

2019 ESCP audit

CASE REPORT FORMS

Management of Acute Severe Ulcerative Colitis (MASC)

Study period: 1st February 2019– 31st January 2020

CRF version 3.0 (16th April 2019)

Case report form A – Patient Data at Admission

To be completed at admission / diagnosis of ASUC

Inclusion criteria

- Patient with previous diagnosis of ulcerative colitis, hospitalized for acute severe colitis (ASUC)

OR

- Patient without a previous diagnosis of ulcerative colitis, hospitalized for acute severe acute colitis, in whom infectious/ischemic colitis has been discarded

Note that the patient can be admitted for the treatment of ASUC or this could have developed whilst an inpatient

Exclusion criteria

- Patient younger than 16 years old
- Diagnosis of infectious or ischemic colitis in patients without previous diagnosis of UC

-Date of admission:

- Was the patient admitted primarily for the treatment of ASUC? Yes / No

If “Yes”: date of diagnosis (only the year) Date the colitis was defined as “severe” during hospitalisation:

- Truelove criteria AT DIAGNOSIS OF ASUC

Acute severe ulcerative colitis is defined as bloody stool frequency ≥ 6 per day and at least ONE of the following: pulse rate >90 bpm, temperature >37.8 °C, haemoglobin < 10.5 g/dL, ESR > 30 mm/h or CRP >30 mg/l.

Bloody stools/day ≥ 6 : yes/no

And

Pulse >90 bpm: yes/no/unknown

Temperature >37.8 °C: yes/no/unknown

Haemoglobin <10.5 g/dl: yes/no/unknown

ESR >30 mm/h: yes/no/unknown

CRP >30 mg/l: yes/no/unknown

Demographics and Patient History

- Sex: Male/female

- Age (Patient age at entry to the MASC audit):

MASC Study – Management of Acute Severe ulcerative Colitis

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- Was ulcerative colitis already diagnosed before admission? Yes/No, this is the first episode
If "Yes": Year of diagnosis:
- Previous inpatient admission with a diagnosis of acute severe ulcerative colitis?: Yes/No
If "Yes": How many previous admissions
- Admission ward: Gastroenterology/ Surgery/ Other
If Other ward please specify:
- Previous appendectomy: Yes/No
- History of diabetes mellitus (Include diet, tablet and insulin controlled DM): Yes/No
- Smoking History: Never/Ex-smoker: stopped more than 6 weeks ago/Ex-smoker, stopped less than 6 weeks ago / Current smoker
- Weight (Kg)
- Height (cm)
- Location of Disease (Montreal Classification): E1- Proctitis/E2 - Left-sided colitis/E3 - Extensive Colitis (proximal to splenic flexure)

Investigations at admission (+/- 24 hours)

- Albumin at admission (g/L or mmol/L)
- Haemoglobin at admission (mg/L or g/dl or mmol/l)
- CRP at admission (mg/L or mg/dl)
- Faecal calprotectin at admission (ug/g or mg/kg)
- Colonic dilatation on abdominal x-ray at 3rd day of admission (>5.5cm in transverse colon):
yes/no/x-ray not performed

Concomitant Therapy

- Concomitant therapy for ulcerative colitis immediately before admission: Yes /No
If Yes:
 - Topical Steroids by mouth: yes/no
If yes, specify: budesonide/ budesonide MMX/beclomethasone dipropionate
Dosage (mg/day)
 - Systemic steroids by mouth: yes/no
If yes, specify: methylprednisolone/hydrocortisone/prednisone, prednisolone/other
Dosage (mg/day)
 - Topical Steroids via rectum: yes/no

If yes, specify: Prednisolone suppositories / Prednisolone enema /
Hydrocortisone suppositories / Hydrocortisone enema / Budesonide
enema

Dosage (mg/day)

- Mesalazine: yes/no

If yes: topical/Systemic (both options are possible)

- Thiopurines: yes/no

If yes, specify: azathioprine / mercaptopurine/6-thioguanin

- Methotrexate: yes/no

- Calcineurin inhibitors: yes/no

If yes, specify: Tacrolimus/Cyclosporine

- Tofacitinib: yes/no

- Biologics: yes/no

If yes:

- Anti – TNF: infliximab, adalimumab, golimumab, certolizumab
pegol
- Anti – integrin: vedolizumab
- Anti – IL12/23: ustekinumab
- Other biologicals, please specify

When was the treatment started? (year, month)

When was the last dose given before admission? (DD-MMM-YYYY)

Case report form B – Medical management

To be completed at discharge or 90 days after the date of admission, whichever is sooner

