RETROSPECTIVE COHORT STUDY

Clinical and Health Economic Evaluation of a Novel Device for Fecal Management in Bedridden Patients

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Abstract

Purpose: To evaluate the clinical effectiveness and health economic benefits of a novel indwelling lattice-based device for fecal management in bedridden patients.

Materials and methods: This nonrandomized, two-arm study included 70 bedridden patients (≥18 years exhibiting liquid stool) referred from the ICU of surgery and medicine units of a 2000-bed tertiary care referral hospital, assigned to the intervention and control groups. About 35 patients were eligible to be included in the intervention group while 35 patients with contraindications to the intervention device were included in the usual care control group. Assessments were made before and every 24 hours during the study, and all patients were closely monitored for development of incontinence-associated dermatitis (IAD) and hospital-acquired pressure injury.

Results: The test device was successfully deployed on the first attempt and effectively diverted fecal matter in all 35 patients, with no adverse events. In the control group, 83% of the patients developed IAD, which resulted in prolonged hospitalization and increased expenses. Overall, the control group (with adult diapers) required greater time, resources, and efforts for fecal management and resulted in increased patient morbidity.

Conclusion: The patient management time, resource consumption, overall cost of hospital admission, and the complication rates are significantly lower with the use of the novel lattice-based device than with the use of adult diapers for fecal management.

Keywords: Balloon catheter, Critical care, Dermatitis, Diarrhea, Fecal incontinence, Fecal management, FMS, Hospital-acquired pressure injury (HAPI), Incontinence-associated dermatitis, Pressure ulcer.

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Highlights

The risk of pressure injury in patients with fecal incontinence (FI) or diarrhea is 22 times higher than that in patients without FI, and 37.5 times higher if the patient is bedridden.[23] With the use of novel lattice-based device for the management of FI in bedridden patients, the FI management material cost was reduced by 51% and the risk of skin breakdown was reduced from 82% with traditional methods to 3%.

Introduction

Fecal management in critically ill and bedridden patients is often challenging, particularly when they are incontinent. Such patients exhibit increased risk of developing incontinence-associated dermatitis (IAD) and hospital-acquired pressure injuries (HAPI), thus being hospitalized for longer and incurring greater treatment costs.[1–3]

Conventional fecal management techniques include absorbent pads which require excessive time, labor, and resources.[4,5] They cause skin irritation, require frequent replacement and cleaning of the patient's perianal area after every defecation episode. Therefore, the perineal area is at a higher risk of developing dermatitis, macerations, and pressure injuries if an appropriate post-defecation cleansing protocol is not meticulously followed. In settings with limited staff and resources, the use of diapers/absorbent pads can lead to significant complications, as well as overburden an already constrained healthcare system.

Intrarectal balloon catheters (IBCs) were developed to overcome the limitations of conventional methods. These devices are inserted manually via the anus and placed in the rectum, where a retention balloon is inflated to hold the catheter in place and create a seal.[6,7] However, clinical literature reports that IBCs use leads to complications, such as patient discomfort, anorectal ulceration, and mucosal bleeding.[8–13] Moreover, studies have suggested that prolonged IBC use can lead to anal erosion and anal sphincter dysfunction in some patients.[14,15]

A novel self-conforming device called the Qora™ Stool Management Kit (SMK; Consure Medical) (Fig. 1) was introduced and approved by the United States Food and Drug Administration. This closed-fecal management system comes with a self-conforming indwelling fecal diverter and includes a sampling, fluid delivery, and withdrawal port and a collection bag that hygienically collects

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Fig. 1: The Qora™ Stool management kit

The device includes a preloaded hygienic applicator, a fecal transit sheath for stool diversion, user-friendly access ports, and an odor-barrier collection system

stool and prevents odor. The intervention device is ergonomically designed to improve clinical outcomes, lower healthcare costs, and provides an effective user and attendant-friendly solution for fecal management in bedridden patients.[16] To support the clinical and health economic effectiveness of a novel device for fecal management, a prospective, nonrandomized, two-arm study was conducted at a tertiary care hospital. This study evaluates device effectiveness by observing fecal diversion, its collection, any soiling of pads and linens due to stool leakage, and development of IAD and HAPI. Health economic implications of the device are evaluated by comparing nursing time and resources used for bowel management, linen changes due to soiling, and resource burden due to maceration, IAD, or HAPI for both investigation and control group.

