2012. IMAgINE 1

Phase 3/ADA/paediatric CD

Safety and Efficacy of Adalimumab for Moderate to Severe Crohn's Disease in Children

Phase 3, randomized, open-label induction followed by double-blind maintenance trial. Paediatric CD.
Groups were given double blind maintenance therapy with adalimumab at high (40 mg or 20 mg for body weight >40 kg or <40 kg) or low doses (20 mg or 10 mg for body weight >40 kg or <40 kg) q2w for 48 weeks.

Primary outcome: Clinical remission (defined as PCDAI score 10) at w26. The secondary end points included clinical remission at w52 and with clinical response at w26 and w52.

Results:

- At w26, 33.5% were in clinical remission, with no difference between high- and low-dose groups (36/93 [38.7%] vs 27/95 [28.4%]; p 0.075).

Conclusions:
ADA induced and maintained clinical remission of children with CD, with a safety profile comparable to that of adult patients with CD. More children who received high compared with low dose were in remission at w26, but the difference between dose groups was not statistically significant.

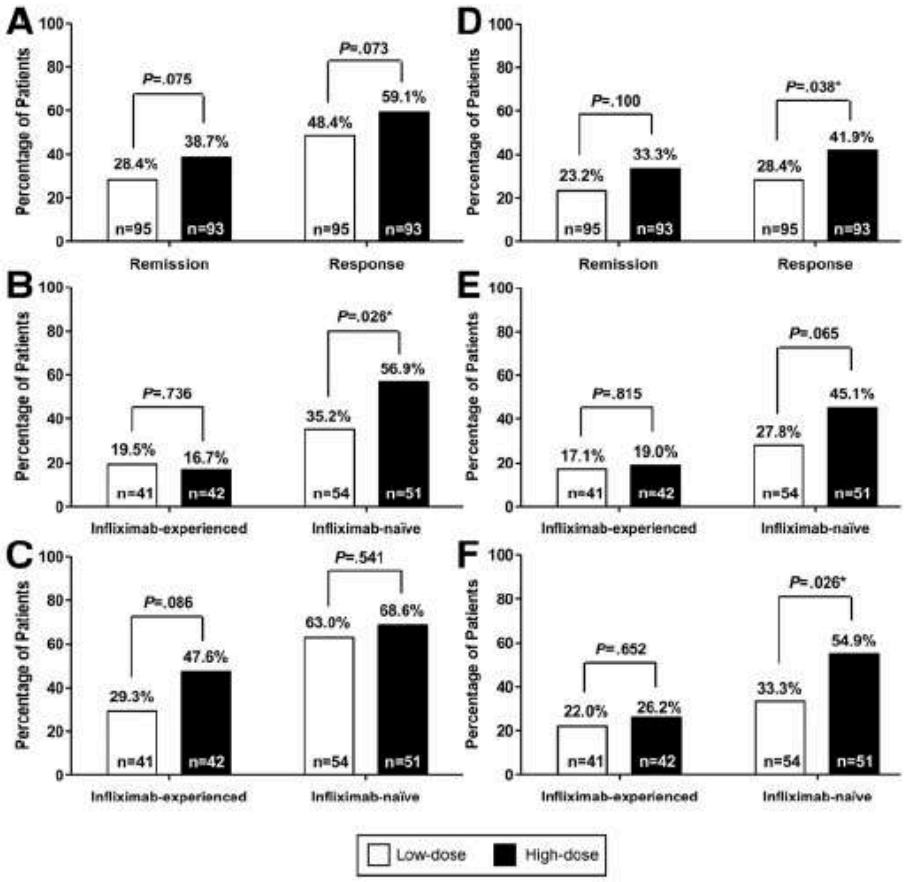

Figure 2. Results at (*A–C*) week 26 and (*D–F*) week 52. (*A*) Clinical remission and clinical response in the low- and high-dose groups at week 26. (*B*) Clinical remission and (*C*) clinical response in the dose groups by prior infliximab use at week 26. (*D*) Clinical remission and clinical response in the low- and high-dose groups at week 52. (*E*) Clinical remission and (*F*) clinical response in the dose groups by prior infliximab use at week 52.

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