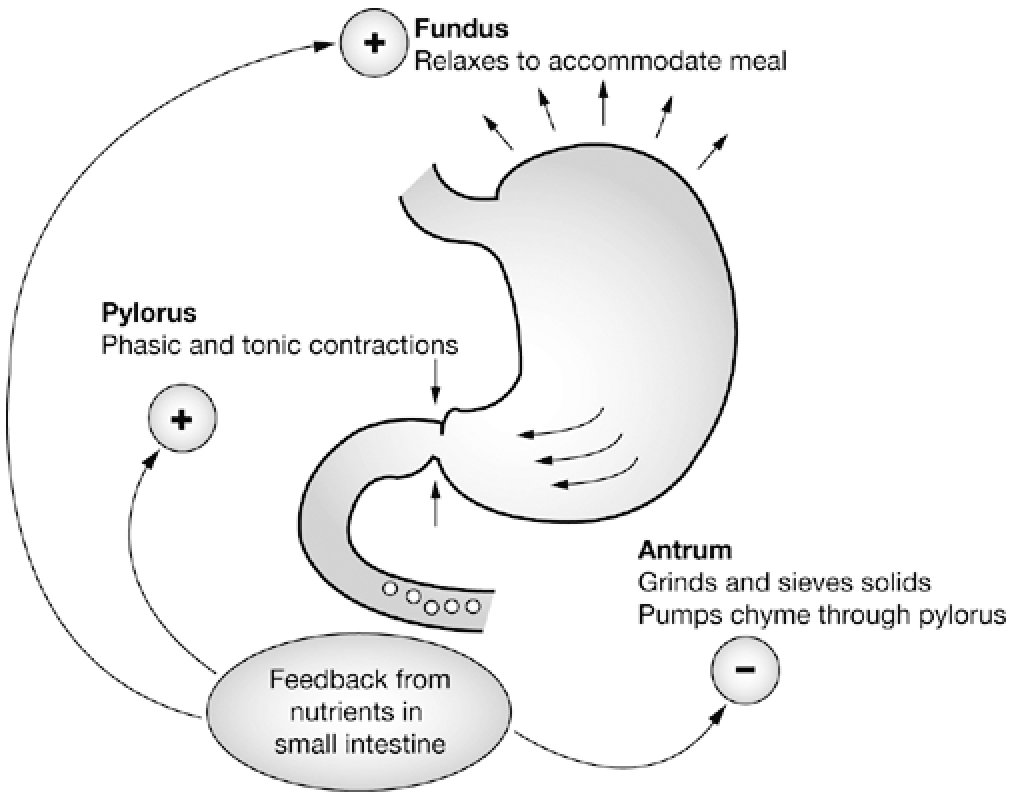
Gastric Motility Studies



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Summary and Explanation

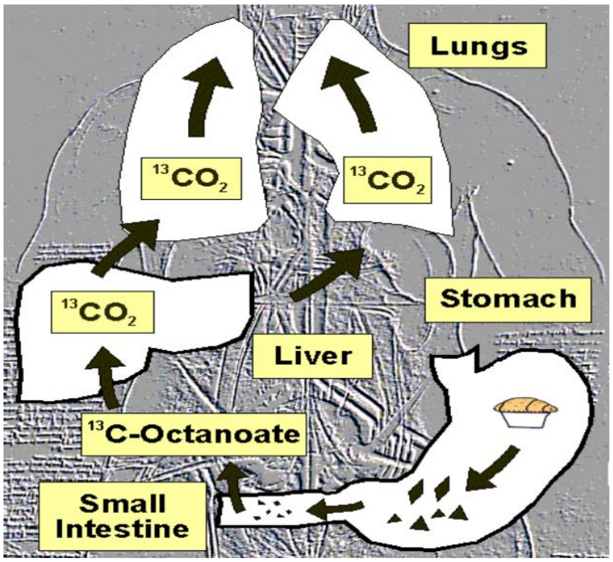
Intended Use

The Gastric Motility Breath Test (GMBT, US patent #6,548,043) uses an **easy to prepare, low-fat muffin meal** along with a simple breath collection system to provide a convenient and reliable means to monitor solid phase gastric emptying. This test is a significant advancement in promoting rapid and successful diagnosis for individuals suffering from motility disorders.

