

ARTICLE



Cross-sectional internet survey exploring symptomatic urinary tract infection by type of urinary catheter in persons with spinal cord lesion in Japan

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STUDY DESIGN: Cross-sectional study by members of patient advocacy groups.

OBJECTIVES: To evaluate the incidence and frequency of symptomatic urinary tract infection (sUTI) in persons with spinal cord lesion (SCL) using different types of catheters based on an internet survey in Japan.

SETTING: An internet survey.

METHODS: We conducted an Internet survey of persons with SCL who were considered to be able to perform intermittent self-catheterization (ISC). We evaluated the incidence and frequency of sUTI over the last year in persons performing ISC and those managed by indwelling catheterization (IDC). We also compared the same parameters between persons in the ISC group using reusable silicone catheters and single-use catheters and those with and without a concomitant use of intermittent balloon catheters (i-IDC).

RESULTS: Two-hundred and eighty-two persons were analyzed. In the ISC and IDC groups, sUTI occurred in 52.2% and 31.4% of persons ($p = 0.021$), respectively, in the last year, and the frequencies were 2.8 and 3.5 times a year ($p = 0.127$), respectively. There were no significant differences in the incidence or frequency of sUTI between persons using reusable catheters and single-use catheters or those with and without the concomitant use of i-IDC.

CONCLUSIONS: sUTI occurred in about 1 in 2 persons with SCL performing ISC, which was significantly higher than in the IDC group, and the frequency of sUTI in persons performing ISC was about 3 times a year. The different types of catheters used for ISC were not associated with the incidence or frequency of sUTI.

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INTRODUCTION

In persons with spinal cord lesion (SCL), including traumatic and non-traumatic spinal cord injury (SCI) and spina bifida, appropriate bladder management is of paramount importance to prevent renal impairment and symptomatic urinary tract infection (sUTI) and to prevent urinary incontinence and improve the quality of life [1]. Bladder management was divided into three categories: voiding, clean intermittent self-catheterization (ISC), and indwelling catheterization (IDC). Of these, ISC is indicated when bladder management by voiding could increase the risk of renal impairment and sUTI [1, 2].

A cardinal complication of ISC is sUTI [3]. Although its lower incidence compared to IDC is considered an advantage of ISC [1, 2], this has not always been clearly demonstrated in the long-term. In a systematic review by Kinnear et al. [4] of six studies comparing ISC with indwelling urethral catheterization (IUC) and of four studies comparing it with suprapubic cystostomy, only two and one studies,

respectively, showed significantly lower rates of sUTI in ISC. In Japan, reusable silicone catheters (RCs) and single-use catheters (SCs) with or without hydrophilic coating have been used for ISC, and recently, a combination of ISC and an intermittent balloon catheter (i-IDC) has occasionally been implemented [1]. On the other hand, it is unclear whether there is a difference in the incidence of sUTI between persons using RCs and SCs or with and without concomitant use of i-IDC. Therefore, real-world findings on the incidence of UTIs among users of different types of catheters for ISC are important.

In Japan, persons with chronic SCL are frequently cared for by non-specialized health-care providers (HCPs), and the actual incidence of sUTI has not been well investigated. This motivated members of the Japan Medical Society of Spinal Cord Lesions to conduct an Internet-based survey on complications of and adherence to urinary catheter management and quality of life to elucidate the burden of illness in persons with SCL. Unlike traditional

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Table 1. Definition of urinary tract infection in this study.

Descriptions	sUTI	fUTI	hcp-sUTI
a. I felt something wrong with my urine (cloudiness, malodorous odor, etc.) and actually took the antibacterial medicine I kept ready.	✓		
b. I felt something wrong with my urine (cloudiness, malodorous odor, etc.) and actually consulted a doctor or nurse, who told me I had a urinary tract infection and prescribed antimicrobials, but was not hospitalized.	✓		✓
c. I felt something wrong with my urine (cloudiness, malodorous odor, etc.) and actually consulted a doctor or nurse, who told me I had a urinary tract infection, and was hospitalized.	✓		✓
d. I thought I had a urinary tract infection because of fever, so I actually took the antimicrobials that I kept ready.	✓	✓	
e. I had fever and consulted a doctor or nurse, who told me I had a urinary tract infection and prescribed antimicrobials, but was not hospitalized.	✓	✓	✓
f. I had fever and consulted a doctor or nurse, who told me I had a urinary tract infection, and was hospitalized.	✓	✓	✓

fUTI febrile urinary tract infection, hcp-sUTI health care provider-diagnosed symptomatic urinary tract infection, sUTI symptomatic urinary tract infection.

