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

Issue

• In an acute or critical care setting, 18% to 33% of patients have fecal incontinence1
• 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 infections2
• 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.
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
- This would correspond to one additional unscheduled bed linen/dressing change for each 2 days of use for catheter B

Table 1 Study Population

<table>
<thead>
<tr>
<th></th>
<th>Age (yrs)</th>
<th>Height (in)</th>
<th>Weight (lbs)</th>
<th>Braden Score at Enrollment</th>
<th>Braden Score at Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A B</td>
<td>A B</td>
<td>A B</td>
<td>A B</td>
<td>A B</td>
</tr>
<tr>
<td></td>
<td>(n=73)</td>
<td>(n=70)</td>
<td>(n=63)</td>
<td>(n=76)</td>
<td>(n=69)</td>
</tr>
<tr>
<td>Mean</td>
<td>61.1</td>
<td>62.3</td>
<td>67.5</td>
<td>67.4</td>
<td>206.0</td>
</tr>
<tr>
<td>Std Dev</td>
<td>15.4</td>
<td>16.8</td>
<td>4.2</td>
<td>3.7</td>
<td>89.1</td>
</tr>
<tr>
<td>Range</td>
<td>18-97</td>
<td>19-86</td>
<td>60-76</td>
<td>59-74</td>
<td>85-369</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Catheter A</th>
<th>Catheter B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burn Unit</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac Intensive Care Unit</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Medical Intensive Care Unit</td>
<td>35</td>
<td>30</td>
</tr>
<tr>
<td>Surgical Intensive Care Unit</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Other Critical Care Unit</td>
<td>4</td>
<td>20</td>
</tr>
</tbody>
</table>

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

Future Directions

- 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
- 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

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

Reference List

**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 use irrigation without air.
- 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 using the RED connector (STOP FLOW 25 mL AIR). 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.

**CAUTION:** Irrigate patient with compromised intestinal wall integrity.

**Manual pumping devices to catheter irrigation lumen. Do not use saline solution, which may adversely affect valve function.**

**Use AIR ONLY to inflate retention cuff. 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 retention lumen and/or pilot balloon and may prevent retention cuff or stop-flow balloon deflation.**

**WARNINGS**
- Do not allowointments 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 device 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