Case Study – Ulcerative Colitis

Ferring Pharmaceuticals have reviewed these slides for technical content

September 2019
GO/2288/2019/UK

Disclosures

- Lisa Younge's - Abbvie, Falk, Ferring, Janssen, Takeda
- Kevin Barrett's - Ferring, Thermo Fisher Scientific, Tillots and Yakult

September 2019
GO/2288/2019/UK

Background

- Adam - 47years old
- Builder
- Married with x2 teenage sons
- Recently gave up smoking, approx 2.5/12 ago
- Presented to GP with increasing bowel frequency and bloody diarrhoea

History

- Well until 3 weeks ago
- BO up to 8x per day
- Loose stool, urgency but no incontinence
- Some blood
- Abdominal pain
- Reduced appetite, weight loss of nearly 1 stone
- Generally feeling awful

September 2019
GO/2288/2019/UK


Dr. Google

GP Visit

- Nil relevant FH or PMH
- No regular medication - occasional paracetamol for pain, increased recently
- Minimal alcohol and recently stopped smoking after 30 years
- No allergies

September 2019
GO/2288/2019/UK

Adam

- Referred on 2WW pathway
- Colonoscopy shows moderate inflammation within rectum - rest normal
- ?infective, ??IBD
- Biopsies taken around colon
- Reassured not cancer
- Discharged back to GP for results

September 2019
GO/2288/2019/UK

Vote Now

Question?

Do you have pathways for suspected UC in your endoscopy units?

1. YES
2. NO

Vote Now

Question?

Do you have pathways for suspected UC in your endoscopy units?

