QORAMATIC® AUTOMATED STOOL MANAGEMENT KIT

A new standard of care in fecal containment for bedridden patients

ABSTRACT

Constant exposure to fecal effluents in critically ill patients can result in several co-morbidities, risk of skin breakdown, and pathogen exposure, which can be both labor and resource intensive. Seemingly benign, fecal incontinence (FI) and diarrhea are ubiquitous in nature and affect nearly 18 million US adults.[1] Fecal exposure causes several hospital-acquired complications (HACs), including incontinence-associated skin damage (IASD), hospital-acquired pressure injury (HAPI), C. difficile infection (CDI), central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), and surgical site infection (SSI). The clinical and health-economic consequences of patients suffering from poor bowel control are frequently devastating. Nurses spend an average of 174 minutes per day toileting and dressing patients with FI. It also impacts other areas of nursing, such as high attrition rates, low morale, and back injuries. Traditionally, liquid stool incontinent patients are managed by use of absorbent pads and cleaning supplies. Over the last few years, several closed fecal management systems in the form of external collector pouches or indwelling bowel drainage catheters have shown promising results in preventing ISAD. However, these newer management options have constricted indications of use and can manifest new morbidities in the form of rectal erythema, necrosis, bleeding, and sphincter dysfunction. The Qoramatic Automated Stool Management, developed by Consure Medical is a novel approach to fecal containment that uses vacuum suction to manage fecal incontinence in non-ambulatory patients. The device proactively voids the rectum before the episode and minimizes the need for manual intervention in managing fecal incontinence. This paper discusses the safety, efficacy and functionality of the Qoramatic SMK technology and discusses clinical benefits over existing solutions. Bowel management solutions have evolved from diapers and absorbent pads, to rectal trumpets and intrarectal balloon catheters (IBCs). The innovation arc from absorbent pads to catheters was driven by clinical outcomes and health-economics. Balloon catheters were a step up from under pads since it significantly reduced cross contamination and improved hygiene. However, while improving some of the existing shortcomings, IBCs introduced a myriad of new complications associated with the high-pressure balloon. Hygienic and pliable stents such as the Qora SMK were the next step toward superior clinical outcomes. Qoramatic Automated Stool Management further enhances nursing efficiencies while improving clinical safety. Qoramatic SMK provides the same safety benefits of Qora SMK, but with 1) an even lower pressure of 0 mmHg, 2) pro-active fecal diversion leading to less leakage, and 3) automation that saves time, avoids medical errors related to inflation of the balloon, and prevents back injuries for nurses associated with rigorous patient turning and performing hygiene due to pads and linen soiling. To evaluate clinical efficacy and nurse efficiency of using Qoramatic Automated Stool Management, a clinical evaluation was conducted on 20 patients admitted in critical care unit. Qoramatic significantly showed reduced leakage rates (1.8%), and brought down the nursing time to 6.8 mins per day thus reducing nursing burden while providing superior clinical outcomes.

INTRODUCTION

Fecal Incontinence

Fecal incontinence (FI) is a highly prevalent and debilitating condition that impacts patients and care providers across various healthcare settings. Although FI is a benign condition, its clinical sequelae and associated expenses are often devastating to both the patient and the health system. FI depends upon a wide variety of anatomic and physiologic factors. Colonic transit, stool consistency, rectal reservoir function, anal sampling reflex, muscle innervation, and function of the internal and external anal sphincters all contribute to the maintenance of normal continence. The three main pathophysiological factors for incontinence, which often overlap, are (1) abnormal stool consistency and volume, (2) neurological disorders leading to sphincter weakness, and (3) anatomic defects in the sphincter.

Bowel evacuation and Pathophysiology

The rectum can accommodate approximately 300ml of possible stool volume before the increase in intrarectal pressure and subsequent distension of the rectal tissue triggers the "urge to defecate" sensation.[2] The internal anal sphincter muscle (IAS), external anal sphincter muscle (EAS), and the three mucosal folds (rectal valves) play a role in controlled bowel movement. The IAS, which is innervated by the enteric nervous system and both the sympathetic and parasympathetic nerves, is usually contracted and contributes to approximately 70-85% of the anal canal resting sphincter pressure.[3] As an involuntary action that is facilitated by the enteric nerves, the IAS relaxes transiently when the rectum starts to distend. The EAS and puborectalis muscles, which are both innervated by the pelvic and pudendal nerves, are smooth muscles that control the voluntary functions of rectal motility.

