

Therapeutic Drug Monitoring of Adalimumab During Long-term Follow-up in Paediatric Patients With Crohn Disease

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Abstract

Objectives:

We investigated the therapeutic drug monitoring of adalimumab (ADL) on clinical remission (CR) and mucosal healing (MH) rates in paediatric patients with Crohn disease (CD). Furthermore, long-term treatment efficacy of ADL in paediatric CD was evaluated through 3-year follow-up.

Methods:

We conducted a prospective study of 31 patients with CD who received ADL maintenance therapy and underwent endoscopic evaluation of MH and pharmacokinetic analysis. Patients in CR were identified based on Paediatric Crohn Disease Activity Index (PCDAI) scores less than 10. Patients with MH were identified based on Simple Endoscopic Scores for Crohn Disease (SES-CD) of less than 2.

Results:

At 4 months and 1 year of ADL treatment, 28 and 26 patients, respectively, were under CR; 13 and 17 patients, respectively, achieved MH. The median trough levels (TLs) of ADL were higher in patients in CR (7.6 ± 3.5 $\mu\text{g/mL}$) than in patients with active disease (5.1 ± 2.2 $\mu\text{g/mL}$). ADL TLs were significantly higher in patients who achieved MH than in those who did not (14.2 ± 7.6 vs 7.8 ± 5.2 $\mu\text{g/mL}$). The optimal cut-point for predicting MH at 1 year of ADL treatment was 8.18 $\mu\text{g/mL}$. During long-term follow-up, ADL TLs were stably maintained over 10 $\mu\text{g/mL}$; not only CR and MH but also histologic remission was obtained at a high rate. ADL administration maintained a positive effect on growth during the maintenance period.

Conclusions:

ADL TLs were significantly higher in paediatric patients with CD who achieved CR or MH. ADL treatment showed long-term stable efficacy and positive effects on growth indicators.