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Right hemicolectomy anastomotic leak study: a review of right hemicolectomy in the binational clinical outcomes registry (BCOR)

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Abstract

Backgrounds: Surgery remains mainstay management for colon cancer. Post-operative anastomotic leak (AL) carries significant morbidity and mortality. Rates of, and risk factors associated with AL following right hemicolectomy remain poorly documented across Australia and New Zealand. This study examines the Bowel Cancer Outcomes Registry (BCOR) to address this.

Methods: A retrospective cohort study was undertaken of consecutive BCOR-registered right hemicolectomy patients undergoing resection for colon cancer (2007–2021). The primary outcome measure was AL incidence. Clinicopathological data were extracted from the BCOR. Factors associated with AL and primary anastomosis were identified using logistic regression. AL-rate trends were assessed by linear regression.

Results: Of 13 512 patients who had a right hemicolectomy (45.2% male, mean age 72.5 years, SD 12.1), 258 (2.0%) had an AL. On multivariate analysis, male sex (OR 1.33; 95% CI 1.03–1.71) and emergency surgery (OR 1.41; 95% CI 1.04–1.92) were associated with AL. Private health insurance status (OR 0.66; 95% CI 0.50–0.88) and minimally-invasive surgery (OR 0.61; 95% CI 0.47–0.79) were protective for AL. Anastomotic technique (handsewn versus stapled) was not associated with AL ($P = 0.84$). Patients with higher ASA status (OR 0.47; 95% CI 0.39–0.58), advanced tumour stage (OR 0.56; 95% CI 0.50–0.63), and emergency surgery (OR 0.16; 95% CI 0.13–0.20) were less likely to have a primary anastomosis. AL-rate and year of surgery showed no association ($P = 0.521$).

Conclusion: The AL rate in Australia and New Zealand following right hemicolectomy is consistent with the published literature and was stable throughout the study period. Sex, emergency surgery, insurance status, and minimally invasive surgery are associated with AL incidence.

Introduction

Colorectal cancer (CRC) is a common malignancy in Australia.[1] Surgical management remains the mainstay of treatment for right-sided colon cancer. Anastomotic leak (AL) is a serious complication of colectomy and is responsible for significant morbidity and mortality. In particular, AL is associated with a delay to commencing adjuvant chemotherapy and poorer cancer-specific and overall survival.[2–4]

In the Australian and New Zealand context, individual colorectal unit and multicentre state databases have enabled the examination of the AL rate in colorectal surgery, including following a right hemicolectomy for colon cancer.[5–8] However, risk factors contributing to AL in right hemicolectomy have not been extensively studied at the national or binational level, particularly with respect to the impact of different anastomotic techniques which may contribute to AL.

The Bowel Cancer Outcomes Registry (BCOR) is a prospectively collected clinical quality registry established in 2007 by members of the Colorectal Surgical Society of Australia and New Zealand (CSSANZ). It is a prospective audit of patients presenting with CRC, including those who have undergone colectomy

with or without anastomosis for colon cancer. The BCOR currently includes patients from 175 hospitals, with participation mandated for colorectal training units. This study aimed to examine the AL rate from the BCOR patient information collated from 2007 to 2021 to identify potential factors that may contribute to AL.[9]

Materials and methods

Study population

A retrospective cohort study was undertaken of consecutive patients who had undergone a right hemicolectomy for presumed colon cancer registered in the BCOR from 2007 to 2021. Right hemicolectomy was defined as a procedure for a primary cancer of the colon with ligation of the ileocolic vascular pedicle and right branch of the middle colic artery, with or without formation of an anastomosis. For the purposes of this study, the population of interest was patients who had a primary anastomosis to re-establish intestinal continuity. Patients younger than 18 years of age were excluded.

Data collection and clinicopathological variables

BCOR data extracted were patient age at the time of surgery, sex, American Society of Anaesthesiology (ASA) status, and public/private health insurance status. Details of anatomical pathology data collated were the American Joint Committee on Cancer (AJCC) Stage of Disease. Operative data collected were operative approach (open/minimally invasive), anastomotic technique (stapled/handsewn), presence of a consultant at surgery (operating/supervising) and whether the operation was urgent or emergent.

Outcome measures

The primary outcome measure was the incidence of AL in patients who had a right hemicolectomy with a primary anastomosis. In the BCOR, anastomotic leak is defined as 'clinical and/or radiological evidence of leak from an anastomosis'. Secondary outcome measures were an analysis of risk factors for AL, specifically the role of anastomotic technique, comparing clinicopathological variables of patients who had a primary anastomosis versus a non-restorative resection and the trend of the AL leak rate over the study period.

