Prognostic Factors for Vedolizumab Remission in IBD Patients

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Vedolizumab, a humanized monoclonal antibody targeting the $\alpha 4\beta 7$-integrin, is used as treatment of inflammatory bowel diseases (IBD). Clear recommendations for its use in IBD patients lack. To publish more comprehensive recommendations for the clinical practice, one needs to know what factors influence the patient's response to the treatment and the variability of such response over time, which is the goal of this study. This research is a retrospective observational study looking at data of IBD patients treated with vedolizumab, provided by the Balsiger, Seibold & Partner practice and the swiss IBD cohort. The eligibility criteria were a diagnosis of either Crohn disease or ulcerative colitis, and having received at least one dose of vedolizumab, between January 2015 and June 2020. Of the patients initially enrolled (N=263), 18 were excluded due lack of remission data for the two time ranges used for measuring remission (T1 = 4-8 months after start vedolizumab, and T2 = 12-16 months after start vedolizumab), leaving the final number of patients at 245 (CD=149, UC=96). Having a remission status for only T1 or T2 was not a criterium for exclusion. Remission was defined as fecal calprotectin <200 µg/g and/or an endoscopic score of 0 for the Mayo score, and <3 for the SES-CD score. Statistical significance between groups was assessed with Pearson's chi square test. The alpha level used for all statistical analyses was 0.05. If the Pearson's chi square test's assumption was violated, likelihood ratio (LR) was used instead. The primary outcome was achievement (or not) of remission at T1 and/or T2. Four prognostic factors with a positive effect on long-term remission (T2) were uncovered : presence of other auto-immune diseases χ^2(1, N=215)=5.91 (LR), .01 (Phi=0.168, strong association), disease duration (≤ 15 years) χ^2(8, N=215)=16.62 (LR), .03 (Cramer's V=0.259, very strong association), absence of perianal manifestations χ^2(3, N=215)=9.39 (LR), .02 (Cramer's V=0.172, strong association), and vedolizumab blood concentration (>14 µg/mL) χ^2(3, N=69)=7.99 (LR), .04 (Cramer's V=0.344, very strong association). Presence of other auto-immune disease χ^2(1, N=216)=4.47 (LR), .03 (Phi=0.145, moderate association) and smoking χ^2(1, N=216)=8.21, .004 (Phi=0.195, strong association) both had a positive effect on short-term remission T1. The positive effect seen with smoking and the presence of other auto-immune diseases warrants further studies and could bring new insights into the pathophysiology of IBD. The effect of disease duration shows the importance of acting early on IBD, which should push clinicians to develop better screening tools. Finally, the negative effect perianal manifestations had on long term remission should emphasize the need for treatment of such disease manifestations.

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