Original Article

Int Neurourol J 2022;26(4):308-316
https://doi.org/10.5213/inj.2244146.073
pISSN 2093-4777 · eISSN 2093-6931

INTERNATIONAL NEUROUROLOGY JOURNAL
INJ
OPEN ACCESS

A Multicenter, Open-Label, Observational Study Evaluating the Quality of Life After Using a Hydrophilic-Coated Catheter (SpeediCath) With Self-Intermittent Catheterization

Kwang Jin Ko[1], Myung-Soo Choo[2], Sun-Ouck Kim[3], Jang Hwan Kim[4], Kyung Jin Chung[5], Eun Sang Yoo[6], Myung Ki Kim[7], Won Jin Cho[8], Jong Bo Choi[9], Jihwan Lee[1], Kyu-Sung Lee[1,10]

[1]Department of Urology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea
[2]Department of Urology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea
[3]Department of Urology, Chonnam National University Hospital, Gwangju, Korea
[4]Department of Urology, Yonsei University College of Medicine, Seoul, Korea
[5]Department of Urology, Gachon University Gil Medical Center, Gachon University of School of Medicine, Incheon, Korea
[6]Department of Urology, School of Medicine, Kyungpook National University, Daegu, Korea
[7]Department of Urology, Jeonbuk National University Medical School, Jeonju, Korea
[8]Department of Urology, Chosun University Hospital, Chosun University School of Medicine, Gwangju, Korea
[9]Department of Urology, Ajou University College of Medicine, Suwon, Korea
[10]Research Institute for Future Medicine, Samsung Medical Center, Seoul, Korea

Purpose: We evaluated the change in patient quality of life after the use of a hydrophilic-coated catheter (SpeediCath) in adults requiring intermittent catheterization (IC).
Methods: This was a multicenter, open-label, observational study using the Patient Perception of Intermittent Catheterization (PPIC) questionnaire and the Intermittent Self-Catheterization questionnaire (ISC-Q) and safety at 12 and 24 weeks in adult patients who had already used other type of catheters prior to switching to SpeediCath or in patients undergoing self-IC for the first time for any reason.
Results: Among a total of 360 subjects, 215 (59.7%) were women, and the mean age was 62.0±13.2 years. At 24 weeks, the satisfaction rate after using SpeediCath was 84.1%, and 80% of patients responded that they could easily perform IC. In total, 81.6% of patients were willing to continue using SpeediCath. The mean ISC-Q score was 54.90±18.65 at 24 weeks. Men found less interference in their daily life by performing IC than women and found it easier to handle the catheter before it was inserted into the urethra. At week 12, the mean change in ISC-Q was significantly greater in patients <65 years (20.24±23.55) than in those ≥65 years (7.57±27.70, P=0.049), but there was no difference at 24 weeks. The most common adverse events were urinary tract infection in 9.72%, gross hematuria in 2.78%, and urethral pain in 1.39%.
Conclusions: The use of a SpeediCath provided good quality of life for patients who needed self-IC regardless of age or sex.

Keywords: Bladder; Intermittent catheterization; Quality of life; Urinary retention

- **Research Ethics:** The study was approved by the Institutional Review Board of Samsung Medical Center (IRB No. 2028-02-057).
- **Conflict of Interest:** This study was supported by a research grant from Coloplast A/S. The funding source had no role in the design or conduct of the study; data collection, management, analysis, or interpretation; manuscript preparation, review, or approval; or the decision to submit the manuscript for publication. The authors declare no conflict of interests.

Corresponding author: Kyu-Sung Lee https://orcid.org/0000-0003-0891-2488
Department of Urology, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-ro, Gangnam-gu, Seoul 06351, Korea
Email: ksleedr@skku.edu
Submitted: June 17, 2022 / **Accepted after revision:** August 30, 2022

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (https://creativecommons.org/licenses/by-nc/4.0/) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

Intermittent catheterization (IC) is the recommended method to solve voiding problems in patients with neurogenic bladder dysfunction as well as in patients with chronic urinary retention due to temporary or long-term bladder dysfunction [1]. Emptying the bladder through IC at regular intervals leads to lower detrusor pressure, which can preserve renal function, reduce the occurrence of urinary incontinence and the possibility of urinary tract infection (UTI), and improve the quality of life [2-5]. It also allows for comfortable activities of daily living without requiring an indwelling urethral catheter [6].