The puborectalis muscle forms a sling around the lower rectum when it meets the fibers from the opposite side. It acts in association with the internal and external anal sphincter in the process of defecation.[4] Once the rectum has accumulated fecal matter, the rectum distends and relaxes the IAS, which

triggers an urge to defecate. If the patient chooses to defecate, the anorectal angle reduces and the intraluminal pressure increases due to thoracic and abdominal muscle contractions. The tonic activity of the EAS, which provides 15-20% of the rectal tone, is also inhibited and results in a successful bowel episode.[5] The influence of external pressures, exhibited from a balloon catheter, can impede the normal physiological functioning of this GI motility. That impediment frequently causes pain, trauma, and discomfort, as it can damage internal anatomy. This, in turn, leads to the need for a low-pressure or zero-pressure mechanism that proactively diverts fecal exudate in sedated patients. In a conscious patient or normal adult, the changes in intra-rectal pressure and muscular contractions can be coordinated. However, sedated patients do not have this ability. Therefore, there is clinical utility in proactively diverting fecal effluent without using pressure or muscle strength. As an example, a non-sedated person can spit out their own saliva but a sedated person cannot, and there is value from suctioning it instead.

An interruption in the normal defecation mechanism can result in fecal incontinence. When the anal sampling reflex is intact, a person is able to distinguish between a liquid, solid, or gas in the rectal vault. Disruption of the anal sampling reflex results in FI. Neurological disorders or trauma are also commonly associated with fecal incontinence, especially amongst hospitalized patients. Conditions such as stroke, spinal cord trauma, diabetes mellitus, and degenerative disorders of the nervous system alter normal gastrointestinal sensation, feedback, or function that helps to maintain continence. These effects are especially exacerbated in bedridden and institutionalized patients. Other factors apart from neurological disorders or trauma are also causes of fecal incontinence. In the acute care setting the use of laxatives, some medications, and pre-existing conditions such as Acute Kidney Injury (AKI), or Chronic Liver Disease (CLD) can also contribute to FI. Other causes include sedation and mobility concerns.

Epidemiology

Fecal incontinence is predominantly found in critically ill patients in acute care facilities and other long-term care facilities such as psychiatric and rehabilitative institutions. FI affects nearly more than 5.5 million patients in the United States[6] and 28 million patients across the globe, with prevalence rates of 9-37% in Intensive Care Units[7] (ICUs), 20-46% in Long Term Acute Care (LTAC), 42-50% in short term, 60% of long term nursing residents[8] and 43.3% in home hospice care facilities.[9] In addition to the prevalence, the duration of the condition is equally important. Incontinence in institutional patients typically lasts for 1 to 5 days depending on the clinical condition, prescribed treatment, and dietary intake. Outside the institution, incontinence in geriatric and psychiatric patients can last from 30 days to years, until a definitive therapy in the form of surgical intervention is undertaken.

Clinical Complications

Fecal incontinence is an established risk factor for skin breakdown, pressure injury, and the spread of hospital-acquired infections (HAIs) in bedridden patients.[10-13] The manifestation of these complications arises when the acid mantle of the perineal or peri genital skin is suffused with stool and moisture, therefore causing perineal rashes. Sebum, an oily substance secreted by the sebaceous glands, maintains the skin integrity by maintaining an acidic pH of 4 – 6.0 (acidic mantle).[14-16] Feces containing protease and lipase, both alkaline in nature, can digest perianal skin and soft-tissue. These pathological manifestations can lead to further skin breakdown when combined with the physical forces of body weight and shear force from restlessness or patient agitation. An incontinent patient is 22 times more likely to develop PU compared to patients without fecal incontinence[17-18], and is 37.5 times more likely to develop HAPI if both incontinent and immobile.[19]

Continual exposure to moisture from fecal matter through inefficient conventional fecal management practices causes the skin to macerate, thus compromising the skin's integrity as a barrier. Unattended or untreated macerated skin results in erythema and painful pressure points over a period. Skin that has an impaired barrier function can easily be invaded by bacteria causing IAD.[20] In addition to IAD, incontinent patients are also at risk of acquiring secondary infections such as urinary tract infections (UTIs). Inefficient fecal containment is a major risk factor for the spread of HAIs, most commonly Clostridium difficile infection (CDI). C. difficile causes severe diarrhea and has seen an increasing incidence among nursing home and acute care patients.[21-22] CDI is easily transmittable in a healthcare setting and requires strict hand hygiene and contact precautions to avoid contamination.

