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CASE STUDY

A case of pressure ulceration and associated haemorrhage in a patient using a faecal management system

Mark G. Reynolds BA (Hons), RN, PG Dip[a,*], **Frank van Haren MD, PhD, FCICM**[b,1]

[a] *ICU, Waikato Hospital, Hamilton, New Zealand*
[b] *Intensive Care Department, the Canberra Hospital, Canberra, Australia*

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Summary Diarrhoea is a difficult patient problem to manage in the intensive care setting, causing odour, discomfort and embarrassment for the patient and potential for loss of skin integrity and cross contamination. Caring for these patients is resource-intensive. A recently developed product for the management of faecal incontinence is the Flexi-Seal Faecal Management System (FMS©).

Whilst this product is usually effective for managing diarrhoea, there are uncommon but serious complications associated with its use. Rectal bleeding attributed to pressure ulceration of the rectal mucosa can be severe, especially in conjunction with the use of anticoagulation.

We report a case of severe rectal bleeding requiring surgical intervention and administration of large amounts of blood products, caused by pressure ulceration as a result of the use of a Flexi-Seal FMS©. The case report is followed by a review of the literature. Similar complications have been described by others. Although, based on the number of reported complications, the incidence of serious complications appears to be low, a publication bias cannot be ruled out.

Knowledge of the complications associated with the device is important for evaluating the appropriateness of insertion and for ensuring the safe and effective on going care of patients using Flexi-Seal FMS©.

* Corresponding author at: ICU, Level 3, Menzies Building, Waikato Hospital, Pembroke St., Private Bag 3200, Hamilton 3240, New Zealand. Tel.: +64 78398899; fax: +64 78398912; mobile: +64 21762901.
E-mail addresses: Mark.Reynolds@waikatodhb.health.nz, Markreynolds@clear.net.nz (M.G. Reynolds), frank.vanharen@act.gov.au, fvanharen@me.com (F. van Haren).
[1] Address: Intensive Care Department, Canberra Hospital, PO Box 11, Woden, ACT 2606, Australia. Tel.: +61 02 6244 3300; fax: +61 02 6244 3507; mobile: +61 04 6705 1809.

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Introduction

Diarrhoea is a difficult problem to manage in the intensive care unit (ICU) setting. Although there is no uniform definition, faecal frequency, consistency and quantity are considered important criteria.[1] The use of 'stool charts' has been shown to improve standardisation of the description of diarrhoea.[1,2] Reported incidences of diarrhoea may vary over a very wide range (from 2% to 95%), because of the lack of standardisation in the definition of diarrhoea.[3–5] In an observational multi-centre study performed in 37 Spanish ICUs where a cohort of 400 patients was followed prospectively over one month to assess the rate of gastrointestinal complications related to enteral nutrition, the total frequency of complications was 62.8%, whereas diarrhoea represented 15.7% of these complications.[6]

Diarrhoea in the enterally tube fed ICU patient is a multi-factorial problem. In a recent study, risk factors for diarrhoea in ICU patients included duration of enteral feeding, severity of disease, albumin levels, peripheral oxygen saturation, white blood cell count and glucose control.[7] Enteral feeding in itself is not associated with the development of diarrhoea, and discontinuation of enteral feeding to treat or prevent diarrhoea is not justified.[5,8,9] The incidence of diarrhoea is also not influenced by the site of enteral feeding. In a large multicentre prospective randomised study, the efficacy and rate of complications associated with the early gastric versus the early jejunal route in 101 patients was studied. The incidence of diarrhoea was identical (14%) in both groups.[10] Clostridium difficile-associated diarrhoea is frequent during antibiotic therapy, especially with quinolones and cephalosporins, and requires specific management. The role of probiotics, prebiotics and soluble fibre in the prevention and management of diarrhoea is promising but more research is needed before this can be routinely implemented.[5,11]

Diarrhoea in ICU patients causes numerous problems, including potential cross contamination, loss of skin integrity, discomfort, embarrassment, odour, dehydration and sleep deprivation. Caring for patients with diarrhoea also uses large amounts of resources, such as nursing/ancillary staff time and linen.[4,12]

