

**Background:** Vedolizumab (VDZ) inhibits gut lymphocyte trafficking by binding to  $\alpha 4\beta 7$  integrin, which can be effective for patients with Crohn's disease (CD) or ulcerative colitis (UC). We aimed to investigate the clinical outcomes and response predictors of VDZ treatment for Korean patients with CD or UC, who were previously failed to anti-tumour necrosis factor (TNF) therapy.

**Methods:** Between August 2017 and November 2019, a total of 159 patients with CD ( $n = 81$ ) or UC ( $n = 78$ ) received a VDZ induction therapy from 16 centres and were prospectively enrolled. Of those, patients who were evaluated at week 14 after three induction doses of VDZ (week 0, 2, and 6) were analysed. The co-primary endpoints were corticosteroid-free clinical remission and endoscopic remission/response (for UC) at week 14. We also analysed predictors of corticosteroid-free clinical remission, persistence of vedolizumab and safety.

**Results:** A total of 153 patients were analysed (CD, 77 [50.3%]; male, 94 [61.4%]; median age, 40 years [range, 17–80]; median disease duration, 8.0 years [range, 0.1–38.0]). All patients had previously experienced failures to at least one anti-TNF agent (one, 105 [68.6%]; two, 44 [28.8%]; three, 4 [2.6%]). Corticosteroid-free clinical remission/response rates in CD and UC patients were 44.6%/51.8% and 39.4%/62.0%, respectively. In patients with UC, endoscopic remission and response rates defined by Mayo endoscopic subscore/ulcerative colitis endoscopic index of severity were 33.8%/14.1% and 55.4%/39.1%, respectively. Multivariate analysis revealed that a clinical response at week 6 were associated with a corticosteroid-free clinical remission at week 14 in both CD (Odds ratio [OR] 33.84, 95% confidence interval [CI] 6.25–183.31,  $p < 0.001$ ) and UC (OR 12.22, 95% CI 1.30–115.28,  $p = 0.029$ ). In addition, UC patients with higher baseline levels of C-reactive protein (CRP) and faecal calprotectin were less likely to be in corticosteroid-free clinical remission (CRP  $> 0.31$  mg/dl: OR 0.05, 95% CI 0.00–0.60,  $p = 0.019$ ; faecal calprotectin  $> 2,000$   $\mu$ g/g: OR 0.04, 95% CI 0.00–0.93,  $p = 0.045$ ). The cumulative probabilities of continuing VDZ after one year were 48.7% for CD and 65.7% for UC, respectively. During median 10 months of follow-up periods (range, 3–26 months), disease exacerbation was the most common adverse event ( $n = 73$ , 47.7%), followed by nasopharyngitis ( $n = 23$ , 15.0%) and arthralgia ( $n = 19$ , 12.4%).

**Conclusion:** In anti-TNF-failed Korean patients with CD and UC, VDZ induction therapy was effective with an acceptable safety profile. Early clinical response and higher inflammatory burden at baseline were associated with corticosteroid-free clinical remission after VDZ induction therapy.

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#### Infliximab in inflammatory bowel disease: Is premedication necessary?

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**Background:** The use of infliximab (IFX) in inflammatory bowel disease (IBD) has been associated with a 1–6% risk of infusion reactions. The usefulness of premedication with corticosteroids, paracetamol and/or antihistamines is controversial. The aim of this study is to assess, in IBD patients on IFX, whether there are differences in secondary reactions to the infusion between those who use premedication or not.

**Methods:** A retrospective cohort study was performed identifying patients with a diagnosis of IBD who received IFX at a tertiary centre in Santiago-Chile, since 2009. Acute reactions were defined as those that occurred in the first 24 h post-infusion and late reactions for more than 24 h. Infusion reactions were classified as mild, moderate and severe. Descriptive and association statistics were used ( $\chi^2$ ;  $p < 0.05$ ).

**Results:** Sixty-four patients were included with 1,263 infusions in total, 52% men (characteristics in Table 1). Median infusions per patient were 22 (2–66). All induction infusions were administered with premedication and in maintenance, 57% of them. Premedication was given with hydrocortisone, chlorphenamine and paracetamol. Flow chart according to premedication use or not is shown in Figure 1. In the maintenance group, there were 10/718 (1.4%) infusion reactions with premedication and 3/358 (0.8%) without it, non-significant differences ( $p = 0.432$ ). In the induction group, there were 8/187 (4%) infusion reactions, significantly higher when compared with both maintenance groups (Figure 2).

**Table 1.** Demographic and clinical characteristics of patients on infliximab therapy

$n = 64$ patients (%)	
Diagnosis	23 (36)
UC	40 (63)
CD	1 (1)
Non-classified IBD	
Age (median; range)	34 (16–74)
Years of disease (median; range)	5 (0–49)
Difference between diagnostic and use of IFX (median; range)	4.5 (0–38)
<b>Biological therapies</b>	57 (89)
Naïve	3 (5)
Previous use of Adalimumab Previous use of Infliximab (more than 1 year ago)	4 (6)
<b>Infliximab infusions</b>	
Induction ( $n = 187$ )	167 (89)
Standard or conventional	
Optimised (10 mg/kg or accelerated 0-1-4 weeks)	20 (11)
Maintenance ( $n = 1076$ )	845 (79)
Standard or conventional	
Optimised (10 mg/kg / 4–6 weeks)	231 (21)

