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Clinical Evaluation of a Novel Intrarectal Device for Management of Fecal Incontinence in Bedridden Patients

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ABSTRACT

PURPOSE: The primary objective of the study was to evaluate the safety and efficacy of a stool management kit (SMK) for containment of fecal incontinence in hospitalized bedridden patients.

DESIGN: A single-group quasi-experimental study.

SUBJECTS AND SETTING: Twenty bedridden adults who had at least 1 episode of fecal incontinence in the prior 24 hours participated in the study. The study setting was the neurological unit of the All India Institute of Medical Sciences in New Delhi, India.

METHODS: The study was carried out in 2 phases. The device was placed in situ for up to 24 hours in 10 patients during phase I of the study and up to 120 hours in an additional 10 patients during phase II. Participants were assessed for anorectal injury and peripheral device leakage on a 4- to 6-hourly basis. Sigmoidoscopy was performed to evaluate for any mucosal trauma or alteration of anorectal pathology after retrieval of the device.

RESULTS: The device was successfully placed in all patients following the first attempt to place the device; 80% of patients retained the device until planned removal. The SMK diverted fecal matter without anal leakage in 174 (93.5%) out of 186 assessment points in a group of 20 patients. The devices remained in situ for 21 ± 0.2 and 84.5 ± 38.9 hours during phase I and phase II, respectively. None experienced anorectal bleeding, sphincter injury, or mucosal ulceration with device usage. Post–device sigmoidoscopy revealed erythema at the site of diverter placement in 2 participants.

CONCLUSION: Study findings suggest that the SMK successfully diverted liquid to semiformed fecal exudate without peripheral device leakage in 93.5% of bedridden patients. No serious adverse events occurred. Additional research is needed to compare its effectiveness with that of currently available intrarectal balloon devices.

KEY WORDS: Critical care, Diarrhea, Fecal incontinence, Quasi-experimental study, Stool management.

INTRODUCTION

Fecal incontinence (FI) affects as many as 16% to 30% of patients in acute care settings.[1] Amongst critically ill bedridden patients, FI and diarrhea pose an increased risk of incontinence-associated dermatitis, pressure injury development, and spread of nosocomial infections.[2-5] Traditional nursing care of these patients involves collection and containment of stool by the use of absorbent underpads and body-worn products. Such containment devices may trap feces against the perineal skin for prolonged periods of time, resulting in development of incontinence-associated dermatitis in 36% to 50% of critical care patients with FI over the span of their hospitalization.[6]

An alternate method of fecal containment is the application of an external collection pouch affixed around the anus. These external pouches have similar shortcomings as absorbent pads, resulting in significant leakage and prolonged exposure of the perineal skin to feces.[7] Evidence concerning the efficacy of these pouches is not well established.[5]

Traditional fecal containment methods are time-, labor-, and resource-intensive.[7,8] They often result in patient discomfort and may contaminate the hospital environment, via spread of pathogenic bacteria or spores.[9,10] Poor fecal containment procedures are linked to several hospital acquired complications which ultimately increases the duration of hospital stay and cost of healthcare.[9,10] The additional length of stay

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and cost associated with hospital-acquired complications are summarized in Table 1. Outcomes associated with FI in hospitalized patients such as pressure injuries, urinary tract infections, and hospital-acquired *Clostridium difficile* infections cost approximately US $10,700 to $30,049 per hospitalization.[11,28] In 2016, the aggregate penalties imposed by Medicare on US hospitals due to hospital-acquired conditions were approximately $364 million.[29]

Indwelling fecal drainage catheters were designed to address the aforementioned limitations. Conventional closed-system fecal drainage catheters have an inflatable retention balloon that anchors the catheter on the anorectal junction. These intrarectal balloon catheters (IBCs) are manually inserted by trained care providers and have been shown to contain liquid and semiliquid stool in hospitalized bedridden patients.[30,31] Closed-system fecal drainage catheters not only reduce the risk of hospital-associated complications compared to traditional methods but also more cost-effective.[32-34] However, clinical use of IBCs complications such as anorectal ulceration, mucosal bleeding, and patient discomfort has been reported.[35-40] In addition, prolonged use of these devices may result in anal erosion and anal sphincter dysfunction in some patients.[41,42]

