ESCP Pan-European snapshot audit

Left colon, sigmoid and rectal resections

Study period: 1 February – 25th May 2017

Protocol version 1.2 (22nd Dec 2016)

Key dates:	
22 December 2016	**Protocol published**
1 February 2017 **to 28 February 2017**	**Patient inclusion window starts** ***Sites should start collecting at least 8 weeks of consecutive patients within this window. Sites should follow up each patient for 30 days.***
25 April 2017	**Last day of operation to include in data collection**
25 May 2017	**Last day of patient follow up (8 weeks from patients operated on 25 April 2017).**
30 June 2017	**REDCap database locked** ***This is the deadline for data submission***
22 September 2017	**Preliminary data at ESCP 2017 Berlin**

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ABSTRACT

Background: Left hemicolectomy, sigmoid, and rectal resection are commonly performed colorectal resections. Variability exists in the techniques utilised to undertake these operations, as well as at patient, surgeon and unit level. This high quality pan-European prospective audit will establish current practices and correlate them against outcomes.

Aim: To explore differences in patients, techniques and outcomes across the international cohort to identify areas of practice variability resulting in apparent differences in outcome warranting further study.

Endpoints: A three-stage data collection strategy collecting patient demographics, operative details and outcome markers. Several outcomes measures will be used including mortality, surgical morbidity (including anastomotic leak) and length of hospital stay.

Primary research question: Does anastomotic technique impact upon post-operative outcomes?

Methods: This two-month prospective audit will be performed across Europe in early 2017, and co-ordinated by the European Society of Coloproctology. This will be preceded by a one-week, five centre pilot. Sites will be asked to pre-register for the audit and obtain appropriate regional or national approvals. The ESCP cohort studies sub-committee shall assist sites to register where possible. During the study period all eligible operations will be recorded contemporaneously and followed-up through to 30 days. The audit will be performed using a standardised pre-determined protocol and a secure online database. In the first ESCP conducted audit in 2015, 38 countries registered 3208 patients undergoing right hemi-colectomy, while in the second audit 2441 patients undergoing stoma closure were recruited from 48 countries. It is expected that equivalent numbers will be obtained in this audit. The report of this audit will be prepared in accordance with guidelines set by the STROBE (strengthening the reporting of observational studies in epidemiology) statement for observational studies.

Discussion: This multicentre, pan-European audit will be delivered by colorectal surgeons and trainees in an organised and homogenous manner. The data obtained about areas of variability in provision or practice, and how this may impact upon outcomes, will serve to improve overall patient care as well as being hypothesis generating and inform areas needing future prospective study.

1 - Introduction

Multicentre, snapshot cohort studies or audits have the ability to gather large patient numbers in short time periods from many hospitals. They allow exploration of differences in patients, techniques and management across the cohort to identify areas of practice variability that may result in apparent differences in outcome. As such, whilst not providing true evidence of efficacy or the impact of a particular variable, they can be hypothesis-generating and can identify areas warranting further study in future randomised controlled trials.

The European Society of Coloproctology has recognised the strengths of this form of research, as well as its power in bringing together surgeons and colorectal units across multiple regions or countries for a common research goal, thus strengthening an active network of research participation across Europe.

The first pan-European snapshot audit promoted by the ESCP focused on right hemicolectomy and ileocecal resection surgery succeeded in recruiting 3208 patients from 38 countries, five of them were outside Europe. This success continued with the second audit on stoma closure, which recruited 2527 patients from 312 centres in 48 countries.

Scope

Left colon, sigmoid and rectal resections are frequent colorectal operations performed in almost all hospitals where gastrointestinal surgery are performed. We anticipate that any hospital undertaking general surgery will undertake these procedures on a routine basis.

Despite the frequency of the operation, there remains uncertainty about the optimal method of undertaking it, which results in a range of methods currently utilised to access, mobilise and anastomose the bowel. In addition, patient demographics and disease characteristics vary between units and countries, as do unit policies and throughput levels.

Examples of the areas of variability that this snapshot audit will provide contemporaneous international data upon:

- Method of access (laparoscopic/open/conversions) versus outcome

- Method of anastomosis (handsewn/stapled) versus outcome

- Method of stapling technique versus outcome

- Patient factors versus outcome

- Hospital and surgeon factors versus outcome

- Inflammatory bowel diseases (IBD): factors and perioperative interventions versus outcome.

