Baseline characteristics and nutrition in patients with moderately to severely active inflammatory bowel disease: Results from the phase 3 UNITI Jr and UNIFI Jr trials

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Key Takeaways

- The cross-sectional data presented here offers insight into nutritional status of treatment refractory pediatric IBD participants in the UNITI Jr and UNIFI Jr clinical studies and EEN usage in pediatric participants with CD
- Approximately half of the participants with CD in UNITI Jr (42.6%) were previously treated with EEN
- Approximately two thirds (64.2%) of the pediatric participants with moderately to severely active Crohn's disease or ulcerative colitis across both studies met the WHO criteria for mild or moderate anemia at study enrollment
- These data suggest that despite being at increased nutritional risk, only a small portion of participants met the criteria for mild malnutrition and vitamin D deficiencies, indicating appropriate use of international treatment guidelines for pediatric CD and UC

Background

Few clinical trials investigating the efficacy of pediatric inflammatory bowel disease (IBD) treatments evaluate the nutritional parameters and diet history of participants at enrollment

The pathophysiology of IBD may be influenced by nutritional factors
- IBD impacts nutrient absorption, loss, and contribute to a hypermetabolic state[1]

Exclusive enteral nutrition (EEN) is an effective induction therapy, and along with Crohn's disease (CD)-diet therapies improves CD-related disease symptoms[2]

Objective

Here, we characterize the nutritional parameters and growth status of participants in two phase 3 pediatric IBD studies (ie, UNITI Jr and UNIFI Jr) and nutritional therapy usage in CD

Methods

Population and Eligibility Criteria

Study Population
- Participants, 2 to <18 years of age, enrolled in two ongoing phase 3 trials evaluating the efficacy and safety of ustekinumab in moderately to severely active CD (UNITI Jr) or ulcerative colitis (UC; UNIFI Jr) with a history of inadequate response to corticosteroids, immunomodulators, and/or biologics

Nutritional History Eligibility Criteria
- UNITI Jr (CNTO1275CRD3004): Participants receiving EEN had to have a stable regimen for ≥2 weeks prior to ustekinumab induction initiation
- UNIFI Jr. (CNTO1275PUC3001): Participants previously receiving >80% of their daily caloric needs via EEN had to stop or reduce the percentage of nutritional therapy ≥4 weeks prior to ustekinumab induction initiation

Collected Data and Assessment

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Demographics and disease characteristics
- Height, weight, and BMI were assessed to evaluate growth parameters and nutrition status

Nutritional labs
- Vitamin D, total iron, and methylmalonic acid (MMA) were assessed to determine nutritional abnormalities (ie, deficiency of vitamin D, vitamin B12, or iron)

Hematology and chemistry
- Hematology and chemistry lab results were examined to evaluate eligibility for enrollment
  - Hemoglobin levels were assessed for the presence and severity of anemia as defined by the WHO guidelines

Nutritional therapy history (UNITI Jr only)
- Participants' nutritional therapy history were collected to assess therapeutic management of CD prior to and at study enrollment

Results

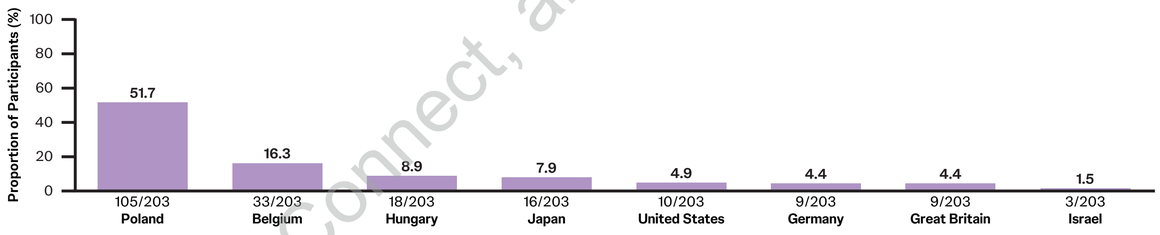
Table 1. Baseline Demographics and Disease Characteristics

