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ORIGINAL COMMUNICATION

Real-World Evidence of Treatment, Tolerance, Healthcare Utilization, and Costs Among Postacute Care Adult Patients Receiving Enteral Peptide-Based Diets in the United States

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Abstract

Objective: Peptide -based (PB) enteral tube feeding (ETF) formulas have been shown to reduce gastrointestinal (GI) intolerance in patients receiving enteral nutrition. However, limited data exist in relation to their use in the postacute/home care setting. We sought to assess the real-world GI tolerance, healthcare utilization, and resource use costs of 100% whey-protein PB ETF in adults in a postacute care setting and describe their demographic, clinical, and treatment characteristics.

Method: Using medical claims data from the United States, we analyzed GI intolerance events occurring in adults receiving 100% whey-protein PB ETF (Peptamen® adult formulas) for one year before and after initiation of ETF. Resource use costs were subsequently estimated using a multivariate general linearized model and adjusted for age, gender, and Charlson Comorbidity Index score.

Results: The proportion of adults experiencing no GI intolerance events increased from 41% (418/1022) to 59% (601/1022) in the one-year period after initiation of 100% whey PB ETF ($P < .001$). The proportion of patients with at least one hospital inpatient visit also decreased from 100% (1022/1022) to 72% (737/1022) over the same period, and the mean number of inpatient visits per patient decreased from 15.6 to 13.0. Cost modeling revealed that outpatient visits accounted for 42% ($1174/$2820) of total estimated healthcare resource costs in the first 30 days after 100% whey PB ETF initiation, with only 9% ($255/$2820) due to emergency room visits.

Conclusion: These 100% whey-protein PB ETF formulas are a valuable nutrition treatment option for patients with or at risk of malnutrition who show intolerance to standard ETF formulas and may reduce hospital inpatient visits and associated costs.

KEYWORDS
gastrointestinal tolerance, home enteral nutrition, peptide-based diet, real-world evidence, tube-feeding

CLINICAL RELEVANCY STATEMENT

The efficacy and tolerability of semi-elemental peptide-based (PB) enteral tube feeding (ETF) formulas have been demonstrated in a wide range of nutritionally high-risk populations. However, limited data are available in relation to the use of PB ETF formulas for home enteral nutrition. To better inform decision making around the value and importance of 100% whey-protein PB ETF in the home care setting, the real-world tolerance, healthcare utilization, and resource use costs of these formulas in adults in the postacute care setting are further investigated.

INTRODUCTION

Disease-related malnutrition, defined as undernutrition associated with a disease,[1] is a highly prevalent condition that can lead to impaired muscle strength, immune function, and wound healing.[2,3] Malnutrition has serious implications for patient morbidity and disease recovery[3] and is widely associated with poor clinical outcomes, including longer hospitalization, higher rates of complications, and increased mortality.[4] Malnutrition affects an estimated 10% of all chronically ill patients in the community[4,5] and is common in patients with chronic obstructive pulmonary disease,[6,7] cancer,[8] chronic liver disease,[9] heart disease,[10] renal insufficiency,[11] inflammatory bowel disease,[12] and cystic fibrosis,[13] among other conditions. In older adults in the postacute care setting, the risk of malnutrition has been reported at 47%–62%.[14]

Disease-related malnutrition negatively impacts patient functional status, health outcomes, and quality of life and also places a considerable economic burden on healthcare systems,[3,4,15] increasing patient hospitalization costs by ~20%.[16] The direct medical cost burden of disease-related malnutrition has been estimated at >$9.5 billion in the United States[4] and €31 billion in Europe.[17]

Enteral tube feeding (ETF) is used to help meet nutrition requirements in patients unwilling or unable to achieve adequate intake orally in the acute care setting. Dependent upon a patient's nutrition requirements and disease pathophysiology, there are multiple types of specialized ETF formulas accessible, including polymeric and predigested (elemental and semi-elemental) feeds.[18]

ETF may also be an option for outpatients who require a long-term alternative or supplement to oral nutrition but are otherwise able to live away from a hospital facility.[19] Indeed, enteral nutrition is often initiated in the hospital setting and may continue as part of postacute care, as indicated and tolerated.[19] In the United States, ~250,000 adult patients are estimated to receive home enteral nutrition (HEN).[20]

Gastrointestinal (GI) intolerance is characterized by one or more upper- or lower-GI symptoms, including nausea, vomiting, bloating, constipation, and diarrhea.[21,22] It can interrupt feeding, reducing the rate or amount of nutrients delivered, and is associated with reduced patient quality of life and an increased risk of malnutrition.[21,22] Furthermore, poor tolerance to an enteral feeding regimen may also be a factor against admission to a HEN program.[19] Well-tolerated ETF formulas are therefore highly desirable from a patient, healthcare provider, and payer perspective.