Hospitalized patients may require heavy doses of antibiotics, which disrupts the equilibrium of intestinal microflora thereby allowing the pathogenic microbes to proliferate, resulting in HAIs. Bacteria found in stool is representative of the bacteria in the gastrointestinal tract, and causes infections such as CLABSI, CAUTI, and SSI through the spread of antibiotic-resistant microorganisms via healthcare workers and other surfaces contaminated with fecal bacteria. A combination of HAPI and exposure to nosocomial infections adversely impacts the patients' mortality, morbidity, treatment costs, and length of stay.[22]

Health Economics

Fecal exposure causes over 135,000 HACs annually, attributing to over $1.34 billion in healthcare expenditure.[42] HACs associated with inadequate fecal containment, namely HAPI, CDI, CAUTI, SSI, and sepsis result in an additional cost of $0.6k - $30k per complication.[23-27] Table 1 summarizes the additional length of stay (LOS) per patient and cost per complication developed due to poor fecal management. As a result of new regulations such as the Hospital-Acquired Complication Reduction Program (HACRP), healthcare facilities are incentivized to contain the spread of HAIs to

avoid exorbitantly high penalties. The HAC Reduction Program imposes a 1% reduction to Medicare inpatient payments for hospitals in the worst performing quartile (25 %) of risk-adjusted national HAC rates.[28] The government has recently suggested that such measures are also necessary in long term acute care facilities (LTACs) and Skilled Nursing Facilities (SNFs) to improve clinical outcomes of the increasing number of admitted patients and to reduce the economic burden of chronically institutionalized patients.

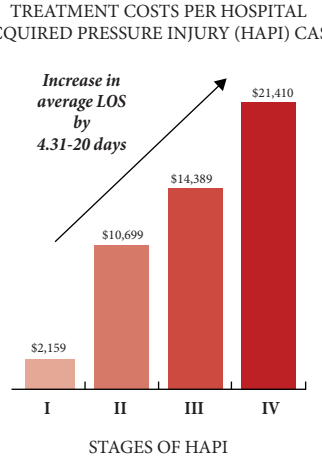

FIGURE 1 : COST OF TREATING VARYING STAGES OF HOSPITAL ACQUIRED PRESSURE INJURIES

Complication	Additional LOS (days)	Additional Cost ($)
HAPI[29-32]	4.31 - 20	$ 2,159 - $ 21,410
CDI[33]	2.95 - 11.1	$ 7,286 - $ 29,000
CLABSI[34-35]	8.8 - 10	$ 10,750 - $ 23,242
CAUTI[36-37]	0.4 - 2	$ 876 - $ 10,197
SSI[38-40]	4.9 - 10	$ 21,040 - $ 34,434

TABLE 1 : ADDITIONAL LENGTH OF STAY AND COST ASSOCIATED WITH HOSPITAL ACQUIRED COMPLICATIONS

MANAGEMENT OPTIONS

Treatment options for FI can be classified into four main categories: containment, pharmacological, electro muscular stimulation, and surgical repair of the anorectal anatomy. Due to multiple comorbidities in institutionalized patients and the care provider's focus on treating their primary condition, FI is mostly managed by containment or pharmacological options. Options for fecal containment in bedridden patients are often the utilization of absorbent pads or diapers, fecal collectors in the form of collection bags or pouches, or indwelling balloon catheters (IBCs).

The use of absorbent pads requires cleaning of the patient after every defecation, which can lead to Incontinence-associated skin damage (IASD) if not performed consistently and appropriately. Hence, the effectiveness of the absorbent pads is limited to preventing the soiling of patient's clothes and bedsheets. The management of FI using pads is also time and resource intensive. Nurses spend approximately 174 minutes every day checking, turning, and cleaning patients.[41] This takes time away from other activities, and puts nurses at risk of injury and fatigue due to the cleaning, turning, and repositioning of patients on a repetitive basis.[42] Because pads are an open system, they create a higher risk of spreading infection. Additionally, there is no barrier to odor with the use of absorbent pads, which can cause embarrassment, discomfort to the patient, and those around them, reducing patient quality of life. Hospital quality metrics usually are degraded using pads, as incidence of IASD. HAPI, CAUTI, CLABSI and most importantly CDI will rise with their use.[43-44] The fatigue and injury concerns for nurses who care for these patients can also lead to staffing problems and an inability for nurses to perform other essential tasks for all the patients under their care.

