Cases of Note features peer-reviewed case reports and case series that document clinically relevant findings from critical and high acuity care environments. Cases that illuminate a clinical diagnosis or a management issue in the treatment of critically and acutely ill patients and include discussion of the patient's experience with the illness or intervention are encouraged. Proposals for future Cases of Note articles may be e-mailed to ajcc@aacn.org.

Massive Gastrointestinal Hemorrhage as a Complication of the Flexi-Seal Fecal Management System

By Aaron M. Mulhall, MD, and Shivani K. Jindal, MD, MPH

Abstract Use of the Flexi-Seal fecal management system, a safe and effective means of fecal diversion in patients with fecal incontinence and diarrhea, can be associated with rare, life-threatening complications. For example, a critically ill patient had 2 episodes of massive rectal bleeding associated with use of the system that required transfusion of blood products. Hemorrhage was controlled during the first episode by angiography with selective coil embolization; the second required colonoscopy with suture ligation of the affected lesion. A literature review revealed 9 other cases that were managed endoscopically, surgically, or with angiography. Although none of the patients died, they experienced obvious complications that required transfusion of blood products, endoscopy, surgery, use of conscious sedation or general anesthesia, angiography, and exposure to intravenous contrast material. Patients receiving therapeutic doses of anticoagulation and antiplatelet drugs, which may precipitate or aggravate hemorrhaging, are particularly at risk for complications with the Flexi-Seal system. (*American Journal of Critical Care.* 2013;22:537-543)

Fecal incontinence and diarrhea are challenging issues that affect many critically ill patients, complicate treatment, and often result in increases in a patient's morbidity. The etiology of fecal incontinence, or diarrhea, in critically ill patients is often unknown, multifactorial, or associated with a treatment that cannot be discontinued.[1] Caring for patients with fecal incontinence can be both time-consuming and labor demanding for nursing staff. Skin hygiene and minimizing the risk of perineal dermatitis are the highest priorities.

Management of fecal incontinence has historically involved various techniques to divert stool away from the skin by using catheters, absorbent pads, and pouching systems. However, absorbent pads do not help prevent local skin breakdown or control infection and rectal pouches do not reliably contain fecal material. In theory, rectal tubes are ideal because they completely divert the stool away from the skin.[2]

The use of urinary catheters or poorly designed rectal tubes can cause rectal perforation and fistulas.[3-6] Newer intrarectal collection devices, such

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as the Flexi-Seal fecal management system (ConvaTec Professional Services), provide safe and effective diversion of liquid stool away from the skin and have been adopted by many intensive care units (ICUs) worldwide.[1]

Although the Flexi-Seal system is safe and effective, rare, and sometimes life-threatening, complications associated with its use have been reported.[1,7-11] We report the case of a massive gastrointestinal hemorrhage as a complication of the Flexi-Seal system.

Case Report

A 58-year-old man with a renal transplant was transferred to the ICU because of respiratory failure, renal failure, and sepsis. The respiratory failure progressed and required intubation and mechanical ventilation. Bronchoalveolar lavage fluid contained cytomegalovirus, and treatment with ganciclovir was started. Renal function progressively declined, and continuous renal replacement therapy with heparin anticoagulation was initiated. On the second ICU day, the patient had marked fecal incontinence, and a Flexi-Seal device was inserted.

Thirteen days later, the patient had an episode of rectal bleeding of bright red blood. Assessment of the perianal area revealed that the Flexi-Seal device had dislodged. A massive hemorrhage of bright red blood occurred, and the patient became hypotensive. The patient was given 16 units of packed red blood cells (pRBCs), 16 units of fresh frozen plasma (FFP), 2 units of cryoprecipitate, and 2 pools of platelets, and his blood pressure became stable. Because he required blood pressure support with norepinephrine and vasopressin and the hemorrhaging was persistent, the decision was made to evaluate the bleeding via angiography. Angiography of the abdomen and pelvis revealed extravasation of contrast material from a medial branch of the superior rectal artery (see Figure). Fluoroscopically guided digital subtraction angiography showed no extravasation of contrast material, vascular malformation, or pseudoaneurysm in the abdominal aorta; the common hepatic, left gastric, splenic, or inferior mesenteric arteries; or branches of the superior mesenteric arteries. The patient still had active rectal bleeding, so digital subtraction angiography of the inferior mesenteric artery was repeated in the lower part of the rectum. The images showed rapid extravasation of contrast material, primarily from a medial branch of the superior rectal artery, with associated extensive

