Background: Golimumab (Simponi) is a TNFα inhibitor approved for patients with ulcerative colitis (UC) since 2013. Pre-clinical work showed superiority to both infliximab and adalimumab in its mechanism of action. Initial trial data showed 51% achieved clinical remission by Week 6 and 47% by Week 54. However, there is no real world data to correlate these findings. We aimed to assess the effectiveness of golimumab in a real world setting.

Methods: A retrospective multi-centre study was conducted between 2014 to date. Data were obtained from five hospitals around the West Midlands, UK. Inclusion criteria included patients with a diagnosis of moderate-to-severe ulcerative colitis (endoscopic Mayo score ≥2). Dosing was weight dependent (≥80 mg = 50 mg 4-weekly; ≥80 mg = 100 mg 4-weekly following an induction dose). Data were collected using patient notes and endoscopy reports. Fisher's exact test was used for statistical significance.

Results: There were a total of 56 patients with a mean age of 39.2 years (M = 39; F = 17). The majority of patients had left sided disease (48%; n = 27) followed by pancolitis (45%; n = 25) and proctitis (7%; n = 4). 64% were on concurrent immunosuppressants. The mean duration of golimumab treatment was 12 months. One patient developed deranged liver function tests on golimumab. They were switched to vedolizumab. Twenty-two patients (39%) showed endoscopic and clinical remission (proctitis n = 3; left sided n = 9; pancolitis n = 10). There was no statistically significant difference between disease extent and remission (p = 1.00). Of these 22 patients, 17 patients were on the higher dose of 100 mg, with a statistical significance between the dosing (p = 0.03). Three patients who were initially on 50 mg and relapsed had their dose increased to 100 mg. They remain in remission. Of the 50% (n = 28) who switched biologic therapy, 23 were to vedolizumab, 1 to infliximab and 4 to adalimumab. Despite changing to vedolizumab, 3 (13%) patients still required surgery. Patients switched to adalimumab and infliximab are currently in remission. In total, 14% (n = 8) required surgery, of which 3 patients had emergency surgery.

Conclusions: Golimumab has not proven as effective in our real world data. Two important inferences were made from this study. Firstly, of those patients that went into remission, 75% were on the higher dose of golimumab. This may be secondary to higher trough levels; however, therapeutic drug monitoring is currently unavailable in the UK for golimumab. Secondly, five patients who were switched to an alternative anti-TNF, where drug monitoring is available, had a good clinical response. This leads us to propose that drug-monitoring is of clinical importance and should be available for golimumab in the UK to help maintain clinical remission.

P621
Faecal calprotectin after the induction of anti-TNF therapy predicts mucosal healing in patients with ulcerative colitis: A prospective single-centre study

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Background: In the last few years, adalimumab (ADA) and golimumab (GOL) have been developed as a therapeutic option for ulcerative colitis (UC). Infliximab (IFX) remains the gold standard therapy for severe UC. Mucosal healing (MH) is emerging as primary goal of anti-TNF therapy in UC. Limited data are known about potential early predictors of MH, especially regarding ADA and GOL.

Methods: A prospective observational study was carried out among the patients with moderate–severe UC who started treatment with IFX, ADA and GOL in monotherapy between January and September 2016 at our centre. The basal therapy with mesalazine was maintained stable during the follow-up period (1 year). Primary non-responder was excluded. Partial Mayo score (PMS), C-reactive protein (CRP) and faecal calprotectin (FC) were assessed before treatment and every 8 weeks during the follow-up. All the patients underwent colonoscopy at baseline and at the end of follow-up or in case of discontinuation of therapy due to loss of response (LOR) or side effects (SE). MH was defined as a Mayo Endoscopic Score ≤1. All the colonoscopies were performed by a single-blinded operator. Clinical remission (PMS <2), a normal CRP value (<0.5 mg/dl), and a value of FC <150 mg/kg (chosen on the basis of previous studies1-2) were evaluated as potential predictors of MH. Statistical analysis was carried out using Fisher’s test for categorical variables.

