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Title: Anastomotic Leaks in Colorectal Surgery.

Short Title: Anastomotic Leaks.

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ABSTRACT

Introduction: Anastomotic leaks are a serious complication of bowel surgery. This study aimed to evaluate the rate and severity, and identify risk factors for leaks in patients undergoing bowel anastomoses.

Methods: Prospective evaluation was performed on patients undergoing bowel surgery within a colorectal surgical unit. Anastomotic leak was defined and graded according to severity. A nurse independently collected the information. Stepwise logistic regression analysis was performed.

Results: 2363 patients underwent 2944 anastomoses. Their median age was 64 years. 7% were emergency operations. Anastomotic leak occurred in 82 patients (2.7%). 63% of leaks were managed with drainage or re-operation. Ultra-low anterior resection was associated with the highest sub-group leak rate (7.3%). In multivariable analysis, independent predictors for a leak included 'other' pathologies (iatrogenic, ischaemia, radiation enteritis) (p=0.016, OR 6.3, 95% CI 1.4 – 28.0), ULAR (p=0.001, OR 8.5, 95% CI 2.3 – 31.2), and the surgeon (A: p<0.001, OR 3.4, 95% CI 2.1 – 5.6).

Discussion: Majority of predictors for anastomotic leak were fairly intuitive. Approximately one third of leaks had minor clinical manifestations. Nonetheless, it was relevant to note the importance of the individual surgeon as an independent predictor for leaks.

Keywords: Colorectal surgery; Anastomotic leak; Intestinal neoplasms; Inflammatory bowel diseases; Effect modifier.

INTRODUCTION

A severe anastomotic leak (AL) is a devastating post-operative complication; associated with increased morbidity and mortality, often requires further surgery, and necessitates stoma formation[1]. ALs place increased demands upon critical care, radiology, and nutritional support. Long-term adverse consequences include poor bowel function, anastomotic stricture, and reduction in overall and disease-free survival[2]. In spite of these detrimental outcomes, it remains difficult to define what an appropriate leak rate is[3]. Hence, high quality and risk-adjusted information on ALs is required in order to define an 'acceptable' leak rate.

This study aimed to evaluate the rate and severity, and identify independent predictors for ALs in patients undergoing intestinal anastomoses.

METHODS

A prospective database was maintained on patients undergoing elective/emergency, small/large intestinal resections and/or anastomoses, for benign/malignant disease. Data was inputted by an independent nurse. This prospective audit included five colorectal surgeons. Four surgeons (2006 to 2012) performed procedures at SJOG Subiaco and Murdoch, and one surgeon (1996 to 2012) at SJOG Subiaco and Fremantle Hospital. All patients received peri-operative intravenous antibiotic prophylaxis. Mainly patients undergoing rectal surgery received bowel preparation. A treatment pathway standardised post-operative care.

Baseline data collected included age, gender, pathology (indication), pathology location, surgical procedure, surgical margins, anastomotic type (composition), anastomotic level from the anal verge in patients undergoing anterior resection, and use of a de-functioning (covering) stoma. ASA (American Society of Anaesthesia) score functioned as a global measure of health. BMI and smoking records were markedly incomplete and therefore excluded. Some recent studies demonstrate these two variables don't significantly impact upon ALs[4,5,6] which supports their exclusion. Anterior resections were divided into three groups: high (HAR; above 10cm from the anal verge), low (LAR; within 10cm), and ultra-low (ULAR; within 6cm). Surgical techniques varied between surgeons.

AL was defined radiologically (CT scan with oral/enema contrast) or surgically (faecal leakage at laparotomy). Leak severity was graded according to AL management (no treatment, antibiotics only, drainage (percutaneous/transanal), or re-operation).

Statistics

Associations between categorical variables were tested using Chi-square tests when expected cell frequencies were greater than five, and exact tests performed otherwise. Means were compared using t-test and medians using Kruskal-Wallis rank test. The primary outcome, presence of an AL, was assumed to have binomial distribution and exact confidence intervals were estimated.

