Methods: A questionnaire about disease (type, localization, diagnosis, treatment and surveillance) was distributed to IBD patients who attended outpatient gastroenterology clinic at our Hospital. The answers were categorized as appropriate or inappropriate. Demographic data, education level and features of the disease were recorded.

Results: 73 patients were included (41 females) with a mean age of 44 years-old and a mean duration of IBD of 9.4 years. There were 42 patients with Ulcerative Colitis, 29 with Crohn’s disease and 2 with unclassified IBD. The mean of appropriate answers was 53.6%. The type of IBD was correctly marked in 86% of patients whereas the specific localization of the disease was recognized in only 27%. 95% of the responders considered colonoscopy important in diagnosis. Only 55% of the patients were aware of the increased risk of bowel cancer. A better performance in the questionnaire was associated with: younger patients at diagnosis ($r = -0.593; p = 0.000$) and at the time of the questionnaire ($r = -0.451; p = 0.000$), a higher education level ($F = 5.976; p = 0.001$), presence of Crohn’s Disease (65% versus 46%, $F = 6.990; p = 0.000$), previous hospitalization (60% versus 42%, $t = 4.197; p = 0.000$) or surgery related to the disease (66% vs 51%, $t = 2.401; p = 0.019$) and multiple past medications (including 2 anti-tumor necrosis factor therapy) ($F = 4.194; p = 0.000$).

Conclusions: The age, the educational level of the patient and the severity of the disease requiring hospitalization, surgery or aggressive therapy, were associated with a better knowledge of the disease. The low percentage (marginally positive) of appropriate responses highlights the need for better educational strategies.

P516 Discrepancy between fecal biomarkers and their intestinal gene expression in ulcerative colitis: Results from an anti-IL-13 antibody study

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Background: IMA-638 is a humanized antibody that binds and inhibits human interleukin 13 (IL-13). Elevated levels of IL-13 transcripts have been found in rectal biopsies of ulcerative colitis (UC) patients and lamina propria mononuclear cells (LPMC) from UC patients secrete high titers of IL-13 upon re-stimulation in vitro. In this study, we explored fecal calprotectin (FC), lactoferrin, and YKL-40 as non-invasive biomarkers for the evaluation of IMA-638 efficacy in UC. All three proteins are abundant in neutrophils and monocytes and are elevated in the stools of patients with UC.

Methods: This was a double blind, placebo-controlled study with a randomization of active UC q.i.d. with active UC (Mayo Score 4-10) randomized to receive IMA-638 at one of 3 doses levels (200 mg, 400 mg, 600 mg) or placebo (P). The primary endpoint was fold change from baseline in FC at week 14 measured (200 mg, 400 mg, 600 mg) or placebo (P). The primary endpoint was fold change from baseline in FC at week 14 measured using a highly sensitive ELISA (Buhlmann Labs). Fecal lactoferrin and YKL-40 were measured using independent ELISAs (Techlab; R&D Systems) from the same homogenized stool samples. The expression of genes encoding calprotectin (S100A8, S100A9) and YKL-40 (CHI3L1) were measured on TLDAs using RNA expression of genes encoding calprotectin (S100A8, S100A9)

Results: The modified intent to treat population (mITT) included 84 patients with 2 patients/arm. At week 14, the superiority of 200, 400 and 600 mg compared to P in terms of fold change of FC from baseline was not met. This result was supported by a similar lack of effect seen in fecal lactoferrin and YKL-40. The levels of all 3 proteins, at both baseline and week 14, were well correlated to each other. FC and YKL-40 proteins measured in the stool, however, did not correlate with expression of their respective genes in inflamed colon biopsies. The expression levels of S100A8, S100A9, and CHI3L1 were increased in inflamed compared to non-inflamed biopsies, but did not change with treatment. No evidence of safety and tolerability concerns were noted and only a numerical trend was observed in the efficacy parameters measured by the Mayo score for the 200 and 400 mg doses but not for the 600 mg dose. Lastly, a statistically significant correlation was observed between FC and Total Mayo Score ($p = 0.038$).

Figure: Spearman correlations between (A) FC (x-axis) and fecal lactoferrin (left) or YKL-40 (right) proteins and (B) FC and YKL-40 proteins and corresponding genes.

Conclusions: This study was unable to confirm the effect of IMA-638 after 14 weeks of treatment in patients with UC using FC as a primary endpoint. This study, however, does not rule out the use of fecal proteins in future studies as biomarkers of efficacy in UC.

P517 Discrepancy between efficiency and effectiveness of biological therapy in inflammatory bowel disease: EFFECT study

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Background: Randomized controlled trials (RCTs) provide the best scientific evidence for the efficacy of biological drug in the treatment of inflammatory bowel disease (IBD) in selected conditions. In contrast, observational studies provide the biological drug effectiveness in real clinical practice (CP). We aimed to compare the theoretical efficiency of biological drugs (RCTs conditions) in IBD patients with their effectiveness in PC and to assess factors impacting this discrepancy.

