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RESEARCH ARTICLE

Balancing Risk in Rectal Cancer Surgery: A Retrospective Cohort Study Examining the Consequences of Anastomotic Leaks and Diversion

Matthew Marino[1], Charlotte Verberne[2], Julia F Merchant[3], Sarah A Hassan[4], Carlijn DM Witjes[5], Ian Lindsey[1]

[1]Oxford University Hospitals Trust, United Kingdom
[2]Amstelland Hospital, Amstelveen, The Netherlands
[3]Suth Warwickshire University NHS Foundation Trust, United Kingdom
[4]Royal Derby Hospital, United Kingdom
[5]Ijsselland Hospital, Capelle aan de Ijssel, The Netherland

ABSTRACT

Aim: This study aimed to aid decision-making concerning selective diversion in rectal cancer surgery by examining the complications and management of anastomotic leaks in diverted and undiverted patients, as well as ileostomy complications and permanence.

Method: A review of all anterior resections performed at our United Kingdom tertiary referral center between 2012 and 2018 was conducted to assess anastomotic leaks and their management and ileostomy-related complications and closure rate.

Results: Of 578 total anterior resections, 223 (38.5%) were diverted. Leaks occurred in 40 (6.9%), of which 25 (62.5%) were diverted and 15 (37.5%) were undiverted; 89% of diverted patients did not leak. There was one death, which was not leak-related. Of the 40 leaks, 24 (60%) were managed transanally and percutaneously with antibiotics or were incidental; these were mostly in the diverted patients. Undiverted patients underwent operative management more frequently, mostly with laparoscopic washout and ileostomy formation (47%). Ileostomy morbidity was common at both creation (27%) and closure (25%), with a leak rate of 3%. Diversion permanence occurred in 16% overall and 10% in ileostomies created at rescue, the most common reason being disease progression (38%) as opposed to leakage (11%).

Conclusion: The anastomotic leak rate is low, with one-third of all patients being "overprotected" and thus unlikely to derive any benefit from index diversion. Although diverted patients are more likely to have non-operative management of a leak, significant ileostomy complication rates and permanence should be taken into account when deciding which patients to divert.

Keywords: Rectal cancer, anterior resection, anastomotic leak, ileostomy, complications

Introduction

Surgical resection, with or without neoadjuvant chemoradiotherapy (CRT), is the established gold standard treatment for localized rectal cancer. Reported leak rates from rectal anastomoses vary in the literature between 1% and 24%.[1] Distance from anal verge <7 cm, number of linear staple firings >2, neoadjuvant CRT, steroid use, and male gender are negative prognostic indicators for anastomotic leaks.[2,3] Anastomotic leaks correlate with an increased risk of postoperative death, return to theatre, prolonged hospital stay, and postponement of adjuvant chemotherapy. Moreover, anastomotic leaks are associated with a higher rate of local recurrence and poorer long-term survival.[4,5]

Temporary diversion with a loop ileostomy, in combination with bowel preparation, has been shown to reduce morbidity associated with anastomotic leaks.[6] However, diversion also carries a risk of significant morbidity, including dehydration and acute kidney injury related to high output, parastomal

Address for Correspondence: Matthew Marino MD, Oxford University Hospitals Trust, United Kingdom
E-mail: mattmarino51@gmail.com **ORCID ID:** orcid.org/0000-0003-2307-3088
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hernia, and contact dermatitis.[7] One recent series found that ileostomy-related complications accounted for 13% of index procedure morbidity and 15% of readmissions,[8] with an associated impact on long-term quality of life.[9] Furthermore, diversion commits the patient to further surgery should they wish to restore gastrointestinal continuity.[1,10] The reported leak rate for reversal of loop ileostomy is 2%-3%, potentially leading to return to theatre, permanent stoma, or-rarely-post-operative death.[11,12]

Anastomotic leaks are unpredictable, even after consideration of individual patient risk factors. This leads to many patients being "overprotected" (i.e., diversion, no leak) and, less commonly, some patients being "underprotected" (no diversion, leak).