Above all, it is important to adhere to IC for long-term use; IC must be performed at a frequency of 4–6 times a day [7]. Various types of catheters have been developed to maximize convenience in long-term use. Most of these products are single-use catheters and significantly reduce the steps required compared with reusable catheters. Recently, hydrophilic-coated catheters that can be inserted into the urethra without prelubrication processes have been widely introduced. Among them, the SpeediCath (Coloplast, Humblebaek, Denmark), observed in this study, is a sterile, ready-to-use, hydrophilic-coated catheter. In patients with spinal cord injury (SCI), hydrophilic-coated catheters significantly reduce the risk of UTI compared with sterile single-use uncoated catheters [8-10]. However, existing studies are limited to patients with SCI and are primarily done in men, and these studies mainly evaluated the risk of UTI.

The purpose of this observational study was to evaluate changes in quality of life in patients who had already used other type of catheters prior to switching to SpeediCath or in patients undergoing self-catheterization for the first time for any reason including patients with emptying failure.

MATERIALS AND METHODS

Study Design and Patients

This study was a multicenter, open-label, observational study to evaluate patient quality of life and safety at 12 and 24 weeks after the use of a hydrophilic catheter (SpeediCath) in any adult patients requiring IC. Patients who newly needed IC at least once a day for more than 6 months or patients who had been regularly performing IC (but had never used SpeediCath) were enrolled. Exclusion criteria were (1) 18 years of age or younger, (2) patients with evidence of UTI requiring antibiotic treatment at the time of screening, (3) patients with urethral stricture, and (4) patients who were judged unsuitable by the person in charge of clinical research. The study was approved by the Institutional Review Board of Samsung Medical Center (IRB No. 2028-02-057).

Assessment

The primary outcome was patient-perceived benefits using the Patient Perception of Intermittent Catheterization (PPIC) questionnaire evaluated after 24 weeks of use. The PPIC questionnaire consists of 8 questions to evaluate a patient's perception during self-IC.

Q1. I am willing to continue to use the current catheter. (Agree/Disagree)
Q2. I find it easy to insert a catheter into the urethra. (Agree/Disagree)
Q3. I find it easy to remove a catheter from the urethra. (Agree/Disagree)
Q4. I can easily handle the catheter before it is inserted into the urethra. (Agree/Disagree)
Q5. I am satisfied with the time consumed to perform catheterization. (Agree/Disagree)
Q6. I can easily perform intermittent catheterization. (Agree/Disagree)
Q7. I am satisfied with my current catheter. (Agree/Disagree)
Q8. Performing intermittent catheterization does not interfere with my daily life. (Agree/Disagree)

The secondary outcomes were PPIC after 12 weeks and validated Intermittent Self-Catheterization questionnaire (ISC-Q) [11] after 12 and 24 weeks. The ISC-Q is used to evaluate aspects of quality of life specific to the needs of patients who perform self-IC. The questionnaire consists of 24 items categorized into 4 domains: ease of use, discreetness, psychosocial well-being, and convenience. Each item is rated on a 5-point Likert scale (ranging from 0: strongly agree to 4: strongly disagree), and after the 14 reverse-coded item responses are converted, scores are calculated by multiplying the mean value of all items within each domain by 25, to give a common range of 0–100. The total ISC-Q score is then derived from the simple average across the 4 domains (0–100) with a higher score representing higher quality of life. At baseline, all questionnaires were evaluated only for patients who had previously used other types of catheters. Safety was evaluated based on adverse events (AEs) during the study period.

Statistical Analyses

As a noncomparative observational study, statistical calculation

of sample size was not considered. All efficacy data were based on the main analysis of the full analysis set. PPIC and other 4-item questionnaires are evaluated with the ratio of 2 categories for each question, and the proportion of patients who responded "agree" and the 95% confidence interval were analyzed. The mean of ISC-Q for each subgroup score and total score were analyzed. The change of ISC-Q at 12 weeks and 24 weeks from baseline in subjects with a history of self-catheterization was confirmed by paired t-test or Wilcoxon signed-rank test. Fisher exact test or chi-square test was performed to determine whether there was a difference in the percentage of positive responses in the PPIC questionnaire at 12 weeks and 24 weeks according to the presence or absence of a history of self-catheterization, sex, and age. Safety analysis consisted of subjects who performed self-catheterization at least once.

RESULTS

Patient Demographics

Among the 360 subjects enrolled at 14 institutions, 215 (59.7%) were women, and the mean age was 62.0 ± 13.2 years. There were 111 subjects (30.8%) who had experienced IC; 15 (13.5%) continued to use the existing catheter until the time of enrollment, and 96 (86.5%) were not in use. The mean (standard deviation) IC duration was 6.96 (8.16) years (range, 1.00–42.00). A silicone catheter was used in 43.2% of patients, and a latex catheter in was used in 36%. According to the number of catheterizations per day, 25.2% of patients performed catheterization 4 times a day. The ratio of patients by number of catheterizations per day is described in detail in Table 1. Reasons for intermittent self-catheterization were acquired SCI (28.6%), congenital spinal lesion (1.9%), and other acquired conditions (69.4%). Urodynamic evaluation of all patients revealed detrusor underactivity in 161 (44.7%), detrusor acontractility in 138 (38.3%), detrusor overactivity and impaired contractility in 40 (11.1%), dysfunctional voiding in 12 (3.3%) and detrusor-external sphincter dyssynergia in 9 (2.5%).

