Spinal Cord (2011) 49, 817–821

www.nature.com/sc

ORIGINAL ARTICLE

Clinical evaluation of a newly developed catheter (SpeediCath Compact Male) in men with spinal cord injury: residual urine and user evaluation

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Objective: To evaluate the performance of a new 30-cm-long, telescoping male intermittent catheter (SpeediCath Compact Male; Coloplast A/S, Humlebæk, Denmark) in urinary bladder emptying, safety and subject acceptance vs a standard-length male intermittent catheter (SpeediCath).
Materials and methods: In a prospective, randomized, multicenter, crossover non-inferiority study, 37 male intermittent catheter users self-catheterized three times with the test catheter on one test day and three times with the standard-length male (reference) catheter on another test day. Residual urine (RU) volume in the bladder after catheterization was measured by ultrasound. Safety was assessed in the entire study period in terms of adverse events (AEs) and adverse device events (ADEs). Subjects evaluated their experience, sensation, disposal, bleeding and discomfort with the test and reference catheters and final catheter preference.
Results: SpeediCath Compact Male did not differ from the reference catheter in terms of performance (bladder emptying). The upper confidence limit of the mean difference between absolute RU volumes for the test and reference catheter groups did not exceed a pre-established non-inferiority limit of 20 ml, thereby showing the test catheter's non-inferiority to the reference catheter (that is, no worse at bladder emptying). The only AE/ADE reported was one instance of mild urethral burning for 30 min after catheterization, which was judged possibly related to the test catheter but resolved quickly.
Conclusions: The SpeediCath Compact Male catheter is as efficient as a conventional intermittent catheter (SpeediCath) at emptying the bladder with the additional benefit of being more discreet and easier to use.
Spinal Cord (2011) **49**, 817–821; doi:10.1038/sc.2011.14; published online 1 March 2011

Keywords: intermittent catheterization; male; residual urine; ultrasound

Introduction

Intermittent catheterization is the preferred method of bladder emptying for people with spinal cord lesions and neurogenic bladder dysfunction.[1] The male urethra has an average length of 223 mm (range 150–290 mm),[2] but existing male intermittent catheters range in length from 340 to 500 mm.[3] A newly marketed intermittent catheter, the SpeediCath Compact Male (Coloplast A/S, Humblebaek, Denmark), is a 30-cm-long sterile, ready-to-use, hydrophilic-coated catheter constructed in two parts using the telescope antenna principle. Shorter catheters may allow more discreet use, an attribute that has been identified as important by users of intermittent catheters.[4] The aim of this study was to evaluate the SpeediCath Compact Male catheter in terms of its performance, safety and subject acceptance when compared with a standard-length male intermittent catheter.

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Received 2 October 2010; revised 20 January 2011; accepted 26 January 2011; published online 1 March 2011

Materials and methods

Subjects

Thirty-seven male intermittent catheter users who were at least 18 years old and able to self-catheterize were included in the study. All had used hydrophilic-coated intermittent catheters for at least 1 month before the study. Exclusion criteria were symptoms of urinary tract infection and known abnormalities in the lower urinary tract. Subjects were

recruited at three participating study sites in Germany. All participating subjects were followed regularly at those sites as defined per study protocol. All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this study. The study was approved by the local ethics committee, and all subjects gave their oral and written informed consent before being enrolled in the study.

Study design
The study was carried out according to a crossover design, in which the subjects were randomized in permuted blocks. One block started with the test catheter (SpeediCath Compact Male), and the other block started with the reference standard-length catheter (SpeediCath straight Ch12; Coloplast A/S).

Sample size
Assuming a non-inferiority limit of a ±20-ml difference in RU volume and an estimated corresponding standard deviation of 4.7 ml (derived from a previous study[4]), the estimated required sample size for this crossover non-inferiority trial (one-sided significance level, 2.5%; power, 90%) was six subjects per sequence group. It was decided, however, to include approximately 36 subjects (to collect evaluable test results from 30 subjects) so that the study could be considered safe against inexact assumptions and provide enough power to allow for the reliable testing of secondary end points. The non-inferiority limit (margin) of a ±20-ml difference in RU volume has been established as it is well known that intermitted catheters do not always completely empty the bladder.[5] Furthermore, a ±20-ml difference in RU volume is considered below the limit of clinical relevance.[6]

Catheters
The test catheter, the SpeediCath Compact Male, is a newly developed, ready-to-use, hydrophilic-coated disposable intermittent catheter for men (Figure 1). The catheter, including the connector, is 34 cm long. The actual catheter length is 30 cm, including a 17.5-cm-long flexible proximal part (inner catheter) and a 12.5-cm-long rigid distal part (outer catheter). The inner and outer parts are Ch12 and Ch18 in diameter, respectively.