The concept of "rescue" in anastomotic leaks is well recognized.[8,13] When anastomotic leaks occur, early recognition facilitates a timely return to theatre for washout, drainage, and diverting ileostomy or transanal repair, thereby potentially salvaging the anastomosis. This approach has the advantage of avoiding stomas and their inherent complications in patients where no leak occurs, thereby reducing the number of "overprotected" patients. In light of this, some practitioners argue that proximal diversion is being overused and that the morbidity associated with diverting ileostomies needs to factor more heavily into the decision-making.[14]

In this study, we describe a large cohort of patients undergoing anterior resection in a tertiary referral center to explore the data regarding leak rates and consequences and ileostomy complication rates. The authors declare no conflicts of interest.

Materials and Methods

This was a retrospective cohort study comprising all patients aged >18 years who underwent anterior resection for primary colorectal cancer at a single tertiary referral unit within the United Kingdom, Oxford University Health Trust, between October 1, 2012, and December 31, 2018, identified from a prospectively maintained database. Patients were excluded if they did not have histologically proven rectal cancer, if there was no primary colorectal/coloanal anastomosis, or if they underwent formation of a loop ileostomy without resection of the primary tumor. Patients with metastatic disease undergoing resection of the primary tumor were included.

High anterior resection (HAR) was defined as laparoscopic or open anterior resection with the anastomosis above or at the level of the peritoneal reflection. Low anterior resection (LAR) was defined as laparoscopic or open total or partial mesorectal resection with an anastomosis below the peritoneal reflection. Patient demographics, operative details, pathological tumor–node–metastasis staging, and 90-day complications (using the Clavien-Dindo classification) were extracted and recorded. An anastomotic leak was defined per the International Study Group of Rectal Cancer as "a defect of the intestinal wall at the anastomotic site (including suture and staple lines of neorectal reservoirs) leading to a communication between the intra- and extraluminal compartments".[15] Leaks were diagnosed radiologically, surgically, and/or endoscopically.

Outcomes of interest were the rate of diversion at the index procedure, anastomotic leak rate, management of anastomotic leak, ileostomy-related complications, time to ileostomy closure, and complications at closure.

Patients were divided into 4 cohorts: undiverted and no leak-"no danger"; diverted and leak-"protected"; diverted and no leak-"overprotected"; and undiverted and leak-"underprotected."

Generic consent was gained from patients prospectively at the time of their operation. As this study was conducted as a retrospective database audit on patients already consented, approval was given by the institution's clinical governance team, which stipulated that it did not require formal ethics approval, in line with the institution's guidelines for de-identified data analysis. Data confidentiality and ethical standards were strictly maintained throughout the research process.

Statistical Analysis

Outcomes with a p-value of <0.05 were considered significant. All analyses were performed using the Statistical Package for the Social Sciences (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY, USA). Chi-squared tests were employed to compare categorical variables using crosstab analysis, and two-sided t-tests were utilized to compare categorical variables with quantitative variables.

Results

A total of 2,267 patients undergoing colorectal resection were identified between October 2012 and December 2018, of whom 1,568 were being treated for colorectal cancer. A total of 578 patients underwent rectosigmoid resections with or without diversion and were included in the study (Figure 1).

Table 1 shows the characteristics of diverted and undiverted patients. A total of 297 (51.4%) patients underwent LAR, and 281 (48.6%) underwent HAR. One (0.3%) postoperative death was observed within 30 days; the cause of death was myocardial infarction, not thought to be directly related to the procedure.

Categorization of Risk

Table 2 shows the categorization of risk: 58.8% of patients were in "no danger" (undiverted/no leak), 4.3% "protected" (diverted/leak), 34.26% "overprotected" (diverted/no leak), and 2.6% "underprotected" (undiverted/leak).

