2014. 5ASA dose kids

RCT/5ASA/ UC/Induction

High- and Low-Dose Oral Delayed-Release Mesalamine in Children With Mild-to-Moderately Active Ulcerative Colitis

Randomized double-blind active control, parallel group study.
Children with mild-moderate active UC.
Patients randomized to: high or low dose of oral mesalamine (body weight-dependent doses) for 6 weeks.

Primary endpoints: W6 complete response (PUCAI<10) and partial response (reduction in the PUCAI score ≥ 20 points from baseline.
ITT analysis.

Results:
- Complete response w6 achieved 46.3% low dose and 42.5% high dose, p=ns
- Treatment success (complete response+ partial response)w6, 56.1%low dose vs 55% high dose, p =ns
- No differences in adverse events depending on high vs low dose

Conclusion:
Both low- and high-dose oral, delayed-release mesalamine doses were equally effective as short-term treatment of mild-to-moderately active ulcerative colitis in children, without a specific benefit or risk to using either dose.

TABLE 3. Efficacy outcomes

	Mesalamine dose groups, n (%)	
	Low dose (n = 41)	High dose (n = 40)
PUCAI treatment success*	23 (56.1)	22 (55.0)
PUCAI complete response	19 (46.3)	17 (42.5)
PUCAI partial response	4 (9.8)	5 (12.5)
Truncated Mayo Score treatment success	30 (73.2)	28 (70.0)
Truncated Mayo Score complete response	14 (34.1)	17 (42.5)
Truncated Mayo Score partial response	16 (39.0)	11 (27.5)

*Treatment success was defined as either a complete response (PUCAI score <10) or a partial response (defined by a reduction in the PUCAI score of ≥20 points from baseline to week 6/withdrawal, but with a week 6/withdrawal absolute PUCAI score of ≥10). PUCAI = Pediatric Ulcerative Colitis Activity Index.

Winter HS et al. J Pediatr Gastroenterol Nutr. 2014; 59 (6): 767-772