Various products and strategies have been developed to help in the management of this problem, with varying degrees of success. Examples of this are absorbent pads, rectal tubes and anal pouches. In recent years intrarectal collection devices have become increasingly popular. The Flexi-Seal FMS© (ConvaTec, a Bristol-Meyers Squibb Company, Princeton, NJ) is a soft, self-retaining silicone catheter specifically designed for diarrhoea management. It consists of a soft silicone tube, 1 m in length, with a low-pressure annular retaining balloon at the proximal end and a faecal collection bag at the distal end. The retaining balloon is collapsed on insertion, to minimise trauma, and has a finger pocket to facilitate digital placement via the anal sphincter. Once inside the rectal vault the balloon is filled with 45 ml of water, which enables it to be retained within the rectum.[13] When working effectively, this device successfully addresses many of the problems caused by diarrhoea. If the system is leak-free at the anus, the perianal skin is generally well protected. Cross infection, discomfort, embarrassment and odour are also minimised.[14–16]

Because of these advantages, Flexi-Seal FMS© had been adopted in 1800 ICU's in the US by 2008, and by 2010 at least a million Flexi-Seal FMS© units had been sold.[17] However, as with all invasive healthcare products, there are also inherent risks. This report describes a case where a patient with Flexi-Seal FMS© developed pressure ulceration in the rectum, resulting in severe haemorrhage.

The ICU was the first department in our institution to start using this product. The ICU is a 15-bedded tertiary multi-specialty centre, admitting surgical, medical and trauma patients from a wide geographical area. After a trial of Flexi-Seal FMS© involving seven patients, with no adverse events, we started using the Flexi-Seal FMS© in our ICU in 2008. An extensive education programme was undertaken to support the introduction of the product. The education included in-service training by the ConvaTec product specialist to all nursing staff, protocol development, and a more extensive education package for a group of nurses trained to assess patient suitability and to insert the device.

Based on written product evaluations and verbal questioning the Flexi-Seal FMS© was generally judged by nursing staff to be very effective in managing faecal incontinence and minimising its associated problems. Use of the device was subsequently adopted by other departments within the hospital. There is no accurate record of the number of patients who have had Flexi-Seal FMS© inserted so far in the hospital, but an estimated total, based on purchases of Flexi-Seal FMS©, is 80.

Case report

The next-of-kin of the patient (now deceased) referred to in this case report has given permission to use the data obtained from the medical record for use in this manuscript. He was a

50-year-old chronic renal failure patient (on long term haemodialysis) admitted to ICU in 2010 with septicaemia and bacterial endocarditis. After a short stay on ICU he was transferred to the high dependency unit (HDU), where he started to have diarrhoea. Over the next few hours in HDU his diarrhoea worsened and the skin in his perianal area was beginning to break down. The Flexi-Seal FMS© was inserted 6 h after his admission to HDU.

The patient continued to require Flexi-Seal FMS© for the next few days. The patient was confused and at one point the Flexi-Seal FMS© came out inadvertently and had to be reinserted, although the medical record does not state whether the dislodgement of the tube could be attributed to his confusion and agitation. There was also no notation in the record of blood being evident or whether a digital rectal examination was performed again prior to re-insertion of the FMS©. This is recommended in the procedure document as anal sphincter tone is required to support the device positioning.

Three days after his HDU admission the patient was transferred to the Cardiac Care Unit (CCU) for further management of his bacterial endocarditis. The Flexi-Seal FMS© was still in situ on transfer to CCU. He remained confused and agitated on CCU for the next two days, at which time he received intermittent haemodialysis treatment with heparin anticoagulation. This was the second time he had received haemodialysis with heparin since the insertion of the Flexi-Seal FMS©. There was no bleeding reported after the first instance. Shortly after completion of this second dialysis treatment a large amount of rectal bleeding was noted and the Flexi-Seal FMS© had fallen out. The Flexi-Seal FMS© had been in place for a total of five days.

This bleeding continued and he underwent a flexible sigmoidoscopy. The endoscopist reported a 'near circumferential ulcer at 10 cm from the anus (separate patches) related to Flexi-Seal FMS©'. There was too much clot in the rectum for endoscopic control of the bleeding and the patient went to operating theatre (OT) and underwent examination under anaesthesia (EUA), cauterisation and injection of rectal ulcers, which were described as 'near circumferential at 11 o'clock, 3 o'clock and 7 o'clock'. A Spongostan© sponge was inserted into the rectum and he was transferred to ICU for his postoperative care. By the end of the day he had received 11 units of blood and four units of fresh frozen plasma (FFP).

