

BACKGROUND Intrarectal fecal management systems rely on inflatable cuffs which are likely to cause multiple complications such as mucosal injury, necrosis, sphincter damage due to the high radial pressure.¹ Clinical studies suggest that radial pressure over 22 mmHg can compress mucosal arteries and impair blood flow, with total occlusion of arteries occurring at 38 mmHg.² High radial pressure also causes patient discomfort and could trigger the urge to defecate due to the sensation of 'fullness' in the rectum.

METHODS The radial pressure of Qoramatic Automated Stool Management was measured in-vitro using linear tensile testing in five samples while radial pressure exerted by balloon cuffs were collected via literature review.

RESULTS Based on in-vitro testing, the radial pressure exerted on rectal walls by Qoramatic's indwelling receptacle was measured at 0.4 mmHg³ whereas literature review revealed IBC A and IBC B exerted 81.2 mmHg and 32.1 mmHg pressure respectively.

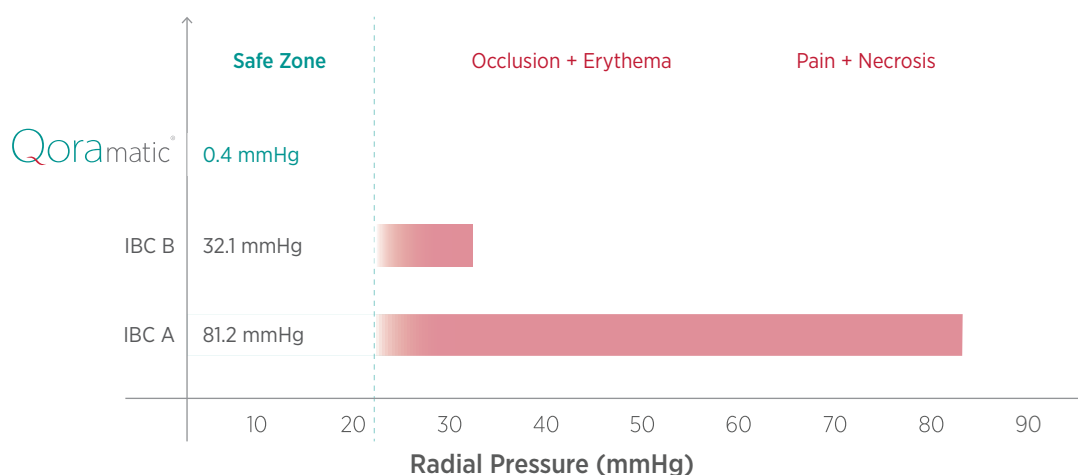


Figure 1: Comparison of mean radial pressures across catheters

CONCLUSION Balloon catheters are often over-inflated to reduce leakage which increases the susceptibility of rectal trauma. **The Qoramatic SMK exerts no radial pressure on the rectal mucosa.** Less pressure on the rectal wall eliminates the risk of erythema, necrosis, and mucosal erosion. The non-balloon stool management kit can be considered a safer alternative for incontinence management for bedridden patients.

1. Ian Whiteley, Gael Sinclair et al A retrospective review of outcomes using a fecal management system in acute care patients 2014 Dec;60(12):37-43.

2. Maira Soliani Del Negro, Gilson Barreto et al Effectiveness of the endotracheal tube cuff on the trachea: physical and mechanical aspects Effectiveness of the endotracheal tube cuff on the trachea: physical and mechanical aspects

3. Data on Company file

BACKGROUND The use of intrarectal balloon catheters has been linked to numerous adverse events including anal erosion, rectal bleeding, perforation, and fistula due to the high radial pressure balloon. The analysis aims to quantify the prevalence of such adverse events using user experience and complaints registered on FDA MAUDE database.

METHODS A thorough search of the MAUDE database was conducted to compile and categorize data on adverse events or complaints involving the use of these catheters. The results were broadly classified as 'Device Limitations' constituting sub-categories such as expulsions, leakage, over-inflation, 'Clinical Complications' including bleeding, mucosal impairment, anal erosion, and pressure injuries, and 'Quality Failure' associated with balloon cuff, irrigation port, and inflation port. Complaints that don't fall under any sub-category were characterized as 'other'.

