

The Real Daily Need for Incontinence Aids and Appliances in Patients with Neurogenic Bladder Dysfunction in a Community Setting in Germany

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Ralf Böthig,¹ Burkhard Domurath,² Johannes Kutzenberger,³ Jörn Bremer,⁴ Ines Kurze,⁵ Albert Kaufmann,⁶ Jana Pretzer,⁷ Jens-Peter Klask,⁸ Birgitt Kowald,⁹ Christian Tiburtius,¹ Klaus Golka,¹⁰ Sven Hirschfeld,¹¹ Roland Thietje¹¹

¹Department of Neuro-Urology, Centre for Spinal Cord Injuries, BG Klinikum Hamburg, Hamburg, Germany; ²Centre for Neuro-Urology, Kliniken Beelitz, Neurologische Rehabilitationsklinik, Beelitz-Heilstätten, Germany; ³Department of Neuro-Urology, Kliniken Hartenstein UKR, Bad Wildungen, Germany; ⁴Centre for Spinal Cord Injuries, BDH-Klinik Greifswald, Greifswald, Germany; ⁵Centre for Spinal Cord Injuries, Department of Paraplegiology and Neuro-Urology, Zentralklinik Bad Berka, Bad Berka, Germany; ⁶Department of Neuro-Urology, Kliniken Maria Hilf GmbH, Mönchengladbach, Germany; ⁷Department of Urology and Neuro-Urology, BG Trauma Hospital Berlin, Berlin, Germany; ⁸BG Trauma Hospital Duisburg, Duisburg, Germany; ⁹Biomechanical Laboratory, BG Klinikum Hamburg, Hamburg, Germany; ¹⁰Leibniz Research Centre for Working Environment and Human Factors at TU Dortmund (IfADo), Dortmund, Germany; ¹¹Centre for Spinal Cord Injuries, BG Klinikum Hamburg, Hamburg, Germany

Correspondence: Ralf Böthig
Department of Neuro-Urology, Centre for Spinal Cord Injuries, BG Klinikum Hamburg, Bergedorfer Str. 10, Hamburg 21033, Germany
Tel +49 40 7306 2608
Fax +49 40 7306 2621
Email r.boethig@bghk-hamburg.de

Purpose: For successful long-term rehabilitation of patients with neurogenic lower urinary tract dysfunction (NLUTD), it is necessary to define the objective requirement for urological aids based on a scientifically validated basis.

Methods: This was a cross-sectional multicenter study, based on a questionnaire. Data concerning bladder management and daily consumption of urological appliances for patients with NLUTD in a community setting were collected through a standardized survey.

Results: Seven hundred and sixty-seven records were analyzed: 543 males, 221 females (N/A = 3). Patients using intermittent catheterization (n= 608) required 5.06 (mean) single-use catheters per day. Out of them, 94 (15.5%) required additional pads (mean: 2.29 per day), 34 patients (5.6%) additionally used pants (mean: 2.55 per day) and 46 patients (7.6%) utilized condom catheters (mean: 3.81 per day) between catheterizations. Among all, 126 patients (16.4%) used pads (mean: 5.03 per day), and 51 patients (6.6%) used pants (mean: 3.03 per day). Women needed both pads (p < 0.0001) and diapers (p = 0.0084) significantly more frequently than men. Eighty-two of the male patients (15.1%) applied condom catheters (mean: 2.8 per day). The target value of the objective daily requirement of incontinence aids for adult patients with NLUTD (based on the upper twofold standard deviation from the mean value) was defined as follows: up to nine single-use catheters, seven condom catheters, nine pads and/or seven pants. A “mixed supply” of different incontinence aids is part of the daily supply for many patients.

Conclusion: For the first time, these results allow a reasonable regulation of urological aids and appliances based on scientific data for patients with neurogenic bladder.

