

Multicenter retrospective study. Propensity score oral or subcutaneous administration and dosing were dictated by the physicians' discretion. All patients were biologic naïve

**Primary endpoints:** sustained steroid-free remission (SSFR) defined as PCDAI  $\leq 10$  and (where applicable) no fistula discharge at 6 months and 12 months without stopping MTX or requiring treatment escalation

#### Results:

- No differences in steroid-free remission between PO and SC at 12 months,  $p=0.52$ .
- No differences in the need for treatment escalation,  $p=0.24$
- No differences in liver enzyme elevation or nausea,  $p=0.59$  &  $p=0.85$
- Height velocity was lower in the PO group  $p=0.006$
- Time to remission was delayed in the PO group,  $p=0.036$

#### Conclusion:

SC MTX was superior to PO, but only in some of the outcomes and with a modest effect size. Therefore, it may be reasonable to consider switching children in complete remission treated with subcut MTX to the oral route with close monitoring of inflammatory markers and growth.

**Figure 1** Outcomes of the treatment groups. (A) Unadjusted outcomes of the entire cohort; (B) Outcomes of the oral group compared with a random subcohort from the subcutaneous group, matched for disease duration and disease activity at baseline. Footnote: Treatment escalation, steroid-free 1 year sustained remission (steroid-free remission), steroid dependency, significant ELE (elevated liver enzymes), and severe nausea are as defined within the text; catch-up growth is defined as a positive height velocity z-score. PO, orally; SC, subcutaneously.