Background

The ^{13}C-octanoate breath test (OBT) has been used by many researchers and has been shown to measure solid phase gastric emptying and correlates with scintigraphic emptying of an egg meal (1). In this test, ^{13}C-octanoate is mixed into an egg and baked into a meal at the clinical site. Gastric emptying is measured indirectly by monitoring the appearance of $^{13}CO_2$ in breath subsequent to ingestion and metabolism of ^{13}C-octanoate. Breath samples are collected at 15 minute intervals over four to six hours. Mathematical analysis of the $^{13}CO_2$ appearance in breath reveals estimates of gastric emptying parameters, including the half-emptying time (T½) and the lag time or time to the maximum rate of gastric emptying (Tlag).

Octanoic acid is a naturally occurring eight-carbon fatty acid typically found in butter as an ester. Generally, this and other medium chain fatty acids (MCFAs) are efficiently absorbed by the small intestine and rapidly transported to the liver bound to serum albumin. In the liver, MCFAs freely enter the mitochondria where they are efficiently oxidized to CO_2 that is then excreted in the lungs. This process is depicted in the diagram below.



The metabolic processing of octanoate is rapid and reproducible, thus delays in emptying are due to differences in gastric motility. Exhaled $^{13}CO_2$ is collected at regular intervals using a breath collection device.

Widespread use of the OBT has not occurred because it is **not clinically practical** due to the inconvenience and lack of uniformity of cooking the egg-based test meal.

Advantages of the Gastric Motility Breath Test

Although scintigraphy is the gold standard for evaluating gastric emptying, there are significant limitations with scintigraphy that prevent its frequent use. A scintigraphic examination is expensive; requires access to expensive equipment and highly trained personnel; and exposes patients to ionizing radiation. In addition, due to the nature of the test procedure, the instrument is only capable of performing a few scintigraphies per day. As a result, scintigraphy is impractical for monitoring the course of treatment and is not an attractive diagnostic option.

The GMBT has several advantages over scintigraphy:

- no radioactivity;
- the test can be administered at any location;
- only limited medical training is required to administer the test;
- lower cost;
- it can be repeated as necessary to monitor treatment; and
- the results are operator independent and will not vary among locations.

Although the principle of the GMBT is biochemically similar to the Octanoic Breath Test described by Ghoos (1), it improves upon the original concept because it replaces the egg meal with a standardized, easy to prepare muffin meal. For the egg-based tests, the yolk and egg white are first separated because the tracer is only readily solubilized in the yolk. The octanoic tracer is added to the yolk, which is then beaten. The egg white is added back and again beaten, followed by cooking by stove top/burner.

In comparison, the GMBT requires just the addition of water to the powered mix, a stir of the contents, and microwaving for 1-2 minutes.

The GMBT has several advantages over the Octanoate Breath Test with egg-based meals:

- standardization of the meal (eggs vary in caloric content, size and composition)
- ease of preparation
- is operator independent
- standardized cooking conditions allow valid inter-clinical site comparisons

GMBT Meal Description

General Information

The standardized meal in the GMBT is a muffin. Muffins are made by adding water and isotope to dry powder ingredients. After mixing the ingredients in the supplied cooking bowl, the ingredients are baked for 2 minutes in a microwave oven. The muffin is made from the combination of two commercially available products. There are no safety concerns with the ingredients. The ingredients of the muffin are kosher certified.