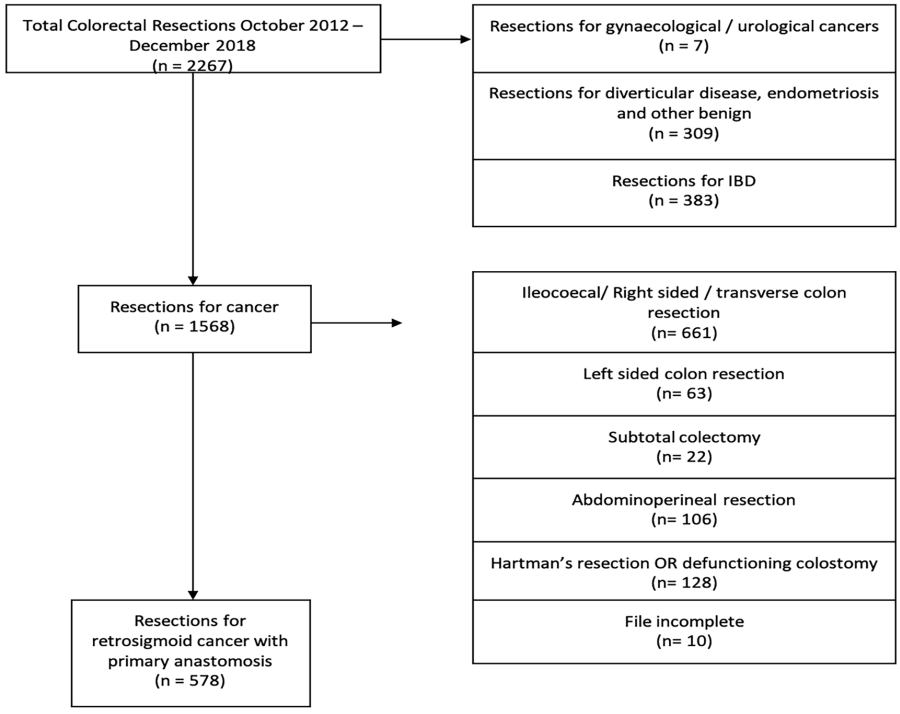

Figure 1. Flowchart of inclusions

Table 1. Characteristics of diverted and undiverted patients

		Diverted (n=223)	Undiverted (n=355)	p-value
Age; median (range)		66 (32-90)	66 (21-90)	
Gender	Male Female	150 (67%) 73 (33%)	200 (56%) 155 (44%)	**p=0.008**
American Society of Anesthesiologists classification	I II III	117 92 14	162 175 18	p=0.165
Resection height	Low anterior resection High anterior resection	209 14	88 267	**p<0.00001**
Stage	T1-2 T3+	79 144	123 232	p=0.848
Neoadjuvant chemoradiotherapy	No Yes	152 71	312 43	**p<0.00001**
Anastomotic leak	No Yes	198 25 (11.2%)	340 15 (4.2%)	**p=0.0012**

Ileostomy Formation Rates

A total of 223 (39%) patients had a diverting ileostomy formed at or before the index procedure (the diverted group), and 355 (61%) had no ileostomy (the undiverted group). The rate of diversion was significantly higher in patients receiving a LAR than in those receiving a HAR (70% vs. 5%, p<0.00001). Diversion rates were also significantly higher in those receiving neoadjuvant CRT (62% vs. 33%, p<0.00001) and male gender (67% vs. 33%, p=0.008). Patient comorbidity, defined using the American Society of Anesthesiologists classification system, and the T-stage did not significantly affect the rate of diversion (p=0.165 and p=0.848, respectively) (Table 1).

Anastomotic Leak Rates

A total of 40 anastomotic leaks were reported, with an overall leak rate of 6.9%. Leak rates were significantly higher in patients receiving neoadjuvant treatment (12.3% vs. 5.2%, p=0.01).

Of the 40 leaks, 25 (11.2%) occurred in the "protected" (diverted) group (3 after HAR and 25 after LAR) and 15 (4.2%) in the "underprotected" (undiverted) group (5 after HAR and 10 after LAR, p=0.0012). There was no leak-related mortality.

Management of Anastomotic Leaks

Table 3 shows the treatment of anastomotic leaks in both groups. Of the 40 leaks, 3 were subclinical radiological leaks identified on rectal contrast studies performed in preparation for ileostomy closure. These were managed conservatively. The remaining 37 leaks were identified within the post-operative period and managed with antibiotics, radiologically, or surgically. The anastomosis was taken down and an end colostomy was formed in 5 patients (13%), of whom 1 was already diverted. All end colostomies were permanent.