Data were considered to be correlated as 20% of patients had more than one anastomotic procedure over the study period. Generalised estimating equations with robust standard errors from the sandwich estimator were used to estimate the marginal effects of patient and operative factors on the odds of AL after taking the longitudinal nature of the data into account. The within-patient correlation was assumed to be exchangeable. Due to the relatively small number of ALs, models were constructed in stepwise purposeful and parsimonious fashion. Only clinically relevant interaction terms were considered. All analysis was performed in Stata 12.0 (Statacorp, USA).

RESULTS

2994 anastomoses at risk of AL were created during 2941 operations on 2363 patients (Figure 1). 44 patients (1.9%) had two or more anastomoses created during a single operation. 557 patients (23.6%) had two or more anastomoses created during different hospital admissions. 82 ALs were recorded in 79 patients; three patients had two ALs from different operations. Thus, the rate of ALs per anastomosis created was 2.7% (82/2994, 95% CI 2.2 – 3.4), per operation was 2.8% (82/2941, 95% CI 2.2 – 3.4), and per person was 3.3% (79/2363, 95% CI 2.6 – 4.1). No AL was observed in any patient who had more than one anastomosis created during a single operation.

Intra-abdominal/pelvic abscesses occurred in 17 patients (0.7%); who were independently reviewed and confirmed to have infection remote from the anastomotic site with no evidence of AL on radiography. Of operations where institution was recorded, 23% (564/2413) were performed at the public teaching hospital, the remainder at the two private hospitals (1670/2413, 179/2413). Mean in-hospital mortality was 3.8% (3/79) in the AL group compared with 0.8% (19/2284) in the non-AL group.

Patient characteristics

Male patients were more prevalent overall (52.4%) and underwent more anastomotic operations, had a higher total number of anastomoses created, and had more ALs recorded (Table 1). Proportionally more males had colorectal cancer, ulcerative colitis, and rectal pathology, whereas females had adenoma, diverticular disease, and right colon pathology. There was no difference in age or admission type by gender.

Operation characteristics

The most common indication for anastomotic operations was colorectal cancer (50.5%) (Table 2). Ileostomy reversals (27.7%) were the most common surgical procedure. Laparoscopic technique alone occurred in 18% of all operations. The most frequently performed anastomotic types were small bowel (SB) to colon and SB to SB, together comprising more than 50%.

Univariate analyses showed proportions of ALs differed by indication, surgical procedure, anastomotic type, and surgeon (Table 2). The highest sub-group AL rates included ‘other’ pathologies (7.3%), ULAR (7.3%), ultra-low rectal anastomoses (7.2%), and surgeon A (6.1%) (and D (14.3%)). No difference in proportion of ALs was observed by ASA, laparoscopic technique, or institution (2.7% (15/564), 3.3% (56/1670), 1.1% (2/179)).

Multivariable models were also constructed using generalised estimating equations. A model of patient factors showed the odds of AL were 70% higher in men, after adjusting for indication (Table 3A). Colorectal cancer, Crohn’s disease, and ‘other’ pathologies had increased odds of AL compared to stoma closure. Age, ASA, and calendar year weren’t significant, after adjusting for gender and indication. A model of operative factors showed that proportions of ALs differed by surgical procedure and surgeon (Table 3B). ULAR, total colectomy, and LAR had increased odds of AL compared to ileostomy reversal. After adjusting for surgical procedure, colorectal cancer and Crohn's disease were no longer significant. However, patients with 'other' pathologies were still six times (95% CI 1.4 – 28.0) more likely to have an AL. Surgeon A (and D) had increased odds of AL compared to surgeon C; however, the small number of procedures performed by surgeon D limits any meaningful interpretation. After adjusting for indication, surgical procedure, and surgeon, male gender was no longer significant. Age, ASA, calendar year, and laparoscopic technique weren't significant in the modelling process and excluded from the final model.

