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- All named persons associated with the study
- Patient identifiers within text, tables, or figures
- By-patient data listings

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1.0 ABSTRACT

Study Title

Clinical effectiveness of vedolizumab used in frames of Drug Program for Crohn's disease treatment in Poland – prospective, observational study considering fatigue and other Patient-reported-outcomes (PROs).

Keywords

Crohn's Disease, fatigue, HR-QoL, PRO, vedolizumab.

Background and Rationale

Research Question(s) and Objective(s)

Primary objectives

- To assess vedolizumab effectiveness in Crohn's disease patients treated in frames of the Drug Program in Poland defined as the response and remission rates assessed using CDAI.

Secondary objectives

- To describe characteristic of the CD patient's cohort eligible for DP in Poland.
- To assess impact of induction therapy with vedolizumab in CD patients treated in DP on patient reported outcomes (PROs) such as Abdominal Pain Score (APS) and Number of Liquid or Very Soft Stools (NLVSS).
- To assess impact of maintenance therapy with vedolizumab in CD patients treated in DP on patient reported outcomes (PROs) such as Abdominal Pain Score (APS) and Number of Liquid or Very Soft Stools (NLVSS).
- To assess impact of induction therapy with vedolizumab in CD patient treated in DP on patient's fatigue measured with IBD-Fatigue (IBD-F) questionnaire.
- To assess impact of maintenance therapy with vedolizumab in CD patient treated in DP on patient's fatigue measured with IBD-Fatigue (IBD-F) questionnaire.
- To assess impact of induction therapy with vedolizumab in CD patient treated in DP on patient's QoL measured with IBDQ.
- To assess impact of maintenance therapy with vedolizumab in CD patient treated in DP on patient's QoL measured with IBDQ.
- To assess rate of emergency room visits, hospitalization rate, surgery rate.
- To assess the real-world safety of vedolizumab in CD patients treated with vedolizumab in DP.

Exploratory objectives

- [redacted]
- [redacted]

Study Design

Prospective, multicenter, Non-Interventional Study to evaluate the effectiveness of treatment with vedolizumab (VDZ) in patients with Crohn's disease who were administered vedolizumab in the scope of the Drug Program (DP, a reimbursement program authorized by Ministry of Health to grant access to highly specialized therapies, e.g. vedolizumab, to patients) in Poland.

Setting

Eligible patients (CDAI above 300) who gave informed consent to participate, were enrolled at Visit 1 and followed up for the duration of DP (24 months). The study consisted of 5 visits at weeks 0, 14, 54, 78 and 102 (V1, V2, V3, V4 and V5, respectively). Demographic data and medical history were collected during the first visit. Medical data including CDAI assessment, concomitant medication and adverse events were collected at each visit, additionally, IBD-F and IBDQ surveys were conducted during each visit. While the inclusion criteria for the DP with vedolizumab were overall consistent with the approved vedolizumab (Entyvio®) label, they only allowed enrollment of individuals with an active Crohn's disease with CDAI score above 300 and who had an inadequate response to, lost response to, or were intolerant to either conventional therapy (such as steroids and immunosuppressants) or a tumor necrosis factor-alpha (TNFα) antagonist. Furthermore, according to the DP conditions at study initiation, the treatment of the individual patient had to be terminated after 102 weeks of therapy, regardless of the actual activity of the disease.

Vedolizumab was prescribed according to the local label and the DP requirements and there were no restrictions on the use of other commercially available medications.

Study Population: Subjects and Study Size, Including Dropouts

Patients with Crohn's disease aged 18 years or older who initiated vedolizumab treatment in the DP were enrolled in the study if they fulfilled its predefined inclusion and exclusion criteria. As no formal hypothesis was tested in this study, sample size was not formally estimated. Instead, based on clinical and feasibility considerations, it was planned that 100 consecutive patients meeting the DP criteria after study initiation would be qualified to participate in the study.

Data Sources and Data Collection

Source data in the study were the data in patient medical files at the respective centers. The data were transferred to patient-specific eCRF according to the schedule of visits in the study design. Therefore, only data available and already existing in patients' files were recorded. PROs were obtained in the paper questionnaires filled in by the patients, the entries were subsequently transcribed into eCRF by physicians. Due to the non-interventional nature of the study, no additional patient data, assessments, laboratory tests beyond those included in the Drug Program requirements were required.