Specifications

Serving Size: 1 muffin (90 gram dry ingredients)

Calories: 350

Total Fat: 7 g — % calories from fat: 17%
- Saturated Fat: 2 g
- Polyunsaturated Fat: 1 g
- Monounsaturated Fat: 2 g
- Cholesterol: 0 g

Total Carbohydrate: 64 g — % calories from carbohydrates: 73%
- Fiber: 3 g
- Sugars: 21 g

Total Protein: 9 g — % calories from protein: 10%

Sodium: 825 mg

Ingredients

Enriched flour (wheat flour, malted barley flour, niacin, iron, thiamin mononitrate, riboflavin, folic acid), yellow corn flour, whole wheat flour, sugar, leavening (baking soda, sodium aluminum phosphate, monocalcium phoshate, aluminum sulfate), vegetable shortening (contains partially hydrogenated soybean and/or cottonseed oil), oat bran, rolled oats, calcium carbonate, nonfat milk, buttermilk, molasses, corn syrup, salt, egg white, dextrose, defatted soy flour, soy lecithin, emulsifier (propylene glycol monoester, monodiglycerides, sodium stearoyl lactylate), whey, food starch modified, extract of malted barley, natural and artificial flavors, spice.

Allergy Information

This product contains wheat, egg, soy and milk. It is made on equipment that also makes products containing tree nuts.

GMBT Reports and Interpretation

The laboratory of Metabolic Solutions uses a gas isotope ratio mass spectrometer to analyze the ratio of breath $^{13}CO_2/^{12}CO_2$. The ratio is reported as the delta per mil versus the international standard Pee Dee Belemnite (PDB) limestone. **Delta per mil** is the relative difference in the $^{13}C/^{12}C$ ratio in the sample and the standard: $\delta = ((R_{samp}/R_{std}) - 1) \times 1000$.

Calculations

The percent dose per hour (%Dose/h) is calculated for all time points. The total CO_2 production is estimated as 5 mmol/min/body surface area (m^2).

- Calculation of atom % C13 from delta per mil of sample

  Atom%C13 = ((Delta C13/1000)+1)/((1/0.0112372)+(Delta C13/1000)+1)* 100%

- Calculation of Atom Percent Excess (APE) from Baseline (time 0) Sample

  $APE_{timeX} = Atom\%C13_{timeX} - Atom\%C13_{time0}$

- Calculation of %Dose/h at each time point

  $$\%Dose/h = ((APE_{timeX}/100)*CO_2\ Prod)/(((Atom\%C13_{dose} - Atom\%C13_{time0})/100)*(Dose_{wt}/MW_{dose}))*100\%$$

  where $Atom\%C13_{dose} = {}^{13}C$ enrichment of octanoate dose (usually 99%)

  CO_2 Prod = BSA(m^2) * 5 mmol/min/m^2 * 60 min/h

  BSA(m^2) = body surface area = $\sqrt{\frac{wt * ht}{3600}}$

  Wt = weight in kilograms

  Ht = height in centimeters

  $Dose_{wt}$ = weight in milligrams of octanoate dose (usually 100)

  MW_{dose} = molecular weight of sodium 1-^{13}C-octanoate = 167.19

The % dose recovered/hour and cumulative % dose curves are modeled according to the method of Ghoos[1]. The final results are T½ (minutes) and Tlag (minutes) are calculated from the Ghoos data model.

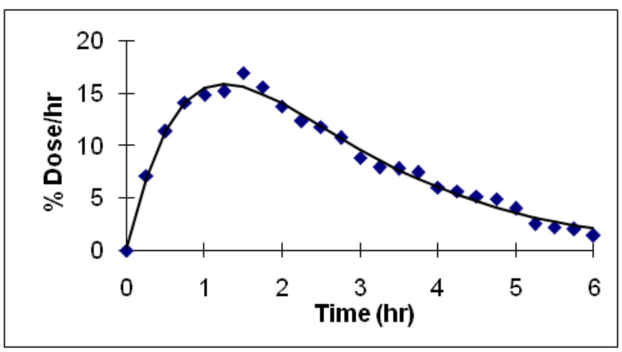
[1]Ghoos YF, Maes BD, Geypens BJ, Mys G, Hiele MI, Rutgeerts PJ, Vantrappen G: Measurement of gastric emptying rate of solids by means of a carbon labeled octanoic acid breath test. Gastroenterology 104:1640-1647, 1993