postal mail and telephone surveys, an internet survey could obviate the problems of low response rates and low response accuracy due to the sensitive nature of the subject [5]. In this study, we aimed to first examine the incidence and frequency of sUTI between persons with ISC and IDC, and then of those using RCs and SCs or those with and without concomitant use of i-IDC.

METHODS

This study was conducted after obtaining ethical approval from the Non-Profit Organization MINS Research Ethics Committee.

Internet-based survey methods

A letter requesting participation in an internet survey was sent to members of a non-profit organization, the Japan Spinal Cord Foundation, the Public Interest Incorporated Foundation Spinal Injuries Japan, and the Spina Bifida Association of Japan, and their consent to set up a questionnaire survey site on the internet was obtained. Persons who fulfilled the following eligibility criteria and did not meet the exclusion criteria were included in order to select those assumed to be feasible to perform ISC for bladder management. Eligibility criteria were: (1) age of 20 years or older, (2) traumatic or non-traumatic SCI or spina bifida, (3) current bladder management with ISC or IDC, (4) internet access and ability to completely or mostly operate the devices by themselves, and (5) giving informed consent. The exclusion criteria were: (1) voiding as the only bladder management, (2) clean intermittent catheterization by caregivers, (3) incontinent urinary diversion such as ureterocutaneousostomy and ileal conduit or continent urinary diversion, (4) use of a ventilator, (5) acute SCL, and (6) living outside Japan. Questions regarding physical disabilities were prepared with reference to the ASIA/ISCoS International Standards for Neurological Classification of Spinal Cord Injury. A questionnaire survey was conducted from September 2020 to October 2020 on a designated website, and the anonymously processed information was transferred to CRECON Medical Assessment Inc. for data management using SAS version 9.4 (SAS Institute, Cary, NC, USA).

Definition of sUTI

The definition of sUTI used in this study is shown in Table 1. To determine the incidence and frequency of each category of UTI, responses to each item in the last year were obtained, and if a positive response was observed to at least one of the items, the patient was deemed to have had a specific category of UTI in the last year.

Catheters used for ISC in Japan

Three types of catheters are used for ISC in Japan: SCs, which are common in many countries; RCs, which were developed for reuse; and i-IDC. The most common type of SCs is a polyvinyl chloride catheter, but a hydrophilic-coated catheter (HCC) became partially reimbursed in 2016. On the other hand, RCs have been widely used for more than 30 years in Japan. RCs should be washed under running water, then kept immersed in a special container filled with 0.025% benzalkonium chloride in glycerin solution, and replaced once a month. The benzalkonium solution should be changed once a day. Because glycerin is added to the storage solution, the application of a lubricant at catheterization is not necessary. The i-IDC is also reusable and

became partially reimbursable in 2016. It is used for up to 12 h per day to prevent bladder overdistension and high-pressure urine storage in persons with nocturnal polyuria or difficulty with ISC when out, and is currently provided by only two companies [6, 7]. Urine can be drained continuously by connecting to a urine bag or intermittently with a dedicated catheter valve [7, 8]. Although there are no reliable data in Japan, reuse of polyvinyl chloride catheters and HCCs, frequently reported in other countries, is supposed to be seldom selected because RCs are the best reimbursed. It should be underlined that the current Japanese healthcare system for inpatients does not ensure that patients have enough opportunity to understand how to correctly handle individual types of catheters.