To address these issues, a non–balloon-based stool management kit (SMK) was developed. The device has been cleared by the United States Food and Drug Administration under the brand names Qora Aeon™ Stool Management Kit and the Qora AIM™ stool management kit (Consure Medical, San Francisco, California). These devices are approved for uninterrupted use up to 29 days, and the later device is compatible with magnetic resonance environment up to 3 T. The SMK comprises 3 components: an indwelling fecal diverter, a fecal transit sheath, and a collection bag (Figure 1). The primary component is a pliable, self-expanding fecal diverter, deployed proximal to the anorectal junction. The odor-proof diverter is connected to a thin transit sheath that traverses the anal canal that, in turn, connects to an external collection bag. A collection bag at the proximal end of the transit sheath is integrated with a 1-way valve that is designed to prevent accidental soiling or leakage during bag exchange.[43] The device is discontinued by activating a withdrawal mechanism that collapses the indwelling diverter, allowing it to move through the anal canal without causing trauma upon withdrawal.

Prior to this study, the SMK was evaluated in situ for up to 20 minutes, as per approved protocol AIIMS/IEC/P-37/04.08.2009 in 10 adult volunteer patients who were scheduled for colonoscopy for a possible diagnosis of irritable bowel syndrome (data on company file). Although not necessary for patients to undergo fluoroscopy of the pelvic region, it was performed in all patients to confirm deployment,

TABLE 1.
Mean Added Hospital LOS) and Cost Associated With Various Hospital-Acquired Complications

Complication	Additional LOS, d	Additional Cost
Pressure injury[11,12-14]	4.31-20	$2,159-$21,410
Clostridium difficile infection[15-19]	2.95-11.1	$7,286-$29,000
Bloodstream infection[20-22]	8.8-10	$10,750-$23,242
Urinary tract infection[20,23,24]	0.4-2	$589-$1,006
Surgical site infection[20,25-27]	4.9-10	$21,040-$34,434

Abbreviation: LOS, length of stay.

Figure 1. The stool management kit comprises a preloaded applicator, low-profile fecal transit sheath, user interface access ports, and odor barrier collection bag.

positioning, retention, and lumen patency of the SMK as expected. This 2-phase study was conducted to evaluate the safety, efficacy, and feasibility of the device in hospitalized bedridden FI patients. Efficacy was measured using the following endpoints: (1) successful fecal diversion operationally defined as collection of fecal exudate in the transit sheath and/or the collection bag, (2) device leakage classified as minor if the leakage was nonproblematic, incidental, and confined to the perineal area and major if there was significant soiling around the device; and (3) duration of device use. Safety was measured using the following endpoints: pre- and post–device use sigmoidoscopic examination for evaluation of the anorectal mucosal injury, and anorectal bleeding operationally defined as visualization of any blood in the perineal region, absorbent pads, transit sheath, or collection. Feasibility was based on (1) radiographic visualization to assess the self-expansion of the SMK at the predetermined location; (2) device dislodgement defined as inadvertent removal of the device due to external interference by the caregiver, family member, or patient; and (3) spontaneous expulsion classified as a device being expelled in the absence of any external forces, solely by the patient, due to either change in stool consistency or peristaltic contraction.

METHODS

A single-group quasi-experimental study was conducted on 20 patients from the neurological unit of our institution. The study was performed in 2 phases to mitigate potential risks to the patient while using the device. During phase I of the study, the SMK was deployed in the rectum of 10 patients for a period of up to 24 hours. Based on the safety performance, the SMK usage was extended up to 120 hours (5 days) for phase II, which enrolled an additional 10 patients. Data from these 20 patients were jointly used in our analysis. Study procedures for

each phase were reviewed and approved by the ethics committee of All India Institute of Medical Sciences, New Delhi, India (IEC/NP-433/2012, RP-09/2012; IEC/OP-15/06.01.2014). Written and informed consent was obtained from all enrolled patients or by their legally authorized representatives. Inclusion criteria were at least 1 episode of FI in the prior 24 hours due to a neurological disorders. Patients having FI attributed to local causes were excluded from the study. Inclusion and exclusion criteria for the study are listed in detail in Table 2.

