of psoriasis), and 10 (8%), including 7 women, a RPM (all with severe and disabling polyarthralgia). Median ITL were 5.87 (range: 0.52–19.53) μg/mL in patients with CPM and 5.12 (0.00–49.12) μg/mL in those without (P = 0.560), and 1.9 (0.00–13.5) μg/mL in patients with RPM and 5.57 (0.00–49.12) μg/mL in those without (P = 0.058). ATI have been detected in 16 (13%) patients, including 3 with RPM (P = 0.128) and none with CPM (P = 0.605). In multivariate analysis, no predictive factor associated with CPM could be identified and, the sole factor associated with RPM was anti-nuclear antibodies >1/100 at inclusion.

Conclusions: ITL and ATI levels were similar in patients developing IFX paradoxical manifestations. As suggested by elevated antinuclear antibodies, RPM could be related to an autoimmune disorder induced by IFX.

P262
Patients with refractory pouchitis receiving adalimumab may avoid permanent ileostomy
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Background: A substantial proportion of patients with ulcerative colitis (UC) undergoing proctocolectomy with ileal pouch-anal anastomosis (IPAA) develop debilitating complications of the pouch. Since clinical evidence for the use of adalimumab (ADA) in patients with refractory pouchitis is limited, we evaluated the efficacy of ADA in our tertiary referral centre.

Methods: Since May 2008, 8 IPAA patients (3 female, median age 40 years) received treatment with ADA (induction 160/80 mg, maintenance 40 mg every other week) for chronic refractory pouchitis. Short-term clinical response was evaluated at week 10 and was defined as complete in case of cessation of diarrhoea, urgency, incontinence, blood loss and abdominal pain, and as partial in case of marked clinical improvement, but persisting symptoms. The modified pouchitis disease activity index (mPDAI) was calculated available. All patients had undergone IPAA for intractable UC and developed pouchitis and chronic refractory pouchitis after a median (IQR) of 0.9 (0.7–2.0) and 3.6 (2.6–4.1) years, respectively. Three patients also developed a pouch fistula, 6 pre-pouch ileitis and 2 cuffitis. In none of the patients the diagnosis was changed to Crohn’s disease after revision of the colectomy specimen by a senior pathologist.

Results: Prior to ADA, all 8 patients had been treated with antibiotics and infliximab (IFX), 2 with mesalazine, 7 with corticosteroids and 4 with immunomodulatory agents. Four patients – who all had received IFX prior to surgery – had to stop IFX after development of severe infusion reactions. The 4 other patients lost response after a median (range) of 17 (11–39) months on maintenance IFX. After 10 weeks on ADA therapy, 7/8 patients showed clinical response (5 partial and 2 complete). Median (IQR) C-reactive protein levels dropped from 12 (5–44) to 5 (1–7) mg/L (p = 0.063) and median (IQR) mPDAI dropped from 9 (9–10) to 4 (4–9) points (p = 0.102). After a median (IQR) follow-up of 13 (7–32) months, 2 patients had a sustained clinical response, while 6 needed dose escalation to ADA 40 mg every week. At the end of follow-up, six patients were clinically still benefitting from ADA therapy. Two needed pouchectomy with permanent ileostomy after 8 and 15 months, respectively. One patient developed a catheter sepsis under ADA therapy.

Conclusions: ADA may be effective in IPAA patients with refractory pouchitis facing permanent ileostomy, but more data are required to conclude on its more generalised use.

P263
Elaboration and validation of a questionnaire to evaluate patients satisfaction with healthcare services: CACHE questionnaire
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Background: The quality of life of patients with inflammatory bowel disease (IBD) is often considered in the centres in which they are treated. However, there is no tool to evaluate satisfaction of these patients with healthcare services. The aim of this study was to design and validate a questionnaire focused on evaluation of the IBD patient’s satisfaction with healthcare services.

