Patient Reported Bladder Related Symptoms and Quality of Life after Spinal Cord Injury with Different Bladder Management Strategies

Jeremy B. Myers,*† Sara M. Lenherr,† John T. Stoffel,† Sean P. Elliott,† Angela P. Presson, Chong Zhang, Jeffery Rosenbluth,† Amitabh Jha,† Darshan P. Patel,† and Blayne Welk† for the Neurogenic Bladder Research Group

From the Department of Surgery (Urology) (JBM, SML, DPP), Division of Epidemiology and Biostatistics, Department of Internal Medicine (APP, CZ) and Department of Physical Medicine and Rehabilitation (JR), University of Utah and Department of Physical Medicine and Rehabilitation (AJ), Salt Lake City Veterans Medical Center, Salt Lake City, Utah, Departments of Urology, University of Michigan (JTS), Ann Arbor, Michigan, and University of Minnesota (SPE), Minneapolis, Minnesota, and Western University (BW), London, Ontario, Canada

Abbreviations and Acronyms

ASIA = American Spinal Injury Association

CIC = clean intermittent catheterization

IDC = indwelling catheter

KHQ = King's Health Questionnaire

NBSS = Neurogenic Bladder Symptom Score

NGB = neurogenic bladder

PROM = patient reported outcome measure

QoL = quality of life

SCI = spinal cord injury

SCI-QoL = SCI QoL Measurement System

SCI-QoL Difficulties = SCI-QoL Bladder Management Difficulties

UTI = urinary tract infection

Purpose: Neurogenic bladder significantly impacts individuals after spinal cord injury. We hypothesized that there would be differences in bladder related symptoms and quality of life for 4 common bladder management methods.

Materials and Methods: In this prospective observational study we measured neurogenic bladder related quality of life after spinal cord injury. Study eligibility included age 18 years or greater and acquired spinal cord injury. Bladder management was grouped as 1) clean intermittent catheterization, 2) an indwelling catheter, 3) surgery (bladder augmentation, a catheterizable channel or urinary diversion) and 4) voiding (a condom catheter, involuntary leaking or volitional voiding). The primary outcomes were the NBSS (Neurogenic Bladder Symptom Score) and the SCI-QoL Difficulties (Spinal Cord Injury Quality of Life Measurement System Bladder Management Difficulties). Secondary outcomes were the NBSS subdomains and satisfaction with urinary function. Multivariable regression was done to establish differences between the groups, separated by level.

Results: Of the 1,479 participants enrolled in the study 843 (57%) had paraplegia and 894 (60%) were men. Median age was 44.9 years (IQR 34.4–54.1) and median time from injury was 11 years (IQR 5.1–22.4). Bladder management was clean intermittent catheterization in 754 cases (51%), an indwelling catheter in 271 (18%), surgery in 195 (13%) and voiding in 259 (18%). In regard to primary outcomes, in cases of paraplegia and tetraplegia an indwelling catheter and surgery were associated with fewer urinary symptoms on the NBSS compared to

Accepted for publication March 16, 2019.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

Supported by PCORI (Patient-Centered Outcomes Research Institute) Award CER14092138.

All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI.

No direct or indirect commercial, personal, academic, political, religious or ethical incentive is associated with publishing this article.

* Correspondence: Genitourinary Injury and Reconstructive Urology, 30 North 1900 East, Room 3B420, Salt Lake City, Utah 84132 (telephone: 801-213-2700; FAX: 801-585-2891; e-mail: Jeremy.myers@hsc.utah.edu).

† Financial interest and/or other relationship with PCORI.

Editor's Note: This article is the third of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 623 and 624.

0022-5347/19/2023-0574/0
THE JOURNAL OF UROLOGY®

https://doi.org/10.1097/JU.0000000000000270
Vol. 202, 574-584, September 2019
Printed in U.S.A.

clean intermittent catheterization while voiding was associated with more symptoms. In paraplegia and tetraplegia cases surgery was associated with fewer bladder management difficulties according to the SCI-QoL Difficulties. In regard to secondary outcomes, surgery was associated with improved satisfaction in individuals with paraplegia or tetraplegia.

Conclusions: In individuals with spinal cord injury fewer bladder symptoms were associated with an indwelling catheter and surgery, and worse bladder symptoms were noted in voiding individuals compared to those on clean intermittent catheterization. Satisfaction with the urinary system was improved after surgery compared to clean intermittent catheterization.

Key Words: urinary bladder, neurogenic; spinal cord injuries; urinary incontinence; patient reported outcome measures; quality of life

NEUROGENIC bladder develops in most individuals after SCI. NGB often involves the inability to empty the bladder voluntarily, overactivity, loss of capacity and worsened compliance of the bladder wall due to fibrosis. These changes may lead to urinary incontinence and high bladder pressures, which can lead to urinary tract complications such as hydronephrosis, renal failure, urinary stones, UTIs and urosepsis.[1] In fact, urinary complications are the second leading reason for hospitalization among individuals with SCI.[2] In addition to the morbidity associated with urinary complications, bladder management is a leading health concern for individuals after SCI, reflecting its importance to QoL.[3] There are several common bladder management methods after SCI, including CIC, chronic IDCs, augmentation cystoplasty (surgical expansion of the bladder with a patch of bowel), urinary diversion (bypass of the bladder altogether) or spontaneous voiding, often with a condom catheter.

Previous studies have shown a higher complication rate in individuals with an IDC compared to those who perform CIC.[4,5] However, little is known about patient reported bladder symptoms or QoL with different managements. Most studies of QoL have been limited by small size[6] and the use of general QoL measures rather than PROMs specific for NGB.[4,7] We hypothesized that different bladder management strategies affect how individuals with SCI experience bladder symptoms and QoL. Understanding these QoL issues are paramount to shared decision making surrounding bladder management.

METHODS

Study Design

The NBRG (Neurogenic Bladder Research Group) registry (https://www.NBRG.org) is a prospective observational study to measure NGB related QoL after SCI in the NBRG-PCORI (Patient-Centered Outcomes Research Institute) trial (ClinicalTrials.gov NTC02616081). Participants were recruited throughout the United States and Canada, and could enter the study remotely by phone interview and electronically administered questionnaires. The study protocol detailing recruitment and aims was previously published.[8] Eligibility requirements included age 18 years or greater, English speaking, and acquired SCI including traumatic, spinal cord bleed/abscess/stroke, spinal cord tumor without active malignancy, transverse myelitis, iatrogenic (eg laminectomy complication) and miscellaneous other disorder. Exclusion criteria were congenital conditions (myelomeningocele, cerebral palsy, etc) or progressive SCI (multiple sclerosis or neuromuscular disorders). The study received Institutional Review Board approval (IRB No. 82971).

