Rectal ulceration due to using the Fexi-Seal fecal management system: a case report*

ULCERAÇÃO RETAL COMO UMA COMPLICAÇÃO DO USO DO SISTEMA DE CONTROLE FECAL FEXI-SEAL: RELATO DE CASOS

RECTAL ULCERATION DUE TO USING THE FEXI-SEAL FECAL MANAGEMENT SYSTEM: A CASE REPORT

Francisco Javier Carmona Monge[1], Irene Álvarez Angorrilla[2], Elena Sánchez Aguado[3], Felisa Rodríguez Ruiz[4]

ABSTRACT

The Flexi-Seal Fecal Management System is a device designed to offer improved care to critical care patients with fecal incontinence. Studies have proven the safety and effectiveness of the device, but there are scarce reports on the adverse events. This article presents two cases of critical care patients who developed complications associated with the use of the Flexi-Seal FMS. The System proved to be effective for the treatment; however, it requires special care in the handling, particularly regarding the periodical relief of pressure from the retention balloon and the correct positioning of the collection bag on the bed, so as to avoid excessive traction. The Flexi-Seal is useful to manage diarrhoea in critical patients, improving their well-being and reducing associated complications. Nevertheless, there is a need to improve knowledge related to the complications that may occur.

DESCRIPTORS

Diarrhea
Fecal incontinence
Intensive care
Equipment
Nursing

RESUMO

O Sistema Fexi-Seal é um dispositivo desenvolvido com o objetivo de proporcionar melhores cuidados aos pacientes críticos com incontinência fecal. Existem trabalhos que demonstram a segurança e a eficácia do dispositivo, sendo, porém, escassos os relatos relacionados aos eventos adversos. O presente artigo apresenta dois casos de pacientes críticos portadores de Fexi-Seal que desenvolveram complicações com seu uso. O Sistema mostrou-se eficaz para o tratamento, no entanto, é necessária atenção especial no seu manejo, particularmente quanto ao alívio periódico da pressão na ampola retal e o posicionamento correto da bolsa coletora na cama para evitar tração excessiva. O Sistema Fexi-Seal permite manejar adequadamente a diarreia em pacientes críticos, melhorando o bem-estar e diminuindo as complicações associadas a ela, porém faz-se necessário aumentar o conhecimento sobre as complicações relacionadas ao seu emprego.

DESCRITORES

Diarreia
Incontinência fecal
Cuidados intensivos
Equipamentos
Enfermagem

RESUMEN

El Sistema Fexi-Seal es un dispositivo desarrollado para proporcionar mejores cuidados a los pacientes críticos con incontinencia fecal. Existen trabajos que demuestran la seguridad y eficacia del dispositivo, siendo escasos los relatos relacionados con eventos adversos. El presente artículo presenta dos casos de pacientes críticos portadores de Fexi-Seal que desarrollaron complicaciones con su uso. El sistema se mostró eficaz para el tratamiento, sin embargo, es necesaria atención especial en su manejo, particularmente en cuanto al alivio periódico de la presión de la ampolla rectal y al posicionamiento correcto de la bolsa colectora en la cama para evitar tracción excesiva. El Sistema Flexi-Seal permite manejar adecuadamente la diarrea en pacientes críticos, mejorando su bienestar y disminuyendo las complicaciones asociadas a ella, aunque se torna necesario aumentar el conocimiento sobre las complicaciones relacionadas con su empleo.

