a median time of 35 weeks (IQR 27–47). TLs were 5.2 µg/ml (IQR 2.1–8.8), 1.7 µg/ml (IQR 0.3–4.3) and 2.6 µg/ml (IQR 0.6–4.1) at week 8, 16 and 24, respectively. TLs at week 8 were correlated to the induction IV dose administrated (r = 0.3, p = 0.03). At week 16, low TLs were associated with higher endoscopic activity in the follow-up (p = 0.02), although this was not the case at week 8 (p = 0.5) (Figure 1).

Patients not requiring an optimisation had higher TLs in maintenance than patients requiring optimisation (2.45 µg/ml (IQR 1.3–4.4) vs. 1.15 µg/ml (IQR 0.1–2.24), p = 0.008). Obviously, optimisation significantly increased TLs (1.15 µg/ml (IQR 0.1–2.24) vs. 6.6 µg/ml (IQR 2.3–11.3), p < 0.001). ADA were undetectable in all the measured samples in maintenance.

Conclusion: This real-world experience confirms a drug exposure-endoscopic response relationship. Week 16 seems to be an appropriate time point to monitor drug exposure. Earlier USK TLs, at week 8, appear less valuable to be monitored due to the influence of initial IV dose. The absence of immunogenicity suggests that it is not a key driver in the loss of response.

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Undetectable levels of adalimumab in clinical practice: Should we say goodbye to the drug?

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Background: Therapeutic drug monitoring (TDM) is used in inflammatory bowel disease to guide dosing of biologics to individualise drug exposure and optimise outcomes. In case of undetectable levels of Adalimumab (levels <1.6 µg/ml) some authors recommend to discontinue the treatment, although this strategy is not universally accepted. The aim of this study was to describe the evolution (recovery of levels and persistence of treatment) of patients with undetectable levels of ADA and its relationship with the different treatment strategies (dose escalation and/or addition of an immunosuppressant)

Methods: Since October 13 to August 19, 758 TDM were performed in 260 patients treated with ADA. We selected the patients who had at least a level <1.6 µg / ml. Patients with follow-up fewer than 90 days after level detection and those in whom the drug was withdrawn at that time were excluded

Results: We identified 46 patients with undetectable levels; 12 were excluded. Thirty-four patients were included, 29 (85.3%) with Crohn's disease and 5 (14.7%) with ulcerative colitis. Ten (29.4%) patients had combined treatment and 17 (50%) had previously received another anti-TNF. In 24 (70.6%) TDM was performed proactively. After detection of levels <1.6 µg /ml, ADA was intensified in 20 patients (58.8%) either shortening the interval in 18 (90%), increasing the dose in 8 (40%) or with both interventions in 6 (30%). In 5 (14.7%) patients an immunomodulator was added and in 14 (41.2%) the treatment was not modified. At the end of the follow-up (mean 1101 days; SD 510) 61.8% (21/34) of the patients continued with ADA: 75% (15/20) in the intensified group and 42.9% (6/14) in the group of those who did not receive changes in treatment. Fourteen patients (41. 2%) recovered therapeutic levels (>5 µg/ml), 12 (60%) in the intensified-patient group and 2 (14.3%) in the group in whom the treatment was not modified. ADA was withdrawn in 13 patients (32.8%) after a mean time of 358 days (SD 258). The ADA maintenance rate (HR=3.88; 95% CI 1.2–12.4; p = 0.02) and the recovery ratio of ADA levels (HR = 6.75; 95% CI 1.1–39, 8; p = 0.03) was higher in the intensified group. Hypoalbuminemia was associated with an earlier withdrawal of ADA (p = 0.03)

Conclusion: The intensification of ADA in patients with IBD and undetectable plasma concentrations allows recovery of levels and maintenance of the drug in a high percentage of patients. The decision to withdraw treatment in patients with undetectable levels should be individualised.

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Clinical outcomes and response predictors of vedolizumab treatment for anti-TNF-failed patients with IBD in Korea: A prospective multicenter cohort study

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