

Foreign body reaction mimicking local recurrence from polyactide adhesion barrier film after laparoscopic colorectal cancer surgery

A retrospective cohort study

Tien-Chan Hsieh, MD^{a,b,c} , Chao-Wen Hsu, MD^{a,d,*} 

Abstract

Polyactide (PLA) barrier is one of the most commonly used materials to prevent the formation of postoperative adhesion. Even though previous studies supported the anti-adhesion efficacy of PLA barrier, there have been limited reports focusing on the associated foreign body reaction. We sought to investigate the potential complication of PLA barrier placement that could lead to unnecessary intervention.

This is a retrospective study of colorectal cancer patients with laparoscopic surgery. Cases with stage IV unresectable disease, poor Eastern Cooperative Oncology Group Performance, death within 3 months after the surgery, and insufficient record were excluded. A total of 296 cases were identified in our study and 220 patients received PLA film placement. We compared the incidence of foreign body reaction between the patients with and without PLA film.

Among PLA film group, 16 cases had signs of local recurrence on the follow-up image studies. The subsequent operation found 10 patients had no cancerous lesions but only foreign-body-associated granulomas. The incidence of foreign body reaction mimicking local recurrence on image study was 4.5% with high false positive rate of 62.5% on positron emission tomography scan in patients with PLA film. There were only 2 cases without the antiadhesive barrier developed signs of recurrence during active surveillance. Both cases were later confirmed to have malignant peritoneal seeding.

The PLA film was associated with rare foreign body reaction that could interfere the accuracy of follow-up program and result in unnecessary surgical intervention. Hence, we recommend avoiding the use of the PLA barrier.

Abbreviations: CT = computed tomography, ECOG = Eastern Cooperative Oncology Group, FDG = ¹⁸F-fluorodeoxyglucose, PET = positron emission tomography, PLA = polyactide, SUVmax = maximal standardized uptake value.

Keywords: antiadhesive film, colorectal cancer, foreign-body reaction, laparoscopy

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The data that support the findings of this study are available from a third party, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are available from the authors upon reasonable request and with permission of the third party.

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1. Introduction

Postoperative adhesion is common and usually clinically silent. However, it can potentially cause significant morbidity, such as bowel obstruction, infertility, chronic pain.^[1] The formation of adhesion is a result of tissue damage during the operation, which induces inflammatory reaction and tissue cells proliferation and regeneration.^[2] Increasing efforts such as antiadhesive barriers have been developed to prevent postoperative adhesion.^[3]

The anti-adhesive barriers, in the form of film, solution or gel, mainly function by covering the surgical wound and preventing contact with surrounding tissues. They are often coated with antiadhesive agents that have fibrinolytic, anti-inflammatory activities.^[3] These products have been used widely and demonstrated evidence of lower adhesive complications.^[4–6]

Despite the proposed anti-inflammatory mechanism of these barriers, recent studies reported that the chronic inflammatory response to the polyactide (PLA) adhesion barrier could mimic local recurrence in gynecological malignancies.^[7–9] In these reported cases, laparoscopic exploration indicated by the positive image studies only identified foreign body reaction without malignancy. The chronic inflammatory reactions associated with antiadhesive barriers can interfere with follow-up image studies, such as ¹⁸F-fluorodeoxyglucose (FDG)-positron emission tomography (PET)/computed tomography (CT), and lead to unnecessary operations. PET-CT has been shown as a both sensitive and specific tool to detect distant lymph node metastases and predict prognosis of colorectal cancer. The maximal standardized uptake value (SUVmax) of FDG activity is associated with malignant

lymph node lesions and poor prognosis. The high SUVmax of undesirable foreign body reaction can be falsely interpreted as local recurrence.

To our best knowledge, there is no study in the field of laparoscopic colorectal cancer surgery focusing on the foreign-body granuloma formation associated with the placement of antiadhesive barriers. Here we present this retrospective study on the foreign body reaction related to PLA adhesion barrier film, one of the antiadhesive barriers in laparoscopic colorectal cancer surgery.

2. Methods

2.1. Data collection and literature review

We conducted a retrospective study by reviewing our digitalized medical charts of patients who received laparoscopic colorectal

cancer surgery between January 2015 and February 2020 consecutively at Kaohsiung Veterans General Hospital, Taiwan. Patients with stage IV colorectal cancer with unresectable metastasis ($n=9$), poor performance status with an Eastern Cooperative Oncology Group score >3 ($n=7$), death within 3 months after surgery ($n=5$), and incomplete information ($n=10$) were excluded from this study. A total of 296 patients were registered. Among them, 220 patients receiving the SurgiWrap PLA adhesion barrier adhesion barrier film placement after laparoscopic colorectal cancer surgery (Fig. 1). Fisher exact test was used to analyze the incidence of foreign body reaction. We searched the relevant studies by connecting keywords “antiadhesion”, “adhesion barrier”, and “local recurrence” in MEDLINE and PubMed with “OR” from year 2011 to 2021.

