinal Cord Injury Data Set (version 2.0) has been endorsed by the American Spinal Injury Association and the International Spinal Cord Society.

Questions and suggestions regarding the International Spinal Cord Injury Lower Urinary Tract Function Basic Data Set should be directed to Jürgen Pannek: juergen.pannek@paraplegie.ch or Fin Biering-Sørensen: fin.biering-soerensen@regionh.dk.

Collection of data on the urodynamic observations made during urodynamic studies is universal when individuals with spinal cord lesions are evaluated for their lower urinary tract function.
The purpose of the Urodynamic Spinal Cord Injury (SCI) Basic Data Set is to standardize the collection and reporting of a minimal amount of information from the urodynamic study in daily practice in accordance with the purpose and vision of the International Spinal Cord Injury Data Sets (Biering-Sørensen et al. 2006). This will also make it possible to evaluate and compare results from various published studies.

The data in this International SCI Urodynamic Basic Data Set will generally be used with the International SCI Core Data Set (Version 2.0) (Biering-Sørensen et al. 2017), which includes information on date of birth and injury, gender, the cause of spinal cord lesion, the neurologic status, and the International SCI Lower Urinary Tract Function Basic Data Set (Version 2.0) (Biering-Sørensen et al. 2018).

For individuals with SCI, video-urodynamics are the recommended gold-standard, and should be performed if possible, at least for the initial evaluation. For standardized collection and reporting of radiologic findings during video-urodynamics, the International SCI Imaging Basic Data Set (Biering-Sørensen et al. 2009) should be used. If video-urodynamics are not available, filling cystometry and a pressure flow study (if applicable) should be performed.

The aetiology of a spinal cord lesion may be traumatic or non-traumatic. In the present context, all lesions to the spinal cord are included.

It is extremely important that data are collected in a uniform manner. For this reason, each variable and each response category within each variable has been specifically defined in a way that is designed to promote the collection and reporting of comparable minimal data.

Use of a standard format is essential for combining data from multiple investigators and locations. Various formats and coding schemes may be equally effective and could be used in individual studies or by agreement of the collaborating investigators.

In this document The Standardisation of Terminology of Lower Urinary Tract Function: Report from the Standardisation Sub-committee of the International Continence Society. (Abrams et al. 2002) was followed to describe the variables.

Revisions to the International Spinal Cord Injury Urodynamic Basic Data Set – Version 2.0

The International SCI Urodynamics Basic Data Set Version 1.0 is the accepted standard for collecting minimal clinical data relevant for urodynamic investigations for individuals with spinal cord lesions. All International SCI Data Sets undergo periodic review to ensure continued relevance, acceptance and usage by the SCI clinical/research community. In 2016, the International SCI Data Sets Committee proposed review of the International SCI Urodynamics Basic Data Set. In 2016, the International SCI Data Sets were reviewed to ensure they are relevant for pediatric SCI and some revisions to the syllabus were recommended. When reviewing proposed revisions, the Working Group weighed the potential benefits of the proposal against the loss of continuity resulting from any revision. These changes, apart from minor corrections, are summarized in the ensuing narrative, followed by the revised syllabus and the data collection form Version 2.0.

List of specific revisions incorporated into the International SCI Urodynamic Basic Data Set - Version 2.0

1. For the variable “Bladder sensation during filling cystometry”, for children 0-5 years of age the response category ‘Unknown’ is to be used. In addition, the terminology was adjusted to the most recent International Continence Society terminology (Gajewski et al, 2018).

2. Although in the first version of the International SCI Urodynamic Basic Data Set the classification of detrusor function was not separated between filling and voiding it has been discussed and decided that the detrusor function should be rated separately for filling cystometry and voiding. This is done in order to make the use of the data set easier and to avoid misinterpretation. Therefore, there are **now two variables**: “Detrusor function during filling cystometry” with the response categories: ‘Normal, Neurogenic detrusor overactivity, and Unknown’, and “Detrusor function during voiding” with the response categories: ‘Normal, Underactive detrusor, Acontractile detrusor, and Unknown’.