Rectal anastomoses

Multivariable analysis indicated that anastomoses containing rectum had higher odds of AL; 56 (68.3%) ALs involved a rectal anastomosis (Table 2). Additional multivariable analysis was performed on the patient-subset whom underwent rectal anastomoses to identify specific risk factors associated with these ALs (Table 4). ULARs were almost seven times more likely to leak than HARs but only without a covering stoma. ULAR with a covering stoma had equivalent odds of AL compared to the other surgical procedures. After adjusting for surgical procedure, anastomoses within 7cm of the anal verge, positive tumour margins (R1/R2), and 'other' pathology still had increased odds of AL. Surgeon differences in rectal ALs even remained after adjusting for these factors, with surgeon A (and D) having higher odds of AL.

Leak severity

Of 82 recorded ALs, 37 (45%) required re-operation, 15 (18%) required drainage, 12 (15%) had antibiotics, and 18 (22%) had no further treatment. Overall, the proportion of ALs requiring re-operation was 1.3% (95% CI: 0.9 – 1.7%). Cross-tabulations of leak severity with individual factors indicated possible associations with age, pathology location, anastomotic type, use of a covering stoma, and surgeon (Table 5). Observed differences in leak severity by surgeon were mainly due to surgeon C having less severe ALs compared to the other four surgeons. A covering stoma was used in 28% of all operations by surgeon C, whereas 19%, 12% and 13% by surgeons A, B and E respectively. The very small numbers of leaks in each severity category preclude any further in-depth analysis and interpretation.

DISCUSSION

Our overall AL rate of 2.7% is comparable to the reported incidence of 3 – 14% from other series reviewed in the literature[1,3,4,7,8]. Trying to determine an acceptable leak rate is not straight forward. A previous review of this issue highlighted the diverse reporting of ALs in the literature depending on whether the data was derived from a clinical trial, prospective series, or retrospective series[3]. Our focus was to try and determine AL rate as accurately as possible in a large cohort of patients. Even so, clearly diagnosing an AL is not easy. Because of the wide spectrum of presentations from a minor phlegmon to catastrophic peritonitis, we suspect that many ALs may go unreported. Thus we attempted to grade ALs according to their severity. The most difficult leaks to detect were those in patients with a de-functioning stoma which were incidentally identified on limited contrast studies, usually performed 6 weeks after surgery. Some of these ALs may have been overlooked by the colorectal nurse. In general, the harder you look the more you find.

Various patient, operative, and disease-specific factors have been described as predisposing to ALs. Many of these factors seem quite intuitive on reflection. One such factor initially observed in our study was male gender[3,4]. Once this association was adjusted for other known risk factors (i.e. colorectal cancer, rectal pathology), male patients were no longer at increased odds of AL. Similarly, surgery performed for a diagnosis ‘other’ than neoplasia or inflammatory bowel disease (i.e. iatrogenic injuries, ischaemia, radiation enteritis) was identified as an independent predictor for ALs. Perhaps the high AL rate in this group reflects the poor quality of tissues that may be encountered in such clinical situations.

A sub-analysis of rectal anastomoses found that independent predictors for ALs included ULAR without a covering stoma, anastomosis within 7cm from the anal verge, having microscopic (R1) or macroscopic (R2) residual disease at the surgical margin, and the surgeon. The presence of a covering stoma appeared to have a protective effect on ULAR as no significant increased risk of AL was found when compared with other rectal surgical procedures. The technically demanding nature of creation of these anastomoses could account for the importance of the surgeon, or rather their technical skills and surgical competence, in influencing the results.

Leak severity was also associated with specific risk factors including age, pathology location, anastomotic type, use of a covering stoma, and the surgeon. A covering stoma significantly reduced the severity of ALs and subsequent need for surgical intervention. 71% of patients without a covering stoma who developed an AL required surgical revision, whereas only 18% of patients with a covering stoma needed re-operation. These findings are not unexpected as the use of a covering stoma has been well documented as a protective factor for reducing the clinical impact of ALs[9,10]. For patients undergoing ULAR, our results would suggest a standard approach to provide a de-functioning stoma in order to decrease the rate and severity of ALs.