Bladder management was grouped by participant identified primary bladder management. If participants used multiple bladder management methods, such as CIC during the day but a Foley catheter overnight, they were asked which method they considered the primary method of management. Primary bladder management groups included 1) CIC, 2) a Foley or suprapubic catheter, 3) surgery (bladder augmentation with or without a catheterizable channel, a catheterizable channel alone or urinary diversion with a conduit or a continent catheterizable pouch) and 4) voiding (a condom catheter, involuntary leaking or volitional voiding). Included in the surgery group were participants who underwent surgery but used an IDC, such as an individual with a failed catheterizable channel who relied on a suprapubic tube.

Outcomes

Primary. The primary outcomes were 1) the NBSS and 2) the SCI-QoL Difficulties item bank. The NBSS (range 0 to 74 with lower scores indicating better function) was validated in SCI and it primarily focuses on bladder symptoms.[9,10]

The SCI-QoL consists of many different item banks, which were validated in individuals with SCI, to assess multiple aspects of the health and psychosocial impact of SCI.[11] We used the SCI-QoL Difficulties item bank, which assesses the ability to perform a bladder program, incontinence concerns and impacts on daily life.[12] The questionnaire concentrates on feelings about bladder function and symptoms while the NBSS instead characterizes symptom magnitude. The SCI-QoL questionnaires rely on item response theory and computer adaptive testing, which enables the questionnaire to adapt to participant answers. The SCI-QoL item banks have a mean score of 50 and a range of 0 to 100 with lower scores indicating less bladder difficulty.

Secondary. Secondary outcomes included the 3 subdomains of the NBSS, namely incontinence (range 0 to 29), 2) storage and voiding (range 0 to 22), 3), and consequences (range 0 to 23) as well as the final NBSS QoL question about satisfaction with urinary function (satisfaction) (range 0 to 4).[9]

Injury Level

The injury level is one of the most defining characteristics of physical disability after SCI. In the patient advisory group formed as part of this study the belief was that extrapolating QoL from individuals with paraplegia to tetraplegia or vice versa would not have face value to individuals with SCI and participants should be separated based on these injury levels. We evaluated whether there were objective reasons to separate participants based on level by testing for interaction effects between participants with paraplegia and tetraplegia using different bladder managements. Given our findings of significant interaction effects and the recommendations of the patient advisory group, we separately analyzed the paraplegia and tetraplegia groups. Level was defined as tetraplegia (cervical level 1 to 8) or paraplegia (thoracic level 1 and below, including sacral levels and cauda equina).

Covariates

Analysis covariates were demographics, including 1) age, 2) gender, 3) obesity (body mass index greater than 30 kg/m^2), 4) education (bachelor degree or higher), 5) employment (employed for wages, including self-employment) as well as injury characteristics, including 6) years since injury and 7) complete or incomplete injury, that is ASIA Impairment Scale A or, if unknown, participants were asked whether they had complete or incomplete injury and SCI complications, including 8) chronic pain (the patient was asked, "Do you experience chronic pain?"), 9) the number of self-reported UTIs in the last year (categorical, including 0, 1 to 3, or 4 or more), 10) hospitalization for UTI in the last year and 11) severe bowel dysfunction (Neurogenic Bladder Dysfunction Score greater than 14).[13]

Statistical Analysis

Demographics, injury characteristics and SCI complications were summarized and compared in participants with paraplegia vs tetraplegia. Continuous variables were compared by the t-test and categorical variables were compared by the chi-square test.

We constructed multiple linear regression models to test the interaction between bladder management type and injury level (paraplegia vs tetraplegia) for the primary and secondary outcomes. After assessing interaction effects between the bladder management type and the injury level, which showed significant differences by level for several outcomes, separate regression analyses were done in participants with paraplegia and tetraplegia adjusted for the mentioned covariates.

CIC was the reference bladder management strategy since it has the lowest complication rate.[4,5] We report the predicted marginal mean of each outcome with the associated 95% CI. For other bladder management types and covariates we report estimated regression coefficients, which measure the magnitude of change associated with that variable, with the 95% CI and the p value. A negative change for all PROMs in this study indicates improvement. Statistical analyses were done in R, version 3.4.1 (https://www.r-project.org/), significance was assessed at the 0.05 level and all tests were 2-tailed.

RESULTS

Study Participants

The figure shows the study recruitment diagram. Table 1 summarizes participant characteristics and compares characteristics by SCI level. Of the 1,479 participants 843 (57%) had paraplegia and 894 (60%) were men. Median age was 44.9 years (IQR 34.4–54.1) and median time from injury was 11 years (IQR 5.1–22.4). Bladder management included CIC in 754 cases (51%), IDC in 271 (18%), surgery in 195 (13%) and voiding in 259 (18%). In participants with paraplegia there was a higher rate of CIC than in those with tetraplegia (62% vs 36%) and less use of IDC (10% vs 30%). Other differences between the groups with paraplegia and tetraplegia included age, gender, obesity, employment, chronic pain, injury completeness and hospitalization for UTI.