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Table 1
Clinical synopsis of the literature on hemorrhage associated with the Flexi-Seal fecal management system

Reference	No. of cases	Age, y	Sex	Reason for admission to ICU	Days with Flexi-Seal	Anticoagulation or antiplatelet therapy
Padmanabhan et al[1] (2007)	1/42	NS	NS	GI bleed	4	Anticoagulation and antiplatelet therapy
Page et al[7] (2008)	1	65	Male	Myocardial infarction	11	Aspirin, LMWH
Bright et al[8] (2008)	1	79	Male	Respiratory failure	11	None
Sparks et al[9] (2010)	3	72	Female	Patient at ECF	NS	Aspirin
		54	Female	Patient at ECF	NS	Warfarin
		59	Male	Sepsis, respiratory failure	22	Warfarin
Monge et al[10] (2011)	2	71	Male	Septic shock	25	Enoxaparin 40 mg/d
		67	Female	Respiratory failure	3	NS
Reynolds and van Haren[11] (2012)	1	50	Male	Sepsis, endocarditis	5	Heparin with hemodialysis
This study	1	58	Male	Sepsis, renal failure, and respiratory failure	13	Heparin with hemodialysis

Abbreviations: ECF, extended care facility; FFP, fresh frozen plasma; GI, gastrointestinal; ICU, intensive care unit; LMWH, low-molecular-weight heparin; NS, not specified; pRBCs, packed red blood cells.

collateralization from the lateral branch of the superior rectal artery. Coil embolization of the artery was successful, and the bleeding stopped. Digital subtraction angiography after embolization revealed decreased vessel enhancement in the distribution of the superior rectal artery. No colonoscopy was performed at this time. The patient's condition stabilized, and he continued to receive care in the ICU for respiratory and renal failure. The Flexi-Seal device was not reinserted; a rectal pouch was placed for management of fecal incontinence.

Eleven days after the first episode of bleeding, another episode of massive rectal bleeding occurred. The patient required 12 units of pRBCs, 8 units of FFP, 2 units of cryoprecipitate, and 1 pool of platelets. Repeat angiography did not reveal a source of bleeding. A colonoscopy performed with general anesthesia in the operating room showed a posterior rectal laceration that was not actively bleeding and an anterior rectal ulcer with active hemorrhaging. Hemostasis of the ulcer was achieved by suture ligation and application of topical thrombin. The laceration was repaired by suture ligation. No further bleeding occurred, and the patient was ultimately transferred to a skilled nursing facility for continuation of care.

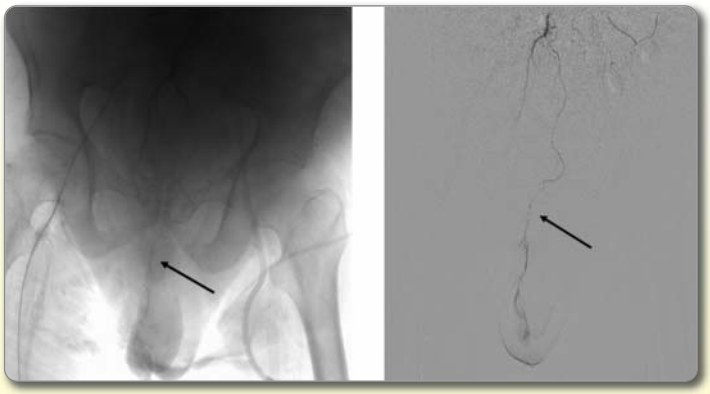

Figure Visceral arteriogram (left and right) shows extravasation of contrast material (arrows), primarily from a medial branch of the superior rectal artery, with associated extensive collateralization from the lateral branch of the superior rectal artery.