Methods: The CACHE questionnaire was developed in three steps: (i) literature review identifying a list of 37 items, (ii) focus group meeting with 5 experts to define the items and structure of the questionnaire, (iii) edition of the questionnaire and administration to a sample of 20 patients to evaluate their understanding of the items. The final version of the questionnaire (31 items) was used in the validation. An epidemiological, prospective, naturalistic, multicentre study (35 gastroenterologists) of adult patients with Crohn’s (CD) or Ulcerative Colitis (UC) was performed. All patients were controlled in hospital, had a disease evolution >1 year and were in treatment. Each patient had 3 visits (baseline, 2 months and 4–6 months).

Results: The study included 327 patients (171 CD and 156 UC). Slightly more patients were men (53%). The mean (SD) age was 41 (13) years. Ninety one percent of patients answered all items on the questionnaire at the baseline visit. CACHE questionnaire consists in 31 items distributed in six dimensions (healthcare staff attention, doctor attention, facilities, information, accessibility to the centre and received support) which explained the 56% of the information variability. Results are scored in a scale from 0 (minimum satisfaction) to 100 (maximum satisfaction). Four percent of patients showed maximum satisfaction (100), and none reported no satisfaction. The mean overall score was 82 (11). The overall score did not correlate with clinical variables, but correlated with the waiting time in the consultation. The CACHE questionnaire showed good internal consistency (0.925). No statistically significant changes in the overall score of CACHE questionnaire between visits were shown. The effect size was 0.016.

Conclusions: The CACHE questionnaire has been shown to be a valid and reliable tool to measure the satisfaction of IBD patients with health care services. The results obtained from the validation process indicated that CACHE is a useful tool for use both in routine clinical practice and clinical studies.

P264
Cytokine ratios in Crohn’s disease clinical remission before and after the intake of a probiotic
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Background: There are only several studies discussing changes in a cytokine ratio in Crohn’s disease (CD) and they are all focused on the ratio between the anti-inflammatory IL-1 receptor antagonist and the pro-inflammatory IL-1-beta (IL-1ra/IL-1-beta ratio). We could not find any reports discussing changes in cytokine ratios modified by probiotics in CD clinical remission. The aim of our study was to investigate the changes and the correlations between the ratios of the anti-inflammatory IL-10, IL-13 and the pro-inflammatory IL-8, IL-12 and IFN-gamma in CD clinical remission before and after the intake of a probiotic.
Methods: The study included 15 patients with CD (3 men, 12 women, mean age 43.1±11, 22-59 years) in clinical remission (CDAI <150) and 15 controls (6 men, 9 women, mean age 37.6±13.6, 25-60 years). All subjects received daily 3.75 billion colony forming units Lactobacillus bulgaricus ATCC 21815 for 28 days. The serum levels of cytokines were measured by ELISA on day 0 and day 28.

Results: Before the probiotic intake we found no significant difference between the cytokine ratios and their correlations in CD and controls (p >0.05). However after the probiotic intake in CD we found a positive correlation between the ratios IL-10/IL-12 and IL-13/IL-8 (R = 0.571; p = 0.028) and it was different than the correlations found in controls – IL-10/IL-12 and IL-13/IFN-gamma (R = 0.525; p = 0.044); IL-13/IL-12 and IL-10/IL-8 (R = 0.575; p = 0.025).

Conclusions: Cytokine ratios are a novel marker of immune reactivity in CD. Our results raise the question whether the differences in cytokine ratios after the probiotic intake may be a result of altered immune reactivity in CD clinical remission.

P265
Work productivity and activity impairment in Spanish Crohn’s disease patients

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Background: Crohn’s disease (CD) is usually diagnosed in early adult life, a peak time of work productivity, and may interfere with the patient’s ability to work and perform daily activities. It often requires hospitalizations and surgery which imply work absences and disability. The relation between CD and the health related quality of life (HRQoL) has been extensively explored, but data about work productivity are scarce. The aim of our study was to determine how CD affects work productivity in a large sample of CD patients in Spain.