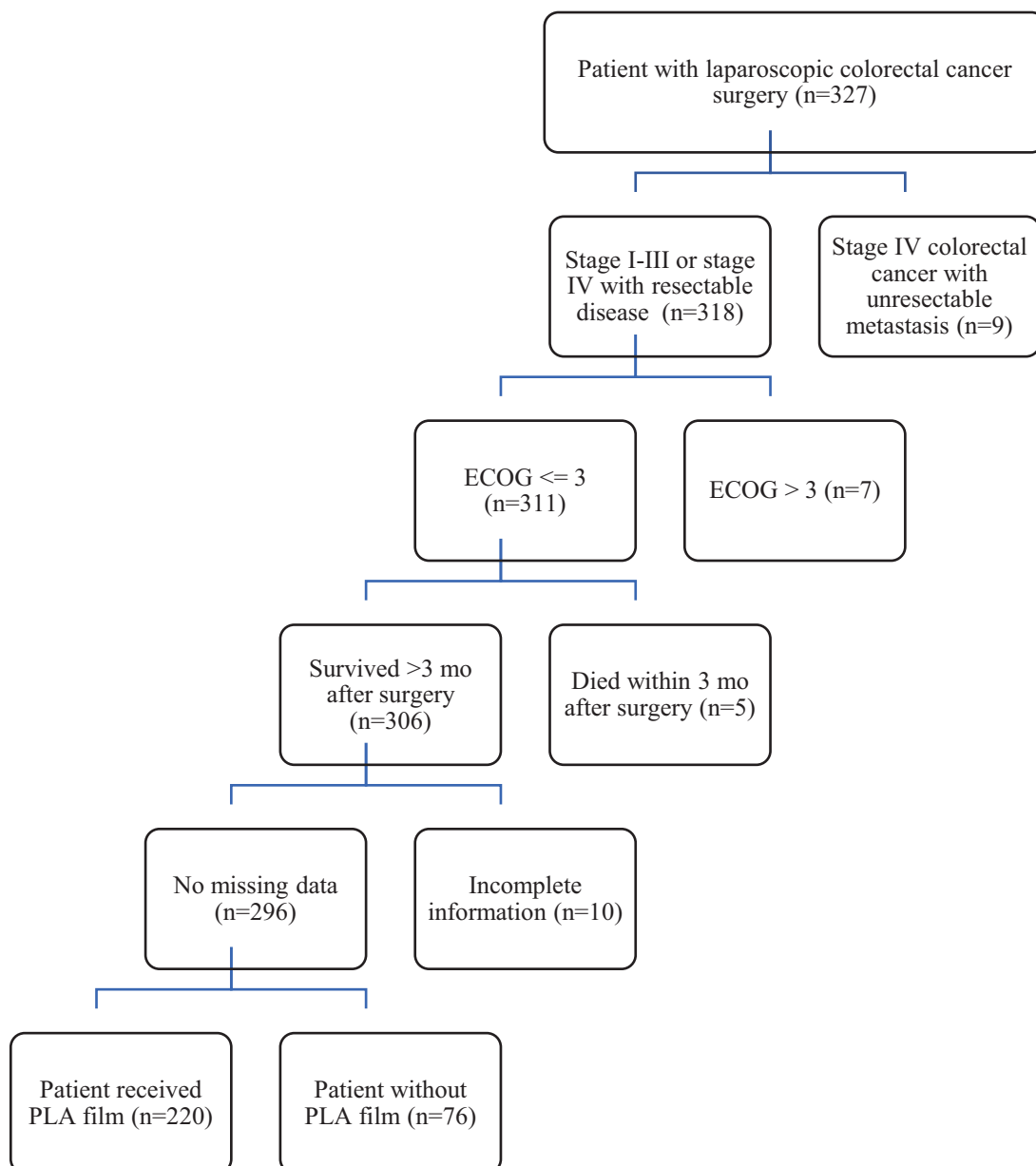


Figure 1. Flow diagram of inclusion and exclusion criteria applied. ECOG = Eastern Cooperative Oncology Group, mo=months, PLA = polyactide.