2 - Methods

A) Summary

Pan-European, prospective audit of consecutive patients undergoing any left hemicolectomy, sigmoid and rectal resections over a minimum 2-month period. The audit shall include operations from 1 Feb 2017 to 25 Apr 2017. The sites must include operations for at least 8 consecutive weeks. In order to meet this minimum 8 weeks criterion, sites must start enrolling operations by 28 February 2017.

Commencement timeframe: The sites will start within a time window from 1 February to 28 February 2017. Following commencement, the sites will be required to include patients for at least 8 consecutive weeks.

Final date for operation inclusion: The sites can include operations that occur up to 25 April 2017.

All patients will be followed for 30 days post-operation. Data collection should therefore be completed by 25 May 2017.

As this is an audit, no change to normal patient management is required.

B) Primary Objective

To explore differences in patients, techniques and outcomes across the entire cohort to identify areas of practice variability resulting in apparent differences in outcome warranting further study.

Examples of the postoperative outcomes that the study will examine are:

- Complications (type, grade and rate) within 30 postoperative days
- Length of postoperative stay in the hospital
- Re-admission within 30 postoperative days
- Histopathological results

C) Primary Research Question (should this be required for local approvals process)

Does anastomotic technique impact upon post-operative outcomes?

D) Inclusion Criteria

1. Left hemicolectomy, sigmoid and rectal resections
2. Any approach (open, laparoscopic or robot assisted)
3. Benign and malignant indications
4. Resection without anastomosis
5. Emergency, expedited and elective setting
6. Abdomino-perianal resection (APR)

E) Exclusion Criteria

1. Colostomy reversal/take down
2. More than one anastomosis
3. Total, subtotal and panproctocolectomies
4. Proximal resection above the hepatic flexure
5. Patients with Crohn's disease who undergo upstream stricturoplasty at the same time of left colon resection.
6. Pelvic exenteration

F) Methods for identifying patients

Multiple methods may be used according to local circumstances/staffing:

1. At the pre-operative assessment clinic (for elective operations)
2. Daily review of elective theatre lists
3. Daily review of team handover sheets / emergency admission lists / ward lists
4. Review of theatre logbooks

G) Centre eligibility

All hospitals/units performing gastrointestinal surgery are eligible to join this audit. No unit size or case throughput stipulations are made. Countries outside Europe can also participate in this audit.

All participating centres will be required to register their details with the ESCP cohort study office and will be responsible for their own local approvals process prior to the start of the data collection period.

Centres should ensure that they have appropriate pathways and manpower to include all consecutive eligible patients during the study period and provide >95% completeness of data entry before locking of RedCap database on the 30 June 2017.

H) Patient follow-up

The audit is designed so 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 normal follow-up. These may include reviewing the patient notes (paper and electronic) during admission and before discharge to note 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 between 4 and 6 weeks post-operation in most circumstances.

I) Data completion and organisation

CRFs are shown in section 4.

This research takes the form of an audit study and no changes to the normal patient pathway need to be instigated for it to be run. Case report forms (CRFs) have been designed to reflect the normal practice and be completed with minimal extra work from the clinical team. We envisage that most hospitals opening for the study will identify a team of 4-5 members, including one or more Consultant-level members (which most centres require to be the official local 'lead' of the study), and trainee surgeons, junior doctors or data administrators who will undertake the organisational and logistical roles as well as co-ordinate data entry.

CRF A (patient demographics) and CRF C (follow-up information) can be completed by any suitably qualified member of the local team.

We do stipulate the CRF B (operative details) must be completed by, or in direct conjunction with, a surgeon who was present during the operation itself. It should ideally be completed immediately after surgery, at the same time as the operation notes are written, to ensure data accuracy and completeness.

J) Missing data and retrospective patient entry

The online database has been designed to allow sites to securely access an individual patient's data for all CRFs throughout the study period. This means that any missing or erroneous data can be altered by the local investigators whilst the data collection

period is ongoing. In order to maximise data completion and emphasise its importance to collaborators, participating centres with >5% missing data in **mandatory fields** (ie less than 95% data completeness) will be excluded from the study.

The study design means that sites may retrospectively identify eligible patients that were missed primarily and for whom contemporaneous patient and operation data was not entered. We are happy for these patients to be entered during the study period providing that CRF B (operative details) is completed by, or in direct conjunction with, a surgeon who was present during the operation itself.

