M101 - Plant-Based Peptide Enteral Nutrition with Phytonutrients in a Pediatric Patient Status Post Bone Marrow Transplant: A Case Report

Melissa Bailey, MS, RD, CNSC, LDN[1]; Kelsey Bullard, MS, RD[2]; Vanessa Millovich, DCN, RDN, LDN[3]
[1]Kate Farms, Philadelphia, Pennsylvania; [2]Phoenix Children's Hospital, Phoenix, Arizona; [3]Kate Farms, Carpinteria, California

Purpose: Patient, AJ, is a 3-year-old male, with a history of Hemophagocytic Lymphohistiocytosis (HLH) diagnosed at one month of life, now status post (s/p) 10/10 matched unrelated donor stem cell transplant on 2/11/17 at 4 months of life. This case report documents the patient's transition to a plant-based pediatric peptide formula (PBPP) containing a powdered and concentrated phytonutrient blend, s/p bone marrow transplant (BMT). This case report demonstrates the successful concomitant use of an enteral formula containing phytonutrients and immunosuppressive medications, supporting the findings of other similar human trials. Prior to BMT, AJ was on standard dairy-based infant formula (22kcal/oz) PO ad lib. After developing pneumatosis (prior to transplant) patient was NPO on TPN from 12/2016-3/2017 when a nasojejunal (NJ) tube was placed. BMT occurred on 2/11/17. Status post BMT, enteral feeds were slowly advanced with a hypoallergenic infant formula (20kcal/oz), and then changed to another hypoallergenic infant formula (20kcal/oz). At 12 months, AJ was transitioned to a Junior version of a hypoallergenic formula (20kcal/oz). The concentration of the formula was slowly increased to 28kcal/oz. On 4/12/18 a G-tube was placed. From 4/12/18 through 10/2/18, patient had intermittent recurrent vomiting and/or diarrhea. From 10/2/18 to 11/16/18, AJ trialed a partially hydrolyzed dairy pediatric formula with soluble fiber (diluted to 26 kcal/oz) and continued to exhibit poor GI tolerance characterized by nausea, vomiting, large/loose stools, and blood in stool. On 11/16/18 patient was transitioned to a PPBP formula with phytonutrients (Kate Farms Pediatric Peptide 1.5 formula-diluted to 24.5 kcal/oz) due to presumed milk protein intolerance. Vomiting episodes significantly decreased, stools began to form, blood was no longer visible in the stool, and the patient began to show an increased interest in PO intake within a few days of the transition. Pertinent medications at time of transition to plant-based pediatric peptide formula 11/16/18: Oral suspensions of: Tacrolimus, Ranitidine, Acyclovir, pediatric multivitamin/mineral, Sirolimus, Fluconazole, Hydroxyzine, Ondansetron

Conclusion: Patient was able to successfully transition to a plant-based pediatric peptide enteral formula containing phytonutrients s/p BMT while on two immunosuppressive medications. There was no documentation of the phytonutrient blend interfering with any of the immunosuppressive medications. Prior to being placed on a PBPP enteral formula, patient had frequent episodes of nausea, emesis, diarrhea, and bloody stool and limited interest in oral intake. Within a few days of transitioning to a PBPP, all gastrointestinal symptoms began to improve, and the patient began to consume more from a regular oral diet for age. This case report demonstrates that a plant-based pediatric peptide formula containing phytonutrients improved GI tolerance, assisted with weight gain, and did not alter the efficacy of immunosuppressive medications in a pediatric patient status post BMT.

Table 1: Patient weight (kg) and corresponding formula type/concentration

Date	Weight (kg)	Formula Type/Concentration (kcal/oz)
10.23.17	10.8	Hypoallergenic; 20
6.4.18	11.43	Hypoallergenic; 22
6.11.18	11.32	Hypoallergenic; 24
7.19.18	11.61	Hypoallergenic; 26
9.11.18	11.49	Hypoallergenic; 28
10.2.18	12.05	MBPP*; 26
11.16.18	11.52	PBPP; 24.5
12.17.18	11.92	PBPP; 24.5
1.3.19	11.94	PBPP; 25
2.18.19	11.1	PBPP; 25
3.6.19	11.52	PBPP; 28
5.20.19	12.5	PBPP; 28
9.6.19	12.68	PBPP; 30

*MBPP=Milk-based pediatric peptide

(2020), Plant-Based Peptide Enteral Nutrition with Phytonutrients in a Pediatric Patient Status Post Bone Marrow Transplant: A Case Report, Bailey, M., Bullard, K., Millovich, V.; ASPEN NUTRITION SCIENCE AND PRACTICE CONFERENCE: Tampa, Florida, March 28 – 31, 2020. Journal of Parenteral and Enteral Nutrition, 44(3): 226-227.doi.org/10.1002/jpen.1813

