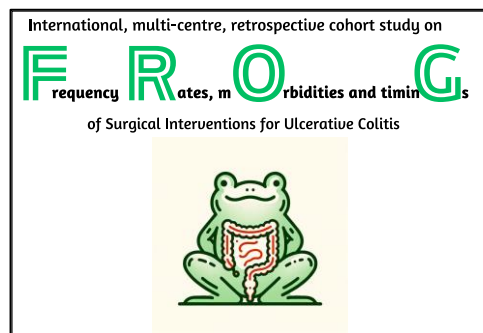


Dear ECCO National Representatives,
Dear IBD National Study Group Representatives,
Dear Colleagues,

We are delighted to invite you to participate in the FROG study of Surgical Interventions for ulcerative colitis.

FROG (Frequency Rates, mOrbidities and timinGs) of Surgical Interventions for Ulcerative Colitis

International, Multi-centre, Retrospective Cohort Study on Frequency Rates, Morbidities and Timings of Surgical Interventions for Ulcerative Colitis



What is the purpose of this study?

Our study intends to serve as a snapshot of the current practice in surgery for ulcerative colitis (UC) in Europe, by assessing patients' surgical journeys, starting from the index subtotal colectomy.

By inviting and recruiting multiple European and UK centres, we intend to investigate variation, but also collect large volume data, on the whole range of surgical procedures in Ulcerative Colitis.

Why is this study needed?

The literature demonstrates large variations in practice in surgery for UC, in a number of aspects and stages:

- Subtotal Colectomy (indications, timing, surgical approach, techniques)
- Rates of Reconstructive Surgery after Subtotal Colectomy
- Reconstructive Surgery (choice, stages, timings between stages, techniques)
- Subsequent operations for complications and poor function (operations for fistulae, pouch diversion/excision, conversion from IRA to IPAA)
- Morbidity and Complications of all above procedures

What are the main aims of the study?

1. Document morbidities and complications of procedures in UC in large volumes
2. Describe and understand variations in practice, particularly regarding reconstruction:
 - Rates of reconstructive surgery after subtotal colectomy
 - Choice of reconstructive technique
 - Stages used in IPAA surgery
 - Timings between stages in IPAA surgery
 - Surgical technique

What main outcomes will this study be reporting on?

We have opted to collect data and report on the following outcomes:

- Morbidity after total/subtotal colectomy
- Morbidity after any type of restorative surgery/stages
- Percentage of patients that proceed with restorative surgery after colectomy (and which type)
- Percentage of IPAA surgery performed in 1, 2 or 3 stages
- Percentage of patients, following restorative surgery, that proceed with revisional surgery, excision or diversion, with respective morbidities.

We believe these to be appropriate for addressing the aims of our study, as we expect data collection to be feasible and efficient, and will subsequently allow for sub-group analyses and comparisons, and their implications for the patient's surgical pathway.

Who can participate?

Any hospital in Europe or UK, where surgery for UC is performed, irrespective of the annual volumes, is invited to contribute data to this study.

Which patients can be included?

Eligible patients must meet the following inclusion criteria:

- Age > 18 years old
- Confirmed diagnosis of UC
- Having undergone an index colectomy

In order to capture the complete surgical journey, from the index subtotal colectomy to any procedures for complications post restorative surgery, we will be including patients that have undergone an index subtotal colectomy at any point within the past 15 years, and analysis will be performed according to the available follow-up.

This has been defined based on reports in the literature, on the timings from subtotal colectomy to reconstruction, as well as from reconstruction to excision.

How will data be collected?

Local investigators will identify patients according to the inclusion criteria.

Data will be collected and uploaded on REDCap®, on electronic Case Report Forms (eCRF).

Ethics Approval

After finalisation of the protocol, this will be submitted to the lead researcher's local ethics committee. After approval, this will be shared with all collaborating centres, to be submitted for their local approvals.

How will the results of this study be disseminated?

The results of this piece of work will be published as part of the researcher's thesis, but publication at peer reviewed journals will also be pursued. Collaborative authorship for all contributors will be guaranteed.

Who to contact if interested to participate?

The lead researcher for this study is Mr Orestis Argyriou, who is a trainee in General and Colorectal Surgery in North-West London, and is undertaking a PhD on Ulcerative Colitis at St Mark's National Bowel Hospital & Academic Institute, and Imperial College London.

To register your interest, please email orestis.argyriou@nhs.net

We strongly believe that this study can generate much-needed evidence, in large volumes, combining experiences and practices from all around Europe and the UK.

This will help us identify practices with favourable outcomes, that can be studied in more depth, and will ultimately allow us to learn from each other, for the benefit of UC patients requiring surgery.

Looking forward to your interest and collaboration,

Mr Orestis Argyriou – research fellow – lead investigator

Dr Itai Ghersin – research fellow

Mr Guy Worley – consultant colorectal surgeon

Mr Kapil Sahnan – consultant colorectal surgeon

Professor Ailsa Hart – consultant gastroenterologist

St Mark's National Bowel Hospital & Academic Institute