Of the 360 patients, 7 had ceased self-IC due to an AE, and 5 of them were caused by catheter-related UTI. A total of 64 patients arbitrarily discontinued self-IC on their own, and 20 patients stopped self-IC because their bladder function was restored.

Patient Perception of Intermittent Catheterization

The response rate of each item in the PPIC at week 12 and week 24 are described in Table 2. The changes at 12 weeks and 24

Table 1. Patient characteristics

Variable	All subjects (n = 360)	FAS (n = 271)
Sex		
Female	215 (59.7)	174 (64.2)
Male	145 (40.3)	97 (35.8)
Age ≥ 65 yr	62.0 ± 13.2	60.9 ± 13.3
Female	108 (50.2)	83 (48.2)
Male	66 (45.5)	49 (50.5)
Body mass index (kg/m^2)	23.7 ± 3.5	23.8 ± 3.4
Previous history of IC	111 (30.8)	88 (32.5)
Duration of using catheter (yr)	6.96 ± 8.16	6.53 ± 7.72
Catheter material types		
Silicone	48 (43.2)	41 (46.6)
Latex	40 (36.0)	32 (36.4)
Polyvinyl chloride	2 (1.8)	1 (1.1)
Polyvinyl pyrrolidone	1 (0.9)	1 (1.1)
Unknown	20 (18.0)	13 (14.8)
Currently performing IC	15 (13.5)	11 (12.5)
No. of catheters used per day		
≤ 1	6 (5.4)	6 (6.8)
2	16 (14.4)	14 (15.9)
3	13 (11.7)	11 (12.5)
4	28 (25.2)	19 (21.6)
5	16 (14.4)	10 (11.4)
6	13 (11.7)	11 (12.5)
7	9 (8.1)	8 (9.1)
8	5 (4.5)	5 (5.7)
≥ 10	3 (2.7)	3 (3.4)
Reason for bladder management		
Congenital spinal lesion	7 (1.9)	7 (2.6)
Acquired spinal cord injury	103 (28.6)	75 (27.7)
Other condition	250 (69.4)	189 (69.7)
Urodynamic findings		
Detrusor underactivity	161 (44.7)	132 (48.7)
Detrusor acontractility	138 (38.3)	97 (35.8)
DOIC	40 (11.1)	28 (10.3)
Dysfunctional voiding	12 (3.3)	8 (3.0)
DESD	9 (2.5)	6 (2.2)

Values are presented as number (%) or mean ± standard deviation.
FAS, full analysis set; IC, intermittent catheterization; DOIC, detrusor overactivity and impaired contractility; DESD, detrusor-external sphincter dyssynergia.

Table 2. The response rate of each item in Patient Perception of Intermittent Catheterization at 12 and 24 weeks

Question		12 Weeks (n=264)		24 Weeks (n=271)	
		%	95% CI	%	95% CI
Q1	I am willing to continue to use the current catheter.	83.0	77.9–87.3	81.6	76.4–86.0
Q2	I find it easy to insert a catheter into the urethra.	73.1	67.3–78.4	75.7	70.1–80.6
Q3	I find it easy to remove a catheter from the urethra.	89.0	84.6–92.5	87.8	83.3–91.5
Q4	I can easily handle the catheter before it is inserted into the urethra.	79.6	74.2–84.2	83.4	78.4–87.6
Q5	I am satisfied with the time consumed to perform catheterization.	75.0	69.3–80.1	76.4	70.9–81.3
Q6	I can easily do intermittent catheterization, in general.	76.1	70.5–81.2	80.1	74.8–84.7
Q7	I am satisfied with my current catheter.	79.6	74.2–84.2	84.1	79.2–88.3
Q8	I do not interfere with my daily life by performing intermittent catheterization.	54.6	48.3–60.7	55.4	48.2–61.4

CI, confidence interval.