Statistical analysis

Descriptive statistics of clinicopathological variables of the patient population were analysed. Univariate logistic regression and Pearson chi-squared tests were used to assess the relationship between the study outcomes and explanatory variables. All study variables with a P-value of <0.05 on univariate analysis were included in multivariate models to determine if the associations were still present when accounting for confounding variables. All analyses were conducted using Stata version 17 (StataCorp LLC, College Station, TX, USA), with a P-value <0.05 considered statistically significant. Approval for this study was obtained from the Sydney Local Health District Human Research Ethics Committee of Concord Repatriation General Hospital (Protocol number: 2022/ETH00250) and the CSSANZ BCOR Operations Committee.

Results

Study population

Over the study period, 13 512 patients who had a right hemicolectomy were recorded in the BCOR. Of these patients, 13 147 had a right hemicolectomy with a primary anastomosis and were included in this analysis. Their mean age was 72.5 years (SD 12.1) and 5946 patients (45.2%) were male.

Clinicopathological variables

The clinicopathological variables of the study population are shown in Table 1. Overall, 5758 (45.2%) patients had an advanced American Society of Anesthesiologists (ASA) status (III-V). The majority of patients, 7673 (58.4%), were of public health insurance status at the time of surgery. Patients most commonly had American Joint Committee on Cancer (AJCC) stage II disease (n = 4606, 37.0%).

Table 1 Clinicopathological data and outcomes of patients who had a right hemicolectomy with primary anastomosis

Variable		Number (%) (n = 13 147)
Age	≥75 years	6458 (49.1)
	<75 years	6689 (50.9)
Sex	Male	5946 (45.2)
	Female	7199 (54.8)
ASA	I	1280 (10.1)
	II	5694 (44.7)
	III–V	5758 (45.2)
Public/private status	Private	4772 (38.3)
	Public	7673 (61.7)
AJCC stage	0	353 (2.8)
	I	2599 (20.9)
	II	4606 (37.0)
	III	3655 (29.3)
	IV	1231 (9.9)
Operative approach	Minimally invasive	8086 (61.8)
	Open	4994 (38.2)
Anastomotic technique	Stapled	7827 (85.7)
	Handsewn	1306 (14.3)
Consultant operating or supervising	Yes	11 935 (95.7)
	No	535 (4.3)
operative urgency	Emergency/urgent	1974 (15.0)
	Elective	11 158 (85.0)
Outcomes		Number (%)
Anastomotic leak		258 (2.0)
Radiological diagnosis		60 (23.3)
Clinical diagnosis		61 (23.6)
Radiological/clinical diagnosis		84 (32.6)
Not recorded		53 (20.5)
Management of anastomotic leak		
Non-operative (or No procedure)		37 (14.3)
Percutaneous drainage		19 (7.4)
Abdominal surgery without stoma		85 (32.9)
Abdominal surgery with stoma		20 (7.8)
Not Recorded		97 (37.6)
30-day mortality		210 (1.6)
30-day readmission		1043 (7.9)

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A total of 353 patients (2.8%) were found to have no malignancy upon histopathological examination of the resected right colon and were included in the study analysis.

The majority of operations were performed using a robotic or laparoscopic approach (n = 8085, 61.5%) and were either supervised or performed by a consultant surgeon (n = 11 935, 95.7%). A total of 11 158 (85.0%) surgeries were performed in an elective setting. In the 9133 patients where anastomotic technique was recorded, 85.7% (n = 7827) of anastomoses were constructed using a stapled technique.

Outcome measures

The study outcomes are shown in Table 1. Overall, 258 (2.0%) patients who had a right hemicolectomy with primary anastomosis had an AL. Approximately one-third of the patients with AL were diagnosed using a combination of clinical findings and radiological assessment (n = 84). There were 37 patients (14.3%) with AL who were managed without intervention, 40.7% (n = 105) underwent re-operation and 7.4% (n = 19) were managed with a percutaneous drain. In 97 patients (37.6%) with AL, management was not recorded. The 30-day mortality rate was 1.6% (n = 210) and the 30-day readmission rate was 7.9% (n = 1043). Analysis of the annual anastomotic leak rate showed no trend over the study period (P = 0.521).