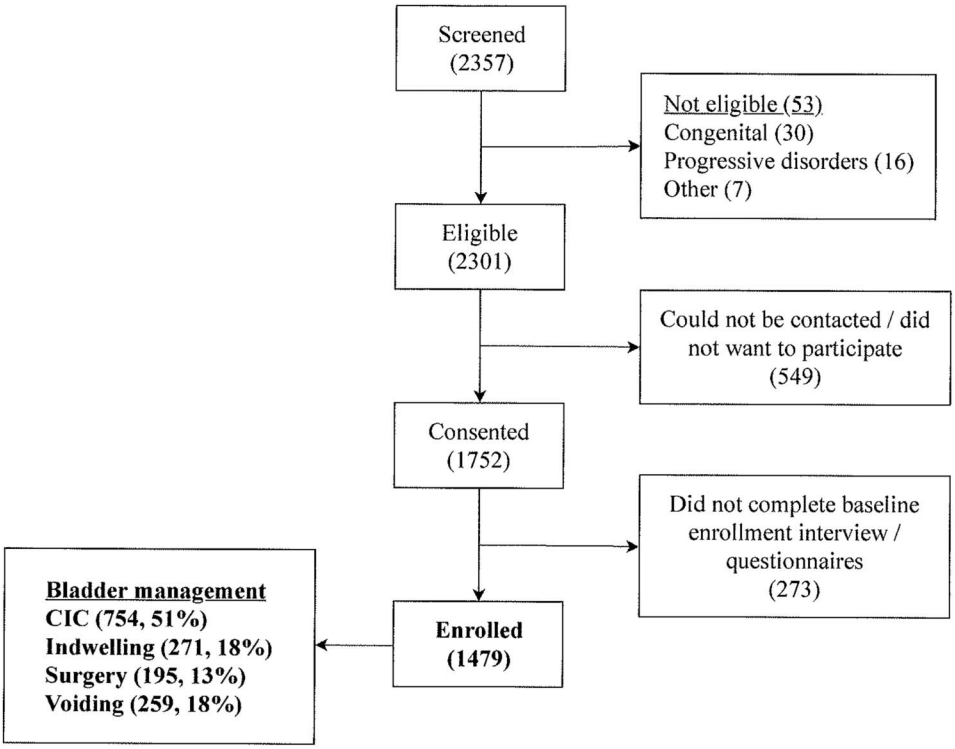
Injury Level and Outcomes

In an unadjusted comparison of our primary and secondary outcomes there were differences in responses between participants with paraplegia and tetraplegia (table 1). For most outcomes the levels also differed by bladder management group as indicated by the significant interaction effect between level and management type, which we assessed using linear regression (table 2). As mentioned, due to these significant interaction effects participants were separated by level for further analyses.

Outcomes

Primary. For paraplegia and tetraplegia the IDC and surgery groups had improved (lower) NBSS scores while the voiding group had worse scores than the CIC group (table 3). In participants with paraplegia NBSS scores were better for increasing age and male gender, and worse for UTIs (1 to 3 and 4 or more per year). In participants with tetraplegia the NBSS was better in men and worse in participants with obesity and with UTIs (table 3).

The SCI-QoL Difficulties scores were better (lower) for surgery in the paraplegia group (table 3). In the tetraplegia group the SCI-QoL Difficulties scores were better for IDC and surgery, and worse for voiding. As in the NBSS findings, there were some similar associations between covariates and better or worse scores.



Study flow diagram

Secondary. The incontinence subdomain was improved in participants with paraplegia and tetraplegia in the IDC group compared to the CIC group (table 4). The surgery group with paraplegia also had improved incontinence scores. Participants with tetraplegia in the voiding group had worse incontinence scores. Compared to CIC the storage and voiding subdomains regardless of level were better for IDC and surgery and worse for voiding (table 4). The consequences subdomain was improved in those with tetraplegia (table 4). Satisfaction was better in the surgery group than in the CIC group in patients with paraplegia and tetraplegia (table 4).

DISCUSSION

We assessed 2 important aspects of bladder related QoL after SCI, including 1) bladder symptoms using the NBSS and 2) feelings related to these bladder symptoms using the SCI-QoL Difficulties. Participants who managed the bladder with an IDC or surgery had fewer bladder symptoms while voiding participants had more bladder symptoms than those who used CIC. This association was seen in participants with paraplegia and tetraplegia. There were fewer bladder management difficulties for surgery than for CIC regardless of the injury level. In addition, participants with tetraplegia also had fewer bladder management difficulties when an IDC was present. Regardless of level, participants treated with surgery had better associated satisfaction with urinary function than those who performed CIC.

Regarding bladder symptoms, few data have been published on different bladder managements after SCI, primarily due to lack of PROMs addressing bladder symptoms until the recent NBSS. We found fewer overall bladder symptoms in participants with an IDC and after surgery compared to those on CIC. While our study shows that IDCs work well to decrease bladder symptoms, clinicians and individuals with SCI must understand the well established higher complication rate associated with IDCs.[4,5] Participants after surgery also had fewer associated bladder symptoms, which is in line with the goal of surgery to establish a low pressure system which prevents incontinence.

The impact of and feelings about bladder symptoms were measured in our study by the SCI-QoL Difficulties and the final NBSS question on satisfaction. Using bladder specific PROMs several groups have analyzed feelings and QoL differences in patients with SCI and different bladder management strategies (table 5). Akkoç et al administered the KHQ to assess differences in QoL for different bladder managements in 195 cases.[14] The KHQ is a bladder specific questionnaire which is not validated for NGB or SCI but has many questions relevant to individuals with SCI. The authors reported that voiding participants had the best bladder related QoL. However, in that group only 8 participants did not have normal volitional control,

Table 1. *Characteristics of 1,479 participants by paraplegia vs tetraplegia level and unadjusted comparison of primary and secondary outcome measures*