Statistical analysis

This study was primarily aimed at showing the incidence and frequency of sUTI, febrile urinary tract infection (fUTI), and HCP-diagnosed sUTI (hcp-sUTI) in the last year in persons performing ISC (ISC group) and those managed by IDC (IDC group). Secondary objectives were to determine the incidence and frequency of the three categories of UTI between persons with RCs and SCs and those with and without a concomitant use of i-IDC (i-IDC and ISC only group, respectively). In addition, we explored the incidence of recurrent UTI, which was defined as the occurrence of UTI three times or more in the last year [9]. In the ISC group, we analyzed complications other than UTI. Since this was an exploratory study, the sample size was not calculated. Statistical analysis was performed using a chi-square test or Fisher's exact test for categorical data, and Mann-Whitney *U* test for continuous data with SAS version 9.4 (SAS Institute, Cary, NC, USA). $P < 0.05$ was considered to be statistically significant.

RESULTS

Demographics of participants

Demographics of participants are shown in Table 2. A total of 282 persons agreed to participate in the study and were included in the analysis, of which 247 (87.6%) performed ISC and 35 (12.4%) were managed by IDC. Of persons in the ISC group, 136 (55.1%) and 111 (44.9%) used RCs and SCs, respectively, and 45 (18.2%) used i-IDC concomitantly, which were indwelling for 3 to 5 h in 4 (8.9%), 6 to 11 h in 31 (68.9%), and 12 to 18 h and more than 18 h in 5 (11.1%) each. The most common reasons (multiple responses possible) for choosing IDC were to prevent or reduce urinary incontinence [$n = 18$ (51.4%)] and to obviate the need for caregiver assistance during ISC [$n = 15$ (42.9%)], followed by reduction of the rate of sUTI, and not needing to perform ISC as frequently [$n = 9$ (25.7%) each].

Incidence and frequency of UTI

The incidences and frequencies of each category of UTI in the prior year are shown in Tables 3 and 4, respectively. Compared with persons in the IDC group, those in the ISC group had a statistically higher incidence only in sUTI among the three categories of UTI, but the incidences of recurrent UTI in each category were similar between the two groups. Although the

Table 2. Demographics of participants.

Descriptions	ISC	IDC	<i>p</i>
<i>N</i>	247	35	
Age, years, (SD)	47.8 (14.9)	54.0 (11.5)	0.042
Male, <i>n</i> (%)	185 (74.9)	21 (60.0)	0.070
Disease, <i>n</i> (%)			0.031
Spinal cord injury	184 (74.5)	32 (91.4)	
Spina bifida	63 (25.5)	3 (8.6)	
Years since onset (SD)	26.0 (12.8)	26.1 (12.1)	0.947
Physical disabilities, <i>n</i> (%)			
Manual dexterity			
No or a little inconvenient in daily life	197 (79.8)	18 (51.4)	<0.001
Significantly inconvenient in daily life	50 (20.2)	17 (48.6)	
Ambulation			
Walking with or without inconvenience	42 (17.0)	2 (6.7)	0.573
Use of brace or walk	16 (6.5)	2 (6.7)	
Wheelchair bound	189 (76.5)	31 (88.6)	0.129
Living at home, <i>n</i> (%)	243 (98.4)	33 (95.3)	0.163
Current workers, <i>n</i> (%)	131 (53.0)	17 (48.6)	0.718
Duration of present bladder management, years (SD)	20.3 (9.8)	18.1 (9.7)	0.202
Stocks of antibiotics, <i>n</i> (%)	103 (41.7)	8 (22.9)	0.041
Catheters, <i>n</i> (%)			
Reusable silicone catheter	136 (55.1)		
Single-use catheter	111 (44.9)		
Indwelling urethral catheter		27 (77.1)	
Suprapubic cystostomy catheter		4 (11.4)	
Not specified		4 (11.4)	

Data are presented as mean (standard deviation, SD).
IDC indwelling catheterization, ISC intermittent self-catheterization.

frequencies of sUTI, fUTI, and hcp-sUTI were not significantly different between the ISC and IDC groups as a whole, their frequencies in the IDC group were significantly higher than in the ISC group when restricted to persons who had suffered from at least one UTI in the last year. On the other hand, the incidences as well as frequencies of UTI across each category did not significantly differ between the RCs and SCs groups or between the i-IDC and ISC only groups.