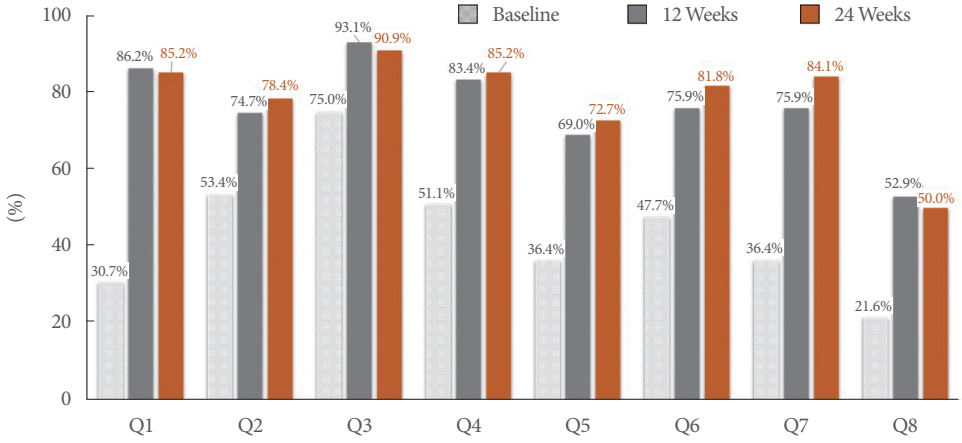

Fig. 1. Patient Perception of Intermittent Catheterization responses for patients with a history of intermittent catheterization (n=111) at 12 and 24 weeks. Q1, I am willing to continue to use the current catheter; Q2, I find it easy to insert a catheter into the urethra; Q3, I find it easy to remove a catheter from the urethra; Q4, I can easily handle the catheter before it is inserted into the urethra; Q5, I am satisfied with the time consumed to perform catheterization; Q6, I can easily do intermittent catheterization, in general; Q7, I am satisfied with my current catheter; Q8, I do not interfere with my daily life by performing intermittent catheterization.

weeks from the baseline of the PPIC for subjects with a history of intermittent self-catheterization were statistically significant in all questions (Fig. 1). According to subgroup analysis, the proportion of male patients who agreed to Q8 was 63.83%, which was significantly higher than for females (49.41%, P=0.049) at 12 weeks, and the proportion of male patients who agreed to Q4 was 90.72%, which was significantly higher than for female (79.31%, P=0.031), at 24 weeks. There was no significant difference in PPIC according to the previous history of IC or age (Table 3).

Intermittent Self-Catheterization Questionnaire

The subscores (ease of use, convenience, discreetness, psychological well-being) and total score of ISC-Q are shown in Table 4. In subjects with a history of IC, changes in the ISC-Q total score and each subgroup score at 12 weeks and 24 weeks from the baseline were significantly improved (Table 4). There were no statistically significant differences in subgroup scores every visit or in mean change from baseline according to gender (Table 5). In patients under the age of 65, the mean change from baseline of total score at 12 weeks was significantly higher than 65 years of age or older, but there was no difference of mean change at 24 weeks according to age (Table 5).

Safety

A total of 83 AEs occurred in 51 patients (14.2%). Of the total

Table 3. Differences in Patient Perception of Intermittent Catheterization questionnaire according to sex, history of intermittent catheterization, and age at 12 and 24 weeks

Question	12 Weeks			24 Weeks		
	Male (n = 94)	Female (n = 170)	P-value	Male (n = 97)	Female (n = 174)	P-value
Q1	89.36%	79.41%	0.079	90.72%	76.44%	0.007
Q2	79.79%	69.41%	0.137	82.47%	71.84%	0.101
Q3	93.62%	86.47%	0.151	91.75%	85.63%	0.279
Q4	82.98%	77.65%	0.608	90.72%	79.31%	0.031
Q5	80.85%	71.76%	0.205	81.44%	73.56%	0.286
Q6	82.98%	72.35%	0.105	85.57%	77.01%	0.182
Q7	79.79%	79.41%	1.000	84.54%	83.91%	1.000
Q8	63.83%	49.41%	0.049	57.73%	54.02%	1.000
	IC history (+) (n = 87)	IC History (-) (n = 177)	P-value	IC history (+) (n = 88)	IC History (-) (n = 183)	P-value
Q1	86.21%	81.36%	0.649	85.23%	79.78%	0.558
Q2	74.71%	72.32%	1.000	78.41%	74.32%	0.925
Q3	93.10%	87.01%	0.273	90.91%	86.34%	0.563
Q4	79.31%	79.66%	1.000	85.23%	82.51%	1.000
Q5	68.97%	77.97%	0.225	72.73%	78.14%	0.651
Q6	75.86%	76.27%	1.000	81.82%	79.23%	1.000
Q7	75.86%	81.36%	0.597	84.09%	84.15%	1.000
Q8	52.87%	55.37%	0.702	50.00%	57.92%	0.438
	< 65 (n = 148)	≥ 65 (n = 116)	P-value	< 65 (n = 152)	≥ 65 (n = 119)	P-value
Q1	83.78%	81.90%	1.000	79.61%	84.03%	0.702
Q2	73.65%	72.41%	1.000	75.00%	76.47%	1.000
Q3	89.86%	87.93%	1.000	88.82%	86.55%	1.000
Q4	83.78%	74.14%	0.108	86.18%	79.83%	0.326
Q5	75.00%	75.00%	1.000	76.32%	76.47%	1.000
Q6	77.70%	74.14%	1.000	80.26%	79.83%	1.000
Q7	79.73%	79.31%	1.000	82.89%	85.71%	1.000
Q8	55.41%	53.45%	1.000	52.63%	58.82%	0.618