Hospitalized patients may require heavy doses of antibiotics, which disrupts the equilibrium of intestinal microflora thereby allowing the pathogenic microbes to proliferate, resulting in HAIs. Bacteria found in stool is representative of the bacteria in the gastrointestinal tract, and causes infections such as CLABSI, CAUTI, and SSI through the spread of antibiotic-resistant microorganisms via healthcare workers and other surfaces contaminated with fecal bacteria. A combination of HAPI and exposure to nosocomial infections adversely impacts the patients' mortality, morbidity, treatment costs, and length of stay.[22]

The pouch-type collection devices have an open end, which adheres to a patient's anal opening using mainly hydrocolloid adhesives that are attached to a collection pouch. This was once considered a cost-effective 'closed' system that could potentially prevent exposure to fecal matter. However, use of external fecal pouching requires early intervention before IASD occurs. Otherwise, moist and weepy skin inhibits adhesives from attachment causing system failure and subsequent skin damage. Additionally, the use of such fecal pouches requires frequent replacement that can lead to denudation of the skin around the area of application. Furthermore, due to the irregularity in the anatomical topography around the anal opening, the fecal pouches are frequently plagued with fecal leakage, thereby providing minimal advantages in comparison to absorbent pads.[45] The lack of robustness of the pouch adhering mechanism prevents them from being used on agitated patients with altered sensorium – a common condition in acute care or long-term care patients.

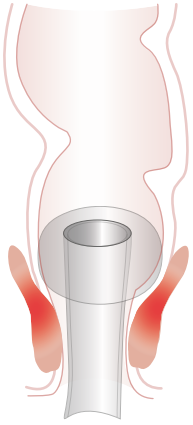

FIGURE 2 : INDWELLING BALLOON CATHETERS ANCHOR UPON THE ANORECTAL JUNCTION

Indwelling balloon catheters (IBCs) for a while proved to be an effective solution for managing liquid stool incontinence in acute care settings. (Figure 2). IBCs are very limited in their indication of use, manifest severe complications and are generally running out of favor with bedside nurses. The region approximately 2-3 centimeters proximal and distal to the anorectal junction is most heavily innervated. Due to their inherent design, anchoring IBCs near or around the anorectal junctional region may lead to patient discomfort, the urge to defecate, peripheral leakage (40-78%), spontaneous expulsion (21-28%), over-inflation (14%), and cause sphincter dysfunction (8-25%), and anal erosion (13%).[46-54] Intrarectal balloon catheters (IBCs) are inserted by a trained care provider, exert high outward radial pressure (32-81 mmHg), and are susceptible to getting over-inflated due to human error and are bane of multiple clinical complications across major healthcare systems.

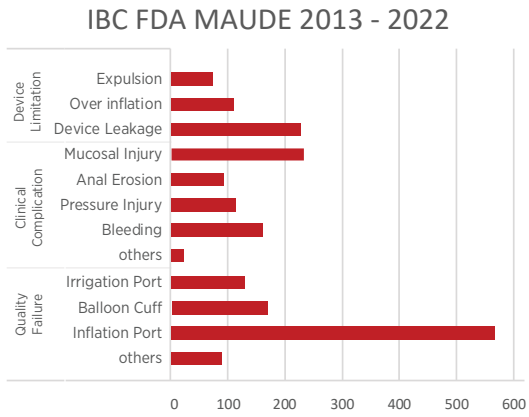

FIGURE 3 : COMPLICATIONS ASSOCIATED WITH HIGH PRESSURE BALLOON REPORTED ON FDA MAUDE

Qora SMK, also developed by Consure Medical, addressed several shortcomings of IBCs and provide a safe and efficacious stool management kit that has shown 75% lower radial pressure[55] (21.2 mmHg vs 81.2 mmHg of IBCs), improved patient comfort by placing the lattice over the transverse rectal valve, enabling diversion of semi-formed to formed stool, a hygienic applicator for safe and accurate deployment, and reduced nosocomial infection by 76%.[55] The pliable lattice of the Qora SMK is the only indwelling diverter that does not interfere with normal pathophysiological functioning of the rectum. Despite all the advancements of Qora SMK, there is still a need for a better technological solution which reduces the radial pressure of the indwelling diverter even further, automates maintenance function of the stool management, and prevents any medical errors from the use of syringes and inflatable balloon based devices.

QORAMATIC : FIRST AUTOMATED STOOL MANAGEMENT KIT

Controlling a patient's urge to defecate, pain tolerance, and enhancing infection control are paramount when developing a new incontinence management solution. Consure Medical has reimagined fecal management with its novel Qoramatic Automated Stool Management. The value proposition of IBCs for the management of fecal incontinence over absorbent pads and diapers has been clinically and economically proven by commercially available products. The Qoramatic technologically solves a myriad of shortcomings that exist with IBCs.

Clinical applications in urinary incontinence, wound care, oral suction and complex surgeries, have long used negative pressure to reduce leakage and keep patients' skin healthy. The Qoramatic uses this same principal to draw stool away from a patient's body in a pro-active manner without burdening the neuromuscular function of the anorectal region. The result is a fecal containment system that is comfortable for the patient, improves skin integrity, and reduces labor of frequent skin cleansing. Automated stool management also eliminates common medical errors associated with inflation, over-inflation, and inaccurate medication deliveries. With intermittent suction and irrigation in tandem, the Qoramatic technology reduces the risk of any patient health issues such as leakage, maceration, dermatitis, and nosocomial infections.