Initial management

- Was there any form of nutritional support? Yes/no
 - if yes: conventional enteral nutrition: yes/no
 - immune-enhanced enteral nutrition: yes/no
 - parenteral nutrition: yes/no
 - if yes: exclusive parenteral nutrition: yes/no
- Were stool cultures obtained on admission? Yes / no
 - If yes: were they positive/negative
 - If positive: specify bacteria
- Were parasites and ova evaluated on admission? Yes / no

- If yes, were they present: yes/no
- Was *Clostridium difficile* infection evaluated on admission? Yes / no
 - If yes, was it present: yes/no
 - If yes, was antibiotic treatment given: yes/no
 - Were prophylactic antibiotics prescribed? Yes / no
 - Was cytomegalovirus (CMV) infection ruled out? Yes / no
 - If yes:
 - Technique: Immunohistochemistry / PCR (viral load) on colonic biopsy / serology / PCR (viral load) in blood
 - Did the patient receive antiviral therapy? Yes / no
 - If yes: oral/iv
 - Was prophylaxis with low molecular weight heparin initiated? Yes / no

Endoscopy

- Was endoscopy performed during the admission? Yes / no
 - o Date of endoscopy:
 - o Type of examination: flexible rectosigmoidoscopy /complete colonoscopy
 - o Most severe Mayo endoscopic score for the rectum (0 – 3)
 - o Most severe Mayo endoscopic score anywhere above the rectum (0 – 3)
 - o Most severe UCEIS score for the rectum:
 - Vascular pattern (normal/patchy obliteration/obliterated)
 - Bleeding (none/mucosal/luminal mild/luminal moderate or severe)
 - Erosion and ulcers (none/erosions/superficial ulcer/deep ulcer)
 - o Most severe UCEIS score anywhere above the rectum:
 - Vascular pattern (normal/patchy obliteration/obliterated)
 - Bleeding (none/mucosal/luminal mild/luminal moderate or severe)
 - Erosion and ulcers (none/erosions/superficial ulcer/deep ulcer)

Initial Medical Treatment

- Type of steroids used: methylprednisolone/ prednisone/
prednisolone/hydrocortisone/ beclomethasone dipropionate/ budesonide,
budesonide MMX/other/ none
 If "none": why? (free text)
- Initial dose of steroids (mg/day)
- Route of administration of steroids: Oral / iv
 - o In case of iv steroids: bolus / continuous perfusion
- Date of beginning of the treatment with steroids (date):

Progress at day 3-5 after starting treatment for ASUC

- Albumin at day 3-5 (g/L or mmol/L)
- Haemoglobin at day 3-5 (g/L or g/dl OR mmol/l)
- CRP at day 3 (mg/L or mg/dl)
- Stool frequency at day 3
- Blood stool frequency at day 3
- Stool frequency at day 5
- Blood stool frequency at day 5

Response and rescue medical therapy

- Response (evaluated by the gastroenterologist at discharge): steroid-refractory/steroid-responsive

If steroid-refractory: Rescue Medical Therapy / Surgery (Please fill out CRF C)

If Rescue Medical Therapy: Cyclosporine/Infliximab

If Cyclosporine

- o Date of first dose:
- o Date of last i.v. dose:
- o Response (adequate/inadequate)
- o Starting Dose: 2 mg/kg or 4 mg/kg
- o Maximum blood levels of Cyclosporine during induction:
 <150 ng/mL, 150- 250 ng/mL, 250-350 ng/mL, >350 ng/mL
 / Not available

If Infliximab

- o Dose of first infusion: 5 mg/kg/10 mg/kg/ other (specify)
- o Date of first dose:
- o Response (adequate/inadequate)
- o Was tuberculosis ruled out before starting infliximab? Yes /
no

- If Yes: Methods (multiple choice): contact history / plain X ray / PPD / IGRA
 - If any of them was positive, did the patient receive prophylaxis against TB?
- First blood determination of levels of infliximab ($\mu\text{g}/\text{mL}$):
- Date of the first blood determination of levels of infliximab
- Second blood determination of levels of infliximab ($\mu\text{g}/\text{mL}$):
- Date of the second blood determination of levels of infliximab
- Was a second dose of infliximab administered during the admission? Yes / No
 - Date of second infusion
 - Dose of second infusion: 5 mg/kg/10 mg/kg/ other (specify)
- Was a third dose of infliximab administered during the admission? Yes / No
 - Date of third infusion
 - Dose of third infusion: 5 mg/kg/10 mg/kg/ other (specify)

If 'Other' rescue medical therapy please specify medication:

If steroid-steroid responsive: Despite responding to steroids was a decision made to start rescue medical therapy whilst an inpatient? Yes / No

