**P562**

**Comparing the efficacy of once-daily or twice-daily mesalazine dosing in the treatment of left-sided ulcerative colitis versus the overall MOTUS study population**

B. Flourié[1], J. Kuyvenhoven[2], C. Probert[3]*, O. Dewit[4]. *[1]Centre Hospitalo-Universitaire Lyon-Sud, Department of Gastroenterology, Lyon, France, [2]Kennemer Gasthuis, Department of Gastroenterology and Hepatology, Haarlem, Netherlands, [3]University of Liverpool, Liverpool, United Kingdom, [4]UCL Saint Luc, Brussels, Belgium*

**Background:** In the treatment of ulcerative colitis (UC), less frequent dosing of 5-aminosalicylic acid (5-ASA) simplifies treatment and improves compliance. The objective of MOTUS was to show that 4g once-daily (OD) dosing of Pentasa granules is non-inferior to standard 2 g twice-daily (BD) dosing for the induction of remission in active UC. As the majority of patients (pts) with UC experience left-sided disease, the aim of this subanalysis was to compare the efficacy of 5-ASA 4 g OD versus 2 g BD for induction of remission in left-sided UC versus the overall MOTUS study population.
**Methods:** Pts with active mild-to-moderate UC were randomised to receive 5-ASA granules 4 g/day: 2× 2 g OD or 1× 2 g BD. All pts also received 5-ASA enema (1 g/day) for the first 4 weeks. The primary endpoint was clinical and endoscopic remission at week 8 (UC disease activity index [UC-DAI] $\leqslant$1). Secondary endpoints included complete remission at week 8 (clinical and endoscopic remission with UC-DAI = 0) and mucosal healing at week 8 (UC-DAI endoscopic subscore $\leqslant$1). Subgroup analyses of the primary endpoint were carried out by disease location (left-sided disease versus overall study population). Statistical data were based on intent-to-treat analyses. If the lower limit of the 95% confidence interval (CI) was -15-0%, then the OD regimen was declared non-inferior to the BD regimen.
**Results:** 206 pts were enrolled (OD n = 102, BD n = 104). Of the overall population, 83% had left-sided or distal UC and 17% had pancolitis or extensive UC. Pts with left-sided/distal UC comprised 81.4% of the OD arm (n = 82) and 84.6% of the BD arm (n = 86). The primary endpoint of clinical and endoscopic remission at week 8 (UC-DAI $\leqslant$ 1) was achieved by 52.9% and 41.5% of pts with left-sided/distal UC in the OD arm and the BD arm, respectively (lower 95% CI limit −3.7%). These remission rates are comparable to those of the overall study population (OD 52.1%, BD 41.8%). For pts with left-sided/distal UC, non-inferiority was also demonstrated for the secondary endpoints of complete remission (UC-DAI = 0; OD 28.0%, BD 24.4%, lower 95% CI limit −9.9%) and mucosal healing (endoscopic subscore UC-DAI $\leqslant$1; OD 86.6%, BD 68.2%, lower 95% CI limit −5.0%) at week 8.
**Conclusions:** These results show that OD treatment with 5-ASA is at least as effective as BD dosing and has similar efficacy in pts with left-sided UC compared to those in the overall MOTUS trial population with regard to inducing clinical and endoscopic remission.

**P563**

**Clinical response and quality of life in patients with Crohn's disease treated with adalimumab in routine clinical practice**

D. Ceballos[1]*, F. Muñoz[2], C. Saro[3], C. De la Coba[3], M.D. Aguilar[4], P. Lazaro[4]. *[1]Dr. Negrín Hospital, Spain, [2]Hospital de León, León, Spain, [3]Cabueñes Hospital, Spain, [4]TAISS, Madrid, Spain*

