EAGLE: ESCP sAfe-anastomosis proGramme in colorectaL surgEry

An international audit of the impact of completion of EAGLE online training modules on anastomotic leak rate following right colectomy and ileocecal resection.

Audit Protocol

Version 1

Version 1.0: 01st February 2024

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SUMMARY

Title: An *international audit of the impact of completion of EAGLE online training modules on anastomotic leak rate following right colectomy and ileocecal resection.*

Background: Anastomotic leak (Al) is a severe, potentially life-threatening complication following right colectomy. Internationally, anastomotic leak occurs after 8% of right colectomies. Prospective cohort data demonstrate that patient selection, intra-operative factors, and technical variation are risk factors for anastomotic leak. The EAGLE study investigated an educational platform to reduce AI. It showed an absolute reduction in leaks of 20% following implementation and found that in centres where 80% of surgeons undertook the training, the anastomotic leak rate fell by almost 50%. EAGLE 2 is a snapshot audit of centres undertaking the educational intervention to validate the findings from the randomised trial.

Aim: To measure the anastomotic leak rate following right sided large bowel anastomosis in centres where the surgical teams have undertaken the EAGLE platform training.

Design: Prospective audit with clinician derived baseline clinical data and short-term 30-day outcomes for patients undergoing right colectomy and ileocecal resection.

Eligibility: Any hospital or surgical unit performing elective and/or emergency colorectal surgery. Adults (age 18 years and above) undergoing right colectomy or ileocaecal resection for any indication are eligible, including elective, expedited or emergency surgery by open, laparoscopic or robotic approaches.

Primary Outcome measure*:* 30-day anastomotic leak rate, defined as clinical or radiologically detected anastomotic leak or intra-abdominal or pelvic collection.

Sample size**:** a consecutive series of cases, collected over an 8 week period, of patients undergoing right sided large bowel anastomosis. The study is open to any centres where the surgical team have untaken the educational training. These may be centres from EAGLE 1 or new centres that did not take part in EAGLE 1.

BACKGROUND

Clinical problem

Right hemicolectomy and ileocaecal resection are the most common colonic procedures performed worldwide (excluding appendicectomy) by both general surgeons and specialist colorectal surgeons, in both referral and general hospitals. Collectively termed 'right colectomy', these are performed for malignancy and benign indications including inflammatory bowel disease, trauma and volvulus. Internationally, anastomotic leak affects 8.1% of patients after right colectomy, with leak being associated with a 10-fold increase in the risk of death. Anastomotic leak also reduces cancer-specific survival and increases risk of recurrence in oncological resection, and has profound effects on patients' quality of life following surgery and risk of permanent ostomy formation.

Existing international data

The European Society of Coloproctology (ESCP) has established a diverse international network of surgeons from around the world who have collaborated in multi-centre audit and research studies to benefit patients undergoing colorectal surgery. The 2015 ESCP audit of right colectomy and ileocaecal resection demonstrated an anastomotic leak rate of 8.1%, with significant variation in practice around the formation of the ileocolic anastomosis. A total of 14 different anastomotic configurations were reported, with 9 of these being performed collectively by less than 10% of surgeons. Stapled anastomosis was associated with a higher risk of anastomotic leak than handsewn anastomosis, despite handsewn anastomoses being performed more commonly in high-risk, emergency operations. Multi-variable regression analyses also indicated that surgeon specialism was associated with risk of anastomotic leak; general surgeons had a 1.5-fold risk of leak compared to colorectal surgeons. These data indicate that training may have a role in reducing the risk of anastomotic leak, and that a targeted Quality Improvement Intervention to harmonise practice and reduce variation could lead to significant patient benefit. The EAGLE study showed that AL was reduced by up to 20% when surgeons implemented the interventions and in centres where 80% of the surgical team undertook the online training, anastomotic leak rate decreased by almost 50%.

STUDY RATIONALE

Need for research

Anastomotic leak has been recognised as a priority research topic by the James Lind Alliance. A comprehensive systematic review and meta-analysis of leak prevention strategies in right colectomy demonstrated a low-quality evidence base to support specific technical and perioperative interventions. Most evidence was based on single-centre observational studies at high-risk of bias. Where randomised studies have been conducted, their interpretation is limited by explanatory designs under-powering, or a lack of contemporary data. International, pragmatic studies are required to improve the evidence base for anastomosis formation, and benefit patients undergoing right colectomy. The 2019 ESCP Hamburg Declaration emphasized the critical importance of addressing unacceptable variation in anastomotic leak rates by quality improvement. The EAGLE 2 audit aims to capture evidence for the beneficial effect of completion of the EAGLE online training to address this variation.

