

The impact of stapling technique and surgeon specialism on anastomotic failure after right-sided colorectal resection: an international multicentre, prospective audit

On behalf of the 2015 European Society of Coloproctology Collaborating Group¹

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Abstract

Aim There is little evidence to support choice of technique and configuration for stapled anastomoses after right hemicolectomy and ileocaecal resection. This study aimed to determine the relationship between stapling technique and anastomotic failure.

Method Any unit performing gastrointestinal surgery was invited to contribute data on consecutive adult patients undergoing right hemicolectomy or ileocolic resection to this prospective, observational, international, multicentre study. Patients undergoing stapled, side-to-side ileocolic anastomoses were identified and multilevel, multivariable logistic regression analyses were performed to explore factors associated with anastomotic leak.

Results One thousand three hundred and forty-seven patients were included from 200 centres in 32 countries. The overall anastomotic leak rate was 8.3%. Upon multivariate analysis there was no difference in leak rate with use of a cutting stapler for apical closure compared with a noncutting stapler (8.4% *vs* 8.0%, OR 0.91, 95% CI 0.54–1.53, $P = 0.72$). Oversewing of the apical staple line, whether in the cutting group (7.9% *vs* 9.7%, OR 0.87, 95% CI 0.52–1.46, $P = 0.60$) or noncutting group (8.9% *vs* 5.7%, OR 1.40, 95% CI 0.46–4.23,

$P = 0.55$) also conferred no benefit in terms of reducing leak rates. Surgeons reporting to be general surgeons had a significantly higher leak rate than those reporting to be colorectal surgeons (12.1% *vs* 7.3%, OR 1.65, 95% CI 1.04–2.64, $P = 0.04$).

Conclusion This study did not identify any difference in anastomotic leak rates according to the type of stapling device used to close the apical aspect. In addition, oversewing of the anastomotic staple lines appears to confer no benefit in terms of reducing leak rates. Although general surgeons operated on patients with more high-risk characteristics than colorectal surgeons, a higher leak rate for general surgeons which remained after risk adjustment needs further exploration.

Keywords Bowel anastomosis, stapler, oversewn, surgical technique, anastomotic leak, colorectal cancer, Crohn's disease, epidemiology, international, surgery

What does this paper add to the literature?

This large, multicentre, international cohort study showed no difference in leak rates with a cutting or noncutting stapler to close the apical enterotomy after stapled side-to-side right-sided ileocolic anastomosis. It also did not find any benefit to anastomotic leak rates for suture reinforcement of the staple line.

Introduction

Colorectal resections carry a high burden of morbidity. Almost two-thirds of patients suffer a postoperative complication, with as many as a fifth of these being

'major', requiring reintervention, reoperation, organ support or leading to death [1]. The most feared complication after colorectal resection is anastomotic leak. This affects not only on short-term survival [2], functional outcomes [3] and quality of life [4,5], but in cancer patients also increases the risk of disease recurrence and cancer-specific mortality [6].

A number of patient-, disease- and technique-specific factors have been associated with anastomotic failure. Many of these are nonmodifiable, such as gender, an unplanned operation, the presence of malignancy, major

Correspondence to: Mr Sanjary Chaudhri FRCS, Consultant Colorectal and General Surgeon, University Hospitals of Leicester, Gwendolen Road, Leicester LE5 4PW, UK.

E-mail: schaudhri@nhs.net

 @chaudhris

¹Collaborating members shown in Appendix S1, in Supporting information.

comorbidities or a poor performance score [7–9]. Surgical technique is an attractive target for improving anastomotic leak rates, as it is operator dependent, and is readily adaptable to new evidence. However, there exists a paucity of high-quality studies to support surgeons' technical decisions.

The most commonly performed anastomotic configuration in stapled ileocolic anastomosis is side to side [9,10] with a linear primary cutting stapler and a linear apical stapler (Fig. 1). Whilst there is no randomized evidence examining the effect of different stapling techniques on anastomotic outcomes, some surgeons believe that a cutting stapler for apical transection may increase the risk of leak when compared with a noncutting stapler, as the cutting apical stapler blade crosses the primary staple line. In addition, stapler device manufacturers do not recommend routinely oversewing the apical staple line, as this may reduce anastomotic tissue perfusion. Despite this, half of surgeons across Europe oversee side-to-side intestinal anastomotic staple lines [11].

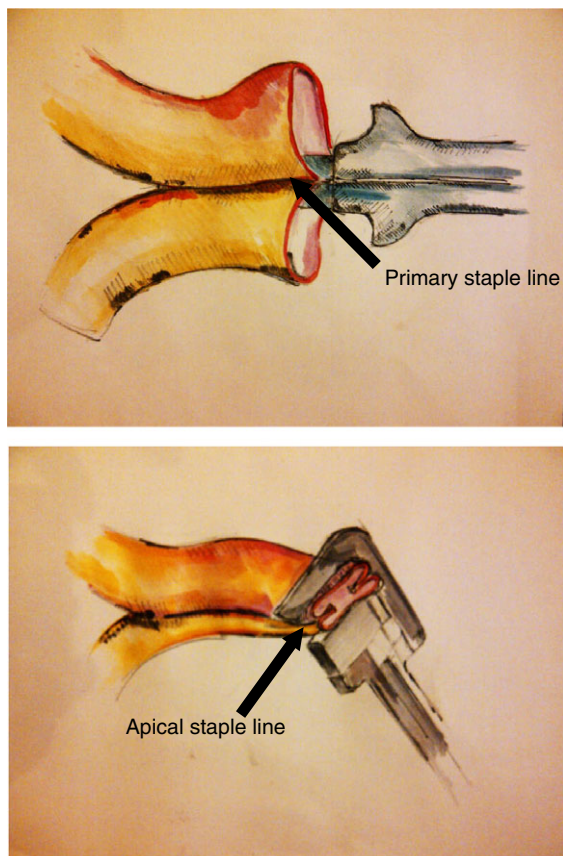


Figure 1 Configuration of side-to-side ileocolic anastomosis in right-sided colorectal resection (with thanks to Professor David Gourevitch for the illustrations).