Complications other than UTI in the ISC group

Complications other than UTI are shown in Table 5. Although persons with ISC seldom experienced pain at catheterization, approximately one quarter of those had difficulty inserting the catheters once a month or more. Bleeding at catheterization occurred significantly or tended to occur more frequently in the i-IDC group than in the ISC only group, or in the RCs group than in the SCs group. However, approximately 97% of bleeding events, including not at all, occurred less than once a month.

DISCUSSION

There have been several reports on the incidence of sUTI in chronic SCL persons discharged from acute care or rehabilitation hospitals by modes of bladder management, but they have

Table 3. The incidence of symptomatic urinary tract infection in the last year.

Type of Catheter	<i>n</i>	sUTI <i>n</i> (%)	fUTI <i>n</i> (%)	hcp-sUTI <i>n</i> (%)
ISC vs. IDC				
Overall				
ISC	247	129 (52.2)	82 (33.2)	96 (38.9)
IDC	35	11 (31.4)	8 (22.9)	9 (25.7)
<i>p</i>		0.021	0.219	0.132
Recurrent UTI				
ISC	247	84 (34.0)	27 (10.9)	51 (20.6)
IDC	35	10 (28.6)	5 (14.3)	8 (22.9)
<i>p</i>		0.523	0.558	0.764
Reusable vs. Single-use				
Overall				
Reusable	136	75 (55.1)	46 (33.8)	58 (42.6)
Single-use	111	54 (48.6)	36 (32.4)	38 (34.2)
<i>p</i>		0.309	0.817	0.177
Recurrent UTI				
Reusable	136	51 (37.5)	17 (12.5)	31 (22.8)
Single-use	111	33 (29.7)	10 (9.0)	20 (18.0)
<i>p</i>		0.200	0.382	0.356
i-IDC vs. ISC only				
Overall				
i-IDC	45	23 (51.1)	13 (28.9)	16 (35.6)
ISC only	202	106 (52.5)	69 (34.2)	80 (39.6)
<i>p</i>		0.868	0.497	0.614
Recurrent UTI				
i-IDC	45	13 (28.9)	6 (13.3)	9 (20.0)
ISC only	202	71 (35.1)	21 (10.4)	42 (20.8)
<i>p</i>		0.423	0.568	0.906

fUTI febrile urinary tract infection, hcp-sUTI health care provider-diagnosed symptomatic urinary tract infection, IDC indwelling catheterization, i-IDC intermittent indwelling catheterization, ISC intermittent self-catheterization, Reusable reusable silicone catheter, Single-use single-use catheter, sUTI symptomatic urinary tract infection.

shown inconsistent results. Singh et al. [10] showed incidences of fUTI of 0.34 times/100 person-days and 2.68 times/100 person-days in the ISC group and the IUC group, respectively, in persons with SCI who were followed for at least 1 year after injury. Weld et al. [11] reported a significantly lower incidence of epididymitis and pyelonephritis in the ISC group than the IUC group with a mean follow-up of 18.3 years. On the other hand, Afsar et al. [12] showed that with a mean follow-up of 53.9 months, the annual frequency of sUTIs was 2 times in the ISC group and 3 times in the IUC group, which was not significantly different. Krebs et al. [9] also found that with a mean follow-up of 20.3 years since injury or onset of SCL, the annual incidences of sUTI in the ISC and IUC groups were 70.5% and 83.3%, respectively, and those of recurrent UTI were 31.2% and 50.0%. Based on participant self-reports like our study, Roth et al. [13] found that 77.2% of persons in the ISC group (mean time since injury 12.5 years) and 81.9% in the IDC group (mean time since injury 15.6 years) had developed sUTI in the last year. Finally, a telephone survey of persons with SCI also showed that the incidence of sUTI in the most recent year was 59%, with a mean frequency of 3.40 times/year [14]. These results suggest that the incidence of sUTI in SCL persons after discharge from acute care or rehabilitation hospitals is regrettably

Table 4. The frequency of symptomatic urinary tract infection in the last year.

