ESCP Pan-European snapshot audit

Right Hemicolectomy / Ileo-caecal resection

January - April 2015

ESCP Cohort Study Steering Committee

Thomas Pinkney (UK)	thomas.pinkney@uhb.nhs.uk
Aneel Bhangu* (UK)	aneelbhangu@doctors.org.uk
Nick Battersby* (UK)	nickbattersby@nhs.net
Sanjay Chaudhri (UK)	schaudhri@nhs.net
Aala El-Hussuna (Denmark)	alaanewemail@gmail.com
Matteo Frasson (Spain)	frasson.matteo@libero.it
Baljit Singh (UK)	bs143@leicester.ac.uk
Sandra Vennix* (Netherlands)	s.vennix@amc.uva.nl
Oded Zmora (Israel)	Oded.Zmora@sheba.health.gov.il

** denotes trainee-level member*

ABSTRACT

Background: Right hemicolectomy and ileo-caecal resection are two of the most commonly performed colorectal resections, with an estimated combined 83,000 undertaken across Europe each year. 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 from a non-trial setting will establish current practices, outcomes and complication rates.

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-phase data collection strategy collecting patient demographics, operative details and outcome markers. Several outcomes measures will be used including mortality, morbidity (including anastomotic leak) and length of 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 2015, and co-ordinated by the European Society of Coloproctology and S-ECCO. This will be preceded by a one-week, five centre/country pilot. Sites will be asked to pre-register for the audit and obtain appropriate regional or national approvals, facilitated by the ESCP cohort studies committee and regional reps. 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. Participation levels are difficult to predict but if 8% of all operations across Europe are obtained over 1000 individual operations will be recorded during the study period. The report of this audit will be prepared in accordance to 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 units across multiple regions or countries for a common research goal, thus strengthening an active network of research participation across Europe.

Scope

This first pan-European snapshot audit is of right hemicolectomy and ileo-caecal resection surgery. These operations are the most frequent colorectal resections performed, with more than 83,000 estimated to be performed across Europe every year (see section 5). 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

- Crohn's disease factors and perioperative interventions versus outcome

2 - Methods

A) Summary

Pan-European, prospective audit of consecutive patients undergoing any right hemicolectomy or ileo-caecal resection over a 2 month period January 15th 2015 – March 15th 2015. All patients will be followed for 30 days post-operation. Data collection should therefore be completed by April 15th 2015. 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.

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

Does anastomotic technique impact upon post-operative outcomes?

D) Inclusion Criteria

- All adult patients undergoing right hemicolectomy or ileocaecal resection at a participating hospital during the study period
- All operations of this type are included, for any pathology, via any operative approach and in both the elective and emergency settings
- Patients not undergoing primary anastomosis, or who are given a temporary defunctioning loop ileostomy are eligible
- Patients undergoing extended right hemicolectomy are eligible, defined as any distal colonic transaction proximal to the splenic flexure

E) Exclusion Criteria

- Right hemicolectomy or ileocaecal resection as part of a bigger procedure like subtotal colectomy or panproctocolectomy
- If the distal colonic transaction point is beyond the splenic flexure the patient is not eligible
- In Crohn's disease, patients will be excluded if they have an additional upstream strictureoplasty or resection/anastomosis to treat disease or strictures at the same operation

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 within the member countries of the European Society of Coloproctology (ESCP) are eligible to join this audit. No unit size or case throughput stipulations are made.

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. Regional or National ethics approval for all large countries will be obtained by the ESCP sub-committee members and/or country representatives to facilitate this process.

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.

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.

An online training module for Clavien-Dindo complication proficiency will be required.

I) Study flowsheet

Please see section 3.

J) Data completion and organisation

Draft 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. Clinical reporting forms (CRFs) have been designed to marry-up with normal practice and be completed contemporaneously 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.

K) 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 fields (ie less than 95% data completeness) will be excluded from the study. The online system will be able to send regular reminders to investigators about missing data to try and minimise the chances of this happening.

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.

