

Blenderized food tube feeding in patients with head and neck cancer

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Real Food Blends provided blenderized tube feeding product.

Abstract

Background: Patients with head and neck cancer (HNC) are at high risk for malnutrition before and during chemoradiation treatment. Many will also require tube feeding to address declines in energy intake, weight, and quality of life (QOL) caused by the impact of treatment on gastrointestinal (GI) symptoms. Blenderized tube feeding (BTF) may ameliorate these adverse conditions.

Methods: In this open-label, prospective pilot study, 30 patients with HNC who required feeding tube placement were recruited to switch from standard commercial formula after 2 weeks to a commercially prepared BTF formula. Weight, body mass index (BMI), GI symptoms, and QOL scores were tracked for 6 weeks from the first week of feeding tube placement.

Results: Of the 16 patients who completed the 6-week assessment period, weights and BMI scores for 15 patients trended upward. For most patients, QOL and oral intake increased and GI symptoms decreased over the 6-week period, particularly during weeks 3 and 4, when the impact of treatment is particularly exacting on patients with HNC.

Conclusion: BTF effectively mitigated weight loss, GI symptoms, QOL scores, and total energy intake in this group of patients with HNC who received tube feeding for 6 weeks.

KEYWORDS

blenderized tube feeding, enteral nutrition, head and neck cancer, malnutrition, quality of life

INTRODUCTION

Cancer is the second leading cause of death in the United States, resulting in about 1700 deaths each day.¹ Specifically, the incidence of head and neck cancer (HNC) has spiked globally in the last 15 years, including a 26% increase

in stage IV HNC cases in the United States—particularly among males.^{2,3} HNC patients are at a high risk for malnutrition, as they frequently experience dysphagia, dysgeusia, mucositis, xerostomia, anorexia, nausea, and vomiting caused by multiple treatment toxicities.^{4–6} Tumor burden, the catabolic and systemic inflammatory nature of cancer,

alterations in digestion and absorption, adverse effects of treatments, and postoperative recovery further exacerbate nutrition risks in this population.⁷ Although malnutrition occurs in 40%–80% of cancer patients during treatment, up to 60% of HNC patients may be malnourished at the time of diagnosis.^{6,8} Nutrition counseling and oral nutrition supplements are the first line of treatment, but HNC patients frequently require enteral nutrition support at some point during treatment intervention.⁹ Enteral tube feeding is recommended when oral intake is <60% of the estimated need for an anticipated or actual >10 days or when a patient is unable to maintain weight.^{9,10} Some healthcare providers (HCPs) recommend feeding tube placement prior to treatment or prior to the development of swallowing problems to prevent malnutrition.¹¹ Unfortunately, weight loss is common in HNC patients, with nearly 60% reporting significant weight loss (>10%⁴) regardless of prophylactic or reactive tube feeding approaches to prevent malnutrition.¹¹ This is largely a result of poor adherence to feeding recommendations because of nausea and early satiety.¹¹ Significant weight loss is an independent predictor of survival.⁴

Although commercial formula (CF) is the predominant tube feeding substrate recommended by HCPs, increased interest and use of blenderized tube feeding (BTF) has emerged in recent years, largely because of patient and caregiver demands as well as HCP interest.^{12–17} Evidence of reduced tube feeding intolerance (gagging, retching, constipation, diarrhea, and abdominal pain), reduced hospital admissions, and reduced need for gastrointestinal (GI) medications is reported in pediatric populations utilizing BTF.^{18–24} Furthermore, these investigations confirm that BTF supports growth and weight goals. Studies in adult populations are scant, but early evidence suggests favorable outcomes, including reduced diarrhea and weight loss prevention.^{25–28} These outcomes are consistent whether full or partial BTF is used for nutrition support. One retrospective chart-review study reported negative outcomes of BTF in adult HNC patients, but the investigation lacked a true control group.²⁹

Given that the majority of BTF studies demonstrate success in ameliorating GI issues and support weight goals, prospective BTF investigations are warranted in the HNC population, in which these issues are especially problematic. The purpose of this open-label, prospective pilot study was to explore the impact of a BTF (full or partial) on GI symptoms, selected anthropometric variables, the ability to meet tube feeding goals, and quality of life (QOL) in patients with HNC who required tube feeding during their treatment. In order to account for any effect of sustained treatment and disease progression, comparisons were planned for three intervals: (1) initial 2 weeks receiving CF, followed by (2) 3 weeks receiving BTF (full or partial), followed by (3) 2 weeks back to 100% CF.

METHODS

The institutional review boards (IRBs) of the university that employs the researchers as well as the medical facility approved the study. Registered dietitians/nutritionists (RDNs) working at an outpatient cancer treatment center recruited participants (adults ≥ 19 years old) with HNC who required gastric feeding tube placement at the time they began radiation and chemotherapy treatments. Patients were given detailed instructions about the study and signed consent forms if they agreed to participate. The recruitment period began on March 1, 2019 with a goal of 30 patients completing the study within 1 year. Reaching the goal of 30 participants was difficult because of the onset of the coronavirus disease 2019 (COVID-19) pandemic and the variable nature of HNC patient treatment experiences (eg, hospitalization, death, shorter period of time needed for tube feeding than anticipated, etc).