3. As the International Continence Society defined *low compliance* as a compliance value lower than 20 mL/cm H_2O (Stöhrer et al. 1999), it was decided to modify the cutoff-value for low bladder compliance from 10 mL/cm H_2O to 20 mL/cm H_2O (also currently the most frequently used cutoff value in the field of neuro-urology (Hackler et al. 1989; Wyndaele et al. 2011)). Further, the option to give the exact compliance value is added to the direct distinction related to low compliance.

4. The order of the variables has been adjusted so that all variables measured during filling cystometry come before the variables measured during or after voiding.

5. For the variable “Detrusor leak point pressure during filling cystometry” the response category ‘Not applicable’ has been deleted to make it consistent with the International Continence Society terminology (Abrams et al. 2002). In addition, the terminology was adjusted to the most recent International Continence Society terminology (Gajewski et al, 2018)

6. For the variable “Cystometric bladder capacity during filling cystometry” the response category ‘Not applicable’ has been deleted to make it consistent with the International Continence Society terminology (Abrams et al. 2002). This is also as written “In the absence of sensation the cystometric capacity is the volume at which the clinician decides to terminate filling.”

7. For the variable “Detrusor function during voiding” the terminology was adjusted to the most recent International Continence Society terminology (Gajewski et al, 2018)

8. For the variable “Urethral function during voiding” the response category ‘Not applicable’ has been deleted to align with the International Continence Society terminology (Abrams et al. 2002). In addition, the terminology was adjusted to the most recent International Continence Society terminology (Gajewski et al, 2018).

Acknowledgements:

Coloplast A/S, Denmark has supported the work with the first version of the International Urodynamic Basic Data Set with an unconditional grant. We are thankful for comments and suggestions to the first version received from Susan Charlifue, Lawrence C. Vogel, Vanessa Noonan, William Donovan, Ralph Marino, Karel Everaert, and Amiram Catz.
For the second version comments and suggestions were received from Susan Charlifue, Eva Widerström-Noga, and Vanessa Noonan.

VARIABLE NAME: Date performed

DESCRIPTION: This variable documents the date of data collection of urodynamic observations, i.e. the date for the performance of the urodynamic study.

CODES: YYYYMMDD
Unknown

COMMENTS: The urodynamic study may be carried out at any time after the spinal cord injury.
Therefore the date of data collection of urodynamic observations is imperative to be able to identify the data collected in relation to other data collected on the same individual at various time points. In addition, the date is likewise important to have the time interval from date of birth (age), and time interval from date of injury (time since injury).

VARIABLE NAME: Bladder sensation during filling cystometry.

DESCRIPTION: This variable documents the bladder sensation during filling cystometry. Although the bladder sensation is assessed during filling cystometry the assumption that it is sensation from the bladder alone, without urethral or pelvic components may be false (Abrams et al. 2002).

CODES: Normal
Increased
Reduced
Absent
Non-specific and/or abnormal
Unknown

COMMENTS: The above terms are according to the International Continence Society defined as (Abrams et al. 2002):
Normal bladder sensation can be judged by three defined points noted during filling cystometry and evaluated in relation to the bladder volume at that moment and in relation to the patient's symptomatic complaints.
First sensation of bladder filling is the feeling the patient has, during filling cystometry, when he/she first becomes aware of the bladder filling.
First desire to void is defined as the feeling, during filling cystometry, that would lead the patient to pass urine at the next convenient moment, but voiding can be delayed if necessary.
Strong desire to void this is defined, during filling cystometry, as a persistent desire to void without the fear of leakage.

Increased bladder sensation is defined, during filling cystometry, as an early first sensation of bladder filling (or an early desire to void) and/or an early strong desire to void, which occurs at low bladder volume and which persists.

Reduced bladder sensation is defined, during filling cystometry, as diminished sensation throughout bladder filling.

Absent bladder sensation means that, during filling cystometry, the individual has no bladder sensation.