Q1, I am willing to continue to use the current catheter; Q2, I find it easy to insert a catheter into the urethra; Q3, I find it easy to remove a catheter from the urethra; Q4, I can easily handle the catheter before it is inserted into the urethra; Q5, I am satisfied with the time consumed to perform catheterization; Q6, I can easily do intermittent catheterization, in general; Q7, I am satisfied with my current catheter; Q8, I do not interfere with my daily life by performing intermittent catheterization; IC, Intermittent catheterization.

AEs, 55 were mild, 15 were moderate, and 13 were severe. The most commonly reported AEs were UTI in 9.72%, gross hematuria in 2.78%, and urethral pain in 1.39%. A total of 7 patients discontinued IC due to AEs.

DISCUSSION

Our study is the first large-scale observational study to evaluate the satisfaction and quality of life after using the SpeediCath in patients with various voiding dysfunction as well as SCI. A few studies have reported that SpeediCath has higher satisfaction than uncoated catheters, but since they were limited to SCI patients. And most of the previous studies have focused on hydrophilic-coated catheters to reduce the risk of UTI and urethral trauma [8-10].

After using SpeediCath for 6 months, the satisfaction rate was 84.1% (Q7 of the PPIC), and 81.6% of patients were willing to continue (Q1 of the PPIC). Responses to Q8 of the PPIC,

Table 4. Intermittent self-catheterization questionnaire at 12 and 24 weeks

Variable	12 Weeks (n = 264)	24 Weeks (n = 271)
Ease of use	67.77 ± 22.02	68.01 ± 22.29
Mean change from baseline[a]	14.33 ± 31.40	13.60 ± 30.01
95% CI	7.64–21.02	7.24–19.96
P-value[b]	< 0.001	< 0.001
Convenience	59.33 ± 27.15	59.50 ± 26.40
Mean change from baseline[a]	20.19 ± 41.22	20.03 ± 40.55
95% CI	11.40–28.97	11.44–28.62
P-value[b]	< 0.001	< 0.001
Discreetness	54.31 ± 25.39	53.98 ± 26.51
Mean change from baseline[a]	20.31 ± 36.12	19.03 ± 35.06
95% CI	12.61–28.01	11.61–26.46
P-value[b]	< 0.001	< 0.001
Psychological well-being	36.92 ± 21.43	38.12 ± 22.06
Mean change from baseline[a]	5.75 ± 28.14	9.66 ± 30.64
95% CI	-0.25 to 11.74	3.17–16.15
P-value[b]	0.009	< 0.001
Total score	54.58 ± 18.16	54.90 ± 18.65
Mean change from baseline[a]	15.14 ± 25.91	15.58 ± 25.95
95% CI	9.62–20.66	10.08–21.08
P-value[b]	< 0.001	< 0.001

Values are presented as mean ± standard deviation.
CI, confidence interval; ISC-Q, Intermittent Self-Catheterization questionnaire.
[a]Comparison of baseline ISC-Q in patients with a history of self-catheterization. [b]Bonferroni correction.

"Performing IC does not interfere with my daily life" indicated that performing self-IC itself is still an uncomfortable behavior that interferes with daily life in about half of patients. In patients who have experience using other types of catheters, less than 50% of patients agreed on Q1, "I am willing to continue to use the current catheter;" Q5, "I am satisfied with the time consumed to perform catheterization;" Q6, "I can easily perform intermittent catheterization, in general;" Q7, "I am satisfied with my current catheter;" and Q8, "Performing IC does not interfere with my daily life." However, the proportion of patients who responded "agree" to all questions except for Q8 at 24 weeks after using SpeediCath increased to as high as 73%–85%. In subgroup analysis, there was no significant difference in all PPIC items between patients with a history of self-IC and those who newly underwent self-IC. Satisfaction was similar when using SpeediCath through the PPIC questionnaire regardless of whether there was experience using other types of catheters in the past.

Through the validated ISC-Q evaluation, patients who had experienced other types of catheters showed improvement in all subscores including ease of use, convenience, discreetness, psychological well-being and total score at 12 weeks and 24 weeks. The majority of patients might use uncoated catheters made of silicone or latex, so changing to a hydrophilic-coated catheter would have affected significant improvement. This study is meaningful in that we focused on quality-of-life evaluation not only for SCI patients but also for many patients who need IC for other diseases.

