Clinical Evaluation of a Novel Intrarectal Device Versus Balloon Intrarectal Device for Fecal Incontinence

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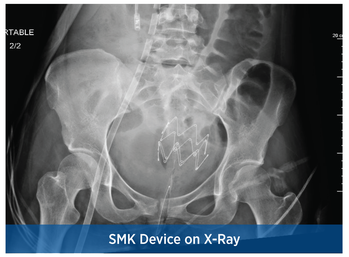
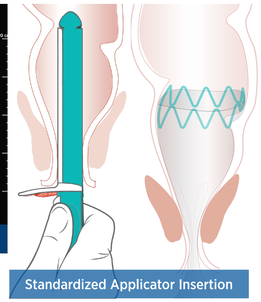
TOPIC/SIGNIFICANCE:

- Management of fecal incontinence is challenging in ICU settings and the treatment of liquid fecal incontinence is imperative to maintain the patient's skin integrity and prevent painful erosive wounds.
- Incontinence Associated Dermatitis (IAD) is a type of Moisture Associated Skin Damage (MASD) that is described as "erythema and inflammation of the skin sometimes accompanied by erosion or denudation caused by exposure to urine or stool."[1] The prevalence of IAD especially in the acute care settings can be high. In a study completed by Gray[2] of 5,342 patients in acute care facilities in 36 states, researchers found that more than one-third, 46.6% were incontinent of urine, stool, or both. The overall prevalence rate of IAD was 21.3%. The prevalence of IAD among patients with incontinence was 45.7%.
- The use of internal fecal containment devices is widely utilized in ICU settings for fecal management. Current products utilize a water filled balloon to anchor the device within the rectal vault. While it provides effective diversion of liquid stool, it also poses some complications such as anal erosion and peri-anal skin breakdown due to leakage around the balloon. One study between 2 balloon based fecal management systems found an incidence of anal erosion of 12.7% with no significant difference between the two trialled products.[3] Another complication that can occur even with correct balloon inflation is erosion of the internal rectal mucosa causing a gastrointestinal (GI) bleed. Patients receiving therapeutic doses of anticoagulation are particularly at higher risk for this complication.[4]
- A novel intra-rectal stool management kit (SMK) that uses 'stent like' technology with a soft lumen diverter that anchors above the anorectal junction was trialled to compare to a balloon-based product.

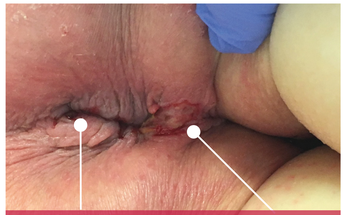
PURPOSE/OBJECTIVES:

To evaluate a novel intrarectal stool management kit (SMK) versus balloon based intrarectal fecal management system (FMS) to assess for fecal containment, skin and GI complications, and staff perception.


SMK Device on X-Ray


Standardized Applicator Insertion


SMK Device Lattice


Anal erosion and perianal pressure injury from FMS

PROCESS:

- IRB approval was obtained.
- Approval was obtained from colorectal surgeons for the SMK before the start of the trial.
- The SMK packaging stated MRI conditional. Approval from the radiology department was obtained for use. The SMK was added as an implant in the Electronic Medical Record upon insertion alerting the radiology department that the SMK was in use.
- A total of 24 ICU patients were evaluated with our current balloon-based FMS from August 2019 through September 2019, with data collection twice per week by the WOC nurse.
- Inclusion criteria for the SMK was based on our current inclusion criteria for the current FMS.
- A total of 22 ICU patients were evaluated between the end of September 2019 and October 2019, with the novel intrarectal SMK. Data was collected three times per week by WOC nurse. Data was collected on only 18 patients due to early removal of device.
- A skin condition rating scale of the buttocks and perianal area was used to describe the skin condition. The scale was based on a previous published clinical evaluation of an incontinence management system.[7]
- Training for the nursing staff on the SMK was completed on 3-day and 3-night shifts including the weekend. A teaching board with a video was available for staff viewing on use of the SMK.
- Evaluations were performed by the nurse at the end of every shift. (N=72). Completed forms were collected three times per week by the WOC nurse.
- Evaluations included:
  - Ease of insertion
  - Patient comfort level
  - Peri-anal skin breakdown
  - Was device easily dislodged
  - Development of pressure injury
  - Ease of removing/attaching collection bag
  - Ease of removal
  - Amount of leakage
  - Stool consistency
  - Odor control

