Randomized Controlled Study of the Effects of Two Fecal Management Systems on the Incidence of Anal Erosion

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Background

- Adult ICU patients are vulnerable to fecal incontinence, that can result in incontinence associated dermatitis, pressure ulcers, C-Diff infections
- FMS use occurred most often in MICU
- Occurrence of anal erosion was within the first 14 days of use; ~ 40% erosion rate
- Development of anal erosion may be associated with the length of time FMS in place, presence of perianal edema, or other co-morbidities
Literature Search

- 3 published case studies documenting the presence of anal erosion or ano-vaginal fistula associated with the use of FMS
- No prospective, randomized studies found (prior to our study) looking at indwelling Fecal Management systems and anal erosion
- Most studies were product evaluations with 1 FMS and a non-randomized observational studies evaluating 2 different FMSs

Purpose and Hypotheses

- Purpose: Determine the prevalence of anal erosions within a 14 day period among adult ICU patients based on receiving one of two Fecal Management Systems through random assignment
- Null hypothesis: There is no difference in the rate of anal erosion between Flexi-Seal and Digni-Care fecal Management systems in a 14 day period
Outcomes

- Primary: Development of anal erosion
  - Anal erosion defined: any tear/erosion of skin in a 3 cm radius surrounding the anus

- Secondary: Factors associated with anal erosion

Methodology

Study Group
- 160 adults (18yrs+) in the MICU or SICU and have an FMS ordered by a physician/licensed independent practitioner
- Cleveland Clinic Main Campus
  - Patients who meet inclusion criteria were randomly assigned to one of two fecal management systems
Inclusion Criteria

- Bedfast patients with liquid to semi-liquid stool requiring FMS (to prevent skin breakdown or contamination of existing wounds)
- Liquid to semi-liquid stool incontinence for past 3 days that is expected to last for extended period due to poor response to anti-diarrhea treatment

Exclusion Criteria

- Allergic to product components
- Rectal or anal injury or active bleeding
- Severe rectal or anal stricture or stenosis (distal rectum cannot accommodate the balloon), diseases of the rectal mucosa (i.e. severe proctitis, ischemic proctitis, mucosal lacerations)
- Rectal or anal tumors
- Severe hemorrhoids
- Fecal impaction
- Loss of rectal tone or prolapsed anal sphincter
- History of ileo-anal anastamosis or internal rectal pouch (e.g. S or J pouch)
- Large Bowel (Colon) surgery or rectal surgery within the last year
- On heparin drip
**Measurement Methods**

- 4 case report forms:
  - Insertion of FMS Form
  - Epic Chart Abstraction Form
  - Daily Assessment Form
  - FMS Removal Form

- Developed by researchers with expert feedback from APNs (face validity)

- Forms use:
  - Multiple choice options
  - Dichotomous (Yes/No) options
  - Short answer response

**Data Collection**

- RN data collector x1 was trained for FMS insertion and data collection of all subjects
- Core group of experienced RNs was trained for FMS insertion
- Data collection: May, 2011 - April, 2012
- Anal erosion assessed daily x 14 days or less if the FMS is discontinued
- If an anal erosion developed within the monitoring period (14 days), then the end point is met and monitoring is discontinued
Statistical Analyses

- Categorical factors summarized using frequencies and percentages
- Continuous measures summarized using mean (standard deviation), medians, (IQR)
- Frequency of anal ulcers between the two systems were compared with logistic regression models
  - Kaplan-Meier estimates
  - Log rank tests
- SAS software used; significance level set at \( p= 0.05 \)

RESULTS: Mid-point Analysis

- 81 patients randomly enrolled
  - 79 subjects included in interim analysis
    - 41 patients received DigniCare
    - 38 patients received Flexi-Seal
Patient Demographics
- Age, mean (SD), 64 ± 13.6 years
- Female gender, 41 (51.9%)
- Body mass index, 30.1 ± 8.4 kg/m2
- Conscious at time of insertion, 44 (55.7%)
- Enrolled from:
  - 59 (74.7%) MICU
  - 3 (3.8%) SICU
  - 17 (21.5%) other nursing floors