If No: Was surgery necessary? Yes (please fill out CRF C) / No

If Yes: If Rescue Medical Therapy: Cyclosporine/Infliximab

If Cyclosporine

- Date of first dose:
- Date of last i.v. dose:
- Response (adequate/inadequate)
- Starting Dose: 2 mg/kg or 4 mg/kg
- Maximum blood levels of Cyclosporine during induction:
<150 ng/mL, 150- 250 ng/mL, 250-350 ng/mL, >350 ng/mL
/ Not available

If Infliximab

- Dose of first infusion: 5 mg/kg/10 mg/kg/ other (specify)
- Date of first dose:

- Response (adequate/inadequate)
- Was tuberculosis ruled out before starting infliximab? Yes / no
 - If Yes:
 - Methods (multiple choice): contact history / plain X ray / PPD / IGRA
 - If any of them was positive, did the patient receive prophylaxis against TB?
- First blood determination of levels of infliximab ($\mu\text{g/mL}$):
- Date of the first blood determination of levels of infliximab
- Second blood determination of levels of infliximab ($\mu\text{g/mL}$):
- Date of the second blood determination of levels of infliximab
- Was a second dose of infliximab administered during the admission? Yes / No
 - Date of second infusion
 - Dose of second infusion: 5 mg/kg/10 mg/kg/ other (specify)
- Was a third dose of infliximab administered during the admission? Yes / No
 - Date of third infusion
 - Dose of third infusion: 5 mg/kg/10 mg/kg/ other (specify)

- Was a third line medical therapy administered (Cyclosporine → Infliximab or Infliximab → Cyclosporine)? Yes / no
 - Type of third line medical therapy: Cyclosporine / infliximab
 - Date of initiation:

- Was surgery necessary? Yes / no

If yes, fill CRF C

- Any other complication of the medical management that did not need surgical treatment?
Yes/no

If yes, please detail (more than one option is possible):

pneumonia/central line infection/ urinary tract infection/ other

infectious (Specify)/cardiac complications/neurologic complications/
renal complications/ other no infectious (specify)

Case report form C – Surgical data and postoperative complications

To be completed at surgery (surgical data) and at discharge (postoperative complications)

- Date of Surgery
- Indication for Surgery: Colitis refractory to medical treatment/toxic megacolon/perforation/bleeding
- Type of procedure: proctocolectomy/proctocolectomy and pouch/total colectomy/subtotal colectomy/right side resection/left side resection
- ASA: I/II/III/IV/V
- Most senior surgeon present at operation: Colorectal Trainee/Colorectal consultant/general surgery trainee/General surgery consultant
- Operative approach: open/mini-invasive

If mini invasive,

- please detail: Laparoscopic/Laparoscopic single incision/ hand-assisted/Robotic
- site of specimen extraction: ileostomy site/Pfannenstiel/other transverse incision/median line incision
- conversion to open surgery? Yes/No

If converted:

- Were flexures taken down laparoscopically? Yes/no
- Main reason for conversion: Access/adhesions/dilated colon/Bleeding/ Visceral injury/ Failure to progress/ To deal with rectal stump transection (due to active disease)/ Difficult mesentery (to deal with mesenteric blood supply on outside)

- Operation duration (minutes from incision to skin closure)
- intra-operative blood transfusion: yes/no
- intra-operative complications: none/vascular injury/ bowel injury (e.g. duodenum)/ injury to other organs or structures (e.g. ureter)
- rectal stump treatment: no rectal stump / open mucous fistula/ mucous fistula closed in the subcutaneous/ closure at the pelvic brim/low closure at the pelvic floor
- postoperative admission to intensive care unit: no admission to ICU/planned from operating theatre/ unplanned, from Ward /unplanned, from operating theatre

Post-operative complications

- Where there any post-operative complications? None / One / More than one

If One:

Type of complication: abdominal infectious complication, extra- abdominal infectious complication, bleeding, medical no infectious complication

Clavien-Dindo grade: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V

If More than one:

Type of worst complication: abdominal infectious complication, extra-abdominal infectious complication, bleeding, medical no infectious complication

Clavien-Dindo grade of the worst complication: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V

Comprehensive complication index (CCI):

- rectal stump leak (if rectal stump was closed): no/yes, no radiological or surgical intervention needed/ yes, radiological drain needed/ yes, surgery needed
date of diagnosis

- intra-abdominal o pelvic collection: yes/no
if yes, date of diagnosis

- surgical site infection: none/ superficial SSI / deep SSI / organ space SSI

- reoperation: yes/no

if yes: date

cause: rectal stump complication/bowel obstruction/stoma-related complications/ wound complications/ bleeding/ other (specify)

Case report form D – Discharge and Follow – up

To be completed at discharge and at the end of follow-up (minimum 90 days after the date of admission)