Abnormal sensations: awareness of sensation in the bladder, urethra or pelvis, described with words like "tingling," "burning," or "electric shock," in the setting of a clinically relevant neurologic disorder (eg, incomplete spinal cord lesion) (Gajewski et al, 2018)

Non-specific bladder awareness: perception of bladder filling as abdominal fullness, vegetative symptoms, spasticity or other "non-bladder awareness," in the setting of a clinically relevant neurologic disorder (eg, incomplete spinal cord lesion) (Gajewski et al, 2018)

Unknown is used if the observation regarding bladder sensation during filing cystometry is not available. This includes children of 0-5 years of age.

VARIABLE NAME: Detrusor function during filling cystometry.

DESCRIPTION: This variable documents the function of the detrusor during filling, i.e. the overactivity is determined during filling, while the acontractility or detrusor underactivity is determined during voiding (see below).

CODES:
Normal
Neurogenic detrusor overactivity
Unknown

COMMENTS: ***Normal detrusor function*** allows bladder filling with little or no change in pressure. No involuntary phasic contractions occur despite provocation. Normal voiding is achieved by a voluntary initiated continuous detrusor contraction that leads to complete bladder emptying within a normal time span, and in the absence of obstruction. For a given detrusor contraction, the magnitude of the recorded pressure rise will depend on the degree of outlet resistance (Abrams et al. 2002).

Neurogenic detrusor overactivity is an urodynamic observation in individuals with a neurological condition characterized by involuntary detrusor contractions during the filling phase, which may be spontaneous or provoked (Abrams et al. 2002).

Unknown is used if the observation regarding detrusor function is not available.

VARIABLE NAME: Bladder compliance during filling cystometry.

DESCRIPTION: Bladder compliance during filling cystometry describes the relationship between change in bladder volume and change in detrusor pressure. Compliance is calculated by dividing the volume change (*ΔV*) by the change in detrusor pressure (*Δpdet*) during that change in bladder volume (*C= ΔV/Δpdet*), expressed in mL/cm H_2O (Abrams et al. 2002).

The International Continence Society recommends to calculate the bladder compliance using two standard points: 1) the detrusor pressure at the start on the bladder filling and the corresponding bladder volume (usually zero), and 2) the detrusor pressure (and corresponding bladder volume) at cystometric capacity or immediately before the start of any detrusor contraction that causes significant leakage (and therefore causes the bladder volume to decrease, affecting compliance calculation). Both points are measured excluding any detrusor contraction (Abrams et al. 2002).

CODES: XXX mL/cm H_20

Low (< 20 mL/cm H_20): Yes
No

Unknown

COMMENTS: The bladder compliance during filling cystometry in individuals with spinal cord lesions is controversial regarding the level of cutoff point for normal and low (Weld et al. 2000). The International Continence Society defines *low compliance* as a compliance value lower than 20 mL/cm H_2O (Stöhrer et al. 1999). This is also currently the most frequently used cutoff value in the field of neuro-urology (Hackler et al. 1989; Wyndaele et al 2011). The exact value should be given.

Unknown is used if the observation regarding bladder compliance during filling cystometry is not available.

VARIABLE NAME: Detrusor leak point pressure during filling cystometry.

DESCRIPTION: This variable documents the detrusor leak point pressure in cm H_2O during filling cystometry. Up to three digits without decimals may be used.

CODES: XXX cm H_2O
Unknown

COMMENTS: ***Detrusor Leak Point Pressure (DLPP)*** is defined as the lowest detrusor pressure at which urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure (Gajewski et al, 2018)

Detrusor Overactivity Leak Point Pressure (DOLPP) is defined as the lowest detrusor pressure rise with detrusor overactivity at which urine leakage first

occurs in the absence of voluntary detrusor contraction or increased abdominal pressure (Gajewski et al, 2018)

Unknown is used if the observation regarding detrusor leak point pressure is not available. If circumstances arise during urodynamics, ie. autonomic dysreflexia that prohibits further urodynamic evaluation, then unknown should be used.

VARIABLE NAME: Maximum detrusor pressure during filling cystometry.

