Fecal Containment in Bedridden Patients: Economic Impact of 2 Commercial Bowel Catheter Systems

By Areta Kowal-Vern, MD, Stathis Poulakidas, MD, Barbara Barnett, RN, Deborah Conway, RN, Daniel Culver, DO, Michelle Ferrari, RN, Bruce Potenza, MD, Michael Koenig, RN, John Mah, MD, Mary Majewski, RN, Linda Morris, PhD, APN, CCNS, Jan Powers, RN, PhD, Elizabeth Stokes, RN, Michael Tan, MD, Sara-Jane Salstrom, BS, Cindy Zaletel, RN, Shirley Ambutas, RN, MS, Kathleen Casey, MD, Jayne Stein, RN, BSN, Mary DeSane, RN, Kathy Berry, WOCN, Elizabeth C. Konz, PhD, RD, Michael R. Riemer, MS, and Malford E. Cullum, PhD

Background  Fecal contamination is a major challenge in patients in acute/critical care settings that is associated with increased cost of care and supplies and with development of pressure ulcers, incontinence dermatitis, skin and soft tissue infections, and urinary tract infections.

Objectives  To assess the economic impact of fecal containment in bedridden patients using 2 different indwelling bowel catheter systems and to compare infection rates between groups.

Methods  A multicenter, observational study was done at 12 US sites (7 that use catheter A, 5 that use catheter B). Patients were followed from insertion of an indwelling bowel catheter system until the patient left the acute/critical care unit or until 29 days after enrollment, whichever came first. Demographic data, frequency of bedding/dressing changes, incidence of infection, and Braden scores (risk of pressure ulcers) were recorded.

Results  The study included 146 bedridden patients (76 with catheter A, 70 with catheter B) who had similar Braden scores at enrollment. The rate of bedding/dressing changes per day differed significantly between groups (1.20 for catheter A vs 1.71 for catheter B; \( P = .004 \)). According to a formula that accounted for personnel resources and laundry cycle costs, catheter A cost $13.94 less per patient per day to use than did catheter B. Catheter A was less likely than was catheter B to be removed during the observational period (\( P = .03 \)). Observed infection rates were low.

Conclusion  Catheter A may be more cost-effective than catheter B because it requires fewer unscheduled linen changes per patient day. (American Journal of Critical Care. 2009;18:S2-S15)
Fecal contamination is a challenge in acutely and critically ill patients who are admitted to intensive care settings. The reported prevalence of fecal incontinence is 18% to 33% among patients in acute/critical care settings, and 3% among elderly persons in residential and nursing homes. Fecal contamination increases cost of care and makes critically ill patients particularly vulnerable for development of skin and soft tissue infection (SSTI), urinary tract infection (UTI), and nosocomial infection. Fecal contamination increases work for nurses by necessitating more unscheduled linen changes.

Feces contain protease and lipase, which can digest perianal skin and soft tissue. These enzymatic activities, combined with physical mechanical forces (pressure and shear), can excoriate and abrade skin in bedridden patients and lead to skin breakdown. In a study of 608 patients, 17.6% (107 patients) had fecal incontinence. Of those 107 patients, 49 (45.8%) had skin injury and 12 (11.2%) had a fungal rash. Results of a separate risk factors analysis model indicated that the odds of having a pressure ulcer was 22 times greater for hospitalized adult patients with fecal incontinence than for hospitalized adult patients without fecal incontinence. Recent reimbursement changes for hospital-acquired pressure ulcers from the Centers for Medicare and Medicaid Services underscore the need for hospitals to develop and implement comprehensive protocols for management of fecal incontinence.

Use of indwelling bowel management systems to divert, collect, and contain liquid stool may provide an economic advantage for hospitals dealing with fecally incontinent patients and help maintain a skin-friendly environment. The effectiveness of fecal diversion in the management of perianal burns has been demonstrated. In a recent study, although 17.6% of patients had fecal incontinence, only 3.7% (4/107) of patients used an indwelling bowel catheter system for fecal containment, despite the fact that 37.4% of these patients were experiencing liquid or semifluid stool.

Nosocomial infections are now recognized as a growing problem by the international health care community. Clostridium difficile–associated disease (CDAD) is the most common infectious cause of hospital-associated diarrhea. CDAD is associated with a spectrum of morbidities including colitis, toxic megacolon, and sepsis. In addition, CDAD is associated with longer hospital stays and increased health care costs.

Strategies to control CDAD include limiting contact with infectious diarrhea. Improved cleaning methods have resulted in significant decreases in contamination of environmental surfaces with C. difficile and vancomycin-resistant enterococci, and effective fecal containment may facilitate cleaning strategies that are often time consuming and difficult to achieve in everyday clinical practice. Effective cleaning of environmental surfaces, including “high touch objects,” is often an inadequate approach, and any method that has the potential to reduce contamination should be beneficial.