In the previously published analysis of the full parent cohort of this audit, we identified that stapled anastomoses overall were at higher risk of anastomotic leak than hand-sewn ones, a difference which prevailed after risk adjustment [9]. This finding warranted further investigation and the primary aim of this current study was to explore the relationship between apical linear stapler type (cutting *vs* noncutting) after stapled side-to-side anastomosis and anastomotic leakage, as well as to assess the influence of (1) oversewing of the apical staple line, (2) primary operator specialty, and (3) primary operator level of training on anastomotic leakage.

Method

This prospective, observational, multicentre study was conducted in line with a prespecified protocol (<http://www.escp.eu.com/research/cohort-studies/2015-audit>). An external pilot of the protocol and data capture system was conducted in eight centres across five countries prior to launch, allowing refinement of the study tool. This paper represents a predefined subgroup analysis of this same data set [9].

Centres and protocol dissemination

Any unit performing gastrointestinal surgery was eligible to register to enter patients into the study. No minimum case volume or centre-specific characteristics were used for exclusion. The study protocol was disseminated to registered members European Society of Coloproctology (ESCP), and through national surgical or colorectal societies, including the European Crohn's and Colitis Organisation.

Patients

Consecutive adult patients (over 16 years of age) undergoing elective or emergency right hemicolectomy or ileocaecal resection for any indication were included. The subgroup who underwent stapled side-to-side ileocolic anastomosis with a linear cutting primary stapler and a linear apical stapler (cutting and noncutting) were extracted for inclusion in this analysis (Fig. 1). Open, laparoscopic, laparoscopic converted and robotic procedures were all included. Patients undergoing right-sided colonic resection as part of a more extensive colorectal resection, defined as a distal colonic transection point beyond the splenic flexure (e.g. subtotal colectomy or panproctocolectomy), were excluded. In the patient subgroup with Crohn's disease, resections requiring proximal stricturoplasty or

resection of proximal small bowel disease were also excluded.

Data capture

All consecutive eligible patients over an 8-week study period were included. Local investigators commenced data collection between 15 and 30 January 2015, with the final patients enrolled on 27 March 2015.

There were three main phases of data collection for each patient, each represented by separate clinical reporting forms, described previously [9]. Briefly, patient- and disease-specific characteristics, technical operative factors and postoperative outcome data were collected. Technical operative factors collected included: operator grade (consultant, trainee); operator speciality interest (colorectal, general surgery); primary and apical stapler type (cutting, noncutting; Table 1); oversewing of anastomosis (continuous, interrupted); extent of surgery (complete, extended, limited). Outcome data were collected up to 30 days through review of patient notes (paper and electronic) during their index admission, reviewing hospital systems to check for readmission or reoperation and reviewing postoperative radiology reports. Within the limits of this observational study, no changes were made to patients' existing follow-up pathways.

Data were recorded contemporaneously and stored on a dedicated, secure, web-based platform without using patient-identifiable information (Netsolving, Croydon, UK) [12]. Centres were asked to validate that all consecutive eligible patients during the study period had been entered.

Outcome measure

The primary outcome measure was overall anastomotic leak, predefined as either (1) gross anastomotic leakage proven radiologically or clinically, or (2) the presence of an intraperitoneal (abdominal or pelvic) fluid collection on postoperative imaging.

An exploratory sensitivity analysis was also undertaken of those with only a 'proven' anastomotic leak

(i.e. excluding those with an intraperitoneal fluid collection alone) for comparison.

Statistical analysis

This report has been prepared in accordance to guidelines set by the STROBE (Strengthening the Reporting of OBservational studies in Epidemiology) statement for observational studies [13].

Patient, disease and operative characteristics were compared by apical stapler type (cutting *vs* noncutting) and by the primary outcome anastomotic leak using a *t*-test for continuous data (e.g. age) or a chi-square test for categorical data. To test the association between overall anastomotic leak and the main explanatory variables of interest (apical cutting *vs* noncutting stapler), a multilevel, multivariable logistic regression model was created. Clinically plausible factors were entered into the model for risk adjustment. These were predefined, and included irrespective of their significance on univariate analysis. A preplanned analysis compared colorectal specialists *vs* general surgeons and consultant *vs* trainee surgeons. Sensitivity analyses were performed for proven anastomotic leakage only. No analysis was planned by stapler manufacturer due to the small numbers included in each group. Centres were entered into the model as a random effect, to adjust for hospital-level variation in outcome. Effect estimates are presented as odds ratios (OR) with 95% confidence intervals (95% CI) and two-sided *P*-values (α level of $P < 0.05$). Data analysis was undertaken using STATA v14.0 (StataCorp, College Station, Texas, USA).

