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ORIGINAL RESEARCH ARTICLE

A prospective randomised pilot study evaluating the safety of the novel LubriShield™ Foley catheter: a permanently coated indwelling urinary catheter

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ABSTRACT

Objective: Catheter-associated urinary tract infections (CAUTIs) are prevalent healthcare-associated infections, arising from biofilm-forming bacteria. This may be prevented by coating the catheter with an antifouling substance. The novel LubriShield™ Foley catheter is coated with a superhydrophilic surface and a covalently bonded antifouling ligand. Preclinical studies revealed that the coating established a persistent local antifouling environment, inhibiting uropathogenic bacteria from forming biofilms. No substance release has been detected from the coating. The coating achieved a 28-fold reduction in surface friction compared to an uncoated catheter. The aim of this study is to assess the clinical safety of the catheter in patients.

Materials & methods: In a prospective single-centre randomised study, 30 patients undergoing transurethral resection of bladder tumour were enrolled and randomly assigned to receive either a standard control catheter or the novel LubriShield™ catheter. Urinary cultures were obtained twice. The duration of catheterisation for the patients ranged from 3 to 24 h. The primary outcome was the assessment of device-specific adverse events (AEs). Secondary outcomes included evaluations of pain, irritation and discomfort, measured using the Numeric Rating Scale (NRS) (0–10) via a patient questionnaire.

Results: There were no serious adverse events (SAEs) or AEs reported for the coated catheters. Urinary cultures showed no significant differences between the coated and uncoated catheters. Both patients and healthcare professionals rated the NRS equally for the two types of catheters.

Conclusions: The novel-coated LubriShield™ catheter was found to be safe for short-term clinical use.

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Introduction

Urinary tract infections (UTIs) are among the most common infections globally [1, 2]. During hospitalisation, 10%–25% of patients receive an indwelling urinary catheter, and of these, approximately 20% develop catheter-associated UTIs (CAUTIs) [3, 4]. 7% of all patients in nursing homes have an indwelling catheter [5]. Biofilm formation, often involving *Escherichia coli* (*E. coli*) or other uropathogens, plays a pivotal role in CAUTI development and can lead to complications such as pyelonephritis, urosepsis and epididymitis [6, 7].

Silver-coated catheters are the most commonly used antimicrobial option to reduce CAUTI risk during long-term catheterisation (> 14 days) [8], but concerns about silver toxicity, environmental impact and antimicrobial resistance highlight the need for safer alternatives [9, 10].

Superhydrophilic surfaces represent a promising non-antimicrobial strategy to prevent fouling by forming a water barrier that inhibits contamination [11–13], and by reducing extracellular polymeric substances (EPS) secretion in both Gram-positive and Gram-negative bacteria, they weaken biofilm formation and increase bacterial susceptibility to antibiotics [14–17].

The LubriShield™ Foley catheter is coated with a permanently bonded superhydrophilic polyacrylic acid hydrogel, integrated with a proprietary antifouling ligand designed to prevent microbial biofilm formation without the use of antimicrobial agents. The coating is applied via a UV-induced polymerisation process to both inner and outer surfaces of the catheter shaft, as well as the outer surface of the balloon. It remains stable, non-toxic and free from antibacterial agents, ensuring it does not disrupt healthy microbial flora. *In vitro* testing confirmed the coating's integrity using gas chromatography–mass spectrometry (GC-MS) with no release of coating components. The LubriShield™ catheter significantly reduces surface friction – exhibiting a coefficient of friction (CoF) 28 times lower than the control catheter [18, 19]. These properties contribute to the coating's antifouling effect and may help preserve the integrity of the surrounding mucosa during short-term use [17–19].

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The novel catheter has never been tested in human subjects even though it has shown promising results *in vitro*. All coated catheters need to be assessed regarding safety. A short-term safety study was based on the hypothetical risk that the LubriShield™ coating may induce immunologic or toxic mucosal reactions. Experimental data suggest that significant biofilm formation does not occur before 24 h of catheter exposure. Thus, it is unlikely that this should influence short-term safety [20].

The aim of the present pilot study was to evaluate short-term safety and tolerability of the novel LubriShield™ Foley catheter in patients undergoing transurethral resection of bladder tumour (TURBT). Demonstrating its safety is a critical step before assessing its efficacy in further clinical studies. We hypothesised that the LubriShield™ Foley catheter would be safe and as well tolerated as a standard Foley catheter.