2.2. Placement of PLA adhesion barrier film

After the whole procedure of colorectal cancer resection, we placed the SurgiWrap film, the PLA barrier film (MAST Biosurgery USA, Inc. San Diego, CA), below the laparoscopic specimen retrieval wound. The choice of the film size was decided by the wound size. The film should be placed smoothly inside the abdominal cavity, covered at least 2 cm around the wound and be fixed on the fascial layer by 1 or 2 stitches (Fig. 2 & Video, Supplemental Digital Content, <http://links.lww.com/MD/G605>)

2.3. Follow-up program

After the surgery, the routine follow-up procedures included serum CEA (every 3 months for 2 years), chest X-ray (every 6 months for 2 years), abdominal CT scan (every 6 months for first 1 year and every year for 5 years), and colonoscopy (every year for 3 years). Once peritoneal seeding or carcinomatosis were noted at CT scan, PET scan would be arranged for differential diagnosis.

2.4. PET scan protocol and measurement of SUVmax

We adapted the protocol of ^{18}F -FDG-PET/CT described in previous published literature for differential diagnosis of suspicious lesions in our follow-up program.^[10,11] Once the diagnosis of limited peritoneal seeding or carcinomatosis was confirmed by PET/CT, surgical removal would be suggested for curative intent.

IRB approval and written consent: this is not required for our study.

3. Results

In 76 patients without the PLA adhesion barrier film placement after laparoscopic colorectal cancer surgery, there were 2 patients had suspicious limited peritoneal seedings during the abdominal CT scan follow-up and confirmed by PET scan. Surgical removal was performed in these 2 patients and both had definite malignant peritoneal seeding in pathologic exam.

On the contrary, among 220 patients with the PLA adhesion barrier film, 16 patients had suspicious limited peritoneal seedings during the abdominal CT scan follow-up and confirmed by PET scan. Surgical removal was performed in these 16 patients and pathological exam found no true cancerous lesions but granulomas consistent with foreign body reaction in 10 patients. Therefore, the false positive rate of the PET scan protocol was 62.5% (10/16) while screening for disease recurrence among the patients with PLA film. The incidence of foreign body reaction mimicking local recurrence was 4.5% (10/220) in patients with a history of the PLA adhesion barrier film. According to this obvious result, we stopped using the PLA adhesion barrier film placement after laparoscopic colorectal cancer surgery since February 2020.

The 10 patients' characteristics were described in Table 1. The average age is 69.4 years old. Nine cases were male and 1 was female without previous evidence of metastasis. The time lapse between PLA film placement to the second operation ranged from 7 to 36 months (mean 14.3 months). The mean of size and SUVmax of suspicious lesions detected by PET scan were 2.4 cm and 4.3, respectively. In all 10 cases, despite the initial positive findings of PET/CT, the final pathological confirmation did not find any reoccurrence but pictures of foreign body reaction. The in-depth review and surgery video were available for all the patients receiving surgical removal of peritoneal seeding. We presented the surgical recording of 3 patients in our study (Video, Supplemental Digital Content, <http://links.lww.com/MD/G605>).

Patient 1 was a 69-year-old male who had laparoscopic anterior resection for sigmoid colon adenocarcinoma with stage I (pT1N0M0). The regular follow-up PET/CT identified a suspicious nodule in left posterior peritoneum (Fig. 3A). Laparoscopic exploration and excision were performed due to high suspicion of reoccurrence. The isolated gray-white soft tumor was found under laparoscopy (Fig. 3B) and sent for pathological study, which later revealed a well-circumscribed nodular lesion without evidence of malignancy (Fig. 3C & D).

Patient 2 was a 45-year-old male with a history of rectal adenocarcinoma stage IIIB (ypT3N2aM0) underwent laparoscopic low anterior resection. The regular follow-up PET/CT located a single lesion near the splenic flexure of omentum 7