Semi-elemental peptide-based (PB) ETF formulas, containing partially predigested protein and a percentage of fat energy in the form of medium-chain triglycerides,[18] are designed to enhance digestion and absorption and can help improve GI tolerance in patients receiving enteral nutrition who are at-risk-of or experiencing GI intolerance.[22–24] The efficacy and tolerability of PB diets have been demonstrated in a wide range of nutritionally high-risk populations,[23,24] including patients with acute and chronic pancreatitis,[25,26] pancreatic cancer,[27] GI and other cancers, neurological conditions, and HIV.[28] Across various diseases, formulas offer similar or improved tolerance, digestion, and nutrient assimilation compared with free amino acid–based or polymeric formulas.[22–24] PB ETF formulas have also been shown to be more efficacious and better tolerated by patients in the postacute setting compared with standard whole-protein formulas.[29]

Despite the need for well-tolerated ETF formulas for use in the postacute setting, limited data are available in relation to the use of PB diets for HEN.[19] The objective of this study was to describe the demographic, clinical, and treatment characteristics of 100% whey-protein peptide-based (w-PB) ETF in adults in a postacute care setting and assess the real-world tolerance and frequency of GI tolerance–related adverse events, before and after initiation of PB ETF. Additionally, healthcare utilization and cost associated with the use of w-PB ETF in this population will be described.

METHODS

Medical claims data were obtained from the Decision Resources Group (DRG) Real-World Evidence Data Repository US database,[30] which links medical claims, prescription claims, and electronic health records (EHRs) from government and commercial insurance plans to provide longitudinal patient-level data across both inpatient and outpatient facilities. Adult patients included in the cohort had to be ≥18 years old and receive w-PB ETF (Peptamen® formulas for adults, Nestlé Health Care Nutrition; Bridgewater, NJ, USA) for any condition after hospital discharge during the period of Q1-2013 through Q4-2017. All patients in the database who met the inclusion criteria were included in the study. The cohort studied during the postindex period did not include patients using standard tube-feeding formulas; to the best of the authors' knowledge, there are no data reporting the cost of healthcare utilization with standard formulas in the postacute setting. Conditions were classified as listed in Figure 1 and included diseases of the digestive system, endocrine nutrition and metabolic diseases, diseases of the respiratory system, and diseases of the circulatory system, among others. Patients were observed for up to one year after initiation of w-PB ETF following discharge. In this study, the preindex period is defined as the period of one year before the product was taken for the first time (the index date), and the postindex period is defined as the period of one year after the index date.