Materials and Methods

Overall Study Design

This study is a quasi-experimental evaluation of a novel device for the management of fecal incontinence (FI). Blinding to group assignment was not possible due to the use of a physical device with an external component visible to the patient and care provider.

Sample and Setting

This study included 70 consecutive patients recruited from the Emergency Department, Surgery Units and referrals from the Intensive Care Unit (ICU), Department of Medicine of a tertiary care referral hospital in Mumbai, India. The Emergency Department ICU had 18 beds, the Surgery Department ICU had 6 beds, and the Medicine Department ICU had 25 beds. Based on convenience sampling, a previous study evaluating similar device,[6] and considering the resource-constrained environment, a pragmatic sample size of 35 patients in each group was considered for the study. All the patients enrolled in the study were admitted in intensive care units, namely, Medical ICU, Surgical ICU, and Emergency ICU of the tertiary care hospital. The enrolled patients were bedridden, ≥18 years, and had at least one episode of defecation in the last 24 hours to ensure liquid stool formation and eliminate chances of formed/impacted stool. All patients were screened as per the inclusion and exclusion criteria (Table 1). Patient considered eligible to receive the intervention device were further evaluated for any contraindications (Table 1) using digital and proctoscopic examination of the rectum. If a contraindication was found, the patient was included in the control group. Accordingly, 35 eligible patients were managed with the intervention device; the remaining 35 were managed with adult diapers (control group) as per the institutional practice.

Table 1: Inclusion criteria, exclusion criteria, and contraindications at the time of study enrollment

Inclusion criteria
• Age ≥ 18 years
• Liquid stool, history of at least one stool episode in the last 24 hours
• Bedridden and hospitalized
• Provision of written informed consent by the patient or legal representative
Exclusion criteria
• Enrollment in another study
• Presence of incontinence-associated dermatitis and/or pressure ulcers of any stage
Anorectal pathologies/contraindications
• Existing use of another indwelling rectal or anal device or delivery mechanism
• Suspected or confirmed rectal mucosal abnormality or pathology (e.g., severe proctitis, ischemic proctitis, and mucosal ulcerations)
• Past or present history of
– Rectal surgery within the last 1 year
– Any rectal bleeding or anal injury
– Large hemorrhoids
– Rectal or anal strictures or stenosis
• Suspicion of
– Tumor(s) in the rectum or anal canal
– Impacted stool
– Constipation

Materials

For both, the intervention group and the control group, all key information were collected in a Case Report Form (CRF). A camera and metric ruler were provided to the study coordinator for gathering photographic data. Objective evidence for IAD and/or HAPI was collected by an independent evaluator using an IAD Severity Scale[17] and the National Pressure Advisory Panel (NPUAP) system of classification.[18] The Caregiver Strain Index (CSI) was measured by an open-source questionnaire developed by The Hartford Institute for Geriatric Nursing, Division of Nursing, the New York University. Other ancillary equipment and requisite resources, such as disposable proctoscopes, lidocaine jelly, and surgical gloves were also made available as needed.