Literature Review

The literature was searched by using MEDLINE (January 1966 to December 2012), EMBASE, and Cochrane databases. PubMed, Ovid, and Google Scholar were used as search engines. The following medical subject heading (MeSH) terms were used with no language restriction: fecal management system, Flexi-Seal, and massive rectal hemorrhage. Additional studies cited within the literature were also searched. Boolean operators (not, and, or) were used to narrow and widen the search. The number of hits was increased when the explode and related-article functions of Ovid were used.

A total of 6 articles and 9 cases were reported in the literature.[1,7-11] Table 1 lists data for these 9

No. of bleeding episodes	Endoscopic findings	Blood products given, units	Treatment
1	Mucosal ulcer in distal part of rectum	NS	NS
2	Laceration on anterior rectal wall 6 cm from anal verge	16 pRBCs 4 FFP 2 Platelets	Tamponade with Sengstaken-Blakemore tube, suture ligation
1	No source of bleeding; mesenteric angiography with bleeding from branch of superior rectal artery	11 pRBCs 2 FFP	Coil embolization of branch of superior rectal artery
2	Rectal laceration 4 cm proximal to dentate line	NS	Observation, suture ligation
1	Mucosal tear of anterior rectal wall 3 cm from anal verge	NS	Direct pressure, topical thrombin, suture ligation
1	Mucosal ulcer in proximal part of anal canal	NS	Reversal of anticoagulation
1	Mucosal ulcer in distal part of rectum	NS	NS
2	Mucosal ulcer in posterior distal part of rectum	NS	NS
4	Mucosal ulcer in distal part of rectum (10 cm)	23 pRBCs 8 FFP	Cauterization, epinephrine injection, suture ligation
2	Mesenteric angiography with bleeding from medial branch of superior rectal artery; posterior and anterior rectal ulceration	28 pRBCs 24 FFP 4 Cryoprecipitate 3 Platelets	Coil embolization of medial branch of superior rectal artery, suture ligation, and direct application of thrombin

cases and for our case. Mean age of the patients was 64 years; 6 were men, 3 were women, and 1 patient's sex was not specified. A total of 60% of the patients were admitted to the ICU because of sepsis, respiratory failure, or both. Among the patients, 1 was admitted after myocardial infarction, 1 had gastrointestinal bleeding, and 2 were at extended care facilities. The mean number of days the Flex-Seal device was inserted before gastrointestinal bleeding occurred was 12 (SD, 8). A total of 80% of the patients were receiving some form of an anticoagulant, antiplatelet medication, or both. One patient did not have any anticoagulation therapy, and treatment of another was not specified. The number of bleeding episodes ranged from 1 to 4. All of the patients had a confirmed mucosal ulceration or a laceration of the rectal wall. The amount of blood products given was specified for 4 cases; a total of 78 units of pRBCs, 38 units of FFP, 5 units of platelets, and 4 units of cryoprecipitate were given. Among the patients, 5 had suture ligation of the culprit lesion, 2 had angiography with coil embolization of a branch of the superior rectal artery, 2 had direct application of thrombin, 1 had local application of epinephrine, 1 had reversal of anticoagulation, and 3 had unspecified treatment.

Another episode of massive rectal bleeding occurred 11 days later.