The reference catheter was the SpeediCath straight Ch12.

Study procedure
The study included three visits at the investigational site: baseline visit, test day 1 (crossover visit) and test day 2 (termination visit). At the baseline visit, written informed consent was obtained, inclusion/exclusion screening was performed and baseline information was collected. To familiarize themselves with the study catheters, subjects also received a box containing 30 test catheters or reference catheters (according to randomization) and were instructed to use them before test day 1 at which they crossed over to the other catheter. The three visits were separated by 5–8 days during which the subjects performed 30 intermittent catheterizations with the relevant catheter. On each of the two test days, the subjects catheterized themselves three times according to their usual procedure with the catheter they had used the preceding 5–8 days. The study nurse was not present during the catheterization so as to remain blinded to the type of catheter used. Before each bladder emptying, the volume of urine in the bladder was measured in triplicate by means of ultrasound. Immediately after bladder emptying, the amount of residual urine (RU) was measured in triplicate by means of ultrasound. The study nurse also measured the amount of urine emptied from the bladder. The study nurse remained blinded to the intervention throughout all measurement procedures.

Figure 1 Drawing of SpeediCath Compact Male catheter.

Ultrasound scanning
All ultrasound measurements were performed on supine subjects by an experienced nurse. Ultrasound measurement of RU has previously been found to be a reliable method, with a good correlation ($r = 0.97$) between ultrasound-estimated volumes and post-scan bladder volumes obtained by catheterization.[7–9]

Safety
Subjects were monitored for the occurrence of adverse events (AEs) and adverse device events (ADEs) during the entire period in which they used each catheter (that is, 6–9 days including the test day). An AE was defined as any untoward medical occurrence in a subject. An ADE was defined as any untoward and unintended response to a medical device (that is, the test or reference catheter). No urinary tract infections were recorded during the study.

Questionnaire
Each subject filled out questionnaires with regard to his intermittent catheterization history; experience, sensation, disposal, bleeding and discomfort with the test and reference catheters; and final preference for either the test or reference catheter.

Statistical analyses
Three measurements were obtained for each catheterization: (i) the volume in the bladder before catheterization measured in triplicate by means of ultrasound; (ii) the volume of urine emptied by the catheter; and (iii) the volume of RU after catheterization measured in triplicate by means of ultrasound. The mean of the results of the triplicate measurements was used for further evaluations. These measurements were obtained for all three catheterizations performed with each catheter type. The primary performance end point was defined as the overall mean of the three absolute RU volumes (catheterizations 1–3) on each test day. The secondary performance end point was defined

as the median of the three absolute RU volumes (catheterizations 1–3) on each test day.

A non-parametric model for a two-period crossover design based on the Wilcoxon signed-rank test was used to analyze the primary end point. Within this model, the non-inferiority hypothesis was tested by calculation of a non-parametric 95% confidence interval (CI) according to Hodges–Lehman for the median difference between catheters in mean absolute RU volume. Non-inferiority of the test catheter to the reference catheter was concluded if the upper bound of the CI was less than 20 ml. The secondary end point was analyzed in the same way.

The incidence rates of AEs and ADEs were determined for each device group.

Subject evaluations of experience, sensation, disposal and bleeding for both the test and reference catheters were tabulated. A two-sided *t*-test and corresponding 95% CI were used to compare the rating of overall discomfort, as captured on a 100-mm visual analogue scale, for the test and reference catheters. Point estimates and exact 95% CIs for binomial proportions were used to compare evaluations of subject preference by device type.

Results

Subjects and catheterization history

The mean age of subjects was 40 years (range, 21–66 years). Of the 37 subjects enrolled in the study, 20 subjects were classified on the American Spinal Injury Association impairment scale as A, 9 as B, 3 as C and 5 as D. All of the included subjects had paraplegia, none had tetraplegia (paraplegia defined as sensory or motor level left or right at T1 and below, tetraplegia defined as sensory or motor level left or right at C8 and above). The mean duration of intermittent catheterization use was 88.76 months (range, 2–264 months). The mean number of catheterizations per day was 5.32 (range, 4–10). The brands of catheters used by the subjects before this study included SpeediCath ($n=10$ subjects), LoFric H_2O ($n=8$), LoFric ($n=7$), Easicath ($n=3$), LoFric Plus ($n=1$), uncoated catheter ($n=1$) and other ($n=10$). (Note that three subjects reported using two different types of catheters.) The most commonly used catheter size was Ch14 ($n=30$), followed by Ch12 ($n=5$), Ch10 ($n=1$) and Ch16 ($n=1$).