**Background:** Several clinical trials have demonstrated the efficacy of adalimumab (ADA) for inducing and maintaining clinical response in patients with Crohn's disease (CD). It would be interesting to know to what extent these results are reproduced in routine clinical practice. The aim of the study was to determine the effectiveness, measured as clinical response using disease activity and quality of life indices, of ADA in CD patients.
**Methods:** Multicentre prospective observational cohort study with follow up of 12 months. Inclusion criteria: Patients with CD naïve to biologics, in which the doctor prescribes ADA according to routine clinical practice. In the medical visit at the beginning of the biologic treatment (V0), sociodemographic variables, Crohn's Disease Activity Index (CDAI), Perianal Disease Activity Index (PDAI), quality of life (QoL) indices [Inflammatory Bowel Disease Questionnaire (IBDQ-9) and EuroQol five dimensions (EQ-5D)] were collected. Such data were again recorded at 1 (V1), 3 (V2), 6 (V3), 9 (V4) and 12 months (V5) later. When the data distribution was normal, the mean ($\pm$SD) were used as statistics. When the data distribution was not normal, the median (Percentil25–percentil75) were used. For hypothesis testing, parametric or nonparametric tests were used according to the data distribution. Differences were considered significant at $p < 0.05$.
**Results:** 126 patients (50.8% men; age 39.1$\pm$13.8 years) from 33 centres were included. The CDAI decreased ($p < 0.05$) at each subsequent visit from V0 to V3, from which the changes were not statistically significant; V0=194 (21–269) vs. V5=48 (10–122) ($p < 0.001$). The PDAI decreased from 4.0 (0.0–4.0) in V0 to 2.0 (0.0–4.0) in V1 ($p < 0.001$), from which the changes were not statistically significant. The quality of life measured by the EQ-5D improved from 0.735 (0.633–0.790) in V0 to 0.790 (0.684–1.000) in V1 ($p < 0.001$), from which the changes were not statistically significant. The IBDQ-9 score increased ($p < 0.001$) from 56.7 (51.6–61.5) in V0 to 64.7 (59.4–72.1) in V1, continuing the significant improvement in V2 (67.5, 60.6–72.1), remaining at similar levels in V5 (66.5, 60.1–73.6).
**Conclusions:** In clinical practice, ADA has proven to be effective with a statistically significant improvement in clinical and quality of life variables. This improvement was observed from the first month of starting treatment, and generally continues improving to 3–6 months, keeping stable until 12 months.

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**Clinical response, quality of life and work activity in patients with Crohn's disease treated with adalimumab in routine clinical practice**

C. Saro[1]*, D. Ceballos[2], F. Muñoz[3], C. De la Coba[1], M.D. Aguilar[4], P. Lazaro[4]. *[1]Cabueñes Hospital, Spain, [2]Dr. Negrín Hospital, Spain, [3]Hospital de León, León, Spain, [4]TAISS, Madrid, Spain*

**Background:** Several clinical trials have demonstrated the efficacy of adalimumab (ADA) for inducing and maintaining clinical response in patients with Crohn's disease (CD). The aim of the study was to determine the effectiveness, measured as clinical response, quality of life (QoL) and work activity, of ADA in CD patients in routine clinical practice.
**Methods:** Multicentre prospective observational cohort study with follow up of 12 months. Inclusion criteria: Patients with CD naïve to biologics, in which the doctor prescribes ADA according to routine clinical practice. In the medical visit at the beginning of the biologic treatment (V0), sociodemographic variables, Crohn's Disease Activity Index (CDAI), Perianal Disease Activity Index (PDAI), quality of life (QoL) indices [Inflammatory Bowel Disease Questionnaire (IBDQ-9) and EuroQol five dimensions (EQ-5D)] and Work Productivity Activity Index (WPAI) were collected. Such data were again recorded 12 months later (V12). When the data distribution was normal, the mean ($\pm$SD) were used as statistics. When the data distribution was not normal, the median (Percentil25–percentil75) were used. For hypothesis testing, parametric or nonparametric tests were used according to the data distribution. Differences were considered significant at $p < 0.05$.
**Results:** 126 patients (50.8% men; age 39.1$\pm$13.8 years; 60.3% active workers) from 33 centres were included. The proportion of patients in remission (CDAI <150) increased from 34.1% in

V0 to 83.0% in V12. The CDAI decreased from 194 (21–269) to 48 (10–122) ($p < 0.001$). The PDAI decreased from 4.0 (0.0–4.0) to 0.0 (0.0–4.0) ($p < 0.001$). The quality of life measured by the EQ-5D improved from 0.735 (0.633–0.790) to 0.797 (0.726–1.000) ($p < 0.001$). The IBDQ-9 score increased ($p < 0.001$) from 56.7 (51.6–61.5) to 66.5 (60.1–73.6) ($p < 0.001$). The work hours lost by the EC in the previous week decreased from 2.0 (0.0–27.0) at V0 to 0.0 (0.0–1.0) at V12 ($p = 0.004$) and the work productivity (0–10 scale) decreased from 3.0 (0.3–5.8) to 1.0 (0.0 to 2.0) ($p = 0.006$).
**Conclusions:** In clinical practice, ADA has proven to be effective with a statistically significant improvement in clinical variables, quality of life, and work productivity.