	Overall		Paraplegia		Tetraplegia		p Value
No. pts	1,479		843	(57)	636	(43)	
No. bladder management (%):							
Clean intermittent catheterization	754	(51)	525	(62)	229	(36)	<0.001
Indwelling catheter	271	(18)	83	(10)	188	(30)	
Surgery	195	(13)	101	(12)	94	(15)	
Voiding	259	(18)	134	(16)	125	(20)	
No. indwelling catheter type (%):	271						
Foley	81	(30)	32	(39)	49	(26)	0.038
Suprapubic tube	190	(70)	51	(61)	139	(74)	
No. surgery type (%):*	195						
Conduit	35	(18)	12	(12)	23	(24)	0.15
Continent pouch	7	(3)	4	(4)	3	(3)	
Augmentation cystoplasty	126	(65)	70	(70)	56	(60)	
Augmentation cystoplasty, no catheterizable channel	79		—		—		
Augmentation cystoplasty + catheterizable channel	47		—		—		
Catheterizable channel alone	27	(14)	15	(15)	12	(13)	
No. voiding specifics (%):	259						
Condom catheter	59	(23)	16	(12)	43	(34)	0.003
Spontaneous	200	(77)	118	(88)	82	(66)	<0.001
Volitional (toilet)	77	(30)	32	(24)	45	(36)	<0.001
Leak (diapers or condom catheter)	71	(27)	26	(19)	45	(36)	
Valsalva or Credé maneuver	97	(37)	67	(50)	30	(24)	
Unspecified	14	(5)	9	(7)	5	(4)	
Demographics:							
Median age (IQR)/(range)	44.9	(34.4–54.1)/(18–86)	45.5	(35.1–54.4)/(18–83.3)	44.7	(33.3–53.3)/(18.4–86)	0.049
No. male (%)	894	(60)	469	(56)	424	(67)	<0.001
No. obese (%)†	351	(25)	227	(28)	124	(20)	<0.001
No. education (%)‡	603	(41)	331	(39)	272	(43)	0.18
No. employment (%)§	866	(59)	516	(61)	350	(55)	0.019
Injury characteristics:							
No. chronic pain (%)‖	1,024	(69)	605	(72)	419	(66)	0.019
Median yrs since injury (IQR)/(range)	11	(5.1–22.4)/(0–54.8)	10.6	(5–21.9)/(0–53.7)	11.7	(5.3–23.1)/(0.1–54.8)	0.33
No. complete injury (%)¶	564	(38)	379	(45)	185	(29)	<0.001
No. spinal cord injury complication (%):**							
0 UTI	388	(26)	226	(27)	162	(26)	0.43
1–3 UTIs	677	(46)	374	(44)	303	(48)	
4 or More UTIs	413	(28)	243	(29)	170	(27)	
UTI hospitalization‡‡	177	(12)	85	(10)	92	(15)	0.009
Severe bowel dysfunction	570	(42)	310	(40)	260	(44)	0.16
Mean ± SD primary outcome (range):							
NBSS	24.2 ± 10.8	(0–63)	26 ± 10.9	(0–63)	21.7 ± 10.1	(1–61)	<0.001
SCI-QoL Difficulties‖‖	58.1 ± 7.6	(37.6–81.5)	59.3 ± 7.5	(37.6–81.5)	56.5 ± 7.5	(37.6–80.7)	<0.001
Mean ± SD NBSS secondary outcomes (range):							
Incontinence	10 ± 7	(0–28)	11.6 ± 6.9	(0–28)	7.8 ± 6.5	(0–26)	<0.001
Storage + voiding	7.5 ± 4.3	(0–20)	7.9 ± 4.2	(0–20)	6.9 ± 4.4	(0–20)	<0.001
Consequences	6.7 ± 3.2	(0–20)	6.6 ± 3.2	(0–19)	7 ± 3.3	(0–20)	0.019
Satisfaction	2.1 ± 1.2	(0–4)	2.2 ± 1.2	(0–4)	2 ± 1.2	(0–4)	0.002

* Conduit—colon or ileal conduit, or ileovesicostomy; continent pouch—right colon or other continent catheterizable pouch; bladder augmentation—enterocystoplasty with or without catheterizable channel and catheterizable channel—separate catheterizable channel without augmentation or catheterizable pouch.
† Body mass index greater than 30 kg/m^2 (21 values missing).
‡ Bachelor degree or higher (1 missing value).
§ Making wages, including self-employment (1 missing value).
‖ Participants were asked, "Do you experience chronic pain?" (2 missing values).
¶ ASIA impairment scale A or if unknown participants were asked whether they had complete or incomplete SCI (6 missing values).
** UTI, number of UTIs and hospitalization in last year (1 missing value), and severe bowel dysfunction defined as neurogenic bowel dysfunction score 14 or greater.
††Final NBSS question, "If you had to live your life with the way your bladder (or urinary reservoir) currently works, how would you feel?"
‡‡ One missing value.
‖‖ Six missing values.

which may have limited the conclusions. In a study by Liu et al using the KHQ in 142 individuals with SCI[15] results were similar to those in the study by Akkoç et al.[14] Individuals with SCI who voided normally had the best QoL. The investigators also found that participants with an IDC and those in whom CIC was performed by an attendant had worse associated QoL in several KHQ subdomains.

In contrast, our study showed that voiding participants with tetraplegia had worse bladder difficulties and those with an IDC had improved bladder difficulties compared to participants who performed CIC. One difference between our study results and those reported by Akkoç et al[14] may have been due to the inclusion of all voiding participants in the voiding group, including those with leakage into a diaper and

Table 2. *Interaction effects by paraplegia vs tetraplegia level and bladder management*

	Mean Coefficient (95% CI)	p Value	Interaction p Value
	Primary outcomes		
NBSS:			
Intercept (CIC-paraplegia)*	26 (25.1—26.9)	—	—
Indwelling catheter (paraplegia)	−4 (−6.4 — −1.6)	<0.001	—
Surgery (paraplegia)	−3.4 (−5.6 — −1.3)	0.002	—
Voiding (paraplegia)†	5.1 (3.2—7)	<0.001	—
Tetraplegia‡	−2.5 (−4.1 — −0.9)	0.002	—
Indwelling catheter × tetraplegia	−2.5 (−5.5—0.6)	0.12	0.033
Surgery × tetraplegia	1.5 (−1.7—4.8)	0.36	—
Voiding × tetraplegia§	−3.2 (−6.2 — −0.3)	0.032	—
SCI-QoL Difficulties:			
Intercept (CIC-paraplegia)	59.46 (58.82—60.09)	—	—
Indwelling catheter (paraplegia)	−0.21 (−1.95—1.54)	0.82	—
Surgery (paraplegia)	−2.84 (−4.44 — −1.25)	<0.001	—
Voiding (paraplegia)	0.99 (−0.42—2.41)	0.17	—
Tetraplegia	−2.29 (−3.45 — −1.13)	<0.001	—
Indwelling catheter × tetraplegia	−2.29 (−4.55 — −0.03)	0.047	0.09
Surgery × tetraplegia	0.97 (−1.42—3.37)	0.43	—
Voiding × tetraplegia	0.62 (−1.54—2.77)	0.57	—
	NBSS secondary outcomes		
Incontinence:		—	
Intercept (CIC-paraplegia)	11.78 (11.22—12.35)	—	—
Indwelling catheter (paraplegia)	−1.01 (−2.55—0.52)	0.2	—
Surgery (paraplegia)	−2.52 (−3.93 — −1.11)	<0.001	—
Voiding (paraplegia)	1.13 (−0.12—2.39)	0.08	—
Tetraplegia	−3.55 (−4.58 — −2.52)	<0.001	—
Indwelling catheter × tetraplegia	−1.14 (−3.13—0.86)	0.26	0.047
Surgery × tetraplegia	2.42 (0.29—4.55)	0.026	—
Voiding × tetraplegia	0.12 (−1.8—2.03)	0.9	—
Storage + voiding:			
Intercept (CIC-paraplegia)	7.68 (7.38—7.98)	—	—
Indwelling catheter (paraplegia)	−3.97 (−4.78 — −3.16)	<0.001	—
Surgery (paraplegia)	−0.87 (−1.61 — −0.13)	0.022	—
Voiding (paraplegia)	4.48 (3.82—5.14)	<0.001	—
Tetraplegia	0.37 (−0.17—0.91)	0.18	—
Indwelling catheter × tetraplegia	−1.16 (−2.21 — −0.11)	0.03	0.011
Surgery × tetraplegia	−0.54 (−1.65—0.58)	0.35	—
Voiding × tetraplegia	−1.57 (−2.58 — −0.56)	0.002	—
Consequences:			
Intercept (CIC-paraplegia)	6.6 (6.3—6.8)	—	
Indwelling catheter (paraplegia)	1 (0.2—1.7)	0.009	—
Surgery (paraplegia)	0.0 (−0.7—0.6)	0.91	—
Voiding (paraplegia)	−0.5 (−1.1—0.1)	0.10	—
Tetraplegia	0.7 (0.2—1.2)	0.007	—
Indwelling catheter × tetraplegia	−0.2 (−1.1—0.8)	0.73	0.002
Surgery × tetraplegia	−0.3 (−1.4—0.7)	0.51	—
Voiding × tetraplegia	−1.8 (−2.7 — −0.9)	<0.001	—
Satisfaction:‖			
Intercept (CIC-paraplegia)	2.23 (2.13—2.33)	—	—
Indwelling catheter (paraplegia)	0.02 (−0.25—0.29)	0.88	—
Surgery (paraplegia)	−0.73 (−0.98 — −0.48)	<0.001	—
Voiding (paraplegia)	0.18 (−0.05—0.4)	0.12	—
Tetraplegia	−0.11 (−0.29—0.08)	0.26	—
Indwelling catheter × tetraplegia	−0.16 (−0.51—0.2)	0.38	0.17
Surgery × tetraplegia	0.15 (−0.23—0.53)	0.43	—
Voiding × tetraplegia	−0.3 (−0.64—0.05)	0.09	—

