



ORIGINAL ARTICLE

Risk factors for anastomotic leakage and postoperative outcomes after total and subtotal colectomy: A nationwide retrospective cohort study (RIALTCOT Study Collaborative Group)

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Abstract

Aim: Anastomotic leakage (AL) following ileorectal (IRA) or ileosigmoid (ISA) anastomosis is associated with a high morbidity. The identification of potential risk factors for AL could change operative planning and reduce further complications. This study assesses the rate, potential risk factors and management of AL after total colectomy (TC) and subtotal colectomy (STC).

Methods: A nationwide, multicentre, retrospective cohort study involved 26 Spanish referral centres. It included TC and STC with IRA or ISA patients between January 2013 and December 2020. Clinical data, primary surgery and complications were collected. Univariate

[†]The collaborators from the RIALTCOT Study Collaborative Work are listed in the Appendix A.

and multivariate analysis to identify risk factors for AL were performed. Management of Grade B–C AL and permanent stoma rate was assessed according to revisional surgeries.

Results: The study included 1074 patients, 433 ISA group (40.3%) and 641 IRA group (59.7%). The overall incidence of AL was 14.3% with no differences between IRA and ISA (14.2% and 14.5% respectively), $P = 0.871$. Male sex, ASA score and lower total preoperative proteins were identified as independent risk factors for global and Grade B–C AL. Diverting ileostomy did not protect against AL ($P = 0.084$). Clavien–Dindo \geq IIIa complication was found in 251 patients (23.3%). Stoma reversal was not possible in 85 patients (8.1%), being more frequent after anastomosis excision and terminal ileostomy in AL Grade C.

Conclusion: Total colectomy and STC with IRA or ISA are high-risk procedures with an increased AL rate. Male sex, ASA score and lower preoperative protein level were associated with global AL and AL Grade B and C. A lower permanent stoma rate could be obtained when diverting ileostomy is performed in revision surgery.

KEYWORDS

anastomotic leakage, ileorectal anastomosis, ileosigmoid anastomosis, risk factors, subtotal colectomy, total colectomy

INTRODUCTION

Ileorectal anastomosis (IRA) or ileosigmoid anastomosis (ISA) following total colectomy (TC) and subtotal colectomy (STC) are frequently performed for severe colitis secondary to inflammatory bowel disease, familial adenomatous polyposis (and colonic polyposis syndromes) and obstructed or synchronous colorectal cancer (CRC) [1–3]. Anastomotic leakage (AL) has an incidence ranging between 3% and 28% and remains a major significant complication following colorectal resection. When AL occurs it is associated with an increased mortality, the frequent need for reoperation and an attendant primary and secondary morbidity [4, 5]. Overall, the rate of AL could be greatly increased with an extra-peritoneal anastomosis [6, 7]. Regardless of the indication for anastomosis [8], similar rates of AL have been reported with TC and STC in patients with inflammatory bowel disease (4%–12%) [9, 10], familial polyposis (20%) [11] and colon cancer (6%–21%) [12, 13]. There is a paucity of data concerning the known determinants of AL following colectomy with IRA or ISA reconstruction with considerable heterogeneity of most retrospective analyses which examine particular risk factors. This study examines the potential risk factors for AL following either an ISA or an IRA along with the morbidity and mortality of these different procedures and the variety of options for AL management.

METHODS

Study design and data collection

This nationwide, multicentre, retrospective study involved 26 Spanish tertiary referral specialist colorectal centres. The conduct of this study followed the guidelines as set out in the STROBE statement [14]. Ethical approval for analysis was obtained by the Ramón

What does this paper add to the literature?

This study identified risk factors to anastomotic leakage following total or subtotal colectomy. This is one of the largest studies about this issue, postoperative outcomes and the surgical management of high grade anastomotic leakage.

y Cajal University Hospital Ethics Committee (approval date 2 June 2020, protocol number 212-20). A prospective database was established where consecutive patients who underwent ISA or IRA following STC and TC between January 2013 and December 2020 were retrospectively identified. In the event of missing data, the patient records were individually reviewed. Patients included consecutive cases undergoing emergency or elective TC or STC with primary IRA or ISA or as a two-stage procedure (anastomosis and protective ileostomy). Those patients managed without a primary anastomosis and with an end-ileostomy as well as those cases who had undergone a prior colectomy were excluded from analysis as were subjects with less than 90 days of follow-up.

