CASE REPORT

Rectal Trauma and Associated Hemorrhage With the Use of the ConvaTec Flexi-Seal Fecal Management System: Report of 3 Cases

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The management of fecal incontinence is a struggle to maintain patient hygiene and limit the transmission of nosocomial infections. Intrarectal devices that cause diversion and collection of the fecal stream have been used with increasing frequency. This method can effectively control patient waste if used in an appropriate setting. We examine a series of 3 patients in whom rectal trauma resulting in life-threatening hemorrhage was associated with use of the ConvaTec Flexi-Seal fecal management system. In 2 patients there was a history of traumatic removal, and the third developed a rectal pressure ulcer associated with use of this device. All 3 patients required surgical or endoscopic intervention to achieve hemostasis. Although effective, the Flexi-Seal fecal management system should be used with caution to avoid rectal trauma. Injury is most likely to occur because of traumatic removal or rectal ulceration secondary to pressure necrosis.

KEY WORDS: Rectal; Trauma; Laceration; Fecal management system; ConvaTec; Flexi-Seal.

Effective management of fecal incontinence is a challenge to both acute and long-term care facilities. Absorbency pads, rectal Foley catheters, and rectal pouches are the most common methods of waste management in the hospital setting. The availability of new rectal collection devices, such as the ConvaTec Flexi-Seal fecal management system (FMS; ConvaTec Professional Services, Skillman, NJ), have allowed effective diversion of the fecal stream to improve patient hygiene and management of fecal-borne pathogens. Although effective, these intrarectal devices have the potential to cause mucosal tearing, ulceration, and acute hemorrhage. We present a case series of 3 patients who developed life-threatening lower GI bleeding secondary to use of the FMS.

PATIENTS

Patient 1

A 72-year-old resident of an extended care facility (ECF) presented with an acute lower GI bleed. Onset of bleeding occurred after an FMS was traumatically pulled from her rectum during transfer from a wheelchair to her bed. Except for aspirin, the patient was receiving no other anticoagulative. A colonoscopy was performed and a 2-cm rectal tear was noted approximately 4 cm proximal to the dentate line. A clot was adherent to the laceration, so no intervention was performed. She had no further bleeding during the next 3 days and was discharged. One week later, the patient returned with hypotension and bright red blood per rectum. Pulsatile bleeding was observed originating from the prior laceration (Fig. 1). A transanal suture ligation was performed, which achieved hemostasis. An interval examination revealed a well-healed site, and the patient has had no further complications.

Patient 2

A 54-year-old woman with an extensive medical history of endocarditis and stroke presented to the emergency department in hypovolemic shock with bright red blood per rectum. Her medications included warfarin for a prosthetic mitral valve, although her international normalized ratio was subtherapeutic (1.7) on presentation. The staff

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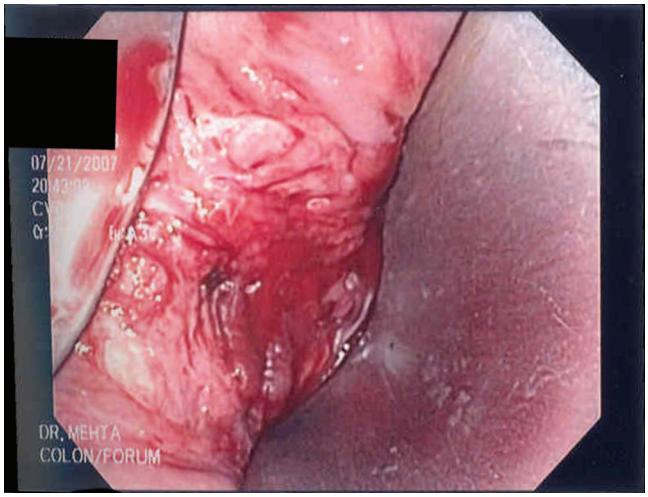

FIGURE 1. Endoscopic view of the patient's mucosal ulceration with active arterial bleeding noted.

at the patient's ECF had found her inflated FMS lying in the bed next to her, and unintentional traumatic removal of the device was assumed. Anoscopy and subsequent colonoscopy revealed a 2-cm mucosal tear beginning 3 cm from the anal verge in the anterior rectal wall. After an attempt at obtaining hemostasis with direct pressure and topical thrombin, a transanal suture ligation was performed on 2 actively bleeding sites. The patient was discharged to her ECF several days later at her baseline condition.