OUTCOMES:

- Balloon FMS: 1 GI bleed confirmed with colonoscopy. Bleeding noted on day 10. Receiving IV Heparin.
- Novel SMK: 1 GI bleed, seen by GI service, no colonoscopy completed. Bleeding stopped after removing SMK. Bleeding noted on day 7. SQ anticoagulation.
- Mean (±SD) days system in place: SMK=5.6±3.5 ; FMS=10.5±9.6
- Peri-anal skin breakdown with redness but intact skin: SMK=0 ; FMS=3
- Denuded or bleeding skin: SMK=0 ; FMS=3
- Pressure Injury: SMK - Stages 2 and 3=0, DTI=1 (patient in chair for 7 hours)
  FMS - Stage 2=2, Stage 3=1, DTI=0
- Anal Erosion: SMK=0 ; FMS=2
- Leakage reported by staff evaluation of SMK (72 completed): None=19, Small=33, Moderate=9, Large=6
- Positive staff evaluation comments:
  - Ease of insertion with the applicator
  - Optimistic for an alternative device
- Negative staff evaluation comments:
  - Ease of dislodgement
  - Gas valve clogging with no way to remove gas
  - Inability to reinsert catheter
- SMK is an alternative to balloon-based FMS. Careful monitoring of both systems is needed to prevent GI and skin complications.

Variables	Balloon FMS n=24	Novel SMK n=18	P Value
ICU N (%) CTICU N (%) Oncology ICU Medical ICU Surgical ICU	 18 (75%) 6 (25%) 0 0	 4 (22%) 0 9 (50%) 5 (28%)	NS
Gender Male N (%)	15 (65%)	8 (44%)	NS
C.diff Yes N (%)	2	0	NS
VRE Yes N (%)	3 (12.5%)	2 (11%)	NS
Vasopressors Yes N (%)*	16 (66%)	6 (33%)	0.021
Anticoagulants Yes N (%)*	13 (54%)	15 (83%)	0.047
Tube Feeding Diet N (%)	19 (86%)	13 (76%)	NS
Stool Thickening N (%)	1 (4%)	1 (65)	NS
Age Mean ± SD	57.8 ± 15.1	56 ± 18.8	NS
BMI Mean ± SD	31.5 ± 11	30.4 ± 11.2	NS
Highest Stool Volume 24 hours Mean ± SD*	806.5 ± 421.4	329 ± 349.2	<0.001
Mean Stool Volume 24 hours Mean ± SD*	636.6 ± 383.1	244.9 ± 345.9	0.002

Variables	Balloon FMS	Novel SMK	P Value
Days FMS in place*	10.5 ± 9.6	5.6 ± 3.5	0.046
Leakage Amount median/mean	2/1.9	2/1.7	NS
Comfort Level median/mean	3/2.7	2.5/2.6	NS
Perinial Skin Breakdown Normal Intact Skin Redness but skin intact Denuded or bleeding skin	 19 (79%) 2 (8%) 3(12.5%)	 15 (83%) 3 (16%) 0	NS
Perinial Pressure Injury None Stage 2 Stage 3 DTI	 21 (88%) 2 (8%) 1 (4%) 0	 17 (94%) 0 0 1 (5%)	NS
Anal Erosion	2 (8%)	0	NS
Rectal Bleeding	1 (4%)	1 (6%)	NS

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