Methods

Baseline demographic features and diagnoses were recorded from the medical charts of all patients (Table 2). Fecal incontinence in control group was managed by body worn absorbent products

Table 2: Patient population, department of enrollment, duration of hospitalization, and duration of enrollment in the study

Patient population	*Intervention group (n = 35)*	*Control group (n = 35)*
Men (no.)	28	30
Women (no.)	7	5
Department of enrollment	*Number*	
Trauma (ESR-ICU)	25	24
Internal medicine	3	7
Surgery	7	4
Duration of hospitalization and enrollment in the study	*Number (days)*	
Average duration of enrollment in the study (days)	8.26	7.69

(adult diapers), which is the standard practice followed at the study hospital. For the intervention group, the study devices deployed at the patient's bedside by one of the study investigators. The device was deployed using an applicator (coated with adequate amount of a local anesthetic agent), which when unsheathed and withdrawn from the rectum, allowed the device to self-expand and conform to the rectal walls. Absorbent pads were placed underneath the patients, with the device *in situ*, to observe any leakage. For the control group, the study was terminated at the end of 29 days, or when the patient was discharged or became ambulatory, whichever was earlier. For the intervention group, in addition to the conditions mentioned in the control group, the study was terminated if the device spontaneously expelled or was accidentally removed, whichever was earlier.

Patients in both groups were followed once every 24 h. At each assessment point, the absorbent pads, patients' clothes, and bed linen were evaluated for soiling, and the number of changed pads and bedsheets was recorded for each group. In addition, the time taken to clean the patients and change soiled pads/diapers and/or linen was recorded, along with the number of nurses required to assist in the cleaning process (Table 3). Patients were closely monitored for the development of skin maceration, IAD, or HAPI. Incontinence-associated dermatitis severity (IAD) score were used to assess the development of skin maceration, IAD, or HAPI.[17] After study completion, patients who developed IAD or HAPI continued receiving the treatment as per the institution protocol.

In addition, in the intervention group, the time taken for and ease of deployment of the device were recorded. After study completion, proctoscopy was performed to evaluate the anorectal mucosa for any trauma, and the findings were compared with those at baseline.

The CSI was assessed,[18] and the questionnaire was administered to the primary caregivers of all enrolled patients at baseline and study completion. Caregiver acceptability for the intervention device was also assessed via a verbal interview with the primary caregiver of the patients in the intervention group. All data were recorded in the CRFs.

Outcome Measures

The primary outcome was the clinical effectiveness of the intervention device, which was assessed on the basis of the following endpoints:

- Successful fecal diversion: Collection of fecal matter in the sheath and/or bag
- Incidence of device leakage
  - Minor: Non-problematic and incidental (confined to perineal area).
  - Moderate: Required an absorbent pad change.
  - Major: Significant soiling around the device (soiling of patient's clothes/bed linen beyond the absorbent pad).
- Duration of device use

The secondary outcomes were the health economic benefits of the intervention device, which were assessed on the basis of the following endpoints:

- Resource utilization: Number of changed bedsheets, diapers/absorbent pads; Time and number of caregivers required.
- Integrity of perianal skin.
- Any increase in the length of stay and related clinical management due to the development of IAD/HAPI.
- Caregiver acceptability.

Data Analyses

All collected data were analyzed for the sole purpose of the study, and only relevant data were collected in accordance with the ethical approval. The post-study IAD scores and CSI index were compared in the intervention and control groups using *t*-tests.

Resource utilization was computed by the number of changed pads/sheets, nursing time, number of caregivers required per day, time invested by doctors, length of hospitalization, and treatment required for IAD (Tables 2 and 3). The linen, hospitalization, nursing, and doctor visit expenses were retrieved from published clinical literature for both groups, and the data were compared using *t*-tests. Additional economic burden due to the management of maceration, IAD, or HAPI was estimated using relevant clinical literature based on the treatment and procedure-related variables captured in CRFs.[19–22] Health economic burden was determined by assigning a cost value to all the aforementioned parameters. All these data were evaluated using Microsoft Excel 2016 software while *t*-tests were carried out using IBM SPSS Statistics Version 23.0.

The results are presented as absolute values, percentages, and means ± standard deviations, where applicable. A 5% level of significance was used for the statistical comparisons.