Risk factors for anastomotic leak: univariate analysis

Risk factors for AL are shown in Table 2. Risk factors associated with AL were age greater than or equal to 75 years (OR 1.38; 95% CI 1.08–1.77), male gender (OR 1.34; 95% CI 1.04–1.71), patients with a high (III-V) ASA status (OR 1.42; 95% CI 1.16–1.74), public health insurance status (OR 0.57; 95% CI 0.43–0.75) and patients who had an emergency operation (OR 1.89; 95% CI 1.42–2.52). Minimally invasive surgery protected against AL risk

Table 2 Univariate analysis and multivariate analysis of clinicopathological features associated with anastomotic leak in right hemicolectomy patients

Univariate analysis

Variable	No leak	Leak	*P*-value	OR[†] (95% CI[‡])
Age				
<75	6578 (51.0)	111 (43.0)		Reference
≥75	6311 (49.0)	147 (57.0)	0.011	1.38 [1.08–1.77]
Sex				
Female	7076 (54.9)	123 (47.8)		Reference
Male	5811 (45.1)	135 (52.3)	0.021	1.34 [1.04–1.71]
ASA				
I	1259 (10.1)	21 (8.3)	0.001	1.42 [1.16–1.74]
II	5607 (44.9)	87 (34.4)		
III–V	5613 (45.0)	145 (57.3)		
Public/private status				
Public	7488 (61.4)	185 (73.7)		Reference
Private	4706 (38.6)	66 (26.3)	<0.001	0.57 [0.43–0.75]
Stage				
0	350 (2.9)	3 (1.2)	0.055	1.14 [1.00–1.29]
I	2558 (21.0)	41 (16.9)		
II	4505 (36.9)	101 (41.6)		
III	3590 (29.4)	65 (26.8)		
IV	1198 (9.8)	33 (13.6)		
Operative approach				
Open	4858 (37.9)	136 (53.5)		Reference
Minimally invasive	7968 (62.1)	118 (46.5)	<0.001	0.53 [0.41–0.68]
Anastomotic technique				
Handsewn	1277 (14.3)	29 (16.5)		Reference
Stapled	7680 (85.7)	147 (83.5)	0.405	0.84 [0.56–1.26]
Consultant operating or supervising				
No	519 (4.3)	16 (6.3)		*Reference*
Yes	11 698 (95.8)	237 (93.7)	0.109	0.66 [0.39–1.10]
Operative urgency				
Elective	10 964 (85.2)	194 (75.2)		*Reference*
Emergency/urgent	1910 (14.8)	64 (24.8)	<0.001	1.89 [1.42–2.52]
Multivariate analysis				
Variable			*P*-value	OR (95% CI)
Age > 75			0.099	1.25 [0.96–1.64]
Male			0.029	1.33 [1.03–1.71]
ASA			0.106	1.20 [0.96–1.49]
Private			0.005	0.66 [0.50–0.88]
Minimally invasive surgery			<0.001	0.61 [0.47–0.79]
Emergency surgery			0.027	1.41 [1.04–1.92]

[†]Odds ratio.

[‡]95% confidence interval.

Table 3 Clinicopathological and surgical variables for patient with and without formation of anastomosis in right hemicolectomy

Variable	No anastomosis	Anastomosis	*P*-value	OR[†] (95% CI[‡])
Age				
<75 years	203 (55.62)	5623 (51.0)		Reference
≥75 years	162 (44.4)	5423 (49.1)	0.079	1.21 [0.97–1.49]
Sex				
Female	189 (51.8)	6051 (54.8)		Reference
Male	176 (48.2)	5002 (45.3)	0.263	0.89 [0.72–1.09]
ASA				
I	26 (7.4)	1023 (9.5)	<0.001	0.47 [0.39–0.58]
II	76 (21.5)	4770 (44.2)		
III–V	251 (71.1)	4989 (46.3)		
Public/private status				
Public	309 (86.6)	6727 (64.8)		Reference
Private	48 (13.5)	3650 (35.2)	<0.001	3.49 [2.57–4.75]
Stage				
0	4 (1.1)	284 (2.7)	<0.001	0.56 [0.50–0.63]
I	27 (7.7)	2266 (21.5)		
II	111 (31.4)	3883 (36.8)		
III	122 (34.6)	3142 (29.8)		
IV	89 (25.2)	987 (9.3)		
Operative approach				
Open	207 (57.2)	3874 (35.1)		Reference
Minimally invasive	155 (42.8)	7163 (64.9)	<0.001	2.47 [2.00–3.05]
Consultant operating or supervising				
No	22 (6.3)	444 (4.3)		Reference
Yes	330 (93.8)	9976 (95.7)	0.071	1.50 [0.96–2.33]
Operative urgency				
Elective	174 (47.9)	9371 (84.8)		Reference
Emergency/urgent	189 (52.1)	1678 (15.2)	<0.001	0.16 [0.13–0.20]

[†]Odds ratio.