Results of indwelling catheter, surgery and voiding are relative to CIC score with negative value indicating lower and better score than CIC. Interaction: p value type 3 is likelihood ratio test comparing goodness of fit between model with interaction and model with only main effects. It tests overall interaction effect, ie H0: whether effect of management type on outcome is same for participants with paraplegia and tetraplegia. In our model this overall interaction was significant for NBSS ($p = 0.033$) and null hypothesis was rejected. Coefficients indicate difference in effect of management type on NBSS total score between participants with tetraplegia and paraplegia (rows 6 to 8).

* Referent is average NBSS in participants with paraplegia using CIC since these values are reference levels of injury level and bladder management strategy variables, and estimated NBSS total score in participants with paraplegia using CIC was 26 (95% 25.1—26.9)1.

† Average NBSS difference between voiding and CIC in participants with paraplegia (NBSS[voiding, paraplegia] — NBSS[CIC, paraplegia]).

‡ Average NBSS difference in participants with tetraplegia vs paraplegia using CIC (NBSS[CIC, tetraplegia] — NBSS[CIC, paraplegia]).

§ Difference in NBSS differences between voiding and CIC, between tetraplegic and paraplegic participants, ie (NBSS[voiding, tetraplegia] — NBSS[CIC, tetraplegia]) — (NBSS [voiding, paraplegia] — NBSS[CIC, paraplegia]), in participants with paraplegia NBSS difference between voiding and CIC was 5.1 and interaction terms indicate that in participants with tetraplegia effect of voiding vs CIC was 3.2 points lower than effect of voiding vs CIC in participants with paraplegia so that in those with tetraplegia difference between voiding and CIC was $5.1 - 3.2 = 1.9$.

‖ Final NBSS question, "If you had to live your life with the way your bladder (or urinary reservoir) currently works, how would you feel?"

Table 3. *Multivariate regression of bladder management method associated effects on primary outcomes, NBSS and SCI-QoL Difficulties in participants with paraplegia and tetraplegia*

	Mean Difference in NBSS (95% CI)				Mean Difference in SCI-QoL Difficulties Score (95% CI)			
Primary Outcomes	Paraplegia	p Value	Tetraplegia	p Value	Paraplegia	p Value	Tetraplegia	p Value
Bladder management:								
CIC (referent)	26.6 (25.8–27.5)	—	23.6 (22.2–24.9)	—	59.8 (59.2–60.5)	—	57.2 (56.2–58.3)	—
Indwelling catheter	−6.21 (−8.75 – −3.67)	<0.001	−7.74 (−9.65 – −5.83)	<0.001	−1.4 (−3.23–0.44)	0.14	−3.08 (−4.64 – −1.53)	<0.001
Surgery	−5.19 (−7.46 – −2.93)	<0.001	−2.64 (−5.1 – −0.17)	0.036	−3.61 (−5.25 – −1.98)	<0.001	−2.81 (−4.82 – −0.8)	0.006
Voiding	5.02 (3.01–7.03)	<0.001	3.64 (1.51–5.77)	<0.001	0.78 (−0.67–2.23)	0.29	2.54 (0.81–4.28)	0.004
Demographics:								
Age	−0.09 (−0.15 – −0.03)	0.003	−0.06 (−0.13–0)	0.054	−0.05 (−0.1 – −0.01)	0.013	−0.04 (−0.09–0.01)	0.15
Male	−3.78 (−5.23 – −2.33)	<0.001	−4.12 (−5.79 – −2.45)	<0.001	−2 (−3.04 – −0.95)	<0.001	−2.56 (−3.92 – −1.2)	<0.001
Obese*	1.27 (−0.31–2.86)	0.12	3.29 (1.38–5.2)	<0.001	0.5 (−0.65–1.65)	0.39	2.46 (0.9–4.02)	0.002
Education†	−0.83 (−2.31–0.66)	0.27	−0.69 (−2.27–0.89)	0.39	−0.29 (−1.36–0.78)	0.59	0.83 (−0.46–2.12)	0.21
Employment‡	−1.4 (−2.9–0.09)	0.07	−0.54 (−2.12–1.04)	0.50	−0.99 (−2.07–0.09)	0.07	−0.52 (−1.81–0.77)	0.43
Injury characteristics:								
Yrs since injury	−0.02 (−0.09–0.05)	0.60	−0.04 (−0.11–0.03)	0.29	−0.04 (−0.09–0.01)	0.09	−0.06 (−0.12–0)	0.036
Complete	−0.03 (−1.49–1.43)	0.97	0.07 (−1.65–1.79)	0.94	0.28 (−0.77–1.33)	0.60	−0.06 (−1.46–1.35)	0.94
SCI complication:								
Chronic pain§	1.52 (−0.04–3.07)	0.06	1.53 (−0.05–3.11)	0.06	0.34 (−0.78–1.46)	0.56	0.12 (−1.17–1.41)	0.86
1–3 UTIs	2.79 (1.08–4.5)	0.001	2.71 (0.88–4.54)	0.004	1.28 (0.05–2.52)	0.042	1.1 (−0.39–2.59)	0.15
4 or More UTIs	7.24 (5.3–9.18)	<0.001	5.41 (3.21–7.61)	<0.001	3.6 (2.2–5.01)	<0.001	2.49 (0.7–4.29)	0.006
UTI hospitalization in last yr	0.45 (−1.97–2.86)	0.72	0.91 (−1.34–3.16)	0.43	−1.53 (−3.3–0.23)	0.09	−0.15 (−1.99–1.68)	0.87
Severe bowel dysfunction‖	1.25 (−0.18–2.69)	0.09	1.39 (−0.15–2.94)	0.08	1.46 (0.43–2.5)	0.006	1.17 (−0.09–2.42)	0.07