**P565**
**Clinically significant safety issues during long-term azathioprine use in patients with ulcerative colitis**

K. Katsanos[1]*, V. Tsianos[1], S. Zachariadou[1], I. Vagias[1], S. Liamas[1], A. Tatsioni[2], D. Sigounas[1], I. Mitselos[1], D. Christodoulou[1], E. Tsianos[1], for the NW Greece IBD Study Group. [1]*University of Ioannina, Ioannina, Greece,* [2]*Department of Family Medicine University of Ioanninaand Tufts-New England Medical Center Evidence-Based Practice Center, Institute for Clinical Research and Health Policy Studies, Boston, USA*

**Background:** The aim of the study was to investigate the long-term safety of azathioprine (AZA) in patients with ulcerative colitis (UC).
**Methods:** Tertiary referral center retrospective IBD chart study. In total 443 UC patient files were retrieved for any AZA use during a 30-year period 1981–2010. Patient data included demographics, clinical information on diagnosis and therapy and routine laboratory tests. Diagnosis of UC was based on clinical, endoscopic and histologic criteria. All UC patients who were currently on AZA or who had received AZA in the past were included in statistical analysis.
**Results:** In total 72 UC patients (46 males) aged 47.3 years (range 16–80) were analyzed. Disease location was proctitis in 11 (15.3%), left-sided colitis in 35 (48.6%) and pancolitis in 26 (36.1%). The median follow up time was 7.3 years (range 0.5 to 16 years) and the median dose of AZA was 100 mg/day (range 50–200 mg). Six patients (8.3%) underwent bowel surgery while on AZA. Permanent discontinuation of AZA was decided in 7/72 (9.7%) patients due to bone marrow toxicity (leucopenia or/and anemia) while in 6 (8.3%) patients AZA dose was decreased due to hepatotoxicity. Transient aphthous stomatitis was observed in 2 patients and 1 patient experienced significant but reversible hair fall. Infections were recorded in 17 (23.6%) patients (11/17 microbial) of whom 4 needed hospitalization. No case of allergic pancreatitis was recorded. Two patients (2.8%) were diagnosed with basal cell skin cancers and were treated with local surgery. During follow up 4 deaths (5.6%) unrelated to the use of AZA were recorded.
**Conclusions:** According to this thirty-year observational study on AZA use in UC in total 19/72 (26.3%) patients presented with clinically significant safety issues the most frequent being bone marrow toxicity. Azathioprine permanent discontinuation or dose decrease was needed in 13/72 (18%) of patients and 2 skin cancers (2.8%) were recorded. Hospitalization for infection was needed in 4 (5.5%) patients.

**P566**
**Clinical course of severe colitis; a comparison between Crohn's colitis and ulcerative colitis**

E. Sinagra[1]*, F. Mocciaro[1], A. Scalisi[1], V. Criscuoli[1], A. Orlando[1], M. Olivo[1], M. Giunta[1], M. Cottone[1]. [1]*Ospedali Riuniti Villa Sofia – Cervello, DIBIMIS, Division of Internal Medicine, Palermo, Italy*

**Background:** Few data are available about the clinical course of severe colonic Crohn's disease. Usually, although supporting evidence is limited, severe colitis not responding to the medical treatment should be treated with surgical interventction, because of the risk of perforation or toxic megacolon. The aim is to describe the clinical course of severe Crohn's colitis in a patients cohort with isolated colonic or ileocolonic CD, and to compare it with the clinical course of patients with severe ulcerative colitis (UC).
**Methods:** 34 Patients with severe Crohn's colitis were retrospectively identified in our cohort of 593 hospitalized patients (2003–2012) through the evaluation of Crohn's Disease Activity Index score and Harvey–Bradshaw Index. 169 Patients with severe ulcerative colitis were retrospectively identified in our cohort of 449 hospitalized patients (2003–2012) through the evaluation of Lichtiger score and Truelove–Witts score. We evaluated the following outcomes: response to steroids, response to biologics, acute colectomy rate, colectomy rate during follow-up, megacolon and cytomegalovirus infection rate.
**Results:** We did not find significant differences in the response to steroids and to biologics, in the percentage of cytomegalovirus infection and of megacolon, while the rate of colectomy in acute turned out to be greater in patients with severe Crohn's colitis compared to patients with severe UC, and this difference appeared to be the limit of statistical significance (Chi square 3.31, $p = 0.069$, OR 0.39); the difference between the colectomy rates at the end of follow up was also not significant. In the whole population by univariate analysis, according to the linear regression model, a young age at diagnosis is associated with an increased risk of colectomy in absolute ($p = 0.024$) and in election ($p = 0.022$), but not in acute, as well as an elevated ESR is correlated with an increased risk of colectomy absolute ($p = 0.014$) and in acute ($p = 0.032$), but not in the election. This correlation was significant on multivariate analysis.
**Conclusions:** The overall rate of colectomy in the cohort of patients with severe Crohn's colitis is greater than that of our cohort of patients with severe UC, but this figure is not supported by a different clinical response to steroid therapy or rescue therapy with biologics. The real clinical course of severe Crohn's colitis requires to be clarified by prospective studies that include a larger number of patients in this subgroup of disease.