[‡]95% confidence interval.

compared with open surgery (OR 0.53; 95% CI 0.41–0.68). A consultant present and supervising the operation did not significantly modify the AL rate ($P = 0.109$). A higher stage of disease tended towards a slightly higher risk of AL; however, this was not statistically significant ($P = 0.055$). Compared with a handsewn anastomotic technique, stapled anastomosis did not significantly impact AL ($P = 0.405$).

Risk factors for anastomotic leak: multivariate analysis

On multivariate analysis, male sex (OR 1.33; 95% CI 1.03–1.71) and an emergency operation (OR 1.41; 95% CI 1.04–1.92) remained statistically significantly associated with AL. Private health insurance status (OR 0.66; 95% CI 0.50–0.88) and minimally invasive surgery (OR 0.61; 95% CI 0.47–0.79) remained protective for AL. Patient age and ASA status did not retain significance in multivariate analysis ($P = 0.099$ and $P = 0.106$ respectively) (Table 2).

Clinicopathological features of patients who had a primary anastomosis compared with no anastomosis

Clinicopathological features of patients who had a primary anastomosis compared with those who had a stoma formed are detailed in Table 3. Age ($P = 0.079$) and sex ($P = 0.263$) were not significantly different between the two populations. Patients with a higher ASA status (OR 0.47; 95% CI 0.39–0.58), more advanced disease (OR 0.56; 95% 0.50–0.63) and emergency surgery (OR 0.16; 95% CI 0.13–0.20) were less likely to have a primary anastomosis. Private health insurance status (OR 3.49; 95% CI 2.57–4.75) and minimally invasive surgery (OR 2.47; 95% CI 2.00–3.05) were significantly associated with the formation of a primary anastomosis.

Discussion

This study examined the Australian and New Zealand experiences of AL in patients who had a right hemicolectomy intended for colon cancer. This is the first study to provide a comprehensive review of the clinicopathological features of patients who underwent a primary anastomosis together with risk factors associated with an anastomotic leak recorded in the binational registry. An AL rate of 2.0% was identified using BCOR data. Risk factors associated with AL were age greater than or equal to 75, male gender, public health insurance status, open surgery and emergency surgery.

A wide range of AL rates has been reported in the literature. Globally, national, international, and local studies have reported an incidence between 1.3% and 8.4%.[2,10–13] It is noteworthy that the AL rate in this study is lower than that in similar national and international studies with mandatory data collection, likely reflecting the difference between voluntary and involuntary data collection and

analysis. Additionally, the wide-ranging reported leak rate reflects the continuing heterogeneity in the definition of AL.[14] In the BCOR, AL is broadly defined as 'clinical and/or radiological evidence of leak from an anastomosis'.[9] The lack of an international consensus definition impedes standardized reporting and comparability between databases.[15,16] The inherent subjectivity in the clinical and radiological assessment of AL presents a significant barrier to achieving such a consensus, an issue noted in multiple Delphi studies.[15,17,18] We strongly advocate for a uniform definition to enable meaningful comparisons between different datasets and to more accurately document the incidence of AL.

In this analysis, higher ASA status, open surgery, emergency operation, public health insurance status, and male sex significantly contributed to the AL rate. These risk factors are consistent with those identified in previous studies.[2,10,12,19] Public health insurance status likely reflects that the majority of open and emergency cases with higher ASA status are undertaken in a public hospital setting. This is supported by the strong association found in this study between public health insurance status, increasing ASA status, open surgery, and emergency surgery. Previous studies have demonstrated an association between AL and additional risk factors including poor nutritional status, diabetes mellitus and smoking.[10,12,20–22] Unfortunately, this degree of data granularity was not available in the BCOR database, which is a limitation of this study. Specific reference to pre-existing patient comorbidities and the likelihood of developing an AL would likely improve the quality of information and assist in better risk stratification for AL.

In the 13 147 patients examined, the anastomotic technique was not a risk factor for AL ($n = 7827$ stapled anastomoses versus $n = 1306$ handsewn anastomoses). The majority of patients in the BCOR had a stapled anastomosis, reflecting the clinical practice of Australian and New Zealand surgeons. The clinical significance of this finding, however, is difficult to determine given that this data point was not recorded in close to one third of patients.

