Stoma Cylinder; a Novel and Simple Technique for Management of Stoma Complications

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Background: Intestinal stoma creation is indicated for several gastrointestinal diseases. The incidence of stoma complications ranges from 10% to 70%. The current study aimed to assess the potential benefits of the application of our new appliance during the conservative management of stoma retraction with or without peristomal skin complications (PSCs).

Patients and methods: This is a randomized controlled study that was conducted on patients with stoma retraction with or without PSCs, indicating conservative management. Patients were randomly allocated to group 1, where the novel appliance was used, or group 2, where patients underwent conventional treatment.

Results: 41 patients were the final study population; 22 were in group 1 and 19 were in group 2. One patient in group 1 (4.5%) and six patients in group 2 (31.6%) indicated surgical reoperation (p = 0.022). Group 1 had a significantly lower hospital stay length (p<0.001) and time to complete epithelization (p<0.001). Using our cylinder appliance was significantly effective in decreasing the time to healing (p<0.001). Infection and diabetes mellitus significantly affected the time of healing (p = 0.017 and 0.002, respectively).

Conclusion: We adopted a new, simple, feasible, and safe appliance. Using a stoma cylinder was associated with overall better patient outcomes and less cost. It offered high rates of success for stoma retraction and the PSCs without complications.

Key words: Stoma retraction, peristomal skin complications (PSCs), stoma cylinder.

Introduction

"Stoma" is a Latin word meaning "Mouth," and it is used when a hollow organ is surgically opened to the body's surface. During ileostomy or colostomy, an intestinal stoma is created by exteriorizing the small or large intestine via the anterior abdominal wall, respectively.¹

Intestinal stoma creation is indicated for several gastrointestinal diseases, including inflammatory bowel disease, colorectal cancer, ischemic colitis, fecal incontinence, and radiation injury.² When the stoma is functioning well, the patient has a satisfactory quality of life with very minimal impairment to their usual lifestyle. On the other hand, if the stoma is complicated, the patient's health is greatly impacted in physical and mental aspects.^{2,3}

The incidence of stoma complications ranges from 10% to 70%, which is a wide range likely reflecting under-reported true incidence. These complications may occur early (Within 30 days of the surgery) or late postoperatively.⁴ Early complications include infection, fluid, and electrolyte imbalance, stoma retraction, mucocutaneous separation, and ischemia/necrosis. Late complications of the stoma include stoma prolapse, pyoderma gangrenosum, and parastomal hernias or varices.⁵

Stoma retraction is produced by frequent tension on the stoma. Suture fixation of the bowel is not sufficient for the prevention of retraction.⁶ Stoma retraction results in irritation of the skin, a predisposition to further peristomal skin complications (PSCs), and inadequate fixation of the stoma appliance.⁶

Actually, the best treatment for stoma complications is to make an effort to prevent these complications.⁷ If stoma complications have already developed. They may be treated conservatively or by stoma reversal if this is feasible.³ If conservative management fails or stoma reversal is not possible, then reoperation may be indicated. However, reoperation in this situation may be challenging due to the presence of adhesions and other technical difficulties.⁸

The current study aimed to assess the potential benefits of the application of our new handmade appliance during the conservative management of stoma retraction with or without peristomal skin complications.

Patients and methods

This is a randomized controlled study that was conducted during the period from March 2018 to March 2022. Cases were recruited from our university hospital and another two large private hospitals. The study was commenced after approval of the regional research ethics committee and in accordance with the Helsinki declaration. The study was reported according to CONSORT guidelines.⁹

Adult patients with stoma retraction with or without PSCs indicating conservative management were eligible for the study. Patients who were candidates for stoma reversal or indicated for surgical intervention were excluded from the study. Patients who refused to participate in the study were also excluded. Informed written consent was obtained from the included patients.

Blinding and randomization

During the study period, eligible patients were randomly allocated to group 1 or group 2 after being admitted to the inpatient department and assessed by the surgeon. An independent hospital nurse prepared opaque sealed envelopes containing numbers 1 or 2. Then each patient chose one envelope and was accordingly assigned to the suitable group.

Surgical procedure

For stoma retraction, the mucocutaneous junction was divided, then the full thickness of the bowel was mobilized, and the stoma was stabilized.

