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Nonsurgical faecal diversion in the management of severe perianal sepsis: a retrospective evaluation of the flexible faecal management system

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INTRODUCTION Severe perianal sepsis is often difficult to manage after surgical debridement due to faecal contamination. Diversion of the faecal stream has been attempted with faecal pouches and rectal tubes, and in some cases, a diverting stoma is created. However, reversal of the stoma may be delayed due to prolonged sepsis and this is not without risks. Herein, we review the use of a flexible faecal management system in patients with severe perianal sepsis.

METHODS We retrospectively evaluated 15 patients who made use of the ConvaTec Flexi-Seal® Fecal Management System (FMS) between 1 January 2007 and 31 December 2010. The demographics and comorbidities of the patients, as well as the treatment received, were recorded and reviewed.

RESULTS None of the patients required the creation of a stoma to divert the faecal stream. Nursing requirements and wound care were found to be improved with the use of the Flexi-Seal® FMS (fewer changes were needed). No severe complications were observed in our series. Two deaths were encountered, but the cause of death was not directly due to the initial perianal sepsis. Overall, the wound healing rate was 80.0%, with one graft failure (11.1%).

CONCLUSION The use of the Flexi-Seal® FMS in patients with perianal sepsis following extensive debridement is feasible and can be considered before stoma creation.

Keyword: faecal diversion, faecal management system, flexiseal, perianal sepsis

INTRODUCTION

Severe infections involving the perianal region, such as necrotising fasciitis and Fournier's gangrene, require extensive and repeated surgical debridement for sepsis control.[1-3] One of the most important factors that aid in wound healing is the adequate containment of faeces. Patients with severe infections involving the perianal region may experience various degrees of incontinence due to the loss of central control, damage to the sphincters from surgical debridement, diarrhoea from prolonged antibiotic therapy, or hypersecretions from large wounds. Unless frequent regular nursing and dressings are performed, the wounds of these patients will be continually exposed to faecal contamination, which can aggravate sepsis and delay wound healing. Frequent dressing changes place a heavy burden on nursing resources, and are often uncomfortable and painful for the patient. Traditional methods to contain the faecal stream include the use of faecal pouches, Foley catheters and ill-fitting rectal tubes. The use of rectal tubes can be associated with rectal necrosis and sphincter damage, whereas the use of continence pads and faecal pouches is associated with a high incidence of dermatitis and skin ulceration. Successful treatment is often variable and dependent on nursing care, with the leakage of faeces being a common problem.

Although the use of a stoma to divert the faecal stream has been recommended due to its good results, it is nevertheless an invasive procedure. An ideal diverting stoma involves bringing out the most distal end of the bowel in order to reduce the length of the column of secretions to the perineum. This procedure is ideally performed laparoscopically, with the creation of a sigmoid colostomy. However, this may not be possible for patients with previous abdominal scars (such patients require large laparotomy incisions) and those who are too sick to be subject to general anaesthesia (a majority of patients with perianal sepsis fall into the latter category). In addition, if a stoma is created too early and sepsis is not under control, ascending cellulitis or infection up to the abdominal wall can lead to fasciitis around the stoma sites, creating additional problems for the patient, or worse, potentially resulting in the need for a take-down and re-siting of the stoma. There are also multiple long-term care issues with regard to the use of stomas.[4] Reversal of the stoma is often delayed due to the long rehabilitation period required after the initial severe sepsis.

The use of a flexible faecal management system in bedbound patients with faecal incontinence and patients with perineal burns has been described in previous studies.[5-7] However, these studies mainly evaluated patients with an intact anal sphincter and/or no major perianal/perineal surgery done. Therefore, the aim of the present study was to evaluate the potential advantages and disadvantages of the use of a flexible faecal management system in a group of patients who had undergone extensive surgical debridement for severe perineal sepsis.

METHODS

This study was approved by the Institutional Review Board of Singapore General Hospital, Singapore. All patients who

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underwent extensive surgical debridement for severe perineal sepsis and made use of the Flexi-Seal® Fecal Management System (FMS) (ConvaTec, Skillman, NJ, USA) between 1 January 2007 and 31 December 2010 were included in the present study. The medical records of these patients were retrospectively reviewed.