L) Data collection system and information governance

Data will be recorded contemporaneously and collated on a dedicated, secure, web-based platform. This will be password protected, and no personal data that can identify the individual patient (name, social security number, date of birth, address…etc) will be recorded. Registered local investigators will have individual password-protected access to all of their unit's data entered during the audit and the follow-up phase. During this 3 month period, units will use a local identification number (of their own choice) to identify each individual patient and allow re-accessing of an individual's records to update on progress, complications etc, whilst also preventing duplication of patient entry to the audit. This local identifier will be automatically permanently removed from the database prior to data lock and centralisation of data. As such it will not be visible to the central investigator/analysis teams. During the running of the audit, only local data will be visible to investigators, and other sites' data will be compartmentalised elsewhere.

We are using a dedicated online company (www.netsolving.com) to design, host and support the online tool. This company has extensive experience in this area and is currently the leading supplier of clinical audit data collection solutions for the National Health Service (NHS) in the United Kingdom. They have run major national and international audits for Royal Colleges and the NHS Healthcare Quality Improvement Practice (HQIP). Nearly all hospitals across the NHS currently 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.

M) 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 ay 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.

N) 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 - eg “Pan-European Colorectal Surgery Audit Group” or similar.

An identical process of multicentre audit and publication/authorship has recently been used (by members of our group) on the recent publication: “Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy” – published British Journal of Surgery 2013. The authorship model can be seen on its pubmed entry: http://www.ncbi.nlm.nih.gov/pubmed/23842836