1. YES

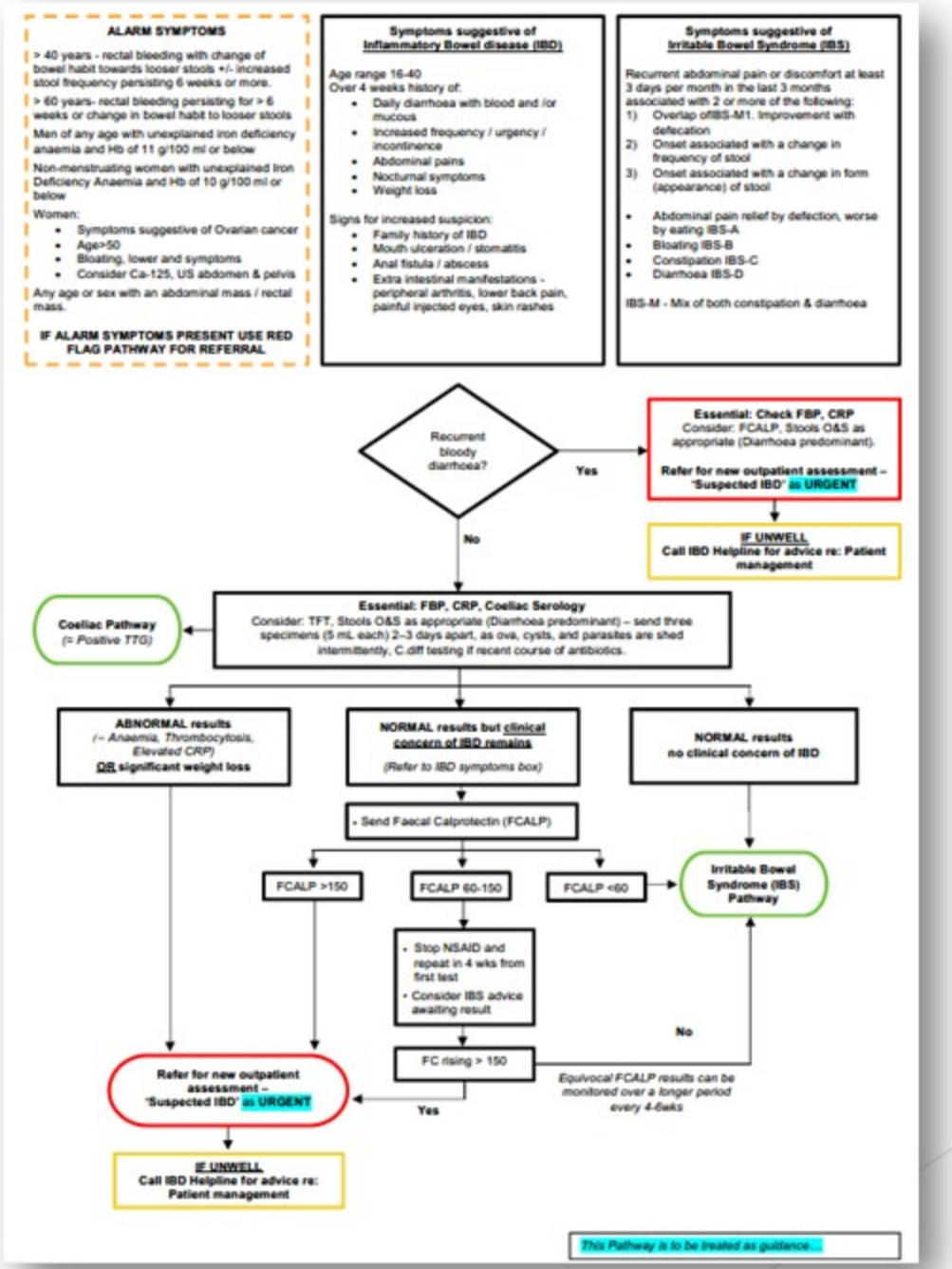
2. NO

Suspected IBD follow-up pathway:

1. Biopsies – For a reliable diagnosis of CD and UC multiple biopsies from six segments (terminal ileum, ascending, transverse, descending, sigmoid and rectum – just the latter three if you are performing a flexible sigmoidoscopy) should be obtained: include some non – inflamed areas if possible. Include detailed clinical information to assist the pathologist (ECCO 2013).
2. Report. – Please add your clinical suspicion in the comments section at the bottom: do you think this looks like Crohn's, UC or IBD-U? Please carefully state what the follow up plans are, who is responsible for this and whether you have or have not started treatment. This is valuable information for the patient, their GP and the IBD team. Your report is all we need to have as a ***New patient*** referral form.
3. Inform the patient of the suspected diagnosis, although it is important to stress that the results of the biopsies will be needed to confirm IBD. Information sheets about what IBD is are available in endoscopy to give to patients. Please DO NOT give the patient the contact details of the IBD helpline until they have a confirmed diagnosis.
4. Prescribe
    a. If you think the endoscopic findings are consistent with IBD and the patient is symptomatic (diarrhoea or rectal bleeding) then please prescribe topical or oral (4 or 4.8g daily) 5-ASA preparations dependent on extent of inflammation. These are very safe and likely to work in the next few weeks whilst they wait for an IBD clinic appointment.

September 2019
GO/2288/2019/UK

Suspected IBD referral pathway



September 2019
GO/2288/2019/UK

Adam

- ‘Likely proctitis’ rest of colon NAD
- Report to be sent to GP with biopsy results
- GP to refer to IBD team if indicated
- ???
- Returns to GP 5/12 later
- Ongoing symptoms
- Fed up ++
- Further weight loss

September 2019
GO/2288/2019/UK

- BO 8-10x per day blood most times, sometimes just blood
- Urgency (incontinent x1)
- Abdominal pain
- O/E abdo soft, tender on palpation
- Temp 37.2, Pulse 88

ASSESSING SEVERITY OF UC

(Truelove & Witts BMJ 1954)

	mild	severe
stools	<5/d, trace blood	>5/d, bloody
temperature	No fever	>37.8
pulse	<90	>90
Hb	Normal	<10.5
ESR	<30	>30

What would you do?