RESULTS The FDA MAUDE data compiled between 2013-2022 showed 1,520 complaints that included 1,988 events. Approximately 48% (954) events were categorized as Quality failure with breakdown occurring in balloon cuff, or irrigation/inflation port. Of the remaining (1034) events - 22% (231) cases of mucosal injury or trauma, 11% (115) cases of pressure injuries, 15% (160) cases of bleeding, and 9% (94) cases of Anal Erosion were observed. Cumulatively, 40% (414) cases of device leakage, expulsion, and over-inflation were seen.

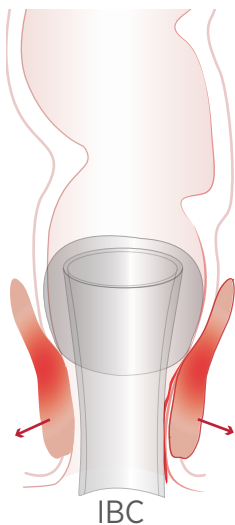


Figure 1: Indwelling balloon catheter exerting high outward radial pressure

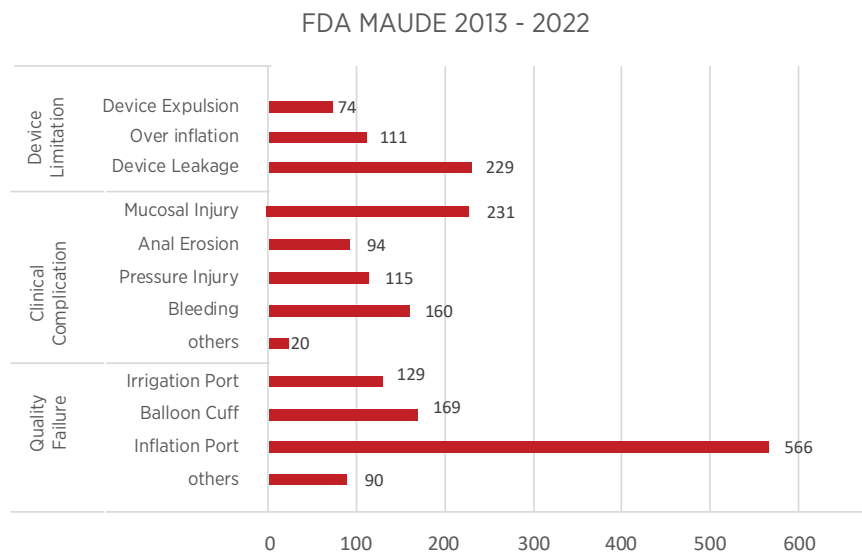


Figure 2: Complications associated with high pressure balloons reported on FDA MAUDE

CONCLUSION Based on the analysis of the Maude database, the findings suggest that the use of intrarectal balloon catheters can lead to high prevalence clinical complications and never events that increase morbidity, mortality, and length of stay in addition to increased cost of care. Majority of such complications are attributed to high pressure exerted by balloon catheters and its inadequate performance. Qoromatic uses a **soft receptacle that exerts no radial pressure on the rectal mucosa, which minimizes chances of rectal trauma**. It uses negative pressure to divert fecal output proactively that **reduces chances of leakage** and the need for manual intervention.

BACKGROUND Managing fecal incontinent patients can be a time and resource intensive task for nurses due to rigorous patient cleaning and re-positioning. This can often take away healthcare providers' attention from numerous other critical tasks and can potentially lead to human errors, exhaustion, and back injuries due to increased burden.

METHODS A systematic literature review was conducted to evaluate nursing time with absorbent pads and indwelling catheters. Additionally nursing time for Qoramatic was obtained from a study performed involving 20 volunteers to analyze clinical efficacy and nurse efficiency

RESULTS Studies show managing incontinence with absorbent pads requires 174 minutes each day, while intra-rectal balloon catheters require 60 minutes¹. Qoramatic automates tasks such as irrigation and milking and minimizes the need for manual intervention. The clinical study revealed Qoramatic reduced daily average nursing time by up to 96% (6.8 minutes/day)².