O) Pilot phase

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

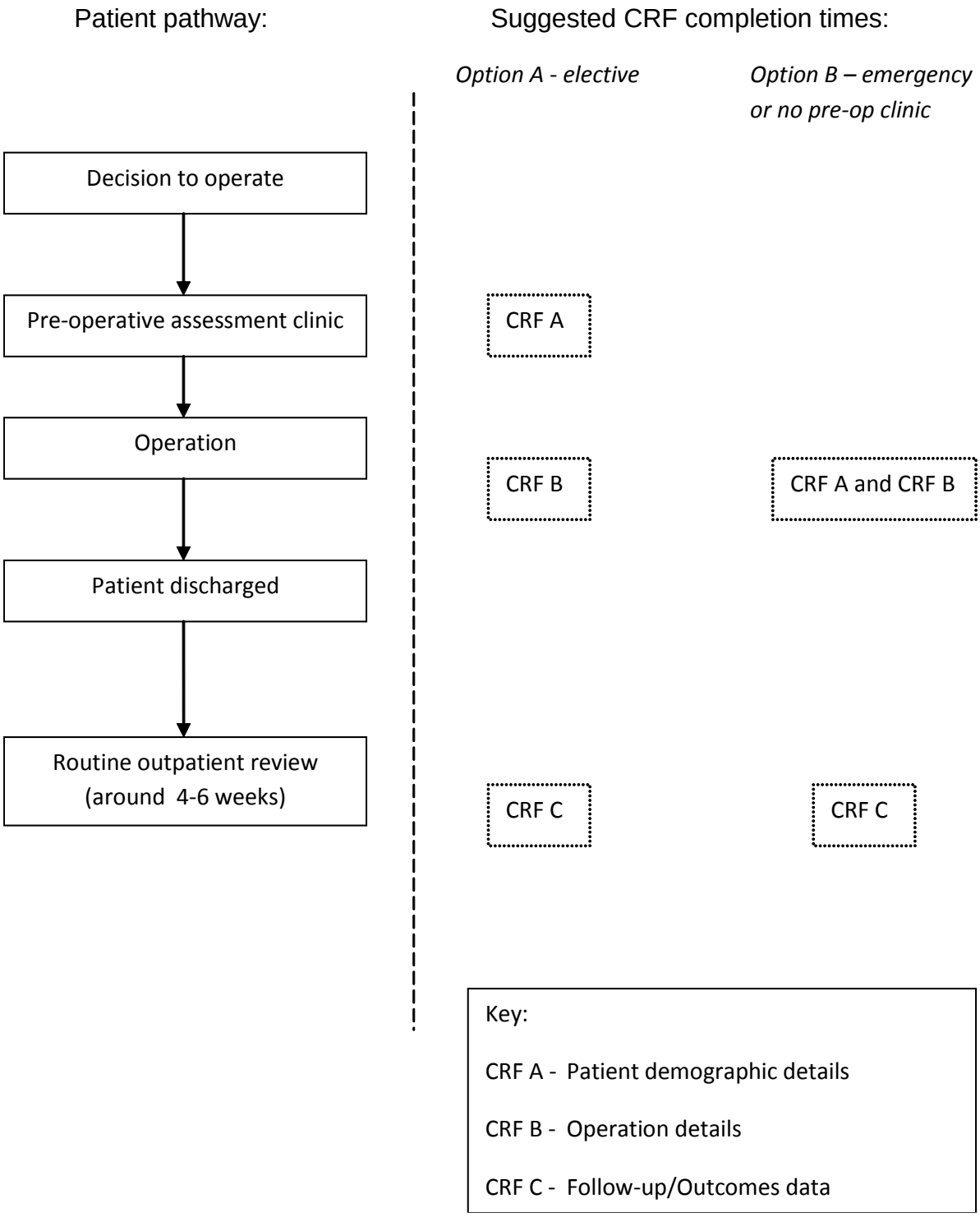
P) Publication of data

The primary aim of this project is 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. As such, the majority of data will be published as a collated 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.

Q) Financial arrangements

This study is supported by the European Society of Coloproctology, who have paid the necessary costs to design and host the secure online data collection system. No registration fee is payable by units to join the project or to enter data online. 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) Clinical Report Forms (CRFs)

CASE REPORT FORM 1 – *patient demographics*

A	*LOCAL HOSPITAL ID NUMBER as identifier*	
1	Patient age (on day of operation)	years
2	Patient gender	Male, Female
3	History of ischaemic heart disease or cerebrovascular disease (stroke or TIA)	Yes/No
4	History of diabetes	No, diet, controlled, tablet controlled, insulin controlled
5	Abnormal (elevated) serum creatinine	Yes/No
6	Smoking status	Current (pack years…….), Ex-smoker (pack years……), never
7	Body Mass Index (BMI)	Absolute value to one decimal place *[with pop-up calculator for conversion from height and weight]*
8	Pre-operative statin medication	Yes/No
9	Nature of surgery	Elective, Emergency, Expedited (surgery within 2 weeks of decision)
10	Reason for resection	Malignancy, known or possible Crohn's disease, other……

Crohn's extension questions [optional – only appear if Crohn's is selected in Q10]:

A) Preoperative medications (within 4 weeks prior to surgery):
- Systemic steroids *(name, dose, frequency – drop-down menu)*
- 5-ASA agents *(name, dose, frequency – drop-down menu)*
- Immunosuppressants (eg Azathioprine, 6MP, Methotrexate, ciclosporin) *(name dose, frequency – drop-down menu)*
- Biological agents (eg Infliximab, adalimumab) *(name, dose, frequency – drop-down menu)*

B) Pre-operative known intra-abdominal abscess? Y/N
If yes: i) percutaneously drained Y/N
ii) Interval from drainage to surgery (days)

C) Pre-operative albumin level within normal limits? Y/N

D) Pre-operative nutritional support? Y/N
If yes: oral supplementation / enteral feeding (any route) / parenteral nutrition

CASE REPORT FORM 2 – *operative details*

B	*LOCAL HOSPITAL ID NUMBER as identifier*	
1	Date of operation	dd/mm/yyyy
2	Actual operation performed	Ileocaecal resection/limited right hemicolectomy, right hemicolectomy, extended right hemicolectomy, other..... *Diagram of extent of incision here*
3	Previous surgery in this area	None, appendicectomy, previous ileocaecal resection for IBD, other……
4	Operation duration	Minutes (surgical time, not anaesthesia time)
5	Grade and speciality of primary operating surgeon	Consultant colorectal surgeon / trainee colorectal surgeon / consultant general surgeon / trainee general surgeon
6	ASA Grade	I, II, III, IV, V
7	Haemoglobin at start of operation (or last recorded level, within previous 2 weeks)	Absolute value in g/L to one decimal place *[with pop-up converter to change from g/dL to mmol/L]*
8	Operative approach	Laparoscopy, laparoscopy converted to open midline, laparoscopy converted to transverse, midline, transverse
9	Anastomosis performed	Handsewn, stapled, no anastomosis done
9b	Anastomosis details (*auto-tailored fields depending on response to Q8)	Handsewn – continuous or interrupted, Handsewn – suture used…. Stapled – side to side, side to end, end to side Stapled side-to-side – device used for primary anastomosis, device used for apical staple line, oversewn yes/no *[drop-down menu listing staplers to select from]*
10	Defunctioning or end ileostomy	Yes [defunctioning / end ileostomy] /No
11	Skin closure	Subcuticular suture, staple, other .....
12	Intra-operative complication or unplanned event/finding	*[drop-down menu - Bleeding (need to quantify amount), Ureteric injury, Duodenal injury, Renal injury, Liver laceration/injury, Gall Bladder injury, Vascular injury, Inadvertent enterotomy, Injury to other organs (this will capture lesser complications ie uterine, ovary, gastric), Revision of anastomosis, Other…..]*