The first reported case of a rectal hemorrhage associated with the Flexi-Seal system occurred during the original product trial by Padmanabhan et al.[1] This trial was a prospective, multicenter, phase 2 clinical study involving 42 patients. One of the patients had gastrointestinal bleeding. This patient (unknown age or sex) had bleeding 4 days after insertion of the Flex-Seal device. This patient was admitted to the hospital because of the gastrointestinal bleeding, but was one of the patients in the study who did not a have baseline colonoscopy before the device was inserted. The patient was also receiving antiplatelet and anticoagulation medications at the time of ICU admission. The Flex-Seal device was removed, and colonoscopy revealed hemorrhage from a rectal ulceration. Because this patient had not had a baseline colonoscopy, Padmanabhan et al could not conclude that the Flex-Seal device caused the ulceration. Treatment of the rectal hemorrhage was not specified.

Page et al[7] reported a case of a 65-year-old man who had massive rectal bleeding 11 days after insertion of a Flex-Seal device. This patient was admitted to the ICU for a coronary angioplasty after receiving thrombolytic therapy for an acute myocardial infarction. The patient was taking aspirin and low-molecular-weight heparin at the time of the initial gastrointestinal hemorrhage. The source of bleeding was a laceration of the anterior rectal wall 6 cm from the anal verge that was successfully repaired by tamponade with a Sengstaken-Blakemore tube and suture ligation. A second massive hemorrhage occurred 15 days later from the same ulcer, and additional suturing was required. Page et al concluded that the laceration most likely was associated with insertion of the Flexi-Seal device or dislodgement of the device rather than with pressure necrosis. The patient received a total of 16 units of pRBCs, 4 units of FFP, and 2 units of platelets.

Bright et al[8] reported hemorrhaging in the lower part of the gastrointestinal tract in a 79-year-old man 11 days after insertion of a Flexi-Seal device. The patient was originally admitted to the ICU because of respiratory failure and was not receiving any anticoagulation or antiplatelet medications at the time of the hemorrhage. Colonoscopy at the time of the hemorrhage showed no obvious source of bleeding, but changes from a previous colonoscopy were suggestive of pressure necrosis. Mesenteric angiography showed extravasation of contrast material from a branch of the superior rectal artery, and coil embolization was successfully performed. The patient received a total of 11 units of pRBCs and 2 units of FFP.

Sparks et al[9] reported 3 cases of massive gastrointestinal hemorrhage associated with use of the Flexi-Seal device. One patient, a 72-year-old woman residing in an extended care facility, had 2 episodes of gastrointestinal bleeding. She was taking aspirin, and the number of days the Flexi-Seal device was in place before hemorrhaging occurred was not specified. Endoscopy revealed a rectal laceration 4 cm proximal to the dentate line after the first bleeding episode; the laceration was closed by suture ligation after the second episode. The use of blood products was not specified for this case. The second patient was a 54-year-old woman residing in an extended care facility who had a single episode of gastrointestinal bleeding. She was taking warfarin, and the number of days the Flexi-Seal device was in place before hemorrhaging occurred was not specified. Endoscopy revealed a mucosal tear of the anterior rectal wall 3 cm from the anal verge. Treatment included direct pressure, direct application of thrombin, and suture ligation. Use of blood products was not specified. The third patient was a 59-year-old man who was admitted to the ICU because of sepsis and respiratory failure. He was taking warfarin and experienced one episode of gastrointestinal hemorrhage 22 days after insertion of a Flexi-Seal device. Endoscopy revealed a mucosal ulcer in the proximal part of the anal canal. The patient was treated by reversal of anticoagulation. Use of blood products was not specified.

Monge et al[10] reported 2 patients with rectal ulcerations associated with the Flexi-Seal device.

The first patient was a 71-year-old man admitted to the ICU because of septic shock. The patient was taking enoxaparin as prophylaxis for deep venous thrombosis, and a Flexi-Seal device was inserted because of diarrhea. The patient had one rectal hemorrhage 25 days after insertion of the device. Endoscopy revealed a mucosal ulcer in the distal part of the rectum. Treatment and use of blood products were not specified in this case. The second patient was a 67-year-old woman admitted to the ICU because of respiratory failure. The use of antiplatelet or anticoagulation medications was not specified. The patient had 2 episodes of rectal bleeding; the first was 2 days after insertion of a Flex-Seal device. Endoscopy revealed a mucosal ulcer in the posterior distal part of the rectum. Treatment and use of blood products were not specified.