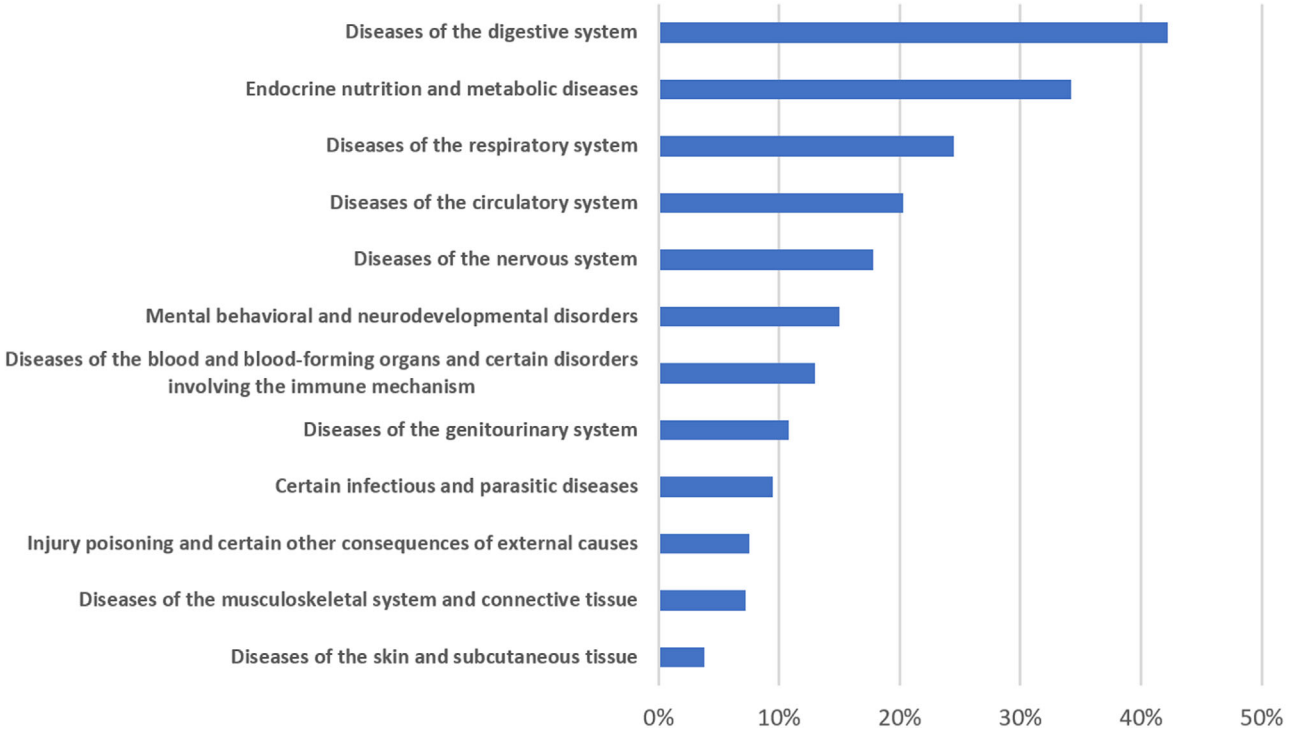

FIGURE 1 Most frequently reported underlying conditions in adult patients receiving 100% whey-protein peptide-based enteral tube feeding (w-PB ETF)

Evaluated outcomes (events) reported in the database were reported in either medical claims, pharmacy claims, or EHRs and were recorded as binary (yes or no) values, as indicated by the caregiver or patient in the postacute care setting. Outcomes such as diarrhea, for example, are therefore not defined by a specific number of events (eg, a minimum number of stools per day). Univariate descriptive statistics, including means, SDs, and proportions, were calculated for all study variables. Resource use costs were estimated using a multivariate general linearized model and adjusted for age, gender, and Charlson Comorbidity Index (CCI) score.

RESULTS

A total of 1022 adult patients were eligible for inclusion in the study, with an average (SD) age of 47.5 (18.7) years (Table S1). Thirty-nine percent (403/1022) of patients who received w-PB ETF were 55 years of age or older. Gender distribution was slightly higher for women (54%; 548/1022). Eighty percent (825/1022) of patients were insured with commercial insurers, and 19% (189/1022) were insured through Medicaid/Medicare.

Patients included in the study had a mean (SD) of 2.06 (1.29) Charlson comorbidities, as categorized according to the *International Classification of Diseases* diagnosis codes (Table 1).[31] The CCI quantifies an individual patient's disease burden and associated 1-year mortality risk. Patients had a mean (SD) CCI score of 3.47 (3.00).

The most common underlying medical conditions in the eligible patient population included diseases of the digestive system (42.2%; 431/1022 patients), endocrine nutrition and metabolic diseases (34.2%; 350/1022 patients), diseases of the respiratory system (24.5%; 250/1022 patients), diseases of the circulatory system (20.3%; 207/1022 patients), diseases of the nervous system (17.8%; 182/1022 patients), and mental behavioral and neurodevelopmental disorders (15.0%; 153/1022 patients) (Figure 1).

Clinical patient characteristics such as weight and body mass index (BMI) were collected for up to one year before and one year after the index date (Table 2). A small decrease in weight and BMI between the preindex and postindex periods was observed.