Information on the patients' sociodemographics, comorbidities, significant investigations, surgical management, complications and final outcome (of the wound) were recorded. Initial treatment consisted of wide surgical debridement and antibiotic therapy, depending on the results of wound cultures. To evaluate the progression of sepsis, re-look and repeat surgical debridements were typically performed within 24–48 hours. Once the wounds are satisfactorily clean and healing, the patient would undergo skin grafts, if necessary. The decision to use the Flexi-Seal® FMS was made by the primary team managing the patient, in consultation with the nurse clinician specialist who was trained in managing such a system. Contraindications to tube insertion include previous rectal surgery, inflammatory bowel disease, existing mucosal lacerations, stricture and obstructive masses. The Flexi-Seal® FMS tube was inserted either in the ward with or without sedation by a nurse clinician, or in the operating theatre under general anaesthesia after wound debridement.

The Flexi-Seal® FMS is a closed system consisting of a tube and a collection bag (Fig. 1). The tube is made of silicone and has a fully collapsible retention cuff that can be inflated with 45 mL of water and sealed by resting it against the pelvic floor. To ensure patency of the tube, regular irrigation with normal saline (2–3 times a day) is done and patients are often prescribed with laxatives (in our institution, oral lactulose solution is used) to maintain a soft consistency of stool. The tube is attached to a collection bag, which is emptied as required or changed weekly. Regular wound inspection of the anorectal region was performed by the doctors in charge. In our study cohort, the maximum duration that the tube was left *in situ* was 29 days (as recommended by the manufacturer). The device was removed when the patient improved clinically, was able to pass solid stools, or when it was deemed no longer necessary due to adequate wound healing and coverage. The end points of our study were: (a) the efficacy of faecal containment using the Flexi-Seal® FMS, as determined by its success in containing all faecal flow in the collection bag; and (b) the safety of the Flexi-Seal® FMS device.

RESULTS

Between 1 January 2007 and 31 December 2010, Flexi-Seal® FMS was used in 15 patients with severe perianal sepsis. Among these 15 patients, 11 (73.3%) were male and 4 (26.7%) were female. The mean age was 55 (range 33–76) years and most (66.7%) were of Chinese ethnicity (Table I). Ten out of the 15 patients were immunocompromised to a certain extent – diabetes mellitus (n = 10), end stage renal failure requiring haemodialysis (n = 4), and long-term steroids for systemic lupus erythematous (n = 1).

After the extent of the disease was determined, the primary diagnosis was made by the surgeon during the first operation, when the patient was under anaesthesia in the operating theatre. In all, nine patients were diagnosed with severe abscesses with extensive involvement of the perianal/ischiorectal regions, five were diagnosed with Fournier's gangrene, and one was diagnosed with necrotising fasciitis of the perineum (Table I).

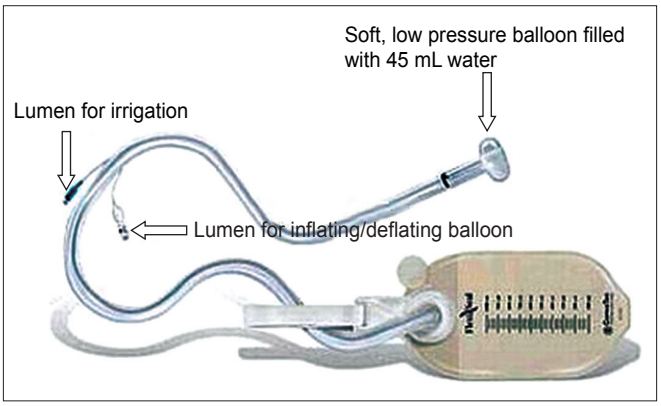

Fig. 1 Illustration shows the parts of the Flexi-Seal® Fecal Management System device.

Table I. Demographics and clinical diagnosis of patients with perianal sepsis (n = 15).

Parameter	No. (%)
Gender	
Male	11 (73.3)
Female	4 (26.7)
Age (yrs)	
≤ 50	4 (26.7)
> 50	11 (73.3)
Ethnicity	
Chinese	10 (66.7)
Malay	4 (26.7)
Indian	1 (6.7)
Diagnosis	
Fournier's gangrene	5 (33.3)
Ischiorectal/perianal abscess	9 (60.0)
Necrotising fasciitis	1 (6.7)

The extent of disease, total number of debridements done, wound culture results, inflammatory markers and length of hospitalisation of the patients are listed in Table II. The top three most common wound culture microorganisms were *Klebsiella* spp. (n = 5), Group B *Streptococcus* (n = 4) and *Enterococcus coli* (n = 3). The mean total white blood cells count at the time of diagnosis was 19.07 × 10^9/L (range 8.24–31.10 × 10^9/L). The mean number of debridements was 4 (range 2–8) and the average length of hospitalisation was 48 (range 12–193) days. To aid wound healing, 9 (60.0%) patients underwent vacuum-assisted closure (VAC) dressing after the operation.