For the purposes of definition, an ISA was defined as an anastomosis higher than the level of the sacral promontory and an anastomosis below this level was considered as an IRA. An AL was defined as a defect of the integrity of the intestinal wall at the anastomotic site leading to a communication with an intra- or extra-luminal pelvic abscess adjacent to the anastomosis in accordance with the definition set by the International Study Group of Rectal Cancer [15, 16]. An AL was classified as Grade A when it corresponded to a radiological leakage which was not associated with clinical symptoms and which did not require any interventional procedure. An AL requiring active therapeutic

TABLE 2 Operative features according to ileorectal anastomosis or ileosigmoid anastomosis

	IRA, n (%)	ISA, n (%)	Total	P value
Indication of surgery				<0.001
Oncological	379 (59.1)	351 (81.3)	730	
Ulcerative colitis	44 (6.9)	3 (0.7)	47	
Crohn's disease	11 (1.7)	8 (1.9)	19	
Polyposis	163 (25.4)	53 (12.3)	216	
Other	44 (6.9)	17 (3.9)	61	
Surgical planning				<0.001
Emergency	81 (12.7)	103 (23.8)	184	
Elective	559 (87.3)	330 (76.2)	889	
Surgical approach				<0.001
Laparoscopic	343 (53.4)	153 (35.4)	496	
Open	299 (46.6)	279 (64.6)	578	
Conversion lap to open				0.731
No	463 (89.9)	309 (90.6)	772	
Yes	52 (10.1)	32 (9.4)	84	
Derivative ileostomy				<0.001
No	570 (88.9)	428 (99.3)	998	
Yes	71 (11.1)	3 (0.7)	74	
Anastomosis technique				<0.001
Handsewn	57 (8.9)	170 (39.4)	227	
Stapled	580 (91.1)	262 (60.6)	842	
Anastomosis set-up				<0.001
Side-to-side	58 (9.2)	303 (70.1)	361	
Side-to-end	424 (67.5)	88 (20.4)	512	
End-to-end	141 (22.5)	33 (7.6)	174	
End-to-side	5 (0.8)	8 (1.9)	13	
Type of stapler				<0.001
Linear	29 (51.1)	171 (65.5)	200	
Circular	543 (94.4)	90 (34.5)	633	
Anastomotic leak				0.871
No	550 (85.8)	370 (85.5)	920	
Yes	91 (14.2)	63 (14.5)	154	
Anastomotic leak (grade)				0.965
A	4 (4.3)	2 (3.1)	6	
B	14 (15.4)	11 (17.5)	25	
C	73 (80.3)	50 (79.4)	123	
Readmission (90 days)				0.739
No	584 (91.5)	392 (91)	976	
Yes	54 (8.5)	39 (9)	93	
Postoperative complication				0.863
No	303 (47.4)	203 (46.9)	506	
Yes	336 (52.6)	230 (53.1)	566	
Clavien-Dindo \geq IIIA				0.325
No	213 (59.8)	135 (55.8)	348	
Yes	143 (40.2)	107 (44.2)	250	

Abbreviations: IRA, ileorectal anastomosis; ISA, ileosigmoid anastomosis.

IRA was also more likely to be performed for ulcerative colitis and for polyposis syndromes ($P < 0.001$). An ISA was more likely to be performed for oncological reasons ($P < 0.001$), for patients with diabetes ($P = 0.024$), for those with a higher rate of heart disease ($P < 0.001$) and in those with a lower preoperative haemoglobin ($P = 0.018$).