In group 1, our novel appliance was used under sterile conditions. This was a plastic or silicon sheet that was wrapped around the stoma. The wrap was fashioned in a cylindrical manner by stitching the ends of the plastic/silicon sheet together. Interrupted absorbable polyglactin sutures (Vicryl® 3/0) were performed to fix the base of the cylinder to the peristomal abdominal wall if there was surrounding granulation tissue, or to the stoma itself in the absence of granulation tissue. Then, the stoma was bound to the neighboring bowel loops.

In cases of peristomal skin complications (PSCs), the appliance was positioned, then the opening of the skin barrier piece of the two-piece ostomy bag was adjusted to the cylinder's upper portion by adhesive paste, stitches, or sometimes just fitting into it. An umbrella isolating the stoma from the damaged skin was formed, allowing the application of repeated dressings using the indicated emollients and topical skin care products (**Figures 1-3**).



Fig 1a: A retracted ileostomy with peristomal skin complications.



Fig 1b: The same ileostomy after application of the stoma cylinder with improvement of PSCs.



Fig 2: Ileostomy with PSCs and then application of stoma cylinder.

When the stoma was surrounded by a gap as a consequence of debridement or massive subcutaneous infection, negative pressure wound therapy (NPWT) or vacuum-assisted closure (VAC) was applied first.⁺

In group 2 (Control group), the same steps were followed as in group 1, apart from using the cylinder appliance. Nutritional supplementation and electrolyte management in both groups were similar.

Follow-up of patients

Patients were followed up during the hospitalization



Fig 3: Application of stoma cylinder to ileostomy -with peristomal skin debridement due to necrotizing fasciitisallows application of VAC system enhancing healing and then abdominal closure.

period, and every three days after hospital discharge. The study endpoints were complete healing or the need for reoperation.

Study outcomes

The outcomes of the study were the differences between both groups in the reoperation rate, postmanagement recurrence of retraction, healing rate, and length of hospital stay.

Statistical analysis

The patients' data were analyzed using the statistical software SPSS (IBM, Armonk, New York, United States), version 26. Comparisons between categorical variables were made using the Chi-square test, Fisher's exact test, or Z test for proportion as appropriate. After normality testing,

independent t-test or Mann-Whitney test was used to compare numerical variables. A Kaplan-Meier analysis was used to assess the healing rate, and a Cox regression analysis was used to assess factors affecting healing time. P-values less than 0.05 were considered statistically significant.

Results

During the study period, 60 patients were included. Based on the eligibility criteria and acceptance to participate in the study, 14 patients were excluded. Then, 46 patients were enrolled in the two groups, with 23 in each group. One patient in group 1 and four patients in group 2 did not complete the study and were lost during the follow-up. Then, 41 patients were the final study population; 22 were in group 1 and 19 were in group 2 (**Figure 4**).



Fig 4: A stoma with PSCs then stoma cylinder & VAC application.

The patient's age ranged from 19 to 76 years, with a mean of 59.19 \pm 12.44 years. Males constituted 56.1% of cases (24 patients). Severe obesity (BMI \geq 40 kg/m2) was encountered in 8 patients (19.5%). Patients' associated comorbidities were diabetes mellitus (18 patients; 43.9%), hypertension (25 patients; 61%), dyslipidemia (27 patients; 65.9%), chronic interstitial chest disease (1 patient; 2.4%), and ischemic heart disease (7 patients; 17.1%). Patients in the two groups were matched in age, sex, the prevalence of severe obesity, and the prevalence of comorbidities (p>0.05) **(Table 1)**.

As for surgical data, the operative cause of stoma creation was laparotomy for intestinal obstruction in 16 patients (39%), traumatic bowel injury in 11 patients (24.9%), colorectal carcinoma in 7 patients (17.1%), inflammatory bowel perforation in 5 patients (12.2%), bowel injury during hysterectomy in 1 patient (2.4%), bowel injury during debulking of ovarian mass in 1 patient (2.4%), and traumatic fecal incontinence in 1 patient (2.4%). The stoma type was mainly colostomy (25 patients; 61%), followed by ileostomy (14 patients; 34.1%), and jejunostomy (2 patients; 4.9%). The patients of the two groups were comparable in the surgical data (p>0.05). All patients (100%) had stoma retraction. 23 patients (56.1%) had skin infections, 17 patients (41.5%) had irritant dermatitis, 15 patients (36.6%) had skin maceration, 12 patients (29.3%) had mechanical trauma, 8 patients (19.5%) had subcutaneous tracks. Seven patients (17.1%) had electrolyte imbalances. No statistically significant differences were found between both groups in the type of stoma complications (p>0.05) **(Table 2).**