Baseline Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Dignicare n = 41</th>
<th>FlexiSeal n = 38</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin, g/dL</td>
<td>2.6 ± 0.59</td>
<td>2.6 ± 0.68</td>
<td>0.31</td>
</tr>
<tr>
<td>Total Protein value, g/dL</td>
<td>5.5 ± 0.87</td>
<td>5.6 ± 0.85</td>
<td>0.80</td>
</tr>
<tr>
<td>Lympohcytes, %</td>
<td>10.3 ± 5.6</td>
<td>9.6 ± 6.3</td>
<td>0.64</td>
</tr>
<tr>
<td>Platelets, k/ul</td>
<td>181.2 ± 141.6</td>
<td>180.5 ± 118.1</td>
<td>0.75</td>
</tr>
<tr>
<td>ProThrombin Time, sec.</td>
<td>39.8 ± 14.7</td>
<td>38.0 ± 16.0</td>
<td>0.12</td>
</tr>
<tr>
<td>Water in cuff, cc</td>
<td>42.7 ± 3.7</td>
<td>39.3 ± 6.1</td>
<td>0.008</td>
</tr>
<tr>
<td>Manometer reading, mmHg</td>
<td>25.9 ± 6.6</td>
<td>50.4 ± 22.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Results: Mid-Point

- No statistically significant difference in anal erosion between the two groups
- The documented percentage of anal erosions for all patients was 13%
- Study stopped for futility
  - Implausible that anal erosion rates would differ over time if data collection continued
  - Unlikely that more subjects will lead to statistically significant differences in anal erosion between groups

Results: Mid-Point

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Dignicare</th>
<th>Flexiseal</th>
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</thead>
<tbody>
<tr>
<td>0%</td>
<td></td>
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<tr>
<td>5%</td>
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<tr>
<td>10%</td>
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<tr>
<td>15%</td>
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<tr>
<td>20%</td>
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<tr>
<td>25%</td>
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</tbody>
</table>

$P = 0.88$
Results: Mid-Point

Factors Associated with Anal Erosion

Factors associated with anal erosion in both groups:

- Peri-anal stool leakage occurring anytime while FMS in place; \( p = 0.027 \)
  - All anal erosion patients experienced leakage before anal erosion development
- Trends in higher anal erosion were found in patients with:
  - Less water in the balloon; \( p = 0.072 \)
  - Lower balloon pressures in rectum; \( p = 0.080 \)
Mean Rectal Manometer Readings by Day

Bold lines represent mean manometer readings per group

Limitations

- Single center study with small sample size
  - Large quaternary care medical center
  - Results could be different in a different environment or in a different population of patients (lower or higher acuity)
- Did not reach intended sample size
- Nurses at our setting may have different procedures than nurses from other settings
Summary

- Anal erosion was well below the perceived rate by nurses
- Incidence of anal erosion did not differ based on FlexiSeal or DigniCare indwelling FMS
  - Incidence of anal erosion should not be a deciding factor in product choice
- Stool leakage was associated with anal erosion development
- Need to explore ways to prevent leakage; i.e., amount of water in balloon, etc.

Research Implications

- More research is needed on:
  - Ways to prevent erosions
  - Staging of anal erosions
  - Ways to heal erosions when an indwelling FMS in place
Clinical Implications

- Developing a rating scale for anal erosions
  - To standardize assessment of erosion
  - To determine clinical action
    - System removal
    - Treatment of erosions and outcome
- Daily assessment to prevent anal erosion
- Using other devices (i.e., fecal incontinence collector) prior to inserting FMS
- If a coordinated patient management plan involving medicine, nursing, and nutrition would improve patient selection of FMS

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