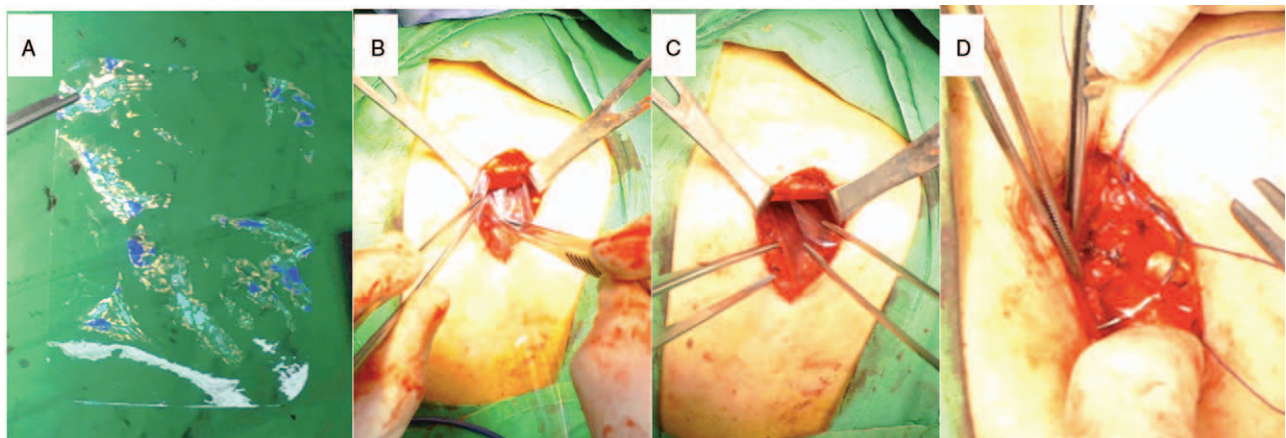


Figure 2. Illustration of PLA adhesion barrier film placement. After the surgery, we placed the PLA film below the specimen retrieval wound. (A) First, prepare the film, choose the appropriate size. (B) & (C) Introduce the film into the abdominal cavity by forceps through the abdominal wound. (D) Fix the film on the fascial layer by 1 or 2 stitches. PLA = polylactide.

Table 1**Characteristics of patients with foreign body reaction mimicking tumor recurrence.**

Patient	Age	Gender	Primary site	Stage	Follow-up (mo)	Size (cm)	SUVmax	Tumor site	Pathology
1	69	M	Sigmoid	pT1N0M0, I	17	0.8	2.8	Left retroperitoneum	Foreign-body granuloma
2	45	M	Rectum	ypT3N2aM0, IIIb	7	2	5.8	Omentum	Fat necrosis with calcification
3	70	M	Rectum	ypT3N0M0, IIa	9	5	6.1	Mesosigmoid	Chronic inflammation and fibrosis
4	76	M	Rectum	pT3N0M0, IIa	14	2.1	5.1	Ileal mesentery	Foreign-body granuloma
5	74	M	Rectum	pT3N0M0, IIa	15	2	3.8	Presacral	Foreign-body granuloma
6	68	M	Cecum	pT2N0M0, I	10	4	6	Preaortic region	Chronic inflammation and fibrosis
7	76	M	Sigmoid	pT2N1aM0, IIa	36	3	4.7	Below the wound	Foreign-body granuloma
8	70	M	Sigmoid	pT1N0M0, I	16	0.7	2.9	Left abdominal wall	Foreign-body granuloma
9	75	M	Descending	pT3N0M0, IIa	12	1.1	3.1	Below the wound	Foreign-body granuloma
10	71	F	Cecum	pT4aN1bM0, IIIc	7	3	2.6	Around the wound	Foreign-body granuloma

SUVmax = maximal standardized uptake value.

months later (Fig. 4A). Subsequent laparoscopy identified and removed a solid tumor in the greater omentum (Fig. 4B). Pathological study of the surgical specimen showed a picture of fat necrosis, calcification, and histiocyte aggregation without evidence of neoplasm (Fig. 4C & D).

Patient 3 was a 70-year-old male with rectal adenocarcinoma that was treated with neoadjuvant concurrent chemotherapy and laparoscopic low anterior resection (ypT3N0M0, stage IIa). Routine follow-up PET/CT showed an enlarging mass in mesosigmoid near the abdominal aorta (Fig. 5A). During the