Crohn's extension questions (optional; only appear if Crohn's is selected on previous page)

A) Unexpected abdominal abscess Y/N

B) Fistula identified Y/N

If yes: small bowel to small bowel / small bowel to colon / small bowel to urinary bladder / small bowel to skin / more than one of the above

C) Bowel obstruction (defined as narrowing with proximal dilatation) Y/N

D) More than one anastomosis or any additional strictureplasties Y/N

CASE REPORT FORM 3 – *follow-up data*

C		
1	Post-operative critical care admission?	Planned from theatre, unplanned from theatre, unplanned from ward, none
2	Total length of post-operative stay in hospital	Days
3	Surgical Complication Grade (Clavien-Dindo Classification, list most severe Grade I-V)	None, I, II, III, IV, V and date; brief description of details
4	Clinically suspected anastomotic leak?	Yes/No ➔ If Yes: Grade A - Anastomotic leakage requiring no active intervention (diagnosed by radiological examination) Grade B - Anastomotic leakage requiring active radiological intervention but manageable without surgical reintervention Grade C - Anastomotic leakage requiring surgical reintervention *NB -Highest score during follow up; e.g. Grade C if percutaneous drainage is followed by laparotomy* *- An abscess close to the anastomosis is also considered as anastomotic leakage.*
5	Intra-abdominal/pelvic collection	Yes/No
6	Peak CRP level within 72 hours of surgery	…… mg/L
7	30-day reoperation	Yes/No
8	30-day re-admission	Yes/No
9	Surgical site infection	Yes/No

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)
Right hemicolectomy/Ileocaecal resection policies	
Is there a unit policy for the following, relating to right hemicolectomy / ileocaecal resection operations:	
1) Preoperative antibiotics are provided routinely	Yes/No
2) Postoperative antibiotics are provided routinely	Yes/No
3) Bowel preparation is provided routinely for laparoscopic surgery	Yes/No
4) Bowel preparation is provided routinely for open surgery	Yes/No
5) Is there a formal enhanced recovery after surgery (ERAS) programme at your hospital?	Yes/No
6) Are NSAIDs used routinely for postoperative analgesia?	Yes/No

5) Cohort size and statistical analysis

A) Estimation of number of eligible operations performed across Europe

i) English data

Hospital Episode Statistics (HES) is a data warehouse containing details of all admissions, outpatient appointments and A&E attendances at NHS hospitals in England. This data is collected during a patient's time at hospital and is submitted to allow hospitals to be paid for the care they deliver. It is a records-based system that covers all NHS trusts in England, including acute hospitals, primary care trusts and mental health trusts. HES information is stored as a large collection of separate records - one for each period of care - in a secure data warehouse.

HES database interrogation shows that over the period 2001 – 2011, an average of **6000** right hemicolectomy operations were performed per year in England.

ii) Extrapolation across Europe

England population is approximately 53 million

Europe population = 739.2 million

Therefore if we accept the same rate ((6000/53,000,000) x 739,200,000) there will be around **83,700 operations** performed across Europe per year.

B) Accrual projections

This prospective study will only pick-up a proportion of these cases, and this depends upon three factors:

- Penetration - the proportion of hospitals who sign up to recruit patients to the study across Europe
- Pick-up - the proportion of the eligible patients at each centre are entered into the study
- Study duration – the length of time patients are recruited for

The following projection models have been made by varying the values of these 3 factors:

5% penetration

80% pick-up	
1 month recruitment	= 279 cases

10% penetration	
80% pick-up	
1 month recruitment	= 558 cases

20% penetration	
90% pick-up	
1 month recruitment	= 1255 cases

10% penetration	
90% pick-up	
3 months recruitment	= 1883 cases

8% penetration	
90% pick-up	
2 months recruitment	**= 1004 cases**