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Fecal containment using indwelling bowel catheters to potentially prevent multidrug-resistant organism nosocomial infections

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Issue

- In an acute or critical care setting, 18% to 33% of patients have fecal incontinence[1]
- Multidrug-resistant organisms, which are spread by direct or indirect contact, such as Clostridium difficile and Vancomycin-resistant Enterococcus (VRE), both contribute to the prevalence of diarrhea-associated enteric nosocomial infections[2]
- A practical method for containment of the diarrhea is needed to reduce exposure to these organisms

Project

- A study was conducted to assess and compare the impact of fecal containment with use of indwelling bowel catheters in the acute/ICU setting
- The study was conducted at 12 hospital sites using either catheter A (n=7) or catheter B (n=5)
- Bedridden patients in the critical care setting requiring fecal containment were followed for 29 days or until leaving the critical care setting
- Bed linen and dressing change visits per patient day (frequency of nursing visits per day spent changing bed linen/dressings due to fecal contamination) were used as an indirect measure of catheter leakage and fecal containment
- Routine daily bed linen/dressing changes were not included, only catheter-related bed linen/dressing changes were recorded
- The study evaluated the number of devices used, number of insertions, reason for a new device to be inserted, device repositioning, and leakage associated with each device

* Catheter A was Zassi® bowel management system marketed as ActiFlo indwelling bowel catheter by Hollister Incorporated, Libertyville, IL and catheter B was Flexi-Seal® fecal management system by ConvaTec, Inc., Skillman, NJ.

Table 1 Study Population

	Age (yrs)		Height (in)		Weight (lbs)		Braden Score at Enrollment		Braden Score at Completion	
	A	B	A	B	A	B	A	B	A	B
	(n=73)	(n=70)	(n=75)	(n=63)	(n=76)	(n=69)	(n=73)	(n=70)	(n=73)	(n=67)
Mean	61.1	62.3	67.5	67.4	206.0	188.0	12.5	13.0	13.7	13.5
Std Dev	15.4	16.8	4.2	3.7	89.1	59.8	2.6	2.7	2.9	3.0
Range	18-97	19-86	60-76	59-74	95-572	85-369	8-18	7-21	8-21	8-23

Note: No significant differences in mean age, $t(141) = 0.47$, $p = 0.64$, height, $t(136) = 0.26$, $p = 0.80$ or weight, $t(143) = 1.41$, $p = 0.16$ between groups are noted.

Results

- An analysis of 146 patients on the number of bed linen and dressing change visits with a bowel catheter in place was conducted
- Catheter A, 76 patients: 57.9% male, 42.1% female
- Catheter B, 70 patients: 62.9% male, 37.1% female

Bed Linen and Dressing Changes

- Nearly 30% fewer unplanned bed linen and dressing changes (1.20 vs. 1.71) per patient day was observed for catheter A compared to catheter B (Chi-square=8.55, df=1; p = 0.0035)
- For catheter A sites, 735 bed linen/dressing change visits occurred over 612 patient days and for catheter B sites, 705 bed linen/dressing change visits occurred over 413 patient days
- This would correspond to one additional unscheduled bed linen/dressing change for each 2 days of use for catheter B

Table 2 Number of Patients Included by Type of Critical Care Unit

Unit	Catheter A	Catheter B
Burn Unit	10	0
Cardiac Intensive Care Unit	12	5
Medical Intensive Care Unit	35	30
Surgical Intensive Care Unit	15	15
Other Critical Care Unit	4	20

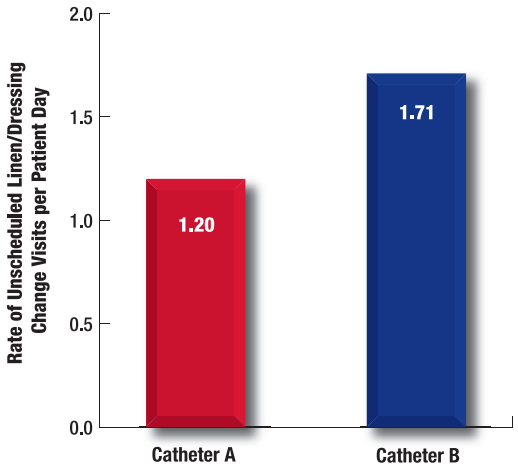

Figure 1 Rate of unscheduled bed linen/dressing change visits per patient day.