Age is an important factor to consider when recommending self-IC to patients. Elderly patients have reduced self-care capaci-

Table 5. Intermittent Self-Catheterization Questionnaire for patients with a history of intermittent catheterization according to sex and age at 12 and 24 weeks

Variable	Male	Female	P-value[a]	< 65 yr	≥ 65 yr	P-value[b]
Ease of use						
Baseline	N = 37	N = 51		N = 53	N = 35	
	52.28 ± 21.34	54.84 ± 21.93	1.000	51.47 ± 21.58	57.23 ± 21.47	0.669
Week 12	N = 37	N = 50		N = 52	N = 35	
	68.24 ± 18.48	68.00 ± 21.24	1.000	70.97 ± 19.33	63.84 ± 20.50	0.249
Mean change from baseline	15.96 ± 32.16	13.13 ± 31.1	1.000	19.53 ± 28.83	6.61 ± 33.83	0.119
Week 24	N = 37	N = 51		N = 53	N = 35	
	64.78 ± 20.96	69.24 ± 20.45	0.834	68.93 ± 20.23	65.00 ± 21.38	0.704
Mean change from baseline	12.5 ± 31.59	14.4 ± 29.10	1.000	17.45 ± 29.12	7.77 ± 30.81	0.118

(*Continued*)

ty, and it may be difficult to perform IC on their own due to lack of motivation, decreased ability to deal with new devices, and decreased visual activity [12]. However, functional and cognitive disabilities are factors that affect the ability to perform IC, but age

Table 5. Intermittent Self-Catheterization Questionnaire for patients with a history of intermittent catheterization according to sex and age at 12 and 24 weeks (Continued)

Variable	Male	Female	P-value[a]	< 65 yr	≥ 65 yr	P-value[b]
Convenience						
Baseline	N = 37	N = 51		N = 53	N = 35	
	38.18 ± 32.93	37.01 ± 27.81	1.000	33.25 ± 28.87	43.93 ± 30.67	0.320
Week 12	N = 37	N = 50		N = 52	N = 35	
	52.70 ± 30.81	61.63 ± 26.93	0.371	58.29 ± 28.24	57.14 ± 30.06	1.000
Mean change from baseline	14.53 ± 48.17	24.38 ± 35.16	0.593	24.88 ± 41.96	13.21 ± 39.67	0.395
Week 24	N = 37	N = 51		N = 53	N = 35	
	50.34 ± 31.66	62.75 ± 27.56	0.130	57.55 ± 29.17	57.50 ± 31.21	1.000
Mean change from baseline	12.16 ± 47.00	25.74 ± 34.52	0.283	24.29 ± 39.92	13.57 ± 41.22	0.454
Discreetness						
Baseline	N = 37	N = 51		N = 53	N = 35	
	33.56 ± 24.49	38.81 ± 27.23	1.000	34.12 ± 23.66	40.36 ± 29.37	0.850
Week 12	N = 37	N = 50		N = 52	N = 35	
	53.83 ± 24.93	59.17 ± 26.42	1.000	61.14 ± 23.88	50.60 ± 27.53	0.270
Mean change from baseline	20.27 ± 37.00	20.33 ± 35.84	1.000	27.08 ± 32.71	10.24 ± 39.00	0.064
Week 24	N = 37	N = 51		N = 53	N = 35	
	52.25 ± 28.05	58.09 ± 28.46	1.000	57.94 ± 26.93	52.14 ± 30.26	1.000
Mean change from baseline	18.69 ± 39.17	19.28 ± 32.16	1.000	23.82 ± 32.85	11.79 ± 37.48	0.231
Psychological well-being						
Baseline	N = 37	N = 51		N = 53	N = 35	
	30.63 ± 25.97	22.71 ± 24.87	0.306	22.80 ± 22.22	30.95 ± 29.43	0.738
Week 12	N = 37	N = 50				
	37.61 ± 23.35	27.67 ± 22.79	0.122	32.37 ± 22.86	31.19 ± 24.55	1.000
Mean change from baseline	6.98 ± 32.38	4.83 ± 24.85	0.823	9.46 ± 25.66	0.24 ± 31.03	0.531
Week 24	N = 37	N = 51		N = 53	N = 35	
	33.78 ± 23.11	37.09 ± 22.92	1.000	34.75 ± 22.70	37.14 ± 23.51	1.000
Mean change from baseline	3.15 ± 33.91	14.38 ± 27.4	0.167	11.95 ± 27.96	6.19 ± 34.42	0.911
Total score						
Baseline	N = 37	N = 51		N = 53	N = 35	
	38.66 ± 17.99	38.34 ± 19.56	1.000	35.41 ± 17.79	43.12 ± 19.61	0.204
Week 12	N = 37	N = 50				
	53.10 ± 19.71	54.11 ± 18.18	1.000	55.69 ± 17.41	50.69 ± 20.45	0.591
Mean change from baseline	14.44 ± 28.71	15.67 ± 23.91	1.000	20.24 ± 23.55	7.57 ± 27.7	0.049
Week 24	N = 37	N = 51		N = 53	N = 35	
	50.29 ± 21.00	56.79 ± 19.05	0.401	54.79 ± 19.82	52.95 ± 20.61	1.000
Mean change from baseline	11.63 ± 29.91	18.45 ± 22.53	0.451	19.38 ± 24.81	9.83 ± 26.93	0.182

