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Original Research Article

Retrospective study in a single unit: outcomes of delays in reversal of loop ileostomy

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ABSTRACT

Background: Formation of loop ileostomy is common after anterior resection to reduce the sequalae of an anastomosis leak. Delays to reversal of ileostomy is associated with complications.
Methods: Retrospective study between 1 July 2017 to 30 June 2023. Patients were included: >18 years old, loop ileostomy formed as part of anterior resection surgery (benign and malignant). Exclusion criteria: loop ileostomy performed during other colonic resections, patients with inflammatory bowel disease, de-functioning ileostomy for obstructions. Primary outcome measures included complications associated with delayed closure of loop ileostomy and readmissions after reversal surgery. Secondary measures included reasons for delay to surgery, complications prior to reversal surgery, and morbidity and mortality associated with it.
Results: 135 patients were included. 85.9% of patients experienced delays in reversal surgery. Those without delays in surgery had higher rate of stoma-related complications (p=0.002). Delays were due to a long waitlist (p<0.01) and adjuvant chemotherapy (p=0.598). There were no significant differences in the delays to surgery during COVID pandemic. Delays were associated with higher rate of wound infection (6.04%), post-operative ileus (12.07%), anastomotic leak (1.72%), and *Clostridium difficile* (C. diff) infection (3.45%). Handsewn end to end anastomosis was associated with higher proportion of post-operative ileus compared to the stapled side to side anastomosis group.
Conclusions: Reversal of ileostomy within 6 months of index surgery after adjuvant therapy could potentially reduce post-operative complications, and alleviate the burden on our healthcare system in the long run. A stapled side to side anastomosis should also be considered.

Keywords: Loop ileostomy, Colorectal surgery, Reversal of ileostomy

INTRODUCTION

Formation of loop ileostomy is a common practice in colorectal units after low rectal cancer surgery and occasionally in benign disease to reduce the sequele of an anastomosis leak.[1-5] Despite the potential benefits, it carries a significant morbidity, and about two-thirds of patients have stoma related morbidity.[3,6-8] There is contention behind the optimal timing for loop ileostomy closure due to its impact on postoperative outcomes. The traditional timing for reversal is 3-6 months with previous studies demonstrating an increase in length of stay and rate of complications with closure after 6 months.[5,7,9] Studies have shown that delays (>6 months) in ileostomy closure is associated with increased post-operative complications, such as higher incidence of pseudomembranous colitis, post-operative ileus, 3.7-fold increase in major bowel dysfunction, decrease in quality of life and greater risk of developing low anterior resection syndrome.[3,6,10-15] Therefore a balance must be

struck between whether a stoma should be fashioned, and the timing of its reversal.

Prolonged presence of stoma also increases the risk of stoma-related complications such as prolapse, parastomal hernia, ileus, high output stoma resulting in kidney injury.[3,4] In addition, it also impacts on patients' quality of life, therefore the concept of early closure has been proposed.[15] Moreover, reversal of ileostomy is not without its own morbidity and complications.[5] A 40% morbidity has been reported.[16] Some of the common side effects after reversal of ileostomy include malabsorption symptoms such as diarrhoea, incontinence and surgical wound infection. Around 20% of patients experience more serious complications such as ileus or anastomotic leakage.[16]

In a study by Waterland et al, 1 in 4 ileostomies are not closed, and 50% of the delay could be attributed to postoperative adjuvant chemotherapy, anastomotic leakages and small bowel obstruction.[5,7,14,15] There has been some literature supporting early closure of loop ileostomies, as early as 2 weeks from index surgery demonstrating better surgical outcomes.[7,17] It is proposed that earlier ileostomy closure may reduce postoperative nausea and vomiting, and reduce stoma-related costs.[4,7] However, it may negatively impact on the completeness of chemotherapy due to complications of anastomotic leakage and low anterior syndrome after reversal.[5] Studies have reported that every 4-week delay in the administration of adjuvant chemotherapy decreases overall survival of colorectal cancer patients by 14%.[18] On the other hand, having an ileostomy during chemotherapy has also been shown to increase the risk of high stoma output, leading to electrolyte disturbances and renal failure.[5] Recent meta-analyses have demonstrated that early closure of loop ileostomy in patients has comparable outcomes with delayed closure.[2,19]

