Background: The mucosa of the anal canal and perianal region in Crohn’s disease (CD) is difficult to cure, it worsens the disease prognosis and the quality of life of patients. Therefore, new approach development is quite important in treatment of perianal CD.

Methods: A prospective randomised study was conducted from April 2014 to May 2016. Fifty-four patients (32 women and 22 men; 30.05 ± 9.5 years) with perianal CD (fistulas and fissures of anal canal) were included in the study. Exclusion criteria were rectovaginal fistulas and strictures of the anal canal. The study group included 32 patients, the control group included 22 patients. Patients of both groups received standard systemic therapy: azathioprine (2 mg/kg/ day). Study group received topical therapy with ointment tacrolimus 1 mg/day, control group received topical therapy with steroid ointment 1 mg/kg and supp. with metronidazol 250 mg/day. All patients received topical therapy over 12 weeks. Examination with determination of perianal Crohn’s disease activity index (PCDAI) and IBDQ was performed at baseline, at Week 12 and after 1 year.

Results: At the baseline PCDAI was 7.44 ± 3.34 in the study group and 6.64 ± 3.16 in the control (p = 0.390). After 12 weeks of treatment, the local examination of patients showed signs of epithelialization of the anal fissure with the statistically significant decrease in the PCDAI (p < 0.05 for both groups), no significant difference was found between groups (p = 0.306): 3.21 ± 1.94 in the study group and 4.41 ± 1.89 in the control. Thus, in both groups the therapy does not have any effect on perianal fistulas. After 1 year of therapy in eight patients of the main group and in two in control recurrence of anal fissures was detected. PCDAI was 4.36 ± 4.03 in the study group and of 5.33 ± 2.24 in the control. When comparing this with the baseline statistical significance persisted in both groups (p = 0.001 and p = 0.003, respectively). However, when comparing between the groups after a year no significant differences obtained (p = 0.621).

When assessing the quality of life questionnaire IBDQ data (p = 0.390). After 12 weeks of treatment, the local examination of patients showed signs of epithelialization of the anal fissure with the statistically significant decrease in the PCDAI (p < 0.05 for both groups), no significant difference was found between groups (p = 0.306): 3.21 ± 1.94 in the study group and 4.41 ± 1.89 in the control. Thus, in both groups the therapy does not have any effect on perianal fistulas. After 1 year of therapy in eight patients of the main group and in two in control recurrence of anal fissures was detected. PCDAI was 4.36 ± 4.03 in the study group and of 5.33 ± 2.24 in the control. When comparing this with the baseline statistical significance persisted in both groups (p = 0.001 and p = 0.003, respectively). However, when comparing between the groups after a year no significant differences obtained (p = 0.621).

When assessing the quality of life questionnaire IBDQ data significantly increased in both groups at Week 12 (p = 0.001 and p < 0.001, respectively) from satisfactory (152.36 ± 33.69 before, 164.73 ± 38.83 after, p = 0.119 in study group and 154.77 ± 14.47 before, 170.38 ± 20.30 after, p = 0.102 in the control) to good (173.06 ± 27.83 and 175.45 ± 20.09, respectively). Between the groups significant differences were not found (p = 0.251 at baseline, p = 0.163 at Week 12 and p = 0.161 after a year).

Conclusions: The use of topical therapy with tacrolimus in patients with anal fissures is effective while receiving the drug. Discontinuation of topical therapy in the treatment of anal fissures lead to it relapse. Topical therapy is ineffective in patients with fistulas.

P560
Granulocyte–monocyte apheresis combination therapy after loss of response to anti-TNF drugs

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Background: Granulocyte-monocyte apheresis (GMA) selectively removes activated leukocytes and some immune mediators, and it is safe and effective in ulcerative colitis (UC). Anti-TNF drugs are also effective in moderate-severe UC but a significant proportion of patients does not respond during the induction phase or lose response over time. The aim of our study was to evaluate the clinical efficacy and safety of the combination of GMA sessions after primary or secondary loss of response to anti-TNF therapy.

Methods: A retrospective, multicentre study was performed in six inflammatory bowel disease (IBD) Units in Spain. We collected data on the disease phenotype, previous medications and past relevant history of the disease. Regarding the GMA therapy the number of sessions, its frequency, filtered blood volume and time of each session were recorded. The efficacy of the treatment was assessed by clinical and analytical parameters 1 and 6 months after finishing the GMA. The need for rescue therapy and colectomy were compiled during the follow-up.

Results: Twenty-seven patients (38 years [IQR 28–48], 63% male, disease duration 47 months [IQR 36–105]) were included. Most of them had a previous diagnosis of UC (93%), 1 of CD and 1 of IBD-U. Fourteen were on infliximab, 10 on adalimumab and 3 on golimumab; 67% under dose/frequency optimisation. GMA was used more frequently after secondary loss of response (74%) and 63% of patients received ≥10 sessions. Fifteen patients (56%) were on their first-line biologic therapy, while 44% have received at least one previous anti-TNF therapy. Partial Mayo score at baseline was 6 (IQR 5–8). Clinical disease activity significantly decreased after 1 month (2 [IQR 1–7]) and 6 months (1.5 [IQR 0–6]), both p < 0.005. Baseline CRP was 2.2 mg/l ([IQR 0.6–8.9], albumin 3.4 g/l [IQR 2.9–4], haemoglobin 11.4 g/dl [IQR 10.8–12.8] and calprotectin 2,239 mg/kg (IQR 1, 189–3, 150). CRP and calprotectin decreased after 1 month (p = 0.5 and 0.008) and 6 months (p = 0.05 and 0.04), respectively. One patient reported adverse events related to the technique (anxiety). Median follow-up was 30.5 months (IQR 11–64). Eight patients (30%) achieved steroid-free remission without anti-TNF intensification, switch of biologic or surgery. Five patients were able to de-escalate therapy. Seven patients (26%) required dose optimisation of the anti-TNF therapy. Nine patients (33%) started a new biologic therapy and three (11%) underwent colectomy during the first-year follow-up.

