EVALUATING THE USE OF AN AMINO ACID FOOD TO ALLEVIATE CHEMOTHERAPY INDUCED TOXICITY IN CANCER PATIENTS

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Significance

Chemotherapy patients are at risk for experiencing treatment-related side effects related to global gastrointestinal (GI) mucosa injury leading to diarrhea, nausea, poor oral intake, and/or weight loss. Symptomatic patients often require unplanned visits to healthcare practitioners, outpatient IV fluid and electrolyte infusions, hospitalizations, and delays or alternations of cancer treatments. Quality of life and survival are negatively impacted by altered, recommended cancer treatments.

Enterade is a commercially available amino acid-based, glucose-free, oral rehydration medical food. Statistically significant improvements in diarrhea, dehydration, and weight loss were reported by cancer patients receiving chemotherapy and/or radiation in a retrospective study using Enterade to alleviate GI toxicity.

Purpose

This quasi-experimental research project will evaluate self-report of GI symptoms, number of unplanned GI toxicity-related healthcare practitioner visits, number of IV fluid/electrolyte infusion visits needed after treatments, number of hospital days after treatments, alterations of treatment plan (dose delays/reductions, and/or missed/stopped treatments), and weight loss in chemotherapy patients with a high risk for GI toxicities who receive Enterade versus those who do not.

Intervention

Cancer patients scheduled to receive FOLFOX, FOLFIRI, FOLFIRINOX, or TCHP chemotherapy treatment regimens were invited to enroll in this study preceding initiation of their first chemotherapy treatment. Participants completed a survey recording baseline symptoms. Standardized surveys self-reporting participant symptom experience were completed prior to each treatment cycle. Patients reporting GI symptoms differing from the baseline assessment were provided 16 bottles of Enterade for each of their next three chemotherapy treatment visits. Retrospective data were extracted from 12 patient charts in each of the four chemotherapy regimens (n=48) treated without Enterade and were compared with data from participants receiving Enterade (n=37). Of 49 participants enrolled, 37 received Enterade.

Results

- In patients consuming Enterade (n=37), lower mean paired scores for:
  - Nausea (p<.001)
  - Vomiting (p=.07)
  - Diarrhea (p<.001)
- Patients who used Enterade experienced:
  - Fewer mean hospital days M=1.03 vs. 2.08 (p=.037)
  - Fewer stopped treatments M=.11 vs. .24 (p<.001)
- Although not statistically significant, patients who used Enterade experienced:
  - Less unplanned healthcare practitioner visits M=.38 vs. .68, (p=.138)

After reanalysis of the data, we removed 2 participants who received Enterade and 15 participants who did not receive Enterade because they did not have GI symptoms (nausea, vomiting, and diarrhea), and the data showed the following:

- No change in nausea, vomiting, or diarrhea Mean scores.
- Patients who used Enterade experienced:
  - Fewer stopped treatments *M*=.11 vs. .25 (p=.053)
  - Less unplanned healthcare practitioner visits *M*=.36 vs. *M*=.82, (*p*=.03)
- Although not statistically significant, patients who used Enterade experienced:
  - Fewer hospital days *M*=1.00 vs. 2.32 (p=.082)
  - Less weight loss
    - 2.0739 kg/4.563 lbs. vs 3.793 kg/8.345 lbs. (*p*=.51)

Please note: Data collection is approximately 75% complete, and some of the statistics presented here may reach significance once all data is analyzed (study enrollment closes June 1, 2023).

Discussion

The role of the oncology dietitian in the infusion area is essential in monitoring GI symptoms and intervening to educate and support our oncology patient. Allowing patients to taste-test the Enterade product prior to starting chemotherapy is optimal. Using a 0-10 assessment scale to document common symptoms is important in early recognition and management of symptoms. Significant cost savings may be realized by organizations that order Enterade for patients receiving chemotherapy regimens that are likely to cause GI symptoms by avoiding unplanned visits, IV hydration, and hospitalizations. This data provides support for our cancer center to evaluate the possibility of adding Enterade orders to our chemotherapy treatment plans going forward.