Anastomotic leak

The cumulative incidence of AL was 14.3% with six patients (0.6%) presenting as Grade A, 25 patients (2.3%) as Grade B and 123 patients (11.5%) as Grade C cases. There were no differences in AL rates evident between the IRA and ISA techniques (14.2% vs. 14.5%, respectively; $P = 0.871$). Table 3 shows the univariate analysis of factors associated with the presence of an AL. This showed significance for male sex ($P = 0.012$) and a lower preoperative total protein level ($P = 0.046$) which correlated with a higher risk of overall AL as well as with Grade B ($P = 0.012$) or Grade C ($P = 0.047$) AL. The need for emergency surgery, the surgical approach, the underlying disease requiring surgery and the type of anastomosis were not associated with the risk of an AL. A protective ileostomy was also not an independent protective factor for an AL overall or for a Grade B or Grade C AL type ($P = 0.0847$ and $P = 0.668$, respectively). The multivariate analysis of risk factors already identified in the univariate assessment is shown in Table 3 showing on logistic regression analysis that male sex (OR 1.06, 95% CI 1.04–2.20, $P = 0.031$), ASA score (OR 1.83, 95% CI 1.12–2.99, $P = 0.015$) and preoperative total protein level (OR 1.10, 95% CI 1.05–1.20, $P = 0.042$) were independently associated with the overall risk of an AL as well as with a Grade B or a Grade C AL type (OR 1.05, $P = 0.039$; OR 1.42, $P = 0.041$; and OR 1.25, $P = 0.004$, respectively).

Perioperative outcomes

The mortality in the patient cohort was 1.8% overall. There were 607 patients (56.5%) who had any type of postoperative complication with 176 patients (16.9%) undergoing reoperation. There were 251 patients (23.3%) amongst those with any surgical complication who had a \geq IIIA Clavien-Dindo (moderate-severe) complication (Table 4). The median length of hospital stay was 11 days (range 7–17 days) with a significant difference noted ($P < 0.001$) between those patients with an AL (23.5 days, range 15–36) and those without an AL (10 days, range 7–15).

The surgical approach to a Grade C AL varied with 80 patients (65%) undergoing resection of the anastomosis with an end-ileostomy, five patients (4%) reinforcement of the anastomosis and 20 patients (16.2%) a proximal loop ileostomy in addition to anastomotic reinforcement. Peritoneal lavage and surgical drainage alone was sufficient in the management of seven patients (5.7%) with a redo anastomosis in 11 patients (8.9%), four of whom also had a loop ileostomy.

The likelihood of a permanent stoma in the reoperated group is shown in Table 5. Throughout the study there were 178 patients (16.57%) with either a terminal or a protective ileostomy with 48% able to undergo stoma closure or restoration of intestinal continuity. The median time to stoma reversal was 7 months (range 4–12 months). There were 87 patients (8.1%) with a stoma but without reconstruction by the end of the follow-up period. In the cohort there were 11/74 patients (14.8%) who had a protective ileostomy fashioned during the first procedure where the stoma was not ultimately closed.

DISCUSSION

The present study assessing the risk of an AL following either an STC or TC with ISA or IRA shows an AL rate of 14.3% overall. In this group 2.3% of AL cases were characterized as Grade B and 11.5% as Grade C leaks. The reported range of AL varies widely between 3% and 21% after an IRA or an ISA somewhat dependent upon the study design [4, 7, 18]. The majority of these studies, however, only report high grades of AL and those requiring surgical treatment without consideration of minor AL grades successfully managed by conservative means [19].

The total incidence of AL found in the present study is similar to that reported by Segelman et al. [12] in one of the largest studies available which focused specifically on TC and STC, with the rate of AL being 13.2%; Bakker and colleagues [13] also reported an AL rate of 13.4% in those patients where a TC or STC was performed for colon cancer. Most of the current evidence is based on single institution studies without comparison of anastomotic techniques. There also appears to be a lack of consensus regarding the definition of TC and STC in these studies. Future studies should focus on reporting the different grades of AL for a better appreciation of the problem and its pathogenesis and to permit stricter comparisons of data between institutions.