Keywords: neurogenic lower urinary tract dysfunction, urological aids and appliances, bladder management, intermittent catheterization, incontinence, spinal cord injury

Introduction

An essential part of the neuro-urological management of patients with neurogenic lower urinary tract dysfunction (NLUTD) is developing an individual bladder management for each individual patient. In addition to the careful video-urodynamic evaluation of the bladder function, this also requires consideration of all aspects of neurological damage (manual function!) as well as the patients' wishes and their social environment.^{1,2} From a neuro-urological perspective, the focus is on establishing an adequate voiding regimen and (in most cases) ensuring low-pressure reservoir function. The various voiding strategies such as intermittent catheterisation using single-use catheters, triggered reflex voiding, implant driven micturition via sacral anterior root stimulation or even

transurethral/suprapubic catheterisation of the bladder need to be adapted to the pathophysiology and the individual abilities of the patient.

One essential prerequisite for a long-term outcome with a low complication rate is the provision of an adequate quantity of high-quality urological aids and appliances.^{3,4}

To date, there have been few dedicated investigations on the actual individual voiding mode^{5,6} and the number of bladder evacuations per day in outpatients with NLUTD. This results in a lack of objective data on the quantity of the urological aids and appliances needed.

The aim of this study is to evaluate the method of bladder evacuation and its frequency in patients with NLUTD in an outpatient setting, thus providing reliable data on the actual amount of urological aids and appliances these patients require.

Methods

During the period from 1 October 2014 to 31 December 2014, six departments for neuro-urology in Germany conducted a survey by a self-reported questionnaire to collect data on age and gender along with the method of bladder evacuation and the type as well as the quantity of the various urological aids and appliances needed per day (Supplement 1). We surveyed all patients who performed an outpatient follow-up appointment as part of their lifelong care at one of the participating centers. Included were all patients with NLUTD for at least 1 year and aged from 2 to 87 years. The data from the questionnaires were pseudonymized during entry.

All patients underwent a video-urodynamic study (video-UDS)⁷ to confirm the diagnosis of NLUTD and to precisely define the individual voiding dysfunction applying standard devices (Laborie/MMS BV, Enschede, The Netherlands). On the basis of the results of the video-

urodynamic study, an individual and specific neuro-urological treatment was conducted in each patient according to the current guidelines. Additionally, all patients were regularly followed-up video-urodynamically.^{1,2,8}

The data were entered into a database and then statistically analyzed using the statistical analysis software SAS 9.2 (SAS Institute Inc., Cary, NC, USA). In descriptive statistics, the modal value is the value recorded most frequently in a series of characteristic attributes. We further computed twice the standard deviation of the mean value. Chi-squared test resp. Fisher's exact test were used. The statistical level of significance was defined as $\alpha=0.05$ for all tests. The approving institutional review board was the Institution for Statutory Accident Insurance and Prevention in the Health and Welfare Services (address: Pappelallee 33, 22089 Hamburg). All applicable institutional and governmental regulations concerning the ethical use of the data were followed.

Results

Six centers for neuro-urology in Germany participated in the data collection (Bad Wildungen n=221, Greifswald n=212, Bad Berka n=153, Mönchengladbach n=71, Berlin n=65 and Duisburg n=45). A total of 767 data sets (Table 1) were collected from 543 men and 221 women (and 3 cases where gender was not specified). The mean age of the patients was 50.6 years (2–87 years). The most common cause of paralysis was spinal cord injury (n=689, paralysis level cervical n=188, thoracic n=348, lumbar n=149, sacral n=4), followed by spina bifida (n=27), multiple sclerosis (n=13), and infantile cerebral palsy (n=2). In 36 cases, the cause of paralysis was not specified.