In a multifactor analysis, urinary incontinent events were the strongest predictor of quantity of
Two indwelling bowel catheter systems are compared for economic impact, effectiveness, and ease of use. until the time the patient had left the acute/critical care unit or 29 days had elapsed, whichever came first. Study sites chosen for catheter A were those whose standard practice was to use catheter A, whereas sites chosen for catheter B were sites whose standard practice was to use catheter B.

The 2 catheters have different design features. Catheter A consists of a silicone catheter with a collapse-resistant annulus, a low-pressure retention cuff, and collection bags. After the catheter is inserted, the retention cuff is inflated with 35 to 40 mL of water. Flow through the catheter can be stopped by using an intraluminal balloon. Catheter A is indicated for the diversion of fecal matter, to facilitate the collection of fecal matter, to provide access for colonic irrigation, and to administer enemas or medications. Catheter B consists of a soft silicone catheter tube assembly, syringe, and collection bags. The catheter is inserted into the rectum and the retention balloon is inflated with 45 mL of water. Catheter B is indicated for fecal management of patients with little or no bowel control and liquid or semiliquid stool.

The primary objective of the study was to assess the economic impact of using catheter A versus catheter B for fecal containment in bedridden patients.

### Population

The study population consisted of males and females, 18 years of age or older, who were bedridden in an intensive care nursing unit and had a physician’s order for the use of an indwelling bowel catheter system for fecal containment.

The study was reviewed by the local institutional review boards at all 12 participating sites. Informed consent was not required at 3 sites. Informed consent was obtained for patients at 7 sites, for nurses at 1 site who completed the questionnaire, and 1 site required a statement of research be furnished to the patient or family member in lieu of informed consent.

### Procedures

Sites using 1 of the 2 indwelling bowel catheter systems in their critical care unit were invited to participate. Sites were specifically chosen on the basis of their current standard practice for fecal containment. Neither the type of fecal containment nor the standard of care were changed during the course of the study. No intervention was prescribed. This was a convenience sample of bedridden patients located in critical care units who met the inclusion criteria.

Data were collected from patients from the time of catheter insertion until the patient left the critical care setting or 29 days after enrollment in the study, whichever came first. The study staff collected data on situations related to unscheduled bedding and dressing changes due to fecal contamination, rate and reasons for fecal leakage, incidence of infections in patients, and general impressions associated with the use of fecal containment systems. Removal of the device was not considered a reason for removing the patient from the study, as reinsertion during the 29-day study period was of interest. Skin condition in the perianal and buttock area, incidence of SSTI/UTI, and scores on the Braden Scale at enrollment and completion (when data were available) were also recorded by study staff.
Key study staff (study coordinators and investigators) were trained by clinical study monitors from Hollister Incorporated on protocol procedures and data collection. Study staff instructed critical care nurses on proper documentation of reinsertion, repositioning or replacement of a device, device removal, and unscheduled bedding/dressing changes. Grants were provided to each study site for the purposes of clinical research conduct. No individuals or patients were paid.

In addition, clinicians who used the catheters were asked to complete a questionnaire regarding their perception of the product, including feedback about ease of product insertion, product labeling, irritation, and other catheter-specific characteristics. The questionnaire consisted of approximately 30 questions including yes or no responses and questions that required use of the Likert scale of 1 (strongly disagree) to 5 (strongly agree). Study sites were asked to have staff members who worked on the study and had directly managed the care of enrolled patients complete this questionnaire.

Demographic, incidence, time-to-event, and clinician assessment data collected were analyzed by using SAS v9.1.3. Conclusions of statistical significance associated with differences in rate of incidence are based on parameter estimates obtained from generalized linear models constructed from the data.

**Results**

**Demographic Data**

The study included 146 patients who required fecal containment at 12 hospitals. Seventy-six of the patients (57.9% male, 42.1% female) were managed at hospitals where catheter A was in use and 70 patients (62.9% male, 37.1% female) were managed at hospitals that used catheter B. Subjects were seen in acute/critical care settings such as medical intensive care units, cardiac units, surgical intensive care units, trauma units, and burn units. Percentages of use for catheter A versus catheter B by type of intensive care unit are as follows: burn, 13.2% versus 0%; cardiac, 15.8% versus 7.1%; medical, 46.1% versus 42.9%; surgical, 19.7% versus 21.4%; other critical care units, 5.3% versus 28.6%. At enrollment, scores on the Braden Scale for Pressure Ulcer Risk26,27 were similar for patients with catheter A (range, 8-18) and patients with catheter B (range, 7-21). Demographic data for study participants are shown in Table 1.

Patients with catheter A were a mean of 18 lbs (39.6 kg) heavier and 1.2 years younger than patients with catheter B. These differences were not statistically significant.