Study Procedures

Baseline demographic and pertinent clinical characteristics of study participants were recorded from the medical records. Participants underwent an anorectal examination using a flexible sigmoidoscope (Olympus, 160 series, Tokyo, Japan) prior to SMK insertion to exclude any preexisting anorectal pathology, as mentioned in Table 2 (Figure 2). The device's fecal diverter is preloaded in an introducer applicator. Investigators and study coordinators were trained for the device deployment process using a functional benchtop model prior to the study. Topical lidocaine hydrochloride (Xylocaine 2% Jelly; AstraZeneca, Cambridge, United Kingdom) was used for lubricating the applicator during insertion. The device was deployed by an investigator or study coordinator with patients in the lateral decubitus position. Once the applicator was unsheathed and withdrawn from the rectum, the SMK self-expanded and deployed along the rectal walls. A supine anteroposterior pelvic radiogram (Figure 3) was obtained after the device deployment to verify device expansion and positioning.

All patients were maintained on absorbent pads while the device was in situ. Each participant was followed up on a 4- to 6-hourly basis during both the phases. At each assessment point, the individual's blood pressure, pulse rate, and temperature were measured and an abdominal examination was completed. The perineal and perianal skin was examined for evidence of device-related bleeding or fecal soiling. The individual's absorbent pads, clothing, and bed linens were also evaluated for soiling. The external components of the SMK, including the transit sheath and the collection bag, were examined for structural integrity and presence of fecal exudate.

TABLE 2.
Inclusion and Exclusion Criteria for Clinical Study (Phases I and II)

Inclusion Criteria
1. Patients must be between 18 and 65 years of age (no gender bias)
2. Patients must be admitted for at least 48 h and must be on a nasogastric feeding tube for at least 24 h
3. Hemodynamic stability
4. The patient or a legal representative of the patient gives written consent for the study
Exclusion criteria
1. Disease or trauma of the muscular apparatus of the anorectal region
2. Pregnant or lactating females
3. Recent history of colorectal surgery
4. Patients suspected to have anorectal malignancy, ulcerative colitis, Crohn disease, or intestinal tuberculosis
5. Sigmoidoscopy revealing hemorrhoids (grade IV), internal ulcers, fissures, strictures, or fecal impaction
6. Scheduled MRI examinations over the study period
7. Any other systemic condition having potential for undue risk to the patient as deemed by investigator
8. Unwilling or unable to provide informed consent
9. Already enrolled in another study

Abbreviation: MRI, magnetic resonance imaging.

Devices were retrieved from the patients at the end of their respective study periods. The device could be removed prior to completion of the study period at the request of the care provider, patient, or his or her legal representative, if the device was no longer clinically indicated, or if the patient was planned for discharge from hospital.

The performance of the device was described in patients who had completed at least 1 follow-up assessment after successful deployment. Assessments were completed by direct observation, radiographic imaging, and sigmoidoscopic examination.