It is generally accepted that AL rates show great variability among surgeons, as shown by our study with individual rates from 1.8 to 14.3%. A closer look at their individual ALs according to severity found that all of surgeons' B, D and E leaks required re-operation. Although surgeon B and E had lower overall AL rates, they were all major leaks. There was also variability in individual surgeons' de-functioning stoma rates, from 12% to 28%. Lower covering stoma rates did not appear to correspond to higher overall AL rates, yet it was interesting to note the high requirement for return to theatre in ALs occurring without a covering stoma. This could possibly explain why surgeons B and E had more severe ALs; they comparatively had the lowest covering stoma rates. The relevance of these observations is important when it is considered that ALs are associated with a higher mortality rate[4,5,9].

There are limitations to interpreting data in a study of this nature. One needs to be mindful of the possibility of under-reporting of ALs. It is well documented that AL rates are proportionally higher when diagnosed with routine radiology when compared to clinical indices[3]. Routine follow-up radiology for all surgical procedures was not employed by our unit. Surgery has also evolved in this period to include more widespread use of laparoscopic techniques and introduction of fast track recovery programs. Furthermore, a high AL rate was noted for one surgeon; a single leak out of a total of 7 operated cases. Clearly such a small sample size has limited validity for analysis. Yet within our surgical community there are many surgeons performing relatively small numbers of anastomoses[3] and so it may never be possible to accurately determine their performance. To gain a meaningful number of cases to interpret probably requires the surgeon to be performing 50 or more anastomoses a year; and needs to take into account the case-mix involved.

Conclusion

This study has identified a number of factors that predict an increased risk of ALs. Many of these factors have previously been recognised in the literature. In particular we have highlighted the importance of the individual surgeon in achieving acceptable results, the variability in leak severity, and use of a de-functioning stoma reduces both rate and severity of an AL. The authors consider AL rates as an important quality indicator of surgical performance in colorectal surgery[10,11]. We acknowledge that collection of this type of information is labour intensive and requires the co-operation of both the surgeon and institution.

LEGEND

Figure 1. Overview of anastomoses created.

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Table 1. Characteristics of patients in the data set by gender (n=2363).

	Male (n=1238)		**Female (n=1125)**		
	Median	IQR	Median	IQR	p-value
Median Age at first operation	64	53-72	64	52-74	0.579
Mean Age at first operation	Mean	SD	Mean	SD	
	61.6	15.2	61.9	16.2	0.632
Number of Operations	n	%	n	%	
1	907	73.3	899	79.9	
2	317	25.6	218	19.5	**0.001**
3	14	1.1	7	0.6	
Total number of Anastomoses					
1	893	72.1	882	78.4	
2	326	26.3	225	20.0	
3	17	1.4	16	1.4	**0.006**
4	2	0.2	1	0.1	
6	0	0.0	1	0.1	
Indication at first operation					
Colorectal cancer	817	66.1	661	58.7	
Adenoma	136	11.0	170	15.1	
Crohn's disease	67	5.4	77	6.8	
Diverticular disease	75	6.1	108	9.6	**<0.001**
Stoma closure	65	5.3	53	4.8	
Ulcerative colitis	40	3.2	17	1.5	
Other[†]	36	2.9	39	3.5	
Pathology Location at first operation					
Small bowel	139	11.2	145	12.9	
Colon	41	3.3	43	3.8	
Left colon	352	28.4	333	29.6	**<0.001**
Right colon	342	27.6	371	33.0	
Rectum	365	29.5	232	20.6	
Anastomotic leak recorded at any time					
No	1187	95.9	1097	97.5	**0.028**
Yes	51	4.1	28	2.5	
Admission type at first operation					
Elective	1164	94.0	1036	92.1	0.064
Emergency	74	6.0	89	7.9	

[†]Other includes iatrogenic injuries, ischaemia and radiation enteritis.

Table 2. Characteristics of anastomotic operations by leak status (n=2941).