Marginal means of CIC are provided for reference.
* Body mass index greater than 30 kg/m^2.
† Bachelor degree or higher.
‡ Making wages, including self-employment.
§ ASIA impairment scale A or, if unknown, participants were asked whether they were in complete or incomplete chronic pain by the question, "Do you experience chronic pain?"
‖ Neurogenic bowel dysfunction score 14 or greater.

Table 4. *Multivariate regression of associated effects of bladder management on NBSS incontinence, storage and voiding, consequences, and satisfaction subdomains in participants with paraplegia and tetraplegia*

Secondary Outcomes	Paraplegia	p Value	Tetraplegia	p Value
	Incontinence			
Bladder management:				
CIC (referent)*	12.2 (11.6–12.8)	—	8.6 (7.7–9.5)	—
Indwelling catheter	−2.17 (−3.84 – −0.5)	0.011	−3.02 (−4.33 – −1.71)	<0.001
Surgery	−3.86 (−5.35 – −2.37)	<0.001	−1.01 (−2.71–0.68)	0.24
Voiding	1.07 (−0.25–2.4)	0.11	1.94 (0.48–3.41)	0.009
Demographics:				
Age	−0.04 (−0.08–0)	0.042	−0.01 (−0.06–0.03)	0.51
Male	−2.56 (−3.51 – −1.6)	<0.001	−3.29 (−4.44 – −2.14)	<0.001
Obesity†	1.25 (0.21–2.3)	0.019	2.18 (0.87–3.5)	0.001
Education‡	−0.2 (−1.18–0.78)	0.69	−0.11 (−1.2–0.97)	0.84
Employment§	−0.92 (−1.9–0.07)	0.07	−0.03 (−1.12–1.06)	0.95
Injury characteristics:				
Yrs since injury	−0.03 (−0.07–0.02)	0.26	−0.04 (−0.09–0)	0.07
Complete injury‖	1.08 (0.12–2.04)	0.028	0.7 (−0.48–1.89)	0.24
SCI complications:				
Chronic pain¶	0.47 (−0.56–1.49)	0.37	0.43 (−0.66–1.52)	0.44
1–3 UTIs	0.36 (−0.77–1.49)	0.53	0.84 (−0.42–2.1)	0.19
4 or More UTIs	2.42 (1.14–3.69)	<0.001	1.72 (0.21–3.23)	0.026
UTI hospitalization last yr	−0.56 (−2.15–1.03)	0.49	−0.09 (−1.64–1.45)	0.91
Severe bowel dysfunction**	1.02 (0.08–1.96)	0.034	0.33 (−0.73–1.39)	0.55
	Storage + voiding			
Bladder management:				
CIC (referent)*	7.8 (7.5–8.1)	—	8.0 (7.5–8.5)	—
Indwelling catheter	−4.3 (−5.2 – −3.4)	<0.001	−5.3 (−5.98 – −4.62)	<0.001
Surgery	−0.85 (−1.65 – −0.05)	0.038	−1.38 (−2.26 – −0.51)	0.002
Voiding	4.13 (3.42–4.85)	<0.001	2.79 (2.04–3.55)	<0.001
Demographics:				
Age	−0.04 (−0.06 – −0.01)	<0.001	−0.01 (−0.03–0.02)	0.53
Male	−0.93 (−1.45 – −0.42)	<0.001	−0.95 (−1.55 – −0.36)	0.002
Obesity†	−0.06 (−0.62–0.5)	0.84	0.75 (0.07–1.43)	0.031
Education‡	−0.52 (−1.05–0)	0.050	−0.48 (−1.05–0.08)	0.09
Employment§	−0.2 (−0.73–0.33)	0.45	−0.13 (−0.69–0.43)	0.66
Injury characteristics:				
Yrs since injury	−0.01 (−0.03–0.02)	0.47	−0.02 (−0.05–0)	0.10
Complete injury‖	−1.11 (−1.63 – −0.59)	<0.001	−0.69 (−1.3 – −0.08)	0.027
SCI complications:				
Chronic pain¶	0.38 (−0.17–0.93)	0.17	0.79 (0.23–1.35)	0.006
1–3 UTIs	0.33 (−0.28–0.94)	0.28	−0.46 (−1.1–0.19)	0.17
4 or More UTIs	0.67 (−0.02–1.36)	0.06	−0.05 (−0.83–0.73)	0.90
UTI hospitalization last yr	0.29 (−0.56–1.15)	0.50	0.38 (−0.42–1.18)	0.35
Severe bowel dysfunction**	0 (−0.51–0.51)	1.00	0.45 (−0.1–1)	0.11
	Consequences			
Bladder management:				
CIC (referent)*	6.7 (6.4–6.9)	—	7.0 (6.6–7.4)	—
Indwelling catheter	0.27 (−0.44–0.97)	0.46	0.58 (0–1.16)	0.051
Surgery	−0.48 (−1.11–0.15)	0.13	−0.24 (−0.99–0.52)	0.54
Voiding	−0.19 (−0.74–0.37)	0.51	−1.09 (−1.74 – −0.44)	0.001
Demographics:				
Age	−0.01 (−0.03–0)	0.11	−0.04 (−0.06 – −0.02)	<0.001
Male	−0.29 (−0.69–0.12)	0.16	0.12 (−0.38–0.63)	0.63
Obesity†	0.08 (−0.36–0.52)	0.72	0.36 (−0.22–0.94)	0.23
Education‡	−0.1 (−0.51–0.31)	0.63	−0.09 (−0.58–0.39)	0.70
Employment§	−0.28 (−0.7–0.13)	0.18	−0.38 (−0.86–0.1)	0.12
Injury characteristics:				
Yrs since injury	0.02 (0–0.04)	0.08	0.03 (0.01–0.05)	0.016
Complete injury‖	0 (−0.41–0.4)	1.00	0.05 (−0.47–0.58)	0.84
SCI complications:				
Chronic pain¶	0.67 (0.24–1.1)	0.002	0.31 (−0.17–0.8)	0.20
1–3 UTIs	2.09 (1.62–2.57)	<0.001	2.33 (1.77–2.88)	<0.001
4 or More UTIs	4.16 (3.62–4.69)	<0.001	3.74 (3.07–4.41)	<0.001
UTI hospitalization last yr	0.71 (0.04–1.38)	0.037	0.62 (−0.06–1.31)	0.08
Severe bowel dysfunction**	0.23 (−0.17–0.63)	0.25	0.61 (0.14–1.09)	0.011
	Satisfaction			
Bladder management:				
CIC (referent)*	2.2 (2.1–2.3)	—	2.1 (1.9–2.3)	—