Results

Patient Characteristics

In total, 70 patients (58 men; mean age, 45.69 ± 20.43 years; range, 18–98 years; 12 women; 48.08 ± 17.27 years; range, 18–72 years) were enrolled in this study. In the intervention group, the device was successfully deployed in the first attempt in all 35 patients (28 men; mean age, 44.32 ± 20.39 years; range, 18–88 years; 7 women: 50.86 ± 15.14 years; range, 27–72 years). The control group constituted of 35 patients (30 men; mean age, 46.97 ± 20.74 years; range, 20–98 years; 5 women; 44.20 ± 21.06 years; range, 18–63 years).

Health Economic Benefits and Comparisons Between Groups

In the intervention group, the average time taken for successful device deployment was 3.57 min. A total of 253 follow-ups were conducted, and the average duration of device use was 7.69 days. No leakage was observed in 130 assessments (51.38%), minor in 76

Table 3: Comparisons between patients who received adult diapers (control group) and those who received the Intervention group for fecal management

Parameter	*Intervention group*	*Control group*	*p-value*
Absorbent pad changes			
Number	287	854.43	0.000395
Unit	Pieces	Pieces	–
Unit cost ($)	1.70[a]	0.93[g]	–
Total cost ($)	488.62	793.47	–
Linen changes			
Number	112	267.82	0.150298
Unit	Pieces	Pieces	–
Unit cost ($)	13.62[b]	13.62[b]	–
Total cost ($)	1,525.51	3,647.88	–
Supplies for cleaning during diaper changes			
Number	123	854.43	–
Unit	Incidences	Incidences	–
Unit cost ($)	0.39[c]	0.39[c]	–
Total cost ($)	48.35	335.9	–
Time invested by nurses			
Number	2529	12,741	0.000125
Unit	Minutes	Minutes	–
Unit cost ($)	0.08[d]	0.08[d]	–
Total cost ($)	327.27	1,599.45	–
Doctor visits			
Number	269	447	–
Unit	hours	hours	–
Unit cost ($)	5.45[e]	5.45[e]	–
Total cost ($)	1,465.41	2,435.08	–
Facility stay			
Number	269	447	–
Unit	days	days	–
Unit cost ($)	105.20[f]	105.20[f]	–
Total cost ($)	28,298.92	47,024.59	–
Comparison of the final IAD score between the Intervention and control groups			
Initial score	0	0	–
Final score	0.11	4.80	4.74E-07
Comparison of the CSI between the Intervention and control groups			
Initial score	8.5	8.4	–
Final score	5.1	7.8	1.23E-10

a, c, g – Cost obtained from the pharmacy; b – Cost calculated for bedsheets, pillow covers, patient shirts, patient pants;[19] d – Cost calculated according to nurses' salary per minute;[20,21] e – Cost calculated according to doctors' fees per hour;[20,21] f – Total cost/bed/day for a multispecialty intensive care unit;[22] h – Cost of materials used for treatment obtained from the pharmacy