Ethical approval

All participating centres were responsible for adherence to local approval requirements for ethics approval or indemnity as required. In the UK, the National Research Ethics Service tool recommended that this project was not classified as research, and the protocol was registered as clinical audit in participating centres.

Table 1 Included stapler types.

Stapler	Configuration	Cutting/noncutting	Manufacturer	Approach
GIA™	Linear	Cutting	Medtronic	Lap/Lap-Ass/Open
TLC®	Linear	Cutting	Ethicon	Lap-Ass/Open
TA™	Linear	Noncutting	Medtronic	Lap-Ass/Open
TX®	Linear	Noncutting	Ethicon	Lap-Ass/Open

Lap, total laparoscopic (intracorporeal anastomosis); Lap-Ass, laparoscopic-assisted (extracorporeal anastomosis).

Results

Data completeness

For included patients, completion and locking of all data fields was mandated, and as such there was 99.95% data completeness.

Patients and centres

Of the 3208 patients captured in this study, 1858 had a stapled ileocolic anastomosis (57.9%), 1663 (51.8%) had a side-to-side anastomotic configuration, 180 (5.6%) had an end-to-side and 15 a side-to-end (less than 0.1%). Of those undergoing side-to-side ileocolic anastomosis, 1484 (46.3% of the total) were formed with a linear cutting primary stapler, with a linear apical stapler being used in 1347 (42.0% of the total) of these patients (Fig. 2). This analysis included these 1347 patients from 200 centres in 32 countries, including seven countries outside Europe. The countries contributing the greatest number of patients were the UK ($n = 391$), Spain ($n = 276$) and the Netherlands ($n = 106$).

Patient, disease and operative characteristics (described in Table 2) were similar between the groups with a cutting and noncutting apical stapler. The mean age of included patients was 65.5 years (range 16–99) and approximately half were women ($n = 695$, 51.6%). A majority of patients underwent surgery for malignancy ($n = 907$, 67.3%) or Crohn's disease ($n = 184$, 13.6%). In the noncutting apical stapler group there was an increased proportion of patients undergoing surgery for malignancy *vs* other indication, but this was not significant ($P = 0.06$). Most operations included were elective ($n = 1169$, 86.8%), and 63.1% began laparoscopically ($n = 850$), with 34.0% performed with an open midline incision ($n = 458$).

Anastomotic leak rate

The primary outcome measure of anastomotic leak and/or intraperitoneal fluid collection rate in this group was 8.3% (112/1347). 'Proven' anastomotic leak was present in 76 patients (5.6%).

Apical stapler type

A cutting linear apical stapler (most commonly GIA) was used in 76.7% ($n = 1033$) of patients and a noncutting linear apical stapler (most commonly TA) was used in 23.3% ($n = 314$) (Table 2). In the unadjusted data, there were no observed differences between overall risk

of anastomotic leak with cutting (overall leak rate = 8.4%) *vs* noncutting (overall leak rate = 8.0%) linear apical staplers ($P = 0.80$). In univariate logistic regression models there was no association between apical stapler type and overall anastomotic leak (OR 0.91, 95% CI 0.56–1.50, $P = 0.71$). Being a current smoker, having an emergency operation, a midline incision or an operation for 'other' indication was significantly predictive of leak (Table 3). In the risk-adjusted multilevel multivariable logistic regression model again there was no association between apical stapler type and overall leak rate (OR 0.91, 95% CI 0.54–1.53, $P = 0.72$). The model had an acceptable fit [area under the curve (AUC) 0.65]. The only independent predictor of overall anastomotic leak was open (midline) approach (OR 1.99, 95% CI 1.24–3.18, $P = 0.004$). Current smoker status (OR 1.76, 95% CI 0.96–3.22, $P = 0.07$) and emergency operation type (OR 1.75, 95% CI 0.95–3.22, $P = 0.07$) reached borderline significance.

Oversewing of the apical staple line

In the cutting stapler group, 725 of apical staple lines were oversewn (70.2%) and 308 were not (29.8%). In the noncutting stapler group, 226 of these anastomoses were oversewn (72.0%) and 88 (28.0%) were not. The suture line was continuous in approximately two-thirds of oversewn anastomoses in both groups (68.2% *vs* 67.2%), with the remainder being performed using interrupted sutures. There were no differences observed in unadjusted leak rates for oversewn *vs* not oversewn anastomoses either in the cutting (7.9% *vs* 9.7%, $P = 0.43$) or noncutting groups (8.9% *vs* 5.7%, $P = 0.35$). In the multivariable model (Table 3) there were no differences in leak rates with oversewing of cutting (OR 0.87, 95% CI 0.52–1.46, $P = 0.60$) or noncutting apical staple lines (OR 1.40, 95% CI 0.46–4.23, $P = 0.55$).