At the initiation of gastric feeding tube placement, RDNs performed nutrition-focused physical exams and patients completed baseline questionnaires on GI symptoms and QOL. Patients also completed weekly logs. Collection tools were developed by the Mayo Clinic, Rochester, MN, USA.^{16,17} Specific anthropometric variables of interest, collected weekly by the RDNs throughout the study, were weight, body mass index (BMI), and fat-free mass (FFM) using a bioelectrical impedance scale (Tanita SC-331S, Chicago, IL, USA) and a portable stadiometer (Seca Model 0123, Chino, CA, USA).

Patients for whom swallowing was deemed safe were encouraged to eat food by mouth in addition to tube feeding administration, but RDNs estimated most nutrient needs were likely to be provided solely by tube feeding based on previous experiences with this population. Patients were provided with standard CF for the first 2 weeks of the study, and baseline anthropometric data and data on GI symptoms were collected. Patients began completing the weekly tube feeding log, and RDNs collected anthropometric data during weekly interactions with patients throughout the entire study.

After 2 weeks receiving 100% CF tube feeding, patients completed a pre-BTF Patient Satisfaction Survey and the symptoms-only portion of the Weekly BTF Log.^{16,17} The BTF Log consists of six questions: the number of days per week that BTF was used; the percent of total calorie intake of BTF; whether supplements, food, or beverages were consumed; what symptoms were experienced; whether the feeding tube became clogged; and additional comments.

The RDNs then instructed patients to replace half of their CF prescription with a commercially prepared BTF product (Real Food Blends, Chesterton, IN, USA). The partial BTF period was to last for 3 weeks with weekly data collection continued. At the end of the 3 weeks receiving

TABLE 1 Reasons for Noncompletion

| Reasons for noncompletion | Number | Percent |
|---|--------|---------|
| Prolonged hospitalization/death | 4 | 28.5 |
| Caregiver/situational noncompliance | 3 | 21.4 |
| PEG tube removed/leaking with bolus feeds | 2 | 14.2 |
| Treatment changed to continuous feeds only because of COVID-19 scheduling | 2 | 14.2 |
| Inconvenience (did not want to mix with water) | 2 | 14.2 |
| Stopped all treatment | 1 | 7.1 |

Abbreviations: COVID-19, coronavirus disease 2019; PEG, percutaneous endoscopic gastrostomy.

partial BTF, patients were to complete the post-BTF Satisfaction Survey^{16,17} in addition to the tube feeding logs and the collection of anthropometric variables by RDNs. Additionally, RDNs followed up with patients weekly via phone and in-person visits to the facility. Patients were questioned about their food intake, and this was documented in the electronic health record. Questions regarding food intake in the RDN visits were comprehensive and included questions about the texture, tolerance, and amount of food and oral liquid supplements consumed, if any.

However, shortly after initiating the partial BTF, none of the patients wanted to return to CF, and all except two opted for full BTF, abandoning any CF tube feeding. Consequently, the IRB protocol was amended and approved, and additional BTF product was provided to participants. Ultimately, the study was completed with the following amendments: (1) initial 2 weeks receiving 100% CF, followed by (2) 25%–100% BTF with weekly data collection for anthropometric variables and tube feeding logs.

RESULTS

Because of the small sample size, inferential statistics were not conducted. Of the 30 participants who enrolled in the study, 16 (53.3%) completed it. Out of the 14 who enrolled but did not complete it, four (28.5%) never began BTF. However, of the 10 participants who began BTF but did not complete the study, nine (90%) tolerated BTF. Reasons for noncompletion are found in Table 1. Noncompliance was driven by a lack of a caregiver or a job that prevented bolus feeds. Of the 16 participants who completed the study, 62.5% were male ($n = 10$). The mean age of participants was 58.7 years (SD = 9.53 years), with a range of 46–75 years. All patients received radiation, and all but one patient (#17) received chemotherapy. Tumor sites ranged from the nasopharynx to distal esophagus.

Table 2 displays the results of weight over time of the

16 participants. A comparison was made of the weight loss percentage from baseline to the end of BTF using a 1-month criteria (5%).³⁰ Only two patients (12.5%) experienced significant weight loss, but one participant experienced weight trending upward after BTF was initiated 114 lbs, 51.8kg to 125.6 lbs, 57.09 kg to 132.2 lbs, 60.09 kg. One participant (#012) continued to lose weight over time. Using 1-month criteria for significant weight loss (5%), 5 of 15 (31.25%) patients experienced significant weight loss; however, all except one trended upward by the end of the study. Mean weight decreased from 159.98 lbs, 72.71 kg (SD = 32.06 lbs, 14.57kg) in week 1 to 152.0lbs, 69.09 kg (SD = 31.48 lbs, 14.3 kg) in week 6 (Figure 1).

