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VEDOLIZUMAB: OUTCOMES AND THERAPEUTIC DRUG MONITORING IN INFLAMMATORY BOWEL DISEASE

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BACKGROUND AND IMPORTANCE

Vedolizumab (VDZ) is an alternative in patients with IBD that have inadequate response or loss of response to previous treatment with tumour necrosis factor-alpha antagonists (TNFα). Therapeutic drug monitoring (TDM) has allowed to optimise anti-TNFα therapy but it is less known its implication with VDZ.

AIM AND OBJECTIVES

To evaluate prescribing **patterns**, **effectiveness** and **VDZ trough levels** (VTL) in clinical practice.

MATERIAL AND METHODS

- **Type of study**: Retrospective observational study from october 2015 to april 2019
- **Inclusion criteria**: age≥18 years, ulcerative colitis(UC) or Crohn's disease (CD) treated with VDZ after antiTNFα

Treatment effectiveness: Mayo Score (MS) and Harvey-Bradshaw Index (HBI) scores in UC and CD, respectively
Clinical remission: MS≤2 or HBS≤4

- **Collected variables**: gender, age, weight, diagnosis, concomitant immunosuppressive treatment, dose and pattern of VDZ, duration of treatment, trough VDZ concentrations and anti-VDZ antibodies(AVA), concentration of C-reactive protein (CRP) and faecal calprotectin (FC).
- **Data collection**: patient's clinical records
- **Statistical analysis**: percentages and 95% confidence intervals

RESULTS

25 patients
(52% male)

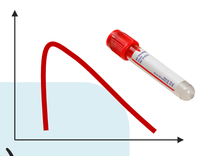
- Average age: **42 years** (Range: 22-75)
- Average weight: **75 kg** (CI95% 67-82)

UC 52% (n=13) CD 44% (n=11)

- **Treatment suspension**: 10 patients (mainly by secondary therapy failure)
- **Intensified schedule**: 7 patients (28%) at 300mg/4weeks
- **Need of extra dose on W10**: **36%** patients(n=9).
- **Clinical remission**: **50%** in **UC** and **67%** in **CD**

- ≥1 immunosuppressant+VDZ: 60% of the patients (in the beginning)
- **Median duration** of the treatment: **79 weeks** (CI95%:59-99)

VTL



Induction phase: 45.3 µg/mL (CI95%: 31.0-60.0) (6 patients)
Maintenance phase: 25.7 µg/mL (range: 6.40-105)

In patients with **CRP≤5µg/mL**, **VTL was higher** (mean 34.3 µg/mL) **than in patients with CRP>5µg/mL** (mean 21.1 µg/mL).

CRP and **FC** concentration were **reduced** by an average of **1.9 µg/mL** and **1454 mcg/g**, respectively, during the treatment.

AVA WERE **NOT DETECTED** IN ANY PATIENT

CONCLUSIONS AND RELEVANCE

Around **1/3 of patients** requires **intensification** of treatment, despite **not identifying the presence of AVA**. Observed CR rates **are quite modest**, therefore VDZ TDM can be a useful tool for the physician in the decision-making process.

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