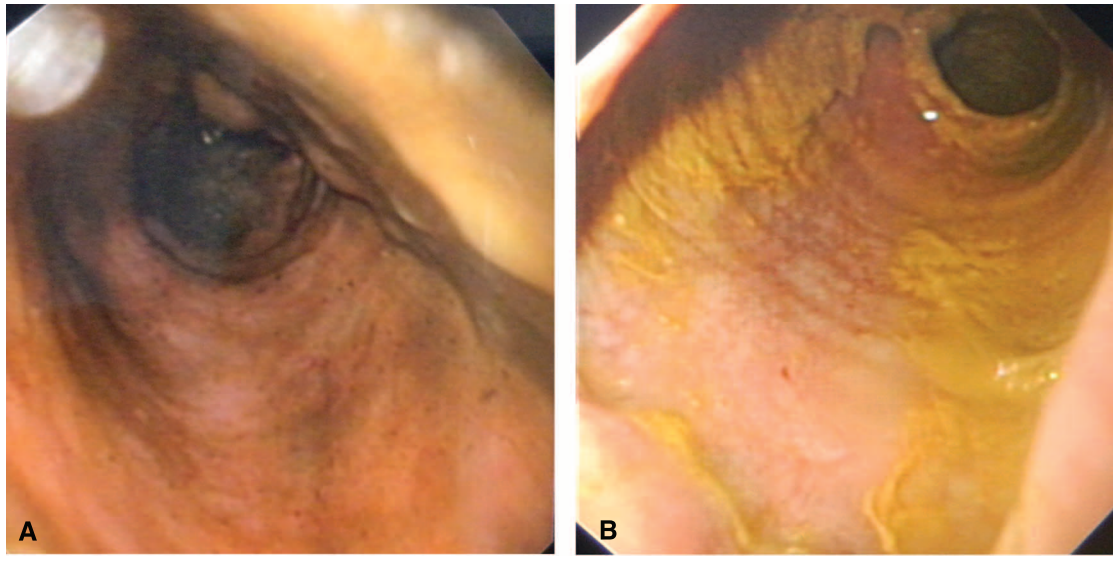

Figure 2. (A) Pre- and (B) post–device use sigmoidoscopic examination show normal mucosa; no signs of anorectal bleeding or major erythema.

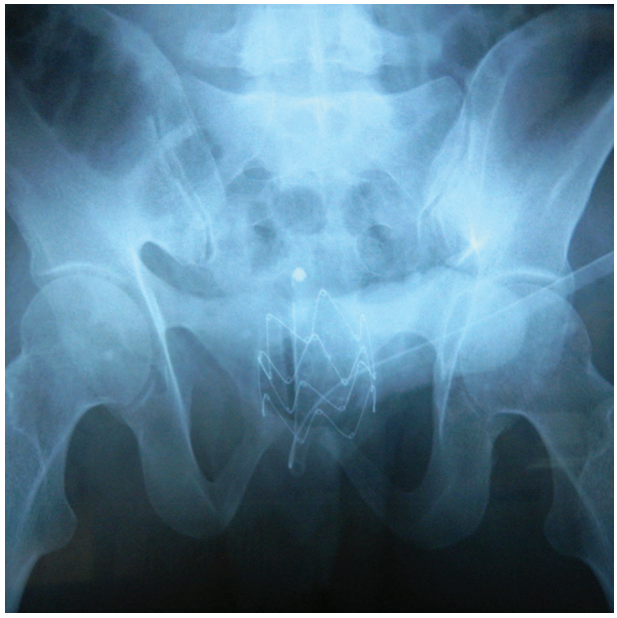

Figure 3. Radiographic image demonstrating proper placement and expansion of the device in the rectum.

Successful fecal diversion was defined as collection of fecal exudate in the transit sheath and/or the collection bag, which was checked at each assessment point. We also evaluated device leakage; leakage from the device was classified as minor if the leakage was nonproblematic and incidental (remained confined to the perineal area) or major if there was significant soiling around the device (soiling of patient's clothes or bed linen beyond the confining absorbent pad area). We assessed for accidental dislodgement and spontaneous expulsion of the device. We also evaluated the duration of device use in hours. Anorectal bleeding was defined as visualization of any blood in the perineal region, absorbent pads, transit sheath, or collection bag. Sigmoidoscopy was completed before and after insertion of the device in order to evaluate the integrity of the anorectal mucosa and check for any bleeding, trauma, or erythema. An image of the sigmoidoscopy was retained for objective evidence. Finally, we inspected the device itself for structural and functional integrity after removal.

Data Analysis

All relevant study data were evaluated using Microsoft Excel 2010 (Microsoft Corporation, Redmond, Washington) software. Safety data and device performance descriptions were summarized on enrolled patients. Results are presented as absolute values, percentages, and mean ± standard deviation, wherever applicable.

