

Advances in Patient Satisfaction and Drinking Compliance When Performing Neutral Imaging of the Small Bowel in CT and MR Enterography

Michael A. Davis, MD, ScD, MBA
Allison L. Ostrout, Beekley Medical®

Purpose

To compare Breeza® flavored beverage for neutral abdominal/pelvic imaging (or Breeza for neutral) to a commercially available oral product for use in CT and MR enterography (CTE, MRE).

Materials and Methods

This study was sponsored by Beekley Medical® and conducted at 5 clinical facilities. All locations previously used a commercially available product. Facilities were provided 500mL bottles of Breeza for neutral. Patients drank the same amount as each facility's current oral protocol for neutral imaging or an amount determined by the radiologist. Patient consent was acquired.

The technologist at each clinical test site documented the amount provided to and consumed by the patient, patient side effects while in the department, and patient acceptance. The radiologist at each clinical test site documented bowel distention, lumen visualization, and transit time. In addition, a post-test survey was conducted regarding taste and patient compliance.

Results

Ninety-seven (97) patients or 96% of the 101 patients that tasted Breeza® flavored beverage for neutral abdominal/pelvic

imaging found it palatable and acceptable. Four (4) of the 5 test sites participated in a post-test survey. All 4 indicated that Breeza for neutral tasted better and increased drinking compliance compared to the commercially available product.

Radiologists reported bowel distention, lumen visualization, and transit time as 100% acceptable for all 96 patients who drank the complete volume of Breeza for neutral prior to their enterography exam.

In comparison to the previously used commercial product, radiologists reported 87 patients or 91% had improved or comparable bowel distention, 95 patients or 99% had improved or comparable transit time, and 93 patients or 97% had improved or comparable lumen visualization. Ninety-one (91) patients or 95% did not experience any side effects.

Conclusion

Breeza® flavored beverage for neutral abdominal/pelvic imaging provided superior taste and palatability for patients – increasing drinking compliance and improving patient satisfaction. In addition bowel distention, lumen visualization, and transit time were improved or comparable in the majority of CTE and MRE exams.

Introduction

One of the key requirements for a successful CT or MR enterography (CTE, MRE) is to have the small bowel well distended with neutral opacity fluid. Scientific manuscripts have been published using fluids such as milk, water with methylcellulose, and a commercially available product for oral administration.^{1,2}

The current commercially available product meets the CT and MR physical requirements; however, it falls short of being ideal with respect to patient palatability.² Patients can find the taste and

palatability undesirable. This, combined with feeling ill, can require a time investment by the technologist to coach the patient to drink. And, if they cannot drink the entire volume, it can result in a suboptimal study or reschedule of the exam.

Although water itself can provide bowel distention and neutral opacity in the small bowel, it also falls short as it is rapidly absorbed from the small intestine causing non-distended loops of small bowel. In previous manuscripts, water was documented as not providing adequate evaluation of the distal small bowel.²

Materials and Methods

This study was sponsored by Beekley Medical® and conducted to validate the performance of Breeza® flavored beverage for neutral abdominal/pelvic imaging (or Breeza for neutral). From May 2014 to December 2014, five (5) clinical sites participated in reporting findings from random CTE and MRE exams using Breeza for neutral. Prior to participation in the study, all 5 clinical locations previously used the commercially available oral product for neutral imaging.

All test sites were provided with 500mL bottles of Breeza® flavored beverage for neutral abdominal/pelvic imaging. It has a light lemon-lime flavor, contains only FDA GRAS ingredients (Generally Regarded As Safe), is sugar-free, and gluten-free.

Patient Participation and Documentation

The only requirement for patient participation was a physician ordered CTE or MRE exam. Each patient signed an informed consent. The technologist at each clinical test site documented the amount of Breeza for neutral provided to and consumed by the patient, patient side effects while in the department, and patient acceptance.