Values are presented as mean ± standard deviation.
[a]Male vs. female. [b]< 65 yr vs. ≥ 65 yr.

itself does not affect learning or performing IC [13]. Even in the elderly, patients who need self-IC should be actively educated and guided so that they can use convenient catheters [14].

The median age of all patients enrolled in this study was 63 years, and about 50% were 65 years or older. There were no statistically significant differences in PPIC responses according to age, and age did not seem to be an obstacle in terms of satisfaction and ease of use in elderly patients over 65 years. For those who had experience with other types of catheters, changes of ISC-Q at 12 weeks and 24 weeks from baseline, which was evaluated on past experiences before using SpeediCath, were evaluated. At 12 weeks, improvement of the ISC-Q total score was significantly higher in <65 years than compared with patients aged 65 years or older, but statistical significance was not maintained at 24 weeks. And, in patients over 65 years, improvement of the ISC-Q subscale at 12 weeks and 24 weeks compared to baseline showed a tendency to be less than that of those under 65, but the difference was not significant, likely due to the relatively lower baseline value of each subscore in patients under 65 years. There was no difference in the subscores at 12 weeks and 24 weeks, and all patients showed a tendency to improve after changing to SpeediCath. That is, age was not an impediment to IC performance, and satisfaction and ease of use obtained by using hydrophilic-coated catheter was considered to be a more important variables in maintaining long-term adherence to IC.

Parsons et al. [15] reported an 88% success rate of self-IC for men and a 76% success rate for women. When we analyzed the difference in PPIC according to sex, the proportion of men who answered that "Performing IC does not interfere with my daily life" (Q8) at 12 weeks and "I am willing to continue to use the current catheter" (Q1) and "I can easily handle the catheter before it is inserted into the urethra" (Q4) at 24 weeks was higher than that of women. In women, it is more difficult than men to perform self-IC because the urethral meatus is not clearly visible. The differences between males' and females' answers are believed to be due to difficulties in performing catheterization due to anatomical perineum access difficulties. There is no statistically significant difference in all subscores including ease of use, convenience, discreetness, psychological well-being and total score, the difference in ISC-Q between men and women at each time point, or in the mean change from the baseline. Both men and women showed similar good quality of life.

This study had some limitations. The PPIC for evaluating the primary endpoint was a tool made by the researcher and was not universally used. However, to overcome this limitation, ISC-Q, which is a validated, IC-specific questionnaire, was used as an evaluation tool, and further subgroup analysis was performed according to age and sex. Second, in the case of patients undergoing self-IC, it was difficult to know what type of initial catheter was used in about 15% of patients, and it was possible that a different type of hydrophilic-coated catheter was used in very few patients. Third, various factors affect quality of life, and prostate size is estimated to be an influencing factor in male patients as well as the frequency of IC, but the size of the prostate and the frequency of using SpeediCath during the study was difficult to analyze, as these were not included in the protocol of this study.

In conclusion, after 24 weeks of using SpeediCath for patients who have experience the IC with other types of catheters or who started IC at first, satisfaction with SpeediCath was as high as 84%, and 82% of patients wished to continue using it. In addition, patients over 65 years of age showed a similar level of satisfaction and quality of life. Male patients were more satisfied than female patients in handling the catheter before insertion into the urethra, but overall quality of life was good with no differences by sex. The recommendation of SpeediCath for patients who need long-term self-IC in various underlying diseases is expected to play an important role in maintaining good adherence.

ACKNOWLEDGEMENTS

This study was funded by Coloplast A/S. The authors would like to thank Khae Hawn Kim (Chungnam National University Sejong Hospital), Joon Chul Kim (Bucheon St. Mary's Hospital), Sae Woong Kim (Seoul St. Mary's Hospital), Seungju Lee (St. Vincent's Hospital), Young-Seop Chang (Konyang University Hospital), Joon Hwa Noh (Kwangju Christian Hospital), Dong Gil Shin (Pusan National University Hospital,), Young-Suk Lee (Samsung Changwon Hospital), Ji-Yeon Han (Seongnam Citizens Medical Center), Hee Chang Jung (Yeungnam University Medical Center), Donghyun Lee (Ewha Womans University Mokdong Hospital), Ju Hyun Shin (Chungnam National University Hospital) for performing the study.