Conclusions: Combination of GMA and anti-TNF drugs offers a safe and effective alternative after loss of response to biologics, with a significant decrease in the clinical disease activity and biomarkers, in a population with limited therapeutic options.

P561
A comparison of medication adherence and persistence between intravenous biologics and oral small-molecule therapies

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Background: Vedolizumab (VDZ) is approved for IBD as an intravenous (IV) infusion. However, new oral small molecule therapies such as tofacitinib (TOF), indicated for rheumatoid arthritis (RA), are currently being investigated in IBD. We examined adherence and persistence metrics of IV VDZ and oral TOF in RA and IBD. To better characterise the comparison between VDZ and TOF, we also examined infliximab (IFX), an IV biologic indicated for IBD and RA.

Methods: We performed a retrospective cohort study using the Truven Marketscan® database to compare adherence and persistence in adult IBD or RA patients (pts) who initiated VDZ or TOF between 1/1/2015 and 12/31/2015, as well as to IFX. Adherence over 12 months of follow-up was assessed as mean proportion of days covered (PDC) and cumulative days with gap ≥20% beyond the expected interval (CG20). The difference in PDC and CG20 between VDZ and TOF was estimated using multivariable generalised equation models. Persistence was assessed as time to treatment discontinuation over 12 months of follow-up using Kaplan–Meier survival analysis; the proportion of persistent patients was determined using a multivariable logistic regression model.

Results: A total of 457 VDZ/IBD, 901 IFX/IBD, 378 IFX/RA, and 898 TOF/RA patients were analysed. Mean PDC was statistically higher in VDZ/IBD (77.71%) than in TOF/RA (68.22%; \( p < 0.0001 \)) (Table 1). PDC for VDZ/IBD was 4.66% higher than the projected PDC for TOF/IBD (\( p = 0.0376 \)). Mean CG20 was 67.35 in VDZ/IBD and 98.61 in TOF/RA and statistically different (\( p < 0.0001 \)). Mean PDC and CG20 in IFX/RA were significantly higher than in TOF/RA but were similar between VDZ/IBD and IFX/IBD (Table 1). The proportion of persistent patients in VDZ/IBD was significantly higher than in TOF/RA (\( p = 0.0001 \)), and time to discontinuation was significantly shorter in TOF/RA than in VDZ/IBD (\( p = 0.0012 \)) and in IFX/RA (\( p = 0.0044 \)) (Table 1).

Conclusions: Although limited by indirect comparisons, adherence and persistence were consistently higher with VDZ than with TOF. Previous studies have demonstrated that oral IBD therapies may be associated with reduced adherence. The decision to treat with oral therapy may be impacted by lower adherence and its effect on overall efficacy. Acknowledgment: We thank Yaping Wang, Charlie Cao, and Michelle Luo (Takeda Pharmaceuticals USA, Inc.) for help with analyses. This study and medical writing assistance (by Stephanie Agbu, PhD, of inVentiv Medical Communications) were supported by Takeda Pharmaceuticals USA, Inc.

### Table 1. Adherence and persistence over 12 months of follow-up in patients receiving IV or oral therapies for IBD and RA

<table>
<thead>
<tr>
<th></th>
<th>VDZ with IBD(^a) (N=457)</th>
<th>IFX with IBD(^b) (N=901)</th>
<th>IFX with RA (N=378)</th>
<th>TOF with RA (N=898)</th>
<th>P-value</th>
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<tbody>
<tr>
<td><strong>Adherence</strong></td>
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<tr>
<td>PDC(^a), Mean±SD</td>
<td>77.71±24.66</td>
<td>79.61±26.16</td>
<td>74.90±27.38</td>
<td>68.22±27.20</td>
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<tr>
<td>CG20(^a), Mean±SD</td>
<td>67.35±88.09</td>
<td>62.35±93.32</td>
<td>78.54±98.13</td>
<td>98.61±99.91</td>
<td></td>
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<tr>
<td><strong>Persistence</strong></td>
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<tr>
<td>Proportion of persistent patients(^c), n (%)</td>
<td>300 (65.6)</td>
<td>641 (71.7)</td>
<td>242 (64.0)</td>
<td>453 (54.9)</td>
<td></td>
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<tr>
<td>Time to treatment discontinuation (20% percentile)(^d), days (95% CI)</td>
<td>196 (154, 221)</td>
<td>255 (215, 271)</td>
<td>189 (155, 211)</td>
<td>156 (139, 177)</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** CD, Crohn’s disease; CG20, cumulative days with gap ≥20% beyond the expected interval; CI, confidence interval; IBD, inflammatory bowel disease; IFX, infliximab; IV, intravenous; PDC, proportion of days covered; RA, rheumatoid arthritis; SD, standard deviation; TOF, tofacitinib; UC, ulcerative colitis; VDZ, vedolizumab.

\(^a\)IBD indicates either UC or CD.
\(^b\)PDC was calculated by dividing the number of days covered by the medication by 365 and multiplying by 100.
\(^c\)CG20 was determined by calculating the summation of days without coverage that were ≥20% of the previous day supply.
\(^d\)Persistent patients were defined as the proportion of patients who did not discontinue treatment over 12 months of follow-up.

Abstract P561

### P562

Role, efficacy and safety of budesonide multiform in ulcerative colitis in real life: A study in three Italian third-level centres

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Background: First-line therapy of mild–moderate ulcerative colitis (UC) is based usually on mesalamine and, most recently, on low-bioavailable steroids such as Budesonide MMX (BDMMX). Controlled