K) Data collection system and information governance

Data will be recorded contemporaneously on a dedicated, secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. No patient identifiable data (name, date of birth, address, etc) will be recorded on REDCap.

Registered local investigators will have individual password-protected access to their unit's data entered on to REDCap. During the running of the audit, only local data will be visible to investigators; other sites' data will not be accessible.

In order to facilitate entry of follow-up data, investigators will need a way to link REDCap records to patient records. This can be achieved by keeping a password protected spreadsheet containing a look-up table. This should cross-reference the automatically generated REDCap ID number for each patient against their local identifier number.

The University of Birmingham (UK) Clinical Trials Unit will design, host and support the online tool. This system was used in the 2016 ESCP audit on stoma closure. Many hospitals already use these data collection tools to measure clinical practice and drive improvements in healthcare in multiple disease settings.

Data will be stored securely on encrypted and certified servers for a minimum of five years under the governorship of the European Society of Coloproctology (ESCP). The data may be used for future research although it should be noted that the anonymised nature of the database means individual patients will not be reverse-identifiable in the future.

L) Local approvals

All data collected will measure current practice, with no changes made to normal treatment. As such, this study should be registered as an audit of current practice at each participating centre. It is the responsibility of the local team at each site to ensure

that local audit approval (or equivalent) is completed for their centre. Participating centres will be asked to confirm that they have gained formal approval at their site.

M) Authorship

A maximum of 5 investigators from each individual site will be included as formal co-investigators in this research, and will be Pubmed searchable and citable. The output from this research will be published under a single corporate authorship – e.g "Pan-European Cohort Studies Group" or similar.

An identical process of multicentre audit and publication/authorship has been used recently in the publication of main study from the first audit: "**The relationship between method of anastomosis and anastomotic failure: an international snapshot audit**" – submitted to Colorectal Disease journal in 2016.

N) Pilot

A one-week pilot across five hospitals across Europe will be performed to test the data collection tool. Adjustments based on these experiences may be made before rolling out the main audit.

O) Publication of data

Data will be published as a pool from all participating units. Subgroup analyses by disease, technique or outcome variables may be presented, but 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 provided upon request.

