Original article

Facilitated early ileostomy closure after rectal cancer surgery: a case- matched study

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Received 5 January 2012 / **Accepted** 8 April 2012

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Abstract

Background: The aim of this study was to evaluate the outcomes of an early stoma closure protocol facilitated by Seprafilm wrapping of defunctioning ileostomies compared to a similar group of patients with conventional stoma formation and closure. **Methods** Consecutive patients undergoing defunctioning ileostomy following rectal resection with pelvic anastomosis were planned for early closure and had their ileostomy wrapped in Seprafilm at the time of formation. Stoma closure was performed at 4-6 weeks if water-soluble contrast enema (WSCE) showed no evidence of leak and the patient's physiological parameters had been optimized. Patients were matched for age, gender, American Society of Anaesthesiologists (ASA) score, neoadjuvant treatment, and procedure, with patients undergoing conventional ileostomy formation and closure. Outcomes were compared using the 2-tailed Mann-Whitney U test and Fisher's exact test. **Results** Following resection twenty-two patients (69%) were suitable for early closure and underwent stoma closure at a median of 37days (range:25-90 days). Seprafilm-wrapped ileostomies were closed earlier than the conventional ileostomies (median 55 days (range: 25-250 days) vs. 213 days (range:86-352 days), $p<0.001$). There was no difference between the groups as regards length of hospital stay or complications following ileostomy closure. Eighteen Seprafilm stoma patients and 22 conventional stoma patients received adjuvant chemotherapy. Median time to starting chemotherapy from resection was 10 vs. 8.5 weeks respectively ($p= 0.36$). **Conclusions** An early stoma closure protocol facilitated by Seprafilm wrapping of the ileostomy is practical, does not increase morbidity and significantly reduces the time with a stoma for the patient. An early stoma closure protocol did not significantly delay in commencement of chemotherapy.

Key Words: Rectal Neoplasms; Ileostomy; Membranes, Artificial

Introduction

The symptomatic leak rate of a low rectal anastomosis that has not been defunctioned is 28% [1]. A proximal loop ileostomy is frequently fashioned to reduce this incidence and the severity of symptomatic leakage [1, 2]. Ileostomy closure is usually delayed for 8-12 weeks to allow post-operative adhesions to mature and the inflammatory reaction to resolve and thus reduce the difficulty, morbidity and risks of ileostomy closure [3, 4]. An ileostomy can cause significant morbidity including medical complications such as dehydration, electrolyte imbalance, acute renal failure, bleeding, dermatitis, parastomal infection, and surgical complications such as retraction, stricture, prolapse, enterocutaneous fistula and parastomal hernia [5, 6]. These complications may be exacerbated by chemotherapy [7, 8] and may result in premature termination of adjuvant treatment. Ileostomies significantly affect patients' body image and quality of life and are associated with a significant healthcare cost [9, 10]. Complications of ileostomy closure have been shown to increase when it is performed after adjuvant treatment [8]. Therefore, early stoma closure, especially in patients receiving adjuvant chemotherapy can offer potential benefits.

Anastomotic integrity can be safely assessed with a water-soluble contrast enema (WSCE) as early as 7 days following surgery [11-13]. The morbidity and operative difficulty caused by post-operative adhesions during early stoma closure can be minimised by performing early stoma closure within 2 weeks of rectal resection before dense adhesions form, or by using an adhesion barrier to reduce peristomal adhesions which will facilitate closure at anytime [14-16]. Seprafilm® (Genzyme Corporation, Cambridge, MA,USA) is a bioresorbable hyaluronate-carboxymethylcellulose membrane that turns into a hydrophilic gel approximately 24 hours after placement. This provides a protective coat around traumatised tissue for up to 7 days during remesothelialization, reducing dense adhesion formation. It has

been shown to facilitate early stoma closure [16] and not to affect survival when used in rectal cancer patients [14].

We aimed to evaluate the outcomes of an early stoma closure protocol facilitated by Seprafilm wrapping of defunctioning ileostomies compared to a similar group of patients who underwent conventional stoma formation and closure.