Table 3 displays the results of the BMI over time. BMI scores improved or held steady for 10 (56.5%) of the 16 participants. Only one participant (#030) began the study with a BMI score below 18.5 (indicating underweight), but that participant maintained their BMI score of 15.8 at the end of the study (Figure 2). The mean BMI score decreased from 23.75 (SD = 4.13) in week 1 to 22.79 (SD = 3.89) in week 6.

Symptoms over time are displayed in Table 4. Overall, all symptoms improved while patients received BTF, including pain (18.8% to 12.5%), vomiting (31.3% to 12.5%), constipation (31.3% to 12.5%), gas/bloating (50% to 18.8%), nausea (62.5% to 12.5%), and diarrhea (37.5% to 0%). Additionally, “other symptoms” decreased from six patients reporting to zero patients reporting.

Other variables recorded in the weekly log are found in Table 5. The amount of BTF taken in increased from week 1 to week 2, with 12 patients (75%) reporting using BTF 7 days per week by the second week of BTF initiation. The percent caloric intake of BTF also improved steadily over the 3-week time frame, with 76%–100% caloric intake from BTF increasing from 0% to 18.8% to 25%, respectively. The number of patients reporting supplements remained steady, but over the 3 weeks receiving BTF, patients reported an increased intake of solid foods from 50% to 77.7%. Only two patients in week 1 (12.5%), two patients in week 2 (12.5%), and one patient in week 3 (6.1%) reported clogging in the feeding tube; this was primarily related to the beef and egg flavors, which had a higher viscosity. Patients reported that the clogged tubes did not require intervention, just manipulation of the tube. The comments related to BTF remained positive throughout the study.

QOL before tube feeding, before the initiation of BTF, and after the initiation of BTF is found in Table 6. Those reporting bad or very bad QOL decreased from 6 (37.6%) before tube feeding was initiated to 3(8.8%) while receiving CF (before BTF) to zero after BTF was initiated. Those reporting a good or very good QOL increased from 6 (50.1%) before BTF initiated to 15 (91.3%) after BTF was initiated. Additionally, 14 (87.6%) patients disagreed or strongly disagreed with the statement, “BTF added stress to my life,”

TABLE 2 Weight of participants over time

| ID | Week 1, lbs/kg | Week 2, lbs/kg | Week 3, lbs/kg | Week 4, lbs/kg | Week 5, lbs/kg | Week 6, lbs/kg | Change, % |
|------|----------------|----------------|----------------|----------------|----------------|----------------|-----------|
| 001 | 188 (85.45) | 190 (86.36) | 189.4 (86.09) | 188.2 (85.54) | 189.2 (86.0) | 189 (85.9) | +0.53 |
| 002 | 197.8 (89.9) | 184 (83.63) | 181 (82.27) | 178 (80.9) | 179.6 (81.63) | 184.4 (83.81) | -6.77 |
| 007 | 147.2 (66.9) | No data | 144 (65.45) | 146.6 (66.63) | 148.0 (67.27) | 150.6 (68.45) | +2.2 |
| 011 | 150.8 (68.54) | 149.2 (67.81) | 147.2 (66.9) | 149.2 (67.81) | 152.4 (69.27) | 151.2 (68.72) | +0.26 |
| 012 | No data | 152.8 (69.45) | No data | 143.8 (65.36) | 139.4 (63.36) | 134.8 (61.27) | -11.7 |
| 014 | 170.4 | 169.2 (76.9) | No data | 163.8 (74.45) | 161.6 (73.45) | 158.2 (71.9) | -7.15 |
| 015 | 160.8 | 159.8 (72.63) | No data | 158.4 (72.0) | No data | 154.8 (70.36) | -3.73 |
| 016 | 148.6 | No data | 114.4 (52.0) | 125.6 (57.09) | No data | 132.2 (60.09) | -11.0 |
| 017 | 138.6 | 135.0 (61.36) | 134.9 (61.31) | 131.0 (59.54) | 127.0 (57.72) | 130.0 (59.09) | -6.2 |
| 019 | No data | No data | 164.0 (74.54) | 162.0 (73.63) | 161.0 (73.18) | 157.6 (78.8) | -0.39 |
| 024 | 114.8 | No data | 111.4 (52.0) | 110.8 (50.36) | No data | 120.2 (54.63) | +4.5 |
| 025 | 228.2 | 230.0 (104.54) | No data | 227.0 (103.18) | 226.8 (103.4) | 227.0 (103.18) | -0.52 |
| 026 | 111.8 | 113.80 (51.72) | 113.80 (51.72) | 108.80 (49.45) | 114.0 (51.81) | 118.60 (53.90) | +5.7 |
| 028 | 152.6 | 152.6 (69.36) | No data | 148.80 (67.63) | 146.8 (66.72) | 151.80 (69.0) | +0.52 |
| 029 | 169.2 | 172.0 (86.0) | No data | 173.8 (79.0) | 175.8 (79.9) | 174.00 (79.09) | +2.7 |
| 030 | No data | 98.0 (49.0) | No data | No data | No data | 97.60 (44.36) | -0.40 |
| Mean | 159.98 | 158.56 (72.07) | 144.45 (65.65) | 154.38 (70.17) | 160.13 (74.6) | 152.0 (69.09) | |
| SD | 32.06 | 35.04 | 29.09 | 30.58 | 30.08 | 31.48 | |

