2017. Budesonide vs 5ASA

RCT/Bude vs 5ASA/ CD/Induction

Efficacy and Safety of Oral Budesonide in Patients with Active Crohn's Disease in Japan: A Multicenter, Double-Blind, Randomized, Parallel-Group Phase 3 Study

Phase 3 non-inferiority study
Patients with active Crohn's disease with CDAI of 180-400 were randomized to budesonide 9mg/day or mesalazine 1gr/8h for 8 weeks.
Patients were allowed to be on AZA/MP if stable dose for 3 months, to be on elemental diet if it was constant for 2 weeks. Excluded patients on biologics

Primary endpoints: Clinical remission at week 8

Results: N=112

- Clinical remission at week 8 was 30.4% budesonide vs 25% mesalazine, noninferiority of budesonide to mesalazine was proved.
- Mean total CDAI decreased more with budesonide than with mesalazine.

Conclusion:
Budesonide is comparably effective to mesalazine in the treatment of Japanese patients with mild-moderate CD

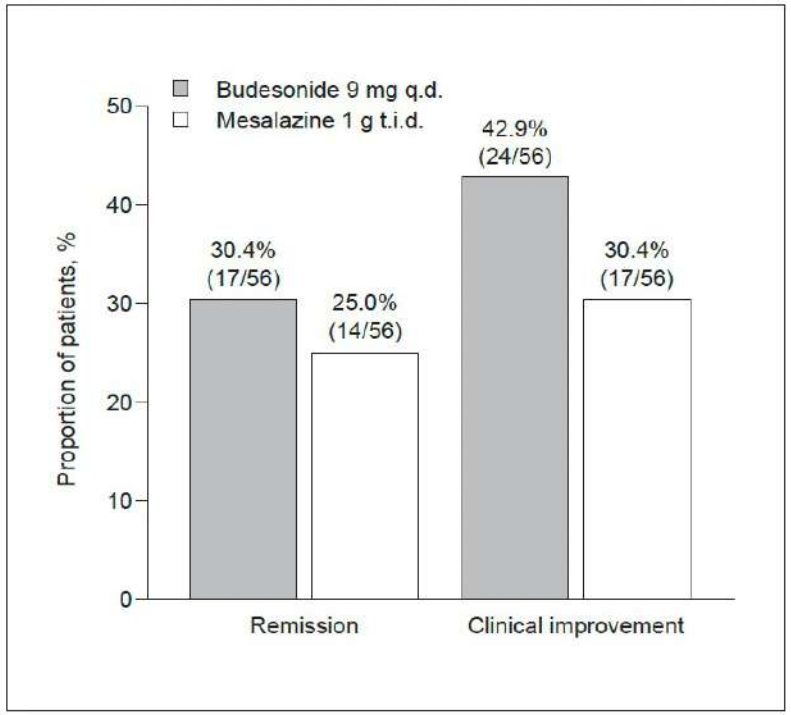

Fig. 2. Rates of remission (Crohn's Disease Activity Index [CDAI] score ≤150) and clinical improvement (CDAI score ≤150 or CDAI score decrease from baseline ≥100) at week 8 of the treatment phase. q.d., once daily; t.i.d., three times daily.

Yokoyama T et al. Inflamm Intest Dis.2017; 2:154-162