November 18th 2015

ESCP Snapshot Audit

Closure of Intestinal Stoma

Protocol version 2.2

Key dates:	
18 November 2015	Protocol published *Sites should start registering the study*
1 January 2016	Final updates to protocol published
18 January 2016 – 28 February 2016	Patient inclusion window starts *Site should start collecting 8 weeks of consecutive patients within this window*
24 May 2016	30-day follow up period ends *Sites should follow each patient up for 30 days. If the 8 weeks of consecutive patient inclusion starts 28 Feb, the follow up would end 24 May.*
30 June 2016	REDCap database locked *This is the deadline for data submission*

ESCP Cohort Study Steering Committee

Thomas Pinkney (UK), thomas.pinkney@uhb.nhs.uk

Nick Battersby* (UK), nickbattersby@nhs.net

Aneel Bhangu* (UK), aneelbhangu@doctors.org.uk

Sanjay Chaudhri (UK), schaudhri@nhs.net

Alaa El-Hussuna (Denmark), alaanewemail@gmail.com

Matteo Frasson (Spain), dr.frasson.matteo@gmail.com

Dmitri Nepogodiev* (UK), d.nepogoidev@bham.ac.uk

Baljit Singh (UK), bs143@leicester.ac.uk

Sandra Vennix* (Netherlands), s.vennix@amc.uva.nl

Oded Zmora (Israel), ozmora@post.tau.ac.il

** denotes trainee-level member*

ABSTRACT

Background: Temporary stoma is commonly used in colorectal surgery, in cases where anastomosis is unsafe, or for the protection of high risk anastomosis. Variability exists in the techniques for closure of stoma, due to patients' characteristics and surgeons' and units' preferences. 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 in closure of intestinal stoma 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 and length of stay.

Primary research question: Does anastomotic technique impact upon postoperative outcomes following stoma closure?

Methods: This two month prospective audit will be performed across Europe in early 2016, co-ordinated by the European Society of Coloproctology and S-ECCO. 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 to 30 days. The audit will be performed using a standardized pre-determined protocol. Data will be entered on to a secure online database. Based on the previous ESCP audit study, ths audit is expected to include >3000 patients. 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 multicenter, pan-European audit will be delivered by colorectal surgeons and trainees in an organized 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

Multicenter, 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 randomized controlled trials.

The European Society of Coloproctology has recognized 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 second snapshot audit deals with closure of intestinal stoma. Temporary stoma is commonly used in colorectal surgery, in cases where anastomosis is unsafe, or for the protection of high risk anastomoses. We anticipate that any hospital undertaking general surgery will perform these procedures routinely.

Despite the frequency of the operation, there remains uncertainty about the optimal method of undertaking it, which results in a range of methods currently utilized. This variability includes the time lag between stoma formation and closure, the method to anastomose the bowel, and different methods for wound closure. In addition, patient demographics and disease characteristics vary between units and countries, as do unit policies.

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

- Type of intestinal stoma performed
- Reason for the creation of stoma
- Time lag between stoma formation and closure
- Access to the abdominal cavity
- Method of anastomosis
- Methods of fascia closure and skin closure
- Hernia repair (in case of parastomal hernia) at time of closure.

2 - Methods

A) Summary

International prospective audit of consecutive patients undergoing any closure of stoma whether ileostomy or colostomy over a consecutive 8 week period in early 2016. All patients will be followed up for 30 days post-operation. No change to normal patient management will be required.

B) Primary Objective

To explore differences in patients, surgical methods 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 postoperative outcomes following stoma closure?

D) Inclusion Criteria

- All adult (>18 years old) patients undergoing closure of intestinal stoma.
- All operations of this type are included, for any pathology, via any operative approach.
- The consecutive 8 week patient inclusion period may start on any date 18 January to 28 February 2016.

E) Exclusion Criteria

- Closure of intestinal stoma which is done as part of a more extensive bowel resection, beyond resection of the stoma site or the distal end stump. For instance, patients with history of total abdominal colectomy with ileostomy undergoing proctectomy and non-diverted ileoanal pouch are excluded.
- Patients undergoing concomitant major abdominal procedure (such as hepatectomy) at the time of stoma closure.

F) Methods for identifying patients

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

1. At the pre-operative assessment clinic
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) Center eligibility

All hospitals/units performing gastrointestinal surgery are welcome to participate.All participating centers 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.

Centers 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 utilized 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, 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 one month post-operation in most circumstances.

I) Study flowsheet

Please see section 3.

J) Data completion and organization

Draft CRFs are shown in section 4.

This research takes the form of an audit study and no changes to the normal patient pathway are needed. 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, 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 organizational 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.

CRF B (operative details) must be completed by, or in direct conjunction with, a surgeon who was present during the operation. 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. The online system will be able to send regular reminders about missing data to ensure completeness of the data.