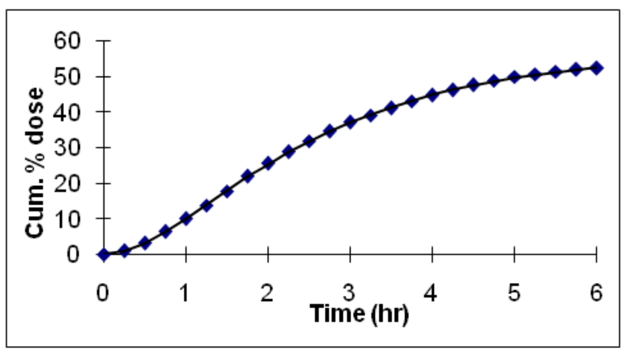
A copy of a standard 6-hour GMBT report is shown on the next page:

GMBT Report

Study #	XXXXXX	**Test Date**	14-Oct-09	**MSI Job #**	08-0299
Site #	10	**Height (cm)**	174	**GMBT #**	1234
Investigator	Jones	**Weight (kg)**	93.1		
Visit	Baseline	**Meal Start Time**	10:45		
Pt Scn #/Initials	101 JEK	**Meal End Time**	10:55		
Pt #	207	**% Meal Consumed**	≥ 90%		

Sample ID	Collection Time	Delta C13	Elapsed Time (hr)	Atom % C13	APE C13	% Dose/h	Cum. % D
1	10:40	-23.42	0.00	1.0855	0.0002	0	0
2	10:45	-23.74	0.00	1.0851	-0.0002	0	0
3	11:10	-18.17	0.25	1.0913	0.0059	7.14	0.89
4	11:25	-14.96	0.50	1.0948	0.0095	11.38	3.21
5	11:40	-12.86	0.75	1.0971	0.0118	14.15	6.40
6	11:55	-12.30	1.00	1.0977	0.0124	14.89	10.03
7	12:10	-12.06	1.25	1.0980	0.0127	15.21	13.79
8	12:25	-10.69	1.50	1.0995	0.0142	17.01	17.82
9	12:40	-11.73	1.75	1.0983	0.0130	15.64	21.90
10	12:55	-13.14	2.00	1.0968	0.0115	13.78	25.58
11	13:10	-14.19	2.25	1.0956	0.0103	12.39	28.85
12	13:25	-14.60	2.50	1.0952	0.0099	11.85	31.88
13	13:40	-15.40	2.75	1.0943	0.0090	10.80	34.71
14	13:55	-16.85	3.00	1.0927	0.0074	8.88	37.17
15	14:10	-17.58	3.25	1.0919	0.0066	7.92	39.27
16	14:25	-17.65	3.50	1.0918	0.0065	7.83	41.24
17	14:40	-17.95	3.75	1.0915	0.0062	7.43	43.15
18	14:55	-19.02	4.00	1.0903	0.0050	6.02	44.83
19	15:10	-19.30	4.25	1.0900	0.0047	5.65	46.29
20	15:25	-19.65	4.50	1.0896	0.0043	5.19	47.64
21	15:40	-19.86	4.75	1.0894	0.0041	4.91	48.91
22	15:55	-20.53	5.00	1.0887	0.0034	4.03	50.02
23	16:10	-21.67	5.25	1.0874	0.0021	2.52	50.84
24	16:25	-21.89	5.50	1.0872	0.0019	2.23	51.43
25	16:40	-22.03	5.75	1.0870	0.0017	2.05	51.97
26	16:55	-22.52	6.00	1.0865	0.0012	1.40	52.40

