

Colorectal Anastomosis Leak Management (CALM) Study

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Introduction

Colorectal anastomoses are associated with a significant morbidity and mortality. Its management is often challenging, and a variety of management options are possible. Furthermore, the difference in clinical and radiological leaks has always introduced an element of uncertainty as to how to manage anastomotic leaks. Anastomotic leaks are also indirectly associated with other non-surgical complications such as Pneumonia, Thrombo-embolic disease, cardiovascular complications, urinary tract infections amongst others.

Definition of a 'Leak'

Despite many variant attempts by various groups throughout the history of colorectal surgery, a clear and universally agreed upon definition has remained elusive. For the purpose of this study, an anastomotic leak will be defined as: any disruption in an anastomosis resulting in leakage of air or fluid from the digestive tract through that disruption; irrespective of whether this causes clinical symptoms or not. The leak may be discovered on imaging (typically CT), although it can also be discovered by other modalities such as endoscopy, and occasionally in asymptomatic patients, Barium enemas. The diagnosis of a 'leak' will be accepted as reported by the clinical team at each site. It is not the purpose of this study to 'discover' leaks which have not been deemed so by local clinicians.

The International Study Group of Rectal Cancer proposed a grading system for the management of colorectal anastomotic leaks. Grade A anastomotic leaks are identified by radiographic findings of a perianastomotic fluid collection, leakage of contrast through the anastomosis, or observation of new drainage of enteric contents through either a drain or through a fistula but without accompanying clinical complaints. These may be managed expectantly. These may become apparent during the preoperative work-up prior to closure of a diverting ostomy and will at least delay reversal. Grade B leakage requires therapeutic intervention but does not necessarily require reoperation. Antibiotics and percutaneous drainage of fluid collections are the most common nonoperative interventions. Grade C anastomotic leakage requires relaparotomy. Surgical treatment is performed with the goal of controlling life-threatening sepsis. The traditional operation with takedown of the anastomosis and end colostomy may be appropriate, but washout with drain placement and diverting loop ileostomy may also be appropriate. ¹

Aim

The main interest of this study is to analyse the natural evolution of leaks and their subsequent treatment(s). Essentially, the aim of this study is to explore the different ways in which anastomotic leaks are managed and the associated outcomes.

Outcomes of Interest

Management of anastomotic leaks and associated outcome in terms of:

Primary objectives:

1. Outcomes of different treatment strategies of Colorectal anastomotic leaks.
2. 2-year mortality after anastomotic leaks

Secondary Objectives include:

- 2-year Mortality
- Need for subsequent management strategies after failure of initial strategy.
- Proportion requiring laparotomy, bowel resection, defunctioning.
- Length of ITU stay, overall length of hospital stay
- Non-surgical complications (pneumonia, urine infection, DVT, PE, MI etc)
- Delay / change in oncological management

Methods

Data will be collected retrospectively going back to 2014 (five years), at multiple East of England sites. The study will initially commence across trusts in the East of England Deanery however efforts will be made to recruit other research collaboratives through existing and established ties with the National Research Collaborative.

Population Identification

Patients can be identified and recruited to the study through a variety of ways:

- Multi-Disciplinary Teams (MDTs): Most MDTs will record data as to who has had a leak and what treatment they have had or are to have
- Colorectal Clinical Nurse Specialists (CNS): In most trusts, the CNS keep records of patients who have had complications
- National Bowel Cancer Audit (NBOCAP): Although this will not capture patients who have had benign disease, it will provide data on patients with cancer
- Consultants: Many consultants collect their own data, and this can be an excellent source of information

An estimated of 10-30 leaks occur every year at each site. We expect to have between 30-60 leaks with 3 year follow up per hospital site.

Study duration

Data collection 3-6 months from date of project launch (October 2019). Reminders for date of study closure will be sent closer to the time.

Variables

It must be stated that the aim of this study is not to investigate 'leak-rates' or comparatively analyse data of individual surgeons or trusts. No patient identifiable or surgeon identifiable information will be requested. Data and outcomes from individual trusts will not be compared against each other. The name of the trust will be recorded as one of the variables only for data validation purposes and to identify the lead investigators at each trust for the purposes of communication only. Names of Trusts or Surgeon level details will not be published. The variables that will be recorded are as follows:

- Trust
- Local Patient ID
- Gender (M/F)
- Age At Time (of Surgery) (Whole number)
- Indication for surgery (where is cancer, IBD?)
- Comorbidity 1 (in any order)
- Comorbidity 2 (in any order)
- Comorbidity 3 (in any order)
- Comorbidity 4 (in any order)
- Date of Index Surgery
- Type of Index Surgery (right, left, segmental sigmoid colectomy, AR)
- Elective / emergency
- Date Leak Detected
- Leak size (description on CT (size, localized, small, free))
- Symptomatic/Non-Symptomatic Leak
- Treatment 1
- date treatment 1 (chronological order)
- Treatment 2
- date treatment 2 (chronological order)
- Treatment 3
- Date treatment 3 (chronological order)
- Type of Rescue Surgery Performed (?laparotomy, bowel resection, defunctioning)
- Length of Stay in ITU Post Leak (in days)
- Length of stay in Leak episode (total in days)
- Number of days of drainage (if drain inserted)
- Date CT confirmed leak resolved
- Date of Death
- Date last seen alive (censored)
- Other Comments

Inclusion:

- Age ≥ 18 years old
- Patients undergoing colorectal anastomosis for any pathology (benign or malignant), during an elective or emergency admission, who had an AL.
- Laparoscopic or open surgery

Ethical approval & Registrations

This is a retrospective audit, aiming to analyse the region trust's management of colorectal anastomotic leaks, and whether this is in accordance with published literature. This study therefore needs to be registered as a retrospective audit in each trust.

References

1. den Dulk M, Noter S L, Hendriks E R. et al. Improved diagnosis and treatment of anastomotic leakage after colorectal surgery. *Eur J SurgOncol.* 2009;35(4):420–426.