1. Refer urgently
2. Start 5ASA
3. Start 5ASA and Steroids
4. Steroids
5. Topical Tx
6. Refer to A&E/Discuss with Gastro Team

September 2019
GO/2288/2019/UK

Adam

- D/W Gastro On Call
- MC&S sent
- Bx found - confirm UC
- Pred 40mg and safeguarding
- Urgent IBD Clinic appt made

IBD OPA

- Feeling better
- BO x3/day - type 4
- Less blood
- Less abdo pain
- Bloods:
  - FBC 109 WCC 10.8 CRP 9

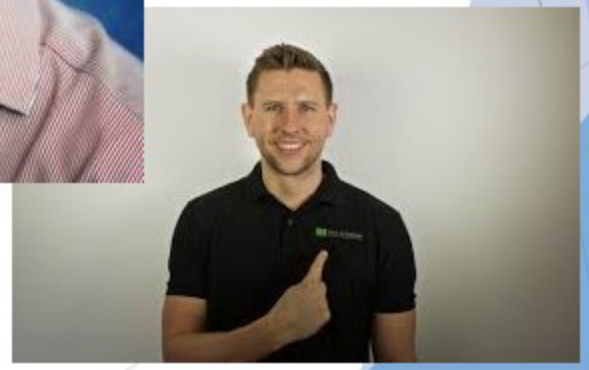
September 2019
GO/2288/2019/UK

Vote Now

Question:

Now What?

1. Watch & Wait
2. 5ASA
3. Other?



Vote Now

Question:

Now What?