AUTHOR CONTRIBUTION STATEMENT

· Conceptualization: *KJK, KSL*
· Data curation: *MSC, SOK, JHK, KJC, ESY, MKK, WJC, JBC*

· Formal analysis: *KJK, JL*
· Funding acquisition: *KSL*
· Methodology: *KJK, KSL*
· Project administration: *KSL*
· Visualization: *KJK*
· Writing - original draft: *KJK*
· Writing - review & editing: *KJK, JL, KSL*

ORCID

Kwang Jin Ko	0000-0003-1085-1266
Myung-Soo Choo	0000-0002-3293-4751
Sun-Ouck Kim	0000-0002-5832-8303
Jang Hwan Kim	0000-0002-9056-7072
Kyung Jin Chung	0000-0003-0153-7814
Eun Sang Yoo	0000-0002-7442-6886
Myung Ki Kim	0000-0001-7361-6242
Won jin Cho	0000-0001-9827-5173
Jong Bo Choi	0000-0002-6474-9913
Jihwan Lee	0000-0001-8242-1551
Kyu-Sung Lee	0000-0003-0891-2488

REFERENCES

1. Ginsberg DA, Boone TB, Cameron AP, Gousse A, Kaufman MR, Keays E, et al. The AUA/SUFU guideline on adult neurogenic lower urinary tract dysfunction: treatment and follow-up. J Urol 2021;206:1106-13.
2. Kessler TM, Ryu G, Burkhard FC. Clean intermittent self-catheterization: a burden for the patient? Neurourol Urodyn 2009;28:18-21.
3. Panicker JN, de Sèze M, Fowler CJ. Rehabilitation in practice: neurogenic lower urinary tract dysfunction and its management. Clin Rehabil 2010;24:579-89.
4. Wyndaele JJ. Intermittent catheterization: which is the optimal technique? Spinal Cord 2002;40:432-7.
5. Woodward S, Rew M. Patients' quality of life and clean intermittent self-catheterization. Br J Nurs 2003;12:1066-74.
6. Turi MH, Hanif S, Fasih Q, Shaikh MA. Proportion of complications in patients practicing clean intermittent self-catheterization (CISC) vs indwelling catheter. J Pak Med Assoc 2006;56:401-4.
7. Seth JH, Haslam C, Panicker JN. Ensuring patient adherence to clean intermittent self-catheterization. Patient Prefer Adherence 2014;8:191-8.
8. Cardenas DD, Moore KN, Dannels-McClure A, Scelza WM, Graves DE, Brooks M, et al. Intermittent catheterization with a hydrophilic-coated catheter delays urinary tract infections in acute spinal cord injury: a prospective, randomized, multicenter trial. PM R 2011;3:408-17.
9. De Ridder DJ, Everaert K, Fernández LG, Valero JV, Durán AB, Abrisqueta ML, et al. Intermittent catheterisation with hydrophilic-coated catheters (SpeediCath) reduces the risk of clinical urinary tract infection in spinal cord injured patients: a prospective randomised parallel comparative trial. Eur Urol 2005;48:991-5.
10. Cardenas DD, Hoffman JM. Hydrophilic catheters versus noncoated catheters for reducing the incidence of urinary tract infections: a randomized controlled trial. Arch Phys Med Rehabil 2009;90:1668-71.
11. Kang SH, Oh SJ, Jeong SJ, Cho SY. Linguistic validation of the Intermittent Self-catheterization Questionnaire for patients with neurogenic bladder who perform intermittent catheterization for voiding dysfunction. Int Neurourol J 2019;23:75-85.
12. Borg C, Hallberg IR, Blomqvist K. Life satisfaction among older people (65+) with reduced self-care capacity: the relationship to social, health and financial aspects. J Clin Nurs 2006;15:607-18.
13. Hentzen C, Haddad R, Ismael SS, Peyronnet B, Gamé X, Denys P, et al. Intermittent self-catheterization in older adults: predictors of success for technique learning. Int Neurourol J 2018;22:65-71.
14. Pilloni S, Krhut J, Mair D, Madersbacher H, Kessler TM. Intermittent catheterisation in older people: a valuable alternative to an indwelling catheter? Age Ageing 2005;34:57-60.
15. Parsons BA, Narshi A, Drake MJ. Success rates for learning intermittent self-catheterisation according to age and gender. Int Urol Nephrol 2012;44:1127-31.