Across the study population, the data showed a statistically significant improvement in GI tolerance after initiation of w-PB ETF (Table 3). Comparing preindex with postindex periods, the proportion of patients experiencing nausea and vomiting, diarrhea, constipation, gastric residual, and abdominal distension decreased following initiation of w-PB ETF.

The percentage of patients experiencing one or more intolerance events also declined after initiation of w-PB ETF, from 59% (604/1022) of patients in the preindex period to 41.2% (421/1022) of patients in the postindex period ($P < .001$) (Table 4).

Healthcare utilization before and after the initiation of w-PB ETF was also assessed. In the 1-year period prior to starting treatment, all patients recorded at least one inpatient visit, with an average of ~16 visits per patient (Table 5). During the postindex period, 72.1% (737/1022) of patients recorded at least one inpatient visit, with a statistically significant reduction in the mean number of visits per patient to 13 visits ($P < .01$). In the first 30, 90, and 180 days following initiation of w-PB ETF, 42.6% (435/1022), 56.9% (582/1022), and 66.4% (679/1022) of patients, respectively, recorded at least one inpatient

TABLE 1 Percentage of Adult Patients With Comorbidities (International Classification of Diseases Diagnosis Codes)

Comorbidities	Number of patients (N = 1022)	Percentage of patients
Chronic obstructive pulmonary disease	462	45%
Cancer	356	35%
Mild liver disease	306	30%
Diabetes	280	27%
Peripheral vascular disease	226	22%
Congestive heart failure	172	17%
Paraplegia and hemiplegia	171	17%
Metastatic solid tumor	165	16%
Cerebrovascular disease	161	16%
Renal disease	135	13%
Peptic ulcers	127	12%
Myocardial infarction	106	10%
Diabetes with complications	90	9%
Rheumatic disease	85	8%
Moderate or severe liver disease	67	7%
Dementia	50	5%
HIV/AIDS	6	1%

TABLE 2 Clinical Patient Characteristics

	Preindex			Postindex		
	N	Mean (SD)	Median	Mean (SD)	Median	*P**
Weight, lb	89	156 (55.3)	145	149 (47.0)	144	.006
Weight, kg	89	70.8 (25.1)	65.8	67.6 (21.3)	65.3	.006
Height, in	82	66.5 (4.44)	66.0	66.6 (4.26)	66.3	.451
Height, cm	82	169 (11.3)	168	169 (10.8)	168	.451
BMI	70	25.0 (7.79)	23.8	24.7 (7.33)	22.2	<.001

BMI, body mass index.
*t-test, $\alpha = .05$ level of significance.

TABLE 3 Number of Adult Patients Affected by Intolerance Events, Preindex and Postindex (Initiation of w-PB ETF)

	Adult patients receiving w-PB ETF (N = 1022)		
Intolerance event	Preindex, n (%)	Postindex, n (%)	*P**
Nausea and vomiting	288 (28.2)	159 (15.6)	<.001
Diarrhea	262 (25.6)	177 (17.3)	<.001
Constipation	295 (28.9)	215 (21.0)	<.001
Gastric residual	78 (7.6)	47 (4.6)	.005
Abdominal distension	144 (14.1)	82 (8.0)	<.001

w-PB ETF, 100% whey-protein peptide-based enteral tube feeding.
*χ^2 test (2 degrees of freedom), $\alpha = .05$ level of significance.

visit, and all patients at all time points assessed had at least one outpatient visit, which is expected for this population.

Modeled healthcare resource use costs for adult patients receiving w-PB ETF are presented in Table 6. The data highlights that outpatient visits represent the largest cost share, followed by inpatient visits, with only a small percentage of the costs due to emergency room visits. Of the 180-day total health resource use costs of $7050 per patient, 38% ($2683) were attributable to inpatient visits, 56% ($3929) to outpatient visits, and 6% ($438) to emergency room visits.

DISCUSSION

The analysis shows that w-PB ETF is most commonly prescribed to adult patients with diseases of the digestive system, endocrine nutrition and metabolic diseases, or diseases of the respiratory system. w-PB ETF formulas have previously been shown to be more efficacious and better tolerated than whole-protein formulas in patients with acute and chronic medical conditions in both the acute and postacute care settings.[22–26,28,29] The data indicate that utilization of w-PB ETF leads to a statistically significant improvement in GI tolerance compared with standard ETF in clinical practice in patients in the postacute care setting. More than half of the adult patients in the study experienced no intolerance events after w-PB diets were used.