The study design means that sites may retrospectively identify eligible patients who were operated during the study period, and 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 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 in two ways:

(i) Uploading the patient's local identifier number on to the REDCap system. REDCap allows secure storage. Local identifiers will be automatically tripped out prior to data analysis and will **not** be available to the data analysis team. Collaborators **must** have their hospital's approval prior to uploading any local identifier numbers.

(ii) 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. 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 anonymized 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 at each participating center. It is the responsibility of the local team at each site to ensure that local audit approval (or equivalent) is completed for their center. Participating centers 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.

This authorship method has been successfully used in the first ESCP cohort study on right hemicolectomy. Authors from each center are expected to participate in registering patients and ensure completeness of data.

O) Pilot phase

A one-week pilot across several 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.

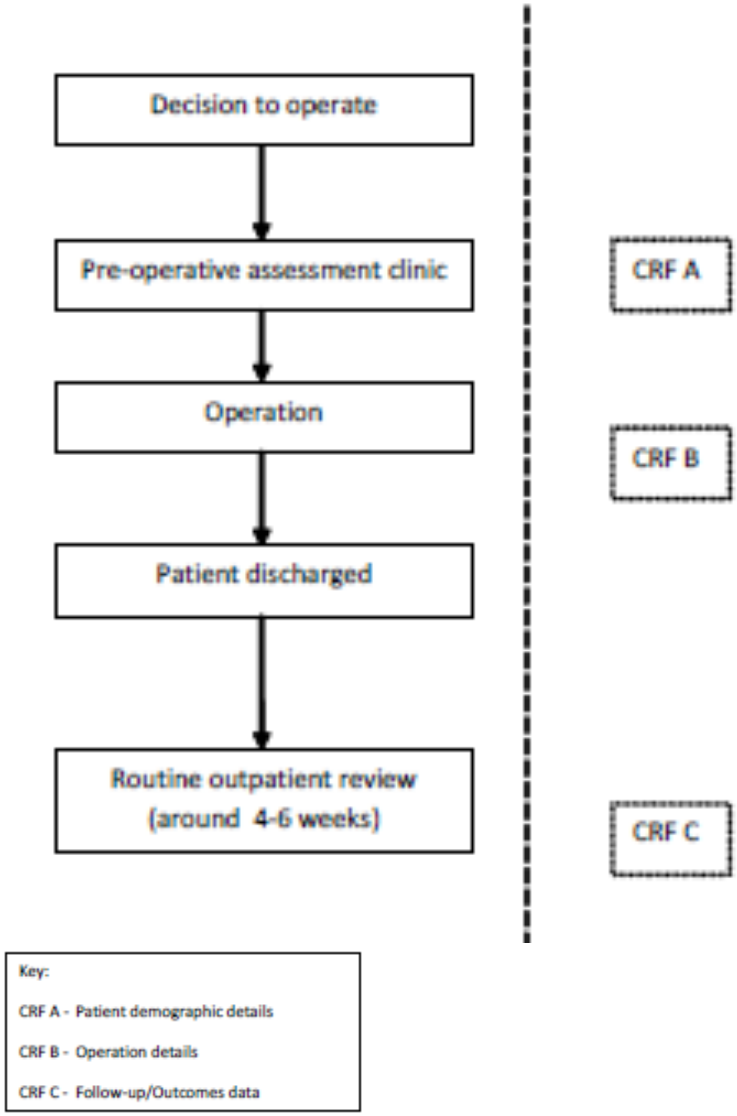
P) Publication of data

The primary aim of this project is to explore differences in patients, surgical methods, 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, which has 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) Case Report Forms (CRFs)