With automated stool management, the Qoramatic technology allows for proactive fecal diversion. There is no inflation required, so there is no overinflation risk. No irrigation or milking is required, and patient comfort is at its highest. The rectum is completely voided, so leakage is negligible. The Qoramatic technology offers, at its heart, a matic hub with LED indicators, one touch operation, a slot for a power adapter, along with a height adjustable hangar for bedside convenience. The dual-chambered bag is connected to an indwelling receptacle, and the three-step application is intuitive and easy to use. Application does not require advanced training, and insertion of the indwelling receptacle is not time-consuming or difficult. After deploying the receptacle, filling and attaching the disposable collection bag is the next step. After the bag is filled and attached, press the

start button and the Qoramatic technology will provide an LED light indicator for at-a-glance information on its operational status.

Pain and Pressure Sensation in the Rectum, Patient Comfort

The anorectal junction has a high concentration of somatic nerve endings, which disqualifies it as a suitable location for diverter placement. Amongst the many variables of gastrointestinal motility, one key parameter associated with rectal sensation is the intrarectal pressure. High intrarectal pressures (above 22 mmHg) result in an 'urge to defecate' sensation, which triggers the natural bowel movement physiology. In a false-positive setting, such as the constant radial pressure (32–81 mmHg) of a fully inflated intrarectal balloon catheter (Figure 2) on the rectal walls and anorectal junction, the patient can become extremely uncomfortable and develop an altered sensorium. Hence, it is advantageous for an indwelling fecal diverter exhibit a pressure on the rectal wall of no more than 22 mmHg for superior patient comfort.

FIGURE 4 : QORAMATIC AUTOMATED STOOL MANAGEMENT

The Qoramatic SMK includes a soft receptacle that exerts 0 mmHg radial pressure on the rectal mucosa, and can safely be inserted immediate past the anal canal on the anorectal junction minimizing any risk of erythema, necrosis, mucosal erosion, etc. Amongst the most under-reported and under-acknowledged problems with indwelling receptacles is overinflation. This comes from the goal of reducing or eliminating leakage. In other words, if there is still leakage around an inflated, indwelling catheter, (off-label) overinflating the catheter may stop or reduce leakage. However, overinflation can lead to significant discomfort for patients and can cause problems with sphincter control, as well as other issues. Because Qoramatic SMK does not require any inflation, and offers a 0 mmHg radial pressure on the rectal mucosa, in tandem with no leakage due to proactive fecal diversion, there is no need for inflation or overinflation that may cause discomfort. This eliminates the challenges and medical errors that can come with IBCs, and ensures good clinical outcomes and improved patient comfort.

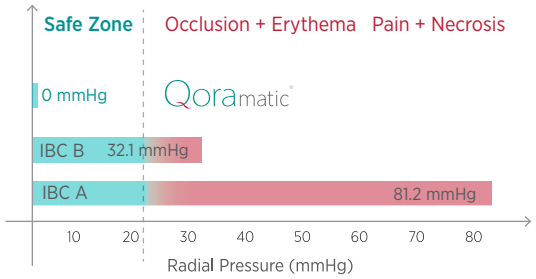

FIGURE 5 : RADIAL PRESSURE OF IBCS V/S QORAMATIC

Nursing Burden

Nurses perform 125 tasks every hour and this overload is the root cause of many errors, fatigue, and attrition.[57] Fecal management requires significant time commitment from care providers. Managing incontinence along with dermatitis, maceration, and HAIs requires deft planning and prioritization. The Qoramatic SMK technology is designed to provide a safe and effective fecal management solution and to help extend the continuum of care. By employing a user-design based approach, the Qoramatic SMK can be used by a minimally trained individual and does not require any maintenance of the indwelling component.

FIGURE 6 : AUTOMATED MILKING, IRRIGATION AND MAINTENANCE WITH ONE TOUCH OPERATION

By automating fecal incontinence management, nursing time required in this area of patient care can be reduced by 90% to 98%.[55] Milking and irrigation are automated, reducing the

nursing burden and adding to the comfort of the patient. The device includes intelligent LED indicators, for ease of use and determination of device's condition at any given time. This further reduces the nursing burden and provides for faster and more efficient patient care.