### Table 1  
**Demographic information of study participants**

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Meana</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Catheter A</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>73b</td>
<td>61.1</td>
<td>15.4</td>
<td>18-97</td>
</tr>
<tr>
<td>Height, in</td>
<td>75c</td>
<td>67.5</td>
<td>4.2</td>
<td>60-76</td>
</tr>
<tr>
<td>Weight, lb</td>
<td>76</td>
<td>206.0</td>
<td>89.1</td>
<td>95-572</td>
</tr>
</tbody>
</table>

| **Catheter B** |     |       |     |       |
| Age, y       | 70  | 62.3  | 16.8| 19-86 |
| Height, in   | 63d | 67.4  | 3.7 | 59-74 |
| Weight, lb   | 69e | 188.0 | 59.8| 85-369|

SI conversion factors: To convert inches to centimeters, multiply by 2.54; to convert pounds to kilograms, multiply by 0.45.

a No significant differences in mean age (t141 = 0.47, P = .64), height (t136 = 0.26, P = .80), or weight (t141 = 1.41, P = .16) between groups are noted.
b Three ages were not reported.
c One height was not reported.
d Seven heights were not reported.
e One weight was not reported.

**Reasons Why Catheter Was Used**

Investigators recorded 1 or more reasons for catheter use (Table 2). Reasons for insertion of the catheters were influenced by several factors, including the individual institution’s guidelines and the previous training of the physicians and other caregiver staff.

**Economic Impact of Catheter Use: Counts of Bedding/Dressing Changes and Nursing Care Costs**

Economic impact of catheter use on fecal containment in bedridden patients was assessed by noting the occurrence of unscheduled bedding and dressing changes and estimating the standard nursing time required to perform this activity. Patient care staff recorded when fecal leakage caused 1 or more items of bedding or dressing to be changed, and each of these occasions was counted as an occurrence of nursing care related to unscheduled bedding and dressing changes. An exposure day was defined as any day that the device was in place and the relevant assessment was recorded by study staff. Table 3 shows the counts of bedding and dressing changes, number of exposure days, and the rate of bedding/dressing changes per patient per day for catheter A and catheter B.

In this analysis, we compared the rate of these unscheduled bedding/dressing changes over days that the device was in place for the 2 indwelling bowel catheter systems. The data suggested a statistically significant (χ2 = 8.55, P = .004) lower rate of incidence for catheter A (1.20 unscheduled
Catheter A had significantly fewer unscheduled bedding and dressing changes per day of device use than catheter B.

Table 2 Reasons why catheter was used

<table>
<thead>
<tr>
<th>Response</th>
<th>Catheter A</th>
<th>Catheter B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal incontinence/diarrhea</td>
<td>58 (32)</td>
<td>66 (56)</td>
</tr>
<tr>
<td>Prolonged sedation/confineinent</td>
<td>38 (21)</td>
<td>27 (23)</td>
</tr>
<tr>
<td>Catheter A/catheter B overall works better (than noncatheter alternatives)</td>
<td>36 (20)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Other modes were ineffective</td>
<td>14 (8)</td>
<td>7 (6)</td>
</tr>
<tr>
<td>Burns/wounds in or near the sacral/perianal area</td>
<td>9 (5)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Burn or donor sites likely to be contaminated</td>
<td>6 (3)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Necrotizing soft tissue infections in or near the sacral/perianal area</td>
<td>3 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Other modes are contraindicated</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (9)</td>
<td>10 (9)</td>
</tr>
<tr>
<td>Total</td>
<td>181</td>
<td>117</td>
</tr>
</tbody>
</table>

*Investigators were instructed to check all responses that apply to this question. The number of responses is not expected to match the number of subjects in the study.*

Table 3 Counts of bedding and dressing changes and exposure days

<table>
<thead>
<tr>
<th>System</th>
<th>Counta</th>
<th>Daysb</th>
<th>Ratec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter A</td>
<td>735</td>
<td>612</td>
<td>1.20</td>
</tr>
<tr>
<td>Catheter B</td>
<td>705</td>
<td>413</td>
<td>1.71</td>
</tr>
</tbody>
</table>

*a Total number of unscheduled bedding and dressing changes.  
b Total exposure days that the device was in place.  
c Rate of unscheduled bedding and dressing changes per patient per day.

bedding and dressing changes per day of device use) compared with catheter B (1.71 unscheduled bedding and dressing changes per day of device use).

In order to calculate the economic impact of the use of the indwelling bowel catheter systems, nursing care cost of unscheduled bedding and dressing changes per patient per day and the cost of laundry services were included in the model. The burden on nursing services for other patients while unscheduled bedding and dressing changes are being performed is acknowledged but was not included.

Nursing care costs for acute/critical care units were estimated from standard pay scales for intensive care unit personnel in the United States.24 The median hourly rate in US dollars updated October 2008 was $22 to $30 for registered nurses, $31 to $34 for wound ostomy care nurses, $36 for nurse practitioners, $40 for nurse managers, and $44 for clinical nurse specialists. A conservative estimate of $22/h for nursing care cost was used. The cost calculation assumes that it takes 2 nurses about 15 minutes to complete an unscheduled bedding and dressing change in the critical care unit. The formula used was as follows: (no. of unscheduled bedding and dressing changes/patient/d) x (2 nurses @ 15 minutes each) x (median pay scale for the lowest paid nurse; $22/h). This resulted in a cost of $13.20/d for catheter A and $18.81/d for catheter B.