	All n=2941		No Leak n=2859		Leak n=82		
	n	%†	n	%‡	n	%‡	p-value
ASA							
1	591	20.1	576	97.5	15	2.5	
2	1583	53.8	1542	97.4	41	2.6	
3	625	21.3	601	96.2	24	3.8	0.210
4	56	1.9	54	96.4	2	3.6	
Unknown/ not recorded	86	2.9	86	100	0	0.0	
Indication at operation							
Colorectal cancer	1485	50.5	1433	96.5	52	3.5	
Adenoma	324	11.0	315	97.2	9	2.8	
Crohn's disease	150	5.1	145	96.7	5	3.3	
Diverticular disease	188	6.4	185	98.4	3	1.6	**0.003**
Stoma closure	638	21.7	632	99.1	6	0.9	
Ulcerative colitis	74	2.5	73	98.7	1	1.4	
Other§	82	2.8	76	92.7	6	7.3	
Anastomotic typeǀ							
Colon to Colon	79	2.7	77	97.5	2	2.5	
Colon to Low rectum	225	7.7	216	96.0	9	4.0	
Colon to Rectum	432	14.7	425	98.4	7	1.6	
Colon to Ultra-low rectum	471	16.0	437	92.8	34	7.2	**<0.001**
SB to Colon	831	28.3	816	98.2	15	1.8	
SB to Low rectum	85	2.9	83	97.7	2	2.4	
SB to Rectum	79	2.7	75	94.9	4	5.1	
SB to SB	739	25.1	730	98.8	9	1.2	
Surgical procedure							
HAR	434	14.8	427	98.4	7	1.6	
Ileostomy reversal	814	27.7	803	98.7	11	1.4	
J-pouch	78	2.7	76	97.4	2	2.6	
LAR	219	7.5	210	95.9	9	4.1	**<0.001**
L. Hemicolectomy	49	1.7	47	95.9	2	4.1	
R. Hemicolectomy	704	23.9	696	98.9	8	1.1	
Total colectomy	176	6.0	167	94.9	9	5.1	
ULAR	467	15.9	433	92.7	34	7.3	
Laparoscopic technique							
No	2419	82.3	2351	97.2	68	2.8	0.506
Yes	522	17.8	508	97.3	14	2.7	
Surgeon							
A	527	17.9	495	93.9	32	6.1	
B	236	8.0	231	97.9	5	2.1	
C	1,777	60.4	1,740	97.9	37	2.1	**<0.001**
D	7	0.2	6	85.7	1	14.3	
E	394	13.4	387	98.2	7	1.8	

† Column percentages. ‡ Row percentages by leak status. § Other includes iatrogenic injuries, ischaemia and radiation enteritis.
ǀ For patients who had multiple anastomoses created during a single operation, only one type was recorded.

Table 3. Parsimonious multivariable modelling using generalised estimating equations to estimate patient and operative factors associated with increased odds of anastomotic leaks.

A: Patient factors model	**OR**	**95% CI**	**p-value**
Gender			
Male	1.7	1.1-2.7	**0.026**
Female	1.0	ref	
Indication at operation			
Colorectal cancer	6.1	1.7-22.7	**0.007**
Adenoma	4.3	0.9-20.5	0.066
Crohn's disease	6.1	1.25-29.7	**0.025**
Diverticular disease	3.0	0.6-15.3	0.176
Stoma closure	1.0	ref	-
Ulcerative colitis	2.5	0.3-19.7	0.371
Other†	13.5	2.9-62.6	**0.001**

B: Patient and Operative factors model	**OR**	**95% CI**	**p-value**
Indication at operation			
Colorectal cancer	1.4	0.2-6.8	0.706
Adenoma	1.6	0.25-9.7	0.628
Crohn's disease	3.1	0.5-18.9	0.223
Diverticular disease	0.8	0.1-4.9	0.794
Stoma closure	1.0	ref	-
Ulcerative colitis	0.7	0.1-6.0	0.708
Other†	6.3	1.4-28.0	**0.016**
Surgical procedure			
HAR	1.6	0.4-6.2	0.533
Ileostomy reversal	1.0	ref	-
J-pouch	4.6	0.8-26.4	0.084
LAR	4.4	1.0-19.2	**0.046**
L. Hemicolectomy	3.6	0.5-26.0	0.200
R. Hemicolectomy	0.9	0.2-3.8	0.893
Total colectomy	4.8	1.2-19.4	**0.028**
ULAR	8.5	2.3-31.2	**0.001**
Surgeon			
A	3.4	2.1-5.6	**0.000**
B	1.1	0.4-3.0	0.780
C	1.0	ref	-
D	12.8	1.7-94.5	**0.014**
E	0.7	0.3-28.0	0.452

† Other includes iatrogenic injuries, ischaemia and radiation enteritis.