765986 - Plant-based Enteral Nutrition Tolerance and Benefit in Pediatric Crohn's Disease: A Case Series

Daniel Orellana, MD[1]; Natasha Avila, RD[2]; Melissa Bailey, MS, RD, CNSC, LDN[3]; Karla Au Yeung, MD[2]
[1]Valley Children's Hospital, Fresno, California; [2]Valley Children's Hospital, Madera, California; [3]Kate Farms, Philadelphia, Pennsylvania

Purpose: Exclusive enteral nutrition (EEN) for 6-8 weeks with polymeric formula as a sole source of nutrition induces remission in up to 70% of pediatric inflammatory bowel disease (IBD) patients. Partial enteral nutrition (PEN) with Crohn's disease exclusion diet (CDED) has also been shown to induce remission in pediatric IBD patients with better tolerance. The CDED is a plant-based diet restricting dairy, emulsifiers, and animal fats. A plant-based diet has been shown to promote mucosal healing, decrease inflammation and growth of healthy gut bacteria. At our institution, we use CDED and PEN with a pediatric peptide plant-based enteral nutrition (PPBEN) 1.5 kcal/mL to provide 80% daily caloric needs including 1-1.5 g/kg/day of protein.

Methods: We present a case series of three pediatric Crohn's Disease patients (CD) patients in clinical remission who were started on PPBEN in conjunction with CDED 3-7 months prior to follow-up visit. All patients were either taking casein-based pediatric peptide EN or elemental formula before trial of PPBEN. Two received PPBEN by gastrostomy tube (GT) and one took it orally. Questionnaires were conducted and labs were analyzed. Anthropometrics were measured.

Results: All three patients preferred the PPBEN over their previous formula. All patients experienced less bloating, gas and fullness after feeds. They also endorsed less gastroesophageal reflux symptoms. With improved tolerance of PPBEN, all patients received the prescribed volume more routinely. All three patients gained weight [+1.1, +0.4, +2.5 (kg)] and increased body mass index (BMI) Z-scores (+0.07, +0.03, +0.25) with PPBEN. Weight-for-age Z-scores increased for Patient 1 & 3, but decreased slightly for Patient 2 despite increase in weight and BMI (+0.02, -0.05, +0.17). (Table 1 & 2) Patient 2 & 3 had Harvey-Bradshaw scores of 2 (symptomatic remission). Patient 1 is status post ileocectomy and has more frequent stooling at baseline since surgery (6/day) with Harvey-Bradshaw 7. Patient 1 labs: CRP remained within normal limits at < 0.1 mg/dL before and after starting PPBEN. ESR remained stable at 4mm/hr. Patient 2 labs: CRP was normal at 0.2 mg/dL at initiation of PPBEN; patient gained weight due to better tolerance of nocturnal GT feeds. Patient 3 labs: ESR, CRP and stool calprotectin decreased. The ESR prior to PPBEN was 75mm/hr and decreased to 47 mm/hr over 7 months. CRP dropped to 1.7mg/dL from 2.7 mg/dL. Stool calprotectin (880 ug/g to 820 ug/g) did not improve as much although patient denied diarrhea or abdominal pain.

Conclusion: This case series supports that PPBEN is an alternative nutritional therapy preferred by pediatric Crohn's patients due to less bloating, gas, and fullness. Patients tolerated the formula, overall felt better, and gained weight. One patient had a decrease in inflammatory markers. Studies are needed to determine the long-term benefit of plant-based enteral nutrition with CDED in pediatric Crohn's disease.

Table 1: Anthropometrics for patients before and after plant-based nutrition initiation.
Duration on plant-based nutrition: **Patient 1 & 2**: three months. **Patient 3**: seven months.

	Weight (kg) / Z-score Before	Weight (kg) / Z-score After
Patient 1	60.9 / 0.84	62.1 / 0.86
Patient 2	37.6 / -0.24	38.3 / -0.29
Patient 3	57.9 / 0.24	60.4 / 0.41

Anthropometrics for patients before and after plant-based nutrition initiation.

Table 2: Anthropometrics for patients before and after plant-based nutrition initiation.
Duration on plant-based nutrition: **Patient 1 & 2**: three months. **Patient 3**: seven months

	BMI Z-score before	BMI Z-score after
Patient 1	0.77	0.84
Patient 2	-0.54	-0.47
Patient 3	0.30	0.55

Anthropometrics for patients before and after plant-based nutrition initiation.

