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ORIGINAL ARTICLE

Placement of SurgiWrap® adhesion barrier film around the protective loop stoma after laparoscopic colorectal cancer surgery may reduce the peristomal adhesion severity and facilitate the closure

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Abstract

Purpose A temporary loop stoma is often created after laparoscopic colorectal cancer surgery. Peristomal adhesions may make stoma closure into a complicated operation. We demonstrated how to place the SurgiWrap® adhesion barrier film and evaluated the peristomal adhesion severity and feasibility of stoma closure.

Methods This is a retrospective case-control study. Patients were divided into a study group (placement of adhesion barrier film) and a control group (no placement). Patient characteristics, operative data, and severity of adhesions were recorded. We used logistic regression to probe the association between the variables and the adhesion severity.

Results A total of 180 patients were identified with 60 in the study group and 120 in the control group. In the study group, the adhesion severity ($p < 0.001$), operative time ($p = 0.025$), and time to flatus ($p = 0.042$) are significantly reduced. In logistic regression analysis, placement of the film ($p < 0.001$), neoadjuvant concurrent chemoradiotherapy ($p = 0.041$), and time interval between stoma creation and closure ≧ 12 weeks ($p = 0.038$) are three significant factors influencing the peristomal adhesion.

Conclusion The placement of SurgiWrap® adhesion barrier film around the loop stoma after laparoscopic colorectal cancer surgery may reduce the peristomal adhesion severity and facilitate the stoma closure in terms of operative time and time to flatus.

Keywords Colorectal cancer · Adhesion · Stoma · Laparoscopy

Introduction

Intra-abdominal adhesions develop in more than 90% of patients after abdominal surgery [1]. These adhesions are known to cause pain, infertility, and small bowel obstruction with prolonged ileus [2–4]. During the repeat abdominal operation, adhesions necessitate adhesiolysis, leading to increased operating times and substantial risk of complications [5, 6], which carry major health and socioeconomic costs [7, 8].

A temporary loop stoma is commonly undertaken to minimize the complication of an anastomotic leak after a low colorectal anastomosis. Loop stoma is often closed after 6–12 weeks when the intestinal edema is recovered and the intra-abdominal adhesions are diminished. This period is long enough for anastomotic healing, which is usually achieved by the second week after operation [9]. However, adhesions may cause serious complications and make stoma closure into a complicated and prolonged operation [10].

A number of products, in the form of film or fluid, are widely used to prevent postoperative adhesion formation [11]. These products normally serve as barriers to separate the contact of the damaged tissue surfaces. Of all the clinically available adhesion barriers, hyaluronate/carboxymethylcellulose barrier film (Seprafilm®, Sanofi, Paris, France) and polyactide (PLA) barrier film (SurgiWrap®, MAST Biosurgery USA, Inc. San Diego, CA) have demonstrated consistent evidence for reducing adhesions in abdominal surgery [12]. In a previous study [9, 10], the placement of Seprafilm® around the loop ileostomy during an open surgery can reduce the peristomal adhesion.

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However, Seprafilm® has limitations through poor handling characteristics because it is sticky on both sides [4] especially during laparoscopic surgery, which makes it difficult to be placed around the stoma. SurgiWrap® is another kind of adhesion barrier film, made from the PLA, which results from a lactic acid derivative that occurs naturally in the human body [13]. Compared with the Seprafilm®, it is not sticky on both sides, resulting in better handling characteristics, especially for laparoscopic colorectal surgery.

In many countries, laparoscopic colorectal resection for malignancy has gained popularity [14]. In the review of the literature, there are no studies focusing on the placement of SurgiWrap® adhesion barrier film around the protective loop stoma after laparoscopic colorectal surgery and the severity of peristomal adhesion during the stoma closure. So in this study, we demonstrated how to place the SurgiWrap® adhesion barrier film around the protective loop stoma after laparoscopic colorectal surgery in a video and conducted a retrospective case-control analysis to evaluate the peristomal adhesion severity and feasibility of stoma closure in terms of operative results and outcomes.