Operator speciality interest

Overall colorectal surgeons (consultant or trainee) were the primary operator for 1008 patients (74.8%), and general surgeons for 339 patients (25.2%). In the unadjusted data, the overall leak rate for the general surgeon group (12.1%) was nearly double that of the colorectal surgeon group (7.0%). However, there were many differences in the patient, disease and operative factors between the two groups (Table 4). General surgeons operated on a higher proportion of 'high-risk' [American Society of Anesthesiologists (ASA) grade 3 and above] patients than colorectal surgeons (38.4% *vs* 29.6%, $P = 0.003$), more patients with 'other'

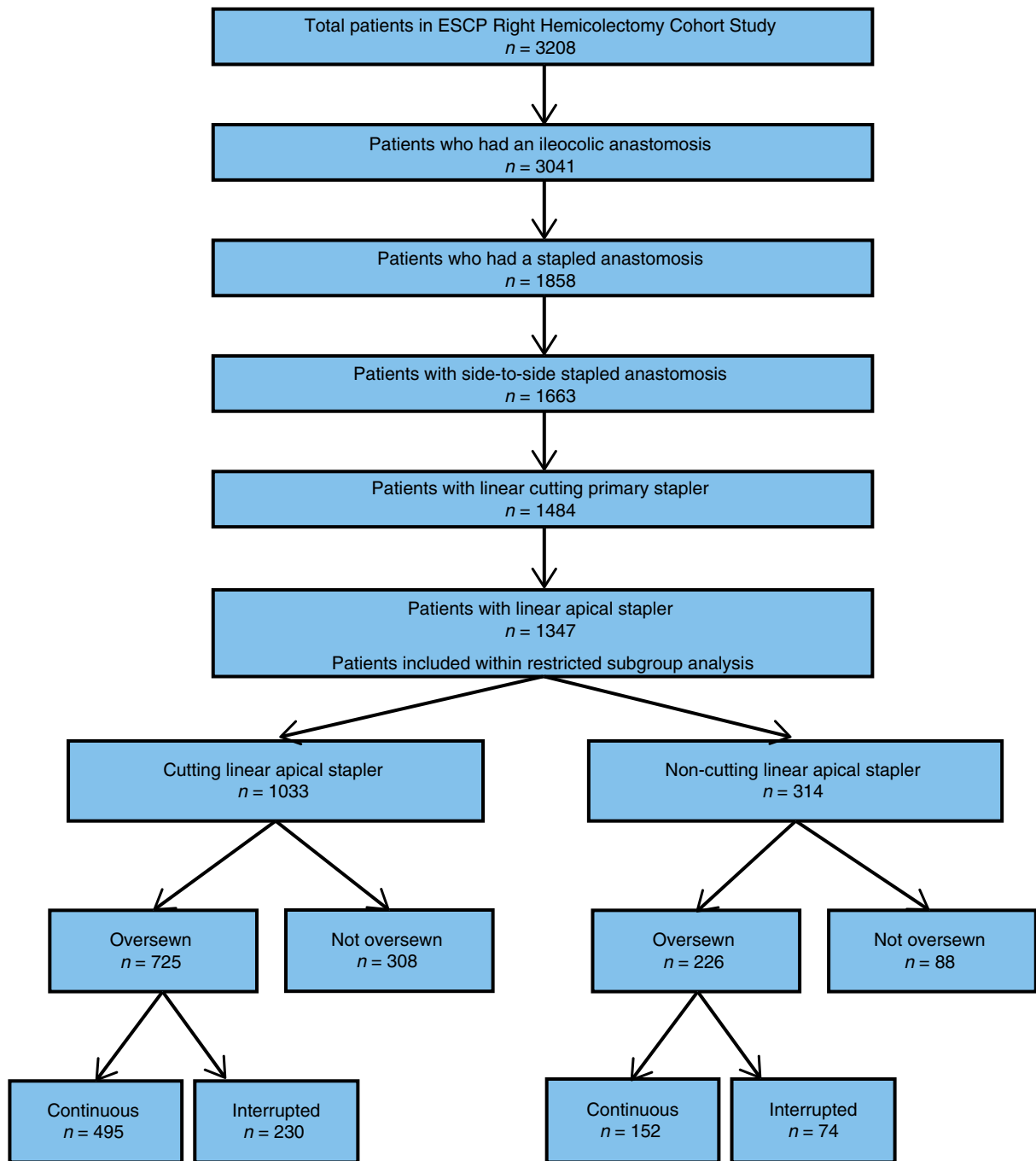


Figure 2 Patients included within this subgroup analysis of stapled, side-to-side ileocolic anastomoses (ESCP, European Society of Coloproctology).

indication (12.1% vs 6.2%, $P < 0.001$) and fewer with Crohn's disease (8.0% vs 15.6%, $P < 0.001$). General surgeons were more likely to use an open (midline) approach (48.7% vs 29.1%, $P < 0.001$) and more likely to operate as an emergency (24.8% vs 9.3%, $P < 0.001$). The preferred stapler types and manufacturers for both

the primary and apical staple lines were also different between the groups.

In a univariate logistic regression model there was a significant association between general surgeons and anastomotic leak (OR 1.85, 95% CI 1.21–2.83, $P = 0.004$). On multilevel multivariate logistic

Table 2 Patient, disease and operative characteristics by apical stapler type (cutting *vs* noncutting).

