

Prospective, outcome-based study in new diagnosed pediatric CD. Study designed to evaluate and prognosticate different adverse outcomes such: relapse, growth retardation, surgery and to evaluate the effect of initial therapy on these outcomes.

Treatment at baseline as the physician discretion : 5ASA, steroids, EEN and infliximab. Maintenance: AZA, MCP, MTX or biologics

Primary endpoints: week-12 steroid-free clinical remission by PCDAI index and normal CRP.

Results:

- Baseline groups statistically different: 5ASA in mild CD, women with ileal CD and severity index.
- Predictor for CS-free PCDAI remission: older age (OR 2.39; 1.1-5); lower CRP levels (OR 0.92; 0.85-0.99)
- W12 clinical remission 73% patients, both EEN and steroids were associated with normal CRP remission at w12.
- Steroid-free remission w12, normal CRP predicted 1-year sustained remission 86% for normal CRP and 61% for elevated CRP, $p=0.02$

Conclusion:

Normal CRP steroid-free remission at week 12 was impacted by type of induction therapy, but not by early immunomodulation. It was associated with more corticosteroids-free remission at week 52 and a trend for less relapses.

Comparison of Outcomes Parameters for Induction of Remission in New Onset Pediatric Crohn's Disease: Evaluation of the Porto IBD Group "Growth Relapse and Outcomes with Therapy" (GROWTH CD) Study

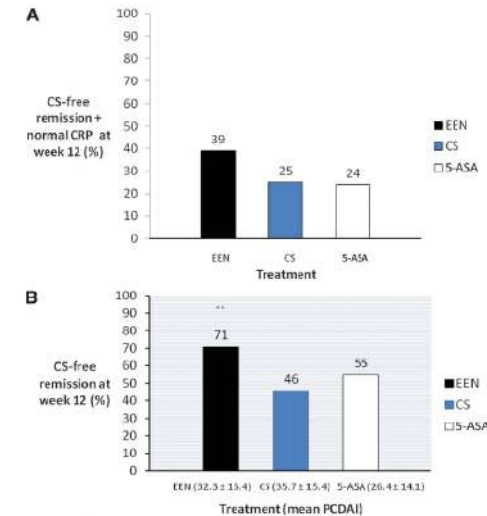


FIGURE 1. Outcomes by treatment. A, Normal CRP CS-free remission. B, CS-free remission at week 12. ** indicates $P = 0.0006$.

TABLE 2. Outcomes of Week 8 and 12, Stratified by the Induction Treatment

	CS (n = 114)	EEN (n = 43)	5-ASA (n = 29)	5-ASA and EEN (n = 15)
Week 8 values				
PCDAI	6.3 (0.6-10)	5 (0-15)	8.8 (4.4-13.8)	5 (1.3-11.3)
Calprotectin ^a	558 (162-1848)	1736 (617-2000)	759 (190-2000)	163 (96-2000)
Week 8 remission rate (%)				
PCDAI	77/109 (71)	31/40 (79)	20/28 (71)	12/15 (80)
Calprotectin <300 µg/g	22/72 (30.5)	3/23 (13)	4/12 (33.3)	5/10 (50)
CRP <0.5 mg/dL	60/103 (58.2)	22/38 (57.9)	13/20 (65)	12/14 (85.7)
PCDAI and CRP <0.5 mg/dL	47/104 (45)	20/39 (51)	10/22 (46)	10/15 (67)
PCDAI and FC <300 µg/g	17/70 (24)	3/23 (13)	1/12 (8)	5/11 (46)
PCDAI and CRP <0.5 mg/dL and FC <300 µg/g	13/67 (19)	3/22 (14)	0/11 (0)	5/11 (46)
Week 12 values				
PCDAI	5 (0-10)	2.5 (0-5)	7.5 (4.4-16)	5 (0-11.3)
Calprotectin (µg/g) ^a	617 (127-1396)	1520 (522-2000)	1717 (222-2000)	209 (133-1809)
CRP <0.5 mg/dL (%)	60/106 (57)	18/41 (44)	15/22 (68)	11/15 (73)
Calprotectin <300 µg/g (%)	26/76 (34)	6/30 (20)	3/13 (23)	6/12 (50)
Week 12 steroid-free remission rate^b (%)				
PCDAI (≤10 or ≤7.5 points)	51/110 (46) ^c	30/41 (71) ^{c,4}	16/29 (55) ^d	11/15 (73)
Calprotectin <300 µg/g	19/76 (25)	6/30 (20)	3/13 (23)	6/12 (50)
CRP <0.5 mg/dL	40/106 (38)	17/41 (42)	13/22 (59)	9/15 (60)
PCDAI and CRP <0.5 mg/dL	27/110 (25)	16/41 (39)	7/29 (24)	9/15 (60)
PCDAI and FC <300 µg/g	14/75 (19)	5/30 (17)	1/13 (8)	5/12 (42)
PCDAI and CRP <0.5 mg/dL and FC <300 µg/g	7/75 (9)	3/30 (10)	1/13 (8)	4/12 (33)

^aNote of the values were significant from each other (Kruskal-Wallis test).

^bThe only significant comparison between EEN and steroids was for PCDAI ($P = 0.006$), whereas the other 3 outcomes were not significant. 5-ASA was not significantly different than steroids (and in 34 outcomes also from EEN).