1. Watch & Wait
   7%
2. 5ASA
   87%
3. Other?
   6%

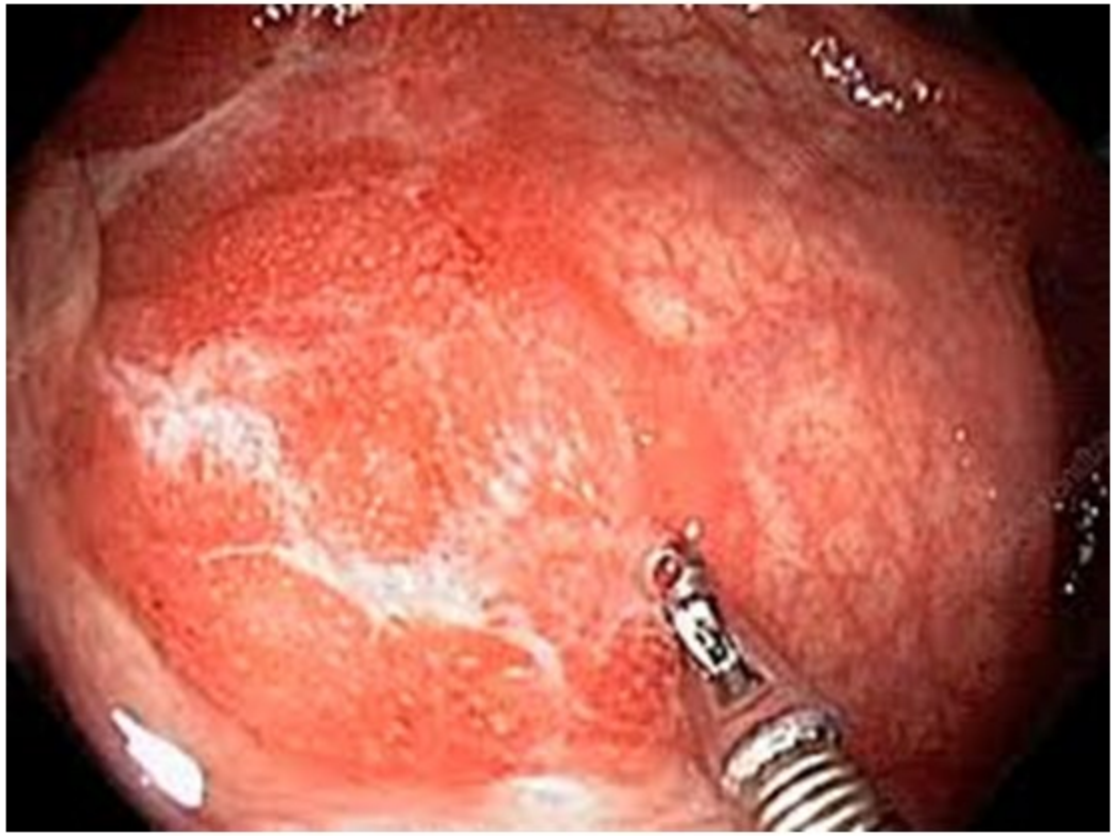
Adam

- Started 5ASA (Pentasa)
- Offered topical tx - non starter..
- Helpline

- 5 weeks later - call to helpline, flare
- Urgent flexi requested

Pentasa Prescribing Information available at Ferring Stand

September 2019
GO/2288/2019/UK



MAYO CLINIC SCORE (UC):

Stool Frequency	Rectal Bleeding	Endoscopic findings*	Clinician assessment
Normal number for patient	No blood	Normal	Normal or Mild disease
1 to 2 stool > normal	Streaks of blood	Mild disease	Moderate disease
3 to 4 stool > normal	Obvious blood	Moderate disease	Severe disease
>= 5 stool > normal	Blood only	Severe disease	

* Findings on endoscopy (If possible)
0 = Normal or inactive disease
1 = Mild disease (erythema, decreased vascular pattern, mild friability)
2 = Moderate disease (marked erythema, lack of vascular pattern, friability, erosions)
3 = Severe disease (spontaneous bleeding, ulceration)

Mayo score (clinical only): ☐
Mayo score (including sig): ☐

September 2019
GO/2288/2019/UK

Vote Now

Question:

Now What?

1. Azathioprine
2. Infliximab
3. Adalimumab
4. Vedolizumab
5. Tofacitinab
6. Other

Vote Now

Question:

Now What?

1. Azathioprine
   87%
2. Infliximab
   7%
3. Adalimumab
   1%
4. Vedolizumab
   0%
5. Tofacitinab
   1%
6. Other
   3%

- Azathioprine - adequate TGNs - flare after 6/12 - settled on pred 40mg from GP
- Anti TNF - Infliximab
- PNR
- Vedolizumab - moderate response but still urgency
- OPA 6/12 into treatment, further course pred 40mg from GP

September 2019
GO/2288/2019/UK

Section 4: Flare Management

Statement 4.1

Local treatment protocols and clear pathways should be in place for the management of IBD patients experiencing flares and include advice for primary care.

Statement 4.2

All patients with IBD should be provided with clear information to support self-management and early intervention in the case of a flare.

Statement 4.3

Rapid access to specialist advice should be available to patients to guide early flare intervention, including access to a telephone/email advice line with response by the end of the next working day.

Statement 4.4

Patients with IBD should have access to review by the IBD team within a maximum of five working days and be able to escalate/start a treatment plan within 48 hours of review.

Statement 4.5

Steroid treatment should be managed in accordance with guidelines and audited on an ongoing basis, with clear guidance to primary care.

September 2019
GO/2288/2019/UK

Helping Patients Own Their IBD

Self-Management for Ulcerative Colitis relapse & how to extinguish the Flame

- **Always remember Crohn's disease and Ulcerative Colitis are chronic conditions. Currently there is no cure. Both conditions alternate between remission (when there are no symptoms) to relapses (when symptoms return) during your life. It can be months of years between them but its important to you to report symptoms as soon as possible, so that they don't get out of control.**

- **Ulcerative Colitis** is a condition that causes inflammation and ulceration of the inner lining of the rectum and colon (the large bowel). In UC, tiny ulcers develop on the surface of the lining and these may bleed and produce mucus. The inflammation usually begins in the rectum and lower colon, but it may affect the entire colon. If UC only affects the rectum, it is called proctitis, while if it affects the whole colon it may be called pancolitis.