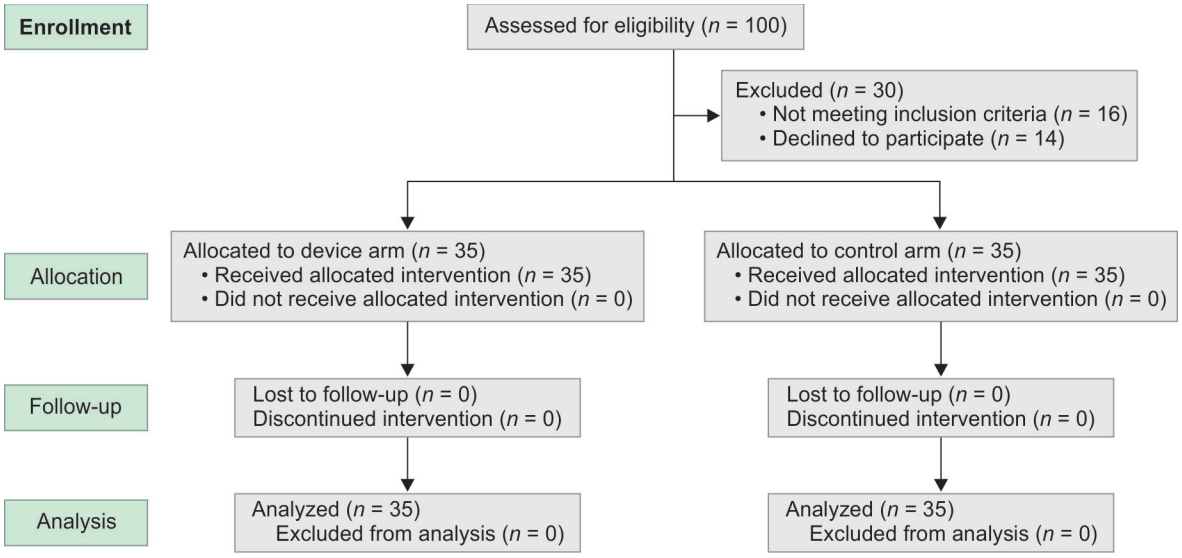


Fig. 2: Patient flow diagram illustrating the flow of participants through each stage of the study: enrollment, allocation, follow-up, and analysis

(30.04%), moderate in 40 (15.81%), and a major leakage was observed in 7 (2.77%). The minor leakage showed spontaneous resolution over subsequent follow-up assessments. If moderate or major leakage persisted, the device was safely withdrawn, the patient was excluded from the study, and fecal management was commenced as per the institutional protocols. At baseline, all patients showed normal findings in proctoscopy. Anorectal bleeding was not observed in any patient throughout the study period. Proctoscopy performed after device removal showed no evidence of damage. Eight patients discontinued the study early because of leakage ($n = 6$), insufficient stool output ($n = 1$), or improper device function ($n = 1$). The device was successfully retrieved from five patients (average *in situ* period, 6.60 days), spontaneously expelled from 12 (average *in situ* period, 10.42 days), and accidentally dislodged by the caregiver or patient in 10 (average *in situ* period 5.40 days). Nine patients developed stage 1 HAPI and were treated for 1 week or until discharge, while another nine developed stage 2 HAPI and were treated for 2 weeks or until discharge. Nine and two patients developed stage 3 and stage 4 HAPI, respectively, and were treated for 3–4 weeks or until discharge. The average duration of HAPI management per day was 21.76 min. One patient who requested to use another diaper type and one who developed IAD discontinued the study early. Patient who developed IAD received further treatment as per institutional protocols.

In the control group of 35 patients, a total of 267 follow-up assessments were conducted, and the average duration of diaper use was 8.26 days. Twenty-nine of the 35 patients developed HAPI (stage 1–4) during the study, and 23 of whom required treatment after study completion; the remaining six were discharged or shifted to another facility (Figs 2 and 3). Nine patients developed stage 1 HAPI and were treated for 1 week or until discharge, while another nine developed stage 2 HAPI and were treated for 2 weeks or until discharge. Nine and two patients developed stage 3 and stage 4 HAPI, respectively, and were treated for 3–4 weeks or until discharge. The average duration of pressure ulcer management per day was 21.76 min. One patient who requested to use another diaper type and one who developed IAD discontinued the study early. Patient who developed IAD received further treatment as per institutional protocols.

The total cost per patient was estimated at $918.69, excluding the cost of the intervention device ($200), for the intervention group and $1900.01, including the additional treatment cost (for IAD and HAPI) for the control group. Thus, the intervention device was found to be cost-effective.