The era of COVID-19 pandemic has severely worsened elective list waiting time with intermittent suspension of all category 2 surgeries in Australia during the peak of the outbreak. This caused further delays in ileostomy closure, exacerbating potential complications related to the index operation, medical co-morbidities or adjuvant chemotherapy.[15] This also impacts the patient physically, psychologically and financially.[15] A review of loop ileostomy reversal between 2009 and 2012 in the NHS showed that only 28% of ileostomies were reversed at 6 months and around 60% at 12 months.[20] Australia has a similarly publicly funded health care system to the NHS with similar delays in ileostomy closure in our health network. A recent study based in Australia and New Zealand reported a median time to ileostomy closure of 7 months.[5]

The objective of this study is to highlight the complications and outcomes associated with a delay in reversal of ileostomy, as well as investigate the reasons for the delay in our colorectal unit.

METHODS

A retrospective study was performed at Dandenong hospital in Melbourne, Victoria for all patients who underwent reversal of loop ileostomy between period of 1 July 2017 to 30 June 2023. Ethics approval was obtained from the local area health network. Specific period was chosen to encompass the period of COVID-19 pandemic as well as its immediate aftermath. The time periods were split into pre-COVID 19, COVID-19 and post-COVID 19. Pre-COVID 19 time period was defined to be from 1 July 2017 to 25 March 2020; there was a nationwide ban on category 2 surgery from 26 March 2020. COVID-19 time period was taken from 26 March 2020 to 20 February 2022. Post-COVID 19 time period included 21 February 2022 to 30 June 2023 as resumption of all category 2 elective surgery was from 21 February 2022.

Patients who underwent a reversal of loop ileostomy was identified from the hospital electronic database using CMBS coding. Convenience sampling was utilised whereby all patients meeting inclusion criteria from the specified timeframe were included in the study. Inclusion criteria were adults (age ≥18 years old), loop ileostomy formed as part of anterior resections for cancer or benign resections such as diverticular disease. Exclusion criteria included loop ileostomy formed during other colonic resections apart from anterior resections, loop ileostomy formed for patients who had inflammatory bowel disease, and defunctioning loop ileostomy for obstructions without colonic resections. Double-barrelled and end ileostomy closures were also excluded.

Data collected included patient demographics such as age, BMI, pathology of resection, type of anterior resections, readmissions after index operation and reasons, date of ileostomy reversal and days between initial surgery and ileostomy reversal, reason for delay for reversal, post reversal complications and type of anastomosis. Individual clinical records were independently reviewed by 2 separate investigators to establish reasons for delay in ileostomy closure.

Complications were defined in accordance with those used by American college of surgeons' national surgical quality improvement programme. Delay in loop ileostomy closure was defined as >180 days (>6 months) from day of index operation with day 0 being the day of initial surgery. Definition of postop ileus was defined as a prolonged time for return of bowel function (>6 days).

Primary outcome measures included complications associated with delayed closure of loop ileostomy and readmissions after reversal surgery. Secondary measures included reasons for delay to surgery, complications prior to reversal surgery, and morbidity and mortality associated with it.

Analysis of the data was performed using statistical software SPSS version 26.0 (SPSS, Inc., Chicago, IL).

All continuous variables were collected as mean and standard deviation. Unpaired t test was used to test differences between groups. Categorical variables were collected as frequencies and percentages and were compared by chi-squared test or Fisher's exact test. A $p<0.05$ was considered statistically significant.