Two days later in ICU he had another episode of copious rectal bleeding, necessitating a second visit to OT, this time for EUA, suturing and diathermy of ulcers. He required six units of blood and four units of FFP on this occasion. By the following day the bleeding had settled again and he was transferred to CCU.

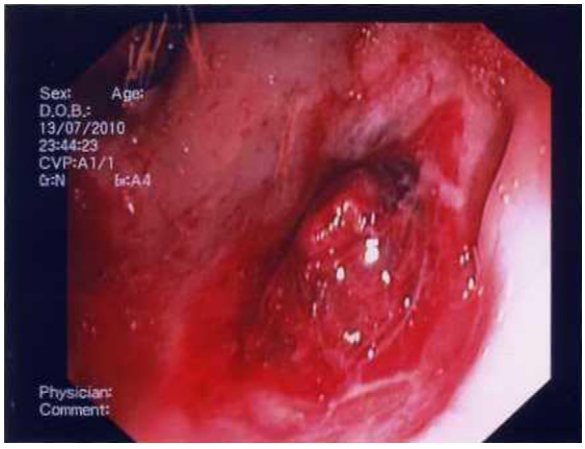

Figure 1 Sigmoidoscopy picture of rectal mucosa taken during the third procedure. A large clot covering a bleeding ulcer.

Five days into his CCU stay he had a third significant rectal bleed, which was conservatively managed with a two-unit blood transfusion. Then, three days subsequently, he had a fourth major episode of rectal bleeding requiring a third surgical procedure in OT. A colonoscopy was performed and there were multiple ulcers in the distal rectum (Fig. 1). The more proximal ulcers were clipped and the distal ulcers were under-run with suture. He needed four more units of blood and was transferred to HDU once again for a short period postoperatively, before returning to CCU.

After this final surgical procedure the bleeding settled and the patient was discharged from CCU to the rehabilitation ward in a stable condition, six weeks after the initial haemorrhage.

Literature review

The CINAHL and Medline databases were searched using the terms 'Fecal Management System' (US spelling), 'F*a*ecal Management System' (UK spelling), and 'Flexi-seal'. The resulting abstracts were then manually checked for any content relating to adverse events involving either pressure ulceration or haemorrhage. There were five journal articles meeting these criteria, involving a total of seven case reports. These are briefly summarised below.

The earliest published paper to report the potential adverse effects of the Flexi-Seal FMS© was the initial clinical product trial undertaken by the product manufacturers, ConvaTec. In this

prospective, multicentre, single arm, descriptive, phase II clinical study, 42 patients (80% from ICU and the remainder from acute care sites) were enrolled.[13] The first 11 of these patients underwent rectal endoscopy as a baseline prior to Flexi-Seal FMS© insertion, and the endoscopy was repeated in 8 of those 11 patients following Flexi-Seal FMS© removal. The remaining 31 patients did not have baseline endoscopy. Adverse events were reported in 11 of the 42 patients, including 5 deaths (unrelated to the Flexi-Seal FMS©) and 2 cases of generalised skin breakdown. Significantly, there was also one case of rectal bleeding resulting from pressure ulceration. This patient had multisystem failure, was on anticoagulant therapy and was admitted to ICU with gastrointestinal bleeding, but whether this bleeding was in the upper or lower gastrointestinal tract is unspecified. The investigator determined that the pressure ulceration was caused by the Flexi-Seal FMS©, but this was unproven because the patient was one of the 31 patients without a preinsertion endoscopy for comparison.

Page et al. report the case of a 65-year-old man admitted to ICU for a rescue angioplasty after an unsuccessful thrombolysis for a posterior myocardial infarction.[18] He was profoundly hypotensive and was subsequently diagnosed with septic shock and multiorgan failure. A Flexi-Seal FMS© was later inserted to manage the onset of antibiotic-related diarrhoea. After six days with the Flexi-Seal FMS© in situ he developed severe bleeding from the rectal mucosa, requiring a massive blood product transfusion. Endoscopy revealed the presence of a laceration 6 cm from the anal verge, which was sutured. A second bleeding episode occurred 15 days later requiring six units of blood and further suturing, after which bleeding ceased and the patient recovered uneventfully.

Although the lesion involved in this case report was a laceration, the authors do not conclude that this necessarily resulted from traumatic insertion of the Flexi-Seal FMS©. They note that pressure necrosis or physical erosion from the indwelling device are likely causes and that the resulting bleeding may have been exacerbated by anticoagulant therapy given for coronary artery disease.

