Real-World Evidence of Clinical Characteristics and Tolerance Outcomes Among Adult Post-Acute Care Patients Receiving Peptide-Based Diets in the US

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BACKGROUND & OBJECTIVES

Background

- Disease-related malnutrition/undernutrition can impair muscle strength, immunity, or wound healing (1), and is associated with a considerable economic burden (2)
- Enteral tube feeding (ETF) is a medical nutrition therapy used to help meet nutritional requirements in patients who have inadequate volitional intake
- Medical conditions and therapies that affect nutrient digestion (e.g. short bowel syndrome, inflammatory bowel disease, cystic fibrosis) may lead to suboptimal nutrient absorption (1, 3-5)
- Standard ETF formulas contain complex nutrients (e.g. whole proteins), which may not be optimal for digestion and adequate nutrient absorption
- Semi-elemental ETF formulas contain enzymatically hydrolyzed protein and a percentage of fat in the form of medium chain triglycerides, designed to improve digestion and absorption (1). Peptide-based diet (PBD) ETF formulas have been shown to be well-tolerated in a post-acute care setting in patients with malabsorption (6)
- ETF typically begins in a hospital setting and is continued as part of post-acute care, as needed

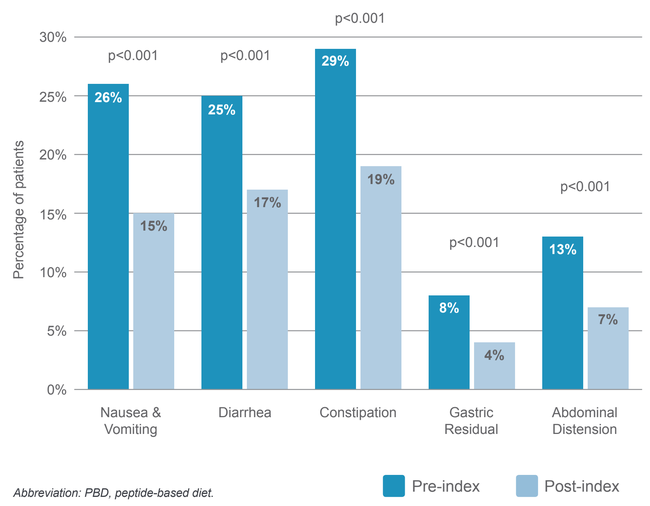
Objective

- Our aim was to describe the demographic, clinical, and treatment characteristics of adult patients receiving (PBD) ETF in a post- acute care setting, and to evaluate the frequency of gastrointestinal-related adverse events pre- and post-initiation of PBD.

METHODS

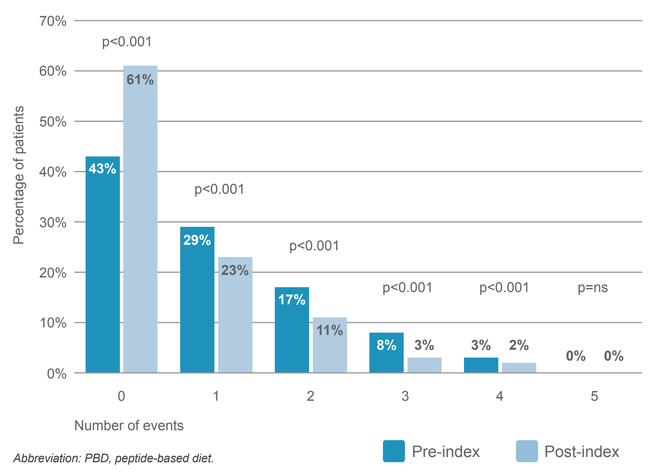
- Medical claims data were obtained from the Decision Resources Group Real World Evidence Data Repository US database
- The cohort of adult patients (≥18 years old) included patients receiving PBDs through ETF for any condition after hospital discharge between Q1-2013 and Q4-2017
- Patients were observed for up to 1 year post-initiation of PBDs after hospital discharge
- There were no restrictions in terms of ETF product brand
- Univariate descriptive statistics, including means, standard deviations, and proportions were calculated for study variables

Figure 2: Percentage of patients affected by intolerance events pre- and post-index (initiation of PBD)