Bladder Evacuation methods

Five hundred and seventy-seven patients (75.2%) emptied their bladder (Table 1) exclusively by intermittent catheterization

Table 1 Bladder Emptying Methods Applied in This Study

Bladder Voiding Methods	Total	%	Male	%	Female	%	p
IC (Intermittent catheterization)	577 ^a	75.2	405	74.6	170	76.9	0.4972
IC+ (IC plus other voiding methods eg V, RV or SARS)	31	4.0	26	4.4	5	2.3	0.1086
RV (Reflex voiding)	26 ^b	3.4	23	4.2	2	0.9	0.0190
SARS (Sacral anterior root stimulator)	17	2.2	11	2.0	6	2.7	0.5582
SPC (Suprapubic catheter)	39	5.1	26	4.8	13	5.9	0.5333
IDC (Indwelling catheter)	13	1.7	8	1.5	5	2.3	0.4444
V (Volitional)	51	6.7	34	6.3	17	7.7	0.4725
S (Straining)	2	0.3	2	0.4	0	0	1.0000
CI (Complete incontinence)	3	0.4	2	0.4	1	0.5	1.0000
MV (Mixed voiding without IC)	8	1.0	6	1.1	2	0.9	1.0000
All	767 ^c		543		221		

Notes: ^aGender unknown in 2 patients; ^bGender unknown in 1 patient; ^cGender unknown in 3 patients; P<0.05 in bold.

(IC) using single-use catheters. Another 31 patients (4.0%) used intermittent catheterisation using single-use catheters in addition to other evacuation methods (IC+, eg intermittent catheterisation and volitional voiding (V), reflex voiding (RV) or sacral anterior root stimulation (SARS)). Volitional voiding of the bladder was reported as the primary bladder evacuation method by 51 patients (6.7%), stimulated reflex voiding by 26 patients (3.4 %). Seventeen patients (2.2%) used implant driven mic-turition via a sacral anterior root stimulator. Permanent catheterisation was only reported by 6.8% (suprapubic catheter SPC 5.1% and indwelling catheter IDC 1.7%) of the patients.

Significant differences between genders ($p=0.0190$) with respect to the bladder evacuation method were only observed for reflex voiding (in favor of men).

Consumption of Single-Use Catheters in Patients with Intermittent Catheterization (IC) or Intermittent Catheterization Plus Other Voiding Methods (IC+)

Patients with NLUTD who reported using IC for bladder evacuation most commonly used 6 single-use catheters per day (modal value) with a median of 5 (range 1–10 catheters (Table 2)). Patients who also used other evacuation methods in addition to IC (IC+) reported fewer single-use catheters per day (modal value = 3; range: 1–6 catheters).

Consumption of Additional Aids and Appliances Among Patients with Intermittent Catheterization (IC) or Intermittent Catheterization Plus Other Voiding Methods (IC+)

Among the 608 patients using single-use catheters (IC and IC+) (Tables 3 and 4), 94 patients also required pads (15.5%)

Table 2 Daily Needed Single-Use Catheters in Patients with IC and IC+

Statistical Parameters	IC (n=577; 75.23%)	IC+ (n=31; 4.04%)	IC and IC+ (n=608; 79.27%)
Mean value (MV)	5.13	3.17	5.06
Median	5	3	5
Modal value	6	3	6
Minimum	1	1	1
Maximum	10	6	10
Standard deviation (SD)	1.36	1.34	1.65
Confidence interval	5.03–5.22	2.77–3.56	4.95–5.17
MV + 2 SD	7.85	5.85	8.46

Abbreviations: IC, Intermittent catheterization; IC+, IC plus other voiding methods.

in addition to single-use catheters. Another 34 patients also required pants (5.6%) and 46 patients also required condom catheters (10.7% of all men). It should be noted that some patients reported the use of condom catheters and additionally several of the stated absorbent incontinence supplies.

Women were significantly more likely to use absorbent supplies than men (33% vs 16.1%, $p<0.0001$). Apart from this, there were no other significant differences between genders in the total of all additional aids and appliances required by patients with IC and IC+ (Table 3).

Every second patient with IC+ required additional supplies (51.6%). Totally 27.4% (every 4th patient) reporting single-use catheters as their method of bladder evacuation (IC) also required condom catheters or absorbent aids and appliances (Table 3).