Materials and methods

Study population

This study was conducted at the Department of Urology, Sahlgrenska University Hospital, Gothenburg, Sweden, from February to November 2024 (ClinicalTrials.gov (ID: NCTC 06242600)).

Catheter usage

The control catheter was a standard, uncoated CE-marked 2-way Foley catheter (Sterimed Group, India) made of 100% medical-grade silicone. The investigational catheter (LubriShield™, Cytacoat AB, Sweden) was identical in design and base material, with the exception of its permanently bonded hydrophilic coating. Both catheters were used per standard insertion and removal procedures.

Patients and study design

This single-blinded, randomised study included 30 TURBT patients requiring short-term catheterisation (< 24 h). Patients were randomised 1:1 using block randomisation without stratification. The randomisation was generated via Sealed Envelope Ltd. 2022 (www.sealedenvelope.com/simple-randomiser/v1/lists), v1.23.0 [21]. The randomisation code was generated using SAS software. The catheters were inserted by 6 different urologists, all competent in the field of catheterisation.

Inclusion and exclusion criteria

Inclusion criteria: Adults aged 18–84 years, requiring a Foley catheter post-TURBT surgery, fluent in Swedish, capable of providing informed consent and able to produce a voided urine sample.

Exclusion criteria: Pregnant or breastfeeding women, immunocompromised individuals, those unable to provide informed consent, or patients with known bacteriuria, UTIs, bloodstream infections, or infections requiring prolonged antibiotic treatment. Patients requiring a Tiemann tip Foley catheter, previously enrolled in this study, or participating in concurrent clinical trials affecting the primary endpoint were also excluded.

All participants provided written informed consent. Urinary cultures were analysed pre- and post-catheterisation, with a bacterial growth of $\geq 10^5$ CFU/ml considered positive. The duration of catheterisation ranged from 3 to 24 h. We chose catheterisation time due to practical reasons, and the patients included were either to be admitted the same day and have the catheter removed as soon as possible or stay as in-patients and have the catheter removed the following day. Catheter removal followed standard clinical guidelines.

Outcome measures

Primary Outcome Measures: Device-specific adverse event (AE) assessments. Safety was assessed by evaluating AE according to ISO 14155:2020.

An AE was defined as an untoward medical occurrence, unintended disease, or injury or any untoward clinical signs, in subjects, in the context of a clinical investigation, whether or not related to the investigational device. An Adverse Device Effect (ADE) is any AE related to the use of an investigational medical device. A Serious Adverse Event (SAE) is any AE that led to any of the following: death, life-threatening illness or injury, permanent impairment of a body structure or a body function, hospitalisation or prolongation of patient hospitalisation, medical or surgical intervention to prevent life-threatening illness or injury, or chronic disease.

AEs were identified via patient interviews, clinical monitoring and review by the study investigators. Severity and relatedness were graded using ISO-based criteria.

Secondary Outcome Measures: Patient-reported pain, irritation and discomfort with catheter were assessed using the Numeric Rating Scale (NRS, 0–10) [22] via structured questionnaires administered at catheter removal and during a telephone follow-up on day 10. A nurse or physician evaluated the same symptoms using the NRS. This dual assessment captured both subjective patient experience and clinical observation of catheter tolerability. NRS was used exclusively for the secondary outcome evaluation.

Assessment by quantitative bacterial culture of urine samples obtained from patients when first included in the study and subsequently after clamping the catheter for 30 min prior to extirpation of the catheter.

Assessment immediately after the removal of the catheter of pain, irritation and discomfort measured with the NRS scale (0–10) using a questionnaire asking patients about their experience using the catheter.

Assessment 7–10 days after the removal of the catheter of pain, irritation and discomfort measured with the NRS scale (0–10) using a questionnaire asking patients about their experience using the catheter.

Ethics approval and consent to participate

Ethical approval was granted by the Swedish Ethical Review Authority (DD-2303-35, 04 20240619). This study adhered to the

Table 1. Baseline characteristics of patients undergoing TURBT and catheter intervention, included in this LubriShield™ short-term safety study, 2024.