Type of Catheter		sUTI (SD)	fUTI (SD)	hcp-sUTI (SD)
ISC vs. IDC				
Overall				
ISC (<i>n</i> = 247)		2.8 (4.95)	0.9 (2.14)	1.5 (2.83)
IDC (<i>n</i> = 35)		3.5 (7.71)	1.3 (3.45)	2.1 (4.67)
<i>p</i>		0.172	0.410	0.385
Only patients with sUTI in each category in the last year				
ISC	<i>n</i>	129	82	96
	Frequency	5.4 (5.75)	2.7 (2.97)	3.8 (3.47)
IDC	<i>n</i>	11	8	9
	Frequency	11.1 (10.44)	5.6 (5.48)	8.1 (6.13)
<i>p</i>		0.012	0.040	0.008
Reusable vs. Single-use				
Overall				
Reusable (<i>n</i> = 136)		2.8 (4.18)	0.8 (1.43)	1.5 (2.45)
Single-use (<i>n</i> = 111)		2.8 (5.77)	1.0 (2.77)	1.4 (3.26)
<i>p</i>		0.316	0.773	0.234
Only patients with sUTI in each category in the last year				
Reusable	<i>n</i>	75	46	58
	Frequency	5.2 (4.45)	2.4 (1.47)	3.5 (2.68)
Single-use	<i>n</i>	54	36	38
	Frequency	5.7 (7.20)	3.1 (4.16)	4.2 (4.42)
<i>p</i>		0.859	0.774	0.694
i-IDC vs. ISC only				
Overall				
i-IDC (<i>n</i> = 45)		2.2 (3.36)	0.8 (1.60)	1.3 (2.38)
ISC only (<i>n</i> = 202)		3.0 (5.24)	0.9 (2.24)	1.5 (2.93)
<i>p</i>		0.562	0.622	0.667
Only patients with sUTI in each category in the last year				
i-IDC	<i>n</i>	23	13	16
	Frequency	4.4 (3.56)	2.8 (1.77)	3.7 (2.70)
ISC only	<i>n</i>	106	69	80
	Frequency	5.6 (6.11)	2.7 (3.15)	3.8 (3.62)
<i>p</i>		0.277	0.420	0.837

Data are presented as mean (standard deviation, SD).

fUTI febrile urinary tract infection, hcp-sUTI health care provider-diagnosed symptomatic urinary tract infection, IDC indwelling catheterization, i-IDC intermittent indwelling catheterization, ISC intermittent self-catheterization, Reusable reusable silicone catheter, Single-use single-use catheter, sUTI symptomatic urinary tract infection.

high in both the ISC and IDC groups. The present study showed a significantly higher incidence of sUTI in the ISC group than the IDC group, but no significant difference between them in fUTI and hcp-sUTI. Although the causes of these findings are unclear, the significantly higher rate of stocks of antimicrobials in the ISC group than IDC groups might have some effect on the incidence of sUTI. Persons with a high suspicion of having recurrent UTI may find it practical to keep antimicrobials ready and take them after self-diagnosis in the case of suspicious symptoms. Therefore, the actual incidence of sUTI may be higher than the incidence based on the diagnosis by HCPs because sUTI is often self-diagnosed and treated without seeing HCPs. In this study, the frequencies of sUTI, fUTI, and hcp-sUTI were significantly higher in the IDC group than the ISC group when restricted to persons who had suffered from sUTI in the last year, suggesting that certain persons in the IDC group are prone to recurrent sUTI. Linsenmeyer [15] emphasized that the possibility of bladder stones should be

considered in case of recurrent sUTI, especially in persons with IDC, which suggested that the cause of recurrent sUTI in IDC groups in this study may not be sufficiently investigated by HCPs.

There have been several systematic reviews and meta-analyses assessing the impacts of reused catheters and SCs on sUTI. It should be noted that most of the catheters reused in these studies were not developed for reuse (e.g., RCs), but that the catheters designed for SCs were recycled. Hakansson [16] showed in his review that UTI rate ranged from 40.3% to 79% with reused catheters, 61% to 82% with single-use non-HCC, and 35% to 64% with HCC. Christison et al. [17] conducted a meta-analysis based on National Institute on Disability and Rehabilitation Research 1992 criteria and found no significant difference in sUTI between reused catheters and SCs. However, using the Infectious Diseases Society of America (IDSA) 2009 criteria, SCs showed a trend toward a 30% lower risk of sUTI than reused catheters. The most recent Cochrane Review by Prieto et al. [18] was also inconclusive on the difference in benefits and harms between

Table 5. Complications other than urinary tract infection in persons with intermittent self-catheterization.