In the ulcerative colitis subgroup TC was performed when there was minimal inflammatory involvement of the rectum, due to potentially better bowel function than with an ileo-anal pouch [20, 21]. The incidence of AL in this group of patients (21.3%) appeared higher than in the other subgroups in the study (11%–14.4%) but was not significantly so. It also appeared higher than reported AL rates from other studies (2%–12%) [22, 23] and it is possible that a larger sample size may have revealed a significantly different AL rate in this patient group undergoing STC or TC.

Risk assessment of AL is crucial for early decision-making. In this regard, several preoperative factors should be considered including the presence of male gender, the ASA score and a low preoperative total protein level, each of which were identified as preoperative independent risk factors for an AL overall as well as for either a Grade B or Grade C AL. Men are consistently at higher risk as has been found in a number of previously published studies [24, 25] where it is suggested that androgens may affect the bowel microcirculation and also influence intestinal endothelial cell function [26].

The preoperative protein is an independent risk factor for AL which can be modified and is an indicator of malnutrition that significantly impacts tissue healing [27]. The effect of stapler type on an ileocolic AL remains controversial. Recently, a European audit assessing right colectomies for CRC showed a lower AL rate for handsewn anastomosis [28], but this report differed from the related findings of a Cochrane review which demonstrated a lower AL rate with stapled anastomoses [29]. In our study we did not find any intra-operative factors that were specifically related to an AL. Our finding that there was no effect of emergency surgery on the AL rate is in keeping with previously published studies of emergency TC or STC for obstructed left colon cancer where AL rates below 10% have been reported [30–32]. The role of a diverting ileostomy remains controversial in IRA or ISA. Whilst it has been suggested that a diverting ileostomy is protective against an AL in low anterior resection [33, 34] as well as in high-risk ileocolic anastomosis in Crohn's disease [35], there are currently insufficient data to recommend routine use of a proximal stoma in an elective TC or STC. In our study, protective loop ileostomy was not significantly associated with a lower total AL rate or with a reduction in either a Grade A or Grade B AL presentation. This finding is in contrast with that reported by Segelman et al. and by Duclos et al. where the AL rate is 7% AL in patients who have a loop ileostomy with a TC or STC [12, 36]. Our results might be explained by the small number of patients (10 cases) who had AL following primary anastomosis and loop ileostomy and the lack of information available in the medical notes in some cases to explain the indication for ileostomy. Future studies are required to define the indications and outcomes of protective ileostomy and the reduction in AL after an IRA or an ISA.

In our study, the height of the anastomosis does not appear to be critical in AL risk. This finding is similar to other reports showing similar AL rates between IRA and ISA [12, 36]. With an IRA or ISA, even though there is no anastomotic tension, a more secure blood supply in theory and no need for pelvic dissection, in general a higher risk of AL is incurred compared with a colo-colic or a colorectal anastomosis [4, 12, 34, 35]. In this regard, despite the difficulty in a retrospective records review in determining which vessels were preserved or sacrificed, an anastomosis involving the distal small intestine is expected usually to have a sufficient blood supply. It is also appreciated that in benign disease the superior rectal artery can often be preserved, allowing sufficient blood perfusion to the anastomosis, as opposed to those cases where a high ligation of the inferior mesenteric artery has been performed [25, 37–39]. This effect on AL of high mesenteric artery ligation remains controversial as does the importance of the perfusion of the distal part of an ISA or an IRA.

The 90-day morbidity overall was 56.5% which is slightly higher than that of other reports [39]. Our morbidity rate would have been lowered by about 12% if analysed at the usual 30-day postoperative period. Our rate of moderate/severe complications (Clavien–Dindo \geq IIIA) of 23.3% is comparable with other studies. Ripollés-Melchor et al. [40] recently reported an overall postoperative complication rate of 42.2% in >2000 elective colorectal operations with nearly two-thirds of the complications being severe in nature. Similarly,

TABLE 3 (Continued)