DESCRIPTION: This variable documents the maximum detrusor pressure in cm H_2O during filling cystometry. Up to three digits without decimals may be used.

CODES:
XXX cm H_2O
Not applicable
Unknown

COMMENTS: ***Maximum*** d***etrusor pressure*** is defined as the highest detrusor pressure measured during filling cystometry.

Not applicable should be used if the individual with spinal cord lesion for example has an acontractile, high compliant bladder.

Unknown is used if the observation regarding maximum detrusor pressure during filling cystometry is not available. If circumstances arise during urodynamics, ie. autonomic dysreflexia that prohibits further urodynamic evaluation, then unknown should be used.

VARIABLE NAME: Cystometric bladder capacity during filling cystometry.

DESCRIPTION: This variable documents the cystometric bladder capacity in mL during filling cystometry. Up to four digits without decimals may be used.

CODES:
XXXX mL
Unknown

COMMENTS: ***Cystometric bladder capacity*** during filling cystometry is the bladder volume at the end of the filling cystometrogram, when "permission to void" is usually given. The end point should be specified, for example, if filling is stopped when the patient has a normal desire to void. The cystometric capacity is the volume voided together with any residual urine. In the absence of sensation the cystometric capacity is the volume at which the clinician decides to terminate filling. The reason(s) for terminating filling should be defined, e.g. high detrusor filling pressure, large infused volume or pain. If there is uncontrollable voiding, it is the volume at which this begins. In the presence of sphincter incompetence the cystometric capacity may be significantly increased by occlusion of the urethra e.g. by Foley catheter (Abrams et al. 2002).

Unknown is used if the observation regarding cystometric bladder capacity during filling cystometry is not available. If circumstances arise during urodynamics, ie. autonomic dysreflexia that prohibits further urodynamic evaluation, then unknown should be used.

VARIABLE NAME: Detrusor function during voiding.

DESCRIPTION: This variable documents the function of the detrusor during voiding, i.e. determining detrusor underactivity, and acontractility during voiding.

CODES:
Normal
Underactive detrusor
Acontractile detrusor
Unknown

COMMENTS: ***Normal detrusor function*** allows bladder filling with little or no change in pressure. No involuntary phasic contractions occur despite provocation. Normal voiding is achieved by a voluntary initiated continuous detrusor contraction that leads to complete bladder emptying within a normal time span, and in the absence of obstruction. For a given detrusor contraction, the magnitude of the recorded pressure rise will depend on the degree of outlet resistance (Abrams et al. 2002).

Neurogenic detrusor underactivity is defined as a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span in the setting of a clinically relevant neurologic disorder (Gajewski et al, 2018)

Neurogenic acontractile detrusor is one that cannot be demonstrated to contract during urodynamic studies in the setting of a clinically relevant neurologic lesion (Gajewski et al, 2018)

Unknown is used if the observation regarding detrusor function is not available.

VARIABLE NAME: Urethral function during voiding.

DESCRIPTION: This variable describes the function of the urethra during voiding. The coordination of voiding in individuals with a spinal cord lesion is a concern.

CODES:
Normal
Detrusor sphincter dyssynergia
Non-relaxing urethral sphincter obstruction
Unknown

COMMENTS: ***Normal***: Normal urethra function during voiding is defined as a urethra that opens and is continuous relaxed to allow the bladder to be emptied at a normal pressure (Abrams et al. 2002).

Detrusor sphincter dyssynergia is defined as detrusor contraction concurrent with an involuntary contraction of the urethral and/or periurethral striated muscle. Occasionally flow may be prevented altogether (Abrams et al. 2002).

Delayed relaxation of the urethral sphincter is characterized by impaired and hindered relaxation of the sphincter during voiding attempt resulting in delay of urine flow (Gajewski et al, 2018)

Unknown is used if the observation regarding function during voiding is not available.

VARIABLE NAME: Post void residual volume.

DESCRIPTION: This variable documents the post void residual volume. Up to four digits without decimals may be used.

CODES:
XXXX mL
Not applicable
Unknown

COMMENTS: ***Post void residual*** is defined as the volume of urine left in the bladder at the end of micturition (Abrams et al. 2002).

