positive for binding antibodies at weeks 4, 12, or 26, with similar percentages in each treatment group (ABP 501, n = 101, 38.3%; adalimumab, n = 100, 38.2%) across all time points. A total of 53 (10.1%) of all randomised patients tested positive for neutralising antibodies at weeks 4, 12, or 26, which was also similar in each treatment group (ABP 501, n = 24, 9.1%; adalimumab, n = 29, 11.1%).

The rate of seroconversion over time for both treatment groups was similar, progressively increasing throughout the study. For subjects testing ADA positive, the magnitude of both the binding and neutralising ADAs across the treatment groups were evenly distributed, with similar median S/N or titre values at each time point.

Conclusions: Similar immunogenicity rates were observed and relative magnitude of the ADAs was similar between the ABP 501 and adalimumab RP treated patients.

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Oral once daily budesonide granules rapidly induce clinical remission in Lymphocytic Colitis: A double-blind, multi-centre, randomised trial

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Background: Lymphocytic colitis (LC) is a common cause of chronic, non-bloody diarrhoea. Budesonide appears to be effective based on small studies, but further randomised placebo-controlled trials were requested by recent Cochrane review.1 Mesalazine has been proposed as a treatment option but no placebo-controlled trials have been reported. Thus, we performed a randomised, placebo-controlled, multicenter study to evaluate budesonide and mesalazine as induction therapy for lymphocytic colitis.

Methods: Patients with active lymphocytic colitis were randomly assigned to either budesonide 9 mg once daily (Budenofalk® granules) or mesalazine 3 g once daily (Salofalk® granules), or placebo for 8 weeks in a double-blind, double-dummy design. The primary endpoint was clinical remission at week 8 defined by the Hjortswang-Criteria.2 Secondary endpoints included median time to remission, histopathology and safety.

Results: Final analysis included 57 patients (19 per group). Most patients were of female gender (72%) and mean age was 59 years. The proportion of patients in clinical remission at week 8 was significantly higher in the budesonide group than in the placebo group (intention-to-treat [ITT]: 79% vs. 42%; p = 0.01). The difference in clinical remission at week 8 between mesalazine (63%) and placebo failed statistical significance (p = 0.09). Median time to remission was significantly shorter in the budesonide group compared with placebo group (ITT: 3 days vs. 21 days, p = 0.04), whereas median time to remission in the mesalazine group was not significantly different compared with the placebo group (ITT: 12 days vs. 21 days, p = 0.21). The proportion of patients with histological remission at week 8 was higher with budesonide (68%) than with mesalazine (26%; p = 0.02) and placebo (21%; p = 0.008). The rate of adverse events did not differ among groups.

Conclusions: Oral budesonide 9 mg once daily induces rapidly and highly effective clinical and histological remission in lymphocytic colitis in a safe manner, while oral mesalazine 3 g once daily was only numerically, but not statistically significant better than placebo.

References

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vedolizumab trough levels during induction in IBD patients: A longitudinal observational retrospective study

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Background: Vedolizumab (VDZ) is effective for the treatment of ulcerative colitis (UC) or Crohn’s disease (CD). Few real-world experience data are available on the relevance of measuring trough levels (TLs) early on to predict loss of response in patients treated with VDZ. Our objective was to evaluate VDZ TLs early on at induction.

Methods: In total, 86 IBD patients (45 CD, 32 UC, 9 IBD unclassified) have been treated with VDZ. 400 samples were prospectively collected from September 2015 to August 2017 and measured retrospectively by Ridascreen VDZ ELISA in parallel with clinical, biological and endoscopic data. Induction analyses include second and third infusion; optional dose at week 10 not included. Treatment failure was defined by the need to optimise VDZ and/or to swap because of active disease. Sustained response was defined by clinical response without need of optimisation. Statistical analyses were performed using the Student t-test. Results were expressed as mean ± standard error.

Results: 34% of patients (n = 29/86) stopped VDZ because of treatment failure during maintenance. The mean duration of VDZ treatment is shorter in patients experiencing treatment failure (145 days±25 days) than patients with sustained response (263 days ± 27, p = 0.004). At the third infusion (week 6), the sustained response group had higher TLs (38.1 mg/ml ± 4.7) than the failure group (24.7 mg/ml ± 3.1) (p = 0.03) (Figure 1).