	Lubrishield	Standard	Total
Number of patients	14	16	30
Age mean (SD)	71.79 (8.95)	74.38 (6.92)	73.17 (7.90)
Female	4 (29%)	5 (31%)	9 (30%)
Male	10 (71%)	11 (69%)	21 (70%)
Bacterial culture pre-op	0	0	0
Bacterial culture post-op	0	0	0
Catheter duration, hours, mean (SD)	8.1 (6.80)	11.00 (8.80)	9.7 (7.90)
Urinary bladder cancer	14 (100%)	16 (100%)	30 (100%)
Cardiac disorders	2 (14.3%)	4 (25%)	6 (20%)
Hypothyroidism	3 (21.4%)	1 (6.2%)	4 (13.3%)
Type 2 diabetes	2 (14.3%)	2 (12.5%)	4 (13.3%)
Prostate cancer	1 (7.1%)	1 (6.2%)	2 (6.7%)
Hypertension	7 (50%)	4 (25%)	11 (36.7%)

Baseline characteristics of the patients included in this study.

Declaration of Helsinki and ISO 14155:2020. Participants could withdraw at any time.

Data collection and statistics

The rationale for including 15 subjects in each group was based on the FDA guidelines for test participants involved in human factors validation. This study was monitored by an independent safety officer reviewing data at regular intervals to ensure subject safety and study integrity. An external safety officer oversaw the study and provided an independent opinion on the safety and adverse event reports. Data were collected via electronic case report forms (eCRFs) and audited for consistency. No major protocol violations were observed. Since outcome variables were ordinal, a Mann-Whitney test was used using SPSS statistics. A *P*-value of < 0.05 was considered statistically significant.

Table 2. The patients in the study who had an adverse event (AE) or severe adverse event (SAE).

	Lubrishield	Standard	Total
Number of patients	14	16	30
AE	0	0	0
SAE	0	2	2
Causality			
Not related	0	2	2
Possibly related	0	0	0
Probably related	0	0	0
Causally related	0	0	0
Severity			
Mild	0	0	0
Moderate	0	0	0
Severe	0	2	2

Results

After randomisation, 30 patients were included in this study: 14 patients in the LubriShield™ arm and 16 in the control arm. No patients were lost to follow-up. The mean age of the patients in the LubriShield™ arm was 71.8 years, and the mean age of the patients in the control arm was 74.4 years (see Table 1). There were 4 females and 10 males in the LubriShield™ group. In the control group, there were 5 females and 11 males. No patients had positive urinary cultures, either before or after catheterisation. Patients' comorbidities are described in Table 1. The mean duration of catheterisation was 8.10 h (SD 6.80) in the LubriShield™ group and 11.0 h (SD 8.80) in the control group. We chose catheterisation time due to practical reasons, and the patients included were either to be admitted the same day and have the catheter removed as soon as possible or stay as in-patients and have the catheter removed the following day.

Regarding the primary outcome, two SAEs were reported in this study, both occurring in a single patient from the control

Table 3. The questionnaire with numerical rating scale (0–10) answered by the healthcare personnel and the patients.

	Lubrishield	Standard	Total	*P*
Number of patients	14	16	30	
Healthcare staff				
At insertion				
Were the catheters instructions easy to follow?	0.14 (0.53)	0.07 (0.26)	0.10 (0.41)	0.960
Was the catheter easy to insert?	0.43 (1.60)	0.44 (1.31)	0.43 (1.43)	0.719
How would you assess the functionality of the catheter?	0.36 (1.34)	1.00 (2.39)	0.70 (1.97)	0.360
At removal				
Were the catheter instructions easy to follow?	0.00 (0.00)	0.06 (0.25)	0.03 (0.19)	0.405
Was the catheter difficult to remove?	0.07 (0.27)	0.12 (0.34)	0.10 (0.31)	0.660
How would you rate the functionality of the catheter?	0.08 (0.28)	0.00 (0.00)	0.03 (0.19)	0.298
Patients				
After removal				
How did you experience pain while using the catheter?	1.79 (2.52)	2.50 (2.78)	2.17 (2.64)	0.501
How did you experience the pain when the catheter was removed?	1.71 (2.23)	2.06 (2.43)	1.90 (2.31)	0.880
How did you experience itching/irritation while having the catheter?	0.79 (1.97)	0.69 (1.74)	0.73 (1.82)	0.882
After 10 days				
How did you experience pain after the catheter was removed?	3.46 (3.57)	1.73 (2.55)	2.54 (3.13)	0.241
How did you experience itching/irritation after the catheter was removed?	0.62 (1.19)	1.00 (2.45)	0.82 (1.94)	0.908
How did you experience urinary urgency after the catheter was removed?	4.46 (3.50)	4.08 (3.93)	4.27 (3.65)	0.795

All numbers in mean (SD). *P*-values below 0.05 are considered significant.