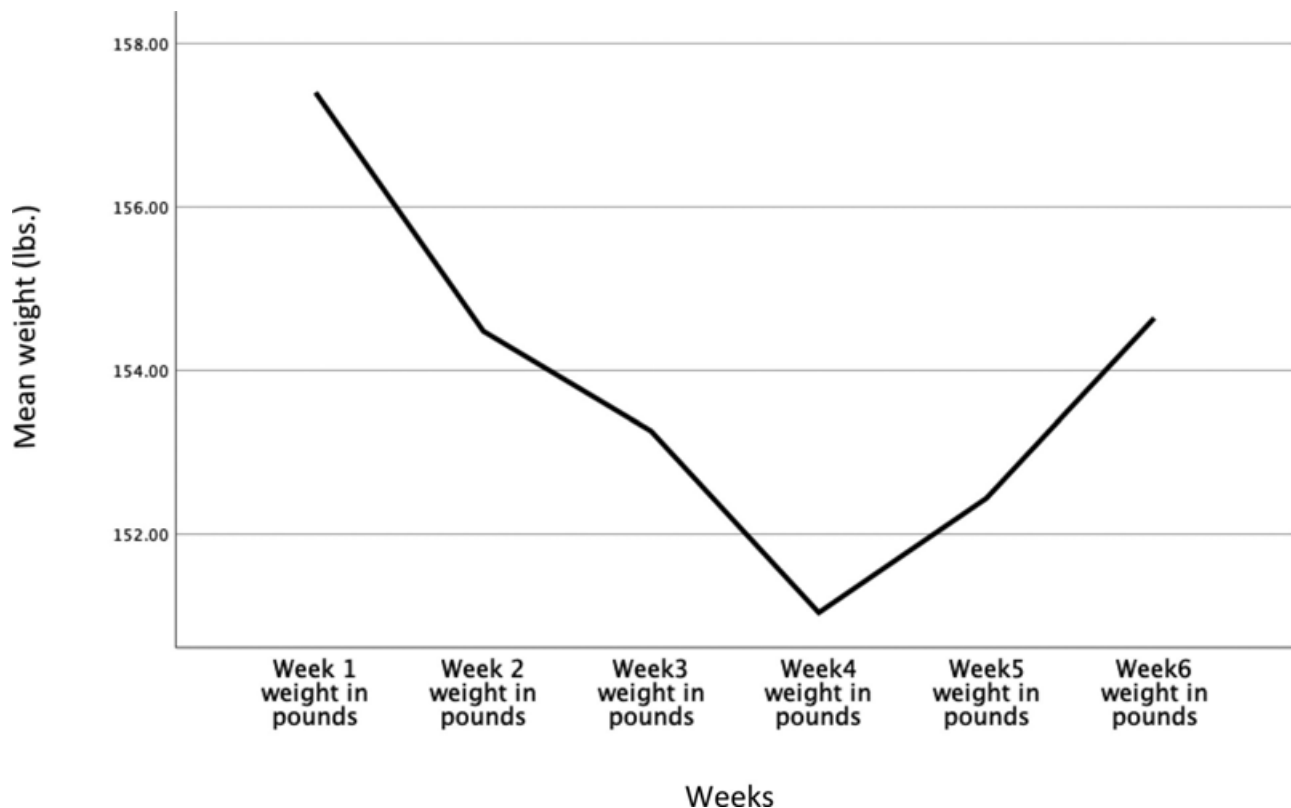


FIGURE 1 Mean weight of participants over time

TABLE 3 Body mass index score of participants over time

| ID | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Change, % |
|------|---------|---------|---------|---------|---------|--------|-----------|
| 001 | 24.4 | 24.7 | 24.6 | 24.5 | 24.6 | 24.6 | +0.8 |
| 002 | 28.4 | 26.5 | 26 | 25.5 | 24.36 | 26 | -3.5 |
| 007 | 19.4 | No data | 18.9 | 19.3 | No data | 19.9 | +2.5 |
| 011 | 25.09 | 25.6 | 25.3 | 25.6 | 26.2 | 26 | +3.5 |
| 012 | No data | 22.6 | No data | 20.9 | 20.6 | 19.9 | -11.9 |
| 014 | 24.8 | 23.6 | No data | 23.8 | 23.4 | 23 | -7.2 |
| 015 | 28.5 | 28.3 | No data | 28.1 | No data | 27.4 | -3.8 |
| 016 | 25.9 | No data | 19.9 | 21.9 | No data | 23.4 | -9.6 |
| 017 | 19.97 | 19.40 | 19.40 | 18.87 | 18.30 | 18.65 | -6.6 |
| 019 | No data | No data | 26.50 | 25.80 | 26.00 | 25.40 | -4.1 |
| 024 | 18.2 | No data | 17.7 | 17.6 | No data | 19.1 | +4.7 |
| 025 | 31.40 | 31.60 | No data | 31.20 | 31.20 | 31.20 | -0.63 |
| 026 | 18.90 | 19.20 | 19.20 | 18.40 | 19.20 | 20.00 | +5.5 |
| 028 | 22.2 | No data | No data | 21.70 | 21.4 | 22.10 | -0.4 |
| 029 | 21.70 | 22.10 | 22.30 | 22.60 | No data | 22.30 | +2.6 |
| 030 | No data | 15.8 | No data | No data | No data | 15.80 | 0 |
| Mean | 23.75 | 23.77 | 21.94 | 23.03 | 23.11 | 22.79 | |
| SD | 4.13 | 4.32 | 3.55 | 3.83 | 3.66 | 3.89 | |