Table 4. Parsimonious multivariable modelling using generalised estimating equations to estimate detailed patient and operative factors associated with increased odds of anastomotic leaks involving rectal anastomoses (n=1292).

	OR	**95% CI**	**p-value**
Surgical procedure without covering stoma			
HAR	1.0	ref	
LAR	2.0	0.6-7.9	0.265
ULAR	6.6	1.8-25.2	**0.005**
Others combined	2.1	0.4-10.8	0.397
Surgical procedure with covering stoma			
HAR	1.0	ref	
LAR	6.8	0.7-64.7	0.097
ULAR	4.5	0.5-39.3	0.175
Others combined	2.5	0.2-27.0	0.445
Anastomosis <= 7cm from anal verge			
No	1.0	ref	
Yes	2.6	1.2-5.4	**0.012**
Positive tumour margins at resection			
No	1.0	ref	
Yes	3.3	1.2-8.8	**0.019**
Other† indication at operation			
No	1.0	ref	
Yes	12.4	3.5-41.3	**<0.001**
Surgeon			
A	2.7	1.4-5.3	**0.003**
B	1.4	0.5-3.9	0.524
C	1.0	ref	
D	19.5	3.2-120.1	**0.001**
E	0.5	0.1-1.6	0.245

†Other includes iatrogenic injuries, ischaemia and radiation enteritis.

Table 5. Cross-tabulation of patient and operative factors with leak severity where evidence of a statistically significant (p<0.05) association was present (n=82).

	No treatment		Antibiotics		Drainage		Re-operation		Total	Exact test
	n	%	n	%	n	%	n	%	n	p-value
Age group										
<40 years	2	33.3	0	0.0	3	50.0	1	16.7	6	0.025
40-49 years	1	10.0	0	0.0	1	10.0	8	80.0	10	
50-59 years	2	14.3	3	21.4	3	21.4	6	42.9	14	
60-69 years	11	39.3	6	21.4	4	14.3	7	25.0	28	
70-79 years	0	0.0	3	18.8	3	18.8	10	62.5	16	
80+ years	2	25.0	0	0.0	1	12.5	5	62.5	8	
Pathology Location										
Colon	0	0.0	0	0.0	1	20.0	4	80.0	5	0.010
Small bowel	2	18.2	1	9.1	2	18.2	6	54.5	11	
Left colon	3	23.1	2	15.4	0	0.0	8	61.5	13	
Right colon	0	0.0	1	10.0	0	0.0	9	90.0	10	
Rectum	13	30.2	8	18.6	12	27.9	10	23.3	43	
Anastomotic type										
Colon to Colon	0	0.0	0	0.0	0	0.0	2	100.0	2	0.019
Colon to Low rectum	2	22.2	2	22.2	1	11.1	4	44.4	9	
Colon to Rectum	2	28.6	0	0.0	0	0.0	5	71.4	7	
Colon to Ultra-low rectum	10	29.4	6	17.6	11	32.4	7	20.6	34	
SB to Colon	1	6.7	2	13.3	0	0.0	12	80.0	15	
SB to Low rectum	2	100.0	0	0.0	0	0.0	0	0.0	2	
SB to Rectum	0	0.0	1	25.0	1	25.0	2	50.0	4	
SB to SB	1	11.1	1	11.1	2	22.2	5	55.6	9	
Covering stoma										
No	2	4.8	5	11.9	5	11.9	37	71.4	42	<0.001
Yes	16	40.0	7	17.5	10	25.0	7	17.5	40	
Surgeon										
A	3	9.4	7	21.9	6	18.8	16	50.0	32	0.001
B	0	0.0	0	0.0	0	0.0	5	100.0	5	
C	15	40.5	5	13.5	9	24.3	8	21.6	37	
D	0	0.0	0	0.0	0	0.0	1	100.0	1	
E	0	0.0	0	0.0	0	0.0	7	100.0	7	