Data Analysis

In order to compare quantitative variables between visits, t-test (in case of normality) or Wilcoxon test (otherwise) were conducted. Normality assumptions were tested by Shapiro-Wilk test. Chi-square or Fisher test were used to compare categorical variables between subgroups. Proportion of responders and patients in remission were compared between visits using a proportion test (as implemented in R's prop.test). Where appropriate, 95% confidence intervals were provided.

For exploratory analyses of factors influencing response and remission rates, a univariate and multivariable logistic regressions were performed [redacted]

[redacted]

Variables (Exposures, Outcomes and/or Endpoints)

Primary Variable

1. Disease activity
   a. CDAI total score

Secondary Variable

1. Disease Activity
   a. CDAI (NLVSS - total number of soft/liquid stools in the last 7 days, APS - sum of results from the last 7 days using following scale: 0 = none, 1 = mild, 2 = moderate, 3 = severe, as a part of CDAI)
   b. Disease phenotype – Montreal Scale - predictor
   c. Extra-intestinal manifestations (EIMs) - predictor
   d. Concomitant treatment – change from baseline
      i. Corticosteroids
      ii. Immunomodulators
   e. Past biological therapies – their number and outcomes (e.g. effectiveness, reasons for discontinuation, if occurred) -
   f. Comorbidities
2. Current treatment with vedolizumab in DP
3. IBD-F questionnaire score – outcome
4. IBDQ questionnaire scores – outcome
5. Safety – number of events, frequency (per 100 patient-years)
   a. Serious infections (infections that were SAEs, including PML)
   b. Other clinically significant infections, not SAEs, that were classified as moderate or severe and required antibiotic treatment
   c. Malignancies
   d. Infusion-related reactions
   e. All other AES, AESI and SAEs
   f. Pregnancy outcomes

Results (Data Analysis)

In total, between 1st April 2020 and 30th October 2023, 98 patients participated in the study. 93 (94.9%) patients completed the induction therapy (Visit 2, Week 14) and half of patients (N = 51, 52%) completed the entire study (Visit 5, Week 102). 47 (48.0 %) patients terminated the study prematurely; the reasons for the termination included mostly lost of response to treatment after Week 14 (N = 31, 66.0%).The median age of patients in the overall study population was 34.0 (range 18.0 - 65.0) years. The majority of patients were male (N = 56, 57.1%). The median BMI score was 21.0 (range 14.3 - 32.7). Non-smokers accounted for the majority of patients (N = 70, 71.4%). In most patients in the overall study population, the extent of the disease was either ileo-colonic (N = 71, 72.4%) or colonic (N = 15, 15.3%). The disease behavior in almost half of patients (N = 45, 45.9%) was non-stricturing/non-penetrating. In a quarter of patients, the disease behavior

was either penetrating (N = 27, 27.6%) or structuring (N = 26, 26.5%). 16 (16.3%) patients had perianal disease. The median disease duration in the overall study population was 7.0 years (range 0.0 - 25.0). The median total CDAI score in the overall study population was 336.5 (range 301.0 - 483.0), with the median abdominal pain in the last 7 days subscale score of 18.0 (range 0.0 - 21.0) and in the stool frequency in the last 7 days subscale score of 37.5 (range 0.0 - 87.0). The median CRP/hsCRP level at study start was 6.0 mg/l (range 0.0 - 189.5). 38 (38.8%) patients presented extraintestinal symptoms at enrollment in the study, mostly arthralgia (N = 23, 23.5%) or anemia (N = 23, 23.5%).

Two-thirds of study subjects were previously bio-exposed (N = 66, 67.3%). Half (N = 33, 50.0%) of these patients had the history of previous treatment with one biologic drug, 23 (34.8%) patients – with two biologic drugs and 9 (13.6%) patients – with three biologic drugs. Most frequently, infliximab (N = 48, 72.7%) or adalimumab (N = 47, 71.2%) were used. 35 (35.7%) patients were bio-failures. In this cohort, half (N = 18, 51.4%) of patients received more than two courses of biologic therapy. In bio-failures, the most frequent reason for termination of infliximab therapy was intolerance (N = 16, 55.2%), followed by loss of response (N = 9, 31.0%) and primary lack of response to treatment as defined in the Drug Program (N = 4, 13.8%). The most frequent reason for termination of adalimumab treatment was primary lack of response to treatment as defined in the Drug Program or loss of response (N = 6, 35.3% for each reason), while 5 (29.4%) patients were intolerant to adalimumab. In the overall study population, technically all (N = 97, 99.0%) patients had the history of steroid use, of these all bio-naive (N = 32, 100.0%) and all bio-failure (N = 35, 100.0%) patients. Only 4 patients did not have a history of immunomodulatory therapy, all in the bio-naïve cohort (12.5%). Approximately a quarter of patients in the overall study population was either steroid-resistant (N = 27, 27.6%) or steroid-dependent (N = 25, 25.5%) and 5 (5.1%) patients were steroid intolerant.