Factors	Cutting (<i>n</i> = 1033)	Noncutting (<i>n</i> = 314)	Total (<i>n</i> = 1347)	<i>P</i> -value
Patient factors				
Age (years)				
Mean (SD)	65.6 (16.3)	65.1 (16.9)	65.5 (16.4)	0.63
Min–max	16–99	18–96	16–99	
Gender (%)				
Female	534 (51.7)	161 (51.3)	695 (51.6)	0.90
Male	499 (48.3)	153 (48.7)	652 (48.4)	
BMI (category) (%)				
Normal	383 (37.1)	113 (36)	496 (36.8)	0.98
Underweight	36 (3.5)	12 (3.8)	48 (3.6)	
Overweight	342 (33.1)	105 (33.4)	447 (33.2)	
Obese	272 (26.3)	84 (26.8)	356 (26.4)	
Smoking status (%)				
Never	657 (63.6)	191 (60.8)	848 (63)	0.47
Ex-smoker	179 (17.3)	64 (20.4)	243 (18)	
Current	118 (11.4)	31 (9.9)	149 (11.1)	
Not known	79 (7.6)	28 (8.9)	107 (7.9)	
History of IHD/CVA (%)				
No	859 (83.2)	255 (81.2)	1114 (82.7)	0.43
Yes	174 (16.8)	59 (18.8)	233 (17.3)	
Diabetes (%)				
No	876 (84.8)	265 (84.4)	1141 (84.7)	0.98
Tablet controlled	123 (11.9)	38 (12.1)	161 (12)	
Insulin controlled	34 (3.3)	11 (3.5)	45 (3.3)	
ASA category (%)				
Low risk (ASA 1–2)	708 (68.5)	211 (67.2)	919 (68.2)	0.66
High risk (ASA 3–5)	325 (31.5)	103 (32.8)	428 (31.8)	
Disease factors (%)				
Indication				
Malignant	798 (77.3)	262 (83.4)	1060 (78.7)	0.06
Crohn's	150 (14.5)	34 (10.8)	184 (13.7)	
Other*	85 (8.2)	18 (5.7)	103 (7.6)	
Operative factors (%)				
Operative approach				
Laparoscopic/assisted	646 (62.5)	204 (65)	850 (63.1)	0.26
Midline (open)	353 (34.2)	105 (33.4)	458 (34)	
Transverse (open)	34 (3.3)	5 (1.6)	39 (2.9)	
Urgency				
Elective	897 (86.8)	272 (86.6)	1169 (86.8)	0.92
Emergency	136 (13.2)	42 (13.4)	178 (13.2)	
Extent of surgery				
Complete (C4)	284 (27.5)	99 (31.5)	383 (28.4)	0.29
Extended (C5–7)	517 (50.1)	148 (47.1)	665 (49.4)	
Limited (C1–3)	226 (21.9)	61 (19.4)	287 (21.3)	
Primary stapler type				
GIA	705 (68.2)	241 (76.8)	946 (70.2)	0.004
TLC	328 (31.8)	73 (23.2)	401 (29.8)	
Apical stapler type				
GIA	700 (67.8)		700 (52)	N/A
TLC	333 (32.2)		333 (24.7)	
TA		297 (94.6)	297 (22)	
TX		17 (5.4)	17 (1.3)	

Table 2 (Continued).

Factors	Cutting (<i>n</i> = 1033)	Noncutting (<i>n</i> = 314)	Total (<i>n</i> = 1347)	<i>P</i> -value
Oversewn apical stapler line				
No	308 (29.8)	88 (28)	396 (29.4)	0.54
Yes	725 (70.2)	226 (72)	951 (70.6)	
Primary outcome				
Overall anastomotic leak				
No	946 (91.6)	289 (92)	1235 (91.7)	0.80
Yes	87 (8.4)	25 (8)	112 (8.3)	

P-value derived from Student's *t*-test for continuous factors, and chi-squared test for categorical factors. Percentage shown by column.

SD, standard deviation; BMI, body mass index; IQR, interquartile range; IHD, ischaemic heart disease; CVA, cerebrovascular accident; ASA, American Society of Anesthesiologists; N/A, not applicable.

*'Other indication' includes: appendix-related resections, ischaemia, volvulus, trauma and miscellaneous.

regression modelling this association persisted despite risk adjustment (OR 1.65, 95% CI 1.03–2.63, *P* = 0.03). The model had an acceptable fit (AUC 0.66).

Training level of primary operator

The primary operator was a consultant surgeon in 76.8% (*n* = 1035) and a trainee surgeon in 23.2% (*n* = 312) of patients. In the unadjusted data, the overall leak rate for the consultant surgeon group (8.21%) was similar to that in the trainee surgeon group (8.65%, *P* = 0.81). In univariate analysis (OR 1.06, 95% CI 0.67–1.70, *P* = 0.78) and multivariate analysis (OR 1.00, 95% CI 0.61–1.63, *P* = 0.99) there was no difference in overall risk of anastomotic leak between these groups (Table 5).

Sensitivity analysis for 'proven anastomotic leak only'

Sensitivity analyses including only radiologically or clinically proven anastomotic leakage demonstrated similar patterns of results for apical stapler type, oversewing of the apical staple line and operator specialty interest and grade (Table S1).

Discussion

This study of right-sided colonic resections with a stapled, side-to-side ileocolic anastomosis showed no difference in overall leak rates when using cutting or noncutting staplers for apical transection, and from oversewing of the apical staple line. There was a higher overall anastomotic leak rate and proven leak rates observed for general surgeons when compared with colorectal surgeons.

