

1979. Prednisone, Sulfasalazine or AZA

RCT/Pred-Sulfas-AZA/CD/ Induct&Maintain

National Cooperative Crohn's Disease Study: Results of Drug Treatment

Two independent double-blind randomized trials. Patients were randomized to prednisone (0.25-0.75mg/kg depending on CDAI), sulfasalazine (1g/15kg part I; 0.5g/15kg) and azathioprine (2.5mg/kg part I and 1mg/kg part II) vs. placebo.

Part I: Active CD therapy for 17 weeks.

Part II: Quiescent CD or complete resection of active disease within a year before entry into the study. Follow-up 2 years.

Primary endpoints: Part I: response CDAI<150 and no disease progression. Part II: prevention of flares.

Results: N=569 (Part I n=295; Part II n=274)

- Part I response (CDAI<150) at 17w : 60% pred; 43% sulfa; 36% AZA; pbo 30%, p=0.0175 (sulfa vs pbo), p=0.0004 (pred vs pbo)
- Previous exposure to prednisone or sulfasalazine and disease location influenced the outcomes in part I.
- Part II flares within 1 or 2 years: no differences between drugs and placebo.

Conclusion:

Prednisone & sulfasalazine are better than placebo inducing remission in CD but not azathioprine. Colonic CD was especially responsive to sulfasalazine & small bowel CD to prednisone. For patients in quiescent disease, none of the drug was superior to placebo preventing flare recurrence or postoperative recurrence.

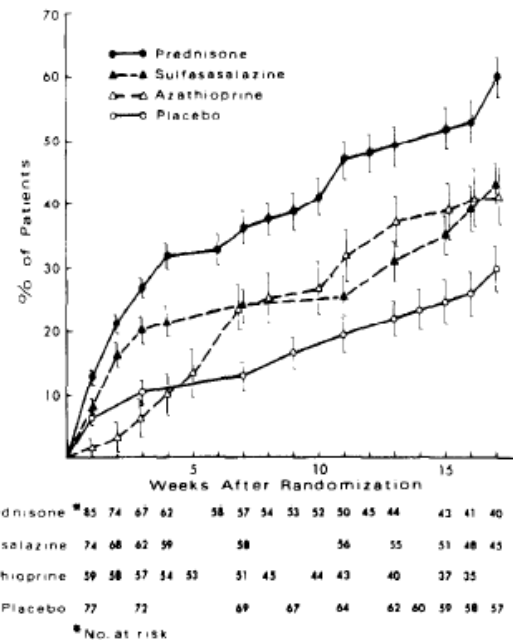


Figure 4. Cumulative percent of patients in remission week-by-week in part I, phase 1. Remission is defined as CDAI less than 150 and continuing below 150 through week 17. Brackets indicate standard errors of the mean. Life table using Kaplan-Meier method.⁶

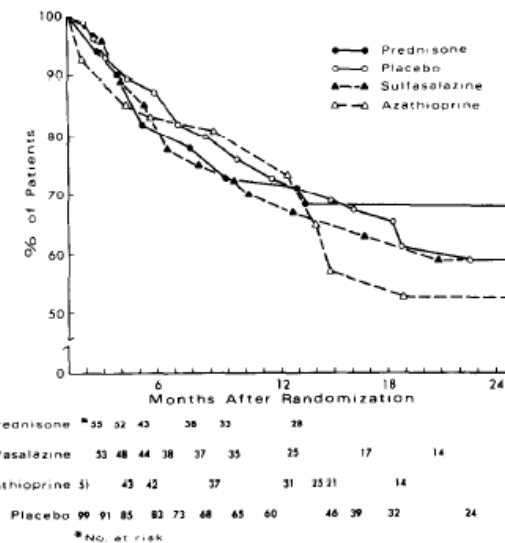


Figure 7. Percent of patients not suffering relapse in part II. Relapse is defined as withdrawal from study for any of the following reasons: CDAI > 150 and over 100 points greater than initial CDAI for two consecutive weeks; need for operation; development of new fistula other than simple fistula-in-ano; persistence of fever over 38.9°C for over 14 consecutive days; interim barium x-rays judged to be worse than initial x-rays. Life-table using Kaplan-Meier method.⁶ The apparent discrepancy between the percentage of patients still in remis-

