



Clinical evaluation of a temporary fecal containment device for non-surgical fecal diversion in perineal burns

Perine yanıklarında kullanılmakta olan geçici fekal diversiyon ve toplama sisteminin klinik değerlendirilmesi

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BACKGROUND

The aim of this study was to evaluate the clinical results of a temporary fecal containment device (Flexi-Seal® FMS) in our burn center.

METHODS

All patients in whom temporary fecal containment devices were applied for perineal burns between August 2008 and August 2009 in our institution were reviewed. Demographics, etiology of burns, total body surface area (TBSA) burned, intensive care unit (ICU) need, early mortality, and post-application data were obtained from a prospectively designed database. In addition, some variables were investigated as potential risks factors for fecal leakage.

RESULTS

The mean age of patients (n=15) was 43.1±22.1 years, and 66.7% of the patients were male. The mean %TBSA burned was 40.7±16.6. Fecal leakage was seen in 6 patients. Local infection in the perineum was observed in 6 patients, including 4 of the 6 patients with fecal leakage. The mortality rate was 33% (5 deaths). All exitus patients had 50% or more TBSA burned. Electrical burn injury was found as a significant risk factor for fecal leakage in surviving patients (p<0.05). Autologous split-thickness grafting was performed in 8 patients without complication. The mean duration of catheterization was 22.5±5.7 days. Except for superficial mucosal erosion in the distal rectum in 2 cases, no complication was observed. The mean hospitalization time was 46.7±12.7 days.

CONCLUSION

If the safety of these devices is proven in further prospective, high-volume studies, they may reduce the necessity of diverting stoma operation in burn patients.

Key Words: Fecal containment devices; perineal burns.

AMAÇ

Hastanemizin yanık merkezinde perine yanıklarında kullanılmakta olan geçici fekal diversiyon ve toplama sisteminin (Flexi-Seal® FMS) klinik sonuçları değerlendirildi.

GEREÇ VE YÖNTEM

Yanık merkezimizde Ağustos 2008 ile Ağustos 2009 arasında geçici fekal diversiyon ve toplama sistemi uygulanan tüm hastalar çalışmaya dahil edildi. Hastaların demografik bilgileri, yanık etyolojileri, yanık yüzdeleri, yoğun bakım ihtiyaçları, erken mortalite ve uygulama sonrası klinik bilgileri prospektif olarak hazırlanan bir veritabanında toplandı. Bunların yanında bu sistemin uygulandığı hastalarda fekal kaçak riskini arttıracak çeşitli faktörler de incelendi.

BULGULAR

Çalışmaya 15 hasta (10 erkek, 5 kadın; ortalama yaş 43,1±22,1) dahil edildi. Ortalama yanık yüzdesi 40,7±16,6 idi. Fekal kaçak 6 hastada görüldü. Perinede lokal enfeksiyon gelişen 6 hastanın 4'ü fekal kaçaklı hastalardı. Elektrik yanığı sistemden fekal kaçak için bir risk faktörü olarak bulundu (p<0,05). Çalışmamızda sistemin uygulandığı 5 hasta kaybedildi. Kaybedilen hastaların tümünde yanık yüzdesi ≥50 idi. Otolog split greft uygulanan toplam 8 hastada ciddi komplikasyon görülmedi. Sistemin ortalama uygulama süresi 22,5±5,7 gündü ve 2 hastada yüzeysel rektal mukozal erozyon dışında sisteme bağlı komplikasyon görülmedi. Çalışmamızda sistemin uygulama ihtiyacı 29 günü aşan 1 hastaya kolostomi uygulandı. Hastaların ortalama yatış süresi ise 46,7±12,7 gündü.

SONUÇ

Geçici fekal diversiyon ve toplama sistemlerinin güvenilirliği yapılacak daha güçlü ve prospektif çalışmalarla kanıtlanabilirse perine yanıklarında sapırtıcı stoma gereksinimini azaltabilirler.

Anahtar Sözcükler: Fekal diversiyon; perine yanıkları.