Methods: We performed a retrospective multicenter cohort study of adult patients with Crohn’s disease (CD) and ulcerative colitis (UC) treated with anti-TNF agents and followed-up for at least 1 year, randomly selected from five Spanish tertiary centers (EFFECT cohort). Patients who met the RTCs selection criteria were included for the analysis. Outcomes of biological therapy in CP were compared with those hypothetically obtained if the patient would be included in RTCs.

Results: One hundred seventy-one patients of 378 (130 CD and 41CU) were included. The overall clinical benefit at one year was higher in CP than hypothetical RCTs (68.4% vs. 44.4%, $p = 0.001$). The percentages of clinical remission and response in CD patients were 50.8% and 19.2% in the CP,
compared to 42.3% and 6.9% in RCTs condition (p < 0.001). For UC, 51.2% of patient achieved clinical remission in CP compared to 29.3% in RCTs condition (p < 0.001). 35% of patients with clinical benefit in CP would be considered failure if they have been included in RCTs. The most frequent reasons for discrepancy between CP and RCTs results were the need of drug intensification (75.6%), short steroid therapy (12.2%) and delay in drug administration (4.9%).

Conclusions: The effectiveness of biological drugs in clinical practice exceeds their efficacy in IBD patients.

P518
Discordance among patients and parents regarding the perceived source of symptom relapse in young inflammatory bowel disease patients

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Background: Inflammatory bowel disease (IBD) is an idiopathic, chronic inflammation of large and small bowel characterized by episode of relapse and remission. The relapse is not predictable although several factors have been suggested. The aims of the present study were to assess and compare the possible causes of the symptom relapse in patients and parents aspect.

Methods: Among 107 young IBD patients under 35 years, 26 patients who experienced recent (<3 months) relapse filled up the questionnaire with their parents at the same time. The baseline characteristics and clinical manifestation were reviewed. We also assess the most commonly perceived causes of the relapse and compared among the patients and parents.

Results: The median age of the patients was 22.5 ± 4.71 years and male to female ratio was 17:9. Crohn’s disease was diagnosed in 23 patients and the other 3 patients were ulcerative colitis and mean disease duration was 39.8 ± 30.3 months. 69.2% of the patients felt stress before relapse and 42.3% of the patients showed non-adherence to their maintenance treatment. In case of parents, 57.7% thought that there was stress to their offspring before relapse. 42.3% of the parents thought that their children were not adherent to medication. Non-adherence to medication showed 100% and stress 73.1% agreement between patients and parents, Stress was considered as the most common possible main causes of the relapse in both. The agreement rate in main cause of relapse among them was 57.7%.

Conclusions: Stress was most commonly noted before symptom relapse in young IBD patients. Both patients and parents considered it as the main cause of the relapse, however, discordance rate between patients and parents was 42.3%. This result suggested that there might be a considerable difference in the understanding of the disease and between young IBD patients and parents.

P519
Direct retrospective comparison of adalimumab and infliximab in preventing early postoperative endoscopic recurrence after ileocolonic resection for Crohn’s disease: results from the MULTIPER database

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Background: Adalimumab (ADA) and Infliximab (IFX) both seem to reduce the rates of early postoperative endoscopic recurrence (EPER) after ileocolonic resections in Crohn’s disease (CD) patients, in comparison with conventional therapy. There is lack of data with direct comparison between the two agents in the postoperative prevention of recurrence scenario. The aim of this study was to compare the rates of EPER in patients treated with ADA and IFX after ileocolonic resections for CD.

Methods: The MULTIPER (Multicenter International Postoperative Endoscopic Recurrence) database is a retrospective analysis of EPER rates in CD patients after ileocolonic resection, from 7 referral centres from 3 different countries. All consecutive patients submitted to ileocolonic resections between 2008 and 2012 that had colonoscopies performed up to 12 months after surgery were included in the analysis. Patients with conventional therapy after surgery were excluded. Recurrence was defined as Rutgeert’s score equal or greater than i2. The patients under postoperative biological therapy were allocated, according to treatment, in two groups: ADA and IFX. The EPER rates were compared between the two groups. Statistical analysis was performed by Fischer and chi-square tests (qualitative variables), and by Student’s t test and Mann-Whitney test (quantitative variables), with p < 0.05 considered significant.

Results: Initially, 231 patients were analyzed (63 excluded, for missing data and for having the first postoperative colonoscopy longer than 12 months). From the 168 patients included in the database, 96 used anti-TNF agents after resection (37 in the ADA and 59 on the IFX group) and were included in this comparative study. The groups were completely homogeneous in all baseline characteristics, mainly age (p = 0.282), gender (p = 0.521), previous resections (p = 0.392), perianal CD (p = 0.262) and mono or combination therapy (p = 0.521). EPER was identified in 9/37 (24.32%) in the ADA group versus 16/59 (27.12%) in the IFX group (p = 0.815).

Conclusions: In this retrospective direct comparison between ADA and IFX therapy after ileocolonic resections, from an international multicenter database, there was no significant difference between the two anti-TNF agents in terms of EPER rates. Prospective randomized studies are needed to confirm these data and better define the role of each agent in the prevention of PER.