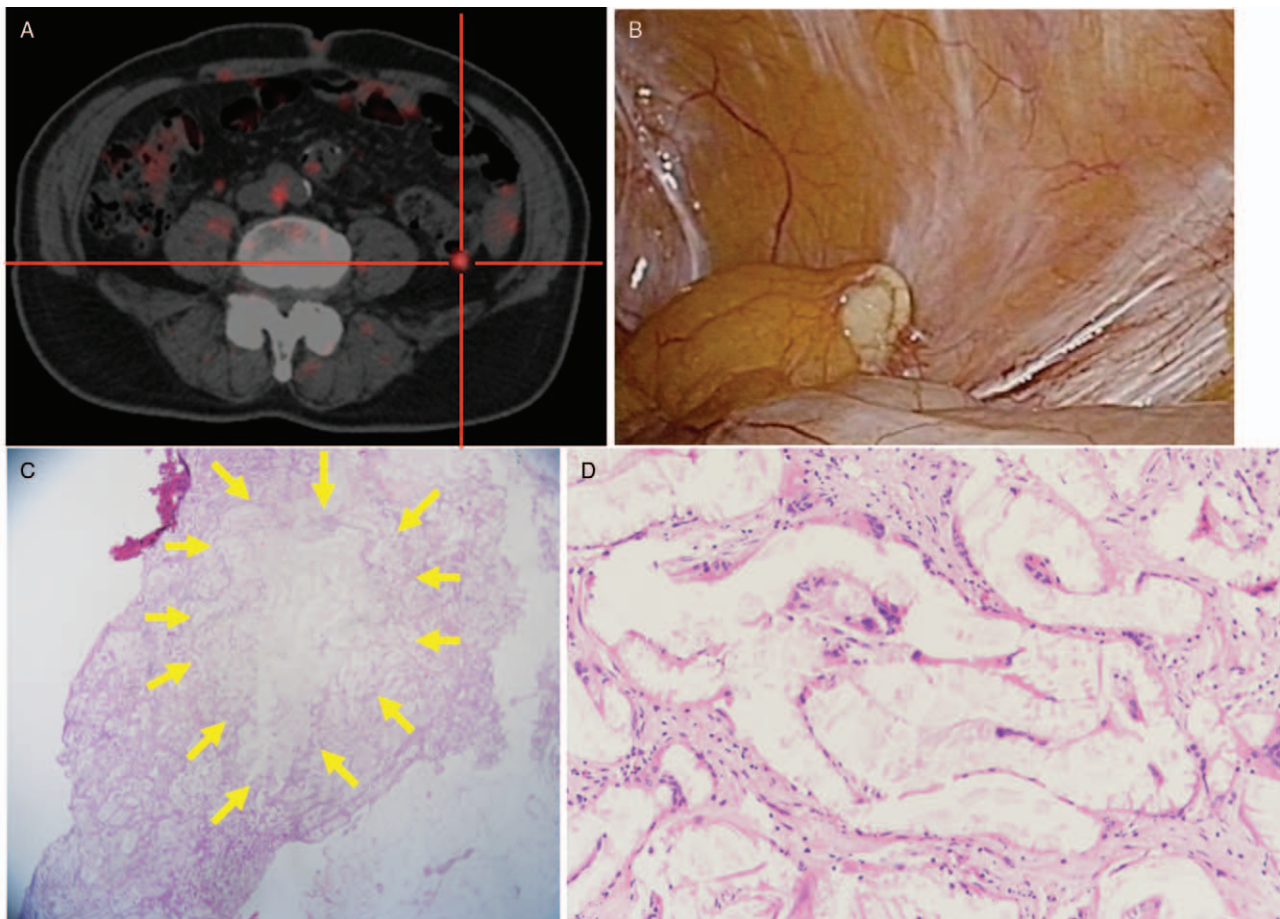


Figure 3. PET/CT scan, surgical images and pathology section of Patient 1. (A) During the regular follow-up 17 mo later, PET/CT revealed a 0.8 cm FDG-avid nodule in left posterior peritoneum (SUVmax: 2.8). (B) A gray-white soft tumor, 2 cm, was located in the white line of descending colon. (C) Hematoxylin-eosin section (100 \times) showed foreign-body granuloma (arrow), featuring well-circumscribed nodular lesions containing washed-out empty streaks and foreign body tissue reaction. (D) Hematoxylin-eosin section (400 \times) showed periodic acid-Schiff-negative pale amorphous foreign material surrounded by multinucleated giant cells, fibrosis, and chronic inflammation without evidence of neoplasm. CT = computed tomography, FDG = 18F-fluorodeoxyglucose, PET = positron emission tomography, PLA = polylactide, SUVmax = maximal standardized uptake value.