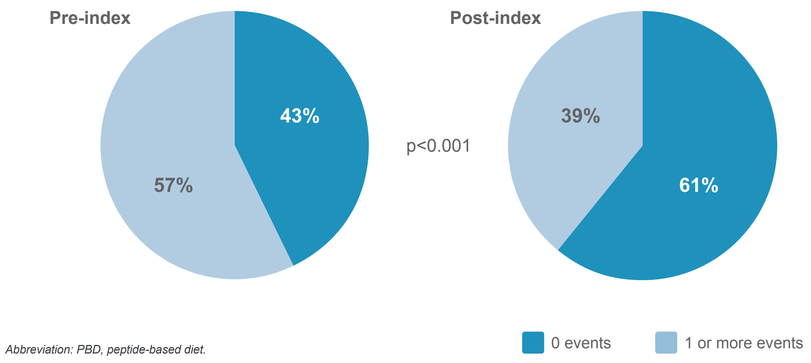
Abbreviation: PBD, peptide-based diet.

Figure 3: Percentage of patients experiencing multiple intolerance events pre- and post-index (initiation of PBD)



Abbreviation: PBD, peptide-based diet.

Figure 4: Percentages of patients experiencing ≥1 intolerance events, pre- and post-index (initiation of PBD)



Abbreviation: PBD, peptide-based diet.

RESULTS

- A total of 2,256 adult patients were eligible for inclusion, with an average age of 53.1 (SD 18.1) years. The distribution of patients across age groups showed a trend of older people being more likely to receive PBD through ETF (Table 1)
- Gender distribution was equal; 47.8% of patients were female (Table 1)
- 80% of patients were insured with commercial insurers and 19% with Medicaid/ Medicare (Table 1)
- The most common observed underlying conditions were digestive system disorders (40.29% of patients), endocrine nutritional and metabolic diseases (34.80% of patients), respiratory system diseases (24.78% of patients), and circulatory system diseases (22.30% of patients) (Figure 1)
- On average, patients had 2.2 (±1.3) Charlson comorbidities, with a mean Charlson Comorbidity index (7) score of 3.7 (±3.1)
- Clinical patient characteristics (weight, body mass index, and glycated hemoglobin [HbA_{1c}]) were collected for up to one year before and after initiation of PBD, and showed no significant differences between pre- and post-initiation (Table 2)
- The data showed a statistically significant improvement in tolerance after initiation of PBD for all outcomes evaluated (Figure 2):
  - Nausea and vomiting, 26.3% vs 15.1% (p<0.001)
  - Diarrhea, 25.4% vs 16.9% (p<0.001)
  - Constipation 28.5% vs 18.9% (p<0.001)
  - Abdominal distension, 12.8% vs 7.3% (p<0.001)
  - Gastric residual, 8.1% vs 4.2% (p<0.001)
- The percentage of patients experiencing one or multiple intolerance events also declined from pre-index to post-index, with a corresponding increase in the percentage of patients experiencing no intolerance events (Figure 3)
- Significantly fewer patients experienced 2 or more adverse tolerance events post-index vs pre-index (28.6% vs 16.2% [p<0.001])
- Significantly more patients were entirely free of adverse tolerance events post-index vs pre-index (61.3% vs 42.6% [p<0.001]], Figure 3 and Figure 4)
- In the 30 days post initiation of PBDs, 46.2% of patients had at least 1 inpatient visit (mean 3.6, SD 4.1). In the same timeframe, 99.8% of patients had outpatient visits recorded (mean 5.0, SD 3.4).

CONCLUSIONS

- The analysis showed that peptide-based ETF formulas are used to optimize digestion and absorption of nutrients in effort to prevent (or manage) disease-related malnutrition across all adult age groups
- PDBs are most commonly prescribed to patients with diseases of the digestive system, endocrine nutritional and metabolic diseases, or diseases of the respiratory system
- There was no significant difference in weight or BMI, and no significant change in HbA_{1c} in the period after PBD initiation, suggesting weight maintenance and no significant changes in glycemic control
- Our data indicate that treatment with PBDs leads to a significant improvement in tolerance, compared with standard ETF or no ETF, in clinical practice in patients with malnutrition or at risk of disease-related malnutrition. The available data indicate that PBDs are predominantly provided to patients who have commercial insurance rather than Medicare/Medicaid, which may signal disparity of care worth exploring further

DISCLOSURES

The study was funded by Nestlé Health Science.

