Benefits of the Insertion Tip and Closed-System Sleeve for Intermittent Catheterization

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Abstract

**Purpose:** Typically performed several times a day, intermittent catheterization (IC) is considered a generally safe and effective method for emptying the bladder and can be used on a short or long term basis as needed. Due to the potential risk of introducing bacteria into the urethra, recurrent urinary tract infections may occur even with appropriate hand washing and disinfection of the insertion site. In patients who routinely self-catheterize, catheter-associated urinary tract infections can be a serious problem. The purpose of this *in vitro* study was to assess the effectiveness of a closed system, which has a sleeved, pre-lubricated catheter with an insertion tip, in reducing bacterial transfer during the catheterization procedure.

**Materials and Methods:** Nine catheters of each of two types were tested: **BARD® TOUCHLESS®** Plus Intermittent Catheter (14 Fr.) and Coloplast Self-Cath® Intermittent Catheter (14 Fr.). The **BARD® TOUCHLESS®** Plus Intermittent Catheter incorporates an introducer tip and a closed system no-touch sleeve, while the Coloplast Self-Cath® Intermittent Catheter consists of the catheter alone. Two tests were conducted to assess the effectiveness of these two design elements on the reduction of bacterial transfer during the catheter insertion procedure compared to the standard catheter. The first study (insertion tip test) measured the contamination of the catheter tip due to contamination from the user’s urethral meatus compared to the **BARD® TOUCHLESS®** Plus Intermittent Catheter with an insertion tip. The second study (closed system sleeve test) measured the contamination of the bare catheter shaft due to transfer from the user’s hands compared to the **BARD® TOUCHLESS®** Plus Intermittent Catheter with a no-touch sleeve. After completing simulated catheter insertion, sections of catheters were tested to determine the colony count of *P. aeruginosa* on the catheter after exposure to the contamination.

**Results:** After the Insertion Tip test, the average colony count was 1.8 CFU/mL and 22.0 CFU/mL for the **BARD® TOUCHLESS®** Plus Intermittent Catheter and the Coloplast Self-Cath® Intermittent Catheter, respectively. After the Closed System Sleeve test, the average colony count was 0.0 CFU/mL and 143.3 CFU/mL for the **BARD® TOUCHLESS®** Plus Intermittent Catheter and the Coloplast Self-Cath®, respectively.

**Conclusions:** *In vitro* studies suggest that incorporation of an insertion tip and a closed-system sleeve, as in the **BARD® TOUCHLESS®** Plus Intermittent Catheter system, reduces bacterial contamination of an intermittent catheter during the catheterization procedure. Further testing is required to determine if these *in vitro* findings have any impact on clinical outcomes.
Introduction

Intermittent catheterization or intermittent self-catheterization (IC) has been used successfully by individuals with conditions that result in incomplete bladder emptying. Typically performed several times a day, IC is considered a generally safe and effective way of emptying the bladder and can be used on a short or long term basis as needed.

Complications and adverse events can arise, especially in patients performing self-catheterizations long term. These include urethral trauma and recurrent urinary tract infections (UTIs). Studies have found that hand washing alone prior to insertion may be insufficient to protect against externally-introduced bacterial contamination.

Recent intermittent catheterization guidelines published by the European Association of Urology recommend aseptic or clean technique for intermittent catheterization. The guidelines define aseptic technique as catheterization in which the catheters remain sterile, the genitals are disinfected, and disinfecting lubricant is used. As a strategy for reducing contamination risks associated with IC, a touch-free technique was developed. This technique involves a closed system that reduces the likelihood the catheter will be inadvertently contaminated in a non-sterile environment. A protective introducer tip is inserted 15 mm into the urethra, guarding the catheter against perineal bacteria in the distal urethra. This potentially reduces the risk of pushing bacteria into the urethra and bladder as the catheter is passed.

Two in vitro tests were performed to assess to what degree the introducer tip and the closed system no-touch sleeve may reduce bacterial transfer during the catheter insertion procedure compared to a standard polyvinyl chloride (PVC) catheter without introducer tip, closed system or no-touch sleeve. The tested hypothesis was that these design features of the Bard® Touchless® Plus Intermittent Catheter system would provide contamination reduction compared to a conventional catheter.

Materials and Methods

The Bard® Touchless® Plus Intermittent Catheter is a closed system kit designed for sterile intermittent catheterization. The system incorporates a pre-lubricated catheter with finger guide, an introducer tip, and a closed system no-touch sleeve designed to facilitate aseptic catheter insertion and drainage of urine (Figure 1).
two catheters. The conventional catheter which served as control was the PVC Coloplast Self-Cath® Intermittent Catheter. *Pseudomonas aeruginosa* (SJ 185, St. Joseph’s Hospital, Atlanta, GA) was used as the contaminating bacterium because it is commonly found in skin flora, it exists in normal as well as hypoxic atmospheres, and thrives on most surfaces.5,6