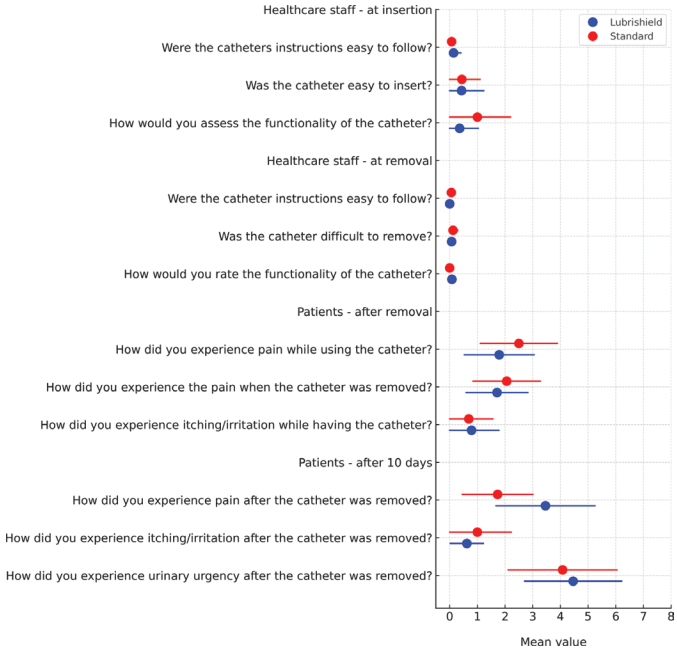

Figure 1. Forest plot analyses between the LubriShield™ catheter and the Standard Foley catheter. The figure illustrates the data from the questionnaire with numerical rating scale (0–10) answered by the healthcare personnel and the patients. Lowest score best performance. All numbers are expressed in mean ± SD. No statistically significant difference was observed for any parameter. (*P*-values below 0.05 was considered significant.)

group. The patient experienced haematuria and an infection requiring hospitalisation for 5 days. Based on clinical evaluation by the safety officer, these events were judged more likely related to the surgical procedure than to the catheter itself (see Table 2). No adverse events were reported in the LubriShield™ group.

The healthcare staff answered a questionnaire regarding the usability of the catheters on a numerical rating scale (0–10, with 0 considered as most favourable and 10 considered least favourable) both after insertion and after removal. The questions after insertion were: 'Were the catheter instructions easy to follow?', 'Was the catheter easy to insert?' and 'How would you assess the functionality of the catheter?' The NRS ratings were low in both groups, with scores below 1 in both the LubriShield™ group and the control group. *P*-values were non-significant (see Table 3 and Figure 1). The questions at removal were: 'Were the catheter instructions easy to follow?', 'Was the catheter difficult to remove?' and 'How would you rate the functionality of the catheter?' Both catheters were considered easy to manage by the healthcare personnel, with NRS scores below 1.

At removal, the patients answered the questions: 'How did you experience pain while using the catheter?', 'How did you experience the pain when the catheter was removed?' and 'How did you experience itching/irritation while having the catheter?' The biggest difference observed was in pain while using the catheter, where patients in the control group had a mean score of 2.50 (SD 2.78), and patients in the LubriShield™ group had a mean score of 1.79 (SD 2.52); these differences were not statistically significant.

At the 10-day follow-up, the patients answered the questions: 'How did you experience pain after the catheter was removed?', 'How did you experience itching/irritation after the catheter was removed?' and 'How did you experience urinary urgency after the catheter was removed?' The biggest difference observed was in the question 'How did you experience pain after the catheter was removed?', where patients in the LubriShield™ group scored a mean of 3.46 (SD 3.57), and patients in the control group scored a mean of 1.73 (SD 2.55). This difference was not considered statistically significant (see Table 3 and Figure 1).

