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Position Paper

French national consensus clinical guidelines for the management of ulcerative colitis

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ABSTRACT

Background: Ulcerative colitis (UC) is a chronic inflammatory bowel disease of multifactorial etiology that primarily affects the colonic mucosa. The disease progresses over time, and clinical management guidelines should reflect its dynamic nature. There is limited evidence supporting UC management in specific clinical situations, thus precluding an evidence-based approach.
Aim: To use a formal consensus method – the nominal group technique (NGT) – to develop a clinical practice expert opinion to outline simple algorithms and practices, optimize UC management, and assist clinicians in making treatment decisions.
Methods: The consensus was developed by an expert panel of 37 gastroenterologists from various professional organizations with experience in UC management using the qualitative and iterative NGT, incorporating deliberations based on the European Crohn's and Colitis Organisation recommendations, recent reviews of scientific literature, and pertinent discussion topics developed by a steering committee. Examples of clinical cases for which there are limited evidence-based data from clinical trials were used. Two working groups proposed and voted on treatment algorithms that were then discussed and voted for by the nominal group as a whole, in order to reach a consensus.
Results: A clinical practice guideline covering management of the following clinical situations was developed: (i) moderate and severe UC; (ii) acute severe UC; (iii) pouchitis; (iv) refractory proctitis, in the form of treatment algorithms.
Conclusions: Given the limited available evidence-based data, a formal consensus methodology was used to develop simple treatment guidelines for UC management in different clinical situations that is now accessible via an online application.
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1. Introduction

Inflammatory bowel diseases (IBD), including ulcerative colitis (UC) and Crohn's disease, affects three million people in Europe, including 200,000 in France [1–4]. The annual incidence of UC is 24.3 per 100,000 person-years in Europe, and studies suggest that the incidence and prevalence of IBD are increasing [5]. Ulcerative colitis is a chronic, incurable and debilitating disease with considerable psychosocial implications [6]. It is characterized by chronic inflammation, and alternating states of active disease of varying intensity and symptom-free phases [7,8]. Despite adequate medical therapy, the impact on patient quality of life is important, with 75.6% reporting that symptoms affected their ability to enjoy leisure activities, while 68.9% had symptoms that interfered with their ability to work [6]. The disease affects people of all ages, but patients are usually diagnosed between the ages of 20 and 30 years [9].

Ulcerative colitis management depends on disease activity, its location and individual characteristics, such as the frequency of relapses, disease progression, response to treatment, extra-intestinal manifestations and drug side-effect profile [7,10,11]. Its

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treatment relies on oral or topical salicylates (5-ASA or mesalazine), corticosteroids, immunosuppressants (azathioprine, methotrexate, cyclosporine), anti-TNF alpha agents (infliximab, adalimumab or golimumab), and recently on anti-integrin α4β7 (vedolizumab). Surgery may be needed in case of medical treatment failure and/or occurrence of acute severe colitis, or complications such as toxic megacolon [11–14].

In 2012, the European Crohn's and Colitis Organisation (ECCO) issued recommendations on definitions, diagnosis and current management of UC [14,15]. These recommendations at times do not reflect everyday clinical practice and do not take into account clinical practice. In addition, available evidence-based guidelines are relatively limited in specific clinical situations such as steroid dependency or pouchitis [14–16]. In order to help create a simple therapeutic decision tool that meets the needs of practitioners, a group of French gastroenterologists with significant experience in UC management met to develop algorithms that takes into account international recommendations, clinical practice and new therapies. First-line management of mild to moderate UC was not debated and relies directly on ECCO recommendations. Treatment algorithms for the following clinical situations were discussed: moderate and severe UC, acute severe UC, pouchitis, and refractory proctitis. Because UC management requires multidisciplinary expertise from gastroenterologists, surgeons, and primary care physicians, among others, a simple treatment algorithm tool available as an online downloadable application would help coordinate, standardize, and optimize treatment, justifying the need for these consensus clinical guidelines.

1.1. Definitions

The definitions briefly outlined below were used for the purposes of algorithm development and are those agreed on by the ECCO evidence-based consensus on the diagnosis and management of UC [15].

