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Alimentary Tract

### Implementation of the French national consensus for the management of ulcerative colitis into clinical practice

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#### ABSTRACT

**Background:** Recently, treatment algorithms were developed in France additionally to ECCO recommendations that should be used as reference for ulcerative colitis (UC) management. Nevertheless, their implementation in clinical practice remains challenging.

**Aims:** To evaluate the prevalence of the use of these UC management algorithms in 127 patients followed by private gastroenterologists.

**Methods:** Charts of all UC patients seen during the year 2015 (n = 127) by 10 gastroenterologists were reviewed. The gastroenterologist's management was then compared to the corresponding algorithm situation and, in case of disagreement, analysed by an expert committee.

**Results:** 94.5% of patients corresponded to a clinical situation described in algorithms. Gastroenterologist's management was adequate to the corresponding algorithm situation in 74.2% of cases. Among the 31 cases of disagreement, the gastroenterologist's decision differed from the algorithm position in 21 cases, and in 76.2% of cases the expert committee would have made the same decision. In the remaining 10 cases, the decision differed from the corresponding algorithm for reasons independent from the gastroenterologist (patient's choice etc.).

**Conclusions:** French national algorithms for UC management allowed coverage of 95% of clinical cases in real world. In three quarters of cases, these algorithms were strictly followed by private gastroenterologists. Dissemination of these algorithms could optimize and strengthen the practitioner's choice.

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#### 1. Introduction

Ulcerative colitis (UC) is the most common inflammatory bowel disease (IBD) [1,2], characterised by an alternation of phases of activity of varying intensity and symptom-free phases. Its management is complex because the characteristics of the disease vary in display, evolution, and response to drugs [1,3].

In 2012, the European Crohn's and Colitis Organisation (ECCO) issued recommendations [4,5] complementary to those of 2008 that accurately validate the use of oral or topical salicylates (5-

aminosalicylic acid [5-ASA] or mesalamine), as well as oral or topical corticosteroids. The ECCO 2012 recommendations focus on management of the attacks and maintenance treatment on ASA, and include the most actual clinical practices in ulcerative colitis (UC). The therapeutic roles of immunosuppressants (azathioprine, methotrexate, and cyclosporine) and anti-tumor necrosis factor alpha (TNF $\alpha$ ) (infliximab, adalimumab, or golimumab) are less consensual however, mainly because indications for these newer compounds are currently being investigated. Thus, in 2015, a French national consensus of clinical guidelines for the management of UC led to publish algorithms called "algorithmICI" [6,7] that take international recommendations, current practice, and new therapies into consideration. In this consensus, first line management of mild to moderate UC and proctitis was not reviewed,

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and the ECCO 2012 recommendations were followed. On the other hand, treatment of moderate to severe UC (excluding proctitis), acute severe UC requiring hospitalisation, refractory proctitis, and pouchitis were actively discussed.

The aim of this study was to evaluate the prevalence of the management algorithms in a private cohort of UC practitioners in 2015, and the actual quality of medical care provided by the gastroenterologists of the study as compared to standards.

## 2. Methods

In order to evaluate the use of UC management algorithms by private physicians, 10 gastroenterologists specialised in IBD management were identified. All participating physicians have over 5 years of experience in the management of IBD (range, 5–35 years) and they follow a mean of 24.4 IBD patients/year (range, 6–102). They all work in private hospitals with an emergency unit and an inpatient care unit. None of them work in a Teaching Hospital or in an IBD unit. Their competences were evaluated based on their participation in at least two IBD-related courses (continuing medical education, CME) annually for the past 3 years.

127 patients diagnosed with UC seen in 2015 were included in the cohort. The French healthcare system offers patients relatively easy access to specialist care (in this case, gastroenterologists). The vast majority of patients were referred by general practitioners.

As a chronic disease, UC treatment is 100% reimbursed in the French healthcare system in accordance with the conditions applied in France.

Data from consultations were standardised and entered in real time using EasyMICI software (IBD electronic Health Record) over the course of year 2015. Following the decision of the data review, the database was locked.

The definitions of clinical situations are described in [Appendix A](#), they follow the ECCO 2012 recommendations and the International Organisation for the Study of Inflammatory Bowel Diseases/Selection of the Therapeutic Target in Inflammatory Bowel Disease (IOIBD/STRIDE) 2015 [4,5,8].