Subject disposition

One subject who had been randomized to use the test catheter first and the reference catheter second withdrew from the study on the day of randomization because he did not consider the catheter material flexible enough. This resulted in a total of 36 subjects evaluable for performance. No protocol violations or deviations were reported.

RU volume after catheterization

For all evaluable subjects, the mean of the mean absolute RU volumes measured by ultrasound bladder scanning after intermittent catheterization with the test and reference catheters (primary end point) was 12.44 vs 9.35 ml, respectively (Table 1). As shown by the Hodges–Lehmann procedure, the 95% CI for the median difference between the two catheters in mean absolute RU volume was −1.94 to 7.72 ml. Non-inferiority of the test catheter to the reference catheter was assumed as the upper confidence limit for the difference did not exceed 20 ml. The range of RU volume was 0–62.33 ml with the test catheter and 0–42.89 ml with the reference catheter.

Table 1 Mean RU volumes and median difference in RU volume by means of ultrasound after three catheterizations with each catheter type

Parameter evaluated	*Catheter*[a]	
	Test	*Reference*
Mean RU volume (s.d.) (ml)	12.44 (15.66)	9.35 (11.43)
Range (ml)	0–62.33	0–42.89
Median difference between the catheters (ml)	2.06	
95% confidence interval	−1.94, 7.72	

Abbreviation: RU, residual urine.
[a]Test catheter = SpeediCath Compact Male; reference catheter = SpeediCath straight Ch12.

For all evaluable subjects, the mean of the median absolute RU volumes after intermittent catheterization with the test and reference catheters (secondary end point) was 8.57 vs 7.034 ml, respectively. As shown by the Hodges–Lehman procedure, the 95% CI for the median difference between catheters in median absolute RU volume was −2.33 to 4.50 ml. Again, non-inferiority of the test catheter to the reference catheter was assumed as the upper confidence limit for the difference did not exceed 20 ml.

Safety

Safety was assessed for the entire period during which the subjects used the catheter, that is, 6–9 days including the test day. In this period, 36 subjects performed 30 catheterizations each, which means that safety was assessed based on 1080 catheterizations.

One subject (American Spinal Injury Association level A, paraplegia) experienced burning in the urethra for 30 min after catheterization with the test catheter. This event did not take place every time and was considered mild and possibly related to the device. It was resolved on the same day it started and was judged by the investigator to be both an AE and ADE. No other AEs or ADEs and no SAEs or deaths were reported. No urinary tract infections were recorded during the study.

User evaluation

The results of the subject evaluations with regard to the use of the test and reference catheters are summarized in Tables 2 and 3.

Experience was evaluated in terms of catheter insertion and control (Table 2). Catheter control during insertion was considered significantly easier in the test catheter group

Table 2 User evaluation of test and reference catheter for all 36 evaluable subjects: experience, sensation, disposal and bleeding

Parameter evaluated	*Catheter*[a]		P-*value*[b]
	Test	*Reference*	
Experience			
How did you experience the insertion of the catheter?			0.1826
Very easy or easy	28	27	
Not easy nor difficult	5	3	
Difficult or very difficult	3	6	
How did you experience the control of the catheters during insertion?			<0.0001
Very easy or easy	32	18	
Not easy nor difficult	2	10	
Difficult or very difficult	2	8	
Sensation			
Did you experience pain during insertion of the catheters?			0.4375
No	33	34	
Yes, mild or moderate	1	2	
Yes, severe	2	0	
Did you experience stinging during insertion of the catheters?			0.5000
No	31	33	
Yes, mild or moderate	5	3	
Yes, severe	0	0	
Did you experience resistance during insertion of the catheters?			0.8604
No	22	19	
Yes, mild or moderate	11	15	
Yes, severe	3	2	
Discretion			<0.0001
How did you experience the disposal of the catheters?			
Very easy or easy	29	20	
Not easy nor difficult	7	12	
Difficult or very difficult	0	4	
How did you experience the overall discretion of the catheters?			<0.0001
Very easy or easy	26	15	
Not easy nor difficult	8	13	
Difficult or very difficult	2	8	
Bleeding			NA
Did you observe visible bleeding during the catheterizations?			
No	34	36	
Yes	2	0	

Abbreviation: NA, not applicable.
[a]Test catheter = SpeediCath Compact Male; reference catheter = SpeediCath straight Ch12.
[b]Wilcoxon's signed-rank test.

($P<0.0001$). No difference was found between catheters with respect to the experience of catheter insertion. It is worth noting that most users in both groups found both insertion and control during insertion 'very easy' or 'easy'.