Materials and Methods

Consent for the study was obtained from the regional ethics committee. From August 2009-January 2011, consecutive patients at our institution who received a defunctioning ileostomy to protect a pelvic anastomosis had their ileostomy wrapped in Seprafilm. Patients were excluded from the study if there was infection or gross contamination of the peritoneal cavity at the time of surgery, if intraperitoneal chemotherapy was being used or if there was a history of allergy to Seprafilm. Two sheets of Seprafilm were wrapped around the ileostomy loop and its mesentery and a third sheet was placed beneath the midline wound if an open resection was performed. Each ileostomy limb was secured to the skin over a flexible rod with interrupted 4-0 absorbable sutures. The rod was removed after a median of 3.5 days (3-6 days). Healing of the anastomosis was confirmed on water-soluble contrast enema (WSCE) 3 weeks post-operatively. If the anastomosis was intact and the patient's physiological parameters had been optimized, ileostomy closure was planned at 4 weeks with endoscopic examination of the anastomosis. If WSCE suggested a defect at the anastomosis, early closure was abandoned and subsequent closure was planned according to clinical judgement, but analysed with intention to treat. Patients were matched for age (within 10 years), gender, American Society of Anaesthesiologists (ASA) score, neoadjuvant treatment and procedure, with patients managed conventionally at our institution by the same surgeons from June

2005-June 2009. Patients' clinical notes and investigations were reviewed and data collected. Outcomes were compared using the 2 -tailed paired Mann-Whitney U test or Fisher's Exact test and considered significant if $p<0.05$.

Results

Over 16 months, 32 patients were planned for early closure [23 males, median age 62.5 years (range:40-85years)]. Twenty-seven out of 32 patients received neoadjuvant chemoradiotherapy. Twenty-five patients were ASA 2, 5 were ASA 3 and 2 were ASA 4. Indications for resection were: a primary colorectal cancer in 24 patients, recurrent colorectal cancer in 5 patients and a rectal tubulovillous adenoma in 3 patients. Resections performed included 13 laparoscopic ultralow anterior resections (ULAR), 16 open ULAR and 5 anterior rectal exenterations. Of the 32 patients booked for early closure, 22 patients (69%) were finally suitable for the procedure. Ten patients were not suitable for early closure: 3 who had asymptomatic radiological anastomotic defects, 3 who were physiologically compromised and 1 patient in whom urgent post-operative chemotherapy was indicated, 1 patient with a severe wound infection and one in whom Seprafilm was removed due to a suspected allergy.

The median time to WSCE in the 32 patients booked for early closure was 21 days (range:13-52 ödays). The 3 patients who had WSCE performed at>4weeks, were previously thought not suitable for early closure.

The 32 early closure protocol patients were retrospectively matched with patients who had conventional stoma formation and closure (Table 1). Following rectal resection 21 complications occurred in 18 patients with Seprafilm stomas, and 39 complications in 26 patients with conventional stomas ($p=0.06$) (Table 2). Seprafilm did not increase the

incidence of wound infection, leak, ileus or high stoma output following rectal resection. Two patients with Seprafilm ileostomies and 3 patients with conventional ileostomies developed small bowel obstruction. In all 5 cases the obstruction resolved with conservative management.

WSCE was performed at a median of 21 days in the planned early closure group and 82 days in the conventionally managed group (Table 3). An asymptomatic radiological leak was seen in 3 patients in each group. The length of inpatient stays for rectal resection and ileostomy closure was similar. Patients planned for early closure had their ileostomies closed significantly earlier (median 55 days vs. 213 days, $p<0.001$). In the 22 patients suitable for early closure, median time for closure was 37 days (range:25-90 days). Seven of these 22 patients had their ileostomy closed at >40 days; in 6 patients this was due to lack of available elective theatre time and in 1 patient in order to co-ordinate stoma closure with simultaneous liver resection.

The number of patients with complications following ileostomy closure was similar in both groups (Table 4). One patient with a proximal ileal stoma wrapped in Seprafilm who required parenteral nutrition to manage high stomal output underwent stoma closure at 25 days. She developed an anastomotic leak, which was managed with parenteral nutrition, and then closed spontaneously. One patient in the conventionally managed group had an unrecognised small bowel injury during ileostomy closure requiring laparotomy and repair.

Adjuvant chemotherapy was given to 18 (56%) patients booked for early closure and 22 (69%) patients in the conventionally managed group. One patient in each group declined treatment. Chemotherapy was not offered to 8 planned early closure patients and 7 patients in the conventionally managed group due to poor performance status and chemotherapy was not indicated in the other patients. The median time to starting chemotherapy from colorectal

resection was 10 weeks in the planned early closure group (range:4-17weeks) vs. 8.5 weeks (range:6-12 weeks) (p=0.36) in the conventionally managed group.

Ten out of 17 (59%) planned early closure patients vs. 9/22 (41%) conventionally managed patients had their adjuvant chemotherapy delayed >8 weeks (p=0.34). Stoma closure was delayed in3 patients in the planned early closure group and 6 in the conventionally managed group due to resolving medical complications or poor performance status. Two patients in the planned early closure group had a delay in commencement of chemotherapy due to delayed ileostomy closure. One patient had stoma closure at 9 weeks and started chemotherapy at 17 weeks and the other had stoma closure at 8 weeks started and chemotherapy at 11 weeks. Five patients in the planned early closure group and 3 in the conventionally managed group had delayed commencement of chemotherapy due to delayed assessment by an oncologist.