Reynolds and van Haren[11] reported a case in which a 50-year-old man, originally admitted to the ICU because of sepsis and endocarditis, had a number of bleeding episodes that first began 5 days after insertion of a Flexi-Seal device. The patient was taking heparin and was being treated with hemodialysis. Endoscopy revealed a mucosal ulcer in the distal part of the rectum 10 cm from the anal verge. The patient was treated with cauterization of the lesion, local injection of epinephrine, and suture ligation. He also received a total of 23 units of pRBCs and 8 units of FFP.

Discussion

Diarrhea and fecal incontinence are common problems in the ICU. An estimated 50% of hospitalized and institutionalized patients experience fecal incontinence.[12] Fecal incontinence can cause discomfort for a patient and distress among the patient's family members and medical and nursing staff. The incontinence is also associated with localized skin breakdown and infection. Fecal incontinence in the hospital is most often managed by using absorbent pads, rectal pouches, and rectal tubes.

Absorbent pads are of little use in preventing local skin breakdown and providing infection control.[13] While rectal pouches can be used to collect the fecal stream and divert it away from the perianal skin, they are often unsuccessful in containing fecal matter, and the adhesives used can lead to skin breakdown. In theory, rectal tubes are ideal because they completely divert the stool away from the skin.[2] A variety of rectal tubes are used; the ones used most commonly at University of Cincinnati Medical Center, Cincinnati, Ohio, are the Zassi Bowel Management System (Hollister Inc) and the Flexi-Seal device. Bowel management systems have been a successful means of fecal diversion in patients with perineal burns.[14-18] A study by Pittman et al[19] compared a bowel management system with rectal trumpets and absorbent pads. Compared with the other 2 groups, patients with the bowel management system had a significant decrease in incontinence-associated dermatitis but no difference in the prevalence of pressure ulcers.

Pressure ulcers related to use of a medical device are a common and recurring problem in the ICU because patients are often unaware of the devices and the devices apply pressure. The risk factors associated with pressure ulcers related to use of a medical device include decreased sensation, increased use of devices, and decreased perfusion of the soft tissues to which the medical device is applied.[20,21] An increasing number of ICUs are using protocols for management of fecal incontinence and are using prediction scores to identify patients at risk for device-related pressure ulcers.[22-24] Current international pressure guidelines for ulcer prevention acknowledge that use of medical devices is a risk factor but provide no guidance on prevention. The National Pressure Ulcer Advisory Panel states that pressure ulcers are often device related, are unstageable, and should not be classified as partial or full-thickness skin wounds.[11,25]

The Flexi-Seal device is the most commonly used fecal management device in the United States.[26] It consists of a silicone cannula 1 m long with a low-pressure balloon at the distal end that is inflated after insertion into the rectum. A digital rectal examination to assess rectal sphincter tone must be done before the device is inserted. The balloon is inflated and secured by filling it with water or physiological saline to a maximum diameter of 53 mm. The balloon can be left in place up to a maximum of 29 days. Indications for placement include poor control of bowel function and diarrhea. Contraindications include previous anorectal surgical procedures or any impairment of the rectal mucosa, including history of trauma, malignant neoplasm, and inflammation.[1,27,28]

All of the patients had a confirmed mucosal ulceration or a laceration of the rectal wall.