Laundry services include the costs for processing, replacement, delivery and stocking, and collection. These were estimated to be $10/d in 199029 and $16.34 in 2008.30 The formula used for this was as follows: (no. of unscheduled bedding and dressing changes per patient day) x (cost of laundry services = $16.34). This resulted in $19.61/d for catheter A and $27.94/d for catheter B.

When cost of nursing time was added to the cost of laundry services and adjusted for total number of unscheduled bedding and dressing changes, use of catheter B was $13.94 per patient per day more costly than was use of catheter A. During the 29 days allowed by the Food and Drug Administration for the use of these devices, the cumulative cost of services for catheter A would be $951.49 and the cost of services for catheter B would be $1355.75 (Figure 1).

The cost differential of $13.94 per patient per day between catheter A and catheter B does not include the cost of the device itself. The results in Figure 2 can be used to estimate how many days of use are needed to determine if one catheter is a more cost-effective option than the other during the maximum 29 days of possible use for this type of device. By knowing the price differential between the 2 catheters and finding that value on the y-axis, the price differential between catheter A and catheter B, the days of catheter A for cost parity is the corresponding value on the x-axis (days to parity).

(Example: If catheter A cost $30 more than catheter B, it would take a little more than 2 days of use for the cost parity point to be reached.)

The difference in cost between the 2 catheters can be estimated from data published by GHX,31 a software and services company for health care providers. The days to cost parity based on a range in 2008 US dollars is shown in Table 4. Based on current estimates of the cost differential between the devices, only if the catheter were used for less than 2 or 3 days would there be a cost advantage of
using catheter B instead of catheter A. Cost difference does not include labor related to unscheduled reinsertions, number of devices used per patient, and differences related to accessories.

**Devices Used per Patient Day**

For sites that used catheter A, 86 devices were used in 76 patients during 612 patient days for a rate of 0.14 devices per patient day, and a mean of 1.13 devices were used per patient. For sites that used catheter B, 85 devices were used in 70 patients during 413 patient days for a rate of 0.21 devices per patient day, and a mean of 1.21 devices were used per patient.

A number of the study participants required additional insertions of the catheter after initial placement of the device. For catheter A, 6 of the 76 patients required reinsertion of the initial device for a total of 10 reinsertions and 11 of the 70 patients for catheter B required reinsertion for a total of 15 reinsertions. The reasons for reinsertion of the initial device are shown in Table 5. In 2 patients, 2 or more spontaneous expulsions were observed.

Thirty-four patients had a new device or the initial device reinserted. The total percentage of patients who required additional insertions after initial placement was 17.1% (13/76) for catheter A and 30.0% (21/70) for catheter B.

Various reasons for removal of the indwelling bowel catheters were recorded. In this group of patients, the indwelling bowel catheters were not generally required for the full 29-day study period. For catheter A, the reasons for removal were as follows: fecal containment no longer necessary (22 times), device reached 29-day maximum usage (1 time), patient was discharged from critical care unit (4 times), fecal modification (1 time), device was expelled (14 times), device was ineffective (3 times), and other unspecified reasons (26 times). For catheter B, the reasons for removal were as follows: fecal containment no longer necessary (18 times), device reached 29-day maximum usage (0 times), patient was discharged from critical care unit (5 times), fecal modification (10 times), device expelled (28 times), removed to perform colonoscopy (1 time), device was ineffective (10 times), and other unspecified reasons (14 times).

A number of the study participants required multiple new devices after placement of the initial device; that is, a number of patients, during their stay in the acute/critical care unit, had more than 1 new catheter placed. The percentage of patients who required additional new devices after removal of the initial device was 12% (9/76) for catheter A and 17% (12/70) for catheter B (Figure 3). Reasons for reinsertion of a new catheter A device included the following: device expelled (3/10), insertion of a different size catheter (3/10), device removed because fecal containment was no longer deemed necessary and then a new device was reinserted at a later date due to recurrent diarrhea (1/10), device deemed ineffective (2/10, due to leakage and odor and stop

![Figure 1](http://ajcc.aacnjournals.org/Downloaded from) Cumulative nursing and laundry service cost.

![Figure 2](http://ajcc.aacnjournals.org/Downloaded from) Cost parity calculator.
flow connector broke after 22 days of use), and other unspecified reasons (1/10). Reasons for reinsertion of a new catheter B device included the following: device expelled (1/15), device removed because fecal containment was no longer deemed necessary and then a new device was reinserted at a later date due to recurrent diarrhea (4/15), and device deemed ineffective (10/15) (tear in the tubing after 4 days of use; balloon port broke off after 10 days of use; balloon appeared to malfunction and would not deflate after 7 days of use).