The radiologist at each clinical test site documented bowel distention, lumen visualization, and transit time. Both the technologist and radiologist signed and dated each patient CTE and MRE data tracking form. In addition, clinical sites participated in a post-test survey based on their experiences regarding taste and patient compliance. The information was gathered and analyzed.

Protocol

Each clinical facility maintained their current enterography drinking protocol. Patients drank the same amount as the facility's current oral protocol for neutral imaging or an amount determined by the radiologist. Patients were most commonly required to drink three 500mL bottles within the 45-60 minutes before imaging.

CTE and MRE also employ IV contrast agents (the active agent or drug) to enhance the bowel wall and improve the diagnostic efficacy of the procedure. No change to each department's standard use of these contrast agents was made.

Results Overview

One-hundred and three (103) patient CTE (90) and MRE (13) data tracking forms were collected (Table 1). Two (2) patient tracking forms were removed from all results because the documentation was incomplete. One-hundred and one (101) patients were then included in the results for palatability and acceptance because they tasted Breeza® flavored beverage for neutral abdominal/pelvic imaging. Ingested volume affects bowel characteristics; therefore, the ninety-six (96) patients that drank Breeza for neutral according to the department's protocol are represented in the results for bowel distention, lumen visualization, and transit time.

Table 1. Results Overview

Total # of Patients Tracked	# of Patients Removed for Incomplete Reporting	# of Patients Represented in Palatability and Acceptance Results	# of Patients Represented in Imaging Results (drank to protocol)
103	2	101	96

Palatability and Acceptance Results

Of the 101 patients tasting Breeza® flavored beverage for neutral abdominal/pelvic imaging (Table 2), 97 patients or 96% found the beverage palatable and acceptable. Therefore, the visually appealing presentation and refreshing lemon-lime flavor can help reduce technologist coaching time and assist with patient compliance.

In the 4 patients or 4% that did not find the beverage palatable and acceptable, reasons noted were feelings of nausea (1), fullness (1), taste (1), and preexisting stomach pain (1).

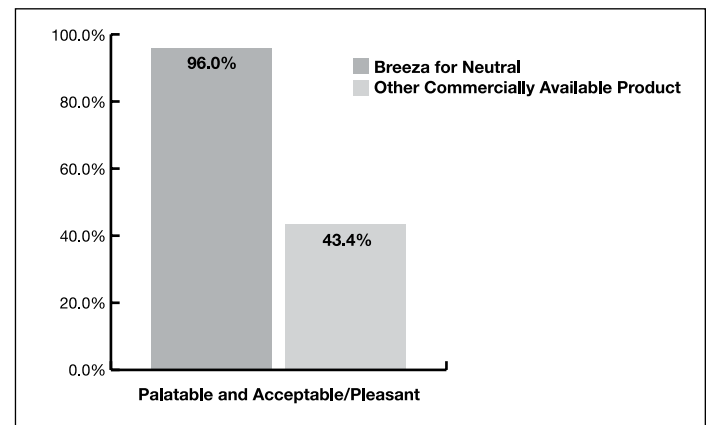
Ninety-six (96) out of 101 or 95% of patients drank Breeza for neutral and complied with the department's drinking protocol.

Table 2. Palatability and Acceptance Results

# of Patients	Palatable and Acceptable	Not Palatable and Not Acceptable
101	97 (96%)	4 (4%)

In a previous study, only 43.4% of patients rated the other commercially available product as "pleasant".² In comparison, Breeza® flavored beverage for neutral abdominal/pelvic imaging was rated "palatable and acceptable" by 96% of patients (Chart 1).

Chart 1. Palatability of Breeza® Flavored Beverage for Neutral Abdominal/Pelvic Imaging Compared to Other Commercially Available Product



Post-test Survey, Taste and Compliance

Four (4) of the 5 clinical test sites also participated in a post-test survey (Table 3). Three (3) radiologists and 1 director provided responses. They were asked in comparison to the previously used commercial product, “Which product would you say is better tasting for patients?”