The patients were followed up for at least one year after discharge, and wound assessment continued until complete wound healing was documented. Nine patients required skin grafts for wound coverage after debridement. One patient had breakdown of the skin graft, which was conservatively managed without further skin grafts, and the wound eventually healed by secondary intention. Of the six patients who did not have skin grafts, four patients' wounds healed, while the remaining two patients died during their stay in the hospital (Table III). The cause of death for these two patients was not directly due to the

Table II. Extent of the severity of the perianal wounds of the 15 patients.

Patient no.	Diagnosis	Extent of disease	Wound cultures	Total WBC count (× 10^9/L)	CRP (mg/L)	Length of hospital stay (days)	No. of debridements	Application of VAC dressing
1	Fournier's gangrene	Extensive involvement of the scrotum and right ischiorectal fossa	Group B *Streptococcus*	21.10	–	49	5	No
2	Ischiorectal abscess	Large bilateral abscess that extends deep into the ischiorectal fossa	*Klebsiella* spp.	28.02	–	65	2	Yes
3	Fournier's gangrene	Extensive perianal abscess that extends to the base of the scotum	Group B *Streptococcus*	13.35	–	12	3	Yes
4	Ischiorectal abscess	Bilateral, extensive and deep ischiorectal abscesses	*Enterococcus* spp.	31.10	219	48	2	No
5	Ischiorectal abscess	Right ischiorectal abscess, measuring 5 cm × 6 cm	*Staphylococcus aureus*	17.50	245	17	4	Yes
6	Fournier's gangrene	Extensive involvement from the left perianal region and vulva, extending up to the mons pubis and the left ilioinguinal region	*Bacteroides fragilis*	14.92	–	60	2	No
7	Ischiorectal abscess	Large circumferential ischiorectal abscess	Group B *Streptococcus*	8.98	–	35	8	Yes
8	Ischiorectal abscess	Large left buttock carbuncle that extends into the bilateral ischiorectal fossa	Group B *Streptococcus*	26.21	–	26	2	Yes
9	Fournier's gangrene	Extensive necrotic tissue that extends from the perianal region to the perineum	*Escherichia coli*, *Enterobacter* spp.	29.60	–	32	2	No
10	Ischiorectal abscess	Large right ischiorectal fossa abscess, measuring 10 cm × 5 cm	*Klebsiella* spp., *Escherichia coli*	8.38	–	30	4	Yes
11	Necrositing fasciitis	Extensive necrotic tissue that extends from the perineum to the nipple line	*Klebsiella* spp., *Enterococcus* spp.	23.90	–	38	8	Yes
12	Gluteal abscess	Large extensive gluteal abscess that tracks to midway along the posterior aspect of the thigh	*Proteus mirabilis*, *Klebsiella* spp.	18.20	–	41	2	No
13	Ischiorectal abscess with sacral sore	Large right ischiorectal abscess, measuring 10 cm × 10 cm	*Proteus mirabilis*	13.15	127	193	5	No
14	Ischiorectal abscess	Large ischiorectal abscess	*Escherichia coli*, *Enterococcus* spp.	8.24	–	24	4	Yes
15	Fournier's gangrene	Extensive necrotic tissue that extends from the left ischiorectal abscess to the left groin	*Enterobacter* spp, *Klebsiella* spp.	23.54	–	45	3	Yes

CRP: C-reactive protein; VAC: vacuum-assisted closure; WBC: white blood cell

initial perianal sepsis – one patient succumbed to complications due to end stage renal failure, while the other death was ruled by the coroner to be secondary to pneumonia. Overall, the wound healing rate was 80.0% (n = 12), with one graft failure (1 out of 9, 11.1%). The outcomes of the patients are illustrated in Fig. 2.

The median duration of Flexi-Seal® FMS use was 11 (range 3–54) days. Nursing issues faced with the use of the Flexi-Seal® FMS tube in the duration of the study included: (a) dislodgement during the transfer of patients and/or during dressing change; and (b) difficulty with anchoring the tube (with adhesive tape) due to wound dressings and/or poor quality of the surrounding skin and hair. Reinsertion of the tube was performed at the bedside and the tube was reused as long as it had not exceeded the recommended duration of use. No complications associated with reinsertion were encountered. The average number of tube changes required for the Flexi-Seal® FMS was 1.6 (range 0–5). One patient required a new Flexi-Seal® FMS tube due to persistent leakage of stool around the old tubing. None of the patients experienced any physical discomfort or severe complications (e.g. bleeding per rectum, mucosal erosion and bowel perforation) associated with the use of the Flexi-Seal® FMS. In addition, none of the patients needed to undergo creation of a stoma for faecal diversion due to failure of the Flexi-Seal® FMS.