Full analysis set	UNITI Jr (CD) (N=101)	UNIFI Jr (UC) (N=102)
Demographics		
Age in years, mean (SD)	13.5 (2.73)	13.4 (2.9)
2-5 years, n (%)	2 (2%)	1 (1%)
6-11 years, n (%)	18 (17.8%)	25 (24.5%)
12-17 years, n (%)	81 (80.2%)	76 (74.5%)
Male, n (%)	60 (59.4%)	44 (43.1%)
Race, n (%)		
Asian	8 (7.9%)	3 (2.9%)
Black or African American	3 (3%)	2 (2%)
White	88 (87.1%)	85 (83.3%)
Multiple	1 (1%)	10 (9.8%)
Weight Z score,[a] median [range]	-0.18 [-1.9; 4.5]	0.00 [-1.4; 2.9]
Height Z score,[a] median [range]	0.37 [-2.8; 2.6]	0.31 [-1.9; 2.6]
Body mass index Z score,[a] median [range]	-0.46 [-1.7; 4.1]	-0.18 [-1.7; 2.7]
Characteristics		
Disease duration, N	101	94
Years, mean (SD)	2.6 (2.24)	2.1 (2.08)
History of inadequate response or intolerance to biologic therapy, n (%)	53 (52.5%)	37 (36.3%)
Involved GI areas, N	99	102
Ileum only, n (%)	11 (10.9%)	-
Colon only, n (%)	18 (17.8%)	102 (100%)
Extensive	-	68 (66.7%)
Limited to left side of colon	-	34 (33.3%)
Ileum and colon, n (%)	58 (57.4%)	-
Proximal small intestine, stomach, and/or esophagus, n (%)	39 (38.6%)	-
Perianal, n (%)	33 (32.7%)	-
PCDAI score, mean (SD)	41.16 (7.6)	-
Mayo score, N	-	88
Mean (SD)	-	8.50 (1.5)
C-reactive protein in mg/L, N	101	100
Median [IQR]	8.3 [2.2; 27.5]	1.45 [0.4; 6.1]
Fecal calprotectin in mg/kg, N	98	76
Median [IQR]	1849 [1183; 2927]	2474 [1184.5; 4737.5]

[a]*Age and sex-specific.* ***GI****=gastrointestinal;* ***IQR****=interquartile range;* ***PCDAI****=pediatric Crohn's disease activity index;* ***SD****=standard deviation.*

The majority of the 203 total participants enrolled in UNITI Jr and UNIFI Jr were from the European Union

Figure 1. Proportion of Participants by Country of Origin



At enrollment, across UNITI Jr and UNIFI Jr:
- ***6 of 189 participants exhibited low vitamin D levels (<20 nmol/L)***
- ***3 of 188 participants exhibited elevated MMA (>378 nmol/L)***

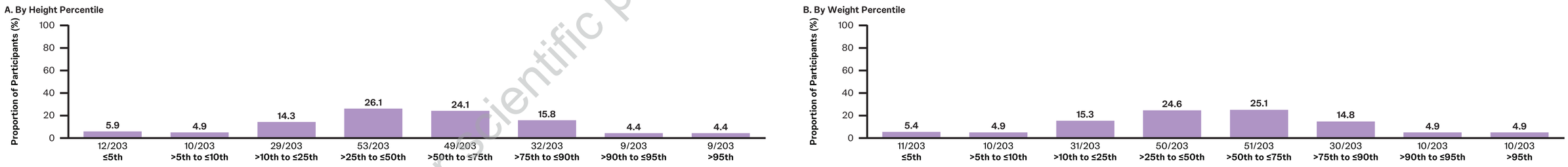
Table 2. Baseline Nutritional Labs and Hematology and Chemistry

	UNITI Jr (CD) (N=101)	UNIFI Jr (UC) (N=102)
Nutritional labs		
Vitamin D in nmol/L,[a] N	98	91
Median [range]	66 [13; 302]	60 [21; 260.1]
Iron in µmol/L, N	97	95
Median [range]	4.48 [1.3; 27.4]	5.00 [1.4; 63.5]
Methylmalonic acid in nmol/L,[b] N	96	92
Median [range]	136 [54; 677]	123 [56; 440]
Hematology and chemistry		
N	101	100
Erythrocyte mean corpuscular volume in fL, median [range]	81 [55; 98]	84 [64; 106]
Hematocrit (fraction of 1), median [range]	0.36 [0.3; 0.5]	0.36 [0.3; 0.5]
Hemoglobin in g/dL, median [range]	11.6 [8.7; 15.4]	11.35 [7.2; 15.3]
Albumin in g/L, median [range]	41 [25; 48]	43 [29; 51]

[a]*Low vitamin D defined as <20 nmol/L.* [b]*Elevated methylmalonic acid defined as >378 nmol/L.*

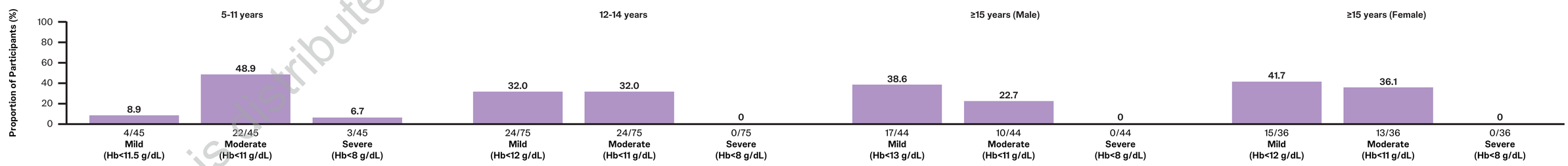
A small proportion of participants across both studies were in the ≤10th percentile by height and weight (10.8% and 10.3%, respectively)

Figure 2. Proportion of Participants by Height (A) and Weight (B) Percentiles at Enrollment



