ACG 2024 Presidential Poster Award
Outstanding Research Award in the Small Intestine Category

TITLE: ORGANOLEPTIC ACCEPTABILITY OF A NOVEL PALATABLE ELEMENTAL DIET VERSUS A COMMERCIALLY AVAILABLE ELEMENTAL DIET: A PROSPECTIVE, SINGLE-BLIND COMPARATIVE TRIAL

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Abstract Body: Elemental diets are complete meal replacements containing the required daily allowance of vitamins, major/trace minerals, triglycerides, amino acids, and monosaccharides. Elemental diets have desirable safety profiles, and their efficacy has been elucidated in several clinical settings including but not limited to Crohn's disease, ulcerative colitis, eosinophilic esophagitis/gastroenteritis, short bowel syndrome, and small intestinal bacterial overgrowth. Palatability remains the main barrier to using complete elemental diets in clinical practice and results in significant poor compliance both in pediatric and adult populations. In this prospective trial, we aimed to blindly assess the organoleptic acceptability of a novel palatable elemental diet (PED) in comparison to a market-leading commercially-available elemental diet (CED).

Methods: Adult subjects with microbial overgrowth undergoing two weeks of exclusive PED (mBIOTA Elemental, USA) were included (NCT05978973). On the initial screening visit, participants blindly tasted and assessed PED and Vivonex Plus (Nestle, USA) (CED). Formulations were prepared as per manufacturer's recommendations. Order of tasting was randomly assigned. Given the known peculiar smell and appearance of the CED, investigators could not be accurately blinded. Participants were asked about their preference between the two formulas and rated the organoleptic characteristics (appearance, smell, taste, aftertaste, and consistency) along with their overall impression of each formulation using a 7-point Likert scale: 1) Like a lot, 2) Like moderately, 3) Like a little, 4) Neither like nor dislike, 5) Dislike a little, 6) Dislike moderately, 7) Dislike a lot. McNemar's test was used for comparison of paired nominal data.

Results: A total of 30 subjects were included (63% women, median (range) age 45 (23-73) years). When asked "Which, if either, of these two shake products tastes better?", all 30 subjects (100%) preferred PED over CED. As compared to CED, the proportion of subjects who liked or were neutral to the PED (Likert scale 1-4) was significantly higher for all organoleptic characteristics: Appearance (90% vs 63.3%, $p=0.027$), smell (86.7% vs 6.7%, $p<0.001$), taste (86.7% vs 0%, $p<0.001$), aftertaste (73.3% vs 6.7%, $p<0.001$), consistency (90% vs 53.3%, $p=0.006$), and overall impression (83.3% vs 0%, $p<0.001$) (Figure 1). All 30 subjects (100%) completed the treatment regimen with exclusive PED.

Conclusion: In this prospective, single-blind comparative study, a novel PED formulation was organoleptically significantly more acceptable for patients compared to a conventional elemental diet, and led to optimal compliance during a 2-week exclusive elemental diet therapy. To our knowledge, these are the highest acceptability and compliance rates reported with regards to an orally ingested elemental diet.

Figure 1. Head-to-head comparison of five organoleptic characteristics along with overall impression of palatable elemental diet (PED) (mBIOTA Elemental) compared to a commercially-available elemental diet (CED) (Vivonex Plus, Nestle) based on a 7-point Likert scale.