CASE REPORT FORM 1 – *patient demographics*		
1	Local patient identifier	
2	Gender	Male, Female
3	Body Mass Index (BMI)	
4	Type of stoma	Jejunostomy, Ileostomy, Colostomy
5	Diverting stoma (proximal to an anastomosis)	Yes, No
6	Stoma configuration	End, Loop, Double barrel, Other
7	Time of stoma creation	During the primary surgery, Subsequently for complication
8	Reason for a temporary stoma *(multiple indications can be selected)*	Routine practice for this type of anastomosis, History of radiation, Steroid treatment, Malnutrition, Intraoperative complications, Positive leak test, Anastomotic leak, Peritonitis, Emergency surgery, Bowel distention, Other patient factors, Other operative factors
9	Approach for the creation of stoma surgery	Open – midline, Open – transverse, Open – peristomal, Laparoscopic, Laparoscopic assisted, Laparoscopyic converted to open, Robotic, Robotic converted to open
10	Lag from creation to closure of stoma	Time in weeks
11	Imaging of the distal segment/ diverted anastomosis prior to closure	Yes, No **If yes, type:** Contrast study, Endoscopy
12	Chemotherapy / biologic agents for cancer within 3 month from closure	Yes, No **If yes, how many weeks since last dose :** <6, 6-12, >12
CASE REPORT FORM 2 – *operative details*		
1	Date of operation	DD/MM/YYYY
2	ASA grade	I, II, III, IV, V
3	Surgeon's degree of training	Colorectal specialist, General surgery specialist, Colorectal trainee, General surgery trainee
4	Access to the abdominal cavity	Open – midline, Open – transverse, Open – peristomal, Laparoscopic, Laparoscopic converted to open
5	Anastomosis technique	**Technique:** Handsewn, Stapled **If hand sewn-** **Suture:** Continuous, Interrupted **Material:** Silk, Vicryl, Prolene, PDS, Other **If stapled-** **Devices:** for primary anastomosis ± for apical staple line **Anastomosis oversewn:** Yes/ No
6	Anastomotic configuration	Side to side, Side to end, End to side
7	Method of fascia closure	**Suture:** Continuous, Interrupted **Material:** Silk, Vicryl, Prolene, PDS, Other
8	Prophylactic mesh used at the time of closure	Yes, No
9	Method of skin closure	**Method:** Complete closure, Partially opened, Completely open, Circumferential purse-string suture, Other **Material:** Staples, Silk, Vicryl, Prolene, PDS, Other
10	Operation duration	Time in minutes
11	Intraoperative complications	Yes, No **If yes:** Bleeding, Enterotomy, Adjacent organ injury, Other
CASE REPORT FORM 3 – *follow-up data*		
1	Total length of post-operative stay in hospital	Time in days
2	Clavien-Dindo Complication Grade	I, II, III, IV, V
3	Anastomotic leak	Yes – Grade A, Yes – Grade B, Yes – Grade C, No
4	Intra-abdominal/pelvic collection	Yes, No
5	Wound infection	Yes, No
6	Wound healed at 30 days follow up (±1 week)	Yes, No, Not known
7	Stoma site hernia at 30 days (±1 week)	Yes, No, Not known
8	30-day reoperation	Yes, No
9	30-day re-admission	Yes, No

5) Definitions

Anastomotic leak	**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
ASA grade	See the American Society of Anaesthesiologists website for definitions: http://www.asahq.org/Home/For-Members/Clinical-Information/ASA-Physical-Status-Classification-System.
BMI	Body mass index (BMI) = mass (kg) / height $(m)^2$.
Clavien-Dindo classification *(enter the highest grade experienced by the patient)*	In the Clavien-Dindo classification, the factor determining the severity of a complication is the treatment required. Consequently, a given complication may be graded differently depending on how it has been managed. E.g. an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade III). Some other considerations: ▪ Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The exception to this is **intra-operative death**; this is classified as grade V. ▪ **All post-operative adverse events** are included, even when there is no direct relationship to the surgery. ▪ **All adverse events within the follow-up** period (30 days) are included, even if they occur following discharge. ▪ **Diagnostic procedures** are not included. For example, a gastroscopy to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic gastroscopy with clipping of a bleeding vessel would be considered a grade III complication. Since **negative exploratory laparotomies** are considered to be diagnostic procedures, they should not be recorded as complications.

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<tr><th>Grade</th><th>Definition</th></tr>
<tr><td>I</td><td>Any deviation from the normal postoperative course without need for intervention other than the “allowed therapeutic regimens.”

Allowed therapeutic regimens are: antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement; physiotherapy and wound infections opened at the bedside.

Examples: Ileus; hypokalaemia; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.</td></tr>
<tr><td>II</td><td>Requiring pharmacological treatment with drugs beyond those allowed in grade I. Blood transfusions and total parenteral nutrition are also included.

Examples: Wound infection treated with antibiotics; myocardial infarction treated medically; blood transfusion for anaemia.</td></tr>
<tr><td>III</td><td>Requiring surgical, endoscopic or radiological intervention.</td></tr>
<tr><td>IV</td><td>Life-threatening complications requiring critical care management or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA).</td></tr>
<tr><td>V</td><td>Death of a patient</td></tr>
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</td></tr>
<tr><td>Intra-abdominal/pelvic collection</td><td>Collection of fluid with or without pus. Include any intra-abdominal or intra-pelvic abscess, detected clinically, by ultrasound or CT scan and/or intra-operatively.</td></tr>
<tr><td>Length of stay</td><td>This should be calculated from the first post-operative day to day of discharge (day of surgery is post-operative day zero). If the patient remains admitted in hospital at the end of 30-day follow-up, enter ‘30’</td></tr>
<tr><td>Surgical site infection</td><td>Use the Centre for Disease Control’s SSI definition, which is any <u>one</u> of:
Purulent drainage from the incision
At least <u>two</u> of: pain or tenderness; localised swelling; redness; heat; fever; <u>AND</u> The incision is opened deliberately to manage infection or the clinician diagnoses a surgical site infection
Wound organisms <u>AND</u> pus cells from aspirate/ swab</td></tr>
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