



Original article

Evaluation of the concordance between biological markers and clinical activity in inflammatory bowel disease[☆]

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ABSTRACT

Background and objectives: Endoscopy is the gold standard to assess disease severity in inflammatory bowel disease, although it is an invasive procedure. Clinical activity and biological markers have been routinely used to determine disease activity in a non-invasive manner. The aim of this study was to determine concordance between common biological markers (C reactive protein, orosomucoid, erythrocyte sedimentation rate, fibrinogen, platelets, leukocytes, neutrophils and haemoglobin) and clinical activity in inflammatory bowel disease.

Patients and method: Consecutive patients with inflammatory bowel disease were included. Clinical activity was evaluated according to the Harvey–Bradshaw index in Crohn's disease and to the partial Mayo score in ulcerative colitis. Serum concentrations of the different biomarkers were analysed. Concordance between clinical activity and elevation of the serological biomarkers was determined using the kappa statistic.

Results: In total, 350 patients were included (median age 46 years, Crohn's disease 59%). Eleven percent of patients had clinical activity. Crohn's disease patients had mild clinical activity in 44% of cases, moderate disease in 44% and only 12% of patients had severe clinical activity. In ulcerative colitis, patients had mild, moderate and severe clinical activity in 50%, 42% and 8% of cases, respectively. None of the biomarkers included had an acceptable concordance with clinical activity (kappa statistic ≤ 0.30).

Conclusions: Concordance between serological biomarkers and clinical activity in inflammatory bowel disease is remarkably low.

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Concordancia entre la actividad clínica y los marcadores biológicos en la enfermedad inflamatoria intestinal

RESUMEN

Palabras clave:

Enfermedad de Crohn

Colitis ulcerosa

Marcadores biológicos

Actividad clínica

Proteína C reactiva

Fundamento y objetivos: La ileocolonoscopia es el patrón oro para determinar el grado de actividad de la enfermedad inflamatoria intestinal. Sin embargo, es una técnica invasiva. La actividad clínica y los marcadores biológicos se han empleado como indicadores indirectos para determinar, de forma no invasiva, el grado de actividad inflamatoria. El objetivo de este estudio fue determinar la concordancia entre los marcadores biológicos séricos más utilizados (proteína C reactiva, orosomucoide, velocidad de sedimentación globular, fibrinógeno, plaquetas, leucocitos, neutrófilos, hemoglobina) y la actividad clínica de la enfermedad inflamatoria intestinal.

Pacientes y método: Se incluyeron prospectivamente pacientes consecutivos en los que se evaluó la actividad clínica medida mediante el índice de Harvey–Bradshaw en la enfermedad de Crohn, y mediante el índice de Mayo parcial en la colitis ulcerosa. Se cuantificaron los valores de los diversos marcadores biológicos. Se determinó la concordancia de la actividad clínica con la elevación de los marcadores biológicos mediante el estadístico kappa.

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Resultados: Se incluyeron 350 pacientes (edad media 46 años, enfermedad de Crohn 59%). El 11% presentaba actividad clínica. De los pacientes con enfermedad de Crohn, el 44% tenía un brote leve, un 44% un brote moderado y un 12% un brote grave. Los pacientes con colitis ulcerosa presentaban actividad leve, moderada y grave en un 50, 42 y 8% de los casos, respectivamente. Ninguno de los marcadores biológicos estudiados se correlacionó aceptablemente con la actividad clínica (índices kappa $\leq 0,30$ en todos los casos).

Conclusiones: La concordancia de los marcadores biológicos con la actividad clínica de la enfermedad inflamatoria intestinal es notablemente baja.

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Introduction

Both Crohn's disease (CD) and ulcerative colitis (UC) present a series of non-specific symptoms affecting mainly the gastrointestinal tract, such as abdominal pain or diarrhoea; patients can also have dermatologic, ocular or musculoskeletal manifestations, among others.¹ Such symptoms may or may not be related to the inflammatory bowel disease (IBD), and may become an obstacle in assessing the rate of activity of IBD. The therapeutic decision-making should be based on the presence or absence of bowel inflammation.

Currently, the gold standard to establish the presence of IBD activity are the findings from an ileocolonoscopy.² Unfortunately this is an expensive and invasive technique, with potential risks for the patient and sometimes of limited access. This is the reason why, for many years now, serological biological markers are used as indirect indicators to monitor IBD activity.^{3,4} Most of these markers are non-specific acute phase reactants, which can be elevated in extra-digestive processes; but they have the advantage of being accessible and cheap, and therefore widely used.⁵ However, there are few studies which have simultaneously analyzed the usefulness of these biological markers in a wide population of patients with IBD.

The purpose of our study was to assess the concordance among the different biological markers most widely used in the monitoring of IBD (C-reactive protein [CRP], orosomucoid, erythrocyte sedimentation rate [ESR], fibrinogen, platelets, leukocytes, neutrophils, haemoglobin) and the clinical activity inherent to the disease.

Patients and method

Patients

A prospective and observational study was carried out, including consecutive patients who attended our hospital's IBD Unit from January 2010 through June, 2011. The study was assessed and accepted by our centre's Ethics' Committee. The Montreal classification was used to define the characteristics of CD and the location of UC.

Inclusion criteria

- (1) CD or UC diagnosis (established based on standard clinical, radiological, histological and endoscopic criteria).
- (2) Consecutive patients who attended IBD clinics at our hospital from January 2010 to June 2011.

Exclusion criteria

- (1) Absence of analytical determinations in the review.
- (2) Patient's refusal to participate in the study.

Data collection: clinical activity and biological markers

During the interview of the physician with the patient, the current presence and rate of clinical activity was established, based on the partial Mayo score (PMS) (Table 1) for patients with UC and the Harvey–Bradshaw index (HBI) (Table 2) for patients with CD. Patients had been subject to analytical determinations from 1 to 7 days prior to the consultation, and therefore the clinical and analytical data (CRP, orosomucoid, ESR, fibrinogen, platelets, leukocytes, neutrophils, haemoglobin) were registered prospectively during the interview with the patient. Biological markers were considered altered if they were above the higher limit of normal lab

Table 1

Partial Mayo score to determine clinical activity in patients with ulcerative colitis.

<i>Frequency of bowel movement (subscore from 0 to 3):</i>
0 = regular number of bowel movements of the patient per day
1 = 1–2 more bowel movements than usual per day
2 = 3–4 more bowel movements than usual per day
3 = 5 or more bowel movements than usual per day
<i>Rectal haemorrhage (subscore from 0 to 3):</i>
0 = no blood observed
1 = traces of blood in the faeces less than half of the times
2 = evident blood in the faeces most of the time
3 = only blood comes out
<i>Global assessment by the physician (subscore from 0 to 3):</i>
0 = normal
1 = mild disease
2 = moderate disease
3 = severe disease

Table 2

Harvey–Bradshaw Index to determine clinical activity in Crohn's disease.

<i>General condition</i>
Very good = 0
Regular = 1
Bad = 2
Very bad = 3
"Terrible" = 4
<i>Abdominal pain</i>
No = 0
Light = 1
Moderate = 2
Intense = 3
<i>Number of liquid stools per day</i>
One point for each liquid stool
<i>Abdominal mass</i>
No = 0
Doubtful = 1
Defined = 2
Defined and painful = 3
<i>Other related symptoms (one point for each complication)</i>
Arthritis
Uveitis
Erythema nodosum/pyoderma/mouth aphthous ulcers
Fistula/fissure/perianal abscess
Other fistulas

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