Method

We conducted a retrospective case-control study by reviewing the charts of patients with the protective stoma after laparoscopic colorectal cancer surgery between October 2009 and September 2018 consecutively at Kaohsiung Veterans General Hospital by a single surgeon, C-W Hsu. A total of 224 patients were registered. Patients with conversion to open surgery ($n = 14$), perforation or peritonitis ($n = 10$), stage IV disease with unresectable peritoneal metastasis ($n = 9$), and poor performance status with an Eastern Cooperative Oncology Group (ECOG) score > 3 ($n = 7$) were excluded from this study. There are two different sizes of SurgiWrap® barrier film: large size (13 × 20 cm, $600 USD) and small size (11 × 13 cm, $450 USD). There were only 4 patients with a large-sized barrier film, who were excluded due to limited number. Ultimately, a total of 60 patients with a small-sized barrier film placement were enrolled in this study. During the same period, a total of 120 patients without film placement were enrolled as the control group.

Patient characteristic data included age, gender, use of neoadjuvant concurrent chemoradiotherapy (CCRT), operative procedure, types of stoma creation, placement of barrier film, size of the barrier film, and time interval from stoma creation to closure. The patients receiving neoadjuvant CCRT for advanced rectal or rectosigmoid cancer would undergo radical surgery 10–12 weeks later. In our computerized surgical chart recording system, the surgeon had to complete all the items in the operation note including the operative time, blood loss, and severity of adhesions which is classified according to the 4-grading scale: nil, mild (adhesions that are filmy and easy to separate by blunt dissection), moderate (adhesions where blunt dissection is possible but sharp dissection necessary, with vascularization), severe (lysis of adhesions possible by sharp dissection only, organs strongly attached with severe adhesions, damage of organs hardly preventable). Other perioperative data included time to flatus, time to diet, hospital stay, and perioperative complications.

Surgical technique of placement of adhesion barrier (see video)

After the whole procedure of laparoscopic colorectal cancer surgery, the site of protective loop stoma was created over the abdomen. First, we create a proper size of defect for stoma in the center of the adhesion barrier film (SurgiWrap®, small size, 11 × 13 cm) and assure 3 cm at least of coverage outside the stoma (Fig. 1). Then, we introduce the film into the abdominal cavity through the specimen retrieval wound over the umbilicus. We pull a segment of the bowel through the film defect and the abdominal wall for stoma creation (Fig. 2a). We re-create the pneumoperitoneum and use a laparoscopic instrument to smooth out the film all around the stoma site (Fig. 2b, c).

Stoma closure is undertaken when an anastomosis has healed and when there is no evidence of distal obstruction of the disease. The integrity of the bowel below the stoma needs to be verified by colonoscopy or contrast radiology. We start the stoma closure by making a circumstomal incision requiring a careful mobilization of the stoma from the skin,

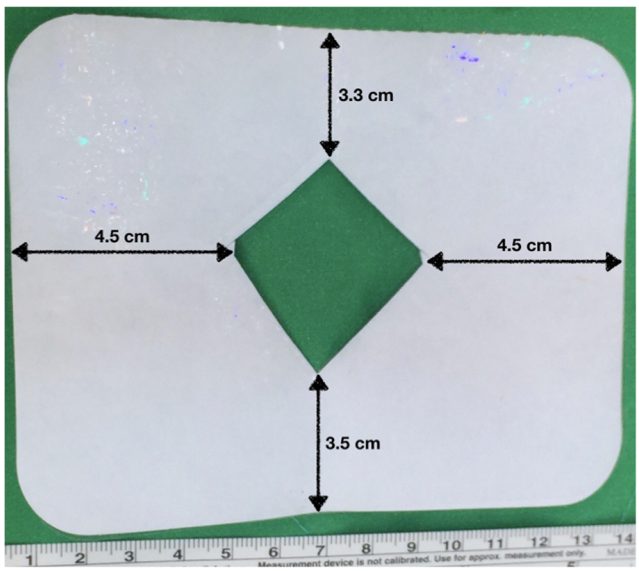

Fig. 1 A proper size of defect for stoma in the center of the barrier film and assure 3 cm at least of coverage outside the stoma