The median amount of additional absorbent aids and appliances per day required by patients with IC and IC+ (Table 4) was 2 pads or 2 pants (range: 1–10 for pads, 1–6

Table 3 Frequency of Additional Supplies (Daily Need) in Patients with IC and IC+ by Gender and for Patients with IC and with IC+ Separately

Supply Groups	Total		Males		Females		Patients with IC		Patients with IC+	
	n	%	n	%	n	%	n	%	n	%
IC and IC+	608	–	429	–	179	–	577	–	31	–
Pads	94	15.5	50	11.7	44	24.6	85	14.7	9	29.0
Pants	34	5.6	19	4.4	15	8.4	31	5.4	3	8.7
Condom catheters	46	7.6	46	10.7	–	–	42 of 405 m	10.4 m	4 of 24 m	16.7 m
Additional absorbent supplies, total	128	21.1	69	16.1	59	33.0	116	20.1	12	37.7
Additional supplies, total	174	28.6	115	26.8	59	33.0	158	27.4	16	51.6

Note: $P<0.05$ in bold.

Abbreviations: IC, Intermittent catheterization; IC+, IC plus other voiding methods; m, male.

Table 4 Additional Aids and Appliances (Daily Need) in Patients with IC and IC+

Statistical Parameters	Additional Pads in IC and IC+ (n=94; 15.5%)	Additional Pants in IC and IC+ (n=34; 5.6%)	Additional Condom Catheters in IC and IC+ (n=46; 7.6%)
Mean value (MV)	2.29	2.55	3.81
Median	2	2	4
Modal value	1	2	1
Minimum	1	1	1
Maximum	10	6	7
Standard deviation (SD)	1.07	1.45	0.47
Confidence interval	2.11–2.47	2.14–2.69	3.70–3.93
MV + 2 SD	4.43	5.45	4.75

Abbreviations: IC, Intermittent catheterization; IC+, IC plus other voiding methods.

pants). Men required on average 4 condom catheters per day between catheterizations (median; modal value 1; range: 1–7 condom catheters).

Consumption of Absorbent Aid and Appliances and Condom Catheters Among All Patients

Irrespective of the bladder evacuation method (Table 5) almost a fourth (23.1%) of all patients with NLUTD required absorbent aids and appliances such as pads (16.4%) and pants (6.6%). The daily consumption varied considerably: 1 to 10 pads per day (modal value 1, median 2) resp. 1 to 20 pants per day (modal value 2, median 2). Among all patients, females were about twice as likely to use pads (63/221 vs 63/543 resp. 28.5% vs 11.6%, $p < 0.0001$) and pants (23/221 vs 28/543 resp. 10.4% vs 5.2%, $p = 0.0084$) compared to men.

Overall, 82 of the 543 men used condom catheters (36 men exclusively and another 46 men in addition to IC and

IC+ (Table 5)). This amounts to 15.1% of all males. The modal value of daily consumption among both groups was 1, the median 2. However, the maximum amount was 7 condom catheters per day.

Discussion

The European Association of Urology¹ emphasized four key aims that are of paramount importance when selecting treatment strategies for patients with neurogenic lower urinary tract dysfunction (NLUTD): protection of the upper urinary tract, improvement of urinary continence, restoration of the lower urinary tract function and improvement of patient quality of life (QoL). This implies that individual solutions must be found for each patient.

Although IC is considered the standard bladder evacuation method in NLUTD, little is known about how this recommendation is implemented in community-based life. To the best of our knowledge, there has been no published data regarding the required amount and type of urological

Table 5 Daily Need for Absorbent Supplies in All Patients and for Condom Catheters in Male Patients