- date of discharge:
- weight (kg) at discharge
- where was the patient discharged? Home/ other recover facility
- date of last follow-up during the study period:
- weight (kg) at last follow-up:
- readmission (minimum follow-up 90 days): yes/no
 - if Yes: Date of readmission
 - cause of readmission, please select all that apply: IBD flare/ post operative complication (specify)/ Admitted for colectomy surgery / other (specify)
- mortality (minimum follow up 90 days): yes/no
 - if yes: Date of death
 - cause: post operative complication (specify)/ other medical complication (specify)/related to IBD/other /specify)
- total days of hospitalization (including readmissions)
- in case of a newly diagnosed ulcerative colitis was the diagnosis confirmed by the pathologist during the admission or the follow up? Yes/No
 - If yes: UC diagnosed in a biopsy obtained by endoscopy: yes/no
 - UC diagnosed in the specimen resected during surgery: yes/no
- Did the patient undergo surgery before the first discharge? Yes /No

If NO surgery before first discharge

- Date of first outpatient visit after discharge
- Partial Mayo score after 60-90 days
 - o Stool frequency (0-3)
 - o Rectal bleeding (0-3)
 - o Physician’s global assessment (0-3)
 - o Date of assessment
- Was oral cyclosporine prescribed? Yes / no
 - o Dose (mg/day)
- Was azathioprine prescribed? Yes / no
 - o Date of initiation
 - o Dose (mg/kg) or mg/day

- Were steroids stopped before discharge? Yes / no
 - o Date of withdrawal
- Did the patient receive prophylaxis against *pneumocystis jiroveci*? Yes/no (previously *P. carinii*)
- Cumulative dose of infliximab during the first 90 days after diagnosis (mg/kg)

Was rescue therapy continued as maintenance therapy after hospital discharge? Yes / No

If Yes:

Was anti-TNF maintenance therapy prescribed (yes/no)

if “yes”:

“which anti-TNF?” (infliximab

/adalimumab/golinumab/certolizumabpegol)

“which dose?” and “frequency of administration” (copy questions already present in CRF)

If “No”:

Was anti-TNF therapy newly prescribed after discharge (yes/no)

if “yes”:

“which anti-TNF?” (infliximab

/adalimumab/golinumab/certolizumabpegol)

“which dose?” and “frequency of administration” (copy questions already present in CRF)

Complications after discharge

Did the patient experience any complications after discharge? No / One / More than one

If One:

Type of complication: abdominal infectious complication, extra- abdominal infectious complication, bleeding, medical no infectious complication, other (specify)

Clavien-Dindo grade of complication after discharge: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V

If More than one:

Type of worst complication: abdominal infectious complication, extra- abdominal infectious complication, bleeding, medical no infectious complication, other (specify)

Clavien-Dindo grade of the worst complication that occurred after discharge: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V

Comprehensive complication index of complications that occurred after discharge (CCI):

If one or more complications after discharge:

- rectal stump leak after discharge (if rectal stump was closed): no/yes, no radiological or surgical intervention needed/ yes, radiological drain needed/ yes, surgery needed

date of diagnosis

- intra-abdominal or pelvic collection after discharge: yes/no

if yes, Clavien-Dindo grade

date of diagnosis

- surgical site infection after discharge: none/ superficial SSI / deep SSI / organ space SSI

if yes, Clavien-Dindo grade

date of diagnosis

- reoperation after discharge (minimum follow up 90 days): yes/no

if yes : date

cause: rectal stump complication/bowel obstruction/stoma-related complications/ wound complications/ bleeding/ other (specify)

Unit Questionnaire

We will contact sites at a later stage to request information on your centre.

Is your centre a:	University hospital/ tertiary centre; District general hospital;
In your centre does exist an IBD digestive Unit (gastroenterologist)?	Yes/No
How many IBD specialists (Gastroenterology, Internal Medicine) are in your hospital?	(number)
Is there a dedicated IBD Nurse specialist in your hospital?	Yes/No
How many beds does the Gastroenterology Department have in your hospital?	(number)
How many admissions per year does the Gastroenterology Department have in your hospital?	(number)
Is there an outpatient facility (Day Hospital) where IBD treatments can be	Yes/No

administered intravenously?	
In your centre does exist a formal multidisciplinary team for IBD?	Yes/No
In case a multidisciplinary IBD team exists, do you meet regularly	No/Once a month/ Twice a Month/ Every week/ Other (specify)
How many consultant-level surgeons perform colorectal resection operations at your site?	(number)
How many surgeries for ASUC per year at your site?	(number)
How many consultant-level surgeons perform IBD resections at your site?	(number)
How many consultant-level specialist colorectal surgeons are at your site	(number)
How many beds are in your hospital in total (all specialties)?	(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)