Patient 3

A 59-year-old man with multiple comorbidities was admitted to the intensive care unit with sepsis and respiratory failure. His medications included warfarin for lower extremity arterial bypass grafts, and on admission his international normalized ratio was 2.6. An FMS was inserted shortly after admission because of fecal incontinence. On inpatient day 22, bright red blood was noted to be oozing around the patient's FMS. The device was removed, and a colonoscopy revealed a 2-cm ulceration with associated clot within the proximal anal canal (Fig. 2). The ulceration was consistent in dimensions with the plastic tubing of the FMS, and was judged to be a pressure ulcer by the consultant endoscopist. A full colonoscopy did not reveal other pathology. The patient's anticoagulation was reversed and he experienced no further bleeding.

DISCUSSION

Management of fecal incontinence is a common and difficult problem. It is estimated that approximately 50% of hospital and institutionalized patients have fecal incontinence.[1] The incontinence rates for critical care patients are about twice that of typical patients.[2] Most authors agree that the rates are higher for women, presumably due to obstetrical trauma. The importance of fecal incontinence management on patient outcomes should not be underestimated. Repeated episodes of incontinence can lead to excoriation of the perianal area, causing skin breakdown.[3] Fecal incontinence is an established risk factor for pressure ulcers[4] and for transmission of nosocomial infections.[5]

A variety of solutions for the management of fecal incontinence exist, including medical therapies such as loperamide and opiates, biofeedback, injectable bulking agents, absorbent pads, rectal pouches or tubes, antegrade and retrograde irrigation methods, sacral nerve stimulation, dynamic gracilloplasty, artificial sphincters, and, as

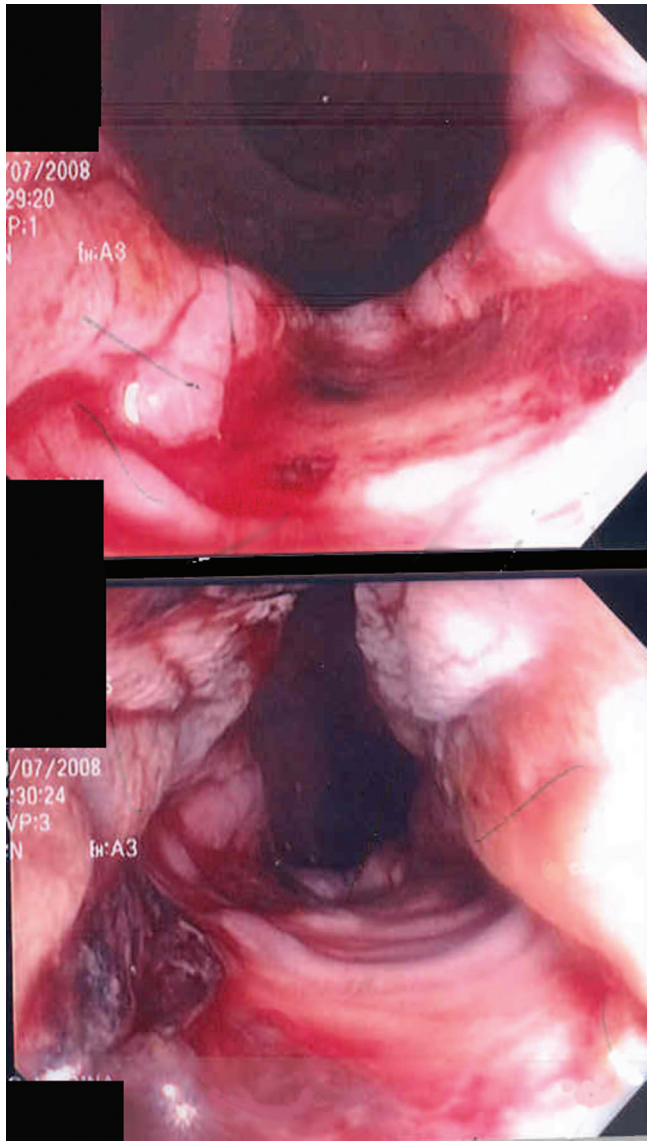

FIGURE 2. Anal canal ulceration secondary to pressure necrosis from fecal management system tubing.