Four (4) out of 4 or 100% indicated that Breeza® flavored beverage for neutral abdominal/pelvic imaging was better tasting than the commercially available product.

They were also asked in comparison to the previously used commercial product, “Which product would increase drinking compliance with patients?”

Four (4) out of 4 or 100% indicated that Breeza for neutral increased drinking compliance with patients over the commercially available product.

Table 3. Post-test Survey Results

Breeza® Flavored Beverage for Neutral Abdominal/Pelvic Imaging	
Better Tasting for Patients	4 (100%)
Increases Drinking Compliance	4 (100%)

Distention, Visualization, and Transit Results

Table 4. CTE and MRE Distention, Visualization, and Transit Results

	# of Patients Improved	# of Patients Comparable	# of Patients Reduced	# of Patients Reported Acceptable
Bowel Distention	26 (27%)	61 (64%)	9 (9%)	96 (100%)
Lumen Visualization	18 (19%)	75 (78%)	3 (3%)	96 (100%)
Transit Time	16 (17%)	79 (82%)	1 (1%)	96 (100%)

Bowel Distention

In enterography, bowel distention is necessary to aid in visualization of the bowel lumen, mucosal fold pattern, and bowel wall. Effective distention of the bowel is reliant on the type of drink provided, amount provided, time to drink, time to image, and bowel absorption of the beverage (Fig. 1, 2).

In comparison to the previously used commercial product (Table 4), radiologists reported 87 patients or 91% had improved or comparable bowel distention: 26 patients or 27% had improved bowel distention, 61 patients or 64% had comparable bowel distention, and 9 patients or 9% had reduced bowel distention. In the 96 patients who drank Breeza for neutral, radiologists reported bowel distention as acceptable for 100% of both CTE and MRE exams. A direct comparison was not made to water; however, water is rapidly absorbed by the small bowel mucosa and can limit distention in the jejunum and ileum.¹

Lumen Visualization

Breeza® flavored beverage for neutral abdominal/pelvic imaging is an adjunct to IV contrast for both CTE and MRE. In CT, it makes the lumen neutral and homogeneous allowing for visualization of the lumen and mucosa (Fig. 1). In MRI, it follows fluid signal intensity on T1-weighted and T2-weighted images also allowing for visualization of the lumen and mucosa (Fig. 2).

In comparison to the previously used commercial product (Table 4), radiologists reported 93 patients or 97% had improved or comparable lumen visualization: 18 patients or 19% had improved lumen visualization, 75 patients or 78% had comparable lumen visualization, and 3 patients or 3% had reduced lumen visualization. In the 96 patients who drank Breeza for neutral, radiologists reported lumen visualization as acceptable for 100% of both CTE and MRE exams.

Transit Time

Transit time was determined by radiologists based on Breeza for neutral reaching the terminal ileum at the time of imaging (Fig. 1, 2).

In comparison to the previously used commercial product (Table 4), radiologists reported 95 patients or 99% had improved or comparable transit time: 16 patients or 17% had improved transit time, 79 patients or 82% had comparable transit time, and only 1 patient or 1% had reduced transit time. In the 96 patients who drank Breeza® flavored beverage for neutral abdominal/pelvic imaging, radiologists reported transit time as acceptable for 100% of both CTE and MRE exams.

Radiologists described improved transit time as “faster!”, “contrast reached the colon”, and “very fast”, while the one case of reduced transit time was described as “too fast”.

Side Effects Results

Minimizing side effects can save time for the technologist, improve the patient’s experience, and increase satisfaction. Technologists often have to care for patients who have nausea and diarrhea associated with drinking neutral beverages. This can result in extra clean up and delays.

The technologists observed patients for side effects while they were in the department. Of the 96 patients who drank Breeza for neutral (Table 5) 91 or 95% did not experience any side effects.

