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

On behalf of the 2015 European Society of Coloproctology collaborating group*

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Abstract

Background

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.

Methods

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

1347 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 to non-cutting stapler (8.4% versus 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% versus 9.7%, OR:0.87, 95% CI:0.52-1.46, P=0.60), or non-cutting group (8.9% versus 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% versus 7.3%, OR:1.65, 95% CI:1.04-2.64, P=0.04).

Discussion

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 in General Surgeons which remained after risk adjustment needs further exploration.

What does this paper add to the existing literature?

This large, multicentre, international cohort study showed no difference in leak rates with a cutting or non-cutting 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 re-intervention, re-operation, organ support, or leading to death (1). The most feared complication after colorectal resection is anastomotic leak. This impacts 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 non-modifiable, such as gender, an unplanned operation, the presence of malignancy, major 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 decision.

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 (Figure 1). Whilst there is no randomised evidence examining the effect of different stapling techniques on anastomotic outcomes, some surgeons believe that a cutting stapler for apical transection may increase risk of leak when compared to a non-cutting 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).

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 compared to hand-sewn, 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 versus non-cutting) after stapled side-to-side anastomosis and anastomotic leakage, as well as to assess the influence of (i) oversewing of the apical staple line, (ii) primary operator specialty, and (iii) primary operator level of training on anastomotic leakage.

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Method

This prospective, observational, multicentre study was conducted in line with a pre-specified protocol (<http://www.escp.eu.com/research/cohort-studies/2015-audit>). 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 pre-defined 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 sixteen 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 non-cutting) were extracted for inclusion in this analysis (Figure 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 the 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 post-operative outcome data were collected. Technical operative factors collected included: operator grade (Consultant, Trainee); operator specialty interest (Colorectal, General Surgery); primary and apical stapler type (cutting, non-cutting (Table 1)); oversewing of anastomosis (continuous, interrupted); extent of surgery (complete, extended, limited). Outcome data was collected up to 30-days through review of patient notes (paper and electronic) during their index admission, reviewing hospital systems to check for re-admission or re-operation, and reviewing postoperative radiology reports. Within the limits of this observational study, no changes were made to patients' existing follow-up pathways.

Data was 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, pre-defined as either i) gross anastomotic leakage proven radiologically or clinically, or ii) the presence of an intraperitoneal (abdominal or pelvic) fluid collection on post-operative 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. non-cutting) and by the primary outcome anastomotic leak using a t-test for continuous data (e.g. age), or a Chi-squared test for categorical data. To test the association between overall anastomotic leak and the main explanatory variables of interest (apical cutting versus non-cutting stapler), a multilevel, multivariable logistic regression model was created. Clinically plausible factors were entered into the model for risk-adjustment. These were pre-defined, and included irrespective of their significance on univariate analysis. A pre-planned analysis compared colorectal specialists versus general surgeons, and consultant versus trainee surgeons. Sensitivity analyses were performed for proven anastomotic leakage only. No analysis was planned by stapler manufacturer due to small included numbers 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, TX, 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.

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%). 1484 (46.3% of total) of those undergoing side-to-side ileocolic anastomosis were formed with a linear cutting primary stapler, and a linear apical stapler was used in 1347 (42.0% of total) of these patients (Figure 2). This analysis included these 1347 patients from 200 centres in 32 countries, including 7 countries outside of Europe. The countries contributing greatest number of patients were UK (n=391), Spain (n=276), and the Netherlands (n=106).

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Patient, disease and operative characteristics (described in Table 2) were similar between the groups with a cutting and non-cutting apical stapler. The mean age of included patients was 65.5 years (range: 16-99) and approximately half were female (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 non-cutting apical stapler group there was an increased proportion of patients undergoing surgery for malignancy versus other indication, but this was not significant (P=0.06). Most operations included were elective (n=1,169, 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 non-cutting 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%) versus non-cutting (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 an '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 (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 non-cutting 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% versus 67.2%), with the remainder performed using interrupted sutures. There were no differences observed in unadjusted leak rates for oversewn versus not oversewn anastomoses either in the cutting (7.9% versus 9.7%, P=0.43), or non-cutting groups (8.9% versus 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 non-cutting apical staple lines (OR: 1.40, 95% CI: 0.46-4.23, P=0.55).

Operator specialty 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' (ASA 3 and above) patients than Colorectal

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Surgeons (38.4% versus 29.6%, $P=0.003$), more patients with an 'other' indication (12.1% versus 6.2%, $P<0.001$), and fewer with Crohn's disease (8.0% versus 15.6%, $P<0.001$). General Surgeons were more likely to use an open (midline) approach (48.7% versus 29.1%, $P<0.001$), and more likely to operate as an emergency (24.8% versus 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 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% of patients ($n=312$). 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 overall risk of anastomotic leak between these groups.