Repositioning and Leakage of Catheter

Catheters may need to be repositioned for numerous reasons, including the following: patient being turned to a new position, elimination of a clog in the catheter, relieving a bedding entanglement, or elimination of odor. Leakage abatement and maximizing stool flow without leakage are the major reasons for repositioning fecal catheters. In general, repositioning is a measure of the number of times nursing staff are required to untangle a catheter so that leakage, odor, or other potential undesirable effects are reduced. In the present study, catheter A was repositioned a total of 199 times (612 exposure days) with a rate of 0.33 repositionings per day. Catheter B was repositioned 195 times (413 exposure days) with a rate of 0.47 repositionings per day. Repositionings due to leakage occurred 156 times (612 exposure days) for catheter A versus 163 occurrences (413 exposure days) for catheter B. The rate of repositioning due to leakage was 0.25 for catheter A and 0.39 for catheter B (Figure 4).

The rate of repositioning per patient due to odor was 0.09 (56 occurrences) for catheter A and 0.21 for catheter B (85 occurrences). The rate of repositioning per patient due to other unidentified reasons was 0.04 (25 occurrences) for catheter A and 0.03 (14 occurrences) for catheter B.

Indwell Time of Bowel Catheters

Indwell time was defined as the time from initial insertion of a device until the time it was removed, the patient left the study, or the 29-day study period was over. For the purpose of calculation of indwell time, reinsertion of the same device on the same day has not been considered a device removal or new insertion. The range of observed indwell times was 0 to 29 days. Where catheter A was in use, 27 of 76 patients left the study with the catheter in place, and where catheter B was in use, 28 of 70 patients left the study with the catheter in place. In these cases, it was assumed that the device was removed at some unknown time after the patient left the study. The data suggest that catheter A was significantly less likely to be removed in the time period studied (Wilcoxon: $P = .048$, log-rank:
of those who evaluated catheter A were comfortable after 3 or fewer insertions and 94% (50 of 53) of those who evaluated catheter B were comfortable using the catheter after 3 or fewer insertions. Additionally, when asked to rate their agreement with a statement indicating that they were satisfied with the overall performance of the catheter being evaluated, 84% (66 of 79) of those evaluating catheter A and 80% (45 of 56) of those evaluating catheter B indicated that they would recommend the catheter that they evaluated.

Of the clinicians who completed the questionnaire, 92% (n = 77) of those who used catheter A and 82% (n = 54) of those who used catheter B indicated that they would recommend the catheter that they evaluated.

Oral Osmotic Agent and Stool Softener Use

Some of the study participants 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, and permitting more fluid fecal flow. Use of such agents was not a part of the study procedures, but was prescribed by the care providers. Twenty-nine patients with catheter A and 18 patients with catheter B were reported to have taken stool softeners during the course of the study (Table 6). Use of osmotic agents and stool softeners was not significantly different in the 2 groups.

Incidence of Skin/Soft Tissue and Urinary Tract Infections

To assess the incidence of SSTI and UTI, the number of newly diagnosed SSTIs and UTIs as reported by study staff as well as the total days of exposure were recorded. In this analysis, an exposure day for SSTI/UTI was defined as any day that the device was in place and the presence of the infection was assessed by study staff. A total of 2 SSTIs (553 exposure days) versus 6 SSTIs (406 exposure days) were observed in patients treated with catheters A and B, respectively. A total of 4 UTIs (548 exposure days) versus 1 UTI (408 exposure days) were observed in patients treated with catheters A and B, respectively. Because of the low incidence of new infections and the observational nature of the study, these data have no statistical value and are included for informational purposes only.

Catheter Ease-of-Use: Clinicians’ Opinion of Indwelling Bowel Catheter Systems

A total of 137 clinicians completed the questionnaire: 81 clinicians completed the questionnaire for catheter A and 56 clinicians completed the questionnaire for catheter B.

Clinicians were asked questions about the ease of insertion and removal of the catheter, inflation and deflation of the retention cuff, connection or disconnection of the collection bag, flushing the drainage tube or milking/stripping the drainage tube, and irrigation.

Not all clinicians made all of the assessments requested; the proportions reported are based on the number of clinicians responding. When asked how many insertions were necessary to feel comfortable using the catheter being evaluated, 94% (65 of 69) of those who evaluated catheter A were comfortable after 3 or fewer insertions and 94% (50 of 53) of those who evaluated catheter B were comfortable using the catheter after 3 or fewer insertions. Additionally, when asked to rate their agreement with a statement indicating that they were satisfied with the overall performance of the catheter being evaluated, 84% (66 of 79) of those evaluating catheter A and 80% (45 of 56) of those evaluating catheter B indicated that they would recommend the catheter that they evaluated.

Of the clinicians who completed the questionnaire, 92% (n = 77) of those who used catheter A and 82% (n = 54) of those who used catheter B...
would recommend the respective catheter to divert fecal material.