At study entry, half of patients (N = 48, 49.0%) were not administered corticosteroids. In patients treated with steroids, prednisone as used most frequently (N = 25, 25.5%) and the median prednisolone dose equivalents was 30.0 mg/day (range 4.0 - 80.0). Half of patients (N = 49, 50.0%) were not administered immunomodulatory therapy. In those administered, the most frequent immunomodulatory medication used was azathioprine (N = 42, 42.9%) and the median daily dose of immunomodulatory therapy was 100.0 mg (range 2.1 - 175.0).

Vedolizumab was administered by intravenous infusion at Week 0, Week 2, Week 6 and then from Week 14 every 8 weeks. An additional dose of vedolizumab at Week 10 was administered in 11 (11.8%) patients. In 29 (43.9%) patients, the maintenance therapy was intensified by administering vedolizumab every 4 weeks.

A significant reduction of CDAI score was observed over the course of vedolizumab treatment. The total CDAI score was reduced from the median 336.5 (range 301.0 - 483.0, N = 98) at study entry to the median 108.0 (range 20.0 - 321.0, $p<0.001$; N = 93) at Week 14 (end of induction therapy). At week 102 (end of treatment), the median total CDAI score reached 85.0 (range 0.0 - 296.0, N = 53). Clinical response (defined as the reduction of the total CDAI score by 70 points and 25% in comparison to baseline value) at Week 14 (end of induction therapy) was achieved in 91.8% (N = 90) patients (including all patients, in whom the induction treatment was intensified), 63.3% (N = 62) patients achieved clinical remission. Steroid-free clinical remission at Week 14 was achieved in 14 (28.0%) patients. Of patients in whom maintenance therapy was intensified, steroid-free clinical remission was achieved in 10 (34.5%) patients. At Week 102 (end of maintenance treatment), durable clinical response was recorded in 49 (54.4%) patients (the decline versus Week 14: -38.8%, 95% CI -51.1%; -26.5%) and durable clinical remission was recorded

in 33 (53.2%) patients (the decline versus Week 14: -15.3%, 95% CI -30.1%; -0.5%). Steroid-free clinical remission was maintained in 6 (42.9%) (increase versus Week 14: 8.0%, 95% CI -12.2%; 28.2%). The response rates slightly favored bio-failures versus bio-naïve patients at the end of the induction treatment (94.3% vs. 90.6%), whereas the decline rate of the durability of response over the course of the maintenance treatment slightly favored bio-naïve group (-37.5% vs. -42.9% in the bio-failure cohort).

A significant reduction of the Abdominal Pain Score (APS) and the Number of Liquid or Very Soft Stools (NLVSS) score was achieved with the induction therapy and maintained during the maintenance treatment. The median APS at study entry (18.0, range 0.0 - 21.0, N = 98) was reduced at Week 14 to the median 2.0 (range 0.0 - 21.0, N = 93). At week 102 (treatment end), the median APS was maintained at 0.0 (range 0.0 - 21.0, N = 53). The median NLVSS at study entry (37.5, range 0.0 - 87.0, N = 98) was reduced to the median 10.0 (range 0.0 - 63.0, N = 93) at Week 14. At Week 102, the median NLVSS reached 5.0 (range 0.0 - 48.0, N = 53).

A significant reduction of fatigue was achieved during the induction therapy and sustained during the maintenance treatment. Among responders, in the fatigue severity and frequency score (median 11.0, range 0.0 - 19.0, N = 89), the mean difference at Week 14 reached -1.8 (95% CI: -2.7 - -0.9). At Week 102, the mean difference versus Week 14 reached -1.3 (95% CI: -2.5 - 0.1). In the fatigue impact on daily activities (43.5, range 0.0 - 116.0), the mean difference at Week 14 reached -12.3 (95%CI: -16.9 - -8.0) and the mean difference at Week 102 versus Week 14 reached -5.1 (95% CI: -11.4 - 0.5).