Reported side effects were feeling of fullness (1), nausea (1), nausea/redness (1), and diarrhea (2).

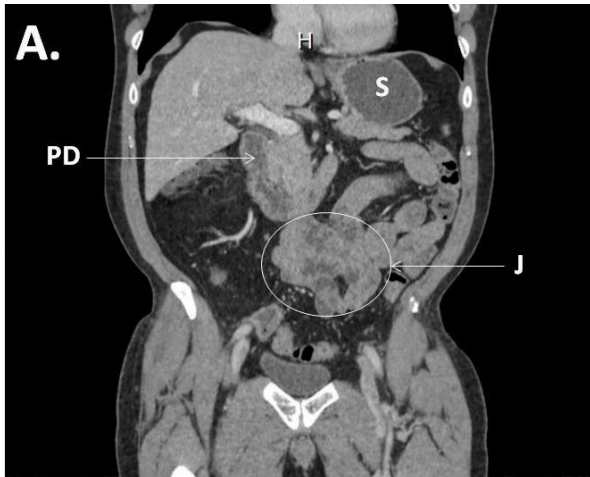
Table 5. Side Effects Results

# of Patients	No Side Effects	Reported Side Effects
96	91 (95%)	5 (5%)

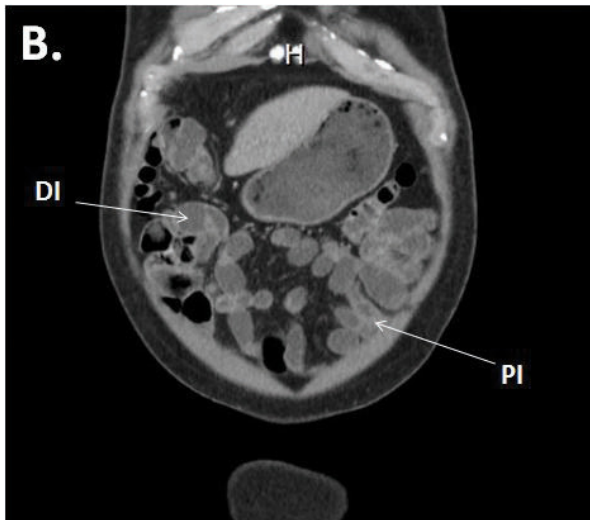
Conclusion

The results of our study strongly indicate that Breeza® flavored beverage for neutral abdominal/pelvic imaging provided superior taste and palatability for patients – increasing drinking compliance and improving patient satisfaction. In addition bowel distention, lumen visualization, and transit time were improved or comparable in the majority of CTE and MRE exams.

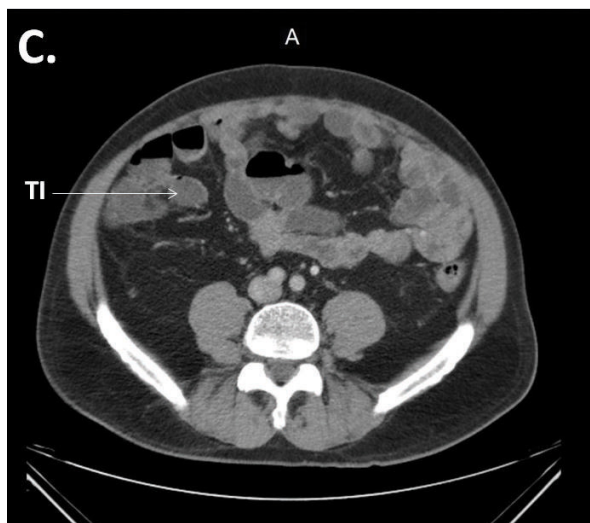
Figure 1. Coronal (A, B) and axial (C) CTE images displaying examples of proximal and distal small bowel distention, lumen visualization, and transit time to the terminal ileum with Breeza® flavored beverage for neutral abdominal/pelvic imaging.