Discussion

This pilot study aimed to evaluate the safety of the novel LubriShield™ coated Foley catheter in patients undergoing transurethral resection procedures. We hypothesised that the LubriShield™ catheter would be as safe and well tolerated as a standard uncoated Foley catheter. The control catheter used in this study has been widely used across various markets. Its manufacturer holds ISO 13485 certification, ensuring compliance to safety, efficacy and functionality standards. Importantly, our findings indicate that the addition of the LubriShield™ coating did not compromise these critical parameters.

To assess non-inferiority, we compared AEs and SAEs between the LubriShield™ and standard catheter groups. No SAEs were reported in the LubriShield™ group, supporting its safety profile. In the control group, two SAEs were documented; however, they were deemed most likely to be related to the surgical procedure than to catheter use by an external safety officer. The two SAEs involved a patient who experienced prolonged hospitalisation due to haematuria and infection.

Both catheters were generally well tolerated, as indicated by the incidence of SAEs and patient-reported outcomes from the questionnaires. There was a slight tendency towards increased pain with the standard catheter (mean score 2.50 vs 1.79), while pain after catheter removal was slightly higher in the LubriShield™ group (mean score 3.46 vs. 1.73). However, these differences were not statistically significant. Additionally, a relatively high proportion of patients in both groups reported urinary urgency (mean score 4.46 for LubriShield™ vs. 4.08 for the standard catheter), a symptom that could be attributed both to the underlying surgical procedure and the catheter itself.

A previous study investigated the use of an earlier version of the LubriShield™ coating on nasal prongs in healthy subjects [23], demonstrating a significant reduction in both Gram-negative and Gram-positive bacteria. Since then, the LubriShield™ coating has been developed. Unlike the nasal prong coating, the LubriShield™ technology now utilises a hydrogel coating that is non-releasable, ensuring long-term stability and biocompatibility [18].

Vopni et al. reported a significant reduction in the number of CAUTIs with coated catheters, though none were hydrogel-coated [24]. Singha et al. highlighted that the market is dominated by silver- and antibiotic-coated catheters, which pose challenges such as substance release and antibiotic

resistance [25]. Dai et al. emphasised the need for novel coatings to replace silver and antibiotic-based options, noting that while hydrogel coatings show promise, their clinical application remains unproven and requires further research [26]. Silicone catheters are widely used due to their biocompatibility, flexibility and low allergenic potential. Various coatings aim to improve performance: antimicrobial coatings release agents to inhibit bacteria, hydrogels reduce friction and discomfort and antifouling coatings prevent biofilm formation. However, none have demonstrated consistent long-term efficacy for indwelling catheters [26, 27].

The LubriShield™ coating has been experimentally tested in-vitro for up to 30 days against common uropathogens, demonstrating stability and resistance to biofilm formation. It creates a superhydrophilic surface that prevents EPS accumulation and fouling without relying on antimicrobial agents, thereby preserving microbial balance. Additionally, subcutaneous implantation studies confirmed no sensitiser release, minimising allergic risks [18]. Given the challenges of multidrug resistance, it is essential to move away from antibiotics and bactericidal elements. A deeper understanding of the host response to urinary catheterisation and infection will be key to developing more effective, long-term solutions [28, 29].

The mean age of participants was 74 years in the standard group and 71 years in the LubriShield™ group, representing an older population with common comorbidities typically seen in routine urological practice. While this cohort is clinically relevant, the limited age range may restrict generalisability to younger patients. Future studies should include a broader adult population to confirm safety and tolerability.

In this study, we evaluated the novel LubriShield™ hydrogel-coated catheter, which was well tolerated by patients and builds on promising *in vitro* anti-biofilm data. This represents the first human trial of the coating, conducted as a randomised, blinded study. The patient cohort was relatively elderly with multiple comorbidities, reflecting a real-world clinical setting. However, limitations include the small sample size and the short indwelling time of less than 24 h. Our findings constitute a platform to embark upon for future studies to assess the LubriShield™ catheter's effectiveness in reducing CAUTIs, bacteria in urine and improving patient comfort compared to uncoated catheters.

Conclusion

The novel LubriShield™ coated Foley catheter was well tolerated by the patients and safe to use. There was no difference between the groups. The antifouling properties and reduced surface friction may, thus, offer a promising alternative for preventing catheter-associated UTI.

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Conflict of interest

This study was sponsored by CytaCoat AB.

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