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The perineum is not a common region for burn injuries. Alghanem et al.^[1] reported the incidence of perineal burns as about 1.2%. However, burns to the perineum that involve the pubic area and structures lying between the thighs, including the external genitalia and peri-anal area, require special attention.^[2] In the acute phase, management of perineal burns can be challenging on its own. The area has a high bacterial load comprising fecal organisms from the anus, which may lead to serious generalized infections by way of the damaged skin or urogenital tract. Fecal contamination may also increase the risk of flap or graft loss. Thus, the most important issue for perineal burns is diverting feces from the burned area to avoid serious infective complications.

Temporary fecal containment devices have been developed to manage bedridden, immobilized and incontinent patients as an alternative to traditional methods such as pads, diapers, fecal pouches, and rectal tubes. Temporary fecal containment devices can also be used for diverting feces from the burned area. Theoretically, these devices may diminish both the risk of skin breakdown and spread of infection by protecting the patients' wounds from feces. These devices may also be an alternative to diverting colostomy. The aim of this study was to evaluate the early clinical results of these devices in our burn center.

MATERIALS AND METHODS

All patients in whom temporary fecal containment devices were applied for perineal (including gluteus and upper thigh) burns between August 2008 and August 2009 in our institution were reviewed in this study. Demographics (age, gender), etiology of burns, total body surface area (TBSA) burned, intensive care unit (ICU) need, early mortality, and post-application data (fecal leakage, infections, complications, graft operations, duration of application, and hospitalization time) were obtained from a prospectively designed da-



Fig. 1. A patient with Flexi-Seal® FMS.

tabase. In addition, some variables (age, gender, etiology of burns, %TBSA burned, and ICU need) were investigated as potential risks factors for fecal leakage in these patients.

We used Flexi-Seal® fecal management system (FMS) as the temporary fecal containment device. Flexi-Seal® FMS consists of a soft silicone catheter, a syringe and a collection bag. At one end, the soft silicone catheter has a retention balloon that is inserted into the rectum. At the opposite end, the catheter has a connector for attaching the collection bag. On the first admission day of the patients, the catheters were inserted into the rectum by a resident under sedation or general anesthesia after a digital rectal examination to detect any fecal impaction or anorectal abnormality. The retention balloon was inflated with 45 ml water and placed carefully into the pelvic floor (Fig. 1). Lactulose (Duphalac® 670 mg/300 ml syrup, Solvay S.A.) was added to the enteral nutrition of patients to increase fluidity of the feces. Additionally, catheters were irrigated 3 times daily with 100 cc water to avoid obstruction of the catheter.

The catheter was removed whenever a satisfactory wound or graft healing was confirmed by a burn surgeon. The length of catheterization did not exceed 29 days based on the manufacturer's recommendation. A digital rectal examination was performed on all patients to detect any mucosal injury after removal of the catheter.

All statistical analyses were performed with SPSS for Windows 17.0. In all sample analyses, means were compared with unpaired Student's t-test and frequency distributions with Fisher's exact probability test or chi-squared test. $p=0.05$ (two-sided) was considered as the limit of significance.

RESULTS

A total of 351 patients were admitted to our burn center between August 2008 and August 2009. Use of temporary fecal containment device was decided for 15 (4.3%) patients.

The mean age of the patients was 43.1 ± 22.1 years (range: 18-76), and 66.7% of the patients were male. The mean %TBSA burned was 40.7 ± 16.6 (range: 20-70%). All patients had burns involving one or more of the perineum, gluteus or upper thigh. Causes of burns were flame in 8 (53.3%), electricity in 5 (33.3%) and hot water in 2 (13.3%) patients.

The devices were placed intra-rectally on the first admission day in all patients. Minimal fecal leakage was seen in 6 (40%) patients. Local infection in the perineum confirmed by tissue culture was observed in 6 (40%) patients, including 4 of the 6 patients with fecal leakage. Two patients had no local infection in

Table 1. Characteristics and demographics of deceased patients

No	Age/Gender	TBSA (%)	Cause of burn	ICU need	Fecal leakage/ Time	Cause of death	Time of death (day)
1	18/M	60	Electricity	Yes	No	Septicemia	7
2	49/F	50	Flame	Yes	Yes/ 2nd day	Septicemia	6
3	72/F	65	Flame	Yes	No	Multiple Organ Failure	5
4	34/M	70	Flame	Yes	No	Multiple Organ Failure	2
5	20/M	60	Electricity	Yes	No	Septicemia	14

