



### **PRACTICE**

### **GUIDELINES**

# Management of ulcerative colitis: summary of updated NICE guidance

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### What's new in the guidance

- New recommendations on inducing remission in people with mild to moderate ulcerative colitis
- Classifying the extents of ulcerative colitis by grouping left sided disease and proctosigmoiditis, to more closely reflect current practice
- In people with proctitis, proctosigmoiditis, or left sided disease, offer a topical aminosalicylate as first line treatment
- In people with extensive disease, offer a topical aminosalicylate and a high dose oral aminosalicylate as first line treatment
- Courses of oral corticosteroids should be time limited (normally 4-8 weeks depending on the steroid)

Ulcerative colitis is a chronic inflammatory disease of the rectum and colon characterised by mucosal inflammation, resulting in symptoms of diarrhoea (both soft stool and an increased frequency of defecation), rectal bleeding, an urgent need to defecate, and abdominal pain.

The condition usually affects the rectum and a variable extent of the colon proximal to the rectum. Inflammation of the rectum is referred to as proctitis, and inflammation of the rectum and sigmoid as proctosigmoiditis. Left sided colitis refers to disease involving the colon distal to the splenic flexure. Extensive colitis affects the colon proximal to the splenic flexure, and includes pan-colitis, where the whole colon is involved.

The most widely used drugs for inducing remission in people with mild to moderate ulcerative colitis are aminosalicylates and corticosteroids. Choice of treatment depends on the extent of disease (proctitis, proctosigmoiditis, left sided colitis, extensive colitis), mechanism of action, route of administration, site and mechanism of drug release, dose, duration, cost of treatment, and patient preference.

This article summarises recent recommendations from the update of the National Institute for Health and Care Excellence (NICE) guideline for the management of ulcerative colitis in children, young people, and adults. The update focuses on inducing

remission in people with mild to moderate ulcerative colitis. All other areas of the guideline, such as surgery, maintenance of remission, and monitoring remain unchanged and are not covered here. Full details of the evidence, a complete list of all recommendations in the guideline, and the clinical pathway are available on the NICE website (www.nice.org.uk/guidance/ng130).

This update is most relevant to specialists involved in prescribing treatments for people with ulcerative colitis but it is also important for primary care practitioners to be aware of what treatments patients may be receiving to manage this chronic condition.

### Why did the guidance need updating?

Since publication of the previous guidance in 2013, a surveillance review identified new trial evidence for medicines to induce remission in people with mild to moderate ulcerative colitis, leading to the decision to update this area of the guideline.

The updated recommendations for inducing remission in people with mild to moderate ulcerative colitis are based on systematic reviews and a series of network meta-analyses of randomised controlled trials, an original cost effectiveness model, and the Guideline Committee's (GC) experience and opinion of what constitutes good practice. Evidence levels for the recommendations are given in italics in square brackets.

### Recommendations

## Inducing remission in people with mild to moderate proctitis

• To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of proctitis, offer a topical aminosalicylate as first line treatment.

[Based on moderate quality evidence from randomised controlled trials and an original cost effectiveness model]

- If remission is not achieved within four weeks, consider adding an oral aminosalicylate. [Based on an original cost effectiveness model using indirect low quality evidence from randomised controlled trials in a greater extent of disease and the experience and opinion of the GC]
- If further treatment is needed, consider adding a time limited course of a topical or an oral corticosteroid. [Based on the experience and opinion of the GC]
- For people who decline a topical aminosalicylate:
- -consider an oral aminosalicylate as first line treatment, and explain that this is not as effective as a topical aminosalicylate [Based on low quality evidence from randomised controlled trials and the experience and opinion of the GC]
- if remission is not achieved within four weeks, consider adding a time limited course of a topical or an oral corticosteroid. [Based on indirect low quality evidence in a greater extent of disease and experience and opinion of the GC]
- For people who cannot tolerate aminosalicylates, consider a time limited course of a topical or an oral corticosteroid. [Based on the experience and opinion of the GC and indirect evidence from low to high quality randomised controlled trials in a greater extent of disease]

