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# Potential Utility of Therapeutic Drug Monitoring of Adalimumab in Predicting Short-Term Mucosal Healing and Histologic Remission in Pediatric Crohn's Disease Patients

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## ABSTRACT

**Background:** Limited data exists regarding mucosal healing (MH) and therapeutic drug monitoring (TDM) in pediatric Crohn's disease (CD) patients treated with adalimumab (ADL). We aimed to investigate the associations between ADL trough levels (TLs) and MH, and between ADL TLs and histologic remission (HR) at 16 weeks from ADL treatment in pediatric CD patients.

**Methods:** This was a prospective study on moderate-to-severe luminal pediatric CD patients receiving ADL. Ileocolonoscopies and biopsies, as well as clinical activity assessments, laboratory exams, including tests for ADL TLs and antibody to ADL, were performed 16 weeks after ADL initiation. MH was defined as a Simple Endoscopic Score for CD of 0. HR was defined as the complete absence of microscopic inflammation.

**Results:** Seventeen subjects (13 males, 4 females) were included. At 16 weeks from ADL initiation, 14 (82.4%), 8 (47.1%), and 4 (23.5%) patients achieved clinical remission, MH, and HR, respectively. ADL TLs were significantly higher in patients who achieved MH compared to those who did not ( $13.0 \pm 6.5$  vs.  $6.2 \pm 2.6$   $\mu\text{g/mL}$ , respectively;  $P = 0.023$ ) and also significantly higher in patients who achieved HR compared to those who did not ( $17.9 \pm 5.3$  vs.  $6.8 \pm 2.5$   $\mu\text{g/mL}$ , respectively;  $P = 0.02$ ). The optimal TL for predicting MH was  $8.76$   $\mu\text{g/mL}$ .

**Conclusion:** Serum ADL TLs at 16 weeks were significantly higher in pediatric patients with CD who achieved MH and HR, respectively. TDM may guide in optimizing treatment efficacy and better target MH in the era of treat-to-target.

**Keywords:** Therapeutic Drug Monitoring; Mucosal Healing; Adalimumab

## INTRODUCTION

The traditional goal of treating Crohn's disease (CD) in the past was to improve symptoms and to obtain clinical remission. However, inflammation can still persist despite the absence of symptoms, and many patients experience complications such as intestinal stricture and perforation.<sup>1</sup> Moreover, clinical symptoms do not always correlate with the disease activity

