Anastomotic technique

No difference in overall leak rates were observed in cutting and noncutting apical stapler types on univariate or multivariate analysis. There were no differences in risk factors between the groups to suggest selection bias, although there was an increased proportion of malignant disease (nonsignificant) in the noncutting apical stapler group. Whilst multiple randomized trials have explored outcomes after stapled or handsewn anastomoses in right colonic surgery [14], only one retrospective study has examined the intricacies of stapler technique and the use of a cutting *vs* noncutting stapler for apical closure after a side-to-side stapled anastomosis [11]. This earlier study included small bowel, ileocolic and colocolic anastomoses in both elective and emergency settings, resulting in a very heterogeneous patient cohort, and found that closure of the apical enterotomy with a cutting stapler had a lower anastomotic leak rate compared with a noncutting stapler (3.7% *vs* 10.6%, *P* = 0.017). However, there was a significantly greater number of emergency resections and longer mean operative time in the noncutting stapling group (a potential surrogate for operative complexity) which might account for the difference in outcome.

Staple line reinforcement has been suggested to be effective in oesophageal resection [15] and sleeve gastrectomy [16], resulting in a higher peak bursting pressure in reinforced anastomoses. One single-centre study has suggested a possible benefit from oversewing of ileocolic anastomoses and ileostomy closures [17], although the study was retrospective and there was no comparison group presented. A recent retrospective study also identified no benefit from staple line oversewing [11] and two well-conducted trials of bio-absorbable staple line reinforcement adjuncts also found

Table 3 Univariate and multivariate, mixed effects logistic regression analysis for overall anastomotic leak.

	Univariate model				Multivariate model			
	OR	P-value	Lower CI	Upper CI	OR	P-value	Lower CI	Upper CI
Primary analyses								
Apical stapler type								
Cutting	1	–	–	–	1	–	–	–
Noncutting	0.91	0.71	0.56	1.50	0.91	0.72	0.54	1.53
Oversewn apical anastomosis								
No	1	–	–	–	1	–	–	–
Yes	0.91	0.68	0.59	1.41	0.97	0.90	0.61	1.54
Patient, disease and operative factors								
Age	0.99	0.37	0.98	1.01	0.99	0.10	0.97	1.00
Gender								
Male	1	–	–	–	1	–	–	–
Female	0.77	0.19	0.52	1.14	0.88	0.56	0.58	1.35
BMI category								
Normal weight	1	–	–	–	1	–	–	–
Underweight	0.79	0.71	0.23	2.71	0.79	0.73	0.22	2.85
Overweight	1.06	0.81	0.66	1.72	1.12	0.64	0.68	1.89
Obese	1.33	0.25	0.82	2.18	1.28	0.36	0.75	2.19
Smoking status								
No	1	–	–	–	1	–	–	–
Ex-smoker	1.52	0.10	0.93	2.51	1.47	0.17	0.85	2.53
Current	1.84	0.04	1.04	3.23	1.76	0.07	0.96	3.22
Not known	1.38	0.37	0.68	2.84	1.58	0.24	0.73	3.41
History of IHD/CVA								
No	1	–	–	–	1	–	–	–
Yes	0.83	0.51	0.48	1.43	0.87	0.66	0.48	1.60
Diabetes								
No	1	–	–	–	1	–	–	–
Tablet controlled	1.04	0.90	0.57	1.89	1.17	0.63	0.62	2.21
Insulin controlled	0.79	0.71	0.24	2.64	0.69	0.57	0.20	2.44
ASA category								
Low risk (ASA 1–2)	1	–	–	–	1	–	–	–
High risk (ASA 3–5)	1.18	0.43	0.78	1.80	1.17	0.53	0.71	1.91
Indication								
Malignancy	1	–	–	–	1	–	–	–
Crohn's	0.96	0.91	0.53	1.75	0.64	0.33	0.27	1.55
Other	1.98	0.03	1.08	3.61	1.08	0.84	0.50	2.36
Approach								
Laparoscopic/assisted	1	–	–	–	1	–	–	–
Midline (open)	2.23	< 0.001	1.47	3.38	1.99	< 0.001	1.24	3.18
Transverse (open)	0.38	0.35	0.05	2.88	0.36	0.33	0.05	2.78
Extent of surgery								
Complete (C4)	1	–	–	–	1	–	–	–
Extended (C5–7)	1.14	0.59	0.72	1.84	1.09	0.74	0.66	1.78
Limited (C1–3)	1.10	0.74	0.62	1.96	0.93	0.83	0.47	1.85
Urgency								
Elective	1	–	–	–	1	–	–	–
Emergency	2.59	< 0.001	1.62	4.14	1.75	0.07	0.95	3.22

OR, odds ratio; CI, 95% confidence interval; BMI, body mass index; IHD, ischaemic heart disease; CVA, cerebrovascular accident; ASA, American Society of Anesthesiologists.

Table 4 Patient, disease and operative characteristics by operator type.