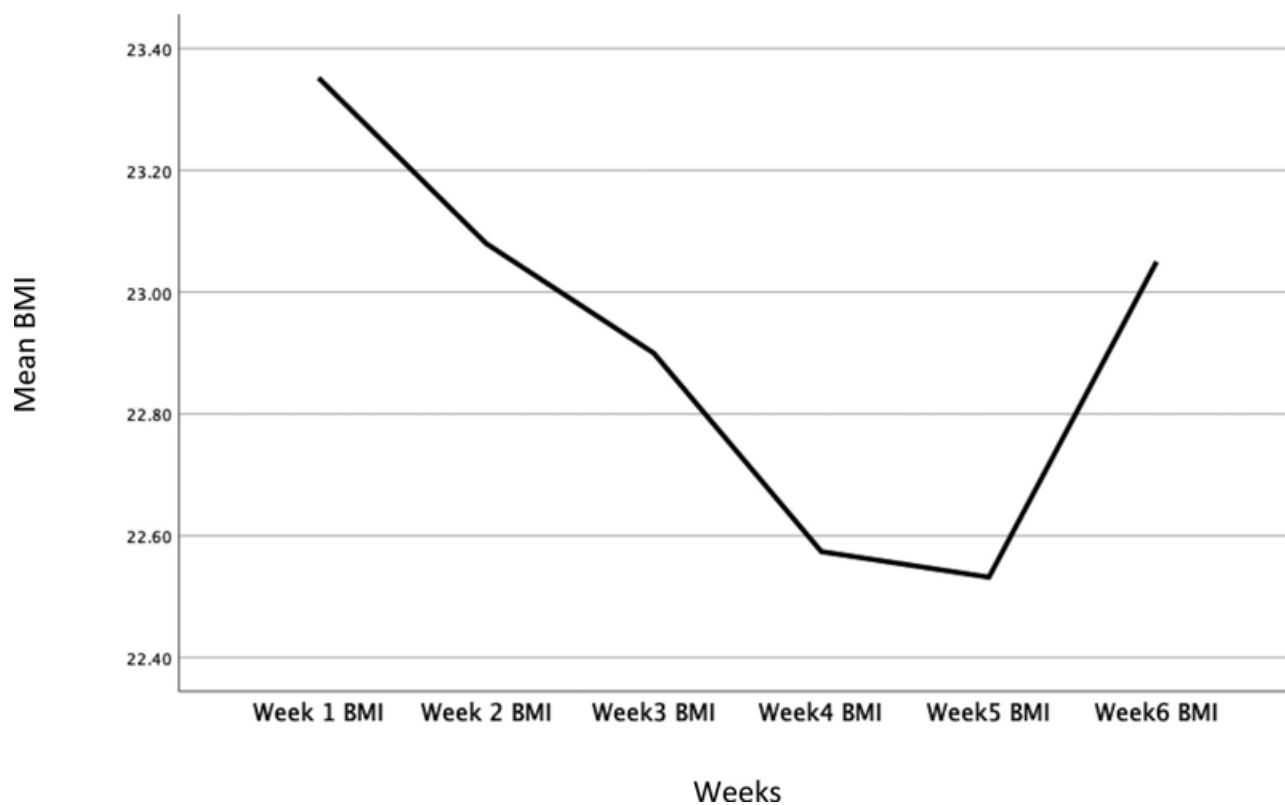


FIGURE 2 Mean BMI of participants over time. BMI, body mass index

TABLE 4 Symptoms of participants over time

| | CF final week, n (%) | BTF week 1, n (%) | BTF week 2, n (%) | BTF week 3, n (%) |
|---------------------|--|-------------------------------------|---|-------------------|
| Nausea | | | | |
| Yes | 10 (62.5) | 7 (43.8) | 7 (43.8) | 2 (12.5) |
| No | 6 (37.5) | 6 (37.5) | 7 (43.8) | 11 (68.8) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Vomiting | | | | |
| Yes | 5 (31.3) | 6 (37.5) | 7 (43.8) | 2 (12.5) |
| No | 11 (68.8) | 7 (43.8) | 7 (43.8) | 11 (68.8) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Fever | | | | |
| Yes | 0 (0) | 1 (6.3) | 1 (6.3) | 2 (12.5) |
| No | 16 (100) | 12 (75.0) | 13 (81.3) | 11 (68.8) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Gas/bloating | | | | |
| Yes | 8 (50.0) | 2 (12.5) | 1 (12.5) | 3 (18.8) |
| No | 8 (50.0) | 11 (68.8) | 12 (75.0) | 10 (62.5) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Diarrhea | | | | |
| Yes | 6 (37.5) | 4 (25.0) | 4 (25.0) | 0 (0) |
| No | 10 (62.5) | 9 (55.3) | 10 (62.5) | 13 (81.3) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Constipation | | | | |
| Yes | 5 (31.3) | 4 (25.0) | 5 (31.3) | 2 (12.5) |
| No | 10 (68.8) | 9 (56.3) | 9 (56.3) | 11 (68.8) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Pain | | | | |
| Yes | 3 (18.8) | 3 (18.8) | 3 (18.8) | 2 (12.5) |
| No | 13 (81.3) | 10 (62.5) | 11 (68.8) | 11 (68.8) |
| Missing | | 3 (18.8) | 2 (12.5) | 3 (18.8) |
| Other symptoms | Heartburn, indigestion, reflux, tinnitus, arm and back pain, and sore throat | Sore throat and pain at cancer site | N and V with Osmolite only, N and V with salmon flavor, and pain at cancer site | None |

Abbreviations: BTF, blenderized tube feeding; CF, commercial formula; N, ; V,.

and 15 (92.7%) disagreed or strongly disagreed with the statement, “BTF overwhelmed my caretaker.”

DISCUSSION

The results of this prospective, open-label pilot study of BTF in HNC patients requiring tube feeding during chemoradiotherapy resulted in positive outcomes, particularly the impacts on weight, GI symptoms, and QOL. These findings are consistent with other published work in adult populations comparing BTF with CF, with one exception. In a retrospective chart analysis, Papakostas et al compared BMI and FFM (measured by bioelectrical impedance analysis) between BTF- and CF-fed HNC patients receiving home enteral nutrition at the time of tube placement,