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 (Supplementary table 1).

Discussion

This study of right sided colonic resections with a stapled, side-to-side ileocolic anastomosis showed no difference in overall leak rates of when using cutting or non-cutting 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 in General Surgeons when compared to Colorectal Surgeons.

Anastomotic technique

No difference in overall leak rates were observed in cutting and non-cutting 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 (non-significant) in the non-cutting apical stapler group. Whilst multiple randomised 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 versus non-cutting 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 to a non-cutting stapler (3.7% versus 10.6%, $p=0.017$). However, there was a significantly higher number of emergency resections and longer mean operative time in the non-cutting 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 proved fruitless 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 non-specialist units may present later and with different severity of disease, 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 (HR: 0.93) and medium (HR: 0.88) volume versus low volume surgeons, and in high versus low volume hospitals (HR: 0.88) (20). A 2012

Cochrane systematic review included 943,728 patients undergoing colon or rectal cancer surgery across randomised and non-randomised studies (21). Overall five-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 shows more favourable outcomes for right sided anastomoses by specialised 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 standardise 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 non-randomised studies including 14,344 resections, which did not show a difference in leak rates (3.2% versus 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 minutes, $p<0.001$). 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

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settings (e.g. patient refusal to consent, restrictive inclusion criteria). The study was conducted using a pre-specified protocol and reporting system, with data capture performed prospectively, 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 generalisation of its findings.

Limitations of this study

Observational research will always be at risk of bias, however *a priori* considerations were made to minimise 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 (intraabdominal/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 minimised by requiring prospective data capture, and including all consecutive patients within a pre-defined 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 to that seen in high-quality randomised 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); isoperistaltic versus 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 non-cutting 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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Tables and Figures

Table 1: Included stapler types. (Lap=Total laparoscopic (intracorporeal anastomosis), Lap-Ass=Laparoscopic-assisted (extracorporeal anastomosis))

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

Table 2: Patient, disease and operative characteristics by apical stapler type (cutting versus non-cutting). P-value derived from Student's T-test for continuous factors, and Chi2 test for categorical factors. (% shown by column. SD=Standard deviation; IQR=Interquartile range; IHD=Ischemic heart disease; CVA=Cerebrovascular accident; N/A=Not applicable. **Other indication' includes: appendix-related resections, ischaemia, volvulus, trauma and miscellaneous)

Factors	Cutting (N=1033)	Non-Cutting (N=314)	Total (N=1347)	P-value
Patient Factors				
<i>Age</i>				
Mean (SD)	65.6 (16.3)	65.1 (16.9)	65.5 (16.4)	0.63
Min - Max	16-99	18-96	16-99	
<i>Gender</i>				
Female	534 (51.7%)	161 (51.3%)	695 (51.6%)	0.90
Male	499 (48.3%)	153 (48.7%)	652 (48.4%)	
<i>BMI (Category)</i>				
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%)	
<i>Smoking status</i>				
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%)	
<i>History of IHD/CVA</i>				
No	859 (83.2%)	255 (81.2%)	1114 (82.7%)	0.43
Yes	174 (16.8%)	59 (18.8%)	233 (17.3%)	
<i>Diabetes</i>				
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%)	
<i>ASA Category</i>				
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				
<i>Indication</i>				
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				
<i>Operative Approach</i>				
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%)	
<i>Urgency</i>				
Elective	897 (86.8%)	272 (86.6%)	1169 (86.8%)	0.92
Emergency	136 (13.2%)	42 (13.4%)	178 (13.2%)	
<i>Extent of Surgery</i>				
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%)	
<i>Primary stapler type</i>				
GIA	705 (68.2%)	241 (76.8%)	946 (70.2%)	0.004
TLC	328 (31.8%)	73 (23.2%)	401 (29.8%)	
<i>Apical stapler type</i>				
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%)	
<i>Oversewn apical stapler line</i>				
No	308 (29.8%)	88 (28%)	396 (29.4%)	0.54
Yes	725 (70.2%)	226 (72%)	951 (70.6%)	
Primary outcome				
<i>Overall anastomotic leak</i>				

No	946 (91.6%)	289 (92%)	1235 (91.7%)	0.80
Yes	87 (8.4%)	25 (8%)	112 (8.3%)	

Table 3: Univariate and multivariate, mixed effects logistic regression analysis for overall anastomotic leak. (OR=Odds ratio; CI=95% Confidence Interval; IHD=Ischemic heart disease; CVA=Cerebrovascular accident)