A significant improvement of the IBDQ total score, as well as the individual domains (bowel symptoms, systemic symptoms, emotional function, social function) scores was achieved with the induction therapy and maintained during the maintenance treatment. In responders, in total IBDQ score (median 133.0, range 53.0 - 223.0, N = 90), the mean difference at Week 14 reached 26.8 (95% CI: 19.7 - 34.3), at Week 102, the mean difference versus Week 14 reached 8.5 (95% CI: -0.3 - 17.1). In bowel symptoms score, from the median 44.5 (range 21.0 - 70.0), the mean difference at Week 14 reached 8.9 (95% CI: 6.6 - 11.3), at Week 102, the mean difference versus Week 14 reached 2.0 (95% CI: -0.4 - 4.3). In systemic symptoms score, the mean change from the median 17.5 (range 6.0 - 35.0) at baseline reached 4.1 (95% CI: 2.7 - 5.6) at Week 14 and 1.7 (95% CI: 0.0 - 3.4) at Week 102 versus Week 14. In emotional function score, the mean changes from the median 47.5 (range 17.0 - 84.0) at baseline reached 8.8 (95% CI: 6.1 - 11.8) and 4.0 (95% CI: -0.1 - 8.1), respectively, in social function score, the mean changes from the median 22.0 (range 5.0 - 35.0) reached 4.9 (95% CI: 3.5 - 6.4) and 0.8 (95% CI: -0.9 - 2.6), respectively.

The increase in the rate of patients not using corticosteroids was observed throughout the study. At baseline, corticosteroids were used in half (49.0%, N = 48) of patients, with the median dose equivalents of prednisolone of 30.0 mg/day (range 5.0 - 80.0). At Week 14, 74.2% (N = 69) of patients were not treated with corticosteroids, the median dose equivalents of prednisolone was reduced to 15.0 mg/day (range 5.0 - 40.0). At Week 102, 83.0% (N = 44) patients were not receiving corticosteroids, the median dose equivalents of prednisolone was 10.0 mg/day (range 5.0 - 30.0). Likewise, the increase in the rate of patients not using immunomodulators was observed throughout the study. At Week 14, 54.8% (N = 51) of patients did not receive immunomodulatory treatment, at Week 102, the rate of patients not treated with immunomodulatory drugs reached 69.8% (N = 37). The median dose of the immunomodulatory drugs remained stable throughout the study, 100.0 mg/day (range 2.1 - 175.0) at Week 14, 100.0 mg/day (range 2.1 - 150.0) at Week 102.

Reduction in extraintestinal manifestations rate was observed throughout the study, from 36 (38.7%) patients at study entry, to 27 (29.0%) patients at Week 14 and 16 (30.2%) patients at treatment end. Fistulas were recorded in 11 (11.8%) patients, 8 (8.6%) patients, and 2 (3.8%) patients, respectively.

The median number of ER visits due to CD exacerbation was 1.0 (range 1.0 - 5.0), the incidence of ER visits/100 patient-years was 10.9. The vast majority (91.4%, N = 85) of patients did not require any hospital treatment due to CD exacerbation, 7 (7.5%) patients required one hospital admission and one (1.1%) patient required 2 admissions. The incidence of hospitalizations/100 patient-years was 7.0. The median duration of a hospital stay was 6.0 days (range 1.0 - 8.0). Total time of hospitalizations (months)/100 patient-years was 0.9. The vast majority (86.7%, N = 85) of patients did not require any surgical intervention.