RESULTS

We identified 135 patients who underwent reversal of loop ileostomy from 1 July 2017 to 30 June 2023. Seventy-eight of these patients were men. Majority of the patients experienced a delay in reversal of ileostomy (85.9%). Only 19 (14.1%) patients underwent reversal of loop ileostomy within 180 days (6 months) of their index surgery, with 116 patients having a delayed reversal. Majority of resections were for cancer, and the commonest surgery performed was ultra-low anterior resections with a defunctioning loop ileostomy. Baseline patient demographics and reason for initial anterior resection are presented in Table 1.

Ileostomy wounds were closed in a purse-string fashion. There was no difference in the rate of readmissions after anterior resection in the delayed or non-delayed reversal group. However, non-delayed group had a significantly higher rate of stoma-related complications (p=0.002). the delayed reversal of ileostomy group also had a greater proportion of patients with the small bowel obstruction, high stoma output and wound infection (Table 1).

The most significant cause of delayed reversal pre-COVID-19 was due to a long elective waitlist ($p<0.01$). During the COVID-19 pandemic, majority of the delays in reversal were due to COVID-19 infection. Adjuvant chemotherapy as a reason for delayed reversal was similar across the three time periods (p value was 0.598) (Table 2).

Table 1: Patient demographics, (n=135).

Variables	No delay in reversal, N (%)	Delay in reversal (>180 days) N (%)	P value
Total patients	19 (14.1)	116 (85.9)	
Sex			0.322
Male	9 (47.4)	69 (59.5)	
Female	10 (52.6)	47 (40.5)	
BMI, median (range, kg/m^2)	26.2 (19.0- 35.1)	26.8 (16.7-44.5)	
Emergency or elective anterior resection			0.146
Elective	12 (63.2)	91 (78.4)	
Emergency	7 (36.8)	25 (21.6)	
Pathology (anterior resection)			0.008
Cancer	9 (47.4)	92 (79.3)	
Diverticular	7 (36.8)	14 (12.1)	
Other	3 (15.8)	10 (8.6)	
Colonic perforation	1	9	
Sigmoid stricture	1	0	
Dysplastic polyp	0	1	
Metastatic ovarian cancer invading mesorectum	1	0	
Type of anterior resection			0.247
High anterior resection	7 (36.8)	23 (19.8)	
Low anterior resection	3 (15.8)	20 (17.2)	
Ultra-low anterior resection	9 (47.4)	73 (62.9)	
Readmission after anterior resection			0.670
Yes	7 (36.8)	37 (31.9)	
No	12 (63.2)	79 (68.1)	
Reasons for readmission after anterior resection			
Small bowel obstruction	1 (5.3)	4 (3.4)	0.537
Stoma related complications	3 (15.9)	0	0.002
Stomal bleeding	0	3 (2.6)	0.478
High stoma output	1 (5.3)	9 (7.8)	0.700
Abdo pain	1 (5.3)	6 (5.2)	0.987
General decline	0	4 (3.4)	0.411
Anastomotic leak	0	1 (0.9)	0.685
Wound infection	0	4 (3.4)	0.411
Anastomotic bleeding	0	1 (0.9)	0.685
Ureteric stricture	0	1 (0.9)	0.685
Pneumonia	0	3 (2.6)	0.478

Table 2: Delays in reversal and reasons for delay.

Variables	Yes, N (%)	No, N (%)		P value
Delays in reversal of loop ileostomy (>180 days)	116 (85.9)	19 (14.1)		0.152
Pre-COVID 19 (1 July 2017-25 March 2020)	57 (49.1)	9 (47.3)		
COVID-19 (26 March 2020-20 Feb 2022)	18 (15.5)	6 (31.6)		
Post-COVID 19 (21 Feb 2022-30 June 2023)	41 (35.3)	4 (21.1)		
Reasons for delay in reversal of loop ileostomy	**Pre-COVID 19, (n=57)**	**COVID-19, (n=18)**	**Post COVID-19, (n=41)**	**P value**
Adjuvant therapy	21 (36.8)	6 (33.3)	11 (26.8)	0.598
Anastomotic leak	2 (3.5)	0	2 (4.9)	0.651
Elective waitlist delay	34 (59.7)	0	0	<0.01
Anastomotic stricture	0	0	1 (2.4)	0.397
COVID-19	-	12 (66.7)	26 (53.5)	0.356
Lost to follow up	0	0	1 (2.4)	0.397