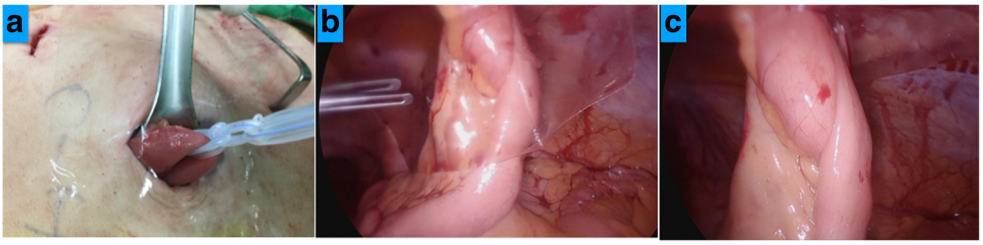

Fig. 2 **a** Introduction of the film into the abdominal cavity through the specimen retrieval wound over the umbilicus. **b** Then, retrieval of a segment of the ileum through the film defect and the abdominal wall for stoma creation. **b**, **c** Use of an laparoscopic instrument to smooth out the film all around the stoma

subcutaneous tissues, and rectus muscle so that the bowel is completely free within the peritoneal cavity. The edges of the stoma are excised and are closed transversely using a continuous 3-0 MONOCRYL® plus antibacterial suture and interrupted silk sutures. After the procedure, the operative time and the estimated blood loss were recorded. The severity of adhesions was recorded as nil, mild, moderate, or severe by the operating surgeon according to our adhesion 4-grading scale.

In the postoperative period, the patients routinely started water intake when the flatus formation was present without abdominal discomfort or fullness. Then, oral intake with soft diet would be started 1 day later when water intake was acceptable. Once the patients had surgical wound infection, the wound would be left open for wet dressing or debridement. Once an anastomotic leakage was suspected, the wound would be left open for secondary healing without any oral intake until the wound was clear. During this period, if any signs of peritonitis were suspected, the surgical intervention would be performed, such as peritoneal lavage with or without re-anastomosis. Finally, the patients would be discharged when oral intake was fine without surgical complications. The hospital stay was defined from the date of stoma closure to discharge.

Results were displayed as the mean, percentage, standard deviation (SD), and range of value. Student's *t* test and chi-square were used to analyze the association between the study group and the control group. We also used multivariate logistic regression analysis to probe the association between the possible variables and the probability of adhesion severity. All data were analyzed by using SPSS®, version 12.0 (SPSS Inc., Chicago, IL). $P < 0.05$ was accepted as statistically significant.

Results

A total of 180 patients were identified with 60 patients in the study group and 120 patients in the control group. Patients' characteristics data are shown in Table 1. There were no distribution differences regarding the age, gender, operative procedure, neoadjuvant CCRT, colostomy or ileostomy, and time interval from stoma creation to closure. Operative and outcome data are shown in Table 2. There were 8 patients (13.3%) in the study group that had complications (wound infection in 5 and minor leakage in 3) and 19 patients (15.8%) in the control group (wound infection in 14 and minor leakage in 5). There were no patients with major anastomosis leakage demanding surgical intervention such as peritoneal lavage or re-anastomosis in this cohort. Regarding the adhesion grading scale in the study group, 38 patients (63.3%) had mild adhesions, 22 patients (36.3%) had mild adhesions, and no patient had severe adhesions. In the control group, 30 patients (25%) had mild adhesions, 66 patients (55%) had mild adhesions, and 24 patients (20%) had severe adhesions. There were significant differences between the two groups ($p < 0.001$). In the study group, there is 1 patient where we used laparoscopy to examine the abdominal cavity during the closure of the stoma to exclude the peritoneal seeding. We observed that there were mild adhesions around the stoma (Fig. 3).

In the meanwhile, there were also significant differences regarding the operative time (32.1 ± 25.4 vs. 49.4 ± 31.2, $p = 0.025$) and time to flatus (2.3 ± 1.2 vs. 2.8 ± 2.2, $p = 0.042$, Table 2). However, there were no significant differences regarding the blood loss ($p = 0.067$), time to diet ($p = 0.123$), hospital stay ($p = 0.272$), and perioperative complications ($p = 0.561$). In the logistic regression analysis, we regrouped the severity of adhesions into two groups (mild vs. moderate + severe) to probe the association between the possible factors and the probability of adhesions severity. The results of logistic regression are presented in Table 3. In univariate analysis, the factors influencing peristomal adhesions were the placement of barrier film (OR = 5.43, 95% CI = 3.97–9.53, $p < 0.001$), neoadjuvant CCRT (OR = 2.31, 95% CI = 1.79–8.85, $p = 0.034$), and time interval from stoma creation to closure ≧ 12 weeks (OR = 4.38, 95% CI = 2.74–3.52, $p = 0.042$). In multivariate analysis, the significant factors influencing peristomal adhesions were the placement of the barrier film (OR = 4.59, 95% CI = 4.71–10.38, $p < 0.001$), neoadjuvant CCRT (OR = 21.89, 95% CI = 2.56–9.52, $p = 0.041$), and time interval from stoma creation to closure ≧ 12 weeks (OR = 2.56, 95% CI = 3.38–5.51, $p = 0.038$).