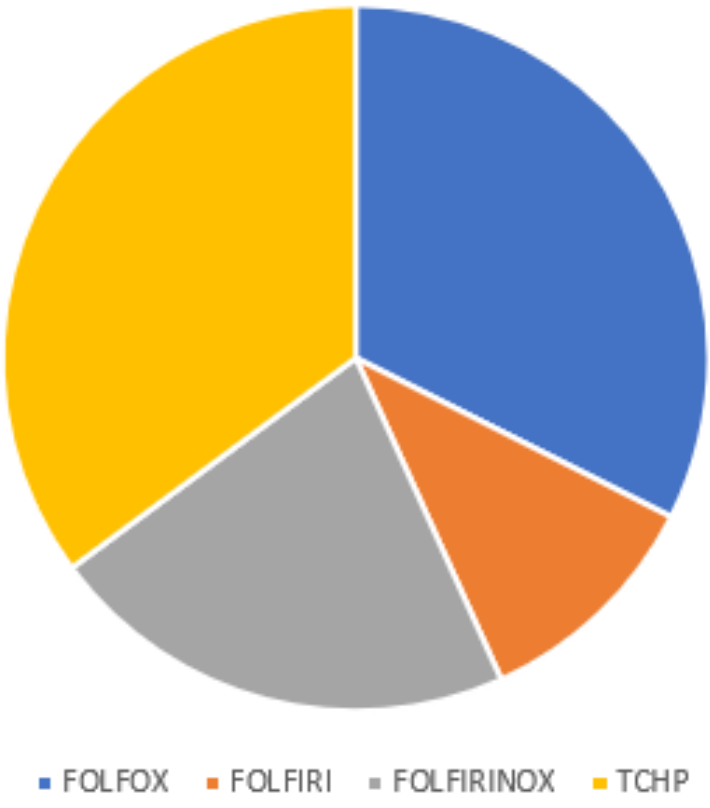
Treatment Plan by Enterade Patient

FOLFOX *n*=12 (32.4%)

FOLFIRI *n*=4 (10.8%)

FOLFIRINOX *n*=8 (21.6%)

TCHP *n*=13 (35.1%)



Demographics

Sex		
	Enterade *n* (%)	Non-Enterade *n* (%)
Female	21 (56.8)	31 (51.7)
Male	16 (43.2)	29 (48.3)

Age		
	Enterade *n* (%)	Non-Enterade *n* (%)
30 – 50 years	10 (27)	5 (8.3)
51 – 60 years	5 (13.5)	19 (31.7)
61 – 70 years	11 (29.7)	20 (33.3)
71+ years	11 (29.7)	16 (26.7)

Race		
	Enterade *n* (%)	Non-Enterade *n* (%)
Asian	1 (2.7)	1 (1.7)
Black / African American	2 (5.4)	5 (8.3)
White / Caucasian	33 (89.2)	54 (90)
Other	1 (2.7)	0 (0.0)

Ethnicity		
	Enterade *n* (%)	Non-Enterade *n* (%)
Hispanic / Latino	1 (2.7)	1 (1.7)
Non-Hispanic / Latino	36 (97.3)	59 (98.3)

Marital Status		
	Enterade *n* (%)	Non-Enterade *n* (%)
Divorced	5 (13.5)	11 (18.3)
Married	26 (70.3)	37 (61.7)
Single	5 (13.5)	8 (13.3)
Widowed	1 (2.7)	4 (6.7)

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Closed Chart Review

Treatment Received:
FOLFIRI☐ FOLFIRINOX☐
TCHP☐ FOLFOX☐

Patient Study ID #_____

Date Started First Treatment _____

Sex: Female☐ Male☐
Age in Years when chemotherapy started: _____

Marital Status: Divorced☐ Legally Separated☐ Married☐ Significant Other☐ Single☐ Widowed☐