ICU: Intensive care unit; TBSA: Total body surface area.

spite of fecal leakage. Positive blood cultures were detected in 3 (20%) patients, all of whom (n=3) died from multiple organ failure caused by septicemia. Besides these 3 patients, another 2 patients who had no sign of infection died from multiple organ failure in the early stage of hospitalization. All exitus patients had 50% or more TBSA burned. These 5 deceased patients (n=5, 33.3%) were excluded from further analysis because of the short follow-up period (Table 1).

Autologous split-thickness grafting was performed in 8 patients for the management of perineal wounds. The operations were performed within 7 days of admission in 6 patients; however, the operations in 2 patients were postponed to the 12th and 14th days of admission due to local infections. No significant graft loss requiring re-grafting was observed in our grafted patients. Electrical burn injury was found as a significant risk factor for fecal leakage in the surviving patients ($p<0.05$) (Table 2).

The mean duration of catheterization was 22.5 ± 5.7 days (range: 12-29) in the surviving patients (n=10). Except for superficial mucosal erosion in the distal rectum in 2 patients, no complication due to the device was observed in our cases. Colostomy was required in 1 patient because of wound healing delay (exceeding 29 days). The mean hospitalization time was 46.7 ± 12.7 days (range: 26-64).

DISCUSSION

In our burn center, the incidence of perineal-involvement burns was 4.3% during the study period. All patients with perineal burns also had extensive burn injuries to the trunk and/or lower limbs (40.7% mean TBSA burned), and the mortality was 33% (5 patients) in our study. All exitus patients had 50% or more TBSA burned. Peck et al.^[3] reported a 28.2% mortality rate in perineal-involvement burns.

Temporary diverting colostomy is a conventional method to avoid contamination of the burned perineal area by feces. Theoretically, diverting colostomy decreases fecal contamination and aids wound healing in perineal burns, but there are only two studies including a limited number and age groups of patients about diverting colostomies in perineal burns. Quarmbly et al. firstly reported 13 pediatric cases with two minimal complications (two stomal prolapse), and then Nakazawa et al. reported five elderly cases without any complications.^[4,5] Although these two limited studies did not report any significant complication, large volume studies on the safety and efficacy of colostomies have demonstrated that some serious complications requiring reoperation, such as necrosis, parastomal hernia and stenosis might arise following colostomies.^[6,7] Furthermore, closure of colostomy carries some serious complication risks (e.g. anastomotic leakage, bowel injury and even mortality).^[8] Additionally, it

Table 2. Characteristics and demographics of surviving patients

No	Age/Gender	TBSA burned (%)	Cause of burn	ICU need	Graft to perineum	Fecal leakage/ Time	Local infection	Catheter duration	Comp.	Hospitalization time
1	76/M	30	Electricity	Yes	Yes	Yes / 4th day	No	21	No	52
2	71/M	40	Flame	Yes	Yes	Yes / 5th day	Yes	29	Yes	58
3	25/M	30	Electricity	No	Yes	Yes / 4th day	Yes	21	No	64
4	23/M	25	Flame	No	No	No	No	14	No	40
5	74/F	20	Flame	No	Yes	Yes / 4th day	No	25	Yes	30
6	21/M	40	Flame	Yes	Yes	No	No	29	No	62
7	19/M	30	Flame	No	Yes	No	No	24	No	45
8	52/F	20	Hot Water	No	No	No	No	12	No	26
9	48/M	30	Hot Water	Yes	Yes	No	No	25	No	44
10	44/M	40	Electricity	Yes	Yes	Yes / 3rd day	Yes	25	No	46

Comp.: Complications; ICU: Intensive care unit; TBSA: Total body surface area.

may not be possible to find an adequate area for colostomy, especially in patients with extensive abdominal burns. Another problem, particularly in patients with extensive burns, is that colostomy may decrease the potential skin surface area for grafting. Perhaps one of the most important issues about diverting colostomies is their effectiveness in preventing sepsis in extensive burns, in which bacterial translocation is more important than direct contamination for the development of sepsis. Thus, well-designed and adequately powered studies are still needed to determine the role of diverting colostomies in the management of perineal burns.