Not applicable should be used if the individual for example empties the bladder with a urostomy.

Unknown is used if the observation regarding post void residual volume is not available.

References:

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A. The Standardisation of Terminology of Lower Urinary Tract Function: Report from the Standardisation Sub-committee of the International Continence Society. Neurourology and Urodynamics 2002:21;167-78.

Biering-Sørensen F, Charlifue S, DeVivo M, Noonan V, Post M, Stripling T, Wing P. International spinal cord injury data sets. Spinal Cord 2006 Sep;44(9):530-4.

Biering-Sørensen F, Kennelly M, Kessler TM, Linsenmeyer T, Pannek J, Vogel L, Wyndaele JJ. International Spinal Cord Injury Lower Urinary Tract Function Basic Data Set (version 2.0). Spinal Cord Ser Cases. 2018 Jul 6;4:60. doi: 10.1038/s41394-018-0090-7. eCollection 2018.

Biering-Sørensen F, Craggs M, Kennelly M, Schick E, Wyndaele J-J. International urinary tract imaging basic spinal cord injury data set. Spinal Cord 2009;47:379-83.

Biering-Sørensen F, DeVivo MJ, Charlifue S, Chen Y, New PW, Noonan V, Post MWM, Vogel L. International Spinal Cord Injury Core Data Set (version 2.0) - including standardization of reporting. Spinal Cord. 2017 Aug;55(8):759-764. doi: 10.1038/sc.2017.59.

Gajewski JB, Schurch B, Hamid R, Averbeck M, Sakakibara R, Agrò EF, Dickinson T, Payne CK, Drake MJ, Haylen BT. An International Continence Society (ICS) report on the terminology for adult neurogenic lower urinary tract dysfunction (ANLUTD). Neurourol Urodyn. 2018 Mar;37(3):1152-1161. doi: 10.1002/nau.23397.

Hackler RH, Hall MK, Zampieri TA. Bladder hypocompliance in the spinal cord injury population. J Urol. 1989;141(6):1390-3

Stöhrer M, Goepel M, Kondo A, Kramer G, Madersbacher H, Millard R, Rossier A, Wyndaele JJ. The standardization of terminology in neurogenic lower urinary tract dysfunction: with suggestions for diagnostic procedures. International Continence Society Standardization Committee. Neurourol Urodyn. 1999;18(2):139-58.

Weld KJ, Graney MJ, Dmochowski RR. Differences in bladder compliance with time and associations of bladder management with compliance in spinal cord injured patients. J Urol 2000;163:1228-33.

Wyndaele JJ, Gammie A, Bruschini H, De Wachter S, Fry CH, Jabr RI, Kirschner-Hermanns R, Madersbacher H. Bladder compliance what does it represent: can we measure it, and is it clinically relevant? Neurourol Urodyn. 2011;30(5):714-22.

INTERNATIONAL SPINAL CORD INJURY URODYNAMIC BASIC DATA SET (Version 2.0)

Data collection form

Date performed: YYYYMMDD □ Unknown

Bladder sensation during filling cystometry:
□ Normal □ Increased □ Reduced □ Absent □ Non-specific □ Unknown

Detrusor function during filling cystometry:
□ Normal □ Neurogenic detrusor overactivity □ Unknown

Maximum detrusor pressure during filling cystometry: _____ cm H_2O
□ Not applicable □ Unknown

Compliance during filling cystometry: _____ mL/cm H_20
Low (< 20 mL/cm H_20) □ Yes □ No □ Unknown

Detrusor leak point pressure: _____ cm H_2O □ Unknown

Cystometric bladder capacity: _____ mL □ Unknown

Detrusor function during voiding:
□ Normal □ Underactive detrusor □ Acontractile detrusor □ Unknown

Urethral function during voiding:
□ Normal □ Detrusor sphincter dyssynergia □ Non-relaxing urethral sphincter obstruction
□ Unknown

Post void residual volume: _____mL □ Not applicable □ Unknown