	Absorbent Pads	IBCs	Qoramatic
Daily Nursing time (mins)	174 ¹	120.44 ¹	6.8 ²
Nursing Cost	\$ 105	\$ 19.80	0

Table 1 : Nursing time and cost associated with FI management

CONCLUSION Nurses perform as much as 125 tasks per hour averaging a switch between tasks every 29 seconds. In intensive care units, nurses dedicate over 75% of their time on patient care activities that includes wound and incontinence management.³ More than 38% nurses experience lower back pain associated with turning and repositioning patients.⁴ Additionally, 44% of nurses quitting their roles have cited burnout as the main reason for seeking out new employment.⁵

Automating manual patient care tasks such as FI management can alleviate physical burden and can potentially reduce burnout. Qoramatic Automated Stool Management automates irrigation and milking, minimizes leakage and the need for multiple pad change thereby reducing the need for manual intervention.

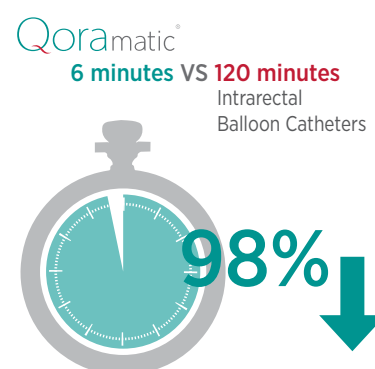


Figure : Graphic representation of Daily Cost Savings

1. Mike Langill A Budget Impact Analysis Comparing Use of a Modern Fecal Management System to Traditional Fecal Management Methods in Two Canadian Hospitals

2. Data on Company File

3. Stephen Douglas, Randi Cartmill, The work of adult and pediatric intensive care unit nurses

4. Deborah X Brown, Nurses and Preventable back injuries, ajcc2003.12.5.400

5. Heather Landi, Third of nurses plan to leave their jobs in 2022

BACKGROUND The anal sphincter muscles are responsible for keeping the anal orifice closed while the body is at rest. These muscles also play a crucial role in maintaining continence mechanism. During evacuation, the mean diameter of the anal canal is around 17 ± 6 mm and studies suggest the sphincter muscles start to experience strain when the anal distension reaches over 10mm.¹² Fecal management systems that retain larger diameters for extended periods of time cause discomfort, pain, and foreign body sensation. Extended use and constant friction could result in more severe complications such as pressure-induced necrosis, anal erosion, and sphincter dysfunction.

METHODS The study compares the insertion diameter of Qoromatic Automated Stool Management and two intrarectal balloon catheters. To draw a comparison, device insertion processes were performed on a bench top model following the instructions for use provided by each system and the maximum diameters created during both insertion and indwelling sustained state by each device were recorded

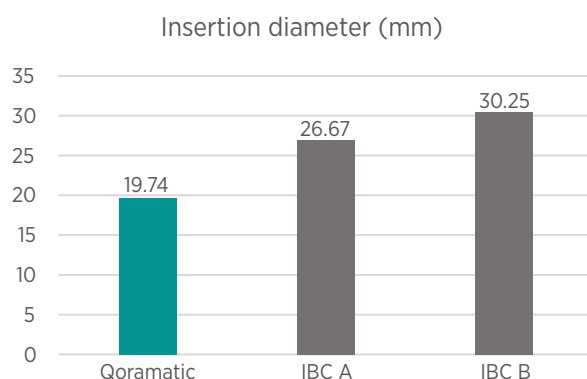


Figure 1: Comparison of insertion diameter among catheters

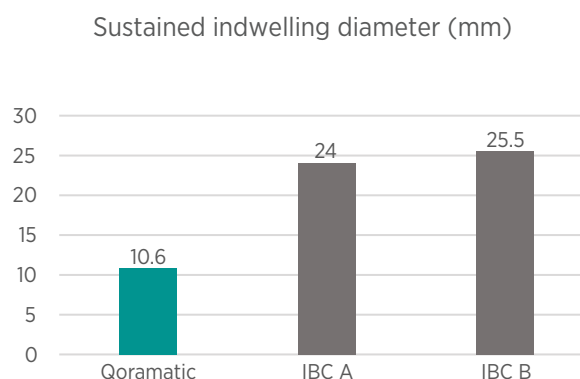


Figure 2: Comparison of indwelling sustained diameter at trans-sphincteric zones among catheters

RESULTS Based on in-vitro testing, the maximum diameters created during insertion procedures for Qoromatic SMK, IBC A, and IBC B, were 19.74mm, 22.29mm, and 30.25mm respectively. Furthermore, diameter sustained inside the anal canal during use for Qoromatic is 10.6 mm, while the same for IBC A is 24mm, and IBC B is 25.5mm³.