Justification of patient population

Right colectomy is the most commonly performed large bowel resection in the world. It is performed for both acute and chronic conditions, across high, middle and low-income settings. Despite the high risk of anastomotic leak demonstrated in ESCP audits, right colectomy is often considered a simpler and lower-risk operation than left colectomy or rectal surgery, and consequently consultants may not always be the lead surgeon; in selected cases trainees may perform this operation independently. Finally, it is performed by specialist colorectal surgeons and general surgeons.

Rationale for study design

The prospective audit will result in the generation of a large, international dataset of real-world data on the impact of completion of the EAGLE training modules on anastomotic leak rate in centres where most surgeons complete the training.

AIMS & OBJECTIVES

Primary objective

- To measure the anastomotic leak rate following right sided large bowel anastomosis in centres where the surgical teams have undertaken the EAGLE platform training.

Secondary clinical objectives

- To assess the uptake and acceptability of the online training platform.

Primary outcome measure

The primary outcome measure is anastomotic leak within 30-days of surgery (with Day 0 as the day of surgery). The denominator for the primary outcome is the total for patients who had a primary anastomosis. The numerator is anastomotic leak, defined as a composite of either:

- Anastomotic leakage identified radiologically or clinically

  or
- Intraperitoneal (abdominal or pelvic) fluid collection identified radiologically, as per the Centre for Disease Control Criteria for Organ Space infection

  or
- Entero-enteric fistula identified radiologically

Secondary outcome measures

- The denominator is the total for patients who had a primary anastomosis:
- Reoperation for anastomotic leak, within 30-days
- The denominator is the total for all patients:
- Reoperation for any cause, within 30-days
- Unplanned admission to critical care, within 30 days
- Readmission within 30 days.
- Post-operative length of hospital stay, up to 30-days
- Mortality within 30-days.
- Rate of ileostomy without anastomosis.
- Rate of defunctioning ileostomy with anastomosis.

Study Design

International prospective audit.

ELIGIBILITY

Hospital inclusion criteria

Any hospital or surgical unit performing elective and/or emergency colorectal surgery. There are no restrictions for hospital/unit size or case volume. Participation in EAGLE 1 is not a pre-requisite.

Participating sites will be expected to recruit all eligible patients within a consecutive 8-week period.

At hospital level, data completeness of 95% will be required to be part of this audit.

Patient inclusion criteria

All adult patients (age 18 years and above) undergoing right colectomy with or without primary anastomosis. Right colectomy is defined as ileocaecal resection or right hemicolectomy (any colonic transection with the distal resection margin proximal to the splenic flexure).

All patients undergoing right colectomy are eligible, including those who do not have an anastomosis and are defunctioned by a proximal stoma.

Procedures for any pathology, via any operative approach (open, laparoscopic, robotic or converted) are eligible.

Elective (surgery on a planned admission), expedited (within 48 hours), and emergency (surgery on an unplanned admission) procedures are eligible.

Patient exclusion criteria

Patients undergoing more than one gastrointestinal anastomosis during the same operation.

In Crohn's disease, additional upstream strictureoplasty or resection/anastomosis to treat disease or strictures at the same operation.

Simultaneous right colectomy and hyperthermic intraperitoneal chemotherapy (HIPEC) and/or cytoreductive surgery.

Each individual patient should only be included in EAGLE once. Following the index procedure that is included in EAGLE 2, patients undergoing additional procedures within the study window should not be included for a second time.

Patient identification

Each participating country and hospital will decide how best to identify eligible patients.

Patients can be identified either before, during, or after surgery. As guidance, it is anticipated that patients may be identified from any of the following settings, but that this should preferentially be performed pre-operatively:

- Pre-operatively: surgical outpatient clinics (e.g. when the patient is being booked for elective surgery); planned theatre lists (e.g. at the time of admission for surgery); emergency surgical admissions (e.g. at the time that a decision to operate is made)
- Intra-operatively: by the operating surgical teams during the in-theatre Safe-anastomosis checklist, once the procedure eligibility has been confirmed.
- Post-operatively but before discharge: by either the operating surgeon or by review from the research team.