DISCUSSION

Faecal contamination after surgical debridement for perianal sepsis complicates the process of wound healing, as the contaminants contribute to skin breakdown and increases the risk of infection. Furthermore, repeated wound debridements are associated with sphincter damage, which can lead to faecal incontinence. This would aggravate soilage of the wound and

Table III. Outcomes of patients with perianal sepsis (n = 15).

Patient no.	Age (yrs)	Diagnosis	Graft	Outcome
1	46	Fournier's gangrene	Yes	Wound healed
2	54	Ischiorectal abscess	No	Died (due to ESRF)
3	61	Fournier's gangrene	No	Died (due to pneumonia)
4	53	Ischiorectal abscess	No	Wound healed
5	53	Ischiorectal abscess	No	Wound healed
6	76	Fournier's gangrene	Yes	Graft broke down
7	61	Ischiorectal abscess	Yes	Wound healed
8	57	Ischiorectal abscess	Yes	Wound healed
9	67	Fournier's gangrene	Yes	Wound healed
10	49	Ischiorectal abscess	Yes	Wound healed
11	51	Necrotising fasciitis	Yes	Wound healed
12	63	Gluteal abscess	Yes	Wound healed
13	57	Ischiorectal abscess with sacral sore	No	Wound healed
14	33	Ischiorectal abscess	Yes	Wound healed
15	49	Fournier's gangrene	No	Wound healed

ESRF: end stage renal failure

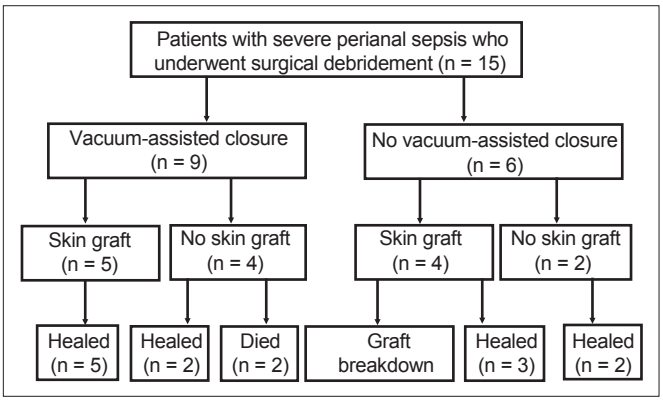

Fig. 2 Flowchart shows the outcomes of the patients with severe perianal sepsis.

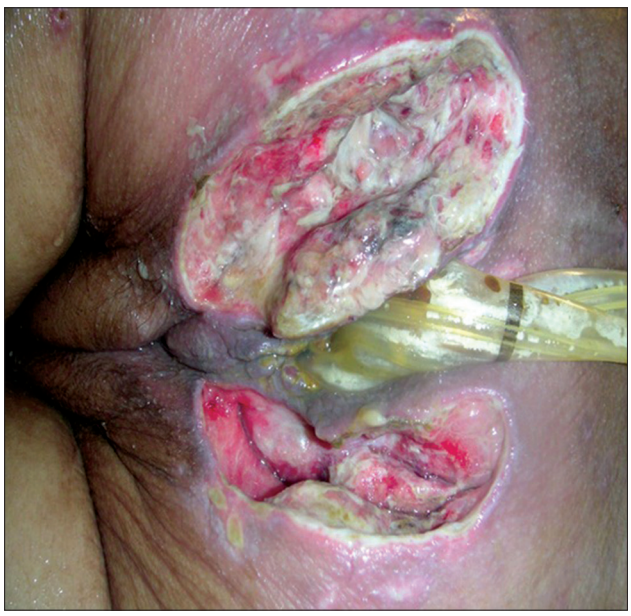

Fig. 3 Photograph shows the Flexi-Seal® Fecal Management System used in a patient with perianal wounds.