The external collection bags are made of specially engineered polymers that contain volatile organic compounds (provides an odor barrier). The bag exchange is designed to be linear in order to prevent any blockage. The easy-to-use collection bag has an integrated luminal one-way valve that prevents any accidental soiling or leakage when changing the bag. The collection bag is integrated with a flatus release filter for automatic odor-free degassing. The device is designed in pleasant neutral color with a translucent interface and remains out of direct sight to maintain the dignity of the patient throughout the duration of hospitalization.

The Qoramatic SMK has been cleared by the U.S. Food and Drug Administration (FDA), and other regulatory notified bodies for non-ambulatory patients incontinent with liquid to semi-liquid stool. The device can be used with a physician's order for a continuous usage of up to 29 days.

Incontinence and Hospital-Acquired Infections

Stool consistency changes over time as the patient's condition improves. The Bristol stool scale is generally used to assess the stool consistency. A patient with multiple liquid stool episodes per day is prone to prolonged exposure to effluent which results in cross-contamination and a sequela of HAIs. Effective containment of fecal matter is necessary to avoid spread of pathogenic bacteria and reduce the incidences of HAIs.

FIGURE 7 : QORAMATIC PROACTIVELY DIVERTS FECAL EFFLUENTS

To address this issue, the Qoramatic Automated Stool Management Kit (SMK) comes with an easy-to-deploy indwelling receptacle, which can be comfortably and efficiently inserted to reduce direct contact between fecal matter and the care provider and ultimately reducing risk of contamination. The indwelling receptacle and negative pressure technology efficiently moves fecal matter into the drainage bag, even as stool consistency improves from liquid to semi-liquid stool while the patient remains bedridden and prone to dermal deterioration. The 0 mmHg of pressure exerted by the receptacle provides an adequate suction force to efficiently divert fecal matter from the rectum into the collection bag via the transit tube. This approach minimizes the risk of peripheral leakage and spontaneous expulsion of the device while helping to contain various infectious carriers found in fecal effluents from the external environment. The Qoramatic Automated Stool Management Kit (SMK) efficiently voids the rectum, and the patient does not need to rely on peristalsis to defecate. The reduction of HAIs/HACs, skin breakdown, IAD, and cross-contamination provides a higher quality experience for the patient.

QORAMATIC CLINICAL EVALUATION METHODS

Study Design

A clinical evaluation was conducted on 20 patients admitted in critical care units to gauge safety, clinical efficacy and functionality of using Qoramatic. The Qoramatic Automated Stool Management was inserted by trained nursing staff and the device was closely monitored every 8-hours to ensure all risks were minimized for enrolled patients. Data for all 20 patients were included in the final study analysis with no patient dropping out of the evaluation. Consent was obtained from all enrolled patients or their authorized representatives and guardians.

Patient Eligibility

Enrolled patients had at least one episode of fecal incontinence, with liquid stool incontinence 24 hours prior to device usage. All patients were bedridden adults. Patients receiving oral anti-coagulation therapy and patients with history of cardiac arrest within the preceding three months were enrolled under the discretion of their care provider. Additionally, patients with suspected or confirmed rectal mucosal impairment, rectal bleeding, hemorrhoids, strictures or other abnormalities were excluded from the study. The inclusion and exclusion criteria are detailed in the Table 2.

Inclusion Criteria
1. Patients must be greater than 18 years of age (no gender bias)
2. Non-ambulatory, hospitalized patients.
3. History of passage of at least 1 stool in past 24 hours.
4. Non-ambulatory, hospitalized patients.
Exclusion Criteria
Patients meeting the following criteria must be excluded:
5. Suspected or confirmed rectal mucosal impairment or pathology
6. Rectal surgery within the last year
7. Any rectal bleeding or anal injury
8. Hemorrhoids of significant size
9. Rectal or anal stricture or stenosis
10. Have or suspected to have tumor(s) in the rectum or anal canal
11. Have or suspected to have constipation or impacted stool
12. Pediatric patient
13. Patients enrolled in other studies

TABLE 2 : INCLUSION AND EXCLUSION CRITERIA FOR CLINICAL STUDY

Interventions and Assessments

All the patients were maintained on absorbent pads with the device in-situ. Follow-up was performed on each participant

every 8 hours. The perineal region was examined for evidence of device related bleeding or fecal contamination. The absorbent pads, patients' clothes, and bed linen were evaluated for soiling. The external components of the Qoramatic Automated Stool Management, including the transit tube, the Matic hub and the drainage bag, were examined for structural integrity and collection of fecal effluents.