(continued)

Table 4. (*continued*)

Secondary Outcomes	Paraplegia	p Value	Tetraplegia	p Value
Indwelling catheter	0.05 (−0.23—0.34)	0.71	−0.18 (−0.42—0.06)	0.15
Surgery	−0.74 (−1 — −0.49)	<0.001	−0.54 (−0.85 — −0.23)	<0.001
Voiding	0.15 (−0.08—0.38)	0.19	0.02 (−0.25—0.29)	0.88
Demographics:				
Age	−0.01 (−0.01—0)	0.025	0 (−0.01—0.01)	0.60
Male	−0.13 (−0.29—0.04)	0.13	−0.21 (−0.42—0)	0.06
Obesity†	−0.15 (−0.33—0.02)	0.09	0.23 (−0.01—0.48)	0.06
Education‡	0.08 (−0.09—0.25)	0.35	0.17 (−0.03—0.37)	0.09
Employment§	−0.2 (−0.36 — −0.03)	0.022	−0.08 (−0.28—0.12)	0.44
Injury characteristics:				
Yrs since injury	−0.02 (−0.02 — −0.01)	<0.001	−0.02 (−0.03 — −0.02)	<0.001
Complete injury‖	−0.18 (−0.35 — −0.02)	0.029	−0.09 (−0.31—0.13)	0.44
SCI complications:				
Chronic pain¶	0.12 (−0.05—0.29)	0.18	0.12 (−0.08—0.32)	0.25
1—3 UTIs	0.17 (−0.02—0.36)	0.08	0.19 (−0.04—0.42)	0.11
4 or More UTIs	0.63 (0.41—0.84)	<0.001	0.57 (0.29—0.84)	<0.001
UTI hospitalization last yr	−0.35 (−0.62 — −0.08)	0.012	0.19 (−0.09—0.48)	0.19
Severe bowel dysfunction**	0.24 (0.08—0.4)	0.004	0.17 (−0.02—0.37)	0.08

* Marginal means of CIC are provided for reference.
† Body mass index greater than 30 kg/m^2.
‡ Bachelor degree or higher (1 missing value).
§ Making wages, including self-employment.
‖ ASIA impairment scale A or if unknown participants were asked whether they had complete or incomplete SCI (6 missing values).
¶ Participants were asked, "Do you experience chronic pain?"
** NBD score 14 or greater.

those who used a condom catheter, rather than having a predominance of participants who voided normally. In our study only 30% of the participants in the voiding group had volitional control.

In another survey study of 242 Dutch individuals with SCI the investigators used the short form of the Qualiveen, a questionnaire similar to the SCI-QoL Difficulties, which was developed and validated in NGB and SCI cases.[6] On multivariable analysis the authors found that IDCs were associated with worse QoL than CIC. This contradicted our results, which demonstrated no difference in associated QoL for IDCs vs CIC in participants with paraplegia while IDCs were associated with better QoL than CIC in those with tetraplegia. Since worse physical limitations affect CIC performance in individuals with SCI and tetraplegia, it is not surprising that IDCs might result in a better bladder related QoL than IDCs in patients with paraplegia. Similar to our study design, the investigators combined continent and incontinent surgeries for analysis but, dissimilar to our results, there was no difference in QoL between surgery and CIC.[6] In the Dutch study only 16 individuals were treated with surgery and none underwent augmentation cystoplasty compared to 13% and 9% of our participants, respectively.

One limitation of survey studies is inclusion bias. Participants with more severe urinary problems may have enrolled in the study at a higher rate in the hope of learning more about NGB. Also, participants who underwent surgery could have had skewed QoL results due to confirmation bias, although average time from surgery was more than a decade in our participants, which would have tended to decrease this effect.

Another limitation is that patient reported data are based on participant perceptions of care and in our study this was not confirmed by an objective review of clinical data. Using data such as the UTI rate we could not confirm UTIs or related antibiotic use and so these infections would have been best described as patient perceived UTI episodes. In addition, some participants used a secondary method of bladder management such as a condom or a Foley catheter overnight.

A further limitation is the generalization of various surgical procedures in a single group. Similarly, the voiding group included participants with volitional bladder control as well as those with leakage into diapers or with a condom catheter. We did not attempt to perform subgroup analysis due to the sample size, although we assumed differences in bladder related QoL among these participants.

A final limitation is that differences in the SCI-QoL Difficulties were small and may not have been clinically significant.

CONCLUSIONS

Patient reported bladder symptoms and QoL after SCI are complex and influenced by multiple patient and injury characteristics. After surgery participants had improved satisfaction with urinary function compared to those who performed CIC in the paraplegia and tetraplegia groups. Indwelling catheters were also associated with decreased bladder symptoms in individuals with SCI, although it is well established that IDCs are associated with worse medical outcomes. Voiding participants had worse bladder function in several measures in the paraplegia and tetraplegia groups.