In univariate logistic regression, stricturing disease behavior (according to Montreal CD classification) was the most potent predictor of response at week 102, with an odds ratio (OR) of 4.56 (95% CI: 1.61; 14.51). Increase in IBD-F (fatigue impact on daily activities) score was associated with reduced chances to achieve response (OR was 0.98, 95% CI: 0.96; 0.99 for one point of difference). For higher hematocrit values, OR 1.12 (95% CI: 1.02; 1.23) of achieving or maintaining response at week 102 was identified. For baseline hemoglobin value of 1 g/dl or higher, OR: 1.36, 95% CI: 1.08; 1.75 was identified. Higher CRP values indicated worse chances for achieving response to the treatment (for the difference between median baseline value of ~6 mg/L and value of 16.4 mg/L, the estimated OR was 0.72, 95% CI: 0.54; 0.94). For remission, stricturing disease behavior, hematocrit and hemoglobin increased odds of remission, with OR of 3.37 (95% CI: 1.24; 9.81), 1.11 (95% CI: 1.02; 1.22) and 1.35 (95% CI: 1.08; 1.74), respectively. Increase in IBD-F score (fatigue impact on daily activities) by 10 points was associated with a reduction in the probability of remission to 0.82. Likewise for response, higher CRP values indicated worse chances for remission (for the difference between median baseline value of ~6 mg/L and value of 16.4 mg/L, an estimated OR was 0.74, 95% CI: 0.56; 0.96). Only hemoglobin at baseline appeared to be a significant predictor of steroid-free remission at week 102 (OR 1.55, 95% CI: 1.07; 2.44).

A total of 41 adverse events were reported during the study in 33 patients. Of these, 23 (56.1%) events were classified as non-serious (in N = 19 patients) and 18 (43.9%) ones as serious events (in 14 patients). The total incidence of non-serious adverse events was 17.6/100 patient-years, the incidence of serious AEs accounted for 13.8/100 patient-years. The most frequent joint group of AEs were infections and infestations, with the incidence of 9.2/100 patient-years. None of them were assessed as related to vedolizumab use (relation was unknown for the most frequently reported respiratory tract infections, N = 3, incidence of 2.3/100 patient-years). *Clostridium difficile* infection was recorded in 1 patient (incidence of 1.5/100 patient-years) and assessed as not related to vedolizumab use. The most frequently reported individual AEs were linked with decrease in hemoglobin level, N = 8 (19.5%), with the incidence of 6.1/100 patient years, followed by a decline in hematocrit and mean cell volume reduction, with the incidence of 2.3/100 patient-years for both. One AE, rash (N =1, 2.4%, the incidence of 0.8/100 patient-years), was reported as related to intravenous vedolizumab administration. No cases of PML were reported.

Discussion

The rate of patients who responded to vedolizumab induction therapy at Week 14 (i.e. achieved a reduction in CDAI score of at least 70 points and at least 25% from baseline) exceeded 90% and the remission rate, defined as achieving the total CDAI score below 150, exceeded 60%. Overall,

a significant reduction of CDAI scores was achieved after the 14-week induction therapy, observed also in abdominal pain scores (APS) and stool frequency scores (NLVSS). Throughout the long-term course of maintenance vedolizumab treatment, the durable response and remission rates showed a steady decline in the subsequent weeks of vedolizumab treatment between Week 14 and Week 102 (-38% and -15.3%, respectively), whereas the reduction of CDAI scores recorded after the 14-week induction therapy continued throughout the study. Consistently, the reduction observed in abdominal pain scores and stool frequency scores after the induction treatment was maintained. In a systematic review and pooled analysis of several real-world experience studies with vedolizumab, response and clinical remission were achieved in 49% and 32% of patients by week 14, respectively. In another comprehensive meta-analysis, the combined clinical response and remission rates at week 14 were 58% and 30%, respectively. In other studies, clinical response and clinical remission were achieved in more than 80% and more than 50% of patients, respectively, after 6 or 14 weeks of induction therapy. Inter-study heterogeneity, including the differences in study population baseline characteristics (e.g., disease severity at vedolizumab initiation, disease duration, prior anti-TNFa use (and number of prior therapies) may partly account for the variability of the published data. Generally, the efficacy of vedolizumab in RWE studies seems to be higher than in corresponding randomized controlled trials. Considering the Abdominal Pain Score and loose stool frequency scores, a significant reduction of the scores achieved after the 14-week induction therapy in this study corresponds to the data provided in the analysis of the pooled GEMINI 2 and 3 populations, in which the rate of patients given vedolizumab who achieved an average daily composite score of abdominal pain ≤1 and loose stool frequency ≤3 at week 2 increased by week 4. CD patients who have not shown early response, may benefit from a dose of intravenous vedolizumab at week 10. In the literature data, the response rate by week 14 in patients who received an additional week 10 dose reached 94.5%. In this study, all patients who received additional vedolizumab dose at Week 10 achieved the response at Week 14. This observation confirms the beneficial effect of an additional vedolizumab dose in such patients. Better response to vedolizumab in bio-naive patients has been broadly reported and is consistent with the findings of this study.