Table 3 lists the complications after reversal of loop ileostomy surgery. Delayed ileostomy reversal had a higher overall complication rate compared to the no delay group (37.9% vs 26.3%; p=0.329), however none of the complications were statistically significant. Delayed reversal was associated with a higher rate of wound infection (6.04%), post-operative ileus (12.07%), anastomotic leak (1.72%), and C. diff infection (3.45%) (Table 3). Nine patients in the delayed group had a return to theatre for: anastomotic leak (2), anastomotic bleeding (1), mechanical small bowel obstruction (1), pseudo-obstruction (1), wound infection/collection (3), and small bowel perforation (1). There was one death in the delayed group due to high grade small bowel obstruction complicated by a myocardial infarction. There was no anastomotic leak in patients with no delay in reversal.

There was no difference in the type of anastomosis performed in each group. Majority of the patients had a handsewn end to end anastomosis (69.2% in the delayed and 68.4% in the non-delayed group). Handsewn end to end anastomosis had more post-operative ileus, and this was more evident in the delayed reversal of ileostomy group (14.8% vs 7.69%). There were 1 anastomotic bleed and 1 anastomotic leak requiring a return to theatre. In the stapled side to side anastomosis group (Covidien GIA™ Stapler-60 mm), there was 1 return to theatre due to an anastomotic bleed in non-delayed group (p=0.019).

Table 3: Complications post reversal of loop ileostomy.

Variables	Delay in reversal, n=116 (%)	No delay in reversal, n=19, (%)	P value
Overall complication	44 (37.9)	5 (26.3)	0.329
Mortality (due to myocardial infarct)	1 (0.86)	0	0.685
Anastomosis leak-return to OT	2 (1.72)	0	0.564
Anastomotic bleeding			
Return to OT	1 (0.86)	1 (5.26)	0.263
Conservative management	1 (0.86)	0	0.685
Ileus	14 (12.07)	1 (5.26)	0.770
Small bowel obstruction (SBO)			
Return to OT	1 (0.86)	0	0.685
Conservative management	3 (2.59)	2 (10.5)	0.165
Pseudo-obstruction-return to OT	1 (0.86)	0	0.685
Small bowel perforation-return to OT	1 (0.86)	0	0.685
Wound infection/collection			
Return to OT	3 (2.59)	0	0.356
Antibiotics	4 (3.45)	0	0.411
C. diffi infection	4 (3.45)	0	0.411
Urinary tract infection	1 (0.86)	0	0.685
Colo-cutaneous fistula-return to OT	1 (0.86)	0	0.685
Delirium	1 (0.86)	0	0.564

Continued.

Variables	Delay in reversal, n=116 (%)	No delay in reversal, n=19 (%)	P value
Clavien-Dindo classification of complication			0.369
I	14	4	
II	14	0	
III	8	1	
IV	2	0	
V	1	0	
30 days mortality	1 (100.0)	0	0.685
Types of anastomosis			
Handsewn end to end			
Post-operative ileus	81 (69.2)	13 (68.4)	0.555
SBO	12 (14.8)	1 (7.69)	
-Return to OT	0	0	
-Conservative	1 (1.2)	1 (7.69)	0.259
Anastomotic bleed			
-Return to OT	1 (1.2)	0	0.687
-Conservative	0	0	
Anastomotic leak-return to OT	1 (1.2)	0	0.687
Stapled side to side	32 (27.5)	6 (31.6)	
Post-operative ileus	2 (10.9)	0	0.529
SBO			
-Return to OT	1 (5.5)	0	0.661
-Conservative	2 (6.25)	1 (16.7)	0.385
Anastomotic bleed			
-Return to OT	0	1 (16.7)	0.019
-Conservative	1 (3.1)	0	0.661
Anastomotic leak-return to OT	1 (3.1)	0	0.661
Handsewn side to side	3 (2.6)	0	
Post-operative ileus	2 (66.6)	0	