Table 1 Clinical characteristics of the study group and control group

Clinical characteristics	Study group ($n = 60$)	Control group ($n = 120$)	p value
Age	61.4 ± 11.2 (33–82)	56.4 ± 17.2 (40–88)	0.478
Female/male	26/34	42/78	0.59
Procedure			0.106
Low anterior resection	28	67	
Anterior resection	18	37	
Left hemicolectomy	8	4	
Subtotal colectomy	4	6	
Right hemicolectomy	2	6	
Neoadjuvant CCRT			0.733
Rectal cancer	13	30	
Rectosigmoid cancer	7	7	
Type of stoma			0.496
Transverse loop colostomy	39	84	
Loop ileostomy	21	36	
Interval from stoma creation to closure (weeks)	11.2 ± 4.9 (10–21)	12.5 ± 6.7 (9–19)	0.523

CCRT, concurrent chemoradiotherapy

Discussion

In literature review, this is the first study demonstrating the placement of the SurgiWrap® adhesion barrier film around the protective loop stoma after laparoscopic colorectal cancer surgery and comparing the peristomal adhesion severity and feasibility of stoma closure between patients with and without the use of an adhesion barrier film placement. In patients with film placement around the stoma, the adhesion severity ($p < 0.001$), operative time ($p = 0.025$), and time to flatus ($p = 0.042$) are significantly reduced. In logistic regression analysis, placement of the film is also a significant factor influencing the peristomal adhesion ($p < 0.001$).

In our hospital, the stoma closure is performed at least 2 months after the creation. This time period interval is necessary for the resolution of peristomal adhesion and anastomotic healing [9]. A previous study [15] also showed stoma closed sooner than 12 weeks after creation had twice the incidence of complications than those which were closed after that time. Our study demonstrated that interval between stoma creation and closure more than 12 weeks is a significant factor influencing the peristomal adhesion ($p < 0.001$). Conversely, some studies found that the time interval between stoma creation and closure did not affect morbidity [16, 17].

In 2006, a similar study [10] was conducted in patients with Seprafilm® around the stoma (mainly loop ileostomy in open surgery). There were significantly more adhesions around the stoma in patients without Seprafilm® (95.2% vs. 82.3%, $p = 0.021$). However, Seprafilm®, which is composed of hyaluronate and carboxymethylcellulose, is very fragile when in contact with the body fluid [4]. Therefore, it is not suitable for placement around the stoma in laparoscopic surgery. By

Table 2 Operative and outcome data of the study group and control group

Operative data	Study group ($n = 60$)	Control group ($n = 120$)	p value
Adhesion grading			< 0.001
Mild	38 (63.3%)	30 (25%)	
Moderate	22 (36.3%)	66 (55%)	
Severe	0	24 (20%)	
Operative time (min)	32.1 ± 25.4 (19–93)	49.4 ± 31.2 (33–108)	0.025
Blood loss (ml)	15.3 ± 6.2 (0–25)	31.4 ± 29.2 (0–100)	0.067
Time to flatus (day)	2.3 ± 1.2 (1–4)	2.8 ± 2.2 (1–7)	0.042
Time to diet (day)	3.4 ± 2.2 (2–5)	3.9 ± 2.8 (2–10)	0.123
Hospital stay (day)	6.4 ± 3.2 (5–12)	7.5 ± 4.2 (5–21)	0.272
Complications	8 (13.3%)	19 (15.8%)	0.561
Wound infection	5	14	
Minor leakage	3	5	