**Number of Patients Discharged From Acute/Critical Care Setting With Catheter in Place**

The number of patients who were discharged from the critical care unit to other nursing units with the indwelling catheter in place was far greater than expected. Fifty-five of the total 146 patients (37.7%) in the study transferred out of the acute/critical care unit with either catheter A (27/76, 36%) or catheter B (28/70, 40%) in place.

**Use of Irrigation With an Indwelling Bowel Catheter**

The unique design and characteristics of catheter A, such as the intraluminal balloon, provides access for colonic irrigation. In this study, 57 of the 76 patients with catheter A (75%) received gravity irrigation through the indwelling catheter. Of these patients, the mean amount of water used to irrigate was 360 mL per irrigation (range, 10-1000 mL). Patients had the catheter irrigated between 1 and 4 times per day (median, 2 times per day; mode, 1 time per day). Catheter B permits syringe (50 mL) irrigation of the catheter itself.

**Discussion**

Indwelling bowel catheters have shown utility in the surgical intensive care unit, burn units, geriatric units, long-term acute care hospitals, and acute care/critical care units. Although bowel ulceration events during use have been reported for both catheters, indwelling bowel catheters are generally safe if used according to their instructions. These indwelling bowel catheters have been useful in averting ostomy for perianal burns, reducing the number of bedding and dressing changes, managing stool of various consistencies, and preventing gastrointestinal enzymes from damaging perianal skin, which facilitates skin ulcers.

This prospective study was the first to compare 2 indwelling bowel catheter systems in the critical care setting for economic impact, effectiveness, and ease of use. Economic impact was assessed by quantifying the occurrence of unscheduled bedding and dressing changes and the estimated nursing time to perform this activity. This study was conducted on a convenience sample of bedridden patients in critical care units in which an indwelling bowel catheter was placed.

In this study, 1.20 unscheduled bedding and dressing changes per day were done for catheter A, and 1.71 unscheduled bedding and dressing changes per day were done for catheter B. Keshava et al found a large reduction in bedding and dressing changes when using catheter A compared with previous methods that did not use an indwelling bowel catheter for fecal containment. The combined data suggest that the overall cost of bedding and dressing changes decreases when an indwelling bowel catheter is used.

In order to calculate overall economic impact, the cost of laundry services was also taken into account. With these costs included, the use of catheter B was calculated to cost $13.94 more per day than use of catheter A. Echols et al evaluated the economic impact of catheter A in a burn unit. Their evaluation considered costs associated with a typical soiling event to include laundering of linens, basic dressing changes, and analgesia/sedation. Nursing costs were not discussed. Their cost of linen laundering per soiling episode was $5.89 compared with our cost of $8.17. Differences in the estimation of cost of linen laundering per soiling episode may be attributed to additional components of the laundry cycle costs that we included in our analysis. Overall, this suggests that independently the 2 groups came to similar conclusions regarding laundry cost estimates.

Skin health is a major clinical goal for fecal incontinence management, and catheter leakage is associated with skin breakdown. A direct causal link between number of nursing care visits, fecal incontinence, and excess resource expenditure has not yet been established. As recently as December 2006, the cause and effect relationship between development of pressure ulcers and incontinence has not been reported in the literature. In combining the information from the literature, one can infer an association between fecal incontinence and increases in resource expenditures (eg, increased number of unscheduled bedding/dressing changes). Unresolved

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**Table 6**

<table>
<thead>
<tr>
<th>Status</th>
<th>No. (%) of patientsa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Catheter A</td>
</tr>
<tr>
<td>Received osmotic agents or stool softeners</td>
<td>29 (38)</td>
</tr>
<tr>
<td>Did not receive osmotic agents or stool</td>
<td>47 (62)</td>
</tr>
<tr>
<td>softeners</td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>76</td>
</tr>
</tbody>
</table>

a The proportion of patients receiving osmotic agents or stool softeners does not differ significantly in the 2 groups ($\chi^2$ = 2.58, $P = .11$).
issues on the topic of best practices to prevent and treat pressure ulcers remain in the latest (2001) National Pressure Ulcer Advisory Panel monograph.36 In a multifactor analysis, urinary incontinence events were the strongest predictor of quantity of soiled linen,7 and it is reasonable to assume that fecal incontinence events would likewise result in soiled linen. Results of the same study showed that mobility and mental function were highly correlated with fecal incontinence.

Our study’s results are similar to the findings of Edman et al.35 They found that the incidence of perianal ulcer for catheter A was 1 of 40 patients in 637 patient days; for catheter B it was 4 of 24 patients in 137 patient days. Using a retrospective analysis, Echols et al34 reported a decrease in SSTIs from 46.2% to 19.8% and a decrease in UTIs from 27.4% to 14.2%, following the introduction of fecal catheters. In our study, the observed incidence of SSTIs was 2 patients in 553 exposure days for catheter A and 6 patients in 406 exposure days for catheter B. Low incidence of UTI events also were observed (4 patients in 548 exposure days for catheter A, 1 patient in 408 exposure days for catheter B).