	Univariate model				Multivariate model			
	OR	P-value	Lower CI	Upper CI	OR	P-value	Lower CI	Upper CI
Primary analyses								
<i>Apical stapler type</i>								
Cutting	1	-	-	-	1	-	-	-
Non-Cutting	0.91	0.71	0.56	1.50	0.91	0.72	0.54	1.53
<i>Oversewn apical anastomosis</i>								
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
<i>Gender</i>								
Male	1	-	-	-	1	-	-	-
Female	0.77	0.19	0.52	1.14	0.88	0.56	0.58	1.35
<i>BMI Category</i>								
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
<i>Smoking Status</i>								
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
<i>History of IHD/CVA</i>								
No	1	-	-	-	1	-	-	-
Yes	0.83	0.51	0.48	1.43	0.87	0.66	0.48	1.60
<i>Diabetes</i>								
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
<i>ASA Category</i>								
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
<i>Indication</i>								
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
<i>Approach</i>								
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
<i>Extent of Surgery</i>								
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
<i>Urgency</i>								
Elective	1	-	-	-	1	-	-	-
Emergency	2.59	<0.001	1.62	4.14	1.75	0.07	0.95	3.22

Table 4: Patient, disease and operative characteristics by operator type. P-value derived from Student's T-test for continuous factors, and Chi2 test for categorical factors. (% shown by column. SD=Standard deviation; IQR=Interquartile range; IHD=Ischemic heart disease; CVA=Cerebrovascular accident. *'Other indication' includes: appendix-related resections, ischaemia, volvulus, trauma and miscellaneous)

Factors	Colorectal surgeon	General surgeon	Total (N=1347)	P-value
Patient Factors				
<i>Age</i>				
Mean (SD)	64.4 (16.5)	68.9 (15.5)	65.5 (16.4)	<0.001
Min - Max	16 - 95	23 - 99	16 - 99	
<i>Gender</i>				
Female	514 (51.0%)	181 (53.4%)	695 (51.6%)	0.44
Male	494 (49.0%)	158 (46.6%)	652 (48.4%)	
<i>BMI (Category)</i>				
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%)	
<i>Smoking status</i>				
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%)	
<i>History of IHD/CVA</i>				
No	832 (82.5%)	282 (83.2%)	1114 (82.7%)	0.79
Yes	176 (17.5%)	57 (16.8%)	233 (17.3%)	
<i>Diabetes</i>				
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%)	
<i>ASA Category</i>				
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				
<i>Indication</i>				
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				
<i>Operative Approach</i>				
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%)	
<i>Urgency</i>				
Elective	914 (90.7%)	255 (75.2%)	1169 (86.8%)	<0.001
Emergency	94 (9.3%)	84 (24.8%)	178 (13.2%)	
<i>Extent of Surgery</i>				
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%)	
<i>Primary stapler type</i>				
GIA	666 (66.1%)	280 (82.6%)	946 (70.2%)	0.001
TLC	342 (33.9%)	59 (17.4%)	401 (29.8%)	
<i>Apical stapler type</i>				
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 (Non-cutting)	224 (22.2%)	73 (21.5%)	297 (22.1%)	
TX (Non-cutting)	17 (1.7%)	0 (0.00%)	17 (1.3%)	
<i>Oversewn apical stapler line</i>				
No	287 (28.5%)	109 (32.2%)	396 (29.4%)	0.20
Yes	721 (71.5%)	230 (67.8%)	951 (70.6%)	
Primary outcome				
<i>Overall anastomotic leak</i>				
No	937 (93.0%)	298 (87.9%)	1235 (91.7%)	0.004