	ANASTOMOTIC LEAKAGE				ANASTOMOTIC LEAKAGE GRADE B AND C			
	No	Yes	Univariate P value OR (95% CI)	Multivariate P value OR (95% CI)	No	Yes	Univariate P value OR (95% CI)	Multivariate P value OR (95% CI)
Ulcerative colitis	37 (78.7)	10 (21.3)			38 (80.9)	9 (19.1)		
Crohn disease	18 (85.6)	31 (14.4)			19 (100)	0		
Polypoid	185 (85.6)	31 (14.4)			186 (86.1)	30 (13.9)		
Other	54 (88.5)	7 (11.5)			54 (88.5)	7 (11.5)		
Surgical planning			0.745	0.954			0.427	0.340
Emergency	159 (86.4)	25 (13.6)			162 (88)	22 (12)		
Elective	760 (85.5)	129 (14.5)			763 (85.8)	126 (14.2)		
Surgical approach			0.079	0.503			0.099	0.440
Laparoscopic	434 (87.7)	61 (12.3)			436 (88.1)	59 (11.9)		
Open	485 (83.9)	93 (16.1)			489 (84.6)	89 (15.4)		
Conversion lap to open			0.172	0.129			0.209	0.818
No	675 (87.4)	97 (12.6)			436 (88.1)	59 (11.9)		
Yes	69 (81.2)	15 (17.9)			489 (84.6)	89 (15.4)		
Derivative ileostomy			0.847	0.850			0.668	0.755
No	855 (85.7)	143 (14.3)			860 (86.2)	138 (13.8)		
Yes	64 (86.5)	10 (13.5)			65 (87.8)	9 (12.2)		
Anastomosis technique			0.881	0.775			0.967	0.995
Handsewn	195 (85.9)	32 (14.1)			199 (87.7)	28 (12.3)		
Stapler	720 (85.5)	122 (14.5)			739 (87.8)	103 (12.2)		
Height of anastomosis			0.847	0.321			0.810	0.803
IRA	550 (85.8)	91 (14.2)			860 (86.2)	138 (13.8)		
ISA	370 (85.5)	63 (14.5)			65 (87.8)	9 (12.2)		
Anastomosis set-up			0.869	0.921			0.921	0.970
Side-to-side	308 (85.3)	53 (14.7)			310 (85.9)	51 (14.1)		
Side-to-end	437 (85.4)	74 (14.6)			441 (86.1)	71 (13.9)		
End-to-end	151 (86.8)	23 (13.2)			151 (86.8)	23 (13.2)		
End-to-side	12 (92.3)	1 (7.7)			12 (92.3)	1 (7.7)		
Type of stapler			0.965	0.840			0.832	0.750
Linear	171 (85.5)	29 (14.5)			171 (85.5)	29 (14.5)		
Circular	542 (85.6)	91 (14.4)			545 (86.1)	88 (13.9)		
Operative time	230 (180–294)	240 (185–300)	0.214	0.150	230 (180–195)	240 (181–296)	0.30	0.250

Abbreviation: ASA, American Society of Anesthesiologists physical status classification; BMI, body mass index; IQR, interquartile range; IRA, ileorectal anastomosis; ISA, ileosigmoid anastomosis.

TABLE 4 Clavien–Dindo complications

Clavien–Dindo scale	N	Percentage subtotal	Percentage total
I	97	15.84	9.03
II	264	43.14	24.59
IIIA	47	7.67	4.38
IIIB	126	20.59	11.74
IVA	34	5.56	3.17
IVB	25	4.09	2.33
V	19	3.11	1.76

TABLE 5 Anastomotic leak Grade B and C management and permanent ileostomy at the end of the study

	No, n (%)	Yes, n (%)	n (% Grade C)
Percutaneous drainage	25 (100)	0	–
End-ileostomy	19 (23.8)	61 (76.3)	80 (65.04)
Anastomosis reinforcement	4 (100)	0	4 (3.25)
Anastomosis reinforcement + derivative ileostomy	18 (90)	2 (10)	20 (16.26)
Surgical lavage and drain	7 (100)	0	7 (5.69)
Re-do anastomosis	6 (85.7)	1 (14.3)	7 (5.69)
Re-do anastomosis + derivative ileostomy	3 (75)	1 (25)	4 (17.39)

Manceau et al. [41] followed those cases undergoing an STC for CRC and reported a 26.4% incidence of moderate to severe postoperative complications. Our mortality rate was 1.8%, which is also in keeping with other previously published data for IRA and ISA after TC or STC ranging between 1% and 2.6% [28, 36, 40].