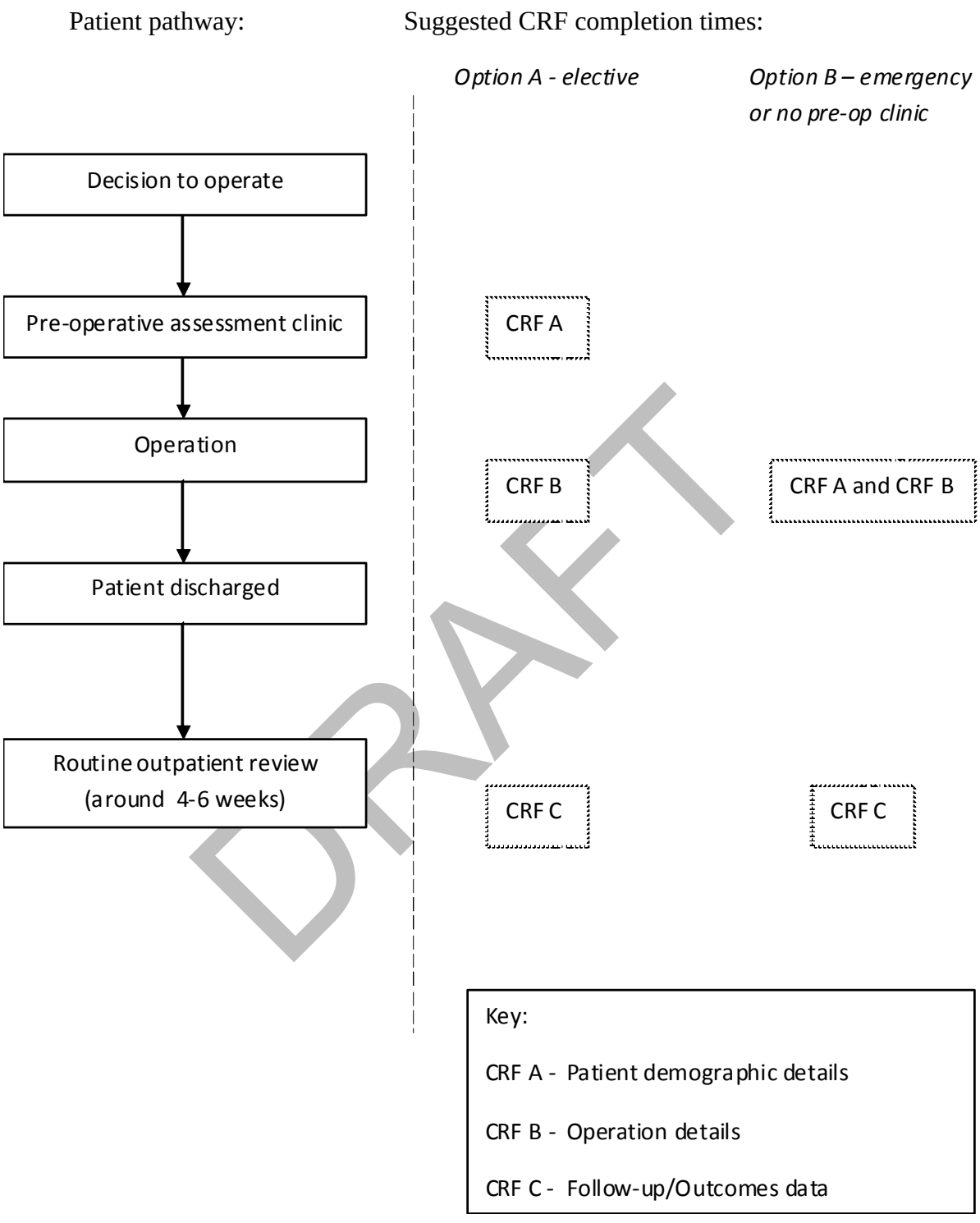
P) Data governance

The ESCP Cohort Studies Committee welcomes the use of the data for further research that benefits patients. Requests can be submitted to the ESCP Cohort Studies Committee. 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. "Pan-European Cohort Studies Group" or similar. 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).

Q) Financial arrangements

This study is supported by the European Society of Coloproctology. Participating centres will not bear any costs. Similarly, no financial reimbursement will be made to units or investigators for their involvement in the project.

3) Study flowsheet showing patient pathway and CRF completion times



4) Case Report Forms (CRFs)

CASE REPORT FORM 1 – *patient demographics*

	REDCap ID	
1	Age	(Patient age on day of operation)
2	Gender	Male Female
3	History of ischaemic heart diseases	Yes No
4	Diabetes Mellitus	Yes No
5	Smoking	Never Ex-smoker Current smoker
6	BMI	Weight kg Height m
7	ASA score I-V	
8	Urgency of surgery (National Confidential Enquiry into Patient Outcome and Death)	Elective (planned) Expedited (within one week) Emergency (within 24 hours)
9	Pre-operative bowel preparation	No bowel preparation Mechanical bowel preparation only Mechanical bowel preparation with oral antibiotics Mechanical bowel preparation with intravenous antibiotics Single dose More than single dose
10	Indication	Malignancy (drop menu: in case of malignancy) IBD (drop menu: in case of IBD) Crohn's disease Ulcerative Colitis Non-IBD colitis (Ischaemic, collagen colitis…etc)
		Diverticulosis coli
		Trauma (drop menu) • Blunt • Penetrating • Post-endoscopic perforation (days)
		Other indication (details)
11	Preoperative albumin (g/dl or mmol/l)	
12	Preoperative Haemoglobin level (g/dl or mmol/l)	

In case of IBD: please fill the following

A	Preoperative medication (4 weeks before surgery)	Name (generic and trade name)	Dose
	Systemic Steroids		
	5- ASA		
	Immuno-modulators		
	Biological agents		
B	Preoperative Antibiotics	No Single preoperative dose Treatment course (days)	
C	Steroid stress dose	Yes No	
D	Preoperative sepsis	Preoperative intraabdominal abscess	Yes No
		US or CT guided percutaneous drainage	Yes No
		Interval from abscess drainage to operation	Weeks
		Preoperative enteric fistula	Yes No
E	Preoperative nutritional support	Oral supplement Enteral nutrition (NG tube, PEG) Parenteral nutrition	