- **Crohn's Disease** is a condition that causes inflammation of the digestive system or gut. Crohn's can affect any part of the gut, though the most common area affected is the end of the ileum (the last part of the small intestine), or the colon. The areas of inflammation are often patchy with sections of normal gut in between. A patch of inflammation may be small, only a few centimetres, or extend quite a distance along part of the gut. As well as affecting the lining of the bowel, Crohn's may also go deeper into the bowel wall.

A relapse of your inflammatory bowel disease (IBD) is often called a **'flare'**. If your bowel habit has been settled and begins to change, it might be that you IBD is becoming active again.

Points to notice!

- Have you been going to the toilet more than 5 times in 24 hours?
- Are your stools loose or have you had any diarrhoea with any blood / slime in them for more than 3 days?
- Have you had abdominal pain?
- If you have had any of these issues you should be assessed by your GP as soon as possible

Step 1. Bloods!

Get some bloods taken at your Health Centre – Full Blood Count, Liver Function tests, Urea and Electrolytes, Inflammatory markers – ESR and CRP

These blood test can be extremely useful in determining whether your IBD has begun to relapse. It will help your IBD team decide on the best treatment options to regain remission quickly.

Step 2. Stools!

Get some Stool sample into the Health Centre – one to check for Bacteria/Parasite cultures (SFC) – the other to check for Faecal Calprotectin.

Did you know that having IBD means you are more at risk of developing infections in your guts? A stool sample can help decide whether you need Antibiotic therapy, in some cases there may be other causes for a change in you bowel habit other than IBD.

Calprotectin is a protein that is released in your gut when you have a relapse. It can be extremely helpful in aiding your IBD team (who can interpret the result) to decide on the best treatment for you.

Step 3. Current Medicines!

Check the Drug Listings here to see whether you can increase therapies safely

This only applies if you are taking Mesalazine. Don't increase immune-adjustment medicines without speaking to your IBD team first, as this could be unsafe.

Mesalazine

Patients with Ulcerative Colitis will usually be prescribed one of these preparations. There are several brands of Mesalazine – Each has a different dose and each releases differently in the bowel. There are two doses 'maintenance' when you don't have symptoms and 'treatment' when you do. It's perfectly safe for you to increase your Mesalazine therapy to 'treatment' when you have symptoms (as indicated above) but if you do, we ask that you increase therapy for 6 weeks. Some patients may need to stay on the treatment dose.

Salofalk - Dr Falk

Granules/tablets – Maintenance is 500mg 3 times daily. Treatment is 3grams once a day.

Asacol - Activis

Tablets – Maintenance is 1.2-2.4grams once a day or in divided doses. Treatment is 4.8grams in divided doses.

Octasa - Tillotts pharma

Maintenance is 1.2-2.4grams once a day or in divided doses. Treatment is 4.8grams in divided doses.

Mezavant XL - Shire

Tablets – Maintenance is 2.4gram once a day. Treatment is 4.8grams once a day.

Pentasa - Ferring

Granules/tablets – Maintenance is 2grams once a day. Treatment is 4grams once a day.

Rectal Therapy

Mesalazine Suppositories and Enemas. If you have a supply of these and are familiar with how to use them, it is safe to start these, normally nightly for two weeks, to help control symptoms. Symptoms should improve after a week or two, but if they don't get in touch with your IBD Specialist Team.

Immune-system 'Adjustment' medicines

These are immunosuppressant medicines and you should not increase or decrease these therapies without discussing with your IBD Specialist Team. While on these therapies blood monitoring is normally directed by your General Practitioner but as a guide, we recommend the following if your symptoms are stable:

Azathioprine & 6-Mercaptopurine – Blood tests should be performed at least every 12 weeks to check Liver Function, Full Blood Count, Urea & Electrolytes and inflammatory markers.