Table 1: Patient demographic characteristics, by age group and PBD ETF administered

Variables	Total n=2,256	Peptamen Adult n=1,022	Peptamen Junior n=37	‡Vital n=861	‡PediaSure n=24	Others n=312
Age group						
18-24	297	165	31	72	22	7
25-34	257	134	1	95	1	26
35-44	293	153	2	106	–	32
45-54	379	167	1	158	–	53
55-64	485	197	2	199	–	87
≥ 65	545	206	–	231	1	107
Gender						
Male	1,120	474	21	428	11	186
Female	1,136	548	16	433	13	126
Payer						
Commercial	1,804	825	31	692	20	236
Medicaid	294	146	6	97	3	42
Medicare	137	43	–	63	–	31
Others†	15	5	–	7	1	2
Unknown	6	3	–	2	–	1

†Veterans Affairs or Other Government, Health Maintenance Organization, Other Non-Federal Programs and others.
‡ Vital and PediaSure are trademark of Abbott Laboratories.
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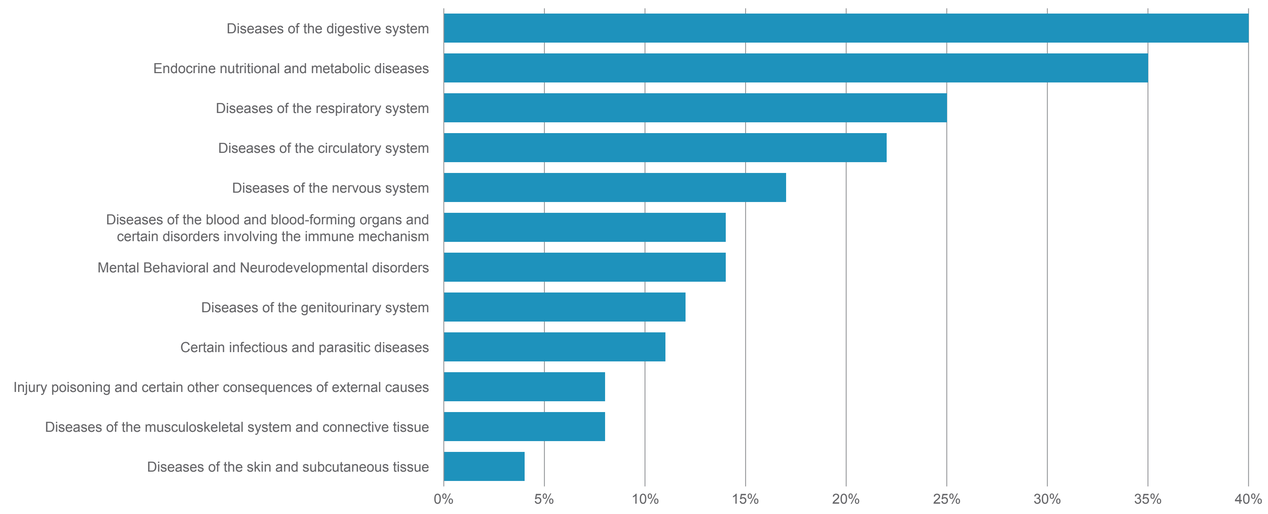
Table 2: Clinical patient characteristics

	Pre Index†			Post Index‡			
	N	Mean	Median	N	Mean	Median	p§
Weight (lbs)	318	150,80±50,66	145,00	296	149,86±60,67	140,00	ns
Height (in)	309	65,86±4,40	66,00	278	65,90±4,53	66,00	ns
BMI	223	24,73±7,73	23,43	206	24,42±8,81	23,29	ns
BMI Percentile	3	51,00±37,36	45,00	2	50,00±69,30	50,00	ns
HbA_{1c} (%)	53	5,00±3,58	5,50	41	5,44±2,67	5,70	ns

†The pre-index period is defined as the first record in the study period (up to 1-year prior). ‡The post-index period is defined as the last record in the study period (up to 1-year post index date). §t-Test, alpha =0.05 level of significance.
Abbreviations: BMI, body mass index; ETF, enteral tube feeding; HbA_{1c}, glycated hemoglobin; PBD, peptide-based diet.

Figure 1: Most frequently reported underlying conditions in patients receiving PBD ETF



Abbreviations: ETF, enteral tube feeding; PBD, peptide-based diet.

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