Patients will be identified by a suitable healthcare stuff who may include:

- The senior operating surgeon
- Any doctor involved in the patients' care (e.g. surgeon in training)
- Research nurse
- Research secretary

Patient Consent

This is a quality control audit. We anticipate therefore that most ethics review boards will waive the requirement for patient consent, as only pseudoanonymised audit data will be collected. However, there may be variation in international regulations and it will be the responsibility of the local project lead to seek local research ethics committee advice in each participating country to determine whether informed consent should be sought.

DATA COLLECTION

The audit is designed so that normal patient follow-up pathways can be utilised to obtain outcomes' data. No additional visits or changes to normal follow-up should be made. However, local investigators should be proactive in identifying post-operative events (or lack thereof), within the limits of the follow-up period (30 post-operative day). These may include reviewing the patient notes (paper and electronic) during admission and before discharge to register in-hospital complications, reviewing hospital systems to check for re-attendances or re-admissions, and reviewing post-operative radiology reports, as well as the notes from the in-person outpatient review which we anticipate will occur within the 30 days post-operation in most circumstances.

Data completion and organisation

As EAGLE 2 is an audit, no changes to the normal patient pathway need to be instigated for it to be run.

Data Management

Information will be collected at the following times:

- Short-term follow-up: At baseline (surgeon level)
- At 30 days after the operation (surgeon level). The day of operation will be considered day zero

Data will be entered directly onto the secure electronic REDCap database by study collaborators at the participating hospital sites using pseudonymised data.

Site study collaborators will be provided with a paper copy of the eCRF to facilitate data collection. If this is used, they should then transfer data from the paper CRF into the online database (https://www.bistc.redcap.bham.ac.uk). Data management staff will check all incoming data CRFs for completeness, data consistency and compliance with the protocol. If discrepancies or missing data are identified, the data management staff will raise queries with the research team at the participating hospital via the study database.

Source Data

Source data within the EAGLE 2 audit will be kept as part of the participants' medical notes generated and maintained at site. As all data collected and analysed within the EAGLE 2 audit are routinely collected, source data will only be within the medical notes.

Data handling and record keeping

The security of the Study Database System is governed by the policies of the University of Birmingham. The study database will be hosted on the REDCap system managed and maintained by BiCOPS.

Data management and data security within BiCOPS will abide by the requirements of the General Data Protection Regulations (GDPR) and any subsequent amendments. The audit will be conducted at collaborating sites in accordance with the country-specific data protection requirements.

Access to data will be restricted by usernames and passwords, at participating sites. Each participant will be allocated a unique study number at entry. All communication will use this as the identifier. All data will be analysed and reported in summary format. No individual patient will be identifiable.

Confidentiality and data protection

Any correspondence between the EAGLE 2 study office and hospital sites will use the anonymous ID code only.

The linkage between the study ID code and participants will be maintained in strict confidence at participating sites. This data will not be submitted to the EAGLE 2 study office and will not be sent outside of the participating site.

Confidentiality of all participant's data will be maintained and there will be no disclosure of information by which participants may be identified to any third party other than those directly involved in the treatment of the participant.

Data is owned by the ESCP and can be used for future research without renewed permissions from the participants centres. However, any publication based on the collected data will include the collaborating participants as co-authors (see below please).

Access to final dataset

The ESCP Cohort Studies Working Group welcomes the use of the data for further research that benefits patients. Requests can be submitted to the ESCP Cohort Studies Working Group. Data Sharing is subject to ESCP approval and the appropriate safeguarding as determined by the ESCP. Any future subprojects should also comply with our policy of a single corporate authorship e.g. "European Society of Coloproctology (ESCP) collaborating group. However, authors'

contributions will be highlighted in accordance with the recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals (commonly referred to as the Vancouver Convention) by the International Committee of Medical Journal Editors (ICMJE).

Timeline and schedule of events

		Baseline data	After Surgery	30-day follow-up
Clinician reported audit - all patients	Patient information	✓		
	Surgery information		✓	
	Short-term Complications / reinterventions			✓

Training platform

The training platform for the audit is the ESCP Safe-anastomosis Online Educational Module. This is an Electronic Learning Management System which houses a five-modular educational platform, freely accessible at https://eagle-escp.eu.com/. The modules are:

1. **Decision making**, including a pre-operative risk stratification tool for anastomotic leak
2. **ESCP Safe-anastomosis checklist**, including components and implementation within a theatre team
3. **Preparing for anastomosis**, including anastomotic healing bowel preparation, choice of stapled versus handsewn anastomoses
4. **Stapled anastomosis**, including harmonising technique and checking for technical failure.
5. **Handsewn anastomosis**, including harmonising technique, common variations and checking for technical failure.