8 weeks after chemoradiotherapy treatment ended, and 6 months after treatment ended.²⁹ They reported the BTF group experienced significant declines in BMI and FFM, but the CF (n = 112) group almost reached levels measured at initial diagnosis. However, both the BTF and CF groups were instructed to consume yogurt, honey, ice cream, and fruit and vegetable juices through their tubes or orally each day. Furthermore, the BTF group (n = 31) lacked insurance and was given a recipe to follow, but follow-up and continued oversight on the feeding was not provided. Also, the original number in the CF group was 181, but 69 patients opted to stop taking the insurance-provided formula during the 8-week follow-up period and made their own BTF, again, with no oversight from HCPs.²⁹ The lack of a true control group and the disparity in nutrition oversight of the three feeding substrates make it difficult to draw

TABLE 5 BTF log over time

| | BTF week 1, n (%) | BTF week 2, n (%) | BTF week 3, n (%) |
|------------------------------|-------------------|--|---|
| Days per week/BTF | | | |
| 1 | 0 (0) | 1 (6.3) | 0 (0) |
| 2 | 0 (0) | 0 (0) | 1 (6.3) |
| 3 | 1 (6.3) | 1 (6.3) | 1 (6.3) |
| 5 | 1 (6.3) | 0 (0) | 1 (6.3) |
| 7 | 9 (56.3) | 12 (75.0) | 10 (62.5) |
| Missing | 5 (31.3) | 2 (12.5) | 3 (18.8) |
| Caloric intake/BTF, % | | | |
| 0–25 | 2 (12.5) | 2 (12.5) | 1 (6.3)5 (31.3) |
| 26–50 | 6 (37.5) | 5 (31.3) | 3 (18.8) |
| 51–75 | 3 (18.8) | 4 (25.0) | 4 (25.0) |
| 76–100 | 0 (0) | 3 (18.8) | 3 (18.8) |
| Missing | 5 (31.3) | 2 (12.5) | |
| Supplements | | | |
| Yes | 8 (50.0) | 9 (56.3) | 7 (43.8) |
| No | 3 (18.8) | 5 (31.3) | 6 (37.5) |
| Missing | 5 (31.3) | 2 (12.5) | 3 (18.8) |
| Type supplements | | | |
| Food | 4 (50.0) | 6 (60.0) | 7 (77.7) |
| Boost/Ensure | 2 (12.5) | 0 (0) | 0 (0) |
| Water/liquids | 2 (12.5) | 3 (30.0) | 2 (22.2) |
| Tube clogged | | | |
| Yes | 2 (12.5) | 2 (12.5) | 1 (6.3) |
| No | 8 (50.0) | 12 (75.0) | 12 (75.0) |
| Missing | 6 (37.5) | 2 (12.5) | 3 (18.8) |
| Comments | | | |
| | “BTF is pleasant” | “I feel full (haven’t felt in a long time)”; “Clogs with BTF beef flavor only”; “The product is very beneficial to me” | “Clogs with egg blend only”; “It (BTF) saved my life”; “BTF takes a little longer but I don’t mind because it improved my symptoms” |