Gender/Statistical Parameters	Pads	Pants	Condom Catheters (CC)	
	Men and Women	Men and Women	Men with CC	Men with CC Exclusively
Male and female (n; %)	126 (16.4%)	51 (6.6%)		
Male (n; %)	63 (11.6%)	28 (5.2%)	82 (15.1%)	36 (6.6%)
Female (n; %)	63 (28.5%)	23 (10.4%)		
Mean value (MV)	5.03	3.03	2.8	2.78
Median	2	2	2	2
Modal value	1	2	1	1
Minimum	1	1	1	1
Maximum	10	20	7	7
Standard deviation (SD)	1.67	1.92	1.95	1.98
Confidence interval	4.78–5.27	2.59–3.48	2.42–3.13	2.24–3.32
MV + 2 SD	8.37	6.87	6.7	5.74

Note: $P < 0.05$ in bold.

aids and appliances in patients with NLITD (single-use catheters, absorbents and drainage supplies) to date.

A recent systematic review⁵ on treatment patterns in neurogenic bladder patients reported a percentage of patients with IC varying between 0% and 84% with very low rates in two older studies in the US (30.5%, 29.1%^{9,10}). In more recent studies in Switzerland, the Netherlands, the US and Turkey^{6,11-13} the percentage was 41.3%, 42.6%, 59.2% and 77.9%, respectively. In the present study, it is 79%. These heterogeneous results are probably based on different study designs and populations, different follow-ups and, above all, different national health care systems. There was no significant difference in the IC percentage between women and men in the present study population as well as in studies mentioned above, and this percentage was only significantly lower among women in another study from Norway.¹⁴

Data on gender-specific differences for other bladder evacuation methods were also heterogeneous: however, most studies showed no significant differences. Only Krebs et al⁶ found suprapubic catheterization was significantly more common among women and, in line with the present investigation, reflex voiding in men. A study in the Netherlands¹¹ reported that indwelling catheterization and continent urinary diversion were significantly more frequent among women with NLUTD.

Data on the daily catheterization frequency resp. on the actual consumption of single-use catheters among patients with NLUTD and IC is rare.

The present study shows a high variability in the consumption of single-use catheters from 1 to 10 per day. The number of catheters used may exceed the number of ICs, since not every attempt to catheterize is successful in paralyzed patients. Data from literature is consistent with this result. Using a small group of 46 patients, Kuhn et al¹⁵ determined a variability in catheterization frequency of 1 to 7 times per day. A recent prospective study by Hagen and Rekan¹⁴ showed that more than 36% of patients had exceeded the recommended catheterization frequency of 3 to 8 times per day. Thirty percent of the patients catheterized less frequently as they were also using other bladder emptying methods.

A British guideline¹⁶ recommends adjusting the catheterization frequency on the individual's voiding volumes over specific parts of the day.

Di Benedetto¹⁷ emphasized that the catheterization frequency depends on other factors such as the functional

bladder capacity, the effects of antimuscarinic therapy, the amount of liquids taken in, and on urodynamic parameters.

This explains the variability in consumption of single-use catheters based on physiological resp. pathophysiological factors and the medical needs in different studies.

In the present study, about 4% of the patients with IC also used other bladder voiding methods in addition to catheterization. According to a study involving several Swiss paraplegic centers,¹⁵ about one third of the patients used other voiding methods in addition to catheterization. Using the "International Lower Urinary Tract Function Basic SCI Data Set"¹⁸ a Dutch study¹¹ showed that a total of 38.8% of SCI patients used a secondary supplementary method in addition to the primary bladder emptying method. This needs to be considered in prescriptions on urological aids and appliances.

The present study shows that the number of patients requiring absorbent supplies is remarkably high. Hagen and Rekan¹⁴ published similar results: 8% of paraplegic males and 35% of paraplegic females also used absorbent incontinence supplies. Adriaansen et al¹¹ also reported that among the investigated spinal cord injury population (n=282), 22.7% of the patients used absorbent supplies and 36.9% used condom catheters. Only 58.2% of the patients surveyed stated being completely continent.

In the present study, additional absorbent supplies were needed by 16.4% (pads) and 6.6% (pants) of all participants resp. 16.1% of males and 33.0% of females (p<0.0001) using IC. Furthermore, 26.8% of man with IC needed some kind of additional aids and appliances. When all patients in the study population are examined irrespective of the bladder evacuation method, 16.4% required pads and 6.6% required pants.