Efficacy Assessments

The evaluation of the device efficacy was measured using the following endpoints:

1. Successful fecal diversion – defined as the collection of fecal effluents in the drainage bag.
2. Device leakage: 1) Classified as Minor, if the leakage was non-problematic, incidental, and confined to the perineal area, and 2) Classified as Major if there was significant soiling around the device.
3. Duration of device use – how long the device remained in place during the study.
4. Time spent by nurses using the device – troubleshooting and standard patient care.
5. Reduction of CSI (Caregiver Strain Index).
6. Patient comfort with insertion, removal, and during the time the device was in use.
7. Accidental expulsion of the device when it was not scheduled for removal at that time.
8. Removal of device due to performance inefficacies.

Statistical Analysis

All relevant study data were evaluated using Microsoft Excel of Microsoft Office 365 (Microsoft Corporation, Washington, USA) software. Safety data and device performance descriptions were summarized from the enrolled patients in the study. The results are presented as absolute values, percentages, with mean ± standard deviation, wherever applicable.

Results

Twenty patients were enrolled for the clinical evaluation. Their mean age was 55.3, range: 27-80 years; where 55% were females. 40% of patients enrolled in the study had stool consistency of Bristol Scale 7 at the time of insertion. The stool consistency at the time of removal was not recorded in the study.

All devices were successfully deployed on the first attempt. 19 out of 20 care providers reported positively regarding the ease of insertion of the device. During insertion, the Digital Rectal Examination Scoring System referred to as DRESS – Resting Score was also recorded. The participants underwent a total of 341 assessment points, with device performance evaluated all 20 patients with all the devices exhibiting successful fecal diversion. No device breakdown appeared; care providers experienced 2 instances of troubleshooting which was resolved independently without the need for any assistance by the customer support representative. The average stool output for all the patients was 441ml per day. Of 341 assessment points, no leakage was seen in 323 (94.72%) and minor leakage in 12 (3.5%) time points. There were 6 episodes of major device leakage (1.8%). All instances of minor leakage were spontaneously resolved. In no instances, the leakage was observed at the connection of the transit tube to the Matic hub due to a loose connection. Only 6 under pads were changed during the study that were directly associated with fecal soiling.

In a total of 87 days of collective use, the device accidentally expelled 2 times but was reinserted by the care-provider after following the necessary hygiene protocols set by the institution.

The nurse efficiency was an important component of the clinical study. Daily average nursing time, instances and the time spent in troubleshooting, and caregiver strain index (CSI) were important factors to determine impact on nursing efficiency. In a total of 341 follow-ups, the daily average time spent by each nurse was 6.8 minutes (±1.29) with average time spent per follow up being as low as 0.4 minutes. The device remained in-situ for 4.4 (±1.57) days.

The insertion of the device did not affect routine patient care including patient mobility, feeding, sitting or standard maneuvering performed on bedridden patients. The devices were evaluated for structural and functional integrity post retrieval and data was available for all 20 devices. All the available devices were found to be structurally and functionally intact after removal. There was no evidence of any tear in the receptacle, transit tube or any damage to the Matic hub.

No episode of anorectal bleeding was observed throughout the study period. Results indicate that the device was used effectively and efficiently in most patients who participated in the study.

DISCUSSION

Effective fecal containment in institutionalized patients is often under-addressed and overlooked. Patients with FI or diarrhea are 22 times more likely to develop pressure injuries; this risk rises to 37.5 higher odds when the individual is bedridden.[17] The risk of serious complications also extends to patients exposed to fecal bacteria such as *Clostridium difficile*, *Escherichia coli*, or *Pseudomonas aeruginosa*. Such pathogens, which are easily transmitted fecal-orally, result in hospital-acquired complications that further complicate treatment and increase healthcare-related expenditure. Health-economic studies have shown that CAUTI, CLABSI, and SSI due to fecal exudate extend the length of hospitalization by 4-22 days, thereby adding an incremental cost of US $0.6k-$30k per complication.

This study was undertaken to determine the safety and efficacy of a novel vacuum enabled, automated stool management kit in bedridden patients suffering from fecal incontinence. Current evidence suggests that intrarectal balloon catheters (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%).[34-35] Additionally, there is a risk of burnout and physical harm to nurses due to the strain of moving, turning, and cleaning patients' multiple times per day. The nursing burden is high with pads, and lower with IBCs, but there are still inherent problems with both current methods.

Qoramatic automated SMK is designed to overcome functional and safety constraints with existing IBCs. Results of the clinical study suggest that it is safe to use Qoramatic SMK in bedridden patients with fecal incontinence and diarrhea.

No incidents of adverse events occurred during the study period. Patients predisposed to bleeding were handled cautiously. Participants (3 out of 20 enrolled patients) did not show any adverse events while on anticoagulant or antiplatelet drugs. The ability to use the Qoramatic SMK in such patients could be an advantage over IBCs. However, a further detailed investigation would be required to arrive at even more conclusive recommendations.