Bright et al. report the case of a 79-year-old man admitted to ICU for post-operative ventilatory support.[19] A Flexi-Seal FMS© was subsequently inserted for noninfective diarrhoea. 11 days later, despite normal laboratory coagulation results, severe rectal bleeding ensued, requiring a 13-unit blood product transfusion and intra-arterial coil embolisation of a rectal artery. In this case the contrast between the normal rectal mucosa seen on preinsertion colonoscopy and the pressure necrosis visualised following Flexi-Seal FMS© removal confirmed that the lesion had been caused by the device.

A 2010 paper by Sparks et al. reports three cases of rectal trauma and haemorrhage associated with use of the Flexi-Seal FMS©.[20] The first two cases involve residents in extended care facilities whose bleeding was attributed to traumatic removal of the device with the retention balloon inflated. The third patient discussed is more relevant to our case report because of the similar patient characteristics and mechanism of injury. This third patient was a 59-year-old admitted to ICU with respiratory failure and sepsis. He was on warfarin to maintain the patency of arterial grafts in his legs and his INR (international normalised ratio) was 2.6. A Flexi-Seal FMS© was inserted soon after admission for diarrhoea. On day 22 of his ICU stay he developed rectal bleeding. The Flexi-Seal FMS© was removed and endoscopy revealed an ulceration corresponding with the site where the tubing was in contact with the anal mucosa, and this was deemed by the endoscopist to be a pressure ulceration. The article does not report the severity of the bleeding, any required blood transfusion, or the eventual patient outcome.

A fifth paper, by Massey et al. reports another instance of apparent pressure ulceration resulting from Flexi-Seal FMS© use, but in this instance no bleeding was noted.[21] A 66-year-old woman was admitted to an ICU with diabetic ketoacidosis and subsequently developed diarrhoea, for which a Flexi-Seal FMS© was inserted. She appeared to recover uneventfully but presented again three months later with an anovaginal fistula. The authors postulate that, in the absence of any other reasonable explanation, the fistula must have been caused by ischaemic trauma occurring while the Flexi-Seal FMS© was in place. The patient required surgical repair of the lesion and made a full recovery.

Discussion

Diarrhoea is a challenging problem in the critical care setting, and there are numerous management options available to nurses to minimise patient discomfort and harm. In recent times the use of indwelling intrarectal faecal collection systems has become increasingly common, because of their efficacy in diverting faecal fluid away from the patient. However, whilst these devices appear to offer advantages in managing faecal incontinence,

they are also associated with some uncommon but serious complications.

We report a case of severe rectal bleeding requiring surgical intervention and administration of large amounts of blood products, caused by pressure ulceration as a result of the use of a Flexi-Seal FMS©. Similar complications have been described by others previously.[13,18–20] The exact incidence of rectal bleeding related to the use of Flexi-Seal FMS© is unknown and only six other cases have so far been identified in the literature. However, underreporting of complications of new drugs or devices is a common source of publication bias, even in randomised trials.[22]

Benefits versus risks of Flexi-Seal FMS©

With Flexi-Seal FMS©, as with all healthcare interventions, there is a need to evaluate the risks against the benefits. The benefits are: preservation of skin integrity; reduced risk of cross-infection; improved hygiene and comfort; reduced odour and embarrassment. The first two of these benefits could arguably help prevent serious physical, potentially life-threatening problems arising in the patient (from loss of skin integrity) or in other patients (from cross-infection), but it is difficult to measure the extent to which the Flexi-Seal FMS© succeeds in reducing skin breakdown and cross infection as this has not been extensively studied.

There are a small number of published studies suggesting that intrarectal faecal collection systems are successful in preventing pressure sores and resolving perineal dermatitis. In a study of three patients with perineal dermatitis, complete successful resolution of the problem was achieved in all patients following insertion of the Flexi-Seal FMS©.[23] The small patient cohort involved in this study reduces its statistical significance, but it is nevertheless a positive affirmation of the product's benefits. Increased patient comfort levels were also reported in this study. Another case study of a single patient reports how use of Flexi-Seal FMS© facilitated the complete healing of a large contaminated grade IV sacral pressure sore.[16] Additionally, in the initial clinical product trial of 42 patients undertaken by the product manufacturers, skin condition was improved or maintained in more than 92% of patients, and patients reports of discomfort were uncommon.[13]

