2019. PAILOT

Phase 3/ADA/ pediatricCD / Remission

Proactive Monitoring of ADA Trough Concentration Associated With Increased Clinical Remission in Children With CD Compared With Reactive Monitoring

Non blinded RCT. Randomization 1:1 proactive TDM vs reactive TDM.

Primary outcome: sustained corticosteroid-free clinical remission (PCDAI <10 points) at all visits from w8 to 72.
Secondary outcomes: corticosteroid-free clinical remission on ADL at weeks 48 and 72; sustained biologic remission (defined by CRP 0.5 mg/dL
and fecal calprotectin 150 mg/g) from week 8 to 72, and at weeks 48 and 72.

Results:

- The primary endpoint was achieved by 82% in the proactive group and 48% in the reactive group (p 0.002).
- Proactive group 42% achieved a composite outcome of sustained corticosteroid-free remission, CRP 0.5 mg/dL, and level of fecal calprotectin 150 mg/g vs12% in the reactive group (p 0.003).

Conclusions:
Proactive monitoring of ADA trough concentrations and adjustment of doses and intervals resulted in significantly higher rates corticosteroid free clinical remission than reactive monitoring in pediatric CD.

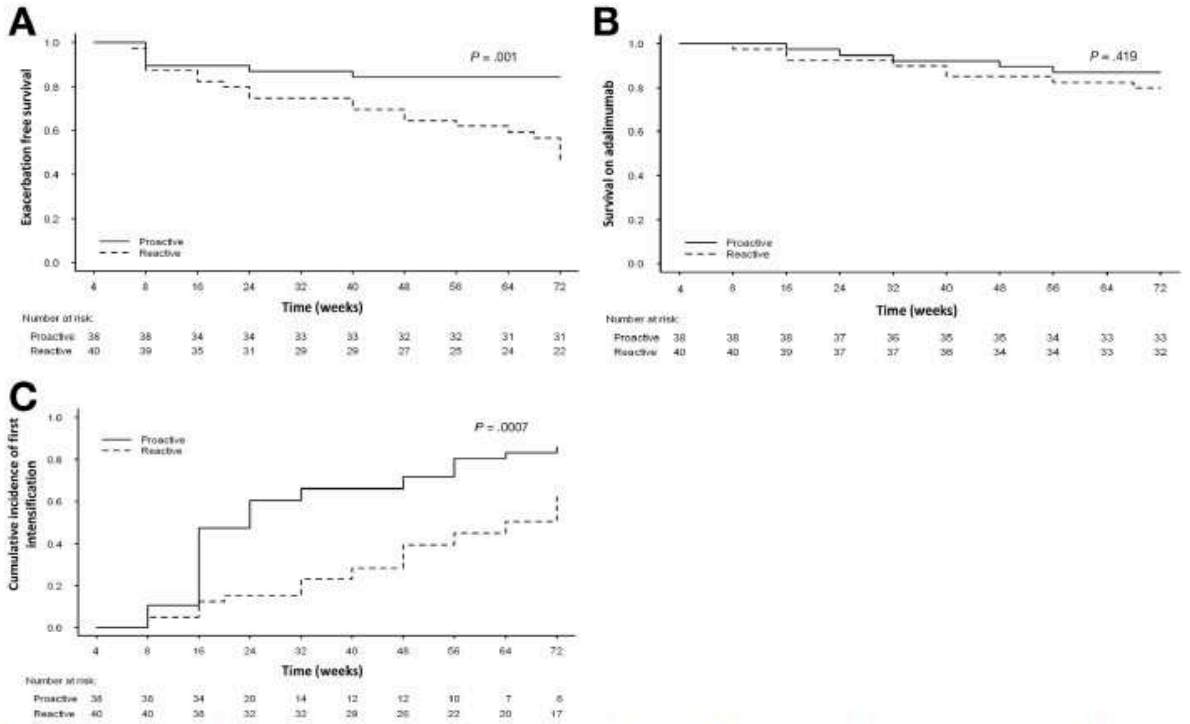

Figure 1. (*A*) Cumulative incidence of sustained corticosteroid-free clinical remission (PCDAI <10), weeks 8 to 72. (*B*) Cumulative incidence of ADL retention, weeks 8 to 72. (*C*) Cumulative incidence of the first ADL intensification.

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