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The use of irrigation with an indwelling bowel catheter in a critical care setting

Purpose

- In an acute or critical care setting 18% to 33% of patients have fecal incontinence¹
- Indwelling bowel catheters can be used to divert, collect, and contain liquid stool from bedridden patients to help maintain a skin-friendly environment²
- More information is needed to reduce expulsions and leakage of these catheters
- Irrigation of an indwelling bowel catheter allows the management of stool consistency, by aiding in the flow of fecal material through the tube
- This presentation provides descriptive data about irrigation by clinicians who use indwelling bowel catheters in a critical care setting

Indwelling Bowel Catheter Characteristics

- The indwelling bowel catheter* system consists of:
 - A silicone catheter with a collapse-resistant annulus
 - A low-pressure retention cuff
 - Intraluminal balloon
 - Collection bags
- The unique design and characteristics of the indwelling bowel catheter system, such as the intraluminal balloon, provide access for colonic irrigation

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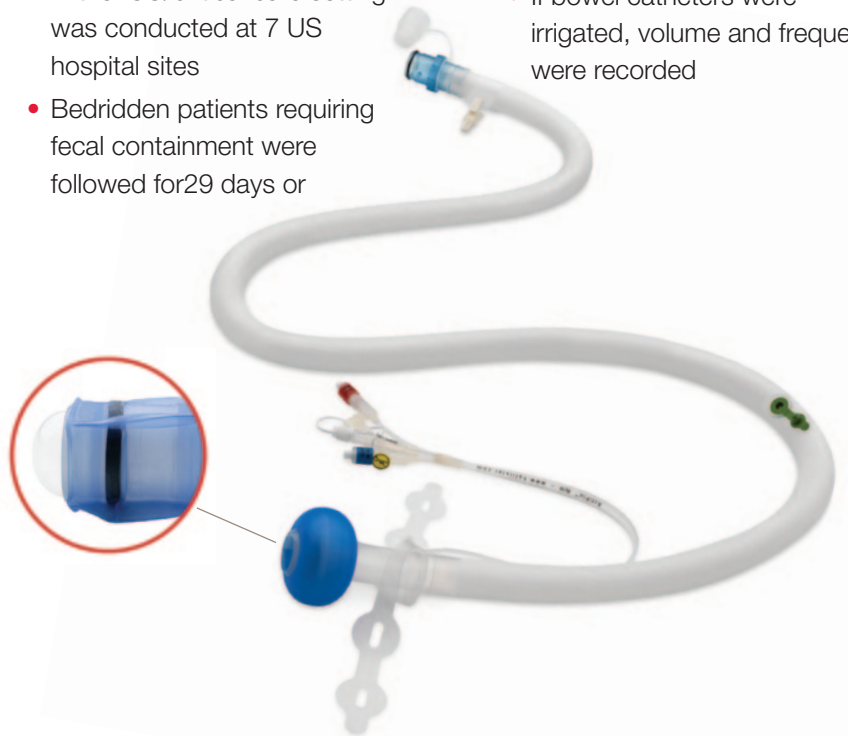
* Catheter was Zassi bowel management system marketed as ActiFlo indwelling bowel catheter by Hollister Incorporated, Libertyville, IL.

Method of Indwelling Bowel Catheter Use

- After the bowel catheter is inserted, the retention cuff is inflated with 35-40 mL of water
- The flow through the catheter can be stopped by using an intraluminal balloon
- The indwelling bowel catheter system is indicated for:
 - The diversion of fecal matter
 - To facilitate the collection of fecal matter
 - To provide access for colonic irrigation
 - To administer enemas or medications

Methodology

- A multi-site evaluation of the use of indwelling bowel catheter systems in the ICU/critical care setting was conducted at 7 US hospital sites
- Bedridden patients requiring fecal containment were followed for 29 days or until leaving the ICU/critical care setting
- If bowel catheters were irrigated, volume and frequency were recorded



Results

- 57 of the 76 patients (75%) in the study had the indwelling bowel catheter irrigated with water (37 males, 20 females)

Table 1 Subject Demographics

	Age (yrs)	Height (in)	Weight (lbs)	Braden Score at Enrollment	Braden Score at Completion
	n=54	n=57	n=56	n=57	n=54
Mean	62	67.9	212.3	12.7	13.9
Std Dev	13.5	4.1	91.9	2.6	2.9
Range	38-97	60-76	102-572	8-18	8-21

Table 2 Number of Patients Seen in ICU/Critical Care Setting

Unit	Number of Patients
Burn Unit	10
Cardiac Intensive Care Unit	7
Medical Intensive Care Unit	23
Surgical Intensive Care Unit	13
Other Trauma Unit	4

“These studies suggest irrigation may play an important role in managing stool consistency during fecal containment using an indwelling bowel catheter.”

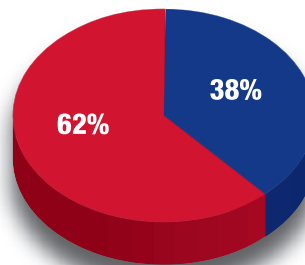
Gravity Irrigation Use with an Indwelling Bowel Catheter

- Of the 57 patients, the average amount of water used to irrigate was 358 mL per irrigation
 - Median: 350 mL
 - Mode: 300 mL
 - Range: 10 mL – 1000 mL
- Patients were irrigated between one to four times per day
 - Median: 2 times per day
 - Mode: 1 time per day
- 29 patients were given lactulose, docusate or milk of magnesia for the purpose of:
 - Alleviating formed stool
 - Reducing the potential of the catheter to clog with formed stool
 - Permitting more fluid fecal flow

Discussion

- Similar observations were seen in a prospective study of 20 patients utilizing an indwelling bowel catheter system for fecal containment. In that study, 300 mL of warm water was used to irrigate once daily for patients with diarrhea and 2-3 times per day for burn patients to modify stool consistency³
- These studies suggest irrigation may play an important role in managing stool consistency during fecal containment using an indwelling bowel catheter
- As stool consistency can change from liquid to formed stool and back to liquid stool in patients that require an indwelling bowel catheter system, it is beneficial to have products with the ability to modify stool consistency
- Reviewing the indications for use for the ability to modify semi-formed and formed stool can be helpful when evaluating indwelling bowel catheters

Use of Osmotic Agents and Stool Softeners



- Received Osmotic Agents or Stool Softeners
- Did not Receive Osmotic Agents or Stool Softeners

References:

1. Bliss DZ, Johnson S, Savik K, Clabots CR, Gerding DN. Fecal incontinence in hospitalized patients who are acutely ill. *Nurs Research*. 2000;49:101-108.
2. Beitz JM. Fecal incontinence in acutely and critically ill patients: options in management. *Ostomy Wound Manage*. 2006;52:56-66.
3. Keshava A, Renwick A, Stewart P, Pilley A. A non-surgical means of fecal diversion: the Zassi Bowel Management System. *Disease of the Colon and Rectum*. 2007; 7:1017-1022.

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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