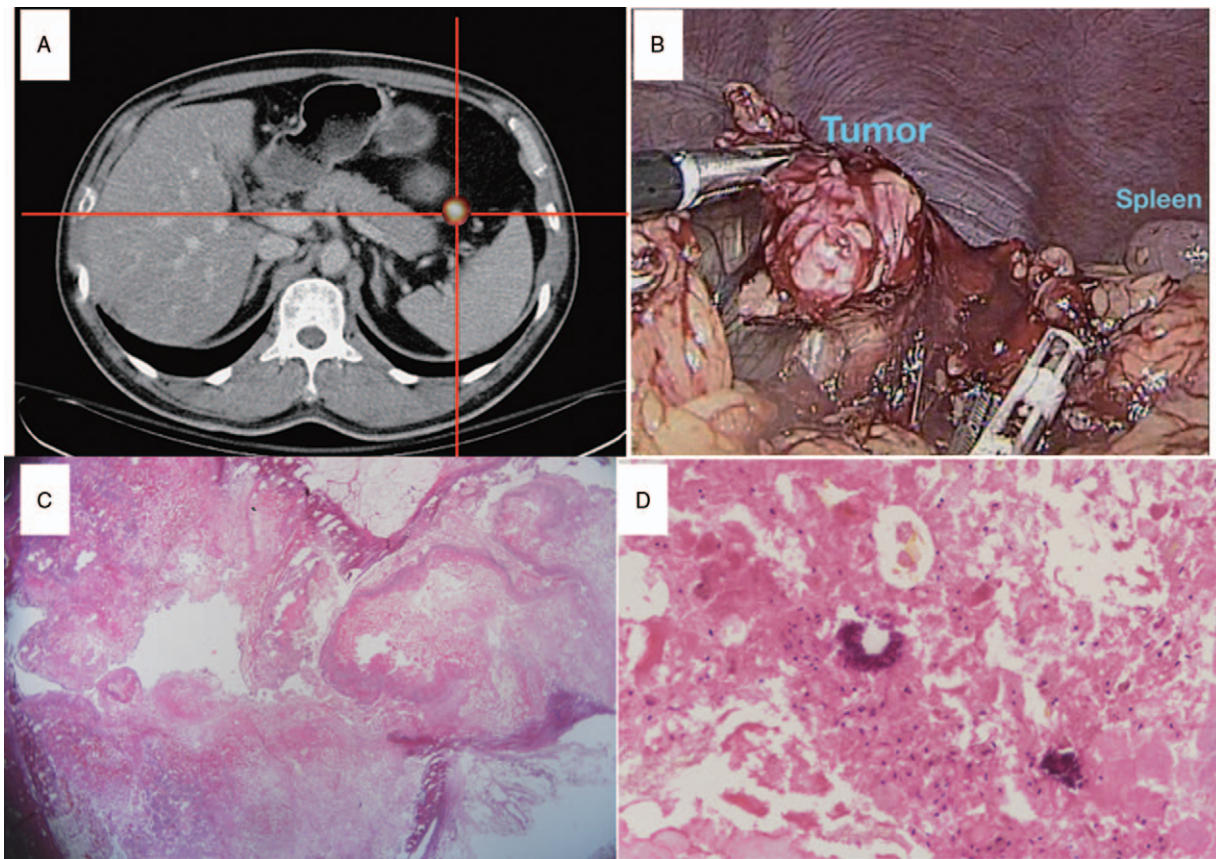


Figure 4. PET/CT scan, surgical images and pathology section of Patient 2. (A) During the regular follow-up 7 mo later, PET/CT revealed a 2 cm FDG-avid nodule near the splenic flexure of omentum (SUVmax: 5.8). (B) A solid tumor, measured $3.9 \times 2.8 \times 1.3$ cm, was identified in the greater omentum. (C) & (D) Hematoxylin-eosin section showed a picture of fat necrosis, calcification, and histiocyte aggregation without evidence of malignancy. CT = computed tomography, FDG = ^{18}F -fluorodeoxyglucose, PET = positron emission tomography, SUVmax = maximal standardized uptake value.

surgery, a solid ill-defined mass (arrow) was located to the anterior wall of aorta with severe adhesion (Fig. 5B & C). The pathological sections of the specimen showed chronic inflammatory cell infiltration of the pericolonic soft tissue in both septal and lobular patterns, phlebitis, granulation tissue and fibrosis (Fig. 5D). Immunostains for beta-catenin, STAT6, IgG, and IgG4 are performed without evidence of neoplasia in the sections examined.

4. Discussion

Even though antiadhesive barriers have gained much popularity and evidence of effectiveness, few previous studies noted the association of foreign body reactions and placement of antiadhesive barriers.^[7,8,12] Despite previous evidence revealed a certain degree of benefit from the placement of antiadhesive barriers,^[6] this study identified a possible association between the formation of foreign body granuloma and previous history of PLA adhesion barriers.