CONCLUSION IBC's higher diameter inside the anal canal, in addition to the higher radial force exerted on the rectal mucosa, contributes towards the sensation of fullness, patient discomfort, and chances of rectal trauma. Qoromatic SMK's smaller insertion diameter and the diameter at trans-sphincteric zone during extended use reduces risk of clinical complications.

1. Palit S, et al., Evacuation proctography: a reappraisal of normal variability. The Association of Coloproctology of Great Britain and Ireland 2014;16:538-2
 2. Lestar B, et al., The composition of anal basal pressure. Int J Colorect Dis 1989;4:118-122
 3. Data on company file

BACKGROUND Digital insertion of fecal management systems can expose rectal mucosa to various forces. The profile size of digitally inserted devices plays a crucial role in patient comfort. The force required for insertion and withdrawal is directly proportional to the profile size of the indwelling component. During accidental expulsions, the design of the indwelling component is detrimental towards the force exerted on the sphincters and the chances of damaging or weakening the sphincter muscles.

METHODS Insertion and withdrawal forces were calculated on five samples of Qoromatic Automated Stool Management and Intrarectal Balloon Catheters (IBC). The forces were measured using a linear tensile testing machine and a silicone-based anatomy model. To calculate force exerted during accidental expulsions, the devices were withdrawn without deflating or following any other withdrawal procedures mentioned in the IFU.

RESULTS In-vitro testing revealed the average insertion force of 3.37 ± 0.39 N and withdrawal force of 5.33 ± 0.73 N is exerted on the anorectal apparatus during the use of Qoromatic SMK. This is 86% and 70% lower respectively as compared to balloon based fecal management system - IBC A. During accidental expulsions, the withdrawal force for Qoromatic remains the same due to its collapsible design, whereas, the withdrawal force observed for IBC A is 17.59 ± 7.80 N. This force remains the same for accidental removal of Qoromatic and is over 3 times higher for intrarectal balloon catheter.

Parameter	Qoromatic SMK	IBC A	Comparison
Insertion force	3.37 ± 0.39 N	25.77 ± 7.02 N	86% less force with Qoromatic SMK
Withdrawal Force	5.33 ± 0.73 N	17.59 ± 7.80 N	70% less force with Qoromatic SMK
Accidental Withdrawal Force	5.33 ± 0.73 N	ABC N	PQ times higher than Qoromatic SMK

Table : Comparison of insertion and withdrawal force among catheters

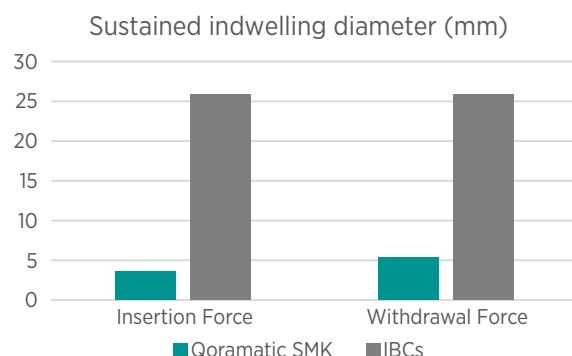


Figure : Graphic representation of insertion and withdrawal force comparison among catheters

CONCLUSION The Qoromatic SMK exerts less force on anorectal mucosa during insertion and withdrawal as compare to balloon-based catheters. During accidental expulsions of balloon catheters, this force is as high as 17.59 ± 7.80 N. Additionally, these balloon catheters are often over-inflated to reduce chances of leakage, thereby further increasing the chances of rectal trauma during use, and in case of accidental expulsion. The indwelling receptacle of Qoromatic reduces risk of trauma during device deployment, while in-site, or during removal.