To our knowledge, the present study is the largest series on temporary fecal containment devices in the management of perineal burns. Keshava et al.^[9] reported 20 patients (13 severe perineal excoriations and only 7 perineal burns). They used the Zassi Bowel Management System (Zassi BMS) for fecal containment. There are some differences between the Flexi-Seal FMS and Zassi BMS. Flexi-Seal FMS consists of a soft silicone catheter tube assembly, syringe and collection bags. The catheter is inserted into the rectum and the retention balloon is inflated with 45 cc of water. Zassi BMS consists of a silicone catheter with a collapse-resistant annulus, a low-pressure retention cuff and collection bags. After the catheter is inserted, the retention cuff is inflated with 35 to 40 cc of water. Flow through the catheter can be stopped by using an intraluminal balloon. Economic impact of these two commercial bowel catheter systems was compared in a multicenter, observational study including 146 bedridden patients, and Zassi BMS was found more cost-effective than Flexi-Seal FMS.^[10] Although Bordes et al.^[11] reported 8 burned patients in whom they used both types of catheters (Zassi BMS in 6 patients and Flexi-Seal in 2 patients), they could not draw a conclusion on the differences in safety or effectiveness between these two models of catheters due to the low number of patients.

Fecal leakage was seen in 6 (40%) patients in our study. Local infection developed in 4 of these 6 patients and 1 of them, who had 50% TBSA burn, died on the 6th day of hospitalization due to septicemia. If the 5 exitus patients were excluded because of the short follow-up period, the fecal leakage rate would increase to 50% in our study. Bordes et al.^[11] reported fecal leakage in 6 of 8 patients (75%) without any mortality. Padmanabhan et al.^[12] reported daily assessment results in a prospective, single-arm, multi-center study with 42 diarrheic and incontinent patients, and they reported some degree of fecal leakage in 140 of 198 daily assessments (71%). In our opinion, the high risk of fecal leakage is still the most bothersome problem for temporary fecal containment devices, even if its importance on mortality was not demonstrated in either our study or that of Bordes et al.

Temporary fecal containment devices may prevent the complications of diverting colostomies. However, it should not be forgotten that any catheterization adjacent to the mucosa may result in serious ischemic ulcerative complications, including perforation. Moreover, the risk of ischemic ulcerative complications may be higher than others in burned patients because of the reduction in peripheral blood flow. We placed the catheters on the first admission day and we did not exceed 29 days in catheter application, as recommended by the manufacturer. The mean duration of catheterization was 22.5±5.7 days (range: 12-29) in our study. We had to perform colostomy in one patient with delayed wound healing (>29 days). Keshava et al.^[9] reported that they had used the Zassi BMS in one patient for 59 days without any mucosal injury. They exceeded 29 days only in this patient; the mean duration of catheterization was 21 days in their study, which was similar to our study (22.5 days). On the other hand, Bordes et al.^[11] reported that they had exceeded 29 days in 6 of 8 patients with 4 complications, including reversible anal atony in 2 patients, bowel occlusion in 1 patient and anal ulceration in 1 patient. The mean duration of catheterization was 35 days (range: 6-70) in their study. Even though we did not exceed 29 days in catheterization, we also observed superficial mucosal erosions in 2 patients. In our opinion, the catheterization should not be prolonged, and colostomy should be performed in the case of wound healing delays.

In the present study, we also investigated the potential risk factors for fecal leakage in these patients, and only electrical burn injury was found as a significant risk factor for fecal leakage. This is probably due to the more harmful effect of electrical burn on sphincter muscles of the anus than other etiologies of burns. However, it is obvious that our results were obtained from a very limited number of patients and should be supported by more powered, prospective trials that include manometric measurements.

In conclusion, temporary fecal containment devices aim to protect patients' wounds from fecal contamination by diverting the feces. If the safety of these devices is proven in further studies, they may reduce the necessity of diverting stoma operation in burn patients.

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