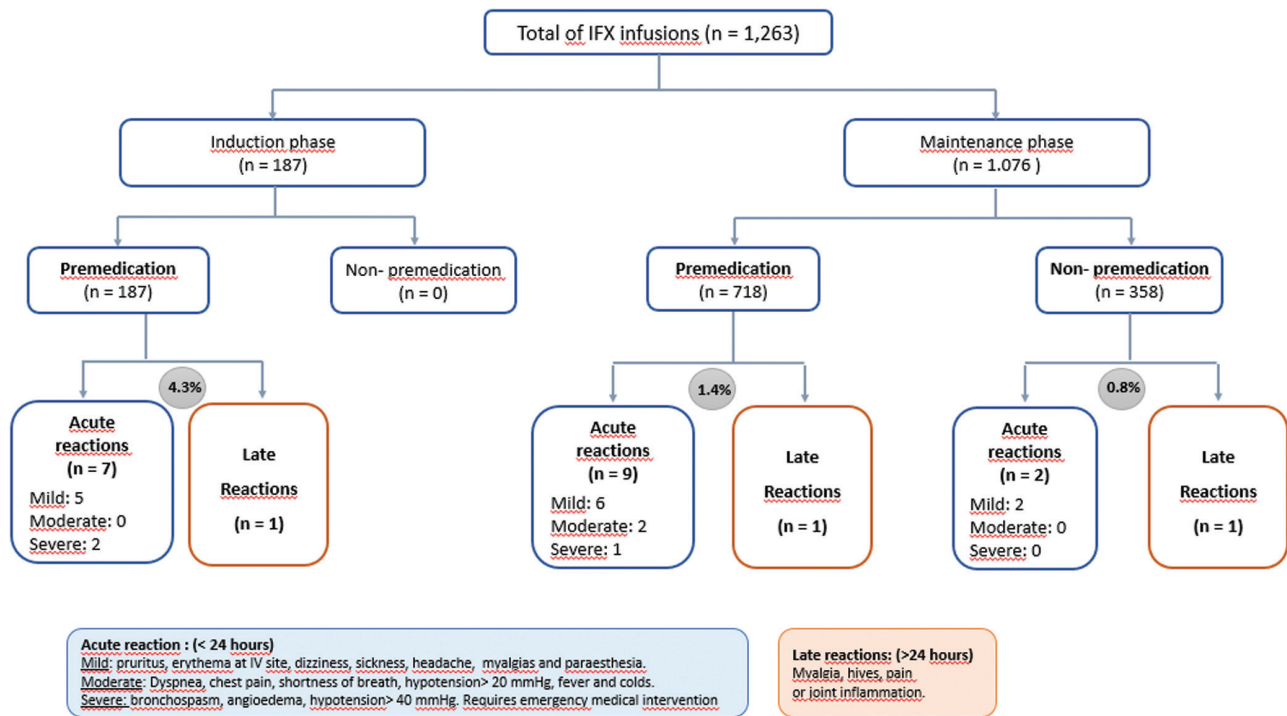


Figure 1. Flow chart according to premedication use or not.

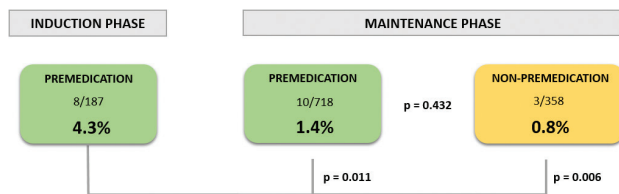


Figure 2. Comparison of infusion reactions rates due to IFX administration with or without premedication.

**Conclusion:** In this cohort, premedication use in maintenance phase was not effective at reducing the rate of infusion reactions due to IFX. These results suggest that premedication would not be necessary during maintenance.

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**Perceptions of faecal microbiota transplantation in patients with ulcerative colitis**

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**Background:** Faecal microbiota transplantation (FMT) is widely being studied for its therapeutic efficacy for a variety of ailments. Despite its gaining popularity, there is a limited understanding of firsthand patient experiences. We explored perceptions of patients who chose to pursue FMT and patients who declined FMT in favour

of conventional medications for the treatment of their ulcerative colitis (UC).

**Methods:** Using qualitative descriptive design, eligible patients were invited to participate in face-to-face semi-structured interviews before and after FMT treatment. Interviews were audiotaped, transcribed, and analysed using a thematic analysis.

**Results:** Main baseline themes across the FMT (n = 9) and non-FMT (n = 8) groups included: (i) knowledge of FMT, (ii) attitudes around FMT, and (iii) factors contributing to the decision to pursue FMT. Post-FMT themes included: (i) experiences with FMT, and (ii) perceived response to treatment. We found a poor general understanding of FMT across both cohorts, suggesting a need for improving patient education. Non-FMT patients were less likely to have heard or researched FMT in the past due to feelings of ‘it just sounds weird’. Similar concerns were found across both groups, including fear of transmissible infections, cost of experimental therapy, and aversion to stool. Expectations varied between the two groups, with feelings of hope and a sense of ‘last resort’ driving patients to pursue FMT. In contrast, the non-FMT cohort felt a need to further research FMT, explore other treatment options before committing to FMT, and were more likely to describe their disease activity as ‘not at the severe end’. This demonstrates that FMT may be perceived as a ‘last-ditch effort’. Despite initial aversion, the non-FMT group demonstrated an interest in learning more about FMT and felt more open to the possibility of pursuing FMT in the future. The FMT group was more likely to harbour a positive view of natural medicine and classify FMT as natural, while the non-FMT cohort expressed ‘I’m not really into the weird stuff’. Post-FMT, some patients expressed delight in the perceived changes in their symptoms, including improved quality of life, decreased urgency, and less concerns with accidents.

**Conclusion:** Our results suggest that important motivating factors for pursuing FMT are a perception of naturality and a sense of last