

AGA SECTION

American Gastroenterological Association Institute Guideline on the Management of Crohn's Disease After Surgical Resection



Geoffrey C. Nguyen,¹ Edward V. Loftus Jr.,² Ikuo Hirano,³ Yngve Falck-Ytter,⁴ Siddharth Singh,⁵ Shahnaz Sultan,⁶ and the AGA Institute Clinical Guidelines Committee

¹Mount Sinai Hospital Centre for Inflammatory Bowel Disease, University of Toronto, Toronto, Ontario, Canada;

²Division of Gastroenterology & Hepatology, Mayo Clinic, Rochester, Minnesota; ³Northwestern University School of Medicine, Chicago, Illinois; ⁴Division of Gastroenterology, Case and VA Medical Center, Cleveland, Ohio; ⁵Division of Gastroenterology, University of California San Diego, La Jolla, California; and ⁶Minneapolis VA Health Care System, University of Minnesota, Minneapolis, Minnesota

This article has an accompanying continuing medical education activity, also eligible for MOC credit, on page e18. Learning Objective: Upon completion of this activity, learners will be able to develop an approach to risk stratifying, monitoring and treating Crohn's disease patients following surgery.

This document presents the official recommendations of the American Gastroenterological Association (AGA) on the management of Crohn's disease (CD) after surgical resection. The guideline was developed by the AGA's Clinical Guidelines Committee and approved by the AGA Governing Board. It is accompanied by a technical review that is a compilation of clinical evidence from which these recommendations were formulated.¹

Nearly one-half of patients with CD will require bowel resection within the first 10 years of disease.¹ However, surgery is not curative, and one-fourth of these patients will require at least another bowel resection within 5 years of index surgery.¹ Surgical recurrence is usually preceded by clinical and endoscopic recurrence, which can occur in the neoterminal ileum in as many as 90% of patients within 12 months of surgical resection.¹ Certain clinical features, such as the presence of penetrating disease, cigarette smoking, and multiple prior resections, are risk factors for disease recurrence. The presence and severity of endoscopic recurrence, as measured by the Rutgeerts' score, is a strong predictor of clinical and surgical recurrence. The prevention of postoperative disease recurrence is a high priority given the morbidity associated with clinical and surgical recurrence and the long-term risk of short gut syndrome that may arise from multiple bowel resections.

These guidelines were developed to outline strategies to reduce disease recurrence in patients who have achieved remission following bowel resection. When considering the effectiveness of these strategies, endoscopic and clinical recurrence were deemed primary outcomes. In these guidelines, we define endoscopic recurrence as a Rutgeerts' score of ≥ 2 on ileocolonoscopy. Although the guideline panel acknowledged the importance of surgical recurrence, there were an insufficient number of events in clinical trials to inform this outcome. Therefore, prevention of endoscopic recurrence, a strong surrogate measure of surgical recurrence, was evaluated. These recommendations address the role of postoperative pharmacological

prophylaxis and endoscopic monitoring in patients with an ileocolonic anastomosis who are asymptomatic without macroscopic evidence of CD after surgical resection. They are not applicable to patients with small-bowel anastomoses that are not accessible by colonoscopy, those who have residual disease following surgical resection, or those who already have clinical symptoms related to active CD.

The AGA process for developing clinical practice guidelines follows the standards set by the Institute of Medicine.^{2,3} This process, described in more detail elsewhere, was used in the writing of the technical review and guideline.² The Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework was used to evaluate the certainty of the evidence and grade the strength of recommendations.⁴ Understanding of this guideline will be enhanced by reading relevant portions of the technical review. The guideline panel and the authors of the technical review met face to face on May 24, 2016, to discuss the findings from the technical review. The guideline authors subsequently formulated the recommendations. Although quality of evidence (Table 1) was a key factor in determining the strength of recommendation (Table 2), the panel also considered the balance between benefit and harm of interventions, patients' values and preferences, and resource utilization. The recommendations, quality of evidence and strength of recommendations are summarized in Table 3.

Abbreviations used in this paper: AGA, American Gastroenterological Association; 5-ASA, 5-aminosalicylate; CD, Crohn's disease; CI, confidence interval; GRADE, Grading of Recommendations Assessment, Development and Evaluation; POCER, Postoperative Crohn's Endoscopic Recurrence; RR, relative risk; TNF, tumor necrosis factor.

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Table 1. GRADE Definitions of Quality/Certainty of the Evidence

High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Recommendations

1. In patients with surgically induced remission of CD, the AGA suggests early pharmacological prophylaxis over endoscopy-guided pharmacological treatment. Conditional recommendation, very low quality of evidence.

Comments: Patients, particularly those at lower risk of recurrence, who place a higher value on avoiding the small risks of adverse events from pharmacological prophylaxis and a lower value on the potential risk of early disease recurrence may reasonably select endoscopy-guided pharmacological treatment over prophylaxis.

It should be emphasized that there was significant uncertainty in estimating the relative effectiveness of early pharmacological prophylaxis (started within 8 weeks of surgery) over endoscopy-guided treatment, in which patients would be started on therapy only if there was evidence of endoscopic recurrence on colonoscopy performed 6 to 12 months after surgical resection. A single clinical trial of 63 postoperative patients with CD failed to show that early pharmacological prophylaxis with azathioprine compared with endoscopy-guided therapy resulted in nonsignificant reductions in clinical (relative risk [RR], 0.83; 95% confidence interval [CI], 0.46–1.50) or endoscopic recurrence (RR, 0.91; 95% CI, 0.59–1.42). Because there is clinical equipoise as to which strategy is superior, the decision of one approach over the other must be individualized and take into consideration the risk of postoperative recurrence and the patient's values and preferences. Although there is no validated clinical score that predicts recurrence, there are clinical features

such as prior bowel resection, penetrating disease, and cigarette smoking that have been associated with higher risk of recurrence. Based on these clinical risk factors, the technical review panel synthesized 2 illustrative risk groups with corresponding rates of clinical and endoscopic recurrence at 18 months in the absence of any intervention in postsurgical patients with CD (Table 4). The panel favored early pharmacological prophylaxis over endoscopy-guided management because it is likely that the majority of patients who have undergone surgical resection in clinical practice may have one or more risk factors, conferring an increased risk of disease recurrence, as was observed in published clinical studies used to derive these estimates. In those with a lower risk of recurrence, the potential risk of adverse events from medical therapy may outweigh the potential benefits. Patients who share similar characteristics as those in the lower-risk illustrative group may reasonably choose endoscopy-guided pharmacological treatment.

2. In patients with surgically induced remission of CD, the AGA suggests using anti-TNF therapy and/or thiopurines over other agents. Conditional recommendation, moderate quality of evidence.

Comments: Patients at lower risk for disease recurrence or who place a higher value on avoiding the small risk of adverse events of thiopurines and/or anti-TNF treatment and a lower value on a modestly increased risk of disease recurrence may reasonably choose nitroimidazole antibiotics (for 3–12 months).

The selection of anti-tumor necrosis factor (TNF) therapy and/or thiopurines as first-line agents for early pharmacological prophylaxis is based on moderate quality of

Table 2. GRADE Definitions on Strength of Recommendation

	Wording in guideline	For the patient	For the clinician
Strong	"The AGA recommends..."	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	Most individuals should receive the recommended course of action. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.
Conditional	"The AGA suggests..."	The majority of individuals in this situation would want the suggested course of action, but many would not.	Different choices will be appropriate for different patients. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Clinicians should expect to spend more time with patients when working toward a decision.

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