Race: Asian☐ Black or African American☐ White or Caucasian☐ Other: _____

Ethnic Group: Hispanic or Latino☐ Not Hispanic or Latino☐

Any past treatment for cancer? No☐ Yes☐
If yes, type of past treatment? Chemotherapy☐ Radiation☐ Surgery☐ Other: _____

1. What type of cancer is being treated? Please check the box(es).
Brain☐ Pancreatic☐ Bladder☐ Mouth or Neck☐ Breast☐ Testicular☐
Esophageal or Stomach☐ Lung☐ Skin or Melanoma☐ Liver or Gallbladder or Bile Duct☐ Gynecological☐
Leukemia☐ Colon or Rectum☐ Neuroendocrine☐ Lymphoma☐
Unknown Primary☐ Other _____

2. Which treatment(s) received by the patient? Please check the box(es).

Chemotherapy☐ Surgery☐ Radiation Therapy☐ Hormone Treatment☐
Monoclonal Antibody Therapy☐ Immunotherapy☐ No Current Treatment☐

3. Check Symptoms documented by the care team:

Symptom	Baseline	Before Cycle 2	Before Cycle 3	Before Cycle 4	Before Cycle 5	
Nausea						
Vomiting						
Diarrhea						
Dizziness						
Thirst						
Dry Mouth						
Dry Skin						
Loss of Appetite						
Mouth pain/ulcers						
Fatigue/Lack of energy						
Acid Reflux						
Gas						
Bloating						

8. Digestive issues documented prior to cancer diagnosis?

Yes ☐ No ☐

If yes, which documented? Crohn's Disease☐ Stomach ulcers☐

Irritable Bowel Syndrome☐ Diverticular disease☐ previous bowel surgery☐

Ulcerative Colitis☐ Celiac disease☐ other _____

9. Documented Weight in kg

Baseline_____

Before Cycle 2_____

Before Cycle 3_____

Before Cycle 4_____

Before Cycle 5_____

10. Dose Delays Yes ☐ No ☐

Details_____

11. Dose Reductions Yes ☐ No ☐

Details_____

12. Missed Treatments Yes ☐ No ☐

Details_____

13. Stopped Treatment Yes ☐ No ☐

Details_____

14. Emergency care for side effects due to cancer diagnosis? Yes ☐ No ☐

Which type: Hospitalized ☐ Urgent Care ☐ Unplanned Office Visit ☐

Reason for emergency care? _____

Document which cycle number completed prior to each unplanned visit. _____

Emergency care for side effects due to cancer diagnosis? Yes ☐ No ☐

Which type: Hospitalized ☐ Urgent Care ☐ Unplanned Office Visit ☐

Reason for emergency care? _____

Document which cycle number completed prior to each unplanned visit. _____

15. Hospitalizations

Reason for hospital care? _____

If hospitalized, for how many days? _____

Document which cycle number completed prior to hospital visit._____

16. Required IV fluid hydration? Yes ☐ No ☐

Pre-Scheduled_____ Unscheduled_____ Unknown_____

Treatment cycle number completed prior to IV Fluid Hydration _____

Evaluating the Use of an Amino Acid Food to Alleviate Chemotherapy Induced Toxicity in Cancer Patients

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BACKGROUND:

- Chemotherapy patients are at risk for gastrointestinal (GI) mucosa injury causing diarrhea, nausea, poor oral intake, and/or weight loss
- Symptoms may lead to unplanned visits to healthcare practitioners, outpatient IV infusions, hospitalizations, and delays or alterations of cancer treatments
- Enterade
  - An amino acid-based, glucose-free, oral rehydration medical food
  - Has been shown to reduce diarrhea, dehydration, and weight loss in chemotherapy patients