## Inducing remission in people with mild to moderate proctosigmoiditis and left sided ulcerative colitis

- To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of proctosigmoiditis or left sided ulcerative colitis, offer a topical aminosalicylate as first line treatment. [Based on high quality evidence from randomised controlled trials and an original cost effectiveness model]
- If remission is not achieved within four weeks, consider:
  adding a high dose oral aminosalicylate to the topical aminosalicylate or
- switching to a high dose oral aminosalicylate and a time limited course of a topical corticosteroid. [Based on low to high quality evidence from randomised controlled trials and the experience and opinion of the GC]
- If further treatment is needed, stop topical treatments and offer an oral aminosalicylate and a time limited course of an oral corticosteroid. [Based on high quality evidence from randomised controlled trials and the experience and opinion of the GC]
- For people who decline any topical treatment:
- consider a high dose oral aminosalicylate alone, and explain that this is not as effective as a topical aminosalicylate
- if remission is not achieved within four weeks, offer a time limited course of an oral corticosteroid in addition to the high dose aminosalicylate. [Based on low to high quality evidence from randomised controlled trials and the experience and opinion of the GC]
- For people who cannot tolerate aminosalicylates, consider a time limited course of a topical or an oral corticosteroid.

[Based on low to high quality evidence from randomised controlled trials and the experience and opinion of the GC]

## Inducing remission in people with mild to moderate extensive disease

- To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of extensive ulcerative colitis, offer a topical aminosalicylate and a high dose oral aminosalicylate as first line treatment. [Based on low to moderate quality evidence from a randomised controlled trial and an original cost effectiveness model]
- If remission is not achieved within four weeks, stop the topical aminosalicylate and offer a high dose oral aminosalicylate with a time limited course of an oral corticosteroid. [Based on low to moderate quality evidence from randomised controlled trials and the experience and opinion of the GC]
- For people who cannot tolerate aminosalicylates, consider a time limited course of an oral corticosteroid. [Based on low to moderate quality evidence from randomised controlled trials and the experience and opinion of the GC]

### **Future research**

The following were identified as important questions for future research:

- In a mild to moderate first presentation or inflammatory exacerbation of proctitis that is resistant to standard treatment, what is the effectiveness of topical immunomodulators, such as tacrolimus, in achieving clinical remission and what is the most effective formulation (suppository/ointment)?
- What is the effectiveness of oral tacrolimus and systemic (intramuscular/subcutaneous/oral) methotrexate in the induction of remission in mild to moderate ulcerative colitis unresponsive to aminosalicylates?
- What is the clinical and cost effectiveness of prednisolone, budesonide, and beclometasone in addition to aminosalicylates compared with each other and with aminosalicylate monotherapy for the induction of remission for people with mild to moderate ulcerative colitis?

### How patients were involved in creation of this guidance

Committee members involved in this guideline update included lay members who contributed to the formulation of the recommendations summarised here.

### Guidelines into practice

- Are all people in your care with left sided ulcerative colitis offered topical therapies where appropriate?
- How many courses of oral corticosteroid do people in your care with ulcerative colitis receive, including those prescribed within primary care and hospital services, and is the dosage, length of treatment course, and tapering appropriate?

#### Methods

The Guideline Committee (GC) comprised a general practitioner (non-specialist chair), a general practitioner with specialist interest in gastroenterology, two gastroenterologists, a paediatric gastroenterologist, two lay members, a pharmacist, a dietitian, a Crohn's and colitis specialist nurse, and two colorectal surgeons. The guideline was developed using standard NICE guideline methodology (2014) (https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf). The GC developed the clinical question, appraised the clinical evidence, and evaluated the cost effectiveness of proposed interventions and management strategies through literature review and economic considerations where possible. Quality ratings of the evidence were based on GRADE methodology (www. gradeworkinggroup.org). These relate to the quality of the available evidence for assessed outcomes rather than the quality of the clinical study. Where standard methods could not be applied, a customised quality assessment was done. Stakeholder consultation was undertaken at the development stage.

The members of the Guideline Committee were Tessa Lewis (chair), Bruce George, Charmian Banks, Janindra Warusavitarne, Jenny Epstein, Joan Gavin, Rachel

Cooney, Richard Harris, Robert Palmer, Sarah Cripps, Sophia Joseph, Themba Mudege.

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Competing interests Jenny Epstein was a member of the NICE guideline committee. The committee's declarations of interests are available on the NICE website (https://www.nice.org.uk/guidance/ng130/history). OA and BL are NICE staff and have no relevant interests to declare.

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