Despite similar numbers of patients in each group receiving combined agent chemotherapy (4/22 (18%) in the conventionally managed group vs. 5/18 (28%) in the planned early closure group (p=0.71)), significant gastrointestinal toxicity symptoms were seen in 6 patients in the conventionally managed group compared to 2 patients in the planned early closure group (6/22(27%) vs. 2/18 (11%), p=0.26). Four patients from the conventionally managed group required admission for a high output stoma, and 2 for nausea, vomiting and abdominal pain. Five had subsequent chemotherapy dose reduction and the chemotherapy of the 6^{th} patient was stopped.. The two patients from the planned early closure group were admitted with diarrhoea and had subsequent chemotherapy dose reduction.

Discussion

Ileostomy closure is generally planned for 8-12 weeks following surgery [17], but patients being treated for rectal cancer often face a significantly longer wait before undergoing reversal to facilitate the timely commencement and completion of adjuvant therapy [1, 8, 18]. Although rectal cancer management guidelines [19, 20] do not explicitly state a time interval within which adjuvant chemotherapy should be commenced, most clinical trials stipulate starting adjuvant treatment 6–7 weeks after surgery because a delay in commencement of treatment may be associated with decreased disease- specific survival [21-23]. Further delays in stoma closure may occur due to surgical waiting list prioritisation [7, 24]. As a result such patients often wait at least 4-6 months for ileostomy closure [7]. The median time for planned conventional closure in our series was 213 days. During this time, up to 40% of patients have stoma related complications [8, 9, 25, 26] and 70% have stoma care problems[9]. Early ileostomy closure may prevent the physical and psychological morbidity,as well as decreased quality of life and limit the costs associated with defunctioning ileostomy [9, 10, 18, 27, 28]. Although the median time to staring chemotherapy was longer in the planned early closure group (10 vs. 8.5 weeks), it did not reach statistical significance. Timely commencement of chemotherapy following early stoma closure at our institution will be further facilitated in the future by prioritisation and forward planning of ileostomy closure on the theatre schedule, efficient communication with oncology colleagues and coordination of future appointments.

This study was designed as a matched cohort study. Selection bias may be present as patients were not randomised, however an attempt to control for this was made by closely matching the cohorts. Comparison of outcomes was performed on an intention to treat basis.

Three prospective comparative studies have evaluated early ileostomy closure in small series of patients and showed that it can be performed safely in selected patients between 10-21 days post-operatively [27, 29, 30]. A recent randomised controlled trial of early ileostomy closure without using an anti-adhesive barrier randomised patients undergoing proctectomy

who were medically fit for early closure on day 8 or late closure on day 60 if WSCE on day 7 showed an intact anastomosis [31]. Ninety-five patients were randomised to early closure , 5 of whom were excluded from the final analysis (4 due to medical problems and 1 for logistical reasons). Small bowel obstruction (3% vs. 16%) and medical complications (5% vs. 15%) were significantly higher in the late closure group and a significantly higher rate of wound complications (19% vs. 5%) was seen in the early closure group.

We elected to use Seprafilm in our early stoma closure protocol based on our personal experience of increased operative difficulty with early stoma closure due to adhesion formation. Two studies supporting the use of Seprafilm for early stoma closure have demonstrated decreased adhesion severity, time for ileostomy closure, blood loss and extent of incision at 6-8 weeks compared to conventional ileostomy closure performed at the same time interval, without any increase in the complication rate [14, 15]. Tang et al. performed the only randomised control trial using Seprafilm to facilitate early stoma closure at 3 weeks [16]. In the first phase of the study the control group had conventional stoma closure after 6 weeks and in the second phase, conventional stoma closure at 3 weeks. Patients who had a radiological leak on WSCE or who were medically unfit for planned closure had closure delayed and were excluded from the final analysis. In phase 1 adhesion scores at closure were not significantly different, however in phase 2 they were significantly lower in the Seprafilm group. The time taken for closure, difficulty of closure and post-operative complications were not significantly different between groups in either phase.

The role of routine WSCE prior to conventional ileostomy closure is debated given the minimal changes in management that result [32-34]. However, many clinical leaks in defunctioned patients may have a delayed presentation and occur 2-6 weeks postoperatively

[32]. In our study the radiological leak rate in patients undergoing WSCE at < 4weeks was double that of patients undergoing WSCE at >4weeks (4/33 vs. 2/31 patients). Endoscopic examination of the planned early closure patients with radiological leaks confirmed an anastomotic defect in all patients. Additionally, we did not find any case in our series in which the WSCE was normal and endoscopy demonstrated an anastomotic defect or the patient developed a clinical leak, confirming the high negative predictive value of early WSCE. We found no morbidity from performance of the WSCE at 3 weeks and no patient developed a rectal anastomotic leak following early closure of their ileostomy.