Factors	Colorectal surgeon	General surgeon	Total (n = 1347)	P-value
Patient factors				
Age (years)				
Mean (SD)	64.4 (16.5)	68.9 (15.5)	65.5 (16.4)	< 0.001
Min–max	16–95	23–99	16–99	
Gender (%)				
Female	514 (51.0)	181 (53.4)	695 (51.6)	0.44
Male	494 (49.0)	158 (46.6)	652 (48.4)	
BMI (category) (%)				
Normal	370 (36.7)	126 (37.2)	496 (36.8)	0.05
Underweight	44 (4.4)	4 (1.2)	48 (3.6)	
Overweight	327 (32.4)	120 (35.4)	447 (33.1)	
Obese	267 (26.5)	89 (26.3)	356 (26.4)	
Smoking status (%)				
Never	620 (61.5)	228 (67.3)	848 (63.0)	0.03
Ex-smoker	191 (19.0)	52 (15.3)	243 (18.0)	
Current	107 (10.6)	42 (12.4)	149 (11.1)	
Not known	90 (8.9)	17 (5.0)	107 (7.9)	
History of IHD/CVA (%)				
No	832 (82.5)	282 (83.2)	1114 (82.7)	0.79
Yes	176 (17.5)	57 (16.8)	233 (17.3)	
Diabetes (%)				
No	868 (86.1)	273 (80.5)	1141 (84.7)	0.02
Tablet controlled	113 (11.2)	48 (14.2)	161 (12.0)	
Insulin controlled	27 (2.7)	18 (5.3)	45 (3.3)	
ASA category (%)				
Low risk (ASA 1–2)	710 (70.4)	209 (61.7)	919 (68.2)	0.003
High risk (ASA 3–5)	298 (29.6)	130 (38.4)	428 (31.8)	
Disease factors (%)				
Indication				
Malignant	789 (78.3)	271 (79.9)	1060 (78.7)	< 0.001
Crohn's	157 (15.6)	27 (8.0)	184 (13.7)	
Other*	62 (6.2)	41 (12.1)	103 (7.7)	
Operative factors (%)				
Operative approach				
Laparoscopic/assisted	688 (68.3)	162 (47.8)	850 (63.1)	< 0.001
Midline (open)	293 (29.1)	165 (48.7)	458 (34.0)	
Transverse (open)	27 (2.7)	12 (3.5)	39 (2.9)	
Urgency				
Elective	914 (90.7)	255 (75.2)	1169 (86.8)	< 0.001
Emergency	94 (9.3)	84 (24.8)	178 (13.2)	
Extent of surgery				
Complete (C4)	281 (28.2)	102 (30.1)	383 (28.7)	0.80
Extended (C5–7)	499 (50.1)	166 (49.0)	665 (49.8)	
Limited (C1–3)	216 (21.7)	71 (20.9)	287 (21.5)	
Primary stapler type				
GIA	666 (66.1)	280 (82.6)	946 (70.2)	0.001
TLC	342 (33.9)	59 (17.4)	401 (29.8)	
Apical stapler type				
GIA (cutting)	485 (48.1)	215 (63.4)	700 (52.0)	0.001
TLC (cutting)	282 (28.0)	51 (15.0)	333 (24.7)	
TA (noncutting)	224 (22.2)	73 (21.5)	297 (22.1)	
TX (noncutting)	17 (1.7)	0 (0.00)	17 (1.3)	

Table 4 (Continued).

Factors	Colorectal surgeon	General surgeon	Total (<i>n</i> = 1347)	<i>P</i> -value
Oversewn apical stapler line				
No	287 (28.5)	109 (32.2)	396 (29.4)	0.20
Yes	721 (71.5)	230 (67.8)	951 (70.6)	
Primary outcome (%)				
Overall anastomotic leak				
No	937 (93.0)	298 (87.9)	1235 (91.7)	0.004
Yes	71 (7.0)	41 (12.1)	112 (8.3)	

P-value derived from Student's *t*-test for continuous factors, and chi-square test for categorical factors. Percentage shown by column.

SD, standard deviation; IQR, interquartile range; BMI, body mass index; IHD, ischaemic heart disease; CVA, cerebrovascular accident; ASA, American Society of Anesthesiologists.

*'Other indication' includes: appendix-related resections, ischaemia, volvulus, trauma and miscellaneous.

Table 5 Univariate and multivariate mixed effects logistic regression analysis for overall anastomotic leak. Patient, disease and operative factors included in the model are described in Table 3.

	Univariate model				Multivariate model			
	OR	<i>P</i> -value	Lower CI	Upper CI	OR	<i>P</i> -value	Lower CI	Upper CI
Secondary analyses								
Surgeon specialism								
Colorectal surgeon	1	–	–	–	1	–	–	–
General surgeon	1.85	0.004	1.21	2.83	1.65	0.04	1.04	2.64
Surgeon level of training								
Consultant surgeon	1	–	–	–	1	–	–	–
Surgical trainee	1.07	0.78	0.67	1.70	1.00	0.99	0.61	1.63

OR, odds ratio; CI, confidence interval.

no benefit in intestinal anastomoses [11,18,19]. Our findings do not support the practice of oversewing of the anastomotic staple line to prevent anastomotic leak.

Specialty of primary operator

We examined the effect of operator specialism (self-reported as either colorectal surgeon or general surgeon) on outcomes. Whilst there was a significantly greater proportion of 'high-risk' (ASA grade 3 and above), open incisions, 'other' indications' (e.g. appendix-related resections, ischaemia, volvulus, trauma) and emergency operations in the group performed by general surgeons. We attempted to risk adjust for these difference, and found that the increased risk associated with procedures performed by general surgeons persisted. There was an international distribution of self-reported general surgeons and colorectal surgeons (i.e. the effect seen was not the effect of country-specific nomenclature), and random centre-specific effects were accounted for within our model. However, it is of course possible that this finding may still reflect

selection biases left unaccounted for in our risk adjustment, for example patients presenting to general surgeons in nonspecialist units may present later and with different disease severity, have less access to essential services (e.g. emergency theatre, imaging, high-dependency support) and lack local multidisciplinary input.