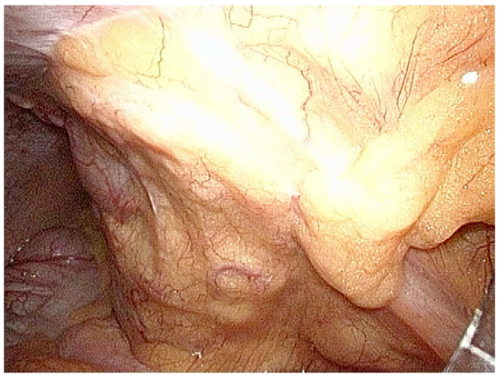

Fig.3 A 71-year-old male received laparoscopic low anterior resection and placement of adhesion barrier film around the loop ileostomy. Two months later, the peristomal adhesion was mild during laparoscopic examination

contrast, the SurgiWrap® is made from an amorphous bioresorbable copolymer, which is a synthetic match to the natural lactic acid produced in the body. This material retains significant tensile strength for the initial 8 weeks and decreases in a controlled fashion through 24 weeks of aging [13]. Therefore, it is not easy to be torn when in contact with the body fluid and surgical instrument, especially in laparoscopic surgery. In patients with a SurgiWrap® around the stoma, 38 patients (63.3%) had mild adhesions, 22 patients (36.3%) had mild adhesions, and no patients had severe adhesions. This result had a significant difference in comparison to patients without SurgiWrap® ($p < 0.001$).

About the severity of adhesions during the initial abdominal operation, Zühlke et al. proposed the Zühlke classification [18] and the extent of adhesions is also scored as the number of quadrants containing adhesions [19]. This is a 5-scale classification (range from 0 to 5). In our hospital, we modified the Zühlke classification into a 4-scale classification (nil, mild, moderate, severe) in our computerized operative reporting system. The score 2 and score 3 in the Zühlke classification were merged together into "moderate." This classification is user-friendlier for the operating surgeons. However, the judgment of the peristomal adhesion grading is very objective to a surgeon, which could be a potential bias in this study.

In our hospital, there were more patients receiving loop colostomy (68%) than loop ileostomy (32%). Ileostomy has some concerns, including high-volume output with high incidence rate of fluid and electrolyte imbalance compared with loop colostomy especially in elderly patients [20–22]. In logistic regression analysis, the type of stoma did not affect the severity of peristomal adhesion.

Abdominopelvic radiation used for the treatment of a variety of malignancies, including colorectal cancer, can cause adhesions as a late sequela, the severity of which depends on the anatomic extent of the area treated, the degree of dose fractionation, and the total dose of radiation [23]. There were 20 patients (33.3%) in the study group and 37 patients (30.8%) in the control group receiving neoadjuvant CCRT including infusion or oral 5-fluorouracil with radiation 5040 Gy in 25 fractions. In logistic regression analysis,

Table 3 Logistic regression analysis of factors influencing peristomal adhesions

Factors	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p* value	OR	95% CI	*p* value
Age (years)			0.561			0.475
≧ 60	1.34	0.34–4.75		1.22	0.22–5.28	
< 60	1	Reference		1	Reference	
Gender			0.785			0.853
Male	1.28	0.12–6.53		1.25	0.29–6.49	
Female	1	Reference		1	Reference	
Placement of barrier film			< 0.001			< 0.001
No	5.43	3.97–9.53		4.59	4.71–10.38	
Yes	1	Reference		1	Reference	
Type of stoma						0.427
Transverse loop colostomy	1.22	6.48–7.44		1.17	3.25–6.18	
Loop ileostomy	1	Reference		1	Reference	
Neoadjuvant CCRT			0.034			0.041
Yes	2.31	1.79–8.85		1.89	2.56–9.52	
No	1	Reference		1	Reference	
Interval to closure (weeks)			0.042			0.038
< 12	4.38	2.74–3.52		2.56	3.38–5.51	
≧ 12	1	Reference		1	Reference	

neoadjuvant CCRT is a significant factor influencing the severity of peristomal adhesion.

There are some limitations to our study. First, the judgment of the peristomal adhesion grading is very objective to the operative surgeons, which could be a potential bias. Second, this is a retrospective case-control study in nature. The patient selection bias could be a limitation. Finally, a prospective randomized controlled study should be performed to confirm the results.

In conclusion, the placement of SurgiWrap® adhesion barrier film around the protective loop stoma after laparoscopic colorectal cancer surgery may reduce the peristomal adhesion severity and facilitate the stoma closure in terms of operative time and time to flatus. Other factors influencing the peristomal adhesions included the time interval from stoma creation to closure (more than 12 weeks) and neoadjuvant CCRT.

Author contribution Chao-Wen Hsu: study concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; statistical analysis.

Min-Chi Chang, Chih-Chien Wu, Yu-Hsun Chen: acquisition of data.

Jui-Ho Wang: critical revision of the manuscript for import and intellectual content.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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