The majority of leaks (15/25, 60%) in the diverted group were managed conservatively; 3 (12%) were subclinical and required no treatment, 11 (44%) were successfully managed with antibiotics only, and 1 (4%) patient had a radiologically placed drain. Six (15%) patients received transanal repair of the anastomotic defect, and 3 (13%) patients required a laparoscopic washout with preservation of the anastomosis. In total, 24/25 (96%) leaks were successfully managed with preservation of the anastomosis, with 1 (4%) patient requiring resection of the anastomosis and end colostomy formation.

Most leaks in the undiverted group were treated surgically (13/15, 87%). In 4 (27%) of these patients, the clinical presentation necessitated resection of the anastomosis and formation of an end colostomy. In 7 (47%) patients, a washout with formation of a "rescue" ileostomy was performed, with preservation of the anastomosis, 1 (7%) had a transanal repair, and 1 (7%) laparoscopic washout without ileostomy formation. The remaining 2 (13%) patients were managed conservatively: 1 with antibiotics and 1 with a radiologically placed drain, without stoma formation.Strict post-operative monitoring of all patients took place with daily senior review and blood tests, including C-reactive protein. All patients with clinical suspicion of an anastomotic leak underwent an urgent computed tomography scan with intravenous (IV) and rectal contrast performed on the day of request. The median time between the index procedure and return to theatre was 4 days. All surgical reinterventions were carried out by a colorectal specialist surgeon within 24 hours of the initial clinical suspicion.

Table 2. Categorization of risk

Total patients =578	Diverted	Undiverted
No leak	198 (34.26%) **"Overprotected"**	340 (58.8%) **"No danger"**
Leak	25 (4.3%) **"Protected"**	15 (2.6%) **"Underprotected"**

Ileostomy-Related Complications

Table 4 depicts ileostomy-related complications. A total of 63 (27%) patients were either readmitted or had a prolonged hospital stay following the index operation. Eleven (5%) patients had a prolonged post-operative ileus, 12 (5%) patients developed stomal obstruction due to parastomal hernia or retraction, with 2/12 requiring ileostomy closure within 7 days of the index operation; neither procedure resulted in an anastomotic leak. A total of 36 (16%) patients required readmission and IV fluids for high output, and 4 (2%) patients developed other ileostomy-related complications.

Time to Ileostomy Closure and Closure-Related Complications

In total, 195 (84%) ileostomies were closed during the follow-up period (≥24 months), with a median time between index operation and ileostomy closure of 19 months (0-106). Of the patients with an ileostomy formed as part of the "rescue" procedure (n=10), 9/10 (90%) had their ileostomy closed within the follow-up period.

Table 5 shows closure-related morbidity and reasons for non-closure. There were no ileostomy closure-related mortalities. The anastomotic leak rate at ileostomy closure was 3%

Table 3. Treatment of anastomotic leak

		Diverted (n=223)	Undiverted (n=355)	Total (n=578)
GRADE A None (incidental finding)		3	0	3
GRADE B Antibiotics		11	1	12
Radiologically placed drain		1	1	2
GRADE C	Transanal repair	6	1	7
Reoperation	Laparoscopic washout	3	1	4
	Laparoscopic loop ileostomy	-	7	7
	Resection anastomosis + end colostomy	1	4	5
Total		25 (11.2%)	15 (4.2%)	40 (6.9%)

(6/195 patients); 5 underwent urgent re-operation with new ileostomy formation, and 1 patient was successfully treated with antibiotics and percutaneous drainage. Of the 5 patients who had a second ileostomy formed, 2 patients ended up with a permanent end ileostomy, 2 patients had ileostomy closure at a later date without further complications, and 1 patient was lost to follow-up. Further common complications following ileostomy closure were ileus (12, 6%), surgical site infection (8.4%), hematoma (5.3%), and incisional hernia (5, 3%). No statistically significant relationship was found between patient comorbidity and the occurrence of ileostomy closure complications.

