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Predictive factors for an uncomplicated long-term course of Crohn's disease: A retrospective analysis

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Abstract

Background: Predictive factors for a mild course of Crohn's disease (CD) may have therapeutic consequences, but as yet have not been identified.
Aims: To identify baseline factors that predict mild CD and design a predictive scoring system.
Methods: A retrospective, multicenter study of newly diagnosed CD patients allocated to mild CD (no therapy, mesalazine only, or mesalazine with a single initial short course of low-dose prednisone) or moderate CD (all other patients including resected patients).
Results: 162 patients (median follow-up 43 months) were analyzed: 47 mild CD and 115 moderate CD. For mild CD versus moderate CD, mean age at first diagnosis was higher (41.1 versus 33.9 years, $p=0.02$), mean C-reactive protein (CRP) concentration was lower (1.6 versus 3.6 mg/L, $p<0.01$), and perianal lesions were less frequent (0% versus 10.4%, $p=0.02$). The combined incidence of complications (stenosis, any type of fistula, extraintestinal complications or fever) was 21.3% in mild CD versus 35.7% in moderate CD ($p=0.07$). A scoring system based on age, CRP, endoscopic severity (adapted Rutgeert's score), perianal lesions and combined incidence of complications was developed which can predict a mild prognosis at the initial diagnosis, giving patients the chance of simplified therapy and accelerated step-up in the event of treatment failure.

Abbreviations: CD, Crohn's Disease; CDAI, Crohn's Disease Activity Index; CRP, C-reactive protein; ECCO, European Crohn's and Colitis Organisation; NPV, negative predictive value; PPV, positive predictive value; TNF-α, tumor necrosis factor alpha.

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Conclusions: Approximately a third of CD patients experience a mild disease course and require only basic therapy. A possible scoring system to predict mild CD which may avoid overtreatment and unnecessary risks for the patient and costs is suggested.
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1. Introduction

Crohn's disease (CD) shows a highly variable clinical course. While up to a third of patients ultimately require surgery,[1,2] 10–25% experience no recurrence after the initial flare-up.[1–3] A significant proportion of CD patients requires only relatively mild treatment. In one population-based cohort, 57% of patients diagnosed with CD did not require corticosteroid therapy at any stage,[4] while in the recent IBSEN study 28% of patients remained steroid-free.[1] Even following referral to a specialist center, one study reported that corticosteroids were not necessary for 35% of first flare-up.[5] Many centers therefore adopt a 'step-up' approach to the management of CD, whereby less potent, safer therapies are initiated first, escalating treatment only in the event of non-responsiveness. Recent studies of 'top-down' versus 'step-up' therapy have shown conflicting results. A prospective randomized comparison between a step-up regimen with corticosteroids and a top-down strategy starting with infliximab showed favorable results for the top-down approach after six months, but significance was lost after 12 months.[6] A five-year prospective observational study concluded that indiscriminate use of biological therapy ('top-down' strategy) is not appropriate for moderate to severe CD.[7] Indeed, the recent European Crohn's and Colitis Organisation (ECCO) management guidelines[8] point out that for selected patients with mild CD, one option is to start no active treatment. The guidelines also suggest that oral mesalazine can be used as first-line therapy for mildly active ileocaecal CD.[8] A single-center pilot study has reported that 18% of newly-diagnosed CD patients can be brought into remission and maintained successfully on mesalazine alone.[9]

While a top-down approach may have prognostic benefits in selected patients, it exposes all patients to aggressive therapy with its associated risks and cost. Step-up treatment, the alternative strategy, can avoid these burdens in patients with mild disease. Intensification of treatment in patients who do not respond to first-line therapy enables the management of the course of CD to become more individualized. It would therefore be useful to predict at the time of diagnosis which patients are likely to have an uncomplicated course and are suitable candidates for mesalazine as first-line therapy. Predictive factors for relapse in CD have been extensively researched and proposed markers include young age, smoking, disease location and presence of stricturing disease,[2,5,10,11] increasing severity of mucosal lesions on endoscopy,[12] and laboratory values such as tumor necrosis factor alpha (TNF-α),[13] other cytokines[14,15] and C-reactive protein (CRP).[16] To date, however, potential predictive factors for a mild course of CD have not been evaluated.

Most treatment studies are performed in secondary or tertiary clinical settings. Such referral centers inevitably have a selected patient population that is unrepresentative of the general health care situation. Here, a retrospective study was undertaken to identify baseline factors that predict a mild course of disease in a sequential cohort of patients newly diagnosed with CD at gastroenterology outpatient centers in Germany and to design a scoring system able to predict a mild course of CD.

2. Methods

2.1. Study design

This was a retrospective study. All patients included in the analyses were referred to gastroenterology practices because of gastrointestinal symptoms, and were thus newly diagnosed cases. A total of 14 gastroenterology practices in Germany documented the initial diagnosis and undertook follow up during the period January 2007 to May 2010. The protocol and a patient informed consent form have been submitted for evaluation to a registered ethics committee, who had no legal or ethical concerns regarding the conduct of the study. Only data of patients who agreed to this data collection and source data verification by independent clinical monitors were captured.

2.2. Study recruitment

Private gastroenterology outpatient practices experienced in inflammatory bowel disease (IBD) management were chosen to participate if they agreed to the protocol, had sufficient experience with IBD and fulfilled the prerequisite of excellent documentation. In addition, all participating centers favored the concept of step-up treatment where possible, depending on disease severity. This concept included administration of mesalazine as a component of first-line treatment for newly diagnosed CD.

Ambulatory patients with a first diagnosis of CD established at the participating gastroenterology practice based on the guidelines of the German Gastroenterological Association (DGVS)[17] were included if they had been treated or observed for at least 12 months by the participating outpatient clinic. Patients who could not be treated as outpatients were excluded.

The proportion of patients who achieved remission and the time to remission was recorded, as well as the proportion of patients in whom step-up therapy was required and what type of therapy was required.

2.3. Data collection

Data were obtained from standard medical records by staff at each center and verified by external monitors. Data capture

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