Methotrexate – Blood tests should be performed at least every 8 weeks to check Liver Function, Full Blood Count, Urea & Electrolytes and inflammatory markers.

Biologic drugs (Adalimumab, Golimumab, Vedolizumab, Infliximab and Ustekinumab) – Blood tests should be performed to check Liver Function, Full Blood Tests, Urea & Electrolytes and Inflammatory Markers. Failing to get bloods done within the recommended guidelines is unsafe, and could mean therapy is withdrawn by either your General Practitioner or IBD Specialist Team.

**** If you have an active, confirmed infection, please withhold the Immune-Adjustment medication and discuss with you GP or IBD Specialist Team****

Steroids

Prednisolone/Budesonide/Beclomethasone

It is important to remember that these medicines are not recommended as a long term treatment and in many cases are only needed when IBD symptoms will not respond to increasing your current therapy. Please let your IBD Specialist Team know (if you are prescribed these).

The current medical treatments for both Crohn's disease and Ulcerative Colitis are designed to spare you from systemic steroids like Prednisolone and their potential side effects. Budesonide is a steroid which does not carry such a high risk of side effects.

Step 4. Call the IBD Helpline!

Having the above information helps your IBD Specialist team make a decision to start Treatment and order other investigations.

Don't forget to leave your Name, Date of Birth, Telephone Number, and when you will be able to receive a return call.

Belfast Trust:	07887476684
Northern Trust - Causeway:	07802869977
South Eastern Trust:	07725637476
Southern Trust:	07788726875
Western Trust - Altnagelvin:	07780449682
South West Acute Hospital	

We will aim to respond to your call within 2 working days where possible

Please DO NOT contact us if your call is an emergency. If we are not available, we are on annual leave, training, or study leave and you should follow the advice on the voicemail.

Supported with an unrestricted educational grant from Dr Falk Pharma UK Ltd. DrF18/1000 Date of preparation: February 2018

Take 5

steps to wellbeing

Most of us know when we are mentally and physically well, but sometimes we need a little extra support to keep well.

There are five simple steps to help maintain and improve your wellbeing. Try to build these into your daily life - think of them as your 'five a day' for wellbeing.

Connect

Connect with the people around you: family, friends, colleagues and neighbours at home, work, school or in your local community. Think of these relationships as the cornerstones of your life and spend time developing them. Building these connections will support and enrich you everyday.

Be active

Go for a walk or run, cycle, play a game, garden or dance. Exercising makes you feel good. Most importantly, discover a physical activity that you enjoy, one that suits your level of mobility and fitness.

Take notice

Stop, pause, or take a moment to look around you. What can you see, feel, smell or even taste? Look for beautiful, new, unusual or extraordinary things in your everyday life and think about how that makes you feel.

Keep learning

Don't be afraid to try something new, rediscover an old hobby or sign up for a course. Take on a different responsibility, fix a bike, learn to play an instrument or how to cook your favourite food. Set a challenge you will enjoy. Learning new things will make you more confident, as well as being fun to do.

Give

Do something for a friend or stranger, thank someone, smile, volunteer your time or consider joining a community group. Look out as well as in. Seeing yourself and your happiness linked to the wider community can be incredibly rewarding and will create connections with the people around you.

The five ways to wellbeing were developed by the New Economics Foundation.

Public Health Agency, 12-22 Linenhall Street, Belfast BT2 8BS. Tel: 0300 555 0114 (local rate)

CROHN'S & COLITIS UK

Ulcerative Colitis Flare Pathway

Pathway for adults with known uncomplicated Ulcerative Colitis who may be having a flare

Exclusions: age under 16, have a stoma or fistula, have had surgery, or on biological therapy (e.g. Humira).