It is well recognized that a volume–outcome relationship exists in colorectal cancer surgery. A recent population-level analysis of 8219 patients undergoing surgery for colonic or rectal surgery in the UK demonstrated significantly better operative mortality and cancer-specific survival for patients operated by high-[hazard ratio (HR) 0.93] and medium-volume (HR 0.88) *vs* low-volume surgeons, and in high- *vs* low-volume hospitals (HR 0.88) [20]. A 2012 Cochrane systematic review included 943 728 patients undergoing colon or rectal cancer surgery across randomized and nonrandomized studies [21]. Overall 5-year survival was significantly improved for patients with colorectal cancer treated in high-volume hospitals (HR 0.90, 95% CI 0.85–0.96), by high-volume surgeons (HR 0.88, 95% CI 0.83–0.93) and colorectal specialists (HR 0.81,

95% CI 0.7–0.94). Our data show more favourable outcomes for right-sided anastomoses by specialized colorectal surgeons and in patients undergoing laparoscopic or laparoscopic-assisted procedures, which is consistent with published literature [22]. At present, surgeons are not required to undergo specific training prior to using stapling devices. Training programmes to standardize best practice in stapler device application may improve familiarity with this technique and drive improvement in outcomes.

Training level of primary operator

No difference was observed in anastomotic leak rates between trainee surgeons and consultant surgeons. This was supported by a recent meta-analysis of 19 nonrandomized studies including 14 344 resections, which did not show a difference in leak rates (3.2% *vs* 2.5%, OR 0.77, $P = 0.08$) or cancer-specific survival (HR 0.76, $P = 0.13$) between expert and expert-supervised trainees, although operative time was longer in the trainee group (weighted mean difference 10.0 min, $P < 0.001$). Our study supports the performance of right colonic surgery by surgical trainees in an appropriately supervised environment.

Strengths of this study

This observational, international ‘snapshot’ data collection method represents a pragmatic, ‘real-world’ view of practice, unrestricted by the limitations of clinical trials across these settings (e.g. refusal of patients to consent, restrictive inclusion criteria). The study was conducted using a prespecified protocol and reporting system, with data capture performed prospectively and with high data completeness, resulting in minimal reporting and performance bias. The study case record forms were designed to be simple enough for frontline surgeons to complete alongside their clinical practice, whilst providing sufficient data for high-quality risk adjustment of datasets, facilitating capture of large numbers of patients across diverse study settings. The broad representation of included patients within this study facilitates generalization of its findings.

Limitations of this study

Observational research will always be at risk of bias; however, *a priori* considerations were made to minimize differential effects of bias across analysed groups. Selection bias was addressed by capturing clinically plausible risk-adjustment data at a patient-, disease- and operation-specific level, and adjusting for random centre-level

effects in our multivariate model. We concede that some risk factors can be missed within the limits of this ‘snapshot’ study model (e.g. physiological and biochemical parameters, the exact position of the anastomosis, assessment of blood supply to the anastomosis, the technique and suture used for oversewing). The outcome measure of both suspected (intra-abdominal/pelvic fluid collections) and confirmed (clinically or radiologically) leak, attempted to give a pragmatic approach to the problem of anastomotic leak in this population, where no validated scoring system exists [23,24]. In addition, adverse outcomes were similar between the groups with a suspected and confirmed leak, as previously described [9]. Risk of reporting bias was minimized by requiring prospective data capture, and including all consecutive patients within a predefined time frame, with *a* pre-planned validation of case ascertainment and data completeness. The overall leak rate of 8.3% (radiologically or clinically confirmed rate 5.6%) is equivalent or higher than that seen in high-quality randomized controlled studies and registries [25–28], where inclusion and follow-up are closely regulated, suggesting that any effects of this bias were minimal.

Only selected technical elements of the side-to-side ileocolic anastomosis were collected and analysed within this study. There remains significant procedural variation that was not explored, for example placement of a ‘crotch’ stitch to reduce stress across the confluence of the primary staple line, staple height (i.e. different stapler cartridges), tissue compression technique prior to cutting [29] and isoperistaltic *vs* antiperistaltic configuration [30].

Finally, operator specialism and level of training were self-reported and lacked consensus definitions within the study population. There exists variance in the nomenclature of ‘trainee’ and ‘consultant’ surgeons around Europe. Similarly, there were no specific volume, training or qualification requirements which qualified a surgeon to report themselves to be a general surgeon or a colorectal surgeon. Further exploration of the impact of familiarity with stapling and anastomotic failure should include more detail regarding the volume and frequency of cases completed by the primary operator.

Conclusion

In this large international cohort, similar anastomotic leak rates were seen whether a cutting or noncutting linear stapler was used to close the apical aspect of a side-to-side ileocolic anastomosis. In addition, oversewing of this staple line did not appear to confer any benefit. A significantly higher leakage rate was seen when the operation was not performed by a colorectal

specialist, a finding which persisted after multivariate analysis correcting for patient and disease differences. This warrants further investigation to determine if there is a role for enhanced training in the use of gastrointestinal staplers to improve outcomes for patients undergoing ileocolic anastomoses.

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Conflicts of interests

None declared.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. 2015 European Society of Coloproctology collaborating group.

Table S1. Univariate and multivariate mixed effects logistic regression analysis for proven anastomotic leak (sensitivity analysis).