A prospective cohort study of a similar product, the Zassi Bowel Management System (ZBMS Hollister©), was conducted on 20 patients.[24] Seven of the patients had ZBMS inserted for perianal burns or trauma, and 13 had perianal excoriation from diarrhoea. The mean duration of ZBMS indwelling was 14 days. The perianal excoriation resolved within 2—3 days in all 13 patients and the remaining wounds were sepsis-free and healing well on removal of the tube. In another study, the incidence of pressure sores decreased from 43% to 12.5% in a surgical ICU after introduction of a pressure ulcer prevention programme centering on use of the ZBMS.[25] Whilst these results relate to the Zassi product rather than the Flexi-Seal FMS©, the two products are sufficiently similar to suggest that the findings might be generalisable to both products.

None of the above studies prove incontrovertibly that intrarectal faecal collection devices reduce the incidence of pressure sore formation in the perianal area, because they are all observational single arm studies without controls. However, it is encouraging that the incidence of skin breakdown reported in these studies is low, considering the increased risk of pressure sore formation associated with diarrhoea. A risk factor analysis study of 608 hospitalised patients showed that pressure sores are 22 times more likely to occur in adults with faecal incontinence than in those without faecal incontinence.[26]

Whilst it seems intuitively likely that containment of faeces within a closed system will reduce cross contamination, the empirical evidence proving that the Flexi-Seal FMS© delivers this perceived benefit is scant. One in vitro study (by ConvaTec, the manufacturers of the Flexi-Seal FMS©) has been conducted demonstrating that Flexi-Seal FMS© effectively contains clostridium difficile and prevents spread to the environment, but this concept has not been studied clinically.[27]

It is often noted that faecal collection devices are expensive, and that this might therefore be a disadvantage. However, two papers have performed cost analyses of these products, and in both cases, because of the considerable savings in nursing time, linen and disposables used to clean patients without intrarectal faecal management systems, the authors conclude that these products are cost-effective.[23,28]

Aside from rectal mucosal pressure sore formation and resulting haemorrhage, the literature contains only a small number of reports of adverse events concerning the Flexi-Seal FMS©. These include temporary loss of anal sphincter tone, a case of autonomic dysreflexia in a man with tetraplegia, and some non-specific complications including infection and wound enlargement.[13,29,30]

Medical device related pressure ulcers

This case report focuses on rectal haemorrhage resulting from pressure ulceration in a critically ill patient. The critically ill population has a high susceptibility to medical device related (MDR) pressure ulcers. ICU patients are often unaware of the device and/or any pressure being applied by the device, because of sedation, encephalopathy or the underlying (neurologic) disease. A recent study showed that decreased mobility, decreased sensory perception, decreased perfusion and higher usage of supportive medical devices in ICUs placed these patients at higher risk for developing MDR pressure ulcers.[31] MDR pressure ulcers represent more than one third of pressure ulcers in acute care, and guidelines to monitor and prevent MDR pressure ulcers have been proposed.[32] The current international pressure ulcer prevention guidelines acknowledge that medical devices are a risk factor, but provide no guidance on prevention. The 2010 NPUAP position statement on mucosal pressure ulcers identifies that they are commonly MDR related, are unstageable and should not be classified as partial or full thickness (statement available on http://www.npuap.org).

The role of anticoagulation in precipitating rectal bleeding with Flexi-Seal FMS©

The patient in this case report appears to have developed pressure ulceration secondary to Flexi-Seal FMS© placement, but the rectal bleeding was apparently precipitated or aggravated by heparin administration. It is worth noting that three of the patients in the above literature review were also anticoagulated, and that anticoagulation could therefore be considered as a risk factor for serious rectal bleeding with patients using Flexi-Seal FMS©. Anticoagulation is not listed as a contraindication to Flexi-Seal FMS© insertion, but the following precaution is included in the Flexi-Seal FMS© Directions for Use: 'care should be exercised in using this device in patients who have a tendency to bleed from anticoagulant/anti-platelet therapy or underlying disease'.

Conclusion

Complications associated with the use of Flexi-Seal FMS© appear to be uncommon but can potentially be serious. Rectal bleeding attributed to pressure ulceration has been described and can be severe, especially in conjunction with the use of anticoagulation.[13,18–20] We currently believe that the benefits of the product outweigh the risks, but knowledge of the complications associated with the device is essential for evaluating the appropriateness of insertion and for ensuring the safe and effective on going care of patients using Flexi-Seal FMS©.

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