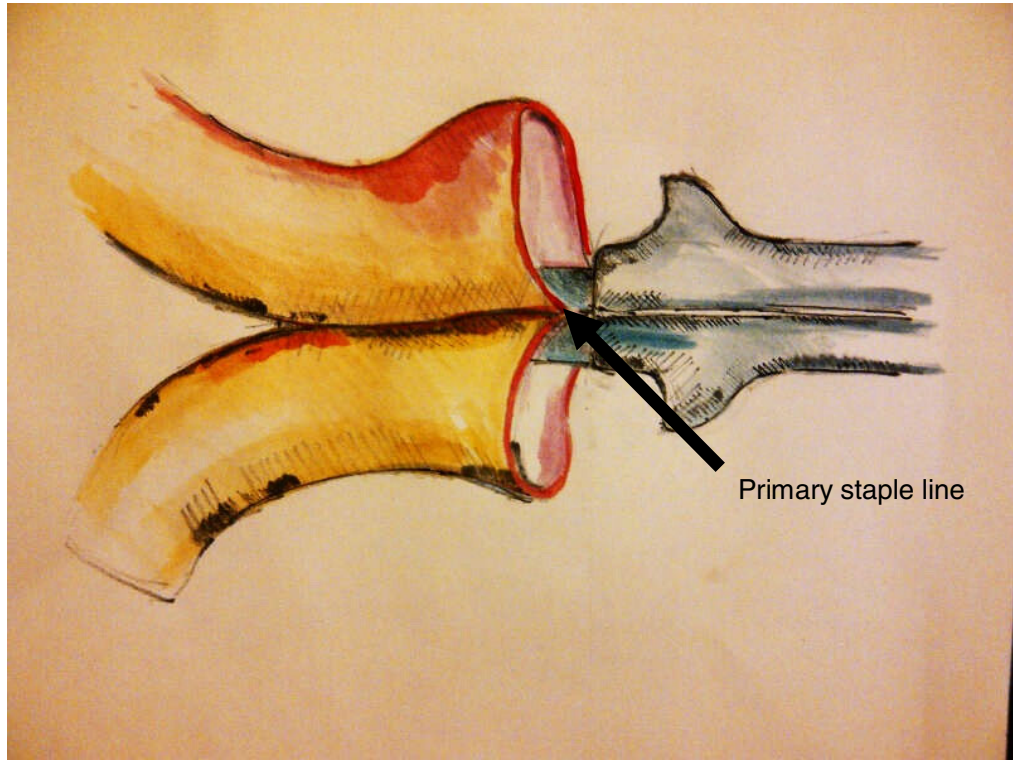
Yes	71 (7.0%)	41 (12.1%)	112 (8.3%)	
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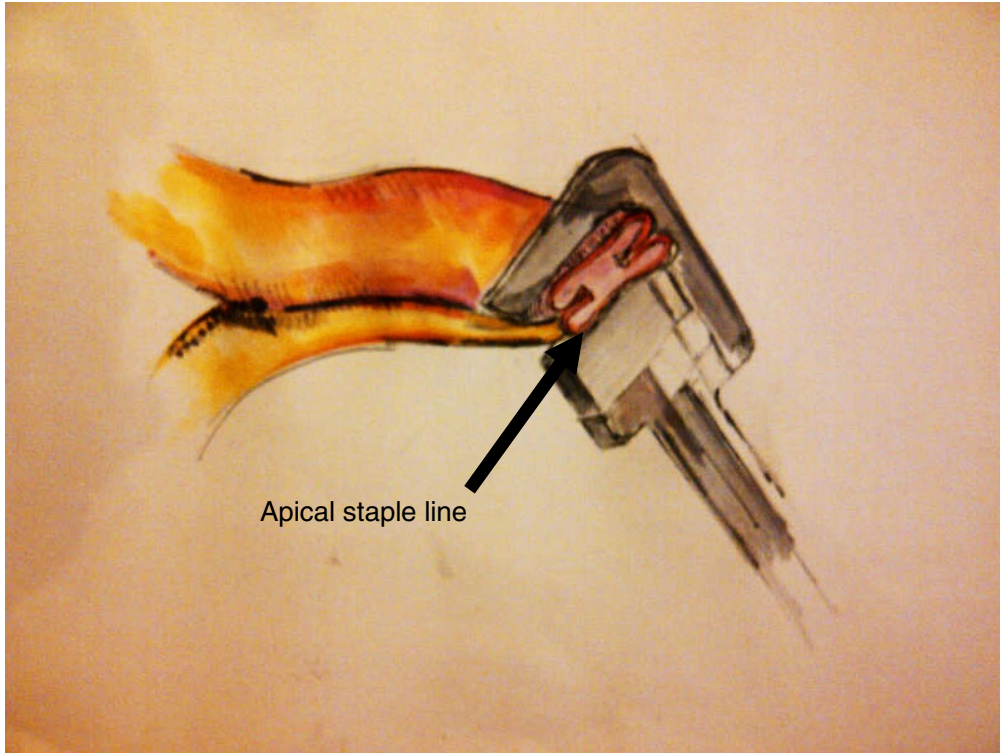
Table 5: Univariate and multivariate mixed effects logistic regression analysis for overall anastomotic leak. Patient, disease and operative factors included in the model are described in

Table 3. (OR=Odds ratio; CI=Confidence Interval).

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

Figure 1. Configuration of side-to-side ileocolic anastomosis in right sided colorectal resection.*





*with thanks to Professor David Gourevitch for these illustrations

Figure 2. Patients included within this subgroup analysis of stapled, side-to-side ileocolic anastomoses