DISCUSSION

Despite being perceived as a relatively minor procedure, reversal of ileostomy is associated with significant morbidity.[11,21] Our study demonstrates the ongoing relationship between the delay and complications when reversal of ileostomy is performed beyond 6 months of the index surgery. This is consistent with studies demonstrating increased rates of complication post operatively when there is a delay to reversal of ileostomy.[3,6,7,12-15,22] Although most stoma are reversible, some patients never undergo reversal surgery due to complications and comorbidities from the index surgery.[20,23] Hence, a balance must be struck between whether an ileostomy should be fashioned, and the timing of its reversal.

It is proposed that in patients with defunctioning loop ileostomy, the distal ileum that is defunctioned becomes atrophic and fibrotic, resulting in dysbiosis, reduction in total bacterial load (TBL) and diversity.[2-25] The nutrient-deprived ileum is subjected to villous atrophy as well as loss of contractility and smooth muscle strength, which is thought to contribute to the post-operative complications.[23] Fibrosis in the bowel promotes stenosis and likely contributes to ileus.[23] Despite the likelihood of the functional consequences of atrophy and fibrosis contributing to many of the complications observed following reversal surgery, there is still a paucity of evidence whether a higher degree of atrophy and fibrosis is associated with an increased risk of complications.[23] Post-operative ileus and small bowel obstructions are often a concern after ileostomy reversal, with a reported overall ileus rate of 13.4%.[26] This is similar to our study with a 12.07% ileus rate in the delayed reversal group.

In a study by Beamish et al he demonstrated that patients with significant loss of TBL experienced more complications post-operatively, such as anastomotic leaks.[23] Interestingly, the study showed no correlation between the time in delay to stoma reversal and the extent of atrophy or fibrosis of the defunctioned ileum, or the risk of developing post-operative complications. Instead, they concluded that the risk of complications was strongly associated with the reduced abundance of gut commensal bacterial.[23] This evidence could suggest that administering probiotics into the distal limb of the ileostomy could potentially reduce post-operative ileus or anastomotic leak. Two patients in our study had an anastomotic leak and both were delayed ileostomy closure. We postulate that a longer delay to surgery with more loss in total bacterial load could potentially result in a higher risk of anastomotic leak post-reversal surgery. However, there has been insufficient evidence to support the routine implementation of the probiotics in this setting.[27]

Delayed reversal of ileostomy is also associated with an increased post-operative wound infection and higher incidence of pseudomembranous colitis.[10] It has been postulated that a defunctioned bowel alters the intrinsic intestinal immune system due to intestinal atrophy. This decreases the commensal bacteria due to the poor nutrient content of the diverted bowel and creates and environment for C. diff bacteria to thrive following intestinal continuity.[10,11,21,28] Published studies report an infection rate of about 12.9%, and a 4.3% incidence of C. diff colitis; with increased complications from 9 months onwards (>30%).[10] This is consistent with our study which demonstrated a 37.9% complication rate in delayed group (>6 months); with 6.04% wound infection and 3.45% C. diff infection.

Current literature also suggested that surgical closure techniques and interval time from ileostomy creation to closure may be contributing factors towards post-operative complications.[10,23,29] Meta-analysis comparing stapled and handsewn anastomosis have suggested that a stapled anastomosis had a significant reduction in surgical time and a lower incidence of bowel obstruction when compared to handsewn anastomosis, with no differences in anastomotic leak rates between the 2 techniques.[10,12,30-32] However, other meta-analysis have also suggested that both techniques were equivalent in preventing post-operative ileus and bowel obstruction.[26, 33, 34] Interestingly, our study also demonstrated a lower rate of post-operative ileus when a stapled side to side anastomosis was performed, especially in patients who underwent delayed reversal (10.9% vs 14.8%). We believe that in selected group of patients who experienced delays to their reversal surgery, with significant atrophy and fibrosis of the distal limb intraoperatively, a stapled side to side anastomosis should be considered to increase luminal size, and reduce post-operative ileus.