A small but statistically significant decline in the mean weight of patients during the one-year postindex period was observed. Monitoring of weight is part of the overall home care management of the enterally fed patient. Although weight change can be a reflection of formula tolerance, it may also be indicative of other factors such as total formula delivery and adequacy, etiology of disease with progression, and patient care management.

TABLE 4 Number of Adult Patients Experiencing Intolerance Events, Preindex and Postindex (Initiation of w-PB ETF)

	Adult patients receiving w-PB ETF (N = 1022)		
Number of intolerance events experienced	Preindex, n (%)	Postindex, n (%)	P*
0	418 (40.9)	601 (58.8)	<.001
1	306 (29.9)	239 (23.4)	.003
2	171 (16.7)	124 (12.1)	.005
3	92 (9.0)	40 (3.9)	<.001
4	32 (3.1)	17 (1.7)	.03
5	3 (0.3)	1 (0.1)	.3
Any intolerance events experienced			
No	418 (40.9)	601 (58.8)	<.001
Yes	604 (59.1)	421 (41.2)	<.001

w-PB ETF, 100% whey-protein peptide-based enteral tube feeding.
*χ^2 test (2 degrees of freedom), $\alpha = .05$ level of significance.

The available data indicate that w-PB ETF is predominantly provided to patients who have commercial insurance rather than Medicare or Medicaid. Given that disease-related malnutrition is particularly prevalent in the elderly,[15] who in the United States receive the bulk of medical services through government-funded programs, the relatively low proportion of patients receiving w-PB ETF through Medicare and Medicaid suggests that a large population of patients that could benefit from PB diets may not be optimally served.

In these analyses, resource cost modeling revealed that after the first 30 days after initiation of w-PB ETF, outpatient visits represented the largest share of healthcare resource costs—as expected, given the comorbidities in the patient population. Although outpatient visits represent the larger cost, the mean number of outpatient visits in the postindex period showed no statistical difference as compared with that in the preindex period, though inpatient visits were reduced. This could be indicative of appropriate management of the patient in the home care setting. Only a small proportion of the resource use costs were due to emergency room visits.

Because of the retrospective design and nature of a data query, there are a number of limitations to this study. The data accessed were limited to those found in the DRG Real-World Evidence Data Repository US database, and patient data assessment was limited to those patients receiving w-PB ETF. Association with GI intolerance vs causation was captured. There was no comparison between w-PB ETF and standard enteral nutrition. Enteral feeding tube placement and method of formula infusion may be associated with GI intolerance. Data on enteral feeding tube site and method of formula delivery are not available from the DRG database and, as such, are considered a potential bias.[32] It is important to note that the retrospective nature of the study provides inferior data points as compared with those from a prospective study. However, the study serves to be descriptive and hypothesis-generating.

TABLE 5 Healthcare Resource Utilization by Adult Patients Receiving w-PB ETF

	Adult patients receiving w-PB ETF (N = 1022)											
	Cumulative preindex		30 days post index		90 days post index		180 days post index		Cumulative post index			
Healthcare resource utilization	Patients with ≥1 visit, n (%)	Mean (SD) visits per patient	Patients with ≥1 visit, n (%)	Mean (SD) visits per patient	Patients with ≥1 visit, n (%)	Mean (SD) visits per patient	Patients with ≥1 visit, n (%)	Mean (SD) visits per patient	Patients with ≥1 visit, n (%)	Mean (SD) visits per patient	P*
Inpatient visits[a]	1022 (100)	15.57 (21.72)	435 (42.6)	3.71 (4.17)	582 (56.9)	6.66 (8.69)	679 (66.4)	9.38 (12.74)	737 (72.1)	13.03 (19.56)	<.01
Outpatient visits	992 (97.1)	29.19 (25.76)	1020 (99.8)	5.01 (3.49)	1022 (100)	11.38 (8.58)	1022 (100)	18.70 (15.51)	1022 (100)	29.06 (27.13)	.92

w-PB ETF, 100% whey-protein peptide-based enteral tube feeding.
[a]Includes hospital or intensive care unit visits.
*t-test, $\alpha = .05$ level of significance.