Methods: Spanish multicenter, cross-sectional observational study. CD patients were recruited between 2009 and 2010 through the Spanish CD patient association and by gastroenterologists. Patients provided socio-demographic and clinical information. They completed the “Work Productivity and Activity Impairment Questionnaire” (WPAI) and the “Inflammatory Bowel Disease Questionnaire” (IBDQ9) to assess the HRQoL. The “Overall Work Productivity Loss” (OWPL) and “Daily Activities Impairment” (DAI) were measured. Multivariable analysis was performed to correlate clinical, socio-demographics and HRQoL with work productivity.

Results: A total of 1688 patients were recruited: 64% members of a CD association, 51% females, mean age 42.5 years (SD 11.2), 86.8% were diagnosed more than two years before and 19.1% underwent surgery in the previous two years. At the time of the survey, 38.5% reported active symptoms. Most patients were “much” or “enough” concerned about the future evolution of their illness (68.3%). Only a 3.6% were not worried all. 42.7% had felt depressed or discouraged in the last 2 weeks before the interview and psychologists were consulted by 27%. Median rate of the emotional scale was 61.5 (SD 21.6). ES mean score was affected by relapses (57, SD 21.3) vs. 64.5 (SD 21.3) between relapses, and by the knowledge of the illness, ranging from not informed (32, SD 28) to much informed (63, SD 22.7). ES significantly increases the DAI (r = -0.6) and OWPL (r = -0.5). HRQoL was also significantly related with DAI (r = -0.7) and OWPL (r = -0.6).

Conclusions: Relapses and knowledge about the illness are closely related with the ES. Patients would benefit from a good knowledge and control of the illness, leading to a better HRQoL, overall work productivity and daily activities.

P266
Emotional and functional status in Spanish Crohn’s disease patients

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Background: Crohn’s disease (CD) has a negative impact on health related quality of life (HRQoL) and in the emotional status (ES). High levels of psychological distress have been reported in these patients that could be soften with a good social support. The aim of this study was to assess the influence of CD in the ES and HRQoL in a large sample of CD patients.

Methods: Multicenter, cross-sectional observational study. Patients were recruited between 2009 and 2010 through the Spanish CD patient association and by gastroenterologists. Socio-demographic and clinical information were recorded. An “ad hoc” ES scale (including concern about the illness, need of psychological support, and mood alterations) was performed. Total score ranges from 0 to 100, with higher scores reflecting a better status. HRQoL, work productivity and daily activity were assessed with the “Inflammatory Bowel Disease Questionnaire” (IBDQ9) and “Work Productivity and Activity Impairment Questionnaire” (WPAI). Finally, the “Overall Work Productivity Loss” (OWPL) and “Daily Activities Impairment” (DAI) were measured. ANOVA, chi-square and Pearson correlation were used.

Results: 1688 consecutive patients were recruited. 64% members of a CD association, 51% females, mean age 42.5 years (SD 11.2), 86.8% were diagnosed more than two years before and 19.1% underwent surgery in the previous two years. At the time of the survey, 38.5% reported active symptoms. Most patients were “much” or “enough” concerned about the future evolution of their illness (68.3%). Only a 3.6% were not worried all. 42.7% had felt depressed or discouraged in the last 2 weeks before the interview and psychologists were consulted by 27%. Median rate of the emotional scale was 61.5 (SD 21.6). ES mean score was affected by relapses (57, SD 21.3) vs. 64.5 (SD 21.3) between relapses, and by the knowledge of the illness, ranging from not informed (32, SD 28) to much informed (63, SD 22.7). ES significantly increases the DAI (r = -0.6) and OWPL (r = -0.5). HRQoL was also significantly related with DAI (r = -0.7) and OWPL (r = -0.6).

Conclusions: Relapses and knowledge about the illness are closely related with the ES. Patients would benefit from a good knowledge and control of the illness, leading to a better HRQoL, overall work productivity and daily activities.