RESULTS

The study sample comprised 20 patients; 10 were enrolled during each phase of the study. Their age was 56.7 ± 13.6 years(mean ± SD) (range, 27-80 years); 16 (80%) were males (Table 3). The mean period of hospitalization of patients prior to study enrollment was 20.3 ± 15.7 days. The majority of participants were admitted following stroke (Table 3). Three (15%) were receiving either low-molecular-weight heparin, an antiplatelet agent, or a combination of both; all continued to take these drugs during the study period.

TABLE 3.
Demographic and pertinent clinical characteristics of participants

Characteristic	Baseline Value (N = 20)
Age (mean ± SD), y	56.7 ± 13.6
Sex	
Male	16
Female	4
Clinical diagnosis	
Stroke	16
Metabolic encephalopathy	2
Viral encephalitis	1
Intracranial vasculitis	1
Comorbid conditions[a]	
Mechanical ventilation	14
Decompressive craniectomy	5
Hypertension	8
Diabetes mellitus	2
Chronic smoking	3
Chronic kidney disease	1

[a]Total exceeds 100% because each patient may have had more than 1 comorbid condition.

All devices were successfully deployed (placed) on the first attempt. A supine anteroposterior abdominal x-ray image was obtained in 16 (80%) patients to verify expansion of the fecal diverter at the correct anatomical site. The pelvic radiogram confirmed proper expansion of the fecal diverter above the anorectal junction in all instances (Figure 3). In the remaining cases, the radiogram could not be obtained and the device's location was confirmed by the collection of feces in the transit sheath and/or collection bag.

The participants were examined at 186 assessment points, 43 during phase I and 143 during phase II. The performance of the SMK was evaluated in 18 patients who completed at least 1 follow-up assessment. Most (n = 17; 85%) of these patients experienced successful fecal diversion while the device was in situ. Of 186 assessment points, no leakage was seen at 174 (93.5%) and minor leakage at 12 (6.4%) time points (Table 4). There was no episode of major device leakage. All instances of minor leakage spontaneously resolved at 1 to 4 follow-up assessment points. In one instance, the leakage was observed at the connection of the transit sheath to the collection bag due to a loose connection. No soiling of the perineal or perianal skin was observed.

The SMK was dislodged or retrieved in 5 (25%) of the 20 patients. In 2 patients, the device was removed within an hour

TABLE 4.
Device

Category	No. of Assessments (N = 186)
No leakage	174 (93.5%)
Minimal leakage	12 (6.5%)
Major leakage	0 (0%)

of deployment, of which one was due to inadvertent dislodgement and the other was retrieved early on request of the treating physician due to deterioration of the patient's underlying condition. In both patients, abdominal x-ray study and post–device sigmoidoscopy were not completed. One patient experienced spontaneous expulsion of the SMK after 74.5 hours due to change in stool consistency to the formed stool. Two patients experienced device dislodgement due to inadvertent pulling of the catheter by the patient, the caregiver, or other external interferences approximately 17 and 41 hours after placement.

The remaining 15 patients, 8 from phase I and 7 from phase II, retained the SMK for the duration of the study or until no longer required clinically. The devices remained in situ for 21 ± 0.2 and 84.5 ± 38.9 hours, respectively. The SMK was successfully retrieved in 16 participants. One was retrieved prior to the end of study period based upon a request from the individual's attending physician. The insertion of SMK did not affect routine care of patient including patient mobility, feeding, sitting, or standard maneuvering performed on bedridden patients. The devices were evaluated for structural and functional integrity postretrieval. Data were available for 19 devices. In one instance, the SMK was discarded by the caretaker without informing the investigator; device assessment could not be performed in this patient. All other devices were found to be structurally and functionally intact after removal. There was no evidence of any tear in the transit sheath or any damage to the retrieval mechanism.