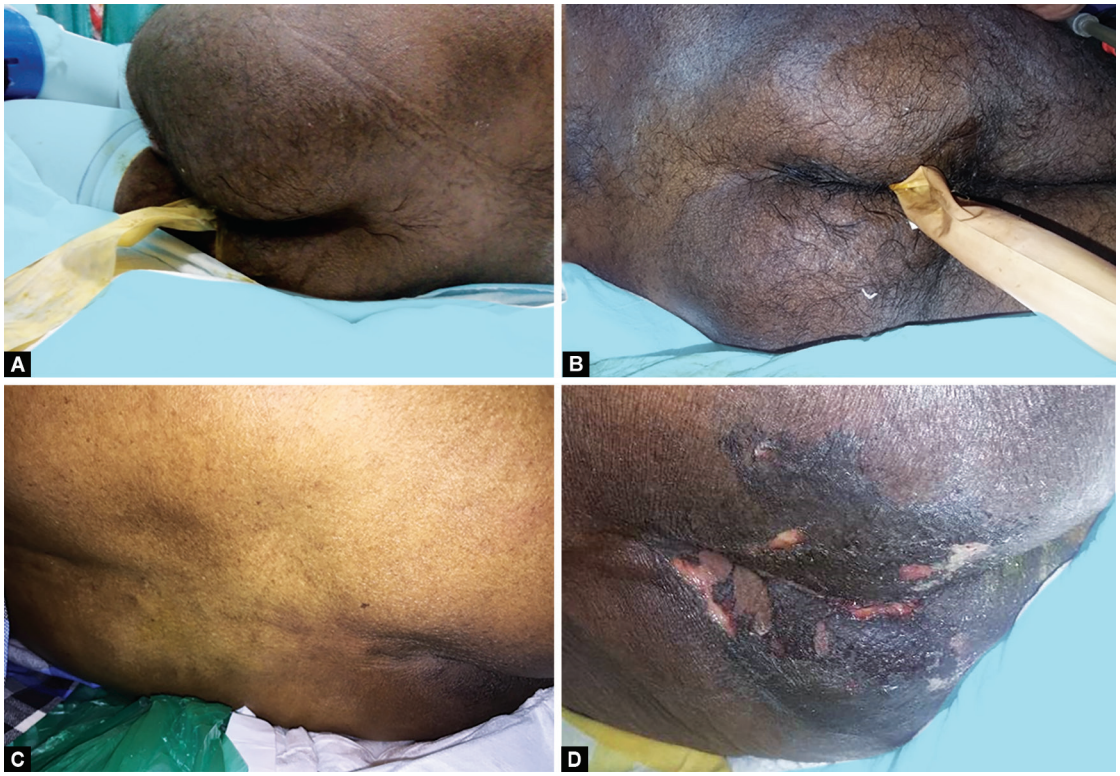
The intergroup comparisons are shown in Table 3. Nursing time was significantly greater in the control group whereas the number of changed diapers/absorbent pads was significantly lower in the intervention group, considering they were replaced only when leakage was observed or along with daily linen changes. There was no significant difference between groups in the number of bedsheets used because the linen was regularly changed as per hospital protocol. The final IAD score was significantly higher in the control group. The final CSI score was significantly lower in the intervention group. This finding indicated that the caregiver felt a decreased care burden with the use of the intervention device.

Discussion

The risk of pressure injury in patients with FI or diarrhea is 22 times higher than that in patients without FI, while it is 37.5 times higher if the patients are bedridden.[23] Intensive nursing care is required to prevent the development of IAD and HAPI in immobilized patients, with frequent inspection and change of linen and absorbent pads as required. Failure to follow these measures can lead to the development of various complications, including IAD and HAPI.

In the present study, the novel fecal management device was successfully deployed (mean time: 3.57 min) in the first attempt in all patients, with successful fecal diversion. The average *in situ* duration was 7.69 days. The device was spontaneously expelled and accidentally dislodged in 12 and 10 patients, respectively. It should be noted that spontaneous expulsions primarily occurred because of an improvement in the patient's condition. On the other hand, accidental dislodgement can be attributed to mishandling during device management and bag exchange by the patient's caregivers, who were actively involved in the patient's care because of lower nurse to patient ratio and limited healthcare providers.