**Insertion Tip Test**

A conventional Petri dish (VWR, Atlanta, GA) was modified to create a contaminated distal urethral model for this study. Holes were drilled in the bottom of the dishes and an autoclavable plate support to temporarily plug the holes was fabricated. The model was created by filling each of the Petri dishes, holes plugged, with 100 mL of trypticase-soy agar (TSA, Fischer Scientific, Atlanta, GA) inoculated to a bacterial concentration of 10^7 CFU/mL. After the agar had solidified, a sterile hollow steel rod was used to punch a hole through the agar no wider than the width of the catheter being tested and the plate plug was then removed (Figure 2). Catheter insertion was simulated by pressing the tip of the test catheter through the inoculated agar (contaminated meatus) and out through the plate plug opening in the bottom of the plate (urethra) (Figure 3). Catheter insertion was conducted according to the manufacturer’s instructions. After the catheter tip passed out through the bottom of the plate, 3 cm of the tip was aseptically cut off and placed into 10 mL of phosphate-buffered saline (PBS). The catheter tip in PBS was sonicated for 10 minutes to suspend any bacteria that were transferred to the catheter as it passed through the urethral model. From the suspension 200 µL was transferred to a microplate and serial dilutions (10^-5-10^-7) were prepared. A 20 µL aliquot of each dilution was then transferred to a nutrient agar plate and incubated 18-24 hours (all samples incubated concurrently) at 37 °C. A colony count was performed to calculate the quantity of recovered organisms for each dilution. The sum of the product of the colony count times the effective dilution factor was calculated for each sample. Each type of catheter was tested in duplicate with 3 sample catheters in each of 3 runs (total of 9 catheters with 18 colony counts for each device tested).

![Figure 2 Creation of a distal urethral passageway through contaminated TSA.](image1)

![Figure 3 Simulation of catheter insertion by pressing the tip of the test catheter through the contaminated agar.](image2)
Closed System Sleeve Test
A “contaminated hand” model was designed for this study. One laboratory technician donned sterile gloves and acted as the “patient”. A helper technician inoculated the gloved hands with 500 µL of a 5x10^5 CFU/mL suspension of *P. aeruginosa* (Figure 4). This concentration was chosen to represent the contamination of skin as reported in the literature. Colony counts of aerobic bacteria from moist areas of the skin may be as high as 10^7 per square centimeter. After the first technician rubbed the organism suspension over the palms of their gloves, catheter preparation and insertion was simulated by opening the catheter packaging, preparing components (if necessary), and manipulating/advancing the catheter. Catheter manufacturers’ instructions for insertion were followed. Once the catheter was advanced the second technician aseptically cut the tip of the catheter off using sterile scissors. To confirm that the gloves were adequately coated with live bacterial suspension for the duration of the simulated use, the gloves were applied to agar plates and allowed to grow (Figure 5). The catheter tip was placed into 100mL of sterile water and sonicated for 15 minutes; serial dilutions of the water were made. Five mL aliquots of the serial dilutions were transferred to 35 mL molten agar (~45°C). The agar mixture was mixed gently, poured into a sterile Petri dish, and allowed to solidify. After 48 hours of incubation at 37 °C colony counts were performed. Each type of catheter (*Bard® Touchless®* Plus Intermittent Catheter and Coloplast *Self-Cath®* Intermittent Catheter) was tested in duplicate with 3 sample catheters in each of 3 runs (total of 9 catheters with 18 colony counts for each device tested). To confirm that bacteria were transferred from the contaminated gloves to the sleeve of the *Bard® Touchless®* Plus Intermittent Catheter, a section of the sleeve was cut and pressed onto a nutrient agar plate using a sterile spreader. After 18-24 hours of incubation the plate was visually assessed for bacterial growth.

**Results**

**Insertion Tip Test**
The average colony count of *P. aeruginosa* was 1.8 CFUs and 22.0 CFUs for the *Bard® Touchless®* Plus Intermittent Catheter and the Coloplast *Self-Cath®* Intermittent Catheter, respectively (Figure 6). A positive control plate was used to confirm the viability of the organism suspension.
Figure 6 Bacteria recovered from catheter tip after passage through contaminated distal urethra, demonstrating fewer bacteria on the Bard® Touchless® Plus Intermittent Catheter with a protective insertion tip compared to Coloplast Self-Cath® Intermittent Catheter.

Closed System Sleeve Test
The average colony count was 0.0 CFUs and 143.3 CFUs for the Bard® Touchless® Plus Intermittent Catheter and the Coloplast Self-Cath® Intermittent Catheter respectively (Figure 7). For all test runs the sleeve section culture was positive for bacterial growth.

Discussion/Conclusion
Both the urethral and contaminated hand models yielded consistent, reproducible results. The in vitro studies suggest that incorporation of an introducer tip will decrease bacterial contamination of the catheter tip during introduction through a contaminated orifice. Additionally, a closed system sleeve significantly reduces bacterial transfer from contaminated hands during the catheterization procedure.

One limitation of these tests includes the fact that only one type of Gram-negative bacterium was tested. It is unclear if the same results would be found if organisms other than P. aeruginosa were tested. An additional limitation of these tests is the fact that they only simulate catheter preparation and insertion. It is unclear if these in vitro results have any correlation to in vivo findings.

Historically, Centers for Medicare and Medicaid (CMS) reimbursement policies covered only four intermittent catheters per month for home use. This required IC users to clean and re-use catheters that were intended for single use only. Recent changes to CMS policies increased coverage to up to 200 catheters per month. However, even a sterile catheter doesn’t prevent introduction of bacteria via a caregiver’s or patient’s hands or through the distal urethra. It remains important to identify methods to reduce the potential for microbial contamination during catheter preparation and insertion procedures. These tests suggest that the design features of the Bard® Touchless® Plus Intermittent Catheter provide contamination reduction compared to conventional catheters. Further testing is required to determine if these in vitro findings have any impact on clinical outcomes.

Figure 7 Bacteria recovered from the catheter after contaminated handling, demonstrating fewer bacteria on the Bard® Touchless® Plus Intermittent Catheter with a protective sleeve compared to Coloplast Self-Cath® Intermittent Catheter.
References