All enrolled participants had a normal rectum and anal canal on sigmoidoscopic examination prior to SMK deployment. No episode of any anorectal bleeding occurred during the study period. Post–device removal sigmoidoscopy was done in 16 patients (Figure 2). Minor mucosal erythema at the site of diverter placement was seen in 2 participants; neither experienced device dislodgement or spontaneous expulsion.

DISCUSSION

Fecal containment in institutionalized patients is often underaddressed and overlooked. Patients having FI or diarrhea are at 22 times higher odds of developing pressure injuries; this risk rises further to 37.5 times higher when the individual is bedridden.[44] The presence of pathogens with diarrhea and FI such as *Clostridium difficile*, *Escherichia coli*, and *Pseudomonas aeruginosa* may lead to additional morbidity and costs.[23,45,46] In addition, studies have shown that catheter-associated urinary tract infections, central line–associated bloodstream infections, and surgical sites infections due to fecal contamination can increase mortality rates by 4% to 40%, extend the length of hospitalization by 4 to 22 days, and add an incremental cost of US $600 to $30,000 per complication.[20,23,47-50]

Current evidence suggests that IBCs are better management options for FI when compared to absorbent pads in acute care settings, but they are less frequently utilized due to their high rates of peripheral leakage (40%-71%) and spontaneous expulsion (17%-28%).[30,41] Furthermore, there are safety concerns due to the high risk of mucosal erosion in the anal canal, mucosal bleeding, and sphincter atony.[35,38,39,42,51-54] The SMK was designed to overcome functional and safety constraints of existing IBCs. Results of this study suggest that the SMK was safe when used in bedridden patients with FI and diarrhea. Postdeployment imaging validated consistent anatomical positioning of the SMK inside the rectum and above the anorectal junction.

Over the duration of use, 80% of the devices remained deployed in situ, and diverted liquid or semiformed fecal exudate into the collection bag. Minimal leakage was observed at 12 assessments points, but episodes spontaneously ceased within 4 to 48 hours. Comparison of the findings of sigmoidoscopic examination before and after the use of the device revealed no adverse effect of the device on the anorectal mucosa, except for mucosal erythema in 2 participants. Device positioning within the rectum did not cause any anorectal erosion, a complication reported with IBCs.[35,38,41,42]

The SMK diverted fecal matter without peripheral device leakage at 174 of 186 assessment points (93.5% in a group of 20 patients). Eighty percent of the patients who were able to retain the SMK until planned removal had a mean indwelling time of 24.06 hours for phase I patients and 91.11 hours for phase II patients, while patients who retained the device throughout the study had a mean indwelling time of 21 hours for phase I patients and 84.5 hours for phase II patients. In 1 instance, the device was extricated by the patient's feet, and in 2 instances by the care provider. No incidents of fistulae, fissures, ulceration, or other adverse events occurred during the study period. Patients predisposed to bleeding were handled cautiously, and no study participant experienced bleeding during data collection despite use of anticoagulant or antiplatelet drugs in some. Additional investigation in a larger patient group is needed to verify the effect of the device in patients at increased risk for bleeding.

The SMK provided an effective barrier between perineal skin and fecal exudate, avoiding the risk of further skin breakdown in a group of 20 patients. The design and placement of the SMK may allow its use in patients with poor anal tone or those with altered sensorium to retain the device when compared to an IBC. Additional studies are needed to compare the SMK to existing IBCs.

LIMITATIONS

We did not evaluate caregiver acceptability or economic outcomes. A structured analysis of management time, ease of workflow, and patient comfort will better quantify its value. A comparative study of the SMK with traditional fecal management strategies that include questionnaires from patients would be required to confirm the benefit to patients' dignity and comfort. Similarly, prospective studies of direct and indirect costs associated with fecal containment are required to compare the cost-effectiveness of the SMK relative to other fecal management strategies.

CONCLUSIONS

We found the SMK effective in diverting liquid to semiformed fecal exudate in a group of 20 bedridden patients. No erosion of the anal mucosa was observed on endoscopic examination, and no gross bleeding was observed during data collection. Further studies are needed to quantify the clinical and economic effects of the device in various groups of acutely and critically ill patients.

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