Type of Catheter	n	Difficulty in insertion n (%)			Bleeding n (%)			Pain n (%)		
		none	<1x/mo	≥1x/mo	none	<1x/mo	≥1x/mo	none	<1x/mo	≥1x/mo
ISC overall	247	68 (27.5)	114 (46.2)	65 (26.3)	143 (57.9)	99 (40.1)	5 (2.0)	173 (70.0)	54 (21.9)	20 (8.1)
Reusable vs. Single-use										
Reusable	136	37 (27.2)	69 (50.7)	30 (22.1)	69 (50.7)	65 (47.8)	2 (1.5)	101 (74.3)	24 (17.6)	11 (8.1)
Single-use	111	31 (27.9)	45 (40.5)	35 (31.5)	74 (66.7)	34 (30.6)	3 (2.7)	72 (64.9)	30 (27.0)	9 (8.1)
p		0.638			0.056			0.441		
i-IDC vs. ISC only										
i-IDC	45	13 (28.9)	21 (46.7)	11 (24.4)	18 (40.0)	25 (55.6)	2 (4.4)	32 (71.1)	8 (17.8)	5 (11.1)
ISC only	202	55 (27.2)	93 (46.0)	54 (26.7)	125 (61.9)	74 (36.6)	3 (1.5)	141 (69.8)	46 (22.8)	15 (7.4)
p		0.514			<0.001			0.439		

<1x/mo less than once a month, ≥1x/mo once a month or more, i-IDC intermittent indwelling catheterization, ISC intermittent self-catheterization, Reusable reusable silicone catheter, Single-use single-use catheter.

reused catheters and SCs. New [19] pointed out that the reused catheters may be an option only in high resource countries where SCs are not reimbursed or in low resource countries. On the other hand, considering the environmental burden of waste of SCs [20] as well as the United Nations Sustainable Development Goals [21], Popolo et al. [22] emphasized that new clinical trials should be required to swing the pendulum back to the use of less expensive and less wasteful RCs. The incidence of sUTI with Japanese RCs has been reported only in 28 male persons with SCI in Thailand [23]. Although it should be noted that the average duration of use of each catheter was 35 months and persons with triggered reflex voiding were included, 64% of persons had malodorous urine and 36% had cloudy urine and fever in the last year. While the incidences of sUTI as well as fUTI in the RCs group seemed compatible with these results, the incidences and frequencies of UTI across the all categories were unexpectedly similar to those in the SCs group. To unveil the benefits and harms of RCs, the results of a multicenter, prospective randomized controlled, non-inferiority trial (COMPaRE) are eagerly awaited [24].

The Japanese i-IDC is an intermittent-use silicone balloon catheter originally designed to help individuals with ISC avoid nocturnal urinary incontinence, diaper use, and incontinence-associated dermatitis [1, 25]. In a study primarily of children with spina bifida, nighttime use of a balloon catheter prevented the syndrome of nocturnal overdistension of the bladder in 79% of users [26]. Although the reasons for using i-IDC were not solicited in this internet survey, i-IDC also benefits persons at work, school, gatherings, and traveling, where ISC is difficult to perform with appropriate timing [1]. Joshi et al. found that 63% of 45 persons with SCI felt some difficulty performing ISC outdoors, which reinforces the use of i-IDC as a viable option [27]. In order to avoid adverse events such as sUTI, hematuria, and urethral complications, the guidelines recommended that the maximum indwelling time should be up to 12 h, but as short as possible [1]. In this internet survey, about 80% of persons used i-IDC for less than 12 h a day, which means that compliance seemed to be generally good. Although the use of i-IDC might increase the frequency of bleeding events at catheterization, there were no significant differences in the incidence as well as the frequency of sUTI between persons with and without a concomitant use of i-IDC. Similar to our findings, Ozawa et al. reported that the frequency of fUTI in persons with i-IDC (only nocturnal use in their study) was almost the same as in those with ISC only in persons with lower urinary tract dysfunctions, mainly SCI [25]. Taken together, the incidence and frequency of sUTI could be reduced to the level of ISC alone if i-IDC is used appropriately only by persons deemed eligible for i-IDC by neurourologists.