In the literature, the beneficial clinical effect of vedolizumab in CD was observed during the maintenance treatment. In a systematic review and pooled analysis of several real-world experience studies with vedolizumab, at week 52, clinical response and remission were recorded in 45% and 32% of patients, respectively. In the current study, despite a steady decline of response and clinical remission rates observed throughout the maintenance therapy, 50% of patients benefitted from the long-term maintenance treatment, achieving durable response or remission. This observation is consistent with in the literature, although the exact response rates may vary.

Corticosteroids are known to cause many adverse effects, which are related to the CS dosage and long-term exposure. Their long-term use worsens the HRQoL of patients who require ≥4 annual CS prescriptions. Steroid-free remission by Week 14 assessed in five studies was achieved in 29% of patients, in other sources the steroid-free remission reached around 30%. Generally, patients receiving biologic treatment who were initially on corticosteroids were mostly able to gradually reduce their intake successfully addressing cortico-dependence and cortico-resistance. The literature data correspond to the results of the current study, where the rate of patents with steroid-free clinical remission achieved at Week 14 increased throughout the treatment. Half of patients were treated with corticosteroids when they initiated the vedolizumab therapy, whereas at study

end after 102 weeks of treatment the rate of steroid-free responders reached 83%, 36% of patients were in steroid-free clinical remission at study end.

In addition to well-recognized clinical measures (i.e. CDAI), patient-reported outcomes (PROs) such as the quality of life (IBDQ), Abdominal Pain Score (APS) or the Number of Liquid or Very Soft Stools (NLVSS) should be included in the assessment of treatment effectiveness. Along with the more general HR-QoL questionnaires, tools to specifically assess fatigue should also be used. Abdominal pain is a very common, critically important and still poorly understood symptom in IBD that is associated with significant consequences to the patient, provider, and society at large. Fatigue, one of the most challenging symptoms that can impact HR-QoL in CD patients is perceived by them to be among the four most important disease symptoms with a burden comparable to that of having a stoma. It is well documented that treatment with biological agents improves clinical outcomes and leads to patient satisfaction and a better HRQoL. In the GEMINI 2 study, exploratory analysis showed clinically meaningful improvements from baseline to week 52 in total IBDQ score, as well as IBDQ subscales of bowel symptoms and systemic function. In a systematic review based clinical data from 16 RCTs, a substantial improvement in the HRQoL measured in the IBDQ questionnaire in patients with CD using biological agents was reported. In a study assessing a longitudinal trajectory of fatigue, a significant improvement of the FACIT-F score was noted after adalimumab induction, and the improvement continued until at least week 56. In HR-QoL assessment, based upon IBDQ and other questionnaires, the scores remained stable in patients over the duration of the GEMINI LTS study. In the current study, in responders to vedolizumab, the significant improvement in patient's QoL measured in the IBDQ questionnaire and fatigue measured in the FACIT-F questionnaire was observed. This improvement corresponded to the improvement in the disease activity recorded in the changes of CDAI score. This observation is consistent with the literature data linking the HR-QoL with the disease activity in IBD patients.

To improve the quality of life in patients with IBD, a successful management of extraintestinal manifestations is essential. Complete remission of inflammatory arthralgia/arthritis was observed in 56.3% of patients who continued vedolizumab therapy for 54 weeks in the OBSERV-IBD study. In the current study, the rate of patients with extraintestinal manifestations was reduced from 38.7% to 30.2%. Regarding the fistulizing type of the disease, out of 11.8% of patients who presented with fistulas at study start, the rate of patients with fistulas was reduced to 3.8% at study end. Therefore, a potential benefit of long-term vedolizumab therapy in the management of extraintestinal manifestations and fistulas in patients with CD has been observed in the study.

91.4% of patients did not require any hospital admission due to exacerbation of Crohn's disease. This observation, including also low number of ER visits required during the study, indicates a potential benefit of long-term vedolizumab therapy in the hospital resource use in patients with CD. In patients who required hospitalization, the duration of the hospital stay was reduced, however the low numbers of patients concerned limit interpretation of these findings.

The safety of vedolizumab was consistent with the known safety profile of vedolizumab in patients with CD.

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*The site ultimately did not participate in the study and did not recruit any patients.