Conference Sponsored by Hollister Incorporated

The support of Hollister Incorporated for this clinical presentation is gratefully acknowledged.

As Presented at

The 22nd Annual Symposium on Advances in Wound Care

April 26 – 29, 2009, Dallas, TX

Comparison of two indwelling bowel catheters on economic impact by number of bed linen and dressing changes per day

J. Powers, PhD, RN,CCRN, CCNS
St. Vincent Hospital of Indianapolis, Indianapolis, IN

K. Berry, RN, BSN, WOCN, CWON
Banner Estrella Medical Center, Phoenix, AZ

M. Koenig, RN
University of California San Diego Medical Center, San Diego, CA

M. Majewski, RN
Northwestern Memorial Hospital, Chicago, IL

M. Tan, MD
Summa Health System, Akron, OH

S. Poulakidas, MD
John H. Stroger Hospital of Cook County, Chicago, IL

B. Barnett, RN
University of Virginia Health System, Charlottesville, VA

E. Stokes, RN, BSN
Sisters of Charity Providence Hospital, Columbia, SC

M. Ferrari, RN
Cleveland Clinic Foundation, Cleveland, OH

S. Ambutas, MS, RN, CCRN, TNS
Provena Saint Joseph Medical Center, Joliet, IL

J. Mah, MD
Hartford Hospital, Hartford, CT

E. C. Konz, PhD, RD
Hollister Incorporated, Libertyville, IL

Introduction

- Indwelling bowel catheters are used to divert, collect, and contain stool from bedridden patients with fecal incontinence[1]
- Fecal incontinence is prevalent in patients in the acute/critical care setting[2, 3]
- Factors such as device cost and time to manage/replace the device may add expense
- Nosocomial infection risk management for fecal pathogens is a key benefit and potentially could be facilitated by bowel catheter use
- A variety of factors and catheter characteristics contribute to the effectiveness and duration of use a given patient

Objective

The primary objective of this study was to assess and compare the economic impact on fecal containment with use of catheter A or catheter B at 12 hospital sites (catheter A, 7; catheter B, 5) in the critical care setting.

Methods

- An analysis of 146 bedridden patients (catheter A, 76; catheter B, 70) was performed on the number of bed linen dressing change visits per day with catheter A or catheter B
- Bedridden patients in the critical care setting requiring fecal were followed for 29 days or until leaving the critical care setting
- Bed linen/dressing change visits per patient day (frequency of nursing visits per day spent changing bed linen/dressings due to fecal contamination) can be used as an indirect economic 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

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.

Bed Linen and Dressing Changes

- Nearly 30% fewer unscheduled bed linen/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)
- This would correspond to one additional unscheduled bed linen/dressing change for each 2 days of use

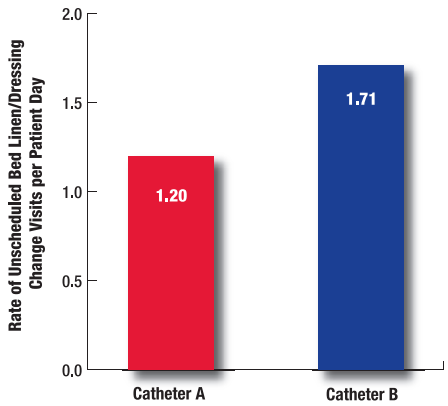

Figure 1 Rate of unscheduled bed linen/dressing change visits per patient day

Devices Used

- Catheter A sites used a total of 86 devices in 76 patients
- Catheter B sites used a total of 85 devices in 70 patients

Reasons for Removal of the Device

Catheter A

- Fecal containment no longer necessary (22 times)
- Device reached 29-day maximum usage (1 time)
- Patient was discharged from ICU/Burn Unit (4 times)
- Colostomy (1 time)
- Device was expelled (14 times)
- Device was thought to be ineffective (3 times)
- Other (26 times). Examples: Patient expired, fecal bag applied, leakage, patient discomfort, no stool, colon surgery

Catheter B

- Fecal containment no longer necessary (18 times)
- Patient was discharged from ICU/Burn Unit (5 times)
- Device was expelled (28 times)
- Device was removed to perform colonoscopy (1 time)
- Device was thought to be ineffective (10 times)
- Other (14 times). Examples: Patient expired, stool firming, per patient request, MD order, fecal modification

Reasons for Reinsertion of the Initial Device

Catheter A (6/76 patients)

- Device was expelled (affected 5 patients for a total of 8 times)
- Device leakage (affected 1 patient for a total of 2 times)

Catheter B (11/70 patients)

- Device was expelled (affected 9 patients for a total of 13 times)
- Patient discontinued device (affected 1 patient 1 time)
- Patient pulled out device (affected 1 patient 1 time)

* 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.