It is intended that this educational module should be completed by any providers of colorectal surgical procedures (including consultant/attending surgeons, trainee/resident surgeons, and surgical care practitioners/allied healthcare professionals in surgery) prior to participation in the audit.

Validation of learning platform

The training program has been reviewed by the ESCP Education Committee and revised. It has also been reviewed by the independent Study Steering Committee. More than 2500 surgeons completed the online training during delivery of the EAGLE 1 study.

Data collection and follow-up

Data will be collected in two phases. During the index admission pre-operative and intra-operative data will be collected. Local Principal Investigators will establish pathways in their hospitals to ensure robust data collection; for example, pre-operative data could be collected on the morning prior to surgery, with intra-operative data fields completed in theatre immediately following completion of the procedure. Alternatively, all data could be collected in theatre, or in the post-operative ward.

All patients, including those who did not have a primary anastomosis, will be followed-up to a maximum of 30-days post-operatively (with Day 0 being the day of surgery) by a review of their inpatient health records, routine clinic visit letters, and reports for post-operative radiological investigations arranged as part of normal patient care. There will be no additional patient contact (telephone or in-person) beyond what is normal clinical practice at each centre. The study is designed efficiently so that existing patient follow-up pathways and health records can be used, with only data that is routinely collected as part of normal clinical care being captured.

Most anastomotic leaks following ileocolic anastomosis occur in the early post-operative period (days 4-14). Although a small number of anastomotic leaks occur beyond day 30, limiting follow-up to 30 days will ensure that the vast majority of leaks are captured.

Statistical analysis plan

This will be conducted on an intention-to-treat basis i.e. all patients recorded in the database during the scheduled 2-month recruitment periods will be included, and those in the second period will be considered exposed to the intervention regardless of whether learning from the intervention was actually implemented. The primary outcome will be 30-day anastomotic leak rate. In the primary analysis, 30-day leak rate will be modelled using mixed effects logistic regression with random cluster (hospital) effects allowing inclusion of baseline risk factors such as co-morbid disease and ASA score and adjustment for a fixed time effect between time periods.

Sample size

Based on feasibility (below), we assume that if each hospital provides data on 10 patients over a 2-month recruitment period (5 per hospital per month) then adequate sample size will be obtained to allow statistical analysis (see below please).

Projected recruitment

Data for 3,208 right colectomies was submitted by 284 centres over a 2 month period to the 2015 ESCP Right Hemicolectomy Audit; an average of 11.3 patients per 2 months. 81% the sites recruited >10 patients over the 2-month period. A mean of 10 patients per centre is required for each 2 month recruitment period.

Patients per centre (2 months)	**Proportion of centres**
1-5	19% (n=53)
6-10	37% (n=104)
11-15	22% (n=63)
16-20	14% (n=39)
21-30	6% (n=17)
31+	3% (n=8)

Planned additional analyses

Pre-planned exploratory sub-group analyses of the primary outcome will be performed in the following groups:

- *At cluster (hospital) level:*
- Number of beds (<500 versus ≥500 total hospital beds).
- Right colectomy volume (<10 patients versus ≥10 patients per 2 month period).
- Early adoption (early versus late study entrants).
- Health service expenditure per capita in purchasing parity (top versus middle versus bottom tertile).
- Proportion of operating surgeons in each centre completing the online training modules prior to 'post-implementation' data collection (high [≥80%], intermediate [50-79%], low [<50%]).
- World Bank income group (high versus middle/low-income country).

At patient level:

- Indication for surgery (malignant versus benign, e.g. inflammatory bowel disease).
- Procedure urgency (elective versus expedited/ emergency).
- Age (≤65 years versus >65 years).
- Operative approach (open versus laparoscopic/ robotic).
- Anastomotic technique (stapled versus handsewn anastomosis).
- Primary operating surgeon experience as reported (trainee versus consultant).
- Primary operating surgeon specialism as reported (general versus colorectal surgeon).
- Reverse analysis will also be undertaken to explore what are the characteristics of hospitals with a big change versus no change, and do these differ in respect of cluster characteristics.

STUDY ORGANISATIONAL STRUCTURE

EAGLE 2 Audit Office

The coordinating centre for EAGLE 2 is based at the University of Birmingham in the Birmingham Centre for Observational and Prospective Studies (BiCOPS). Members of this group also represent the European Society of Coloproctology (ESCP) and sit on both the research committee and cohort studies committee of ESCP.