Abbreviation: BTF, blenderized tube feeding.

TABLE 6 Presurvey and postsurvey results for quality of life

| | Before tube feeding initiated, n (%) | Before BTF initiated, n (%) | After BTF initiated, n (%) |
|-----------|--------------------------------------|-----------------------------|----------------------------|
| Very bad | 1 (6.3) | 1 (6.3) | 0 (0) |
| Bad | 5 (31.3) | 2 (12.5) | 0 (0) |
| Neutral | 1 (6.3) | 5 (31.3) | 1 (6.3) |
| Good | 5 (31.3) | 7 (43.8) | 10 (60.0) |
| Very good | 4 (25.0) | 1 (6.3) | 5 (31.3) |

Abbreviation: BTF, blenderized tube feeding.

conclusions on the efficacy of BTF in HNC patients from this study.

For 6 weeks, Pandit et al tracked the weight of 357 HNC patients who were beginning active chemoradiotherapy treatment. The sample included patients who received CF tube feeding and those who were fed orally. Overall, 67.4% experienced a mean weight loss >5%, and 28.8% of the participants lost >10% of their weight over 6 weeks.³¹ They

observed that maximal weight loss began at week 3 and continued through week 6. These observations are consistent with other published work showing that most HNC patients experience difficulty with eating and subsequent declines in weight during weeks 3–4 of treatment that persist after treatment’s end.^{29,31,32} In contrast, our results demonstrated that BTF promoted weight increase for all except one patient, similar to the results of Hurt et al.²⁵

Furthermore, maximal mean weight loss experienced at the end of week 3 began to rebound at week 4: 2 weeks after the introduction of BTF to their diets. The weight rebound occurred during the time that participants increased the proportion of BTF in their total intake. Similarly, Hurt et al noted that BTF use and weight increased over their 6-week study.²⁵ The potential impact of BTF on arresting significant weight loss at this critical point in care has implications beyond the treatment period.

The favorable impact of BTF on reducing adverse GI symptoms in children is well documented.^{12–16,18–24} At least two studies on the impact of BTF for reducing adverse GI symptoms in adults have been published.^{26,27} In an observational study, Fabiani et al compared diarrhea occurrence between two groups of critically ill patients in a cardiac intensive care unit.²⁶ Both groups were tube fed, but one group (n = 103) received a BTF prepared by hospital staff and delivered by syringe bolus three times a day. The other group (n = 112) received a standard CF delivered by continuous pump infusion for 15 h per day. During the 8-day observation, 48.2% of the CF group developed diarrhea compared with 27.2% of the BTF group, demonstrating a significantly lower probability of diarrhea occurrence in BTF use ($P = .023$).²⁶

In a multicenter, open-label, randomized controlled trial, Schmidt et al followed 118 critically ill neurological patients (eg, stroke, traumatic brain injury, etc) for 30 days who required tube feeding.²⁷ Half the group was fed reconstituted CF and the other half was fed a commercially prepared BTF; both feeds were delivered by pump. Both groups maintained their average BMI of 25. The BTF group had a significantly reduced number of watery stools and fewer days with diarrhea.²⁷

Similarly, participants in our study reported reductions in pain, vomiting, gas/bloating, nausea, and constipation, and the incidence of diarrhea, specifically, declined from 37.5% to 0% from the period ending CF to the period ending BTF. During this time period, patients were able to increase the proportion of BTF, the intake of solid food and supplements by mouth, and the overall calorie intake. These results are remarkable in that they occurred during the time that HNC patients typically experience declines in oral feeding and weight along with increased reports of GI symptoms. Concurrent with improved GI function, patients in our study reported improved QOL scores after tube feeding was initiated, but more so when they were switched from CF to BTF. Mulasi et al noted that QOL scores declined as malnutrition scores increased in their study of outpatients with HNC; this is consistent with other work showing >10% weight loss is positively correlated with declining QOL scores.³³ Preventing nutrition decline has important implications for psychosocial care of patients with HNC.