There are several limitations of this study. First, because this was an internet-based survey in nature, the subjects in this study may

not represent the general population. However, the Communication Usage Trend Survey in 2019 by the Ministry of Internal Affairs and Communications of Japan showed an internet usage rate of over 90% among people in their 20s to 60s, suggesting that being internet-based does not itself cause a significant bias [28]. In addition, a registry system that includes modes of bladder management for SCI and spina bifida has not been established in Japan. Consequently, when conducting various surveys on SCI and spina bifida, the cooperation of the organizations helping us in this project is often solicited, as they are supposed to reflect the actual situations of persons with these disorders in Japan to some extent. Therefore, we believe that the present study did not consist of persons very different from those encountered in everyday practice. Next, this study was an exploratory fact-finding study using data derived from a burden of illness study that, in general, is not sufficiently powered to show what is being inferred from the data. In addition, this study inherently had a selection as well as an information bias, and the sample size was small, especially in the IDC group. That might be the reason why, in the crude analysis with group comparisons, we did not observe results consistent with the risk reduction with ISC expected from those in past studies. Collectively, care should be taken to interpret the results of between-group comparisons. Third, because sUTI was not based on criteria such as those of IDSA, but self-reported, the incidence and frequency of sUTI might be overestimated. In this regard, to reduce the contamination by various diseases other than sUTI, we specified cloudy urine, malodorous urine, and fever in the questionnaire among the wide range of symptoms and signs listed in the International Spinal Cord Injury Urinary Tract Infection Basic Data Set [29] after careful discussion among the investigators, although 'etc.' implied the rest of those listed in the data set. As a result, the incidence and frequency of sUTI in this study were not substantially different from those in past studies. Therefore, we believe that the results reflect the actual frequency of sUTI in persons with SCL to some extent. Finally, because we focused on the incidence and frequency of sUTI in this study, we did not evaluate variables related to sUTI, such as compliance with ISC and management of IDC. We are currently analyzing these variables and planning to report them in the near future.

In conclusion, sUTI occurred in about 1 in 2 persons with SCL performing ISC, and the frequency of sUTI was about 3 times/year. In addition, a clear relationship between the types of catheters used for ISC, including i-IDC, and the incidence or frequency of sUTI was not observed, implying that RCs and i-IDC play a certain role in bladder management for persons with SCL in Japan. Well-designed long-term prospective studies are warranted to elucidate the incidence and frequency of sUTI by the types of catheters.

DATA AVAILABILITY

The data generated and analyzed during this study can be found within the published article.

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AUTHOR CONTRIBUTIONS

NS and MM have equally contributed to this work. MM, NS, RT, AS, MN, TM, TK, and MT conceived and designed the study. FM and MT managed the data. MM, NS, FM, and MT analyzed the data. MM, NS, RT, AS, MN, TM, TK, and MT interpreted the data. MM and NS drafted the manuscript. MM, NS, RT, AS, MN, TM, TK, and MT critically revised the manuscript. MM and NS prepared the final version of the manuscript. All authors thoroughly reviewed and approved the final version of the manuscript.

COMPETING INTERESTS

No investigators have individual conflicts of interest to be disclosed with any company including those manufacturing or selling urinary catheters as well as Coloplast Japan Inc.

ETHICAL APPROVAL

The protocol for this research project has been approved by a suitably constituted Ethics Committee (the Non-Profit Organization MINS Research Ethics Committee (<http://www.npo-mins.com/library/5fcf039bd6164603646daf12/602f7e0c12830e793b214646.pdf>)) and it conforms to the provisions of the Declaration of Helsinki.

ADDITIONAL INFORMATION

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