Local teams

We envisage that most hospitals opening for the audit will identify a team of up to 5 members, which may include surgical colleagues, trainee doctors, nurses, medical students, or others involved in the routine clinical care of eligible patients, depending on local circumstances. Members of this group will be responsible for the local conduct of the audit at their site, including helping to identify potential patients and record data onto the EAGLE 2 REDCap database.

Publication policy

The output from this research will be published under a single corporate authorship group: "European Society of Coloproctology (ESCP) collaborating group".

Each participating hospital may include up to five collaborators for publication(s) regarding the audit study on the condition that data is entered with at least 95% data completeness. An increase in the number of collaborators at a participating hospital is theoretically possible but should be regarded as highly exceptional and prospectively agreed on a case-by-case basis with the EAGLE 2 Study Office. All co-authors will be PubMed searchable and citable.

No hospital-level or surgeon-level data will be published whereby an individual unit or surgeon could be identified. If local investigators would like a breakdown of their own unit's data for benchmarking purposes and local presentation/discussion, this will be available after the end of the study.

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APPENDIX 1. EAGLE 2 Case Report Form

Local Patient Identifier	*not uploaded to REDCap*	**Unique REDCap Identifier**	
Pre-operative data			
Age (on day of operation)		Years	
Sex		Male / Female	
American Society of Anaesthesiologists (ASA) grade		1 / 2 / 3/ 4/ 5	
Previous abdominal surgery		No / Yes	
History of ischemic heart disease or cerebrovascular disease		No / Yes	
History of diabetes mellitus		No / Yes	
Body Mass Index >30		No / Yes	
Oral anti-coagulants		No / Yes	
Pre-operative total protein level (g/dL) *– nearest 0.5 units*			
Pre-operative haemoglobin (g/dL)			
Procedure indication		Malignancy / Inflammatory bowel disease / Other	
Intra-operative data			
Bowel preparation		None / Mechanical bowel preparation only / Mechanical bowel preparation with oral antibiotics	
Primary operating surgeon		Consultant colorectal surgeon / Trainee colorectal surgeon / Consultant general surgeon / Trainee general surgeon	
Most senior surgeon in theatre		Consultant colorectal surgeon / Trainee colorectal surgeon / Consultant general surgeon / Trainee general surgeon	
Procedure urgency		Elective (planned) / Expedited (within two weeks of decision to operate) / Emergency (unplanned)	
Operative approach		Open, Laparoscopic (completion, conversion to open), Robotic (completion, conversion to open)	
Operative field contamination		Clean-contaminated / Contaminated / Dirty	
Anastomosis formed		Stapled / Handsewn / No anastomosis (end ileostomy formation)	
If yes: Anastomotic configuration		Side-to-side / end-to-side / end-to-end	
If yes: Is there a defunctioning loop ileostomy		No / Yes	

*If yes: W*as the anastomosis tested?	No / Yes -air leak test / Yes - probed with forceps
If yes: Did the anastomosis require revision?	No / Yes
Intra-operative complications	Blood loss >1L / Operating time >4h / Solid organ or ureteric injury / Vascular injury / Blood transfusion / Hemodynamic instability / Vasopressor requirement (select all that apply)
Duration of surgery (minutes) *knife-to-skin to completion of skin closure*	1-60 / 61-119/ 120-179/ 180-239/ ≥240
Was an ESCP Safe-anastomosis Checklist completed?	Yes / No
Was anastomotic leak risk calculated **pre-operatively**?	Yes / No
Was anastomotic leak risk calculated **intra-operatively**?	Yes / No
Has the senior surgeon completed the Safe-anastomosis module?	Yes / No
Post-operative data	
Post-operative critical care admission	None / Planned from theatre / Unplanned from theatre / Unplanned from ward
Total length of hospital stay	Days (up to 30 post-operative days)
Anastomotic leak or intra-abdominal/pelvic collection	None / Grade A – requiring no further intervention, radiologically diagnosed / Grade B – requiring radiological reintervention / Grade C – requiring surgical reintervention
If yes: How was the leak diagnosed?	Clinical diagnosis only/ Ultrasound imaging/ CT imaging/ MR imagining/ Intra-operative diagnosis
Re-operation within 30 days	No / Yes
Re-admission within 30 days	No / Yes
Mortality within 30 days	No / Yes