Concerning the patients' outcome, four cases of recurrent stoma retraction (21.1%) were encountered in group 2, while no recurrence occurred in group 1 (p = 0.023). One patient in group 1 (4.5%) and six patients in group 2 (31.6%) indicated surgical reoperation. This difference was statistically significant (p=0.022). Reoperation was indicated due to obstruction, necrosis extending to the fascia, and recurrent stoma retraction. Patients with successful initial treatment had a length of hospital stay ranging from 7 to 15 days, and a complete epithelization in a period ranging from 10 to 18 days. Group 1 had a significantly lower hospital stay length (p<0.001) and time to complete epithelization (p<0.001) **(Table 3)**.

The Kaplan-Meier analysis revealed that using our cylinder appliance was significantly effective in decreasing the time to healing (p<0.001) (**Figure 5**). The Cox regression analysis demonstrated that the presence of peristomal skin infection and diabetes mellitus significantly affected the time of healing (p = 0.017 and 0.002, respectively).



Fig 5a: Stoma cylinder applied to Intestinal fistula isolating it from the surrounding raw area.



Fig 5c: VAC applied allowing better option for healing.



Fig 5b: Wound markedly improved after application of stoma cylinder.

Table 1: Baseline data of the study patients

		Group 1 (N=22)	Group 2 (N=19)	
		Mean ± SD, Me	p-value	
Age (years)		60.73 ± 12.22,	57.37 ± 12.78,	0.205
		63.5 (55-70)	60 (52-65)	0.395
		Count		
Gender	Female	9 (40.9)	8 (42.2)	0.04
	Male	13 (59.1)	11 (57.8)	0.94
BMI > 40.0 Kg/m ²		5 (22.7)	3 (15.8)	0.58
Comorbidities	Diabetes mellitus	11 (50)	7 (36.8)	0.85
	Hypertension	14 (63.6)	11 (57.8)	0.71
	Dyslipidemia	14 (63.6)	13 (68.4)	0.75
	IHD	4 (18.2)	3 (15.8)	0.84
	COPD	1 (4.5)	0 (0)	0.35

IHD: Ischemic heart disease, COPD: Chronic obstructive chest disease.

Table 2: Surgical history of the study patients

		Group 1 (N=22): Count (%)	Group 2 (N=19): Count (%)	p- value
Indicatio	ons of laparotomy			
Intestinal	obstruction	9 (40.9)	7 (36.8)	
Traumatio	bowel injury	5 (22.7)	6 (31.6)	
Colorecta	l carcinoma	4 (18.2)	3 (15.8)	
Inflammatory bowel perforation		2 (9.1)	3 (15.8)	0.73
Bowel injury during hysterectomy		0 (0)	1 (5.3)	
Bowel inj	ury during debulking of ovarian mass	1 (4.5)	0 (0)	
Traumatic fecal incontinence		1 (4.5)	0 (0)	
Stoma ty	уре			·
Colostomy		12(54.5)	13 (68.4)	
Ileostomy		10 (45.5)	4 (21.1)	0.11
Jejunostomy		0 (0)	2 (10.5)	
Stoma c	omplications			
Electrolyte imbalance		4 (18.2)	3 (15.8)	0.53
Stoma retraction		22 (100)	19 (100)	1
PSCs	Skin infections	10 (45.5)	10 (52.6)	0.65
	Irritant dermatitis	9 (40.9)	8 (42.1)	0.94
	Skin maceration	7 (31.8)	8 (42.1)	0.495
	Mechanical trauma	5 (22.7)	7 (36.8)	0.32
	Subcutaneous tracks	5 (22.7)	3 (15.8)	0.58

PSCs: Peristomal skin complications.

Table 3: The outcome of patients who completed conservative management

	Group 1 (N=21)	Group 2 (N=13)	p- value	
	Mean ± SD, Median (range)			
LOS (days)	9.62 ± 1.88, 9 (7-14)	12.38 ± 1.71, 12 (9-15)	<0.001*	
Epithelization time (days)	11.43 ± 1.6, 11 (10-15)	15.08 ± 1.61, 15 (12-18)	<0.001*	

LOS: Length of hospital stay.