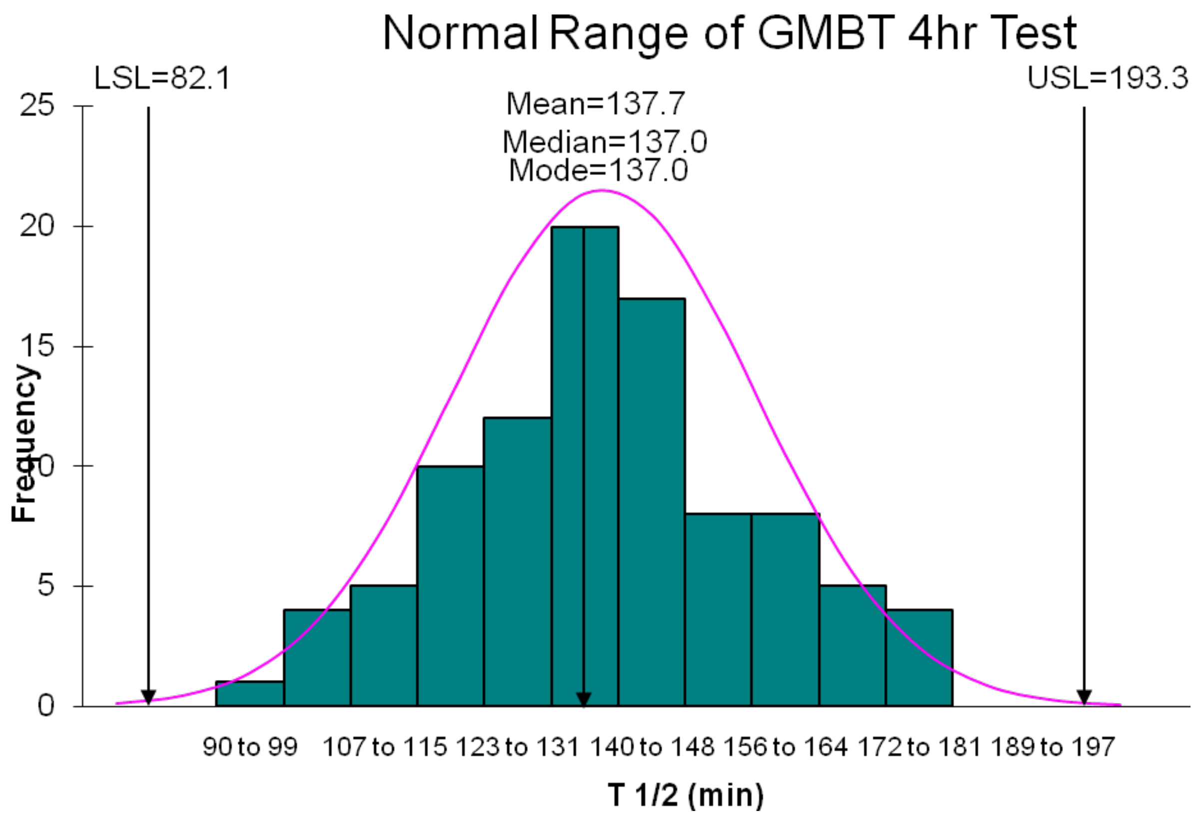




Model	m constant	k constant	beta constant	Curve Fit	T1/2 min	Tlag min
% Dose/hr	56.2910	0.5687	2.0450	0.9857	131.5	75.5
% Cum Dose	56.5020	0.5605	2.0344	0.9999	133.0	76.0
Average					132.3	75.8

Normal Range of the GMBT

One hundred (100) individuals without motility symptoms were administered the 4-hour GMBT to understand the inter-subject variation and normal range of the test. We determined that the normal range (95% confidence interval) for T½ with the GMBT in this population was 82 to 193 minutes. A histogram plot of the results showed a normal distribution for the 4-hour gastric emptying breath test:



LSL = Lower 95% confidence interval; USL = Upper 95% confidence interval

The Anderson-Darling Normality Test had an A squared value of 0.988 (p=0.013). The mean for this population was 66 minutes with a standard deviation of 11 minutes. This mean and standard deviation compares favorably to results reported by Ghoos in 42 normals (mean = 72 and SD = 22). The standard deviation for normal motility measured with the GMBT was about half encountered with the egg-based meal. We attribute this lower variability to the standardization of the GMBT meal and the ease of test administration that minimizes testing protocol deviations and thus improves the reliability of the test.