The rationale behind the efficacy of BTF has not been clearly elucidated. However, the contribution of dietary variety from whole foods (eg, phytonutrients) is associated with an improved intestinal microbiome; this is demonstrated in two studies of BTF in children.^{23,24} High-fiber diets selectively increase the growth of beneficial bacteria that, in turn, reduce infection from enteropathogens.^{23,24,27} Real food provides prebiotics and probiotics that maintain a favorable microbiome in the gut. Conversely, standard CF is a highly processed, monotonous feeding substrate consisting mostly of corn syrup solids, corn maltodextrins, soy and casein proteins, and various ratios of different types of fats/oils and micronutrient mixtures.

Another point to consider is the psychosocial dynamic of BTF. Resurgence of BTF interest and use has been largely patient and caregiver driven. Although many initiate BTF to address tube feeding intolerance, a significant number elect BTF because it represents a more physiologic feeding.^{13,15,20} This perspective aligns with the lifestyle recommendations from the American Institute of Cancer Research (AICR) Third Expert Reports, which include eating a diet rich in whole grains, vegetables, fruits, and beans and limited consumption of processed and red meat, sugar-sweetened beverages, and alcohol during and after cancer treatment.³⁴ Multiple studies of cancer survivors demonstrate that following a healthy diet reduces overall mortality by 22%, but eating a typical Western diet of highly processed foods increases the risk of death by 51%.³⁵ Unfortunately, the diet quality of cancer survivors is rather low, with a Healthy Eating Index score of 55.6 (out of a potential 100 points).³⁶ Utilizing BTF may serve a twofold purpose: to reduce the adverse effects and poor outcomes associated with HNC treatments and to provide a teachable moment convincing patients that following AICR diet recommendations after treatment also confers benefit. Our study results are consistent with other studies demonstrating increased oral intake with BTF use^{13–15,18–22}; this teachable moment may present itself during those critical weeks when tube feeding is needed during chemoradiation therapy.

Many patients make their own BTF using a variety of resources, and the CF industry has responded to consumer demand with the introduction of several prepackaged BTF products.³⁷ However, HCPs have not been as enthusiastic about BTF, citing concerns of the risk of microbial contamination and subsequent infection, clogged tubes, and unknown or inconsistent nutrient composition.^{13,20,37} Ironically, in spite of these concerns, HCPs have rarely, if ever, experienced them in clinical practice.^{13,14,19,34} Furthermore, recent studies demonstrate acceptable microbial loads of hospital- and home-prepared BTF compared with earlier studies conducted in conditions of unknown or unacceptable safe food-handling

methods.^{38,39} The insistence that tube-fed patients be given sterile product may needlessly prohibit them from the benefits of foodborne nonpathogenic bacteria available in whole-food mixtures.³⁷ Studies that show poor weight and/or growth outcomes when BTF is used may be biased by other factors, such as disparate socioeconomic conditions impacting healthcare and inconsistent feeding oversight by HCPs.³⁷

LIMITATIONS

The largest limitation was the small sample size. This study was partially conducted during the COVID-19 pandemic, which severely impacted the ability to recruit and maintain participation. Inconsistent access to patients and variable treatment outcomes (hospitalization, death, or discontinuance of tube feeding) are difficulties reported in the oncology outpatient clinics treating the HNC population.^{25,33} Additionally, depending on the treatment regimen and the physical frailties of the patients, some anthropometric and survey data were not able to be collected. Frequently, consultations with the RDNs working in the clinic occurred around chemotherapy infusion or radiation treatments, and measurements/survey data were not feasible. A further limitation encountered was in the physical frailties of patients as a result of their diagnoses/treatment that made it difficult for them to stand for anthropometric measurements.

CONCLUSIONS

Although the results of this pilot study are not generalizable, they do support existing papers on the efficacy of BTF in children and adults. This investigation and the one by Hurt et al are of particular importance because, in both, weight loss and declining QOL scores typical of weeks 3–4 in HNC chemoradiation therapy were reversed with the addition of BTF.²⁵ Despite the difficulties of conducting larger trials in the HNC patient population, they are needed to further investigate the efficacy of BTF in a population that may benefit at a critical moment in their care.

CONFLICT OF INTERESTS

Ryan T. Hurt is a consultant for Nestlé Nutrition and Lisa Epp is a consultant for Abbott Nutrition, Nestlé Nutrition, and Halyard Avanos. Manpreet S. Mundi has received research grant funding from Nestlé, Fresenius Kabi, and Real Food Blends. All others report no conflicts.

AUTHOR CONTRIBUTIONS

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L. Davidson, Manpreet S. Mundi, Lisa Epp, and Ryan T. Hurt equally contributed to the conception and design of the research; Amy Y. Spurlock, Teresa W. Johnson, Ali Pritchett, and Leah Pierce contributed to the design of the research; Ali Pritchett, Leah Pierce, Amy Y. Spurlock, and Teresa W. Johnson contributed to the acquisition and analysis of the data; Amy Y. Spurlock and Teresa W. Johnson contributed to the interpretation of the data; and Amy Y. Spurlock and Teresa W. Johnson 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.

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