Current literature has no consensus about the optimal timing for reversal of defunctioning ileostomy; the recommendation for reversal within 8-12 weeks is to achieve adequate healing of the anastomosis whilst avoiding the prolonged presence of an ileostomy to prevent stoma related complications.[7] Our study demonstrated that patients who were reversed within 6 months of index surgery had a significantly higher incidence of stoma related complications (p=0.002), suggesting that patients with more stoma related complications tend to be reversed with more urgent priority. Need for adjuvant chemotherapy post-op is a known important contributor to delay of stoma reversal.[12] This was consistent with our results which showed that this was a consistent reason for delay in reversal in 26.8-36.8% across all time points compared.

A randomized controlled trial by Alves et al comparing early (8 days) versus late reversal (2 months) demonstrated that early closure in selected patients is feasible, with reduced hospital stay, bowel obstruction, but with a higher wound complication rate.[35] Results from other similar trials also resonated findings of increased complications after delayed ileostomy closure.[36,37] Study revealed complication rate of 37.9% in the delayed group, compared to 26.3% in group who had their reversal within 6 months of surgery. Although these results add to increasing evidence that delayed loop ileostomy closure increases overall complications, it is still controversial amongst clinicians for early reversal of ileostomy at 8-12 days due to concerns of anastomotic leakage after early ileostomy reversal.

Our study echoes the concerns of many clinicians with regards to delayed closure of loop ileostomy and its complications. Reversal of ileostomy is often classified as a category 2 procedure, and patients often wait for an extended duration for their reversal surgery, especially in the public system. Our study also demonstrated that the majority of our patients experienced delays to their reversal surgery even before the COVID-19 pandemic. During the COVID-19 pandemic, there were limited category 2 surgeries being performed, further exacerbating the waitlist. In the post-COVID 19 era, catch up of the backlog of surgeries also meant that more urgent surgeries were getting allocated as a priority, rather than reversal of ileostomy surgeries, even though patients may have completed their adjuvant therapy a while ago. In a recent study by Barnard et al looking at causes for delay in reversal of ileostomy in Australasian units, he demonstrated that delays in reversal were mainly associated with neo-adjuvant and adjuvant chemotherapy.[5] The delay resulted in increased costs of outpatient stoma care (p<0.001), post-operative care (p=0.004) and total cost of treatment (p=0.014), imposing a significant economic burden no our healthcare system.[5] However, with the increasing adoption of total neoadjuvant therapy (TNT), chemotherapy administered in the neoadjuvant setting may mitigate need for adjuvant therapy, allowing for earlier closure of loop ileostomy.[12]

Limitations

Our study findings should be interpreted in the context of the following limitations. Due to the retrospective nature of the analysis, there is potential of confounding by unmeasured factors. The numbers of the study are low, and results of this study represent a single centre and therefore may not be generalizable to other units who have varying experience in reversal of ileostomy surgery. Larger studies of similar nature with longer term follow up period and length of stay comparisons will be required to follow the outcomes.

There is also paucity of evidence in the current literature to support early versus late closure of ileostomy, or closure of ileostomy during/after adjuvant chemotherapy.

CONCLUSION

This study demonstrates that delayed ileostomy closure is associated with increased risk of complications such as

post-operative ileus, anastomotic leaks, wound complications and *Clostridium difficile* infection. Delays are often due to patients undergoing adjuvant chemotherapy, and elective waitlist delays during the COVID era. Reversal within 6 months reduces the risk of complications which could alleviate the burden on the healthcare system. A stapled side to side anastomosis should also be considered especially in selected group of patients with significant delays to their reversal surgery.

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