(2020), Plant-based Enteral Nutrition Tolerance and Benefit in Pediatric Crohn's Disease: A Case Series, Orellana, D., Avila, N., Bailey, M., Au Yeung, K., ASPEN NUTRITION SCIENCE AND PRACTICE CONFERENCE: Tampa, Florida, March 28 – 31, 2020. Journal of Parenteral and Enteral Nutrition, 44(3): 190-191.doi.org/10.1002/jpen.1813

M147 - Patient-Reported Outcomes Indicate Plant-Based Enteral Formula Improves Nutrition and Gastrointestinal Symptoms

Stanley Cohen, MD[1]; Ana Ramirez, MD[1]; Vanessa Millovich, DCN, RDN, LDN[2]
[1]Children's Center for Digestive Health Care, Atlanta, Georgia; [2]Kate Farms, Carpinteria, California

Purpose: Little information is known on the tolerance and efficacy of plant-based enteral formulas (PBEF). The purpose of this study was to investigate patient-reported outcomes of those who have ever been on a PBEF.

Methods: Potential participants (n=1542) were identified using the manufacturer's online database. An electronic survey, utilizing REDCap®, was sent via email. Participants received a $25 Amazon® gift card for their time and participation. The survey consisted of questions on demographics, health outcomes while on a PBEF, and health outcomes while on the formula used previously, if applicable. Responses to health reported outcomes were on a 5-point scale of agreement with additional options for unsure and prefer not to answer. Strongly agree/agree (SA/A) were considered positive.

Results: Formula-user characteristics: There were a total of 398 respondents to the survey. Of those who completed the survey, (n=392), 46.7% (n=183) of responses were from actual users and 53.0% (n=207) of responses were from their caregivers. More formula users were female (57.0%) and most, 28.2% (n=111), were between the ages of 21-40 years. Primary diagnoses included gastroparesis (17.0%), cancer (16.6%), failure to thrive (7.9%), or malnutrition (7.4%). Of those who had used any of the PBEFs, 63.8% used an intact pea protein formula and 48.7% used a hydrolyzed pea protein formula. Over half of the formula users, 53.6% (n=210) took the formula by mouth and the remainder (n=182) reported it to be used via feeding tube (syringe, gravity, and/or pump). Approximately one-half of formula users (49.7%) were on the PBEF > 6 months. For 71.0% of formula users, the PBEF made up 50% or more of their nutrition. Prior to the PBEF, 45.0% (n=176) were on an intact dairy-based formula, 7.4% were on a blended formula, and 6.6% were on a hydrolyzed dairy formula. Patient-reported outcomes: Among formula users, 78.6% (n=308) felt healthier on the PBEF (SA/A) while 1.3% (n=5) did not. In addition, 88.5% (n=347) reported that the PBEF improved their nutrition; 1.0% disagreed. Two-thirds (n=246) of respondents reported that the PBEF improved digestive symptoms (i.e., easier bowel movements; or less reflux, abdominal discomfort, bloating, or nausea). Weight gain was reported in 58.4% of formula users, 27.8% reported no change in weight, and 6.4% reported weight loss. At the time of the survey, 63.7% (n=249) were still using a PBEF. For those no longer using a PBEF, 12.3% reported that there was no longer a need for a formula, 8.7% reported no insurance coverage, 4.3% didn't tolerate it, and 1.0% didn't like the taste.

Conclusion: This study assessed patient-reported outcomes of pediatric and adult users of plant-based enteral formulas containing intact or hydrolyzed pea protein. PBEF use resulted in the report of improved GI tolerance, improved nutrition, and improved health among users. Limitations to this study include that it is a retrospective survey of formula user and caregiver perceptions of health outcomes, initiated using a manufacturer's database. Prospective and further studies are needed to investigate the responses accumulated here.

Financial Support: Kate Farms, Inc., provided a research grant to Dr. Stan Cohen and Dr. Ana Ramirez.

Table 1: Formula User Diagnosis (%)

Formula User Diagnosis (%)	
Other	23.0
Gastroparesis	16.8
Head and Neck Cancer	8.7
Difficulty Swallowing	8.7
Failure to Thrive	7.9
Malnutrition	7.4
Other cancer	6.1
Cerebral Palsy	5.6
Developmental Delay	4.1
Cystic Fibrosis	3.8
ALS	3.1
Brain Injury	1.8
Esophageal Cancer	1.8
CVA (stoke)	0.5
Achalasia	0.5

Diagnosis reported by respondent

Table 2: Formula User Age (years)

Formula user age (%)	
1-5 years	22.2
6-12 years	10.7
13-19 years	7.7
20-40 years	28.3
41-60 years	16.6
>60 years	14.3

(2020), Patient-Reported Outcomes Indicate Plant-Based Enteral Formula Improves Nutrition and Gastrointestinal Symptoms, Cohen, SA., Ramirez, A., Millovich, V.; ASPEN NUTRITION SCIENCE AND PRACTICE CONFERENCE: Tampa, Florida, March 28 – 31, 2020. Journal of Parenteral and Enteral Nutrition, 44(3): 275.doi.org/10.1002/jpen.1813

Presented at the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Conference, October 17-19, 2019, Chicago, IL.