Various scoring methods can be used to evaluate the catheters’ ability to manage fecal incontinence and forestall ulcer development by keeping perianal skin clean and dry to aid in healing or preventing skin breakdown. Keshava et al12 reported that the Perianal Disease Activity Index score was significantly reduced after the use of catheter A ($P < .001$). The occurrence of pressure ulcers might also be used as an outcome measure for the adequacy of fecal diversion. Benoit and Watts34 reported that after the implementation of a pressure ulcer prevention program including the use of catheter A, the prevalence rate of pressure ulcers decreased from 43% to 12.5% in their surgical intensive care unit after 6 months. Overall, the studies assessing indwelling bowel catheter systems12–14,34,36 reported that maintaining skin integrity is an important benefit resulting from the management of fecal continence. Missing data precluded analysis of skin condition as an outcome measure in this study.

Several factors such as devices used per day, number of expulsions, frequency of repositioning, and leakage of the catheters are important in assessing the effectiveness of these catheters in the management of fecal incontinence. In the present study, the number and rate of catheters used (1.13 vs 1.21 devices per patient and 0.14 vs 0.21 devices per patient per day, respectively) were similar for catheters A and B. Padmanabhan et al36 found that 3 of the 38 patients observed for more than 24 hours did not retain the device, and similar results were observed here. Although the finding was not statistically significant, catheter A required fewer additional insertions after initial placement than did catheter B (13/76 for A vs 21/70 for B). Catheter A also required fewer new devices per patient after the start of the study than did catheter B (9/76 vs 12/70, respectively). The rate of repositioning due to leakage for catheter A was 25%, whereas for catheter B it was 39%. Padmanabhan et al36 estimated the rate of leakage during use of catheter B to be 53%; Edman et al35 found a 15% leakage rate for catheter A and a 62.5% leakage rate for catheter B. Overall, the results of these studies consistently show that leakage was more frequently associated with the use of catheter B than catheter A.

The present study indicated a median indwell time for catheter A of 8 days and an indwell time for catheter B of 6 days. The probability of removal of catheter B differed significantly from the probability of removal of catheter A. Similar results have been shown, where the mean duration of rectal intubation for catheter A was 14 days2 compared with 5.6 days for catheter B.36 Edman et al35 also found longer indwell times for catheter A than for catheter B (22.5 days vs 3 days, respectively). Factors contributing to the observed differences in indwell times between the catheters could include slight differences in the populations of patients studied or the medical setting in which the patients are admitted.

Another important component that may affect indwell time is stool consistency. The ability to use gravity irrigation techniques may explain the longer indwell time for catheter A compared with catheter B. Similar observations were seen in a prospective study of 20 patients using a bowel management system for fecal containment.12 In that study, 300 mL of warm water was used to irrigate once daily for patients with diarrhea and 2 to 3 times per day for burn patients to modify stool consistency. Others have reported effective use of irrigation with this product.13,14,34,35 It may be concluded from the present findings and the studies in the literature...
Indwelling bowel catheters are generally safe if they are used according to the manufacturer’s instructions. Data suggest that the overall cost of bedding and dressing changes decreases when an indwelling bowel catheter is used.

Conclusions

This observational study provided information about how indwelling bowel catheter systems are used and how they are perceived by the nurses who manage the care of patients in critical care settings. The findings demonstrate that indwelling bowel catheters are easy to use and cost-effective. The results suggest that catheter A would provide a greater economic impact than would catheter B for the following reasons: (1) it requires significantly fewer bedding and dressing changes, (2) it requires fewer linen changes per patient day, and (3) the device was less likely to be removed during the course of the observational period. Based on the assumptions described and the results just referenced, only if the catheter were to be used for fewer than 2 or 3 days would there be a cost advantage of using catheter B.

Study Limitations

The limitations of the study are related to the observational design, which was chosen so as not to compromise the current standard of care related to patient risks due to fecal incontinence. Previous research has shown that indwelling bowel catheters are effective in patients with fecal incontinence. A randomized study design with a noncatheterized control group (resulting in general fecal soiling) could cause harm to a patient who would benefit from the use of an indwelling bowel catheter for fecal containment. The current study design was not sufficient to control for extraneous factors or to adequately determine the incidence of SSTIs/UTIs in these cohorts.

The pragmatic choice to enroll and follow patients strictly in critical care settings may have limited the potential information of overall indwell time of the catheters, amount of leakage, and associated unscheduled bed linen and dressing changes that could have occurred in hospital units outside of the critical care unit setting. Similarly, the severity of a leakage episode was not addressed in the current study (ie, if a catheter caused a leak in which only a pad was soiled rather than an entire bed). Recording of the actual amount of nursing time involved in each unscheduled change in bed linens or dressing could have provided more exact data, but accuracy might have been difficult to achieve in this type of busy unit.

