685 *PATIENT-REPORTED OUTCOMES OF GI SYMPTOMS AND ADHERENCE AMONG PEDIATRIC PATIENTS USING A PEA PROTEIN PLANT-BASED ENTERAL FORMULA.*

Stanley Cohen[1] , Dwan Newman[2] , Ana Ramirez[1] , Vanessa Millovich[2]
[1] Children's Center for Digestive Health Care, Atlanta, GA; [2] Kate Farms, Santa Barbara, CA

Background:
Pediatric patients requiring supplemental or sole source nutrition support, many of whom are on tube feedings, are at risk for adverse gastrointestinal symptoms which may influence their ability to adhere to prescribed nutritional regimens. Plant-based formulas are now being used as a novel solution, but limited data exists.

Purpose:
To describe the specific symptom frequency of constipation, diarrhea, vomiting, bloating and adherence reported in pediatric patients who have been on a pea protein plant-based enteral formula (PP PBEF).

Methods:
An electronic survey, utilizing REDCap®, was sent via email to those who had contacted a PP PBEF manufacturer for a formula sample. The survey consisted of questions on demographics, health outcomes while on a PP PBEF, and 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: A total of 392 respondents completed the survey, and 159 were for formula users under 20 years of age; 150 (94.3%) came from the formula user's caregiver. Females comprised 45.9% (n=73); 87 (54.7%) were 1-5 yrs old; 42 (26.4 %) were 6-12; and 30 (18.9 %) were 13-19 yrs old.

It was reported that an intact PP PBEF was used by 108 (67.9%) while 71 (44.7%) reported using a hydrolyzed PP PBEF. Formula was reported to be consumed orally by 90 (56.6%); 55 (34.6%) reported using a feeding pump, 13 (8.2%) a gravity bag and 19 (11.9%) a syringe. For 110 (69.2%), the PBEF was reported to make up > 50% of their nutrition; 87 (54.7%) reported being on the PBEF > 6 months.

The primary reason reported for starting the PBEF were the ingredients were preferred (43, 27%); physician or dietitian recommended the formula (30, 18.9%); intolerance to (25, 15.7%), or poor weight gain on (22, 13.8%), their previous formula.

Prior to the PBEF, 71 (44.7%) reported to be on an intact dairy-based formula, 10 (6.3%) on a blended formula, 31 (19.5%) on a hydrolyzed or elemental dairy formula, and 18 (11.3%) on an infant formula, while 55 (34.6%) indicated "other" as the previous formula type.

Reported outcomes:
123 (77.4%) respondents reported they felt the subjects were healthier on the PBEF; 141 (88.7%) reported they felt that the PBEF improved the subjects' nutrition, while 3 (1.9%) did not; and 98 (61.6%) reported improved digestive symptoms.

Among the respondents who specified the frequency of symptoms, constipation, bloating, vomiting and diarrhea were reported ≤ 1/wk in 90/140 (64.3%), 85/120 (70.8%), 119/149 (79.9%), and 120/144 (83.3%), respectively, on the PP PBEF, compared to 39 /126 (31.0%), 39/103 (37.9%), 73/127 (57.5%) and 82/119 (68.9%) respectively, on their previous formula.

Improved or stable weight on the PP PBEF was reported by 144 (90.6%) but ranged from 77.8 to 100% by disease state (Table). Adherence, defined as consuming ≥ 75% of the formula prescribed, was reported to be achieved by 138/154 (89.6%) on PP PBEF prescribed, compared to 77 (48.4%) for the previous formula

Conclusion:
Patient / caregiver reported outcomes by an electronic survey appear to provide an important tool in assessing symptoms, formula tolerance and adherence. PP PBEF was reported to improve GI symptoms and adherence; and nutrition and health were perceived to improve on PP PBEF. Further studies are needed to investigate these initial findings.

Funding: Research reported in this publication was supported by an unrestricted research grant from Kate Farms (Santa Barbara, CA)

Cohen, SA., Newman, D., Ramirez, A., Millovich, V. Patient-Reported Outcomes of GI Symptoms and Adherence Among Pediatric Patients Using a Pea Protein Plant-Based Enteral Formula. JPGN.2020; 71(Supp1.): S454-456.

Table: Reported Outcomes of Pediatric Formula Users by Diagnosis

Primary Diagnosis	Improved digestive symptoms	Able to consume ≥ 75% of goal volume[2]	Improved nutrition	Weight gained or stable	Felt healthier
CF (n=7, 4.4%)	4 (57.1%)	7 (100%)	7 (100%)	7 (100%)	6 (85.7%)
CP (n=18, 11.3%)	11 (61.1%)	16 (88.9%)	16 (88.9%)	14 (77.8%)	12 (66.7%)
Dev. Delay (n=14, 8.8%)	11 (78.6%)	13 (100%)	12 (85.7%)	13 (92.9%)	11 (78.6%)
FTT/malnutrition (n=34, 21.4%)	20 (58.8%)	30 (88.2%)	31 (91.2%)	33 (97.1%)	26 (76.5%)
Gastroparesis (n=15, 9.4%)	9 (60.0%)	14 (93.3%)	14 (93.3%)	13 (86.7%)	13 (86.7%)
Cancer (n=4, 2.5%)	4 (100%)	3 (100%)	4 (100%)	4 (100%)	4 (100%)
Difficulty Swallowing from other (n=18, 11.3%)	9 (50%)	14 (82.4%)	15 (83.3%)	15 (83.3%)	13 (72.2%)
Brain Injury (n=4, 2.5%)	2 (50%)	3 (75%)	3 (75%)	4 (100 %)	3 (75%)
Other diagnosis (n=45, 28.3%)	28 (62.2%)	38 (88.4%)	39 (86.7%)	41 (91.1%)	35 (77.8%)

1 Responses of “unsure” and “prefer not to answer” were included in total counts & percentages.
2 Counts and percentages do not include response of “No specific amount was recommended.”

Cohen, SA., Newman, D., Ramirez, A., Millovich, V. Patient-Reported Outcomes of GI Symptoms and Adherence Among Pediatric Patients Using a Pea Protein Plant-Based Enteral Formula. JPGN.2020; 71(Supp1.): S454-456.