TABLE 6 Modeled Healthcare Resource Use Costs for Adult Patients Receiving w-PB ETF

	Adult patients receiving w-PB ETF (N = 1022)					
	30 days post index		90 days post index		180 days post index	
Healthcare cost	Expected value[a] (SE), $	95% CI, $	Expected value[a] (SE), $	95% CI, $	Expected value[a] (SE), $	95% CI, $
Inpatient visits[b]	1391 (282)	839–1943	1870 (271)	1339–2401	2683 (386)	1926–3440
Outpatient visits	1174 (74)	1030–1318	2437 (148)	2148–2727	3929 (240)	3459–4399
Emergency room visits	255 (33)	191–319	357 (53)	253–461	438 (55)	330–547
Total	2820	-	4664	-	7050	-

CI, confidence interval; SE, standard error; $, US Dollars; w-PB ETF, 100% whey-protein peptide-based enteral tube feeding.
[a]Multivariate generalized linear model adjusted for age, gender, and Charlson Comorbidity Index score.
[b]Includes hospital or intensive care unit visits.

It should also be noted that real-world data collected from routine clinical practice are subject to coding errors, missing data, and variations in reporting across clinical practices. These analyses were therefore limited by the fact that only patients with complete data were included, and the results may not represent those who disenrolled from a health plan within 12 weeks of therapy initiation and were lost to follow-up or those patients not receiving necessary medical care because of a lack of insurance or resources. Additionally, owing to the open-network nature of the databases used in the current analysis, patients' continuous eligibility cannot be ascertained. Healthcare services provided by out-of-network providers therefore may not be captured by the databases.

These data provide valuable insight to decision makers into the use of w-PB ETF formulas in usual clinical practice, the populations receiving them, and the associated improvement in GI tolerance. This work estimates and describes the resource use and costs associated with the use of w-PB ETF formulas in the home care setting.

Although the potential benefits of w-PB ETF formulas for patients with GI intolerance are acknowledged in some guidelines,[18,33–35] clear recommendations around their use are lacking. Other guidelines on enteral feeding do not discuss w-PB ETF formulas.[36,37] Further research and clinical and economic studies are therefore valuable in this subject area.

CONCLUSION

The use of w-PB ETF formulas is a valuable treatment option for those enterally fed patients who experience or are at high risk of GI intolerance. GI intolerance of enteral feeding leads to frequent feeding interruptions and a reduction in delivery of daily protein and energy, which may lead to malnutrition. Malnutrition is associated with poor clinical outcomes, including longer hospitalizations, higher rates of complications, and increased mortality. In adults, treatment with w-PB ETF is associated with improved GI tolerance, with more than half of patients experiencing no intolerance events. As expected, all patients receiving w-PB ETF reported at least one outpatient visit in the postindex period, and in-hospital visits were less common. After the first 30 days following ETF initiation, outpatient visits represented the largest share of healthcare resource costs, with only a small proportion of the resource use costs due to emergency room visits.

STATEMENT OF AUTHORSHIP

C. LaVallee, C. Lowen, A. Henrikson, B. Kesting, M. Perugini, and K. Araujo Torres equally contributed to the conception and design of the research; P. Seelam, S. Balakrishnan, C. Lowen, A. Henrikson, B. Kesting, M. Perugini, and K. Araujo Torres contributed to the acquisition and analysis of the data; P. Seelam, S. Balakrishnan, C. Lowen, A. Henrikson, B. Kesting, M. Perugini, and K. Araujo Torres contributed to the interpretation of the data; and C. LaVallee, C. Lowen, A. Henrikson, B. Kesting, and M. Perugini drafted the manuscript. All authors critically revised the manuscript, agree to be fully accountable for ensuring the integrity and accuracy of the work, and read and approved the final manuscript.

FINANCIAL DISCLOSURE

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CONFLICT OF INTEREST

C. Lowen, A. Henrikson, B. Kesting, M. Perugini, and K. Araujo Torres are employees of Nestlé Health Science.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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