"Indwelling bowel catheters should be studied against other methods of fecal management."

Repositioning and Leakage of Catheter

- Bowel catheters may need to be repositioned for numerous reasons such as: patient turning procedures, catheter clog elimination, relieving bed linen entanglement, and odor elimination
- Leakage abatement is a major reason for repositioning the bowel catheter

Lessons Learned

- Although nonsignificant, lower observed rates of device leakage (A, 1.1; B, 1.4), repositions due to leakage A, 0.25; B, 0.39), and devices expelled (A, 0.02; B, 0.07) may have contributed to the significant difference in bed linen/dressing changes associated with the use of catheter A compared to catheter B

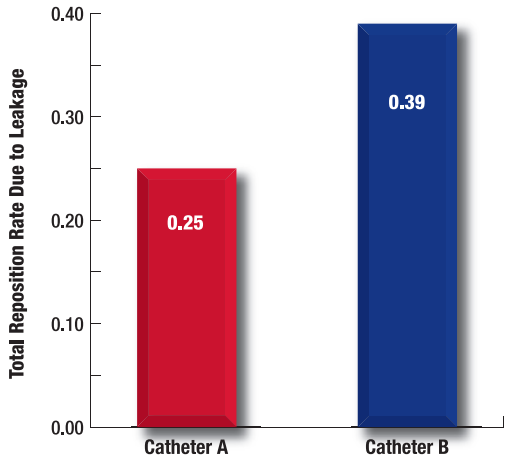

Figure 2 Catheter total reposition rate and proportion of catheters repositioned due to leakage.

- Indwelling bowel catheters divert, collect, and contain liquid stool from bedridden patients with fecal incontinence
- Fewer bed linen and dressing changes related to fecal incontinence may help to control and reduce exposure of fecal contaminants for both patients and clinicians

Future Directions

- Despite thorough hand hygiene practices, use of alcohol-based cleansers, and isolation/contact precautions for infected patients, the prevalence of infection due to resistant nosocomial pathogens is increasing[3]
- Indwelling bowel catheters should be studied against other methods of fecal management to provide evidence of their prevention of nosocomial infections in the hospital setting

Reference List

(1) Junkin J, Selekof JL. Prevalence of incontinence and associated skin injury in the acute care inpatient. *J Wound Ostomy Continence Nurs* 2007; 34(3):260-269.

(2) Miller JM, Walton JC, Tordecilla LL. Recognizing and managing Clostridium difficile-associated diarrhea. *Medsurg Nurs* 1998; 7(6):348-6.

(3) Boyce JM, Havill NL, Kohan C, Dumigan DG, Ligi CE. Do infection control measures work for methicillin-resistant Staphylococcus aureus? *Infect Control Hosp Epidemiol* 2004; 25(5):395-401.

ActiFlo Indwelling Bowel Catheter System
Product Information

NON STERILE: The ActiFlo indwelling bowel catheter is constructed primarily of silicone materials. All system components are latex-free. Single patient use only.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed under state law to order this product. Refer to the complete ActiFlo indwelling bowel catheter system Instructions for Use supplied by the manufacturer for directions on how to properly use this product.

INTENDED USE: The ActiFlo indwelling bowel catheter system is intended for diversion of fecal matter to minimize external contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring stool management, to provide access for colonic irrigation, and to administer enema/medications.

CONTRAINDICATIONS

- Do not use in patients having known sensitivities or allergies to the materials used in this device.
- Do not use if the patient's distal rectum cannot accommodate the inflated volume of the retention cuff or if the distal rectum/anal canal is severely strictured (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).
- Do not use on patients having impacted stool.
- Do not use on patients with a recent (less than 6 weeks old) rectal anastomosis, or a recent (less than 6 weeks old) anal or sphincter reconstruction.
- Do not use on patients with compromised rectal wall integrity (e.g., ischemic proctitis).
- Do not connect irrigation bag to an IV.
- Do not use irrigation bag for enteral feeding.