"Leakage is an important criterion when evaluating bowel management systems as it can be associated with potential skin damage and risk of the spread of infection."

Reasons for Reinsertion of a New Device

Catheter A (9/76 patients, 10 new devices)

- Device expelled (3/10)
- Device with transsphincteric zone of 6 cm replaced with a device with transsphincteric zone of 4 cm (3/10)
- Device was removed due to fecal containment no longer deemed necessary and then a new device was reinserted at a later date due to recurrent diarrhea (1/10)
- Device was deemed ineffective (2/10)
- Due to leakage and odor
- Stop flow connector broke after 22 days of use
- Other (1/10)

Catheter B (12/70 patients, 15 new devices)

- Device was expelled (1/15)
- Device was removed because fecal containment no longer deemed necessary and then a new device was reinserted at a later date due to recurrent diarrhea (4/15)
- Device was deemed ineffective (10/15)
- Tear in the tubing after 4 days of use
- Balloon port broke off after 10 days of use
- Balloon malfunctioned and would not deflate after 7 days of use
- Other

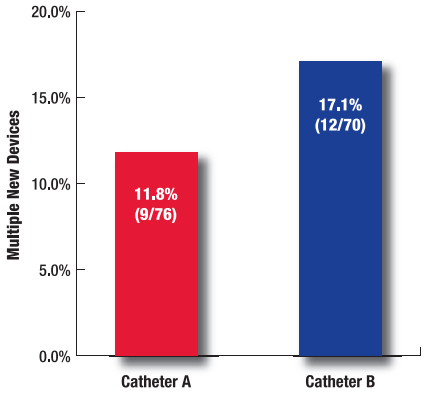

Figure 2 Percent of patients requiring multiple new devices (patients who, during their ICU/critical care stay, had more than one new catheter placed).

Repositioning and Leakage of Catheter

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

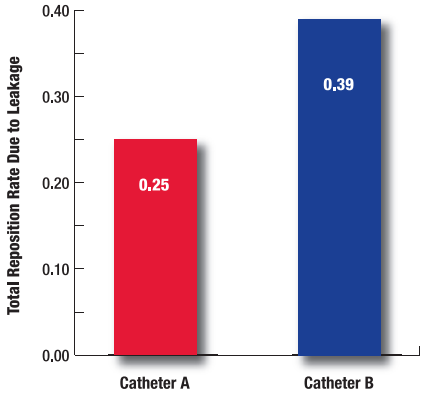

Figure 3 Catheter reposition rate due to leakage.

Discussion and Conclusions

- Results indicate that the use of catheter A may result in greater economic value compared to catheter B
- Use of catheter A may decrease the number of devices used per patient compared to catheter B
- Overall cost to contain fecal material may be reduced using catheter A compared to catheter B
- Leakage is an important criterion when evaluating bowel management systems as it can be associated with potential skin damage and risk of the spread of infection
- The lower rate of unscheduled bed linen/dressing changes seen with catheter A could contribute to lower hospital-associated pathogenic transmission of Clostridium difficile associated diarrhea and Vancomycin-resistant Enterococcus sp.

Reference List

(1) Beitz JM. Fecal incontinence in acutely and critically ill patients: options in management. Ostomy Wound Manage 2006; 52(12):56.

(2) Bliss DZ, Johnson S, Savik K, Clabots CR, Gerding DN. Fecal incontinence in hospitalized patients who are acutely ill. Nurs Res 2000; 49(2):101-108.

(3) 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.

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

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048 USA

For detailed clinical questions:
1.888.740.8999

For orders only:
1.800.323.4060

Distributed in Canada by
Hollister Limited
95 Mary Street
Aurora, Ontario L4G 1G3
1.800.263.7400

www.hollister.com

910638-1112