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BENEFITS OF HYGIENIC DESIGN AS DEMONSTRATED BY LABORATORY TESTING

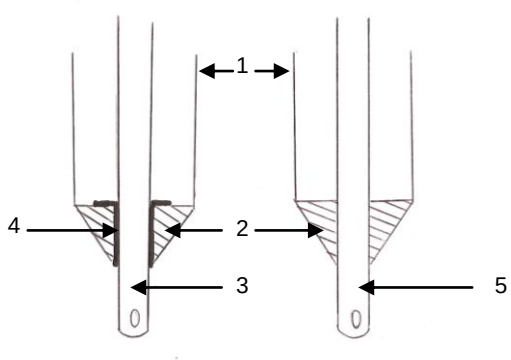
Hypothesis / aims of study

Sterile intermittent catheterization (IC) is considered to significantly reduce the risk of contracting a Urinary Tract Infection (UTI) and/or bacteriuria when compared to clean IC. However, sterile technique is considered to be impractical for application in the community outpatient setting, and aseptic technique has been proposed as providing many of the benefits of sterile IC while being easier for patients. However, aseptic technique poses challenges for many patients, especially in a public toilet or for those with limited dexterity. To address those issues products have been designed to facilitate aseptic IC, namely "no-touch" sleeve and introducer tip. The benefits of the sleeve with respect to reduced potential for catheter contamination were shown by Hudson and Murahata. Here we report the development and application of a laboratory test to demonstrate the benefit of an introducer tip in likewise reducing the potential for contamination. The null hypothesis tested was that contamination resulting from insertion would be equal for catheters with and without a protective tip. The primary outcome measure was the amount of bacteria, expressed as colony forming units (CFU), recovered from the catheters.

Study design, materials and methods

Sterile catheters with a protective tip and catheters without a protective tip were used in the experiment. A model designed to simulate the urethra contaminated at the distal end was constructed from 50 mL centrifuge tube containing a 15 mm thick layer of agar. The agar was inoculated with either Staphylococcus aureus or Escherichia coli after the molten agar had been placed into the tube. A pathway simulating a urethra was created by leaving the pipette in-situ until the agar had set (a diagram of the model is given in Appendix 1). A test for each catheter type was performed in triplicate for each test microorganism. Negative controls for each catheter types were tested in the same way with uninoculated agar.

Diagram of model designed to simulate urethra contaminated in the distal end.



1. 50mL Centrifuge tube
2. Contaminated agar
3. Catheter with protective tip
4. Protective tip
5. Catheter without protective tip

Experimental Procedure

When the catheters were extended through the agar a second technician wearing sterile gloves and using sterile scissors cut the catheters and placed the tip section into sterile containers. For the microbial challenge suspensions of *Escherichia coli* and *Staphylococcus aureus* were prepared with a target suspension level that was at least 1.0×10^6 –1.0×10^7 colony forming units (CFU) per mL.

The number of microorganisms present on all of the catheters and the negative controls was determined according to the bioburden extraction and plate count procedure validated previously. At the conclusion of the incubation period, the number of CFU per plate were counted and verified as the challenge microorganisms via colony morphology. The average number of the challenge microorganisms found on the three catheter replicates of each catheter type tested was determined.

Results

The challenge organisms were identified on every catheter. The average count of *Staphylococcus aureus* (S.aureus) recovered from the catheters with protective tip was 73 CFU per plate compared to 330 CFU per plate recovered from the catheters without protective tip. For *Escherichia coli* (E.coli) the average count recovered from the catheter with protective tip was 20 CFU per plate compared to an average of 78 CFU per plate recovered from the catheters without a protective tip. Observationally the number of bacteria recovered from the catheter without the protective tip was 4 times that recovered from the catheter with the protective tip. A statistically significant difference exists between the two catheters levels of S.aureus (t-

test, two tailed 0.05/2 p=0.0309). The log_{10} adjusted means were 66.89 (67CFU) for the product with a protective tip, and 298.2 (298CFU) for the product without a protective tip. The difference in bacteria recovered between the two catheters for E.coli did not reach statistical significance (t-test, two tailed 0.05/2 p=0.128). The log_{10} adjusted means were 15.18 (15CFU) for the product with protective a tip, and 62.5 (62CFU) for the product without a protective tip. No growth was detected in the negative controls.

Organism	S.aureus		E.coli	
Introducer tip	Yes	No	Yes	No
Sample 1	35	520	20	35
Sample 2	95	300	<5	45
Sample 3	90	170	35	155
Mean	73 CFU	330 CFU	20 CFU	78 CFU

Interpretation of results

Shielding the catheter from directly contacting bacteria containing medium reduced the degree of contamination that could potentially be introduced into the proximal urethra and/or bladder. This laboratory model is intended to reflect the distal urethra, which is reported to have the highest concentration of potentially pathogenic bacteria.

Concluding message

The results obtained using this *in vitro* model premise that catheters with introducer/protective tip can help reduce the level of contamination from the distal urethra on insertion of an intermittent catheter. These products facilitate the use of aseptic technique for IC as recommended by EAU and other guidelines. This is particularly true when IC is performed under challenging conditions, such as a public toilet, and/or by patients with reduced dexterity.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**NONE**