A total of 38 ileostomies were not closed during the followup period. The most common reason was progression to metastatic disease (n=15, 38%), followed by patient comorbidity (n=4, 11%), patient choice (n=4, 11%), anastomotic issues (stricture, persistent leak) (n=4, 11%), death (n=3, 8%) and other/unknown (n=8, 21%).

Table 4. Ileostomy-related morbidity

	Frequency (n=233)†
None	170 (72%)
Prolonged post-operative ileus	11 (4.7%)
Obstructing parastomal hernia	12 (5.2%)
High output requiring readmission for rehydration	36 (15.5%)
Other	4 (1.7%)
Total morbidity	**63 (27%)**

†223 "index" +10 "rescue"

Discussion

In this study, we compared anastomotic leak rates and consequences in diverted and undiverted patients receiving anterior resection for rectal cancer and examined ileostomy complication and permanence rates. Whether to perform a diversion at the index procedure is a decision made by the operating surgeon based on a range of factors including patient characteristics, tumor factors (such as height and prior CRT), institutional factors (access to theatres, availability of senior staff to review post-operatively, "culture" of diversion), and intangible "human factors" related to risk perception.

Diversion was unsurprisingly significantly higher in LAR (68.0%) than in HAR (4.6%), in male patients and in patients who had neoadjuvant CRT. The anastomotic leak rate was significantly higher in diverted patients (4.3% vs 2.6%, p=0.0012). A 2010 Cochrane review and a more recent meta-analysis in 2014 found lower anastomotic leaks and re-operation rates in the presence of diversion.[16,17] Our current data contradict this, likely reflecting appropriate patient selection; surgeons chose to divert higher-risk patients. Additionally, three subclinical leaks were found via rectal contrast study prior to ileostomy closure. These delayed leaks can be difficult to treat, often more so than recognising and dealing with acute leaks.[14,18]

Further suggesting appropriate selection of diversion was a low number of "underprotected" (leak with no diversion) patients, at 2.6%. Advocates of routine diversion would argue that although diversion does not prevent anastomotic leak, it protects against overwhelming pelvic sepsis and possibly preserves more anastomoses.[19] It is important to note that no mortalities occurred within this group, nor was there any

Table 5. Ileostomy closure-related complications and reasons for non-closure

Ileostomy closed		**Yes, 195 (84%)**	**No, 38 (16%)**
Median time to closure in months: (range)		19 (0-106)	-
Complications	None	146 (75%)	-
	Ileus	12 (6%)	-
	Anastomotic leak	6 (3%)	-
	Haematoma	5 (2%)	-
	Surgical site infection	8 (4%)	-
	Incisional hernia	5 (3%)	-
	Other	13 (7%)	-
Ileostomy not closed			
Reason	Progressive disease	-	15 (38%)
	Comorbidity	-	4 (11%)
	Patient choice	-	4(11%)
	Anastomotic problems (stricture, persistent leak)	-	4 (11%)
	Death	-	3 (8%)
	Other		8 (21%)

overwhelming sepsis. The main difference between diverted and undiverted leaks is that the former were much more likely to receive non-operative management, such as antibiotics alone (56% vs. 4%) or a less invasive surgical intervention, such as transanal repair or laparoscopic washout. Although there was an increase in anastomotic loss in the undiverted group, the numbers were small (4 vs. 1) and not statistically significant. This suggests that close monitoring and early rescue can be done safely.

Although a majority (58.8%) of patients were appropriately in "no danger" (undiverted and did not leak), 34.3% of patients were "overprotected" (diverted and did not leak), meaning one-third of patients were exposed to the risks of an ileostomy, with no benefit gained from diversion. Diversion-related complications occurred in 27%, meaning a large proportion of these patients experience unnecessary complications. Although many of these complications were relatively minor, they may delay the time to adjuvant treatment, if this is required. Complications at ileostomy closure were also common, occurring in 25% of cases. Notably, patient-reported outcomes were not measured, which may be an area of future research.