M146 - Improved GI Tolerance and Weight Gain in Pediatric Patients using Plant-Based Enteral Formulas

Stanley Cohen, MD[1]; Ana Ramirez, MD[1]; Vanessa Millovich, DCN, RDN, LDN[2]
[1]Children's Center for Digestive Health Care, Atlanta, Georgia; [2]Kate Farms, Carpinteria, California

Purpose: The purpose of this study was to assess the experience of pediatric patients consuming a novel plant-based enteral formula (PBEF) at a single pediatric gastroenterology center.

Methods: After institutional review board approval, a retrospective chart review was conducted on pediatric patients who had been using a plant-based enteral formula (Kate Farms® Santa Barbara, California) within the previous two years. Age, anthropometrics, medical history, method of administration and nutritional regimen were collected from the patient records. After inclusion, a member of the research team administered a five-question survey with the primary caregiver of each patient by phone.

Results: A total of 11 patients were identified and 9 patients had complete anthropometric data available for analysis. Mean age was 13.1+7.3 years with use of the plant-based formula on an average of 5.9+3.3 months. The two most common diagnoses were feeding difficulties in 66% (n=6) and failure to thrive (FTT) in 44% (n=4). Most patients (n=10) were placed on the intact standard polymeric PBEF (1.0 kcal/mL; mean of 704 mL/day); 2 went onto the peptide PBEF (1.5 kcal/mL; n=1 at 975 mL/day). The prescribed formula and quantities were decided by the dietitian and/or physician. Four (4) patients received the formula by mouth and 5 received it via feeding tube. For those patients with complete available data, 6 were also on a regular diet along with formula. Of the 9 patients with complete anthropometric data, 7 showed weight gain while on the PBEF(Table). For those patients < 21 years old with a documented weight-for-age z-score (n=7), 6 showed improvement. Weight gain did not translate into improved BMI z-scores. Tolerance questionnaires were completed for 10 patients: 90% of caregivers agreed that their child tolerated the PBEF better than their previous regimen and that the PBEF formula improved their child's nutrition; 80% of caregivers also indicated that the PBEF improved their child's digestive symptoms (easier bowel movements, less stomach aches, less nausea).

Conclusion: Improved weight-for-age z-scores, weight gain, and parental-reported outcomes of improved GI tolerance were noted, retrospectively, in this small cohort of patients consuming a PBEF at a single pediatric GI center. The retrospective design, using a small population, are limitations to this study. However, this supports the need to expand upon these initial observations, with a larger prospective trial.

Financial Support: Kate Farms, Inc., provided a research grant to Dr. Cohen and Dr. Ramirez

Table 1: Weight Change in Patients with Complete Data

Pt ID	Sex	Age (years)	Diagnosis	Duration on Formula (months)	Weight (wt.) Change (kg)	Wt.-for-Age Z-Score Before	Wt.-for-Age Z-Score After
006	F	3	FTT	5	+1.8	-1.61	-1.26
003	M	5	Feeding difficulty	8	+2.3	-2.64	-2.00
004	M	6	FTT*, feeding difficulty	8	+2.1	-2.38	-2.11
008	F	7	FTT	13	+2.4	-1.62	-1.41
010	M	12	Feeding difficulty	6	-0.2	-0.63	-1.06
007	F	17	Esophageal dysphagia	2	+0.8	-3.00	-2.84
002	M	19	Feeding difficulty, anorexia, food allergies	6	+0.8	-3.38	-3.32
005	F	20	Feeding difficulty G-tube fed	12	0	N/A	N/A
001	F	23	Feeding difficulty, milk and soy allergy	5	+3.6	N/A	N/A
Mean		13.1	N/A	5.9	N/A	-2.1	-2.00

(2020), Improved GI Tolerance and Weight Gain in Pediatric Patients using Plant-based Enteral Formulas, Cohen, SA., Ramirez, A., Millovich, V.; ASPEN NUTRITION SCIENCE AND PRACTICE CONFERENCE: Tampa, Florida, March 28 – 31, 2020. Journal of Parenteral and Enteral Nutrition, 44(3): 274.doi.org/10.1002/jpen.1813