This is either due to inadequate treatment of reflex incontinence, additional bladder neck insufficiency with urinary stress incontinence, or due to patients with neurogenic bladder dysfunction who also suffer almost consistently from a neurogenic bowel dysfunction with (imminent) fecal incontinence.¹⁹ Absorbent incontinence supplies are, therefore, part of the primary standard supply.

The condom catheter (CC) is an established type of supply for males with neurogenic detrusor hyperactivity or bladder neck insufficiency. In the present study, more than 15% of males used CC to void urine. As expected, the modal value was 1.0; the maximum consumption of CC was 7 - per day. Among others, this variation is because some of these patients also require intermittent catheterization due to inadequate reflex voiding or mixed voiding (with increased

postvoid residual volume). Prior to catheterization these patients have to remove the used and after catheterization to apply a new condom catheter. Some patients have problems with the adhesiveness of the condom catheter, thus requiring several condom catheters per day and possibly additional absorbent incontinence supplies.

The theoretical basis of the suggested upper limit for prescription of urological aids and appliances for patients with NLUTD is defined by the upper limit the of twofold standard deviation of the calculated mean value of the reported daily need.

Based on our data, approximately 95% of adult patients need up to 9 single-use catheters, 7 condom catheters, 9 pads, 7 pants per day, respectively (Table 6). Exceptions are to be made in case of children and in patients with extraordinary health conditions or with extraordinary voiding problems due to their neurogenic bladder. Furthermore, it should be noted that any combination of different urological aids and appliances determined by the individual need represents the rule rather than the exception.

However, as shown by our self-reported questionnaire the subjective need of urological aids and appliances may exceed the objective need considerably, particularly in the case of pants (Table 6).

The definition of the objective need for each group of supplies is based on the statistically sound variation of the self-reported consumption, the physiological requirements, the extent of neurological damage to the lower and upper urinary tract, and the attainable therapy goals.

This data analysis was the first attempt to objectively describe the actual consumption of urological aids and appliances in patients with NLUTD. Our data generally confirm a large variability in the number and types of supplies.

It is important to recognize that the present study has some limitations. First, as no validated questionnaire has been published in this field, the authors used a self-developed questionnaire (Online Resource 1). Second, no additional data on the medication, e.g. anticholinergics, previous surgeries or

botulinum toxin administration or behavioral aspects are indicated. However, the aim of the study was to understand the real-life situation of patients with different NLUTD in their specific situation. As mentioned, all patients were individually neuro-urological managed and video-urodynamically followed-up according to current guidelines. And finally, while this study does provide a baseline estimation for the individual variation of the need of urological appliances and aids required by patients with NLUTD in Germany, given the vast differences in health care systems and cultures across the world, it may be difficult to transfer the results to other countries. Nevertheless, the authors believe that the presented results provide important basic information for the specific situation in other countries.

Conclusions

The results of this study may serve as a sound basis for the prescription of urological aids and appliances in patients with NLUTD. Moreover, the scientifically based data presented may serve as a solid basis for developing guidelines on adequate provision with urological aids and appliances. They also may be used as the basis for the decisions of health insurance companies and lawmakers.

Ethical Approval

Institutional review board: Institution for Statutory Accident Insurance and Prevention in the Health and Welfare Services (address: Pappelallee 33, 22089 Hamburg, Germany). This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent

For this type of study, formal consent is not required.

Data Sharing Statement

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

All authors contributed to data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work. All authors approve the final version to be published.

Disclosure

The authors declare that they have no financial or non-financial competing interests.

Table 6 Objective and Subjective Daily Need for Urological Aids and Appliances

Supply Groups	Maximum Objective Need	Maximum Subjective Need
Single-use catheters	9	10
Condom catheters	7	7
Pads	9	10
Pants	7	20

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