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# PREDICTORS OF REMISSION TO VEDOLIZUMAB THERAPY IN A COMBINED INFLAMMATORY BOWEL DISEASES COHORT

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## Introduction:

The response to the anti-integrin-$\alpha_4\beta_7$ antibody, vedolizumab, is variable in both Crohn's disease (CD) and ulcerative colitis (UC). Apart from prior exposure to anti-TNF agents, there are very few clinical predictors of response to vedolizumab therapy. Previous studies have shown that clinical and biological variables such as body mass index (BMI), baseline disease activity and concurrent immunosuppression influence response to anti-TNF agents but such data are not available for vedolizumab. (1)

## Aim:

We sought to evaluate the role of clinical and biological variables as predictors of response to vedolizumab.

## Methods:

A retrospective, single-centre cohort study was conducted on all patients commencing vedolizumab therapy. Clinical response was defined as a reduction of 3 points from baseline for Harvey-Bradshaw index (HBI) and 2 points for simple clinical colitis activity index (SCCAI). Clinical remission was defined as HBI<5 and SCCAI<2. Response and remission was evaluated at 6 and 12 months. A multi-variate logistic regression was performed to analyse the effect of BMI, baseline calprotectin, prior anti-TNF exposure, disease type (UC or CD) and concomitant immunosuppressants on response and remission to vedolizumab.

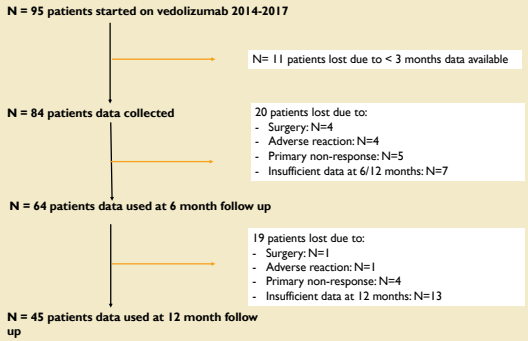


Figure 1: flow chart: showing exclusion of patient cohort

| | OR (95% CI) | p-value |
|---|---|---|
| **BMI*** | 1.07 (0.98, 1.17) | 0.109 |
| **Calpro: baseline*** | 0.9996 (0.9988, 1.0004) | 0.290 |
| **Calpro: change from baseline to 2m*** | 1.000 (0.999, 1.001) | 0.975 |
| **Disease: UC** | **2.45 (0.89, 6.74)** | **0.081** |
| **Current smoker** | 0.17 (0.02, 1.53) | 0.114 |
| **Disease duration: ≥5yr** | 0.65 (0.19, 2.21) | 0.490 |
| **Calpro: baseline ≥ 500** | 0.46 (0.16, 1.29) | 0.139 |
| **Concurrent IM** | 1.73 (0.64, 4.71) | 0.282 |
| **Steroids at baseline** | 0.56 (0.20, 1.53) | 0.258 |
| **Anti-TNF failure** | 0.70 (0.26, 1.88) | 0.480 |

Figure 2: multivariate analysis of factors predicting steroid free remission at 6 months

| | OR (95% CI) | p-value |
|---|---|---|
| **BMI*** | 1.00 (0.92, 1.09) | 0.943 |
| **Calpro: baseline*** | 0.9997 (0.9990, 1.0004) | 0.459 |
| **Calpro: change from baseline to 2m*** | 1.000 (0.999, 1.001) | 0.772 |
| **Disease: UC** | **3.57 (1.20, 10.60)** | **0.022** |
| **Current smoker** | 0.27 (0.03, 2.35) | 0.233 |
| **Disease duration: ≥5yr** | 2.15 (0.53, 8.79) | 0.286 |
| **Calpro: baseline ≥ 500** | 0.46 (0.16, 1.29) | 0.139 |
| **Concurrent IM** | 1.12 (0.40, 3.19) | 0.825 |
| **Steroids at baseline** | 1.47 (0.51, 4.22) | 0.477 |
| **Anti-TNF failure** | 1.24 (0.44, 3.46) | 0.684 |

Figure 3: multivariate analysis of factors predicting steroid free remission at 12 months

## Results:

Of the patients commenced on vedolizumab, 64 had disease activity data at 6 months and 45 had disease activity data extending to 12 months. Baseline clinical factors including BMI, smoking status, concurrent immunomodulatory or steroid therapy were not associated with steroid free remission at 6 and 12 months. Prior anti-TNF failure did not influence clinical remission at 6 months (OR 0.7, 95% CI 0.26-1.88, P=0.4) or 12 months (OR 1.24, 95% CI 0.44-3.46, P=0.6). Patients with UC were more likely to be in steroid free remission at 6 (OR 2.45, 95% CI 0.89-6.74, P=0.08) and 12 months (OR 3.5, 95% CI 1.2-10.6, P=0.02). Neither baseline calprotectin nor a reduction in calprotectin at 2 months predicted steroid free remission at 6 or 12 months.

## Conclusions:

In a single-centre mixed IBD cohort treated with vedolizumab, patients with UC were more likely to be in steroid free remission at 6 and 12 months. None of the other clinical and biological variables were associated with steroid free remission.

## References:

1. Zampeli, E. Gizis, M. Siakavellas, S. and Bamias, G. Predictors of response to anti-TNF therapy in ulcerative colitis. Published 2014. World Journal of Gastrointestinal pathophysiology. Aug 15; 5(3): 293–303. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4133527/

**This presenter has the following declarations of relationship with industry:** NONE