The clinical efficacy of the device can be demonstrated by its ability to prevent the breakdown of the perianal skin. A meta-analysis



Figs 3A to D: Photographs of the perineal area obtained at baseline (A) and on day 14 (B) for a representative case that received the Qora™ Stool Management Kit for fecal management. The patient's skin has remained intact throughout

Photographs of the perineal area obtained at baseline (C) and on day 10 (D) for a representative case that received adult diapers for fecal management. The patient has developed severe incontinence-associated dermatitis (IAD; score, 18) because of the continuous use of adult diapers for fecal containment

of 16 studies demonstrated a higher incidence of pressure ulcers in ICU patients (56%) than in all hospitalized patients (up to 22%).[24] In another study conducted in a tertiary care hospital, the incidences of pressure ulcers in ICU patients and hospitalized ward patients were 24.3% and 7.38%, respectively.[25] In the present study, all enrolled patients had a baseline IAD score of 0. At study completion, the IAD score was 0.11 for the intervention group and 4.8 for the control group. Moreover, 29 of 35 patients in the control group developed HAPI of varying severities compared with 0 patients in the device group. In the intervention device group, no incidences of leakage was significant enough to cause a statistically significant increase in the IAD score. Only one patient in the intervention group developed skin redness; the remaining 34 (97.1%) showed no skin damage. Thus, the use of the intervention device considerably lowered the risk of IAD and HAPI in bedridden patients.

The use of similar fecal management systems, such as IBCs, are associated with significant complications. In a randomized, crossover, open-label pilot study, the incidences of rectal mucosal abnormalities were 40%, 20%, and 60% for the DigniCare SMS, Flexi-Seal FMS, and ActiFlo Indwelling Bowel Catheter System, respectively.[26] In the present study, no adverse events were recorded for the patients in the intervention group, who showed normal findings in digital rectal examination and proctoscopy at baseline and after device removal or expulsion.

This study has some limitations. First, the nature of the study prevented participant and investigator blinding, and the method of patient recruitment was by self-selection and not by randomization. Second, the treatment cost for IAD was relatively low because the study was conducted in a heavily subsidized government hospital setting. The treatment costs for IAD and HAPI are expected to vary according to the geographical location; patients could incur an additional cost of up to $21,410 and require additional hospitalization for up to 20 days according to the severity of the condition.[1,3] Third, the cost value for resource utilization has been calculated using the published data, as expenses in the government controlled tertiary care centers in India are heavily subsidized. Another limitation of this study is that the responses were not collected and analyzed by a trained psychologist, as the departments did not have access to a trained psychologist.

While selecting the method of fecal management for bedridden patients, clinicians should ensure that the method offers maximum comfort and maintains the patient's dignity. The baseline CSI scores for the intervention group and control groups were 8.5 and 8.4, respectively, whereas those at study completion were 5.1 and 7.8, respectively. This indicated that the caregivers in the intervention group experienced lower stress levels. Through additional surveys administered to the caregivers, we found that most of the conscious patients experienced little to no pain due to the device, and that there was no foul smell. Thus, the intervention device was patient- and caregiver-friendly and helped in maintaining a pleasant hospital environment.

Conclusion

In conclusion, we established clinical effectiveness and health economic benefits of the novel device for the management of FI in bedridden patients. The device is convenient and easy to

insert and remove, maintains patient's dignity, and successfully diverts liquid to semi-formed stool, effectively reducing the patient management time, resource consumption, and overall treatment cost. Moreover, the rate of complications, such as IAD and HAPI is low. Finally, caregiver burden is considerably lower than that with the use of conventional methods involving the use of diapers and pads.

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Ethical Approval

The study protocol was approved by the ethics committee (IEC(I) OUT/1322/16), and the study was conducted in accordance with the ethical standards set forth in the 1975 Helsinki Declaration. Written informed consent was obtained from all patients or their legally authorized representatives at the time of enrollment.

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