- *Ulcerative colitis*. According to the ECCO, UC "is a chronic inflammatory condition causing continuous mucosal inflammation of the colon without granulomas on biopsy, affecting the rectum and a variable extent of the colon in continuity, which is characterized by a relapsing and remitting course" [15].
- *Pouchitis* is an inflammation of the ileal pouch created to maintain the intestine-anus continuity after a total colectomy in UC patients. It is the most common long-term complication following a total colectomy and is a chronic disease in many patients [17].
- *Proctitis* describes UC in which colonic inflammation is confined to the rectum (the upper limit of the inflammation does not go beyond the recto-sigmoid junction).
- *Remission* is defined as the complete resolution of symptoms and endoscopic mucosal healing (Mayo score 0 or 1, Table 1). In clinical practice, the ECCO considers that there is remission when the stool frequency is ≤3 bowel movements a day without bleeding or urgency [15].
- *Response* is defined as clinical and endoscopic improvement, depending (for the purpose of clinical trials) on the activity index used [15]. In general, response corresponds to >30% decrease in the Mayo activity index plus a decrease in the rectal bleeding and endoscopy subscores (Table 1).
- *Relapse* is defined as a flare of symptoms in a patient with established UC who is in clinical remission, either spontaneously or after medical treatment. According to the ECCO consensus, relapse is characterized by rectal bleeding, which may be associated with an increase in stool frequency and mucosal abnormalities at sigmoidoscopy [15].

Table 1
Mayo score: UC activity index (excluding proctitis) [23,24].

Criteria	Points
Stool frequency per day (in addition to usual number)	Normal: 0 1–2 stools: 1 3–4 stools: 2 >5 stools: 3
Rectal bleeding	None: 0 Visible blood with stools less than half the time: 1 Obvious bleeding in most cases: 2 Passing blood alone: 3
Endoscopic mucosal observation	Normal or inactive disease: 0 Mild colitis (erythema, mild friability, dry mucosa): 1 Moderate colitis (visible erythema, moderate friability, no vascular pattern): 2 Severe colitis (ulceration, spontaneous bleeding): 3
Physician's global assessment	Normal: 0 Mild: 1 Moderate: 2 Severe: 3
Mild UC	2–5 points
Moderate to severe UC	>6 points

- *Steroid-refractory colitis* describes patients with active disease despite receiving up to 0.75 mg/kg/day of prednisolone over a period of four weeks [15].
- *Steroid-dependent colitis* describes patients who are either (i) unable to reduce steroids below the equivalent of 10 mg/day prednisolone within three months of starting steroid treatment, without recurrent active disease or (ii) who relapse within three months of stopping steroids [15].
- *Immunomodulator-refractory colitis* describes patients who have active disease or relapse in spite of thiopurines at an appropriate dose for at least 3 months (i.e. azathioprine 2.0–2.5 mg/kg/day or mercaptopurine 0.75–1.0 mg/kg/day in the absence of leucopenia) [15].

2. Methodology

The nominal group technique (NGT) was chosen as a formal consensus development method. This methodology combines quantitative and qualitative data collection in a group setting, circumvents issues of group dynamics, and encourages idea generation and problem solving in a structured and balanced group process [18,19]. The NGT is recognized by the French Health Authorities (HAS) and has been used to develop clinical treatment guidelines for a number of conditions [20,21]. The nominal group charged with developing the present expert opinion consisted of 37 gastroenterologists with experience in UC treatment. During the preparatory phase (December 2014 to March 2015), the steering committee (L. Peyrin-Biroulet, Y. Bouhnik, and X. Roblin) conducted a literature review, defined the discussion topics submitted to the nominal group, and proposed treatment algorithm backbones. The nominal group of 37 gastroenterologists met on 8 April 2015 and represented three French professional associations (Association nationale des hépato-gastroentérologues des hôpitaux généraux [ANGH], le Club de réflexion des cabinets et groupes d'hépato-gastroentérologie [CREGG] and the Groupe d'étude thérapeutique des affections inflammatoires du tube digestif [GETAID]). Members of these main IBD Scientific Societies in France were invited by mail to participate in the group. Recruitment of experts in the nominal group was exhaustive for GETAID members (IBD specialists), while for ANGH and CREGG professional associations, only IBD specialists were identified and recruited. Their presence was based on availability at the time of the nominal group meeting. The three coordinators representing these societies and tasked with working group moderation were: H. Hagège (ANGH), G. Bonnaud (CREGG), and X. Hébuterne (GETAID). Two working groups addressed

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