Postoperative chemotherapy regimens that can now extend over 5 or 6 months mean that the patient has a stoma for a similarly extended period of time. While we did not perform a specific cost analysis, the cost of Seprafilm, at approximately $400 Australian dollars per sheet, can be favourably compared to stomal appliance and associated nursing costs over this time. We removed the Seprafilm from 1 patient 48 hours after placement due to a suspected allergy. This patient developed fever, tachycardia and hypotension with non-tender erythema around his ileostomy. At removal, there was no evidence of infection or marked inflammation. Swabs and tissue taken for culture showed no growth. The patient's symptoms improved rapidly over the next 24 hours. Seprafilm has been associated with an inflammatory reaction in a small percentage of patients- presenting as either adhesions in a location where Seprafilm had been placed, a foreign body reaction or a severe inflammatory response [35, 36].

There was a decreased rate of chemotherapy- induced gastrointestinal toxicity in the planned for early closure cohort on intention to treat analysis (2/18 (11%) vs. 6/22 (27%), p=0.26). As both of these patients had delayed stoma closure after completion of their chemotherapy, no patient who underwent early closure of their ileostomy experienced significant gastrointestinal toxicity from chemotherapy compared with 8/24 patients who received

chemotherapy and underwent conventional closure (p=0.01). This may suggest a clinical advantage to ileostomy closure prior to post-operative chemotherapy.

Conclusions

An early stoma closure protocol facilitated by Seprafilm wrapping of ileostomies is practical, does not increase morbidity and significantly reduces the time patient patient has a stoma. Moreover, an early stoma closure protocol does not significantly delay in commencement of adjuvant chemotherapy.

Conflict of Interest: None

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Table 1 Matching of patients booked for early closure with conventionally managed patients

	Planned Early Closure Patients (N)	**Conventionally Managed Patients (N)**
Total patients	32	32
Gender Male	23	23
Female	9	9
ASA 2	25	26
3	5	5
4	2	1
Median age	62.5 years (40-85)	63.5 years (35-89)
Neoadjuvant chemo-radiotherapy	27	28
Pathology: Rectal cancer	29	32
Rectal adenoma	3	0
Operation: Laparoscopic ultra-low anterior resection	13	16
Open ultra-low anterior resection	16	12
Anterior exenteration	5	4

Table 2 Post-operative complications following rectal resection

	Planned Early Closure Patients (N)	**Conventionally Managed Patients (N)**
Wound complication	5	7
Urinary retention	2	2
Anastomotic leak	1	3
Pneumonia	0	3
Abdominal collection	0	1
Urinary tract infection	1	3
Seprafilm allergy	1	0
Ileus	2	4
Small bowel obstruction	2	3
Arrhythmia	0	2
Stomal retraction	0	1
Ileal conduit leak	0	1
High output ileostomy requiring medical treatment	7	9
TOTAL	21 complications in 18 patients	39 complications in 26 patients p=0.06

Table 3 Summary of procedure times and water soluble contrast enema (WSCE) findings

	Planned Early Closure Group	**Conventionally Managed Group**	**P-value**
Days to WSCE	21 (13-52)	82 (11-306)	0.08
Radiological leak	3 patients	3 patients	1
Inpatient stay after rectal resection	11 (5-49)	14 (6-31)	0.13
Days with ileostomy	55 (25-250)	213 (86-352)	<0.001
Inpatient stay after ileostomy closure	4.5 (2-55)	4 (2-21)	0.87

Table 4 Complications following ileostomy closure

	Planned Early Closure Patients (N)	**Conventionally Managed Patients (N)**
SURGICAL COMPLICATIONS		
Wound infection	5	3
Small bowel perforation	0	1
Ileal anastomotic leak	1	0
MEDICAL COMPLICATIONS		
Ileus	2	5
Urinary tract infection	2	0
Acute urinary retention	2	1
Pseudo-obstruction	0	1
Pulmonary embolus	0	1
Fever of unknown origin	0	1
Fractured neck of femur	0	1
Pneumonia	1	0
TOTAL	13 complications in 12 patients	14 complications in 14 patients

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Title:
Facilitated early ileostomy closure after rectal cancer surgery: a case-matched study

Date:
2012-08-01

Citation:
Memon, S., Heriot, A. G., Atkin, C. E. & Lynch, A. C. (2012). Facilitated early ileostomy closure after rectal cancer surgery: a case-matched study. TECHNIQUES IN COLOPROCTOLOGY, 16 (4), pp.285-290. https://doi.org/10.1007/s10151-012-0843-4.