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IMPACT OF VEDOLIZUMAB LEVELS ON CLINICAL RESPONSE IN CROHN'S DISEASE: A RETROSPECTIVE STUDY

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BACKGROUND AND IMPORTANCE

This study contributes to the understanding of therapeutic drug monitoring (TDM) by identifying key factors, such as age and treatment duration, that impact clinical response in long-term vedolizumab (VDZ) patients with Crohn's disease (CD).

OBJECTIVES

To evaluate the correlation between VDZ levels and clinical response in CD patients and explore additional variables influencing treatment outcomes.

METHODS

- Retrospective observational study of all CD patients at our hospital on VDZ maintenance treatment(≥ 14 weeks)
- Serum trough VDZ concentrations were analyzed (ELISA method) along with demographic (age, sex) and clinical variables (age at diagnosis, location, disease pattern, biomarkers)
- Clinical response was assessed with the HBI index (remission < 5), and patients were classified as responders/non-responders
- Samples were grouped using clustering(K-means), with time on treatment as the primary variable.
- Differences in VDZ levels between responders and non-responders were evaluated with Mann-Whitney, and predictive ability was assessed with ROC curves
- Logistic regression was used to identify other response-influencing variables.

RESULTS

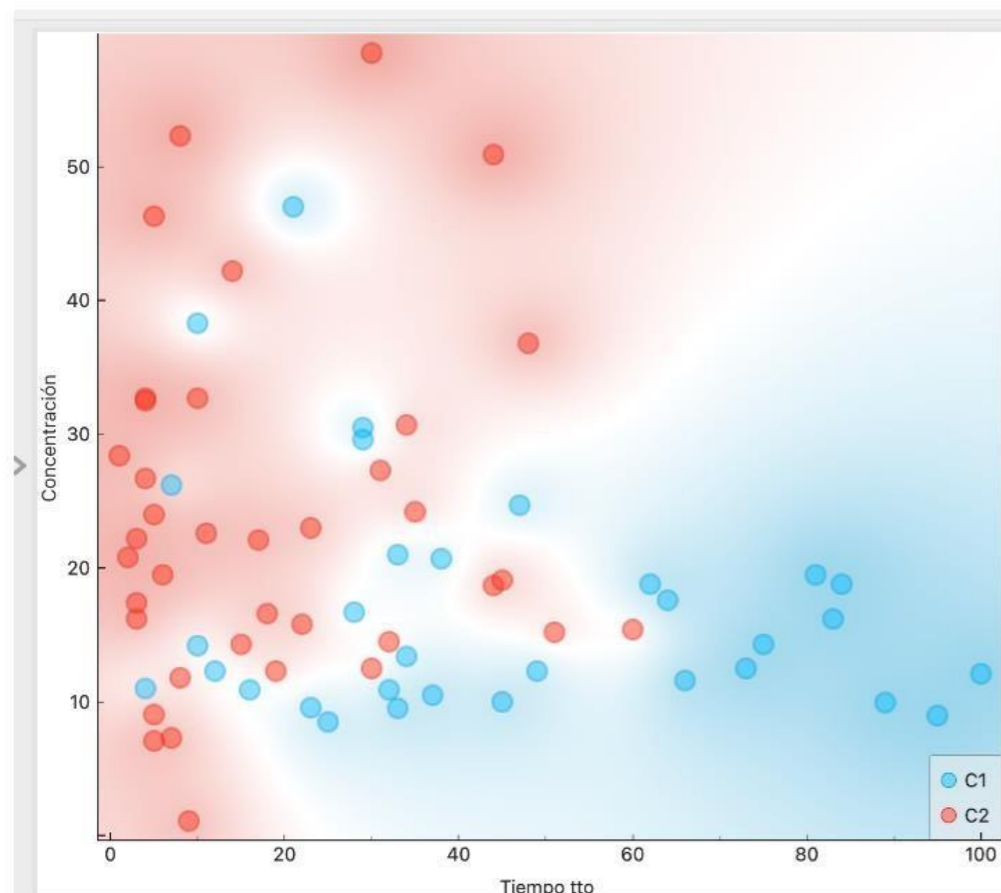


Figure 1. Scatter plot showing the distribution of Cluster 1 (C1) and Cluster 2 (C2)

- ✓ **Cluster-1**, with older patients (66.5 ± 10.3 years) and longer on treatment (44.8 ± 28.4 months), had a response rate of 78.1%. Responders had VDZ levels of 16.2mcg/mL (IQR:12.1-20.7) versus 10.9mcg/mL in non-responders (**$p=0.045$**).
- ✓ In **Cluster-2**, younger patients (45.7 ± 12.4 years) with less time on treatment (18.8 ± 16.6 months) had a response rate of 73.7%. Responders had 21.5mcg/mL(IQR:15.6-30.55), while non-responders had 20.6mcg/mL(IQR:10.8-27.35), with no significant differences ($p=0.155$).