Ten out of 16 patients with a positive follow-up image study had no evidence of malignancy but mostly foreign-body-associated granuloma in the subsequent operation as indicated. No such finding was found in the control group. The loss of follow-up only accounted for a small portion of our patients and the potential bias would be limited. Nevertheless, the control

group was relatively small ($n=76$) and very low incidence condition may not be found. The false positive rate of 62.5% was higher than that of the original study of distant lymph node metastases detection with ^{18}F -FDG- PET/CT protocol we adapted (9.4% and 4.7% using SUVmax or nodal diameter cutoff, respectively).^[10] Due to the small sample size, the power of this study was limited. The Fisher exact test P value was .07. In the previous study, the mean nodal diameter and SUVmax for lymph node metastases of colorectal cancer were 1.16 cm and 6.3. In fact, there would be no false positive cases when using a more stringent SUVmax cutoff at 3.5. It is worthy noting that both the nodal size and SUVmax values of these patients with granuloma were abnormally high (mean nodal size: 2.4 cm; mean SUVmax 4.3). Furthermore, in a past case series of gynecologic malignancies, the median tumor size, and SUVmax of foreign body granuloma related to unabsorbed PLA barrier were 1.9 cm (range 1.0–2.3 cm) and 5.1 (range 3.7–7.9) under ^{18}F -FDG-PET/CT, respectively.^[9] The abnormally high false positive rate could not only potentially result in unnecessary intervention but also inaccurate evaluation of patient's prognosis.^[11,13]

Postoperative foreign body granuloma is considered an uncommon event, and there have only been scattered case reports. It is usually associated with retained foreign body material left in the operative sites, such as surgical staples/

