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SINGLE-USE HYDROPHILIC COATED INTERMITTENT CATHETERS IMPROVE QUALITY OF LIFE: REPORT FROM A CLINICAL TRIAL ON CATHETER REUSE IN THE UNITED STATES.

Hypothesis / aims of study
Intermittent catheterization (IC) is a common therapy for people with neurogenic lower urinary tract dysfunction (NLUTD). Reuse of urethral catheters for IC is common in different regions depending on healthcare system1. Both off label reuse, i.e. reuse of devices intended for single-use (e.g uncoated Polyvinyl choride) and reuse of devices labeled and intended for multiple use (e.g silicon, glass or stainless steel) exist [1] [2]. Off label reuse is not supported by legal requirements or recommended in guidelines and there are general safety concerns related to reuse due to changed physical properties of the catheter material and risk for bacterial contamination due to suboptimal cleaning and re-sterilization. At present, there is an ongoing debate whether catheter reuse is as safe as single-use catheterization as there is a general lack of clinical evidence. The objectives of this study were to explore real life patient-related clinical data on safety and satisfaction of reuse vs. single-use catheters for IC.

Study design, materials and methods

This was a prospective, multi-center, clinical trial conducted in the United States.(U.S.) and in Australia. The set-up was similar in both countries and was conducted as a twin study. Sample size was set to 20 patients per country, considering comparisons of proportions between reuse vs. single-use catheters of approximately 60% vs. 10% (90% power, 5% 2-sided level of significance). The target population was patients who currently practiced catheter reuse, and who agreed to prospectively evaluate single-use hydrophilic-coated (HC) catheters for 4 weeks. Patient reported outcomes and the validated Intermittent Self-Catheterization Questionnaire (ISC-Q) were used to study patient satisfaction and quality of life (QoL) [3]. Safety measures included bacteria contamination of reused catheters and urethral complications.

Results
Recruitment was challenging as few patients practiced catheter reuse and among those who did, many were ineligible due to prophylactic antibiotic use. The Australian cohort is under its final closure stage and the U.S. cohort is completed. The latter consisted of 21 patients (67% male, 33% females), mean age 55 (SD = 13), who practiced IC due to non-neurogenic or NLUTD. The majority (81%) had normal hand function and had practiced IC for a mean time of 7 years (SD = 8). All practiced self-catheterization at least 4 times/day. Urethral sensitivity was normal in 33%, reduced in 38%, and lacking in 29%. At inclusion, all patients reused catheters for a mean of 10 days (SD = 20) per catheter.

In the U.S., a total of 19 patients completed the prospective test period and the ISC-Q score increased by 11.4 (SD = 21.1) units (p = 0.0204) when patients switched to the single-use HC catheters. This corresponds to a 20% increase in health related QoL. Patient reported outcomes on the two catheter techniques are specified in Table 1. At the end of the study, 89% preferred to continue using single-use HC catheters.

Safety measures showed that 19 out of the 21 (90%) collected reused catheter samples were contaminated by bacteria and biofilms were identified in 6 samples (29%). See example in Figure 1. The most common reported species were Enterococcus faecalis, Staphylococcus epidermidis and Klebsiella pneumoniae. At the start of the study, 62% of the patients reported to have experienced urological complications in the last 12 months, mainly urinary tract infections (UTI). During the prospective test period, 79% did not experience any urological complications.

Interpretation of results
Preliminary results from the U.S. cohort show that in this study, the majority of patients preferred performing catheterization with single-use HC catheters. Single-use HC catheters also seem associated with a higher QoL in this study population of men and women practicing IC. Based on these results, clinicians should prescribe single-use IC and HC catheters should be the first and standard choice for catheter type. Catheter reuse pose a potential patient safety issue as almost every collected reused catheter were found to be contaminated with bacteria and occurrence of a biofilm was common.

Concluding message
Single-use HC catheters improved QoL and were preferred over catheter reuse among people practicing IC. Catheter reuse poses a potential patient safety concern.

Table 1. Patient reported outcomes

	Reuse catheter (n = 21)	Single-use hydrophilic catheter (n = 19)	p-value[1]
Sensation during catheterization, n (%)			**0.0361**
- Comfortable	**2 (9.5%)**	**5 (26.3%)**	
- No discomfort	**8 (38.1%)**	**8 (42.1%)**	
- Slight discomfort	**8 (38.1%)**	**6 (31.6%)**	
- Slight pain	**2(9.5%)**	-	
- Disturbing pain	**1 (4.8%)**	-	
Satisfaction, n (%)			**0.0008**
- Very satisfied	**3 (14.3%)**	**12 (63.2%)**	
- Satisfied	**6 (28.6)**	**6 (31.6%)**	
- Neutral	**9 (42.9%)**	**1 (5.3%)**	
- Not satisfied	**2 (9.5%)**	-	
- Absolutely not satisfied	**1 (4.8%)**	-	

[1]p-value calculated with non-parametric tests for paired observations, i.e. Wilcoxon signed rank tests for paired observations.
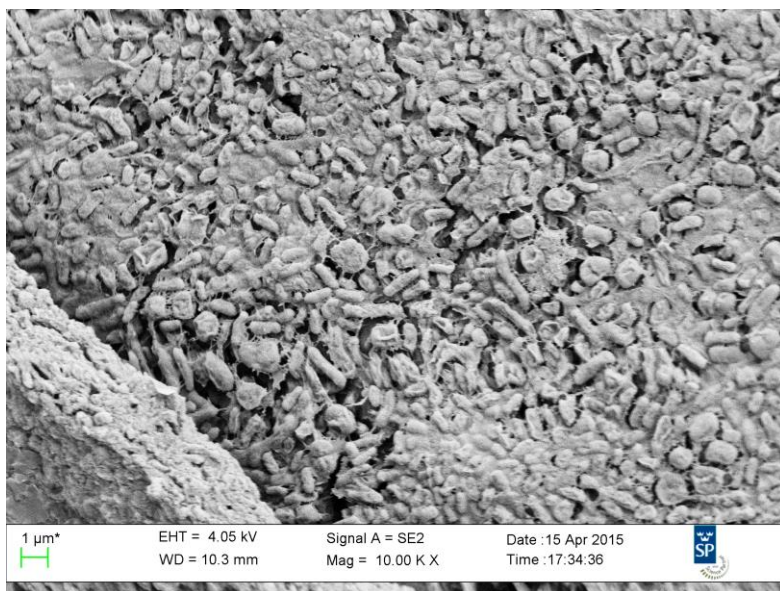

Figure 1. Bacteria contamination and occurrence of biofilm in reused catheter.

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