One of the secondary aims of the study was to assess the surgical management of Grade C AL cases. Excision of the previous anastomosis and an end-ileostomy was the commonest procedure performed and was carried out for 80 patients (65% of Grade C AL cases). Phitayakorn and colleagues [42] have proposed an algorithm for the management of AL recommending an anastomotic repair for defects <1 cm with fashioning of a secondary protective stoma. Repeat anastomosis and a proximal ileostomy is recommended by this group if a major anastomotic defect is evident. Concerning this approach, Fracalvieri et al. [43] have reported better postoperative outcomes (higher stoma reversal, less morbidity and shorter hospital stay) in patients who underwent a diverting ileostomy compared with an end stoma following an AL after a colorectal resection.

A sizeable proportion of patients with an ileostomy in our study did not have their stoma closed with 61/80 (76.3%) cases with an end-ileostomy after an AL not undergoing restoration of intestinal continuity. This discouraging result compares with 87.5% of cases with a protective diverting stoma who successfully had their stoma closed.

This study is one of the largest cohorts of patients that compare IRA and ISA. No randomized clinical trials or systematic reviews

on this issue are available to our knowledge. This study has several limitations due to its retrospective design and relatively long data accrual period. Over the length of time of the study there have been many changes in perioperative management as well as in surgical techniques with the availability of new devices and technologies advancing minimally invasive approaches. This has been supplemented by a trend towards more conservative management of postoperative complications. Another inevitable consequence of retrospective observational research is the potential risk of missing data, as the availability of baseline and outcome data is largely dependent on the completeness of medical records. A strength of this study is that RIALTCOT represents the largest sample of Spanish referral centres so far presented that has as its focus TC or STC procedures, potentially serving as a referral benchmark for future studies. It is accepted that, in this large cohort, the patient group is eclectic although it does permit an analysis of how individual pathology types broadly affect AL. Further, the current criteria for AL definition may significantly under-diagnose its incidence particularly since not all cases suspicious for an AL would have undergone radiological examination.

CONCLUSIONS

In TC and STC, both an IRA and an ISA represent high-risk procedures with a significant chance of developing an AL. Such leaks incur a moderate to severe attendant morbidity and the substantial risk of a permanent stoma. Our study has identified male sex, the ASA score and a low preoperative total protein level as relevant preoperative independent risk factors for an AL overall as well as for either a Grade B or Grade C type AL. A Grade C AL was most commonly managed with an excision of the anastomosis with an end-ileostomy; however, a permanent stoma rate was less likely with the use of loop ileostomy in the reintervention of AL.

AUTHOR CONTRIBUTIONS

Juan Ocaña, José María Fernández-Cebrián and Javier Die-Trill conceptualized and designed the study. The other authors managed the data collection and the conduct of the study at each centre. Juan Ocaña and Javier Die-Trill analyzed the data and drafted the initial manuscript. José María Fernández-Cebrián, Javier Die-Trill and Juan Carlos García-Pérez revised for intellectual content. All authors read and approved the final manuscript for submission.

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CONFLICT OF INTEREST

There are no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS APPROVAL

Ethical approval for analysis was obtained by the Ramón y Cajal University Hospital Ethics Committee (approval date 2nd June 2020, protocol number 212-20).

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APPENDIX A

A.1 | COLLABORATORS FROM THE RIALTCOT STUDY COLLABORATIVE WORK (ALL NAMES TO BE PUBMED CITABLE TOGETHER WITH NAMES IN HEADLINE AUTHORSHIP)

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