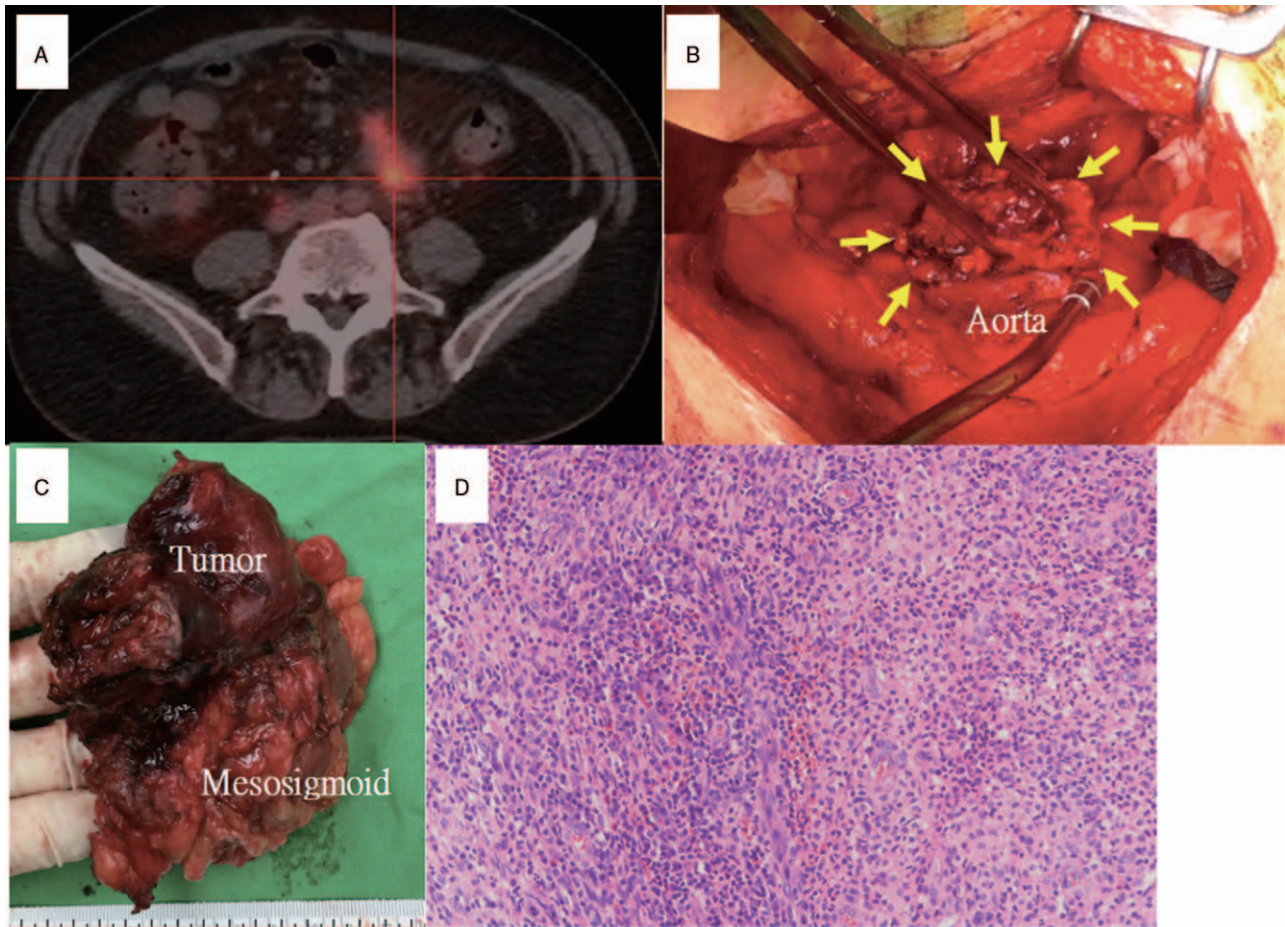


Figure 5. PET/CT scan, surgical images, and pathology section of Patient 3. (A) During the regular follow-up 9mo later, PET/CT revealed an enlarging FDG-avid mass, 5 cm, in mesosigmoid near the abdominal aorta (SUVmax: 6.1). (B) & (C) A solid ill-defined mass (arrow) was located to the anterior wall of aorta with adhesion. (D) The sections of the specimen showed chronic inflammatory cell infiltration of the pericolic soft tissue in both septal and lobular patterns, phlebitis, granulation tissue, and fibrosis. CT = computed tomography, FDG = 18F-fluorodeoxyglucose, PET = positron emission tomography, SUVmax = maximal standardized uptake value.

clipping/suture materials, nonabsorbable cotton and gauze, starch glove powder, and hemostatic agents. Patients may have symptoms related to adhesion, infection or be misdiagnosed with localized peritoneal seeding of previous malignancy.^[13–17] No postoperative colorectal cancer patient without the history of PLA adhesion barrier film placement has been found with a similar pathological finding of foreign body reaction in our hospital. The increasing false positive rate and incidence of foreign body granuloma among our patients indicates the potential relationship with the previous placement of PLA barrier film.

Extensive studies of PLA materials focused on the potential biomedical application.^[18,19] Theoretically, for amorphous bioresorbable poly (L-lactide-co-D, L-lactide) like SurgiWrap, the average degradation time is about 4 to 5 months. Nevertheless, previous observation in gynecologic cases still found unabsorbed remnant contained by foreign body granuloma up to 23 months after the placement of PLA materials.^[7–9] The incidence of foreign body granuloma formation associated with the PLA adhesion barrier were 12% and 5.4% in 2 separate case series of gynecologic cancers, whereas we observed a 4.5% incidence of foreign body granuloma after applying PLA adhesion barrier film in colorectal patients.

In addition to SurgiWrap, other antiadhesive materials commercially available include Seprafilm (carboxymethyl cellulose and hyaluronate acid), Interceed (oxidized, regenerated cellulose), Guardix-sol (carboxymethyl cellulose and hyaluronate acid), Guardix-SG (carboxymethyl cellulose and hyaluronate acid), Medishield (carboxymethyl cellulose and polyethylene oxide), Oxiplex (carboxymethyl cellulose and polyethylene oxide), and Adept (4% icodextrin).^[20] There have been sparse case reports of foreign body reaction associated with these materials,^[21–23] but no meta-analysis or large-scale trial has reported the exact incidence. Seprafilm has been one of the most commonly used and studied antiadhesive materials in the US. The large, postmarketing randomized controlled trial of Seprafilm did not reveal any cases of foreign body reaction. The reaction was only noted in case reports and animal model study.^[24,25] Arguably this could indicate that foreign body granuloma formation is more commonly associated with PLA film than other adhesion materials. Even though PLA film has shown some success in reducing the post-operative adhesion,^[6] the rare complication of foreign body granuloma can result in unnecessary interventions. This also can confuse the diagnosis and management plan for patients with cancer history under follow-

up program. More studies such as larger cohorts are required to identify the contributory factors that induce unabsorbable remnant of PLA materials and the associated granuloma formation. Until then, surgeons should carefully evaluate the necessity of applying the antiadhesive PLA materials, especially in the management of cancer patients.

In conclusion, we identified the uncommon foreign body granuloma associated with PLA adhesion barrier film after laparoscopic colorectal cancer surgery. This rare complication interfered with the diagnostic accuracy of ¹⁸F-FDG-PET/CT in the follow-up program. The subsequent high false positive rate brought unnecessary surgical exploration eventually. Therefore, the placement of PLA adhesion barrier should be avoided.

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Author contributions

All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Chao-Wen Hsu and Tien-Chan Hsieh. The first draft of the manuscript was written by [Tien-Chan Hsieh] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Investigation: Tien-Chan Hsieh.

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Supervision: Chao-Wen Hsu.

Writing – original draft: Tien-Chan Hsieh.

Writing – review & editing: Tien-Chan Hsieh, Chao-Wen Hsu.

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