Future Directions

The present study is observational and has shown the benefit of use of indwelling bowel catheters in a variety of critical care units. The economic impact, effectiveness, and ease of use of 2 indwelling bowel catheter systems in the critical care setting were compared. Additional studies focused on the economic impact of the use of indwelling bowel catheters in other targeted populations should be considered. High-risk populations with need for longer residence times such as heavily burned patients and patients with coagulation and thrombocytopenic abnormalities should be investigated in detail as populations that can benefit from bowel management systems.

In addition, with the increase in nosocomial infections, randomized studies are needed to determine whether use of indwelling bowel catheters can help in decreasing contamination and infection of patients.

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REFERENCES


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Technical and scientific questions should be directed to Malford E. Cullum, PhD, 2000 Hollister Dr, Libertyville, IL 60048-3781; e-mail, malford.cullum@hollister.com. Reprint requests and other communications should be directed to marketinfo@hollister.com.
1. What is the reported prevalence of fecal incontinence among patients in acute/critical care settings?
   a. 8% to 13%
   b. 18% to 33%
   c. 38% to 43%
   d. 48% to 53%

2. Compared to hospitalized adult patients without fecal incontinence, what were the reported odds of pressure ulcer development for those with fecal incontinence?
   a. 8% to 13%
   b. 12 times greater
   c. 22 times greater
   d. 32 times greater

3. What is the most common infectious cause of hospital-associated diarrhea?
   a. *Escherichia coli*
   b. *Shigella*
   c. *Clostridium difficile*-associated disease
   d. *Salmonella*

4. What risk factors are highly correlated with fecal incontinence?
   a. Burns and sepsis
   b. Age and body surface area
   c. Pressure ulcer risk and immobility
   d. Mobility and mental function

5. Which of the following is correct about the design features of catheter A compared to catheter B?
   a. Catheter B is indicated to provide access for enema administration.
   b. Catheter A consists of a rigid silicone catheter tube assembly, syringe, and collection bags.
   c. Catheter B is indicated to provide access for medication administration.
   d. Catheter A is indicated to provide access for colonic irrigation.

6. What tool was used in this study to determine pressure ulcer risk?
   a. Norton scale
   b. Waterlow scale
   c. Braden scale
   d. Douglas scale

7. What hourly estimate was used for nursing care cost in this study?
   a. $22
   b. $31
   c. $40
   d. $44

8. Which of the following is correct about the cost difference between the 2 catheters used in this study?
   a. Catheter B was $13.94 per patient per day more costly.
   b. Cost differences included labor related to unscheduled reinsertions.
   c. The cumulative cost over 29 days of services for catheter A would be $1,355.75 and $551.49 for catheter B.
   d. Cost differences included number of devices used per patient.

9. Which of the following is correct about the study participants' demographics?
   a. Catheter B subjects were slightly heavier than catheter A subjects.
   b. There were no significant differences in mean age, height, or weight.
   c. Catheter A subjects were 1.2 years older than catheter A subjects.
   d. The mean height in both groups was 70 inches.

10. Why did 21% of catheter A subjects and 23% of catheter B subjects require an indwelling bowel catheter?
    a. Burn wound in or near sacral/perianal area
    b. Prolonged sedation/confine
    c. Burn or donor sites likely to be contaminated
    d. Necrotizing soft tissue infections in or near the sacral/perianal area

11. Which of the following is correct about the number of patients receiving osmotic agents or stool softeners in this study?
    a. There was no statistical difference in the groups when comparing osmotic agents and stool softener use.
    b. Forty-seven percent of catheter A subjects received osmotic agents or stool softeners.
    c. Eighteen percent of catheter B subjects did not receive osmotic agents or stool softeners.
    d. Neither group received osmotic agents or stool softeners.

12. Which choice is a finding demonstrated in this study?
    a. Significantly higher bedtimes and dressing changes were associated with catheter A.
    b. A decreased number of patient changes per patient day were required with catheter B use.
    c. Catheter B was less likely to be removed during the study.
    d. Indwelling bowel catheters were easy to use and cost effective.

13. At these study sites, how many patients were transferred out of the critical care unit with the devices remaining in place?
    a. None, it was required to be removed before leaving the ICU
    b. About 10% to 20% of patients
    c. About 35% to 40% of patients
    d. About 80% to 90% of patients

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**Test Answers:**

1. a 2. a 3. a 4. a 5. a 6. a 7. a 8. a 9. a 10. a 11. a 12. a 13. a

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**Program evaluation**

Objective 1 was met ☐ ☐
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Fecal Containment in Bedridden Patients: Economic Impact of 2 Commercial Bowel Catheter Systems

Areta Kowal-Vern, Stathis Poulakidas, Barbara Barnett, Deborah Conway, Daniel Culver, Michelle Ferrari, Bruce Potenza, Michael Koenig, John Mah, Mary Majewski, Linda Morris, Jan Powers, Elizabeth Stokes, Michael Tan, Sara-Jane Salstrom, Cindy Zaletel, Shirley Ambutas, Kathleen Casey, Jayne Stein, Mary DeSane, Kathy Berry, Elizabeth C. Konz, Michael R. Riemer and Malford E. Cullum

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