In case of malignancy

Location of cancer	Splenic flexure Left colon Sigmoid colon High rectum (10-15cm) Middle rectum (5-10cm) Low rectum (0-5cm)
Pre-operative staging of cancer	Clinical CT MRI Other
Neoadjuvant therapy (rectum only)	None Short course radiotherapy Long-course chemoradiotherapy Chemotherapy only
If yes to option above (i.e. not NONE): pre-treatment staging	T1, T2, T3, T4 N0, N1, N2 M0, M1 MRI detected EMVI +/- (extramural venous invasion=tumour invasion of blood vessels outside of rectal wall) CRM threatened (yes/no)

CASE REPORT FORM 2 – *operative details*

	REDCap ID	
1	Date of Operation (dd.mm.yyyy)	
2	Resection sites	Figure
3	Operations duration	Minutes:
4	Surgeon in charge	Colorectal surgeon Colorectal trainee General surgeon Trainee
5	Operations type	Laparoscopic Laparoscopic converted to open Open Robot assisted Ta-TME
6a	Anastomosis type	Hand-sewn Stapled No anastomosis Hartmann type operation (rectal stump left) Inter-sphincteric APER Standard APER Extra-levator APER
6b	Anastomosis details	Hand-sewn: Continuous Interrupted Single layer Two layers Full thickness Sero-muscular Suture material: Suture gauge: Stapled: Intra-corporal anastomose Extra-corporal anastomose Primary device Apical device Stapling device size (28,29,30…etc) Over sewing Continuous Interrupted
6c	Anastomosis configuration	Side to Side Side-to-end End-to-end
7	De-functioning stoma	De-functioning stoma Loop ileo-stomy End ileostomy Loop Colostomy End Colostomy
8	Skin closure	Suturing Stapling
9	Intra-operative complications	Bleeding : ml Ureter lesion Duodenal lesion

		Renal lesion Liver lesion Gallbladder lesion Vascular lesion Revision of anastomose
10	Peri-operative perforation	No Yes If yes Tumour bearing segment Not tumour bearing segment Diverticular perforation
11	Anastomoses distance from anus	Measured with -Rectoscope -Sigmoidioscope -Per rectal examination

For IBD operations:

Intra-abdominal abscess	Yes No
Enteric fistula	Small bowel- small bowel Small bowel to colon Small bowel to urinary bladder Small bowel to skin Colon-colon Other
Bowel obstruction (defined as narrowing with proximal dilatation)	Yes No
CT verified colitis	Yes No
Pouch procedure at time of resection	Yes No Type of pouch (J, N..etc)

CASE REPORT FORM 3 – *follow-up data*

	Hospitals ID	
1	Postoperative admission to intensive care unit	Planned from operation's theatre Unplanned, from operation's theatre Unplanned, from the ward No admission to ICU
2	Length of postoperative stay	Days
3	Grade of postoperative complications (Clavien-Dindo)	Date: Grade I Grade II Grade III IIIa intervention without GA IIIb intervention under GA Grade IV IVa single organ failure IVb Multi organ failure Grade V Details
4	Anastomotic leak	Grad A: No intervention Grad B: US or CT guided intervention Grad C: Surgical intervention
5	Intraabdominal or pelvic collection	Yes No
6	Peak CRP level on 3rd postoperative day	Mg/L
7	30 day re-operation	Yes No
8	30 day re-admission	Yes No Details
9	Surgical site infection	Yes No
10	Histo-pathological findings (malignancy)	Number of harvested lymph nodes Number of lymph nodes with metastases Distance to closest resection margin (mm) TNM (8 edition) staging: T0, T1, T2, T3, T4 N0, N1, N2 M0, M1 If T0, N0, M0 = confirm complete pathological response (yes/no) MRI detected EMVI +/- Grade (good, moderate, poor, anaplastic differentiation) Cellular type: adenocarcinoma, mucinous, signet, other

5) Unit questionnaire – to be completed at site registration stage

Provision of surgical services	
Is your centre a:	University hospital/ tertiary centre; District general hospital;
How many consultant-level surgeons perform colorectal resection operations at your site?	(number)
How many consultant-level specialist colorectal surgeons are at your site	(number)
How many general surgical beds are in your hospital?	(number)
How many high dependency (HDU) and intensive care (ITU) beds are in your hospital?	(number)