2012. ULTRA II

RCT/ADA/UC/ Induct/Maintain

ADA in the Treatment of Mod-Severe UC: ULTRA 2 Trial Results

Randomized double-blind trial. 2 arms: ADA induction 160 mg-80mg-40 mg eow or placebo. Concomitant therapies permitted (AZA, Steroids, 5ASA). Patients stratified per previous antiTNF exposure

Primary end point: Clinical remission w8 and w52

Results clinical remission:

- w8: 16.5% ADA vs 9.3% placebo, p=0.019
- w52: ADA 17.3% vs 8.5% pbo, p=0.004
- antiTNF naïve w8: 21.3% vs 11% placebo, p=0.017
- antiTNF naïve w52: 22% vs 12.4%, p=0.029
- NO naïve w8: 9.2% ADA vs 6.9% placebo, p=ns
- NO naïve w52: ADA 10.2% vs 3% placebo, p=0.039

Conclusions:

Adalimumab was safe and more effective than placebo inducing and maintaining remission in patients with mod-severe UC

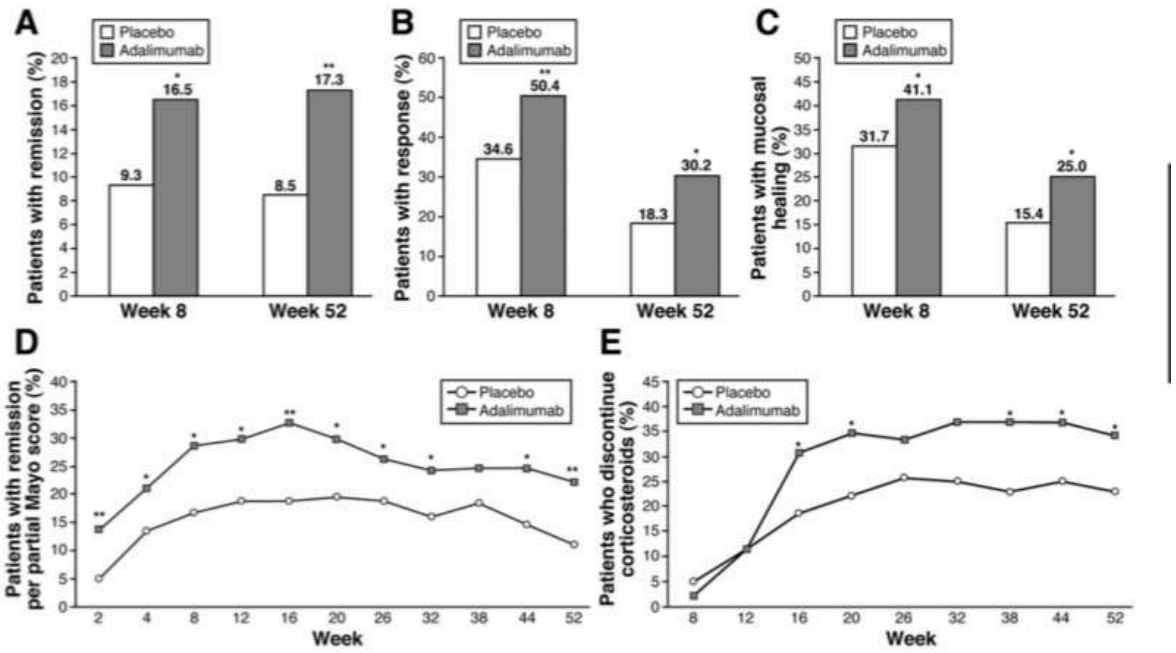

Figure 1. (*A*) Proportion of patients with clinical remission at week 8 and week 52. Proportion of patients with (*B*) clinical response and (*C*) mucosal healing at week 8 and week 52. (*D*) Proportion of patients achieving remission per partial mayo score over time. (*E*) Corticosteroid discontinuation by visit among baseline corticosteroid users. Intent-to-treat population; nonresponder imputation method. $^{*}P < .05$; $^{**}P < .005$ based on Cochran–Mantel–Haenszel test.

Sandborn WJ et al. Gastroenterology 2011; 142; 257-263