DESCRIPTORES

Diarrea
Incontinencia fecal
Cuidados intensivos
Equipos
Enfermería

[1]Nurse, Critical Care Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain. Associate Professor, Nursing Department, Universidad Rey Juan Carlos, Alcorcón. Madrid, Spain. javier.carmona@urjc.es [2]Nurse, Critical Care Unit, Hospital Universitario Fundación Alcorcón. Madrid, Spain. ialvarez@fhalcorcon.es [3]Nurse, Critical Care Unit, Hospital Universitario Fundación Alcorcón. Madrid, Spain. mesanchez@fhalcorcon.es [4]Auxiliary Nursing Care Technician, Critical Care Unit, Hospital Universitario Fundación Alcorcón. Madrid, Spain. frodriguezr@fhalcorcon.es

Português / Inglês
www.scielo.br/reeusp

Received: 10/27/2009
Approved: 02/01/2010

INTRODUCTION

The Flexi-Seal Fecal Management System (FMS) is a recent device that was designed to offer better care to critical patients with liquid or semi-liquid stools or acute fecal incontinence. Its main goal is to enhance perineal skin hygiene, reduce the risk of losing cutaneous integrity, and thus decreasing the risk of pressure ulcers or moisture lesions, the risk of spreading the infection and considerably improving patients' comfort. This system means an alternative to traditional methods used in intensive care (diapers, fecal bags, underpads, etc.). It also saves material resources and nursing time and reduces health spending deriving from the treatment of complications (skin lesions and infections)[1-2].

This system consists of a soft silicon catheter with a low-pressure retention balloon and a closed circuit, so that fecal contents go directly from the rectum to a collection bag placed at the foot of the patient's bed. The retention balloon is stored in the rectum and inflated for its closure with 45 ml of saline or water. When using this device on critical patients, it should be taken into account that the system should not be employed on patients who have undergone any surgical intervention in the distal part of the large intestine or rectum in the last year, with any rectal or anal lesion, rectal or anal stenosis, impaired distal mucosa, rectal or anal tumor, severe hemorrhoids or fecal impaction[3].

Until date, some studies have demonstrated the safe and effective use of the device in different situations, such as diarrhea in patients with Clostridium difficile, burned patients or patients with Fournier gangrene[4]. Research and presentations on the secondary or adverse effects deriving from the device insertion are scarce though, such as rectal ampulla ulcers or rectal fissures due to its use.

Research and presentations on the secondary or adverse effects deriving from the device insertion are scarce though, such as rectal ampulla ulcers or rectal fissures due to its use.

This study aims to present two cases of rectal ulcer related to the insertion of the Flexi-Seal Fecal Management System, which happened at a polyvalent Critical Care Unit.

CASE PRESENTATION

Patient 1

A 71-year-old man is taken to the ICU after an episode of dyspnea, hypotension and desaturation, with fever of up to 39.5ºC. Septic shock is diagnosed, related to infectious colitis. Upon arrival, treatment is started with vasoactive drugs (0.1 ug/kg/min of noradrenaline and 6 ug/kg/min of dopamine) and coverage with broad-spectrum antibiotics.

Few hours after his arrival at the ICU, the patient starts to produce abundant melenic stools. To facilitate exact fecal volume measurement and fecal aspect assessment, a Flexi-Seal FMS device is inserted. This device was kept in place without any complication for six days. It was removed after stool volume decreased and fecal consistency increased. On the patient's eighth day at the unit, enteral nutrition is started, which the patient tolerates badly, with scarce but several stools per day. Moreover, after solving the digestive bleeding episode, antithrombotic prophylaxis was started with 40 mg/day of subcutaneous enoxaparin. On the 25th day after the removal of the device, the patient suddenly starts with two episodes of important rectorrhagia, without hemodynamic instability. An emergency colonoscopy is performed, during which normal mucosa is observed until the distal rectum, where an ulcer is visualized that covers half of the circumference, besides fibrin deposits and necrotic zones, which gives the impression of a catheter-related ulcer.

Patient 2

A 67-year-old woman who arrives at the ICU with acute respiratory failure and sepsis. The patient evolved well. The shock situation was solved, but the removal of mechanical ventilation was complicated. The patient presented prolonged weaning, demanding tracheotomy and extending her stay at the unit.