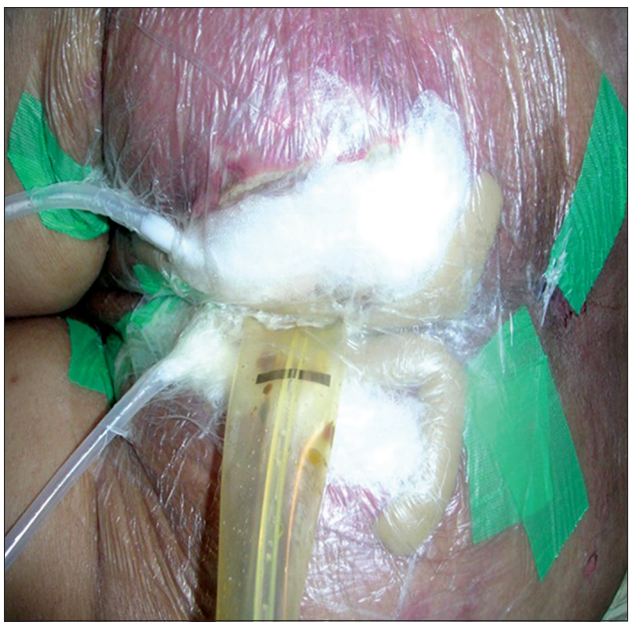

Fig. 4 Photograph shows the Flexi-Seal® Fecal Management System used together with vacuum-assisted closure dressings in a patient with perianal wounds.

further decrease the patient's quality of life. Conventional nonsurgical methods to contain and divert the faecal stream (i.e. using Foley catheters and faecal pouches) are often ineffective and not appropriately designed for patients with such wounds. The use of these conventional methods has also been known to cause problems such as rectal perforation and fistulas.[8]

VAC is an alternative method for managing open wounds. It is often used to aid wound healing, especially if the wound is exudative. In VAC, subatmospheric pressure is applied to the wound surface. The mechanism of action of VAC, which uses negative pressure wound therapy, is described as the stabilisation of the wound environment to increase blood flow and deformation of the wound. Deformation is a powerful stimulus for cellular processes that stimulate granulation tissue, and hence helps accelerate wound healing. More than half of the patients in the present study received VAC therapy to increase the rate of healing. However, VAC dressing requires a tight seal around the wound, and this is often difficult to achieve at the perianal region, as continual excretion of faecal material or gas leads to a loss of the vacuum. The Flexi-Seal® FMS can be used in combination with VAC dressings to create a better fit of dressing material for the wound (Figs. 3 & 4). Proper diversion of the faecal stream also helps ensure that the wound remains clean. The nursing staff involved in the care of the patients in the present study also found that the frequency of wound changes required was reduced, and hence, the discomfort and pain that patients had to endure with each dressing change was also reduced.

Patients with severe perianal sepsis are often on prolonged antibiotics, which can give rise to antibiotic-related pseudomembranous colitis (PMC) with *Cloistridium difficile*. The use of the Flexi-Seal® FMS in combination with VAC dressings has the added benefit of being able to contain infectious body waste in patients with PMC and thus, minimises nosocomial spread.

The creation of a temporary diverting stoma has been the traditional method used to reduce soilage of a perianal wound. However, it is an invasive procedure that is associated with complications (e.g. necrosis, parastomal hernia, stenosis), which may result in the need for repeat surgery; additionally, there is a need for a second procedure to reverse the stoma once the perianal wound has healed.[9] Closure of the stoma is associated with complications such as anastomotic leakage and bowel injury.[10] This increases the overall cost of treatment, the length of hospitalisation and the risk of morbidity. The presence of a stoma may also cause significant psychosocial barriers in the patients upon discharge from the hospital. Despite its many disadvantages, the creation of a stoma for faecal diversion is still the treatment of choice in institutions where specialised wound care and nursing are not available.

Complications with the use of the Flexi-Seal® FMS have been documented, with massive per rectal bleeding secondary to rectal ulceration being the most common complication.[11-13] Fortunately, in the present study, we did not encounter such problems with the use of the Flexi-Seal® FMS. However, it may be premature, based on the findings of the present study, to conclude that the use of the Flexi-Seal® FMS is without any danger. Patients who are on the Flexi-Seal® FMS should still be carefully monitored, with checks of the perianal region performed regularly and investigations (e.g. colonoscopy) done if bleeding per rectum is suspected. Protocols such as regular release of the pressure cuff may be put in place to prevent such an event.

In conclusion, the present study is the first to review the use of a nonsurgical method for faecal diversion in severe perianal sepsis in an Asian population. The use of the Flexi-Seal® FMS appears to be beneficial, as there is reduced wound contamination, as well as the negation of the need for stoma creation. Hence, the Flexi-Seal® FMS can be considered for wound management in patients with severe perianal sepsis.

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