Qoramatic SMK provided an effective barrier between perineal skin and fecal exudate, avoiding the risk of further skin breakdown that could potentially lead to severe complications. The receptacle was easy to deploy and its positioning inside the rectum was easy to visualize. With no syringes or inflation devices involved, the Qoramatic inherently reduces medical errors, and automation of most functions not only saves nursing time but also mitigates learning curve challenges.

Supported by clinical evidence and a strong technological value proposition, a careful assessment of the Qoramatic SMK demonstrates clear advantages over intrarectal balloon catheters. More importantly, the benefits of this technology enable a significantly wider patient applicability, the device does not cause any pain sensation, enables varying consistencies of stool to be diverted, and requires minimal resources for maintenance and management.

The number of injuries due to IBCs, coupled with the nursing burden that comes with pads, indicate that other options are clearly needed. The Qoramatic Automated SMK offers a clear solution for many patients and caregivers. There is additional value in being able to use this device with patients who may be at risk for bleeding, because many indwelling device options are not feasible for patients on any type of blood-thinning medications. Patients who are bedridden and incontinent are already at risk for many additional health problems. Infections, skin breakdown, and related issues are common. With Qoramatic automated SMK, a higher number of these problems could be avoided, improving patient experience and quality of life.

CONCLUSION

The results of this detailed clinical evaluation demonstrated that the Qoramatic automated stool management kit provides patients and care providers with a superior alternative to standard methods of fecal containment and management.

Qoramatic SMK improves health economics associated with inadequate FI management by reducing the treatment costs of IAD, HAPI, and HAIs. Although direct costs associated with traditional and indwelling balloon catheters have been studied, the indirect costs due to new complications, which can be quite costly, are often neglected. Existing balloon catheters contribute to complications in the form of mucosal necrosis and sphincter dysfunction, which can result in significant intervention costs in the form of surgery. Detailed studies will be performed to clearly quantify the economic benefit of Qoramatic SMK over other management modalities. However, an initial analysis portrays a clear expectation of economic advantage.

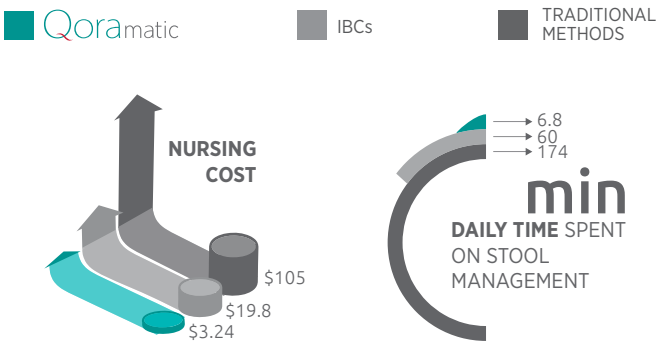

FIGURE 8 : COST ANALYSIS OF FECAL MANAGEMENT SOLUTIONS

Qoramatic Automated Stool Management offers 3 major benefits over existing solutions. 1) Superior patient comfort and no rectal trauma with a soft receptacle that exerts 0 mmHg radial pressure, 2) Significant reduction in leakage with proactive fecal diversion, and 3) Reduction in nursing time and burden with automated FI management.

It is worth noting that although the Qoramatic SMK is easy and intuitive to use, care should be specially exercised when planning to use this device in patients who tend to bleed due to ongoing anticoagulant or antiplatelet therapy. Other underlying conditions, previous procedures, and expected treatments must be crosschecked with the device's contraindications and safety warnings. When appropriately used, the results of the clinical evaluation discussed in this paper illustrate the Qoramatic device as a significant improvement over traditional bowel management practice.

The main areas of improvement include the quality of care the patient receives and the reduced strain on the nurses and other healthcare professionals involved in caring for bedridden patients who experience fecal incontinence. Because this medical condition can quickly start to cause skin breakdown, infection, and related problems, treatment that reduces contact between skin and fecal matter is vital to helping patients remain as healthy as possible during their hospital stay. Additionally, nurses are often overburdened with long hours and short staffing. Shortening the time, they need to successfully care for each of their patients can help them accomplish more during their shift. That translates to better patient care and lower levels of burnout among nurses, benefiting future patients and the hospital system. The right device can make a significant difference in all these areas, and the use of Qoramatic SMK has the potential to revolutionize patient care for several patients needing ongoing support for fecal incontinence. While it may not be right for every patient, the clinical study shows great promise that the Qoramatic Automated SMK can be successfully and comfortably used by a large patient base.

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