From those definitions, each patient was matched with a clinical situation described either by simple algorithms based on ECCO recommendations 5A, 5B, 5C, 6B, 6D and 6E, or by the “algorithmMICI” [6,7] published in 2016.

Recently we published the French national consensus on the management of UC [6,7], based on literature data and adapted to patient management practices in France. Five clinical situations were discussed during this consensus and led to the development of algorithms: relapse of moderate UC on 5-ASA maintenance treatment, severe UC, severe acute UC requiring hospitalization, refractory proctitis and pouchitis. For mild to moderate UC, ECCO recommendations 5A, 5B, 5C, 6B, 6D and 6E on 5-ASA and corticosteroids as induction and maintenance treatment were used as reference, as these clinical situations were not addressed by the French national consensus.

Patient data were classified into six groups:

- Group 0: patient situation did not match any algorithms;
- Group 1: patient situation matched with the initial and maintenance treatment of UC with 5-ASA and corticosteroids algorithm (“ECCO algorithm”);
- Group 2: patient situation matched with moderate to severe UC algorithm (algorithmMICI);
- Group 3: patient situation matched with severe acute UC requiring hospitalisation algorithm (algorithmMICI);
- Group 4: patient situation matched with refractory proctitis algorithm (algorithmMICI);

**Table 1**  
Distribution of 127 patients according to the algorithms.

Group	N	%
Group 0	7	5.5
Group 1	68	53.5
Group 2	44	34.6
Group 3	3	2.4
Group 4	4	3.2
Group 5	1	0.8
Groups 1–5	120	94.5

Group 0: patient situation did not match any algorithms. Group 1: patient situation matched with “ECCO algorithm”-ECCO statement 5A, 5B, 5C, 6B, 6E [5]. Group 2: patient situation matched with moderate to severe UC algorithm [6,7]. Group 3: patient situation matched with severe acute UC requiring hospitalisation algorithm [6,7]. Group 4: patient situation matched with refractory proctitis algorithm [6,7]. Group 5: patient situation matched with pouchitis algorithm [6,7]. Note: ECCO: European Crohn’s and Colitis Organisation, UC: ulcerative colitis.

- Group 5: patient situation matched with pouchitis algorithm (algorithmMICI)

When a patient situation matched an algorithm – “ECCO algorithm” [5] (Group 1) or one of the “algorithmMICI” [6,7] (Group 2, 3, 4 or 5) – the management of UC elected by the gastroenterologist was compared to the recommended treatment described in the corresponding algorithm.

In case of discrepancy between the gastroenterologist’s practice and the algorithm relevant to the situation, the choice supported by the investigator was classified into three categories:

- 1) Therapeutic choice is different from algorithm (discordant),
- 2) Therapeutic choice is in theoretical agreement with the algorithm but refused by the patient,
- 3) Therapeutic choice is in theoretical agreement with the algorithm but unsuccessful in practice for administrative and/or financial reasons.

Therapeutic choices different from the algorithm, called “discordant”, were analysed by an experts’ committee comprised of three practitioners. The committee labelled discordances as “debatable therapeutic choice”, and either decided to maintain the elected treatment option (with possible request for further information), or proposed a change in therapy if the position was not acceptable.

The independent sample test (Student’s test) was used to compare the results.

## 3. Results

### 3.1. Distribution of patients into clinical situation groups

The distribution of 127 UC patients among the situations described in the algorithms is shown in [Table 1](#). Of the 127 patients, 120 (94.5%) matched one of the algorithms, and for the majority, matched the algorithms based on ECCO recommendations (68/120; 56.7%).

Seven cases (5.5%) did not match any clinical situation described in one of the algorithms ([Table 2](#)). Two of these cases corresponded to an interruption of the maintenance treatment with azathioprine, initiated by the patient or the physician, without any indication of relapse management. Two other cases were either relapse or side effect occurring while on maintenance therapy with azathioprine, which was initially effective. One case involved treatment failure improved by pregnancy. One case described side effects during maintenance treatment with anti-TNF $\alpha$ , in a patient who had presented a prolonged remission. Finally, one case involved a situation of early side effect related to azathioprine.

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