Across UNITI Jr and UNIFI Jr, 64.2% of participants (129/201) met the WHO criteria for mild or moderate anemia at study enrollment

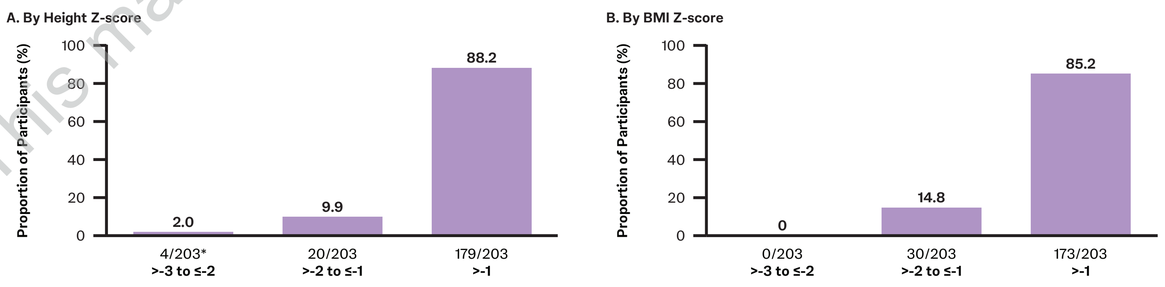
Figure 3. Prevalence of Anemia by WHO Guidelines at Enrollment



Note: There was 1 participant <5 years who did not meet the WHO criteria for anemia of any severity. They are excluded in the figure but included in the total count of participants with evaluable Hb levels (N=201).

According to guidelines,[3] a small percentage of study participants exhibited mild malnourishment (height or BMI z-scores >-2 to ≤-1)

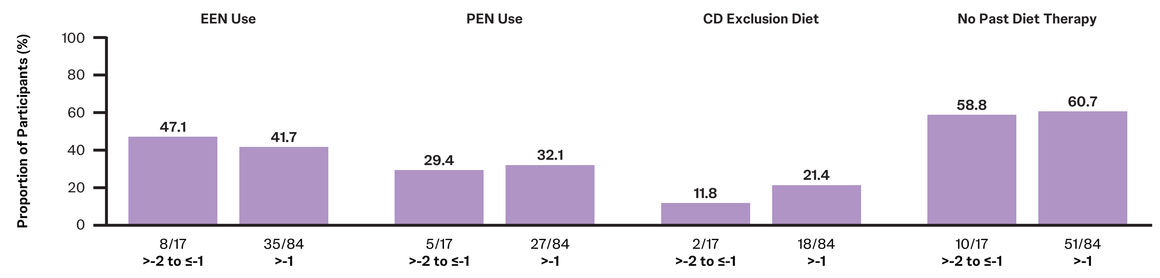
Figure 4. Proportion of Participants by Height Z-score (A) and BMI Z-score (B) at Enrollment



**Meets the definition of moderate malnutrition (>-3 to ≤-2); all 4 participants had CD.*

In UNITI Jr, the proportion of participants on nutrition therapy with low BMI Z-scores was highest among participants on EEN nutrition therapy

Figure 5. History of Nutritional Therapy Use by BMI Z-score for Participants Enrolled in UNITI Jr



Note: Findings are not mutually exclusive.

In UNITI Jr, 42.6% of participants (43/101) were treated with EEN previously

Table 3. Nutrition Therapy History for Participants Enrolled in UNITI Jr

	UNITI Jr (N=101)
Nutritional Therapy History	
History of nutritional therapies for CD, N	70
EEN, n (%)	43 (61.4%)
Duration participant received EEN, n/N (%)	
<1 month	9/43 (20.9%)
≥1 month and <3 months	16/43 (37.2%)
≥3 months and <6 months	10/43 (23.3%)
≥6 months	6/43 (14%)
PEN, n (%)	32 (45.7%)
Duration participant received PEN, n/N (%)	
<1 month	4/32 (12.5%)
≥1 month and <3 months	9/32 (28.1%)
≥3 months and <6 months	4/32 (12.5%)
≥6 months	14/32 (43.8%)
ON supplements, n (%)	28 (40%)
Past dietary therapies to try to improve CD, N	40
CD exclusion diet, n (%)	20 (50%)
Nutritional Therapy at Enrollment	
Nutritional therapy at enrollment, N	32
EEN, n (%)	7 (21.9%)
PEN, n (%)	18 (56.3%)
ON supplements, n (%)	15 (46.9%)
Currently using dietary supplements or alternative treatments, N	67
Vitamins, n (%)	43 (64.2%)
Minerals, n (%)	3 (4.5%)
Protein supplements, n (%)	3 (4.5%)
Other,[a] n (%)	18 (26.9%)

[a]*Includes participants who were taking both vitamin(s) and mineral(s).* ***CD****=Crohn's disease;* ***EEN****=enteral nutrition;* ***ON****=oral nutrition;* ***PEN****=partial enteral nutrition.*

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