Sensation was evaluated in terms of pain, stinging and resistance during catheter insertion (Table 2). In both device groups, the majority of users experienced no pain, no stinging and no resistance. No statistical differences were found between the two catheters.

Discretion was evaluated in terms of catheter disposal and overall discretion (Table 2). The users found disposal of the test catheter significantly easier than the reference catheter ($P<0.0001$). Furthermore, the test catheter was considered more discreet ($P<0.0001$).

Bleeding was evaluated in terms of visibility. Two subjects (both American Spinal Injury Association level A, paraplegia) reported one bleeding episode each during the period in which they used the test catheter: one was a trace of blood at the catheter tip and the other was a small coagulum in the urine. In both cases, the urine stayed clear. For each of the two subjects, bleeding occurred only once during the study period. The bleeding episodes were considered to be minor and were not reported as AEs.

Discomfort was evaluated in terms of subjects' visual analogue scale scores on a 100-mm scale, where 0 mm = no discomfort and 100 mm = worst discomfort imaginable (Table 2). The mean (s.d.) visual analogue scale scores for the test and reference catheter groups were 10.1 (16.65) vs 6.8 (9.77) mm, respectively. The difference was not statistically significant ($P=0.30$, two-sided *t*-test). Hence, the discomfort experienced using the SpeediCath Compact Male was found to be at the same level as that experienced using the reference catheter.

Overall, more subjects preferred the test catheter (Table 2) over the reference catheter (61.1%, 22/36; 95% CI, 43.5–76.9%), but this finding was not significant ($P=0.24$, two-sided *t*-test). Similar preference was seen within each treatment sequence: 64.7% (11/17) for subjects who used the test catheter first and reference catheter second and 57.9% (11/19) for subjects who used the reference catheter first and test catheter second.

Discussion

RU volume after catheterization

This study is the first to investigate the performance of a newly developed hydrophilic-coated 30-cm-long intermittent catheter for men, the SpeediCath Compact Male. This catheter is shorter than existing intermittent catheters, but still long enough to traverse the normal male urethra.[2] We have shown that the SpeediCath Compact Male is non-inferior to a standard-length intermittent catheter at emptying the bladder in men. The maximal residual volumes seen in this study (62.33 ml for the test catheter and 43.89 ml for the reference catheter) did not exceed what was to be expected based on previous studies.[5]

Safety

We have shown the SpeediCath Compact Male to be safe. The one AE/ADE reported was a single instance of mild burning in the urethra for 30 min after catheterization, which was judged possibly related to the test catheter but resolved quickly. Of the over 1080 SpeediCath Compact Male catheterizations performed in this study, two resulted in a minor bleeding episode (not reported as AE), reflecting a risk of less than 1%. Long-term studies are required to assess long-term complications such as urethral strictures.

Table 3 User evaluation of test and reference catheter for all 36 evaluable subjects: discomfort and catheter preference

Parameter evaluated	*Catheter*[a]		P-*value*
	Test	*Reference*	
Visual analogue scale score (mm)[b]			
Mean (s.d.)	10.111 (16.6489)	6.778 (9.7691)	0.30[c]
Median (minimum, maximum)	3.00 (0.00, 72.00)	4.00 (0.00, 48.00)	
Which device did you prefer?			
n	22	14	0.24[c]
% (95% confidence interval)	61.1 (43.5, 76.9)	38.9 (23.1, 56.5)	

[a]Test catheter = SpeediCath Compact Male; reference catheter = SpeediCath straight Ch12.
[b]Per study protocol, subjects were asked to rate discomfort. These ratings were marked on a 100-mm VAS scale, where 0 mm corresponds to 'No Discomfort' and 100 mm corresponds to 'Worst Discomfort Imaginable'.
[c]Two-sided *t*-test.

User evaluation
Most subjects considered the SpeediCath Compact Male easy to use and dispose, comfortable and discreet. Sixty-one percent (22/36) preferred it over the reference catheter.

The SpeediCath Compact Male offers a safe, effective and discreet alternative to longer intermittent catheters for men who depend on them in their daily lives. Nevertheless, any choice between intermittent catheters must take into account each individual's requirements or needs.[10]

Conclusion

Our results show that the SpeediCath Compact Male catheter is non-inferior to (no worse than) a conventional intermittent catheter at emptying the bladder in men. Furthermore, it is safe, easy to use, comfortable and discreet.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

Premier Research Group Limited contributed to the writing of this manuscript. This study was funded by Coloplast A/S. Drs B Domurath, J Kutzenberger, I Kurze and A Kaufmann (Kliniken Maria Hilf, Mönchengladbach, Germany) were investigators in the study and received research funding from Coloplast A/S; ClinicalTrials.gov registry number: NCT 01048541.

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