Several studies have focused on whether a handsewn versus stapled ileocolic anastomotic technique is the more likely contributor to AL rates, with conflicting findings. A 2011 Cochrane review pooling 835 patients who had undergone a right hemicolectomy for cancer from four studies, reported that a stapled technique was associated with a lower AL rate compared with a handsewn technique of re-establishing intestinal continuity (OR 0.28; 95% CI 0.10–0.75).[23] Similarly, in a multicentre study of 957 colon cancer patients who had a right hemicolectomy by Puleo *et al.* (2013),[24] the AL rate was 2.5% for stapled anastomoses and 4.9% for handsewn anastomoses ($P < 0.05$). Conversely, a number of subsequent, large national and multicentre European studies have found in favour of a handsewn technique, demonstrating up to double the risk of AL in stapled ileocolic anastomoses.[11,12,19,25] A Danish retrospective cohort study ($n = 1414$) demonstrated a leak rate of 5.4% (21/391) in the stapled group compared with 2.4% (24/1023) in the handsewn group.[19] Similarly, an international prospective observational study ($n = 2515$) demonstrated a significantly increased risk of leak associated with a stapled anastomosis (OR 1.5; 95% CI 1.1–2.3).[26] A large-scale randomized control trial assessing different anastomotic techniques would be ideal. However, the ethical considerations of such a study are limited by underlying surgeon preference and the requirement for situational intraoperative decision-making regarding the choice of anastomotic technique. An alternative interpretation of this finding is that anastomotic technique is of minor importance. Rather, other considerations, including careful patient selection, surgeon judgement regarding the intraoperative findings, patient physiological response and adherence to sound surgical principles when constructing an anastomosis, are of equal, if not greater, significance.

Comparing the characteristics of patients who had a primary anastomosis constructed with those who did not have intestinal continuity re-established at the index operation, enabled the examination of factors contributing to the intraoperative decision-making regarding primary anastomosis formation. Patients with a higher ASA status, advanced tumour stage and an urgent operation were less likely to have a primary anastomosis formed. Interestingly, only an urgent operation was associated with an increased risk of AL. Not surprisingly, patients with a higher ASA status were more than twice as likely not to have a primary anastomosis formed. This suggests that this is either over-estimated as a risk factor for AL in intraoperative decision making, or more likely, that these patients are simply under-represented in the primary anastomosis group. Patients with private health insurance status and those who had minimally invasive surgery were more likely to have an anastomosis formed. This is consistent with the finding that these factors were associated with a decreased risk of AL. Male sex, which was identified as a risk factor for AL, was not significantly different between the anastomosis and no anastomosis groups. The underlying reason for the role of sex as a risk factor for AL remains unclear.

This study had several limitations. A retrospective review, albeit of prospectively collected data, presents inherent limitations in interpreting causality between the identified significant risk factors and AL. Additionally, a subgroup analysis to clarify the impact of emergency compared with elective surgery on AL would be ideal. This is however impacted by the low event rate of AL which limits the ability of the multivariate model to account for confounding factors, impacting the reliability of such an analysis. Furthermore, comparing outcomes of stapled or handsewn anastomoses, the majority of patients had a stapled anastomosis, introducing the possibility of selection bias. Interestingly, 353 patients are recorded as having Stage 0 disease. It is unclear from the recorded information whether these patients had an endoscopically treated lesion and a subsequent staged resection. The availability of these data points would aid interpretation of data analysis. Although advantageous with respect to providing macroscopic binational data, a large multicentre database has limitations with regards to the completeness of the data and the ability to collect detailed clinicopathological data points (e.g., patient-related risk factors such as smoking and diabetes mellitus). The inclusion of these data points could potentially aid in identification of further causative factors leading to AL.

This study provides a comprehensive overview of AL in patients treated by right hemicolectomy for colon cancer in Australian and New Zealand. Clinically significant patient-related and operative risk factors were identified. Anastomotic technique was not associated with AL incidence. Ultimately, a consensus definition of AL must be implemented in addition to a more comprehensive

documentation of the many additional patient, clinical and institutional factors that contribute to AL. Knowledge of these variables is of critical importance in identifying patients at risk of AL and in the overall tailored management of patients who develop an AL.

Author contributions

Sireesha Koneru: Data curation; formal analysis; investigation; methodology; writing – original draft; writing – review and editing. **Mifanwy M. Reece:** Conceptualization; data curation; investigation; methodology; supervision; writing – review and editing. **Dulani Goonawardhana:** Conceptualization; writing – review and editing. **Pierre H. Chapuis:** Investigation; supervision; validation; writing – review and editing. **Krishanth Naidu:** Investigation; methodology; writing – review and editing. **Kheng-Seong Ng:** Data curation; formal analysis; investigation; methodology; supervision; validation; writing – review and editing. **Matthew J. F. X. Rickard:** Conceptualization; investigation; methodology; project administration; supervision; validation; writing – review and editing.

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Conflict of interest statement

None declared.

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