A. Coronal CTE displaying distention of the stomach (S), proximal duodenum (PD), and jejunum (J).

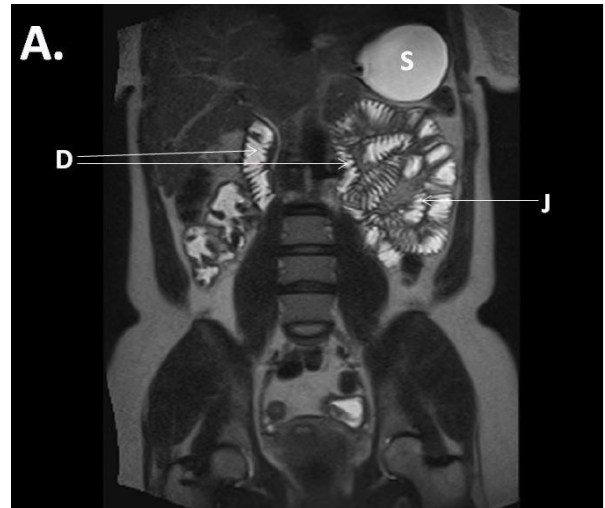


B. Coronal CTE displaying distention of the proximal ileum (PI) and distal ileum (DI).

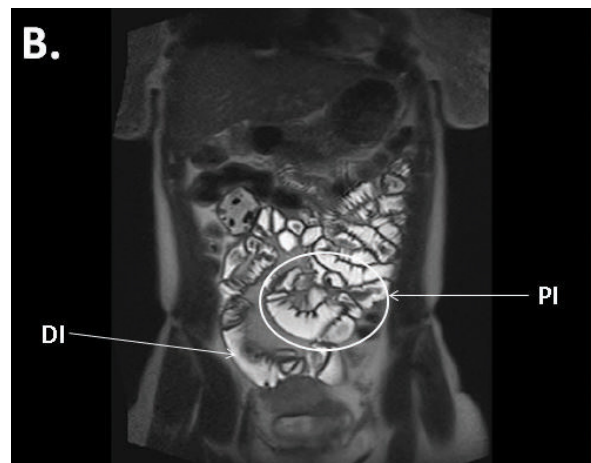


C. Axial CTE displaying distention of the terminal ileum (TI).

Figure 2. Coronal (A, B, C) Single Shot Fast Spin Echo (SSFSE) MRE images displaying examples of proximal and distal small bowel distention, lumen visualization, and transit time to the terminal ileum with Breeza® flavored beverage for neutral abdominal/pelvic imaging.



A. Coronal MRE displaying distention of the stomach (S), duodenum (D), and jejunum (J).



B. Coronal MRE displaying distention of the proximal ileum (PI) and distal ileum (DI).



C. Coronal MRE displaying distention of the terminal ileum (TI).

About the Authors

Michael A. Davis, MD, ScD, MBA is Medical Director and Co-Founder of Regulatory Consultants LTD, St. Augustine, FL and President of Synergy Consulting Group, LTD. providing medical, regulatory and business strategy advice to pharma and medical device industries. His academic career spans 30 years and includes Professorships at Harvard Medical School and University of Massachusetts Medical School.

Allison Ostrout is the Manager for Product Testing and Development in the new products division of Beekley Medical located in Bristol, CT.

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References

- 1 Alec Megibow et al., "Evaluation of Bowel Distention and Bowel Wall Appearance by Using Neutral Oral Contrast Agent for Multi-Detector Row CT," *Radiology*, Vol. 238, No. 1, January 2006, pp. 87-95.
 - 2 Chi Wan Koo et al., "Cost Effectiveness and Patient Tolerance of Low-Attenuation Oral Contrast Material: Milk Versus VoLumen," *American Journal of Roentgenology*, Vol. 190, No. 5, May 2008, pp. 1307-1313.
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