a last resort, diverting colostomy.[6] In the hospital setting the most commonly used techniques are absorbent pads, rectal pouches, and rectal tubes. Each of these techniques has its drawbacks. Absorbent pads do not eliminate the dermatitis caused by incontinence and have limited effect on infection transmission. Rectal pouches often fail to maintain containment of the fecal stream and the adhesives used to hold them in place can have their own adverse consequences for the skin. Rectal tubes with or without balloons are theoretically ideal in that they divert the entire fecal stream away from the patient. Their use, however, is not without risk, as our case series demonstrates. Serious questions remain about the risks of insertion and the safe duration of use for such devices.[7]

To date, the Flexi-Seal FMS is the leading brand in unit sales to distributors, and it has been adopted at more than 1800 intensive care units in the United States.[8,9] First introduced in 2006, the FMS is a silicone cannula with an annular silicone balloon that is inflated in the rectum. The end of the tube is lubricated and inserted through the anal canal into the rectal vault. The balloon is then inflated with 45 mL of water, reaching a diameter of approximately 53 mm. The external end of the cannula is stretched over an adapter and attached to the collection bag. The balloon can be left in place for up to 30 days before a recommended deflation window. It is indicated for patients with little or no bowel control and liquid or semiliquid stool; it is contraindicated in patients with previous anorectal surgery and confirmed or suspected impairment of the rectal mucosa (colitis, neoplasm, or preexisting trauma).[10]

Padmanabhan et al performed a clinical evaluation of the FMS as a prospective, single-arm descriptive study.[11] Of the 42 patients studied, 1 had GI bleeding after 4 days with the device. Endoscopy was performed after the device was removed and showed bleeding from a rectal ulceration. Unlike other patients in the study, this patient did not have baseline endoscopy performed before insertion of the device, so the authors could not conclude that the FMS caused the ulceration.

Page et al reported the first case of significant rectal bleeding resulting from the use of the Flexi-Seal FMS.[12] They described a 65-year-old man admitted to an intensive care unit who developed massive rectal bleeding 6 days after insertion of the FMS device. An abdominal CT angiogram showed the bleeding to emanate from the rectal vessels and a colonoscopy showed an actively bleeding acute laceration of the anterior rectal wall 6 cm from the anal verge. The bleeding was controlled with suture ligation. These authors concluded that the bleeding laceration was likely the result of trauma from insertion of the device or sudden movement of the device in the rectum, rather than from pressure necrosis of the rectal mucosa.

We have presented 3 cases of severe bleeding in connection with use of the FMS device. In our series, there was documented traumatic removal of the tube in 2 cases and apparent ulceration in 1 case. Although the mechanism of injury seems straightforward in traumatic removal, the ulcer apparently caused by the FMS is not as easily explained. The volume of inflation of the balloon is 45 mL, which should not cause enough direct pressure to cause mucosal breakdown, given that the rectum routinely holds a greater volume of stool. The effects of continuous long-term rectal pressure, even of low intensity, remain to be studied, so pressure necrosis cannot be ruled out as a cause of bleeding.[12]

Another significant contributing factor in our cases is the fact that 2 of the patients received warfarin and the third took aspirin. These medications undoubtedly exacerbated the hemorrhage. Although rectal bleeding in association with the FMS is rare, it is possible that anticoagulation status would affect patient selection for the device, and at a minimum should be a factor about which the ordering practitioner is cognizant.

We believe that a manufacturer's warning about use of its product in the patient receiving anticoagulants would be appropriate. In addition, a method of fixing the FMS tubing to the patient's leg in a fashion similar to Foley catheter fixation devices may help prevent traumatic removal. Such a product would also help prevent tension on the intrarectal balloon, thus minimizing the potential for rectal trauma. Finally, in light of our third case of apparent pressure ulceration, we recommend deflating the balloon sooner than the 30 days proposed by the manufacturer.

CONCLUSIONS

The ConvaTec FMS, although performing well in controlling fecal incontinence, is not without causing complications. Specifically, the potential complications include acute life-threatening hemorrhage, rectal ischemic necrosis, sepsis, and even death. At-risk populations include debilitated patients in acute or long-term care facilities who require the FMS for management of incontinence, especially those who receive anticoagulants.

We have presented 3 cases of severe bleeding associated with use of the FMS. Patient selection and awareness of the device's relative indications and contraindications should be considered by any physician ordering the FMS. Furthermore, the transfer of patients with an FMS should be performed cautiously to avoid traumatic removal. Staff should be trained to insert and remove the device correctly, and routine assessments should be performed to ensure that the device is not under tension. Finally, practitioners should also be cognizant of patients' anticoagulation status and the length of time the device has been in place.

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