Table 5. *Studies using bladder specific questionnaires in individuals with SCI to compare QoL among bladder management methods*

References	No. Pts	Pt Reported Outcome Measure		Validated SCI	Results
		Type	Description		
Adriaansen et al[6]	242	Short Form-Qualiveen	Impact of + feelings about bladder symptoms	Yes	Worse QoL for indwelling catheter than CIC
Akkoç et al[14]	195	King's Health Questionnaire	Bladder symptom impact	No	Normal voiding group had improved QoL vs CIC group
Liu et al[15]	142	King's Health Questionnaire	Bladder symptom impact	No	Normal voiding group had improved QoL vs CIC + indwelling catheter groups with worse associated QoL scores for CIC catheterization by attendant
Present series	1,479	NBSS, SCI-QoL Difficulties	Bladder symptom severity impact	Yes	IDC + surgery* groups had fewer bladder symptoms, voiding group had worse bladder symptoms, surgery group had better associated satisfaction, surgical pts had fewer bladder management difficulties regardless of level + in pts with tetraplegia indwelling catheter improved + voiding worsened bladder management difficulties

* Bladder augmentation, catheterizable channel creation or urinary diversion.

Our study provides important information about the complex relationship between bladder management, symptoms and QoL in individuals with SCI. Understanding these relationships is important for shared decision making. It also impacts clinician practice when counseling individuals with SCI regarding bladder management, and guides additional patient centered research on NGB.

REFERENCES

1. Manack A, Motsko SP, Haag-Molkenteller C et al: Epidemiology and healthcare utilization of neurogenic bladder patients in a US claims database. Neurourol Urodyn 2011; **30:** 395.
2. Curtin CM, Suarez PA, Di Ponio LA et al: Who are the women and men in Veterans Health Administration's current spinal cord injury population? J Rehabil Res Dev 2012; **49:** 351.
3. Simpson LA, Eng JJ, Hsieh JT et al: The health and life priorities of individuals with spinal cord injury: a systematic review. J Neurotrauma 2012; **29:** 1548.
4. Cameron AP, Wallner LP, Forchheimer MB et al: Medical and psychosocial complications associated with method of bladder management after traumatic spinal cord injury. Arch Phys Med Rehabil 2011; **92:** 449.
5. Weld KJ and Dmochowski RR: Effect of bladder management on urological complications in spinal cord injured patients. J Urol 2000; **163:** 768.
6. Adriaansen JJ, van Asbeck FW, Tepper M et al: Bladder-emptying methods, neurogenic lower urinary tract dysfunction and impact on quality of life in people with long-term spinal cord injury. J Spinal Cord Med 2017; **40:** 43.
7. Patel DP, Elliott SP, Stoffel JT et al: Patient reported outcomes measures in neurogenic bladder and bowel: a systematic review of the current literature. Neurourol Urodyn 2016; **35:** 8.
8. Patel DP, Lenherr SM, Stoffel JT et al: Study protocol: patient reported outcomes for bladder management strategies in spinal cord injury. BMC Urol 2017; **17:** 95.
9. Welk B, Morrow S, Madarasz W et al: The validity and reliability of the neurogenic bladder symptom score. J Urol 2014; **192:** 452.
10. Welk B, Lenherr S, Elliott S et al: The Neurogenic Bladder Symptom Score (NBSS): a secondary assessment of its validity, reliability among people with a spinal cord injury. Spinal Cord 2018; **56:** 259.
11. Tulsky DS, Kisala PA, Victorson D et al: Overview of the spinal cord injury: quality of life (SCI-QOL) measurement system. J Spinal Cord Med 2015; **38:** 257.
12. Tulsky DS, Kisala PA, Tate DG et al: Development and psychometric characteristics of the SCI-QOL bladder management difficulties and bowel management difficulties item banks and short forms and the SCI-QOL bladder complications scale. J Spinal Cord Med 2015; **38:** 288.
13. Krogh K, Christensen P, Sabroe S et al: Neurogenic bowel dysfunction score. Spinal Cord 2006; **44:** 625.
14. Akkoç Y, Ersöz M, Yıldız N et al: Effects of different bladder management methods on the quality of life in patients with traumatic spinal cord injury. Spinal Cord 2013; **51:** 226.
15. Liu CW, Attar KH, Gall A et al: The relationship between bladder management and health-related quality of life in patients with spinal cord injury in the UK. Spinal Cord 2010; **48:** 319.

EDITORIAL COMMENT

The NBRG fills an important gap in neuro-urology, which is to assess PROMS. This study, in which almost 1,500 patients with SCI were investigated, provides essential insights into the patient perspective on different bladder management strategies. Fewer bladder symptoms were associated with indwelling catheters and surgery, and there were worse bladder symptoms in voiding patients compared to those on CIC. However, from the physician viewpoint these findings are counterintuitive, especially considering that it is well established that indwelling catheters are associated with worse medical outcomes. Moreover, the voiding patients were heterogenous, ie only 30% voided volitionally,

while the others leaked into a diaper, used a condom catheter or applied the Valsalva/Credé maneuver, or it was not specified, ie a relevant percent of the patients with SCI should have been treated differently, including those on CIC. Importantly, the perspectives of patients and physicians might differ substantially,[1] highlighting the significance of including these 2 viewpoints in further prospective studies. It would be crucial to understand how an optimal, suboptimal or inappropriate bladder management influences PROMS to finally reach the ultimate neuro-urological goals: preservation of upper and lower urinary tract function as well as achievement of good quality of life.[2,3]

Thomas M. Kessler
Department of Neuro-Urology
Balgrist University Hospital
University of Zürich
Zürich, Switzerland

REFERENCES

1. Kessler TM, Fisch M, Heitz M et al: Patient satisfaction with the outcome of surgery for urethral stricture. J Urol 2002; **167:** 2507.
2. Panicker JN, Fowler CJ and Kessler TM: Lower urinary tract dysfunction in the neurological patient: clinical assessment and management. Lancet Neurol 2015; **14:** 720.
3. Groen J, Pannek J, Castro Diaz D et al: Summary of European Association of Urology (EAU) Guidelines on Neuro-Urology. Eur Urol 2016; **69:** 324.