WARNINGS

(Failure to comply with the following warnings may result in patient injury)

- Do not use if package is open or damaged.
- Do not use improper amount or type of fluids for irrigation or cuff/balloon inflations. NEVER use hot liquids.
- Do not over inflate retention cuff or stop-flow balloon.
- Inflation of the stop-flow balloon causes complete catheter occlusion. Do not leave stop-flow balloon inflated in an unattended patient. To verify complete deflation of the stop-flow balloon, aspirate all air until RED connector (STOP FLOW 25 mL AIR) pilot balloon is collapsed when the syringe is removed from the connector.
- Use only gravity or slow manual irrigation. Do not connect manual pumping devices to catheter irrigation lumen. Do not irrigate patient with compromised intestinal wall integrity.
- Extreme caution should be exercised in patients at risk for the development of toxic megacolon. Occluding the tube by inflating the stop-flow balloon could aggravate this situation.
- Perform irrigations, and enema/medication administrations, via the CLEAR connector (IRRIG/Rx) AND NOT via the BLUE connector (CUFF 35-40 mL H2O) or RED connector (STOP FLOW 25 mL AIR).
- Blood per rectum should be investigated to ensure no evidence of pressure necrosis from the device. Discontinue use of the device if evident.
- Abdominal distention that occurs while using the device should be investigated.
- Excessive prolonged traction on the catheter, resulting in the retention cuff migrating into the anal canal, could result in temporary or permanent clinical sphincter dysfunction, or catheter expulsion.

PRECAUTIONS

- Do not sterilize.
- The ActiFlo indwelling bowel catheter system is not intended for use longer than 29 days.
- Caution should be used in patients who may bleed easily due to anticoagulant/antiplatelet therapy or underlying disease conditions. Immediately consult a physician if rectal bleeding is suspected
- The ActiFlo indwelling bowel catheter system is not recommended for pediatric use.
- To avoid damage to retention cuff or stop-flow balloon, DO NOT contact either with ANY sharp edge including the enclosed lubricating jelly packets.
- The ActiFlo indwelling bowel catheter system may not be effective in individuals who have had their distal rectum significantly altered by surgical resection or reconstruction.
- Patients with very weak sphincter function may expel the catheter under normal use, or sphincter function.
- Caution should be observed in patients whose rectum may be altered by stricture due to radiation or affected with radiation proctitis.
- Patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of device, may not tolerate the catheter in place.
- Avoid inserting anything (e.g., thermometer, suppository, etc.) into the anal canal with the catheter in place to minimize patient injury or catheter damage.
- Care should be taken when disconnecting syringe from the CLEAR connector (IRRIG/Rx). Fluids may drain or splatter from the connector when it is disconnected.
- Use WATER ONLY to inflate retention cuff. Do not use saline solution, which may adversely affect valve function.
- Use AIR ONLY to inflate the stop-flow balloon. Do not use water or any other fluid.
- Do not use vigorous aspiration to remove fluid from the retention cuff or to remove air from the stop-flow balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon and may prevent retention cuff or stop-flow balloon deflation.
- Do not allow ointments or lubricants having a petroleum base (e.g., Vaseline®, petroleum-based hand/body lotion) to contact the catheter. They may damage the silicone and may compromise the integrity of the device.
- Use only Hollister branded bowel catheter collection bags with the ActiFlo indwelling bowel catheter.
- Feces contains infectious material. Protect from splatter which may occur when disconnecting or emptying the collection bags or during catheter removal.
- After use, this system is a biohazard. Handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste.

ADVERSE EVENTS

- The following adverse events may be associated with the use of any rectal device:
- Perforation
- Pressure necrosis
- Loss of sphincter tone
- Obstruction
- Infection
- Excessive leakage of fecal contents

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