Fifty days after she was hospitalized at the unit, some erosive-ulcerous lesions appear in the intergluteal region, coinciding with persistent diarrhea, which makes it difficult to cure the wound and enhances contamination. Therefore, it was decided to insert the Flexi-Seal FMS device, in order to avoid the advancement of the lesions and deviate the feces to a closed collection system. The system is kept in place for four days without any incident, and finally removed after the positive evolution of the diarrhea.

After a period when the patient's general condition improves, her clinical situation again worsens, including the return of the diarrhea. A Flexi-seal FMS is again inserted without any incident. Seventy-two hours after the device had been inserted, the patient presents a rectal bleeding episode. Suspecting that the Flexi-seal FMS could provoke this, the device is again removed. An emergency colonoscopy is performed, revealing a posterior rectal ulcer, probably of ischemic origin, produced by the FMS Flexi-seal device, as a cause of low digestive hemorrhage. As the bleeding and diarrhea persist and the patient's general condition worsens, a second colonoscopy is performed, confirming the previous diagnosis.

DISCUSSION

Incidence levels of diarrhea are high among critical patients, affecting up to half of individuals hospitalized at

these units. Risk factors associated with its appearance, besides the critical illness itself and the stress situation, include different drugs (especially those containing sorbitol and magnesium), lack of fibers in enteral nutrition and intestinal flora alterations due to the use of broad-spectrum antibiotics[5-6].

Diarrhea has shown to be an independent risk factor for the appearance of moisture skin lesions (basically perineal lesions) and plays an important role in the appearance of pressure ulcers. In case of patients with perineal lesions not produced by diarrhea itself, contamination of the region by fecal microorganisms increases the risk of infection in the lesions, delaying their healing[7].

Diarrhea management represents a problem in critical patients and different types of devices have been used (underpads, rectal catheters…), none of which is fully effective in this population. The most frequently used devices are underpads[1,8], but these do not manage to keep the skin totally dry and, therefore, cannot avoid moisture-related dermatitis.

Today, Flexi-Seal FMS is the most disseminated product for diarrhea management in critical patients. This system, which has been traded since 2006, can remain inserted in patients with liquid or semi-liquid stools for up to 30 days before its obligatory withdrawal. The system has been assessed in clinical practice in a small descriptive and prospective study of 42 patients. In 38 of them, the system continued for more than 24 hours, while one (2%) experienced an episode of gastrointestinal digestive bleeding four days after the catheter had been inserted, leading to its removal[4]. After the removal of the device, a digestive endoscopy was performed, revealing a rectal ulcer that seemed to be associated with the use of the device[4].

Two other cases of digestive bleeding appear in literature, due to a rectal ulcer associated with Flexi-Seal FMS used in ICU patients hospitalized with diarrhea. Authors[9] informed about a 65-year-old woman hospitalized at the ICU with septic shock and multiple organ failure. The device was inserted on the day of hospitalization due to diarrhea. Six days after its insertion, the patient suffered two minor episodes of fresh rectal bleeding, followed by a massive bleeding episode 24 hours later. Posterior diagnostic tests confirmed bleeding from rectal blood vessels and the presence of rectal mucosa laceration located about six centimeters from the anus. The authors conclude that the lesion may have been due to a trauma while inserting the device or its sudden movement after it was inserted[9]. Another study[10] presents the case of a 59-year-old man hospitalized at the ICU with sepsis and respiratory failure, who received a Flexi-Seal FMS soon after hospitalization due to fecal incontinence. On the 22nd day of hospitalization at the ICU, red blood was observed running around the fecal collection system. The device was removed and a two-centimeter ulcer was observed with an associated clot in the proximal anal channel. Ulcer morphology was consistent with the size and shape of the Flexi-Seal[10].

