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Clinical Literature

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

Singh, Sandeep; Bhargava, Balram; Vasantha, Padma; Bhatia, Rohit; Sharma, Hanish; Pal, Sujoy; Sahni, Peush; Makharia, Govind, K.

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Continence Care

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.

Qora™
Stool Management Kit

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Clinical Literature

A Pilot Clinical Study of a Safe and Efficient Stool Management System in Patients With Fecal Incontinence

Authors
1. Ashlee Garcia
2. Sally Fung
3. Karen Lou Kennedy-Evans

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INTRODUCTION

According to the Wound Ostomy Continence Nursing Society's Continence Committee, the incidence of fecal incontinence (FI) can occur from 18% to 37% in an acute care setting. A stool management system has been designed to manage FI in bedridden patients and has proven to be efficacious in wound management and prevention and infection control, provide safer patient outcomes, and enhance ease of nursing.

OBJECTIVE

This study aims to evaluate the safety and efficacy of an intrarectal device intended to manage fecal incontinence in hospitalized bedridden patients through nonclinical and clinical testings.

MATERIALS AND METHODS

An uncontrolled pilot evaluation in 20 patients was performed as part of a value-based purchasing evaluation at a tertiary hospital in Tucson, Arizona, to assess safety and efficacy in infection control and wound care. The company-provided engineering bench-top studies of insertion and withdrawal forces of the device versus existing intrarectal balloon catheters also were evaluated.

RESULTS

The device has broader patient eligibility and potentially allows 3 times more FI patients to be managed safely. It has lower intrarectal pressures compared with indwelling balloon catheters.

CONCLUSIONS

This study, along with pilot clinical findings, suggests that this technology minimizes the pressure exerted on the rectal wall. There were significantly fewer forces against the anorectal mucosa compared with the cuff-based catheter during insertion, withdrawal, and accidental expulsion.

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Clinical Literature

Contemporary non-surgical approach for faecal diversion in a case of Fournier's gangrene

Authors
1.Harsh Sheth,
2.Shilpa Ashutosh Rao,
3.Karthik Venkataramani

SUMMARY

Fournier's gangrene is a fatal necrotising fasciitis of the perineum, genitals and lower abdomen. Patients often need an aggressive surgical debridement, and in few cases, a diverting colostomy. We report the case of a 70-year-old man with multiple comorbidities diagnosed with Fournier's gangrene, who underwent debridement and had a wound complication due to faecal contamination. A novel, self-retaining rectal device was used to perform faecal diversion, which subsequently showed wound healing within a week, hence avoiding the need of a colostomy.