Y → **These patients should have access to an IBD specialist—please contact their team before making any medication changes.**

N

Ask about triggers. Check adherence to medication. Stop NSAIDs. Consider self-care for mild symptoms including dietary advice and reducing stress. See **rcgp.org.uk/ibd and signpost to crohnsandcolitis.org.uk.**

Tests: stool culture, U&E, FBC, ESR/CRP, faecal calprotectin. Stop NSAIDs. Consider self-care for mild symptoms including dietary advice and reducing stress. **Seek advice from the IBD helpline, IBD team or on-call gastroenterologist.**

Acute Severe colitis:
6 or more bowel movements plus two or more features of systemic upset:
Visible blood in stool
Pyrexia (temperature greater than 37.8°C)
Pulse rate greater than 90 bpm
Anaemia (Hb <105g/L)
Erythrocyte sedimentation rate >30 mm/hr or CRP >40 mg/L

Y → **Discuss with on-call gastroenterologist /medical team**

N

Pancolitis/extensive disease

Maximise oral 5-ASA (mesalazine):
Pentasa 4g, Mezavant XL 4.8g, Octasa 4.8g, Asacol 4.8g, Salofalk 3g
Still symptomatic – consider adding topical therapy:
Mesalazine Salofalk foam enema 2g nocte, Pentasa liquid enema 1g nocte, or Salofalk liquid enema 2g nocte
Or add Clipper 5mg (Beclamethasone) OD for 28 days, or Budesonide MMX (Cortiment) 9mg OD for 8 weeks.

Visit the NICE website for further information on doses:
bnf.nice.org.uk/drug/budesonide.html#indicationsAndDoses
bnf.nice.org.uk/drug/mesalazine.html#indicationsAndDoses

Proctitis or left-sided disease

Proctitis
Mesalazine Salofalk suppository 1g nocte, Pentasa 1g suppository nocte
Left sided disease
Mesalazine Salofalk foam enema 1-2g nocte, Pentasa liquid enema 1g nocte, or Salofalk liquid enema 2g nocte
Budesonide Budenofalk foam enema 2mg nocte, or Prednisolone Predsol liquid enema 20mg nocte

Already taking and still symptomatic – Add oral 5-ASA maximum dose (see left)

Assess response after 2 weeks

Deteriorating → **May need admission. Discuss with on-call Gastro team.**

No better

Oral prednisolone 40mg od for 7 days then 35mg od for 7 days. Reducing by 5mg each week over 8 weeks = 252 x 5mg prednisolone tablets in total.
Remember GI and bone protection. Counsel re: side effects
Inform the IBD team when oral steroids are given. Patients should not have more than one course of steroids in a year without considering escalating steroid-sparing agents.
crohnsandcolitis.org.uk/steroids

Assess response after 2 weeks

Deteriorating → **May need admission. Discuss with on-call Gastro team.**

No better

Seek advice from the IBD team via the IBD hotline
crohnsandcolitis.org.uk/ibdnurse

Improving

Continue treatment for 8 weeks then revert to maintenance dose of oral mesalazine
Encourage lifetime compliance
crohnsandcolitis.org.uk/aminosalicylates

Improving → **Complete course**

Managing Functional Symptoms

- Primary symptom urgency & frequency
- Proximal constipation
- FODMAP or alternative
- ‘Holding on Training’

- Repeat Flexi - ongoing inflammation
- CMV negative

September 2019
GO/2288/2019/UK

Vote Now

Question:

Now What?

1. Adalimumab
2. Tofacitinab
3. Tacrolimus
4. Ciclosporin
5. Other

Vote Now

Question:

Now What?

1. Adalimumab — 46%
2. Tofacitinab — 38%
3. Tacrolimus — 6%
4. Ciclosporin — 6%
5. Other — 4%

Surgery for Proctitis..

- Long standing symptoms
- Impaired QoL
- Elective surgery

September 2019
GO/2288/2019/UK

- Currently managing ileostomy well - not keen to proceed to pouch
- Back to work full time
- Still not smoking!