The safety of the Flexi-Seal device was investigated by Padmanabhan et al.[1] Of the 42 patients studied, 11 had adverse events, including 5 deaths (unrelated to the Flexi-Seal device); 2 had generalized skin breakdown. Other complications associated with the use of the Flexi-Seal device have been reported[1,27] (Table 2). In rare instances, the device mimicked a pelvic fluid collection on computed tomography in 3 patients, caused an anovaginal fistula in 1 patient, and caused autonomic dysreflexia in a patient with C5 tetraplegia.[29-31] Complications, including perforation and death, have also been associated with other forms of rectal tubes.[32,33]

Only a few case reports[1,7-11] on gastrointestinal hemorrhage associated with use of the Flexi-Seal

Table 2
Reported complications associated with use of the Flexi-Seal fecal management system

Rectal bleeding from necrosis or ulceration of anal or rectal mucosa
Stool leakage around fecal management system
Skin breakdown of perianal region
Infection
Bowel perforation
Bowel obstruction
Transient loss of tone of anal sphincter muscle

device have been published. The use of anticoagulation or antiplatelet medications appeared to play a role in precipitating or aggravating hemorrhage in 8 of the cases. Of note, the guidelines[27] for use of the Flexi-Seal device state that "care should be exercised in using this device in patients who have a tendency to bleed from either anticoagulant or antiplatelet therapy or underlying disease." Although no deaths were associated with gastrointestinal hemorrhage, patients required massive transfusion of blood products, endoscopic procedures (including conscious sedation and general anesthesia), angiography, and exposure to intravenous contrast material.

Although endoscopic and surgical management of gastrointestinal hemorrhage is well documented, angiography with selective coil embolization was used as treatment in only 2 patients (our case and Bright et al[8]) who had gastrointestinal hemorrhage associated with use of a Flex-Seal device. Angiographic control of hemorrhage in the lower part of the gastrointestinal tract is often reserved for patients who have unstable hemodynamic conditions, such as our patient did, or patients who have recurrent bleeding despite medical and endoscopic management.[34-36] Selective coil embolization of the affected arteries is safe and effective.[37]

In our case, the patient had a massive gastrointestinal hemorrhage that was initially controlled by angiography with selective embolization. Subsequently, massive gastrointestinal hemorrhaging not associated with use of the Flexi-Seal device occurred, and colonoscopy revealed a bleeding ulcer in the anterior part of the rectum. Both episodes of gastrointestinal hemorrhaging were exacerbated by heparin anticoagulation and continuous renal replacement therapy. Most likely the initial hemorrhage was due to a traumatic laceration of the rectal mucosa. A colonoscopy was not performed after the first episode of bleeding, allowing the cause of the ulceration to remain unknown and unproven. Earlier colonoscopy would have added further information about the cause of the initial hemorrhage. The second episode of bleeding was associated with a rectal ulcer that was visualized with colonoscopy. This ulcer was possibly secondary to pressure necrosis from the Flexi-Seal device. Another possible cause is a cytomegalovirus-induced ulcer that spontaneously bled. Unfortunately, biopsies of the ulcer were not performed during colonoscopy to determine an infectious cause.

Conclusion

In conclusion, the Flexi-Seal device has yielded excellent results in control of diarrhea and fecal incontinence. Although complications are uncommon, they can be associated with increased morbidity. Complications include massive gastrointestinal hemorrhage, ischemic pressure necrosis and ulceration, sepsis, and death. The risks of complications appear to be increased with the use of anticoagulant and antiplatelet therapy. In our case, the gastrointestinal bleeding was life threatening.

Although complications can occur, and can be quite serious, a review of the literature indicates that the benefits of the Flexi-Seal device clearly outweigh the risks. We support use of the Flexi-Seal device but caution that medical and nursing staff should be aware of the indications and complications associated with use of the device. They should be mindful in recognizing patients at higher risk for complications. We think special caution should be used for patients receiving therapeutic doses of an anticoagulation or an antiplatelet medication or both medications. We would even consider labeling use of the Flexi-Seal device as contraindicated in critically ill patients receiving therapeutic doses of anticoagulation and antiplatelet drugs.

FINANCIAL DISCLOSURES
None reported.

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