- ✓ We included 70 measurements of trough serum concentrations of VDZ from 39 CD patients in the maintenance phase
- ✓ Samples were grouped into 2 clusters

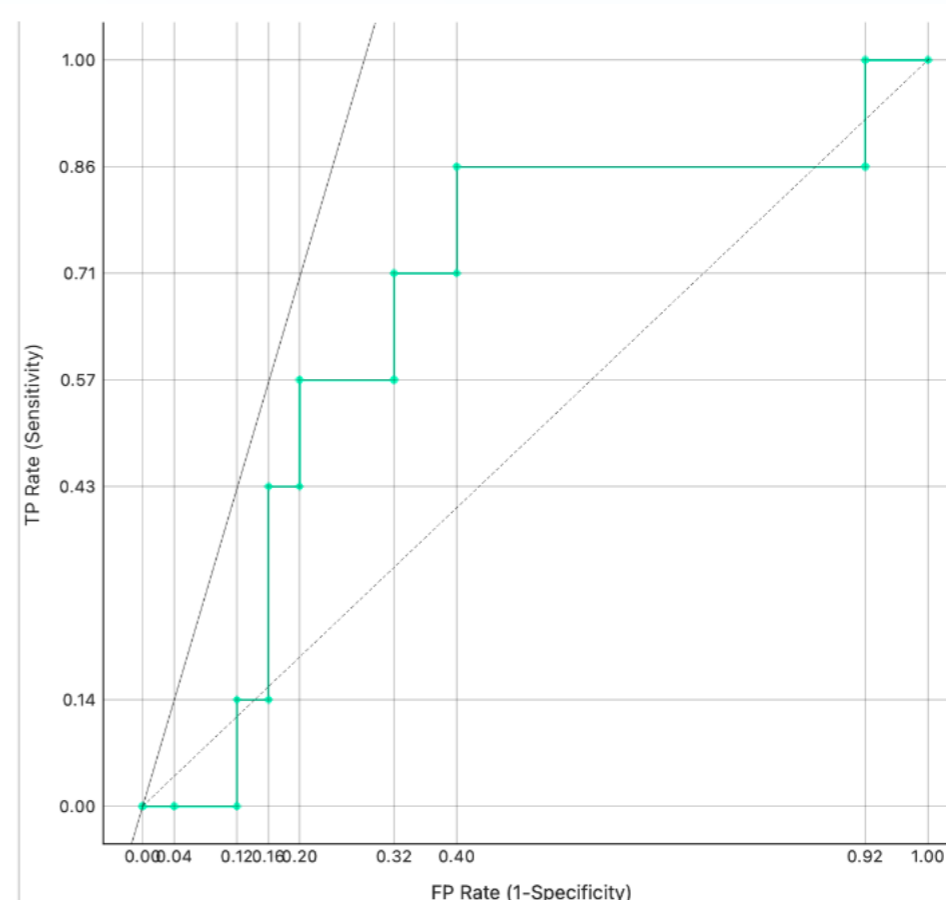


Figure 2. ROC curve of levels as predictors of clinical response, Cluster C1

- ✓ In Cluster-1, sensitivity was 0.712 and precision 0.737, obtained from the ROC curve
- ✓ **Logistic regression** identified age, VDZ levels, and time on treatment as key factors affecting treatment response.

CONCLUSION AND RELEVANCE

In Cluster-1, VDZ levels were significantly higher in responders, highlighting the importance of TDM in patients with longer treatment duration. The ROC curve showed moderate predictive ability, though 30% of responders were not predicted by VDZ levels alone, suggesting other factors like pharmacodynamic variability or subclinical inflammation could influence response. Logistic regression identified age, VDZ levels, and time on treatment as key factors for clinical response.