Discussion

The health of the peristomal skin is a major factor in promoting positive outcomes for those living with stomas.¹⁰ Despite all efforts to prevent stoma complications, retracted stomas do often occur.⁷ A retracted stoma, with the stoma opening located deep in the abdominal plane, predisposes to significant leakage. Thus, the skin is exposed to a persistent chemical irritation that leads to its damage and progression to advanced wounds.¹¹ When PSCs occur, most of them can be managed conservatively.⁷

Advances in stoma technology have resulted in offering appliances that protect skin and control moisture.¹² However, recurrent leaks from the appliance may result in the persistence of the PSCs and delayed healing, which subsequently affects the patient's general health, leads to clothing damage, and may result in stigma and social embarrassment

for the patient.¹³ All these factors aggravate the patient's physical distress and poor general condition.

Traditionally, the idea of a stoma rod has evolved to preclude stoma traction.¹⁴ Nevertheless, a later pooled analysis demonstrated that the stoma rod did not affect the retraction rates. Furthermore, it was associated with a significant increase in the incidence of stoma necrosis and peristomal dermatitis.¹⁵

In this study, we adopted the use of a new, simple, and easily applicable appliance that provides extra barring of the stoma through cylinder-shaped plastic/silicone wrapping of the stoma, and hence prohibits any chance for leakage, supports the stoma not to retract, and offers more protection to the skin. We tested the efficacy of our appliance through a randomized controlled study that is one of the most robust evidence-based studies. Inspired by its advantages, we preferred the use of silicone for our appliance. Silicone is adequately flexible to adapt to the body contours, and it has a characteristically adhesive nature that offers placement stability. Silicone is a hygienic, hypoallergenic, and comfortable material that is nonabsorbable, non-toxic, and non-permeable to bacteria.¹²

In the current work, the group that underwent the stoma cylinder placement showed a significantly lower reoperation rate, non-recurrence of the retraction, shorter hospital stay, and less epithelization time, all of which reflect reduced patient burden and medical costs. No stoma cylinder-related complications were encountered. We argue that applying our stoma cylinder during the initial intervention would result in a considerable reduction in PSC rates. Despite the evolution of several appliances to help reduce PSCs,¹³ To the best of my knowledge, no studies assessed their use in a cohort that already had developed stoma retraction and PSCs. Moreover, our appliance is simple, easily constructed, and suitable for low-resource settings, compared to other appliances that are associated with increased medical costs.

Other attempts to provide a simple, low-cost appliance for controlling PSCs were presented by Davis and colleagues (2020). They provided an external stoma diversion through a condom and a bottle to control PSCs.¹⁶ Despite this being a cost-effective simple method, it was investigated on one patient only in a case report.¹⁶ Moreover, it is suitable only for temporary use. Using a bottle would not be easily accepted by the patients and likely not be easily applicable.

Numerous factors, both intrinsic and extrinsic, can alter the normal physiology of the skin.¹⁷ In this study, the presence of peristomal skin infection and diabetes mellitus significantly affected the time of healing. Our findings are consistent with the fact that infection has been found to commonly impact wound healing.¹⁸ Bacteria release toxins that lead to injury of wound tissue vessels, which results in hypoxemia and acidosis, and in turn, leads to a resumption of bleeding.¹⁹ In addition, bacteria have been shown to inhibit endothelial regeneration.²⁰ Platelets are proposed to bind to bacteria, with consequent local thrombosis. This also establishes a hypoxic environment that assists in the proliferation of bacteria.²¹

As for diabetes mellitus, it is a well-established risk factor for impaired healing.²² Hyperglycemia is associated with microvascular dysfunction, leading to decreased oxygenation of tissues.²³ Hyperglycemia may also disturb leukocyte function.²⁴ In addition, diabetes mellitus-related altered sympathetic and motor functions disturb normal skin physiology.²⁴ We believe that our adopted stoma cylinder should be routinely considered during stoma care protocol. This study is, however, limited by the relatively small sample size and the limited follow-up period.

Conclusion

In conclusion, we adopted a new, simple, feasible, and safe appliance. Using a stoma cylinder was associated with overall better patient outcomes and less cost. It offered high rates of successful stoma retraction and PSC treatment without complications.

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