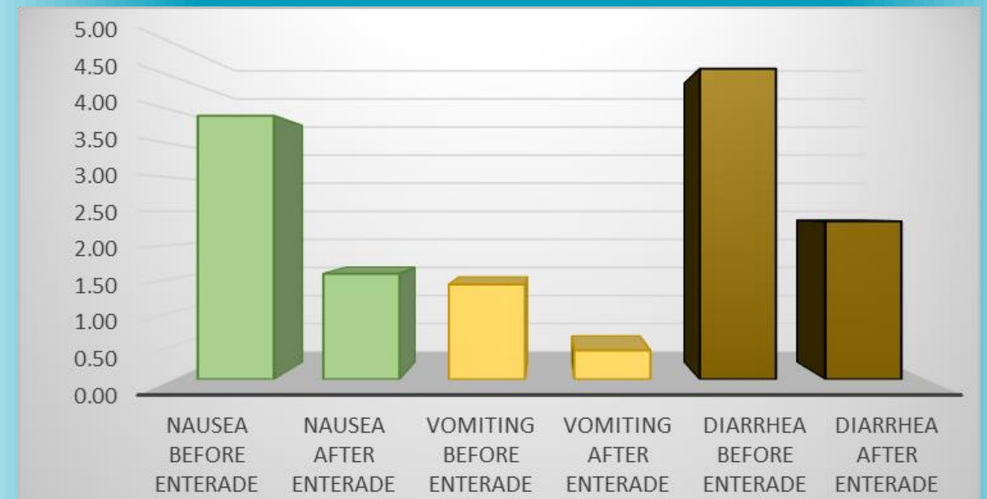
PURPOSE:

- To assess self-report of GI symptoms, number of unplanned GI toxicity-related healthcare practitioner visits, number of IV fluid/electrolyte infusion visits, number of hospital days, alterations of treatment plan (dose delays/reductions, and/or missed/stopped treatments), and weight loss after chemotherapy treatments that pose a high risk for GI toxicities in cancer patients who receive Enterade vs. those receiving standard treatment

METHODS

a) Quasi-experimental study (no randomization)
   a) Comparison group (*n=48*) via retrospective chart review; 12 for each FOLFOX, FOLFIRI, FOLFIRINOX, or TCHP chemotherapy regimens.
   b) Intervention group (*n=49*) 37 of the 49 enrolled received Enterade
   c) 97 total patients were evaluated. (37 used Enterade/60 never used Enterade)
b) In patients agreeing to participate (participants):
   a) Self-report of GI symptoms were recorded at baseline and before treatment cycles 2 through 4.
   b) Provided 16 bottles of Enterade (no cost) w/consumption instructions starting at the treatment cycle the patient reported GI symptoms.
   c) Surveyed prior to each subsequent treatment cycle to document symptoms experienced.

On average, mean scores for nausea (*p*<.001), vomiting (*p*=.07), and diarrhea (*p*<.001) were lower following consumption of Enterade (n=*37*)



Patients who used Enterade experienced:

Fewer hospital days
M=1.00 vs. 2.32 (*p*=.082)

Fewer stopped treatments
M=.11 vs. .25 (*p=.053*)

Fewer unplanned healthcare practitioner visits
M=.36 vs. .82 (*p=.03*)

Of clinical significance, patients also experienced:

- **Less weight loss (2.07 kg/4.56 lbs. vs. 3.79 kg/8.35 lbs. (*p=.51*)**

LESSONS LEARNED:

- Infusion Center Oncology Dietitian is essential for monitoring GI symptoms and educating cancer patients.
- Enterade taste-testing prior to treatment avoids taste aversion during treatment.
- 0-10 self-report symptom assessment scale before each treatment allows early recognition and management of treatment side effects.
- Significant organizational cost savings are realized by avoiding unplanned visits, infusions, and hospitalizations.
- On time administration of planned treatment improves overall survival.

Direct Organizational Cost

Scan for more information and references

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