Evidence on the optimal timing for ileostomy reversal is mixed. Although several studies, including a recent meta-analysis, advocate for early closure to reduce morbidity, a recent study was stopped early due to high complication rates at 2 versus 12 weeks.[20-22] In our study, patients waited a median of 19 months, exceeding the potential benefits of early closure and increasing the risk of ileostomy-associated complications. Despite the support for early reversal, our findings highlight the challenges in implementing this in overburdened public health systems.

In this study, 16% of ileostomies were not closed during the follow-up period (≥24 months). This figure is in line with other studies, which quote 17-18% ileostomy permanence.[23,24] In the United Kingdom, the National Bowel Cancer Audit 2025 shows a persistent ileostomy rate of 38%. Despite the target being a 35% reversal rate by 18 months, this has increased from 35% last year and 29% in 2020, which is thought to be due to persistent long surgical waiting times since the COVID-19 pandemic.[25,26] This increasing wait time should be taken into consideration when choosing to divert and effectively mandating a repeat procedure.

Surprisingly, despite diversion occurring to prevent complications of a leak, anastomotic complications accounted for only 11% of stoma permanence. The major reason for non-closure was progressive disease (38%). The presence of an ileostomy may complicate adjuvant therapy, particularly in the context of high output, and may deleteriously impact palliation. Also worth noting is that 10% in the rescue group versus 16% overall did not have their ileostomies reversed within the following period, suggesting that an ileostomy formed as part of rescue is no more likely to be permanent than if formed at index.

The evidence regarding routine diversion is mixed. A recent meta-analysis of 2,366 patients from 14 studies found a reduced anastomotic leak rate in diverted patients (6% vs. 9%) but a higher overall complication rate, likely reflecting ileostomy-related complications.[27] A 2017 cohort from Sweden showed a decrease in all-cause mortality in diverted patients and no differences in long-term oncological outcomes, leading the authors to recommend routine diversion for LAR.[23]

Contrarily, a growing body of evidence has questioned the premise of routine diversion. A recent Dutch study assessed long-term outcomes in 99 patients undergoing LAR where highly selective diversion was practiced.[28] Stoma permanence was reduced by 9% compared with studies advocating routine diversion. Thirty-day mortality was also reduced, which the authors attributed to strict surveillance and a protocol dictating early intervention in anastomotic leak, thereby avoiding uncontrolled sepsis and failure to rescue.

Multiple papers have since suggested the overuse of diversion and called for a paradigm shift from routine diversion to omitting diversion as a principle.[14,29] Our institution has largely adopted the practice of highly selective diversion, and the data presented support this practice.

This analysis is limited by its retrospective, observational format. The more minor post-operative complications may be underreported in the medical notes, and some patients may have re-presented to other centers. However, in our cohort of 578 anterior resections, we have shown a low overall anastomotic leak rate and no leak-related mortality. Appropriately, leaks were more common in diverted patients. Although diverted patients were more likely to have non-operative management of their leak, anastomotic takedown was marginally higher in the undiverted group, and almost half were managed with rescue ileostomy alone. Ileostomy in this context was no more likely to be permanent than if made at the index procedure. One-third of all patients were "overprotected" and thus unlikely to have derived any benefit from index diversion. These factors, a 27% ileostomy-related complication rate and 16% permanence rate, should be taken into account when deciding which patients to divert, and suggest there is safety in very selective diversion.

Ethics

Ethics Committee Approval: As this study was conducted as a retrospective database audit on patients already consented, approval was given by the institution's clinical governance team, which stipulated that it did not require formal ethics approval, in line with the institution's guidelines for de-identified data analysis.

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.M., C.V., J.F.M., S.A.H., C.D.M.W., I.L.F., Concept: C.V., J.F.M., S.A.H., C.D.M.W., I.L.F., Design: C.V., J.F.M., S.A.H., C.D.M.W., I.L.F., Data Collection or Processing: M.M., C.V., J.F.M., S.A.H., C.D.M.W., I.L.F., Analysis or Interpretation: M.M., C.V., J.F.M., S.A.H., C.D.M.W., I.L.F., Literature Search: M.M., C.V., J.F.M., S.A.H., C.D.M.W., Writing: M.M., C.V., J.F.M., S.A.H., C.D.M.W., I.L.F..

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