Results: Forty-seven patients were enrolled, 21 treated with IFX, 12 with ADA, and 14 with GOL. LOR was observed in 18 patients (38%), 3 patients (6%) experienced SE. Twenty-six (55%) patients maintained the therapy until the end of follow-up, 16 of them (62%) showed MH. Overall, 18 of 47 (38%) patients showed MH. A significant correlation between MH and FC <150 mg/kg at Week 8 (p < 0.001) was observed in patients treated with IFX, ADA or GOL evaluated globally, while no correlation was observed between MH and PMS or CRP at the same time point.

Correlation between FC and MH in the totality of patients.

<table>
<thead>
<tr>
<th>FC Week 8 &lt;150 mg/kg</th>
<th>MH+</th>
<th>MH-</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>FC Week 8 ≥150 mg/kg</td>
<td>16</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>FC Week 8 &gt;150 mg/kg</td>
<td>2</td>
<td>21</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Same results are achieved considering only the subcutaneous drugs (ADA and GOL) or IFX singularly. Moreover, MH was correlated with FC levels at Week 6 and at Week 24, while PMS and CRP showed a significant correlation with MH only at Week 24.

Conclusions: Our results showed that an early drop of FC levels is a good predictor of MH at 1 year in UC patients treated with IFX, ADA or GOL. Therefore, FC could be used as a reliable tool for an early optimisation of anti-TNF treatment in UC patients in order to reach the correct therapeutic target.

References

P622
Surgery for severely active ulcerative colitis in the era of new medical treatment: The impacts of medications on surgery avoidance, and short-term and long-term surgical outcomes

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Quality of life as predictor of biological levels decay in inflammatory bowel diseases

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Background: Inflammatory bowel disease (IBD) is characterised by the presence of inflammatory lesions of autoimmune origin in the digestive tract. It has been suggested that a possible predictive factor of treatment response could be the level of anti-TNFα antibodies. The objective of this study was the measurement of the level of adalimumab and infliximab and its relationship with activity indexes and quality of life.

Methods: Prospective observational study that included adult patients with Crohn’s disease (CD) and ulcerative colitis (UC) under active treatment with IFX or ADA in clinical practice. The study protocol was approved by the Dr Negrín Hospital Ethics Committee. The variables analysed were CDAI, Harvey Bradshaw Index, modified Truelove-Witts, Partial Mayo Scoring index, and IBDQ for quality of life.

Results: Ninety-six patients met the inclusion criteria and were enrolled into the study (87, 5% CD; 12, 5% UC). The main reason for the therapeutic indication was luminal disease refractory to immunomodulators (IMM) in 47 (49%) cases, intolerance to IMM in 27 (28, 1%) and 8 patients had had a severe onset (8, 3%). In relation to the drug that was used, 44 patients (45, 8%) were started on IFX while 52 on ADA. Immunosuppressive co-treatment was needed in 26 subjects (27.1%) and in 22 (22.9%) the treatment was intensified. There were not statistically significant differences for the CDAI in the peak of drug level vs. valley p = 0.11, Harvey-Bradshaw score p = 0.35, Truelove-Witts test p = 0.72 and Partial Mayo index p = 0.41. In contrast, concerning the quality of life assessment using the IBDQ, there were statistically significant differences in the total score: at the peak moment 205.50 (IQR 45.50) vs. valley moment 200 (59.50), p = 0.002.

Total IBDQ.

Also in four out of five subscales of the test: bowel symptoms subscale 5.87 (1.44) vs. 5.50 (1.69) p < 0.001; systemic symptoms subscale 5.35 (1.57) vs. 5.28 (1.71) p = 0.023; functional impairment subscale 5.85 (1.86) vs. 5.57 (2.1) p = 0.01; and emotional function 5.62 (2.06) vs. 5.0 (2.3) p = 0.03 for peak and valley moments, respectively.

IBDQ Dimensions.