In our case, both rectal mucosa lesions seem to be due to the pressure exerted by the balloon that allows the catheter to remain anchored in the rectal ampulla, impeding feces from flowing around it. At the level of the rectal ampulla, a large fecal volume can accumulate, with an average 300 ml. Based on this fact, it can be supposed that it is difficult for the volume of the balloon that closes the device to produce this type of lesions. It should be taken into account though, that tissue perfusion is often deteriorated in critical patients due to hemodynamic instability and that, due to the same reason, possibilities to move the patient will be equally limited. Due to the synergy between these factors, pressure will be maintained during the time the closure balloon is kept in the same position on the rectal mucosa. The placement of the device at the foot of the patient's bed can also contribute to this fact, so as to facilitate rectal emptying without compressing the catheter trajectory. As a result of this catheter situation, sometimes, excessive traction may be produced at the level of the rectal ampulla, reducing blood perfusion even further and enhancing the appearance of pressure ulcers, which can often go by unnoticed if not accompanied by some associated complication that requires further diagnostic tests. In addition, the concomitant existence of other risk factors, like the use of anticoagulants or vasoactive drugs, can increase the risk that this kind of injuries will appear in these patients.

Anyway, the Flexi-seal FMS is an effective device for diarrhea management in critical patients, enhancing adequate skin hygiene, increasing patients' wellbeing and decreasing the appearance of complications. This device has been recently introduced in practice, demanding further research in critical patients to guarantee maximum security in this group. An increasing number of rectal ulcers have been described in literature, which should arouse the need to reassess care for these devices in critical patients.

Some questions should be asked about the lack of clinical studies to offer further information about the management of this device. First, the closure balloon cannot be kept inflated and in the same position during the entire dwelling time of the device. Instead, pressure in the rectal ampulla should be released from time to time to avoid ulcers. Second, the device should be located at the patient's bed to avoid excessive traction, so that neither rectal pressure nor the risk of pressure ulcers are increased even further.

CONCLUSIONS

The Flexi-seal FMS permits adequate diarrhea management in critical patients, enhancing patients' wellbeing

and reducing associated complications. Further knowledge on the complications related with the use of this device in this patient group is necessary though. Greater knowledge on care for this device will help to prevent complications and adverse effects deriving from its use.

REFERENCES

1. Beitz JM. Fecal incontinence in acutely and critically ill patients: options in management. Ostomy Wound Manage. 2006;52(12):56-8.

2. Faro ACM. Risk factors for pressure ulcer: suggestions for prevention. Rev Esc Enferm USP. 1999;33(3):279-83.

3. Marin Vivo G, Calixto Rodriguez J, Rodriguez Martinez X. Sistema de control fecal Flexi-Seal FMS. Rev Enferm. 2008;31(10):16-20.

4. Padmanabhan A, Stern M, Wishin J, Mangino M, Richey K, DeSane M, et al. Clinical evaluation of a flexible fecal incontinence management system. Am J Crit Care. 2007;16(4):384-93.

5. Sabol VK, Carlson KK. Diarrhea: applying research to bedside practice. AACN Adv Crit Care. 2007;18(1):32-44.

6. Wiesen P, Van Gossum A, Preiser JC. Diarrhoea in the critically ill. Curr Opin Crit Care. 2006;12(2):149-54.

7. ller BP, Wille J, van Ramshorst B, van der Werken C. Pressure ulcers in intensive care patients: a review of risks and prevention. Intensive Care Med. 2002;28(10):1379-88.

8. Newman DK, Fader M, Bliss DZ. Managing incontinence using technology, devices, and products: directions for research. Nurs Res. 2004;53(6 Suppl):S42-8.

9. Page BP, Boyce SA, Deans C, Camilleri-Brennan J. Significant rectal bleeding as a complication of a fecal collecting device: report of a case. Dis Colon Rectum. 2008;51(9):1427-9.

10. Sparks D, Chase D, Heaton B, Coughlin L, Metha J. Rectal trauma and associated hemorrhage with the use of the ConvaTec Flexi-Seal fecal management system: report of 3 cases. Dis Colon Rectum. 2010;53(3):346-9.

Correspondence addressed to: Francisco Javier Carmona Monge
Hospital Universitario Fundación Alcorcón
c/ Budapest n.1. 28922
Alcorcón, Madrid, España