Further studies by Bromer et al. using the GMBT method to measure gastric emptying have extended the breath measurements to 6 hours (3). The gastric half-times (T½, minutes) for nine healthy subjects confirmed to have normal emptying times by scintigraphy were:

4-hour test T½ (mean ± SD) = 150 ± 25 min. Upper limit of Normal = 199.4 min
6-hour test T½ (mean ± SD) = 138 ± 15 min. Upper limit of Normal = 166.8 min

Validation of the GMBT

a) Binding of Tracer to Muffin

The amount of tracer remaining associated with the muffin meal after incubation in gastric fluid has been determined to be greater than 99%. These in vitro results show that ^{13}C-octanoate is bound to the muffin during microwave cooking and is suitable to trace solid phase gastric emptying.

b) Determination of Meal Size

The test meal must challenge gastric motility. The size of the test meal is important because it determines the ability of the test to differentiate individuals with impaired motility from normals. Electrogastrography (EGG) was employed as an independent measure of gastric motility. EGG records the gastric myoelectrical activity using cutaneous electrodes. The half emptying time (T½) was compared to the EGG postprandial to fasting (P/F) power ratio obtained for two different sized muffins (250 and 350 calories) in the fasting and postprandial states (2).

The results of the EGG analysis showed that the P/F power ratio was significantly higher with the 350 calorie muffin. Secondly, T½ was significantly longer for the 350 calorie meal. Most importantly, the T½ of the 350 calorie meal was significantly correlated with the P/F power ratio for both the 4-hour test ($r=0.67$, $p<0.01$) and 6-hour test ($r=0.68$, $p<0.01$). However, there was no correlation between T½ and the P/F power ratio for the 250 calorie muffin. These results showed that the 350 calorie muffin meal is able to better stimulate gastric motility than the smaller sized meal.

c) Comparison to Scintigraphy

A double-labeled muffin study was conducted to determine how well the GMBT correlated with the "gold standard" gastric emptying scintigraphy (GES) (3). Added to the muffin mix was ^{13}C-octanoate and technetium-99m sulfur colloid. The meal was ingested also with water labeled with indium-111DTPA. Ten (10) normal subjects (6 females, 4 males; age range: 18-54 years) without gastrointestinal symptoms and twenty-three (23) patients (20 females, 3 males; age range 20-72 years) with dyspeptic symptoms of nausea, vomiting, early satiety, upper abdominal pain and/or discomfort, or abdominal bloating underwent simultaneous GES and the GMBT. Scintigraphic images (anterior and posterior) for Tc-99m and In-111 were obtained with a gamma camera immediately following completion of the meal for four hours. Breath samples were collected every 15 minutes for 6 hours for ^{13}C-carbon dioxide analysis.

Each scintigraphic image obtained was analyzed to determine the gastric counts. The gastric region of interest was manually drawn around the total stomach at each time interval. A geometric mean of the gastric counts was used to correct for depth changes [geometric mean counts = square root (anterior counts x posterior counts)]. The counts were corrected for radioisotope decay. The data was expressed as percent of the initial meal remaining in the stomach versus time and fitted to a modified power exponential function. The breath data was expressed as the percent dose exhaled/hour and cumulative percent of the dose over time. Curves fitted to the percent dose/hour and cumulative percent of dose provided constants to calculate the gastric emptying parameters T½ and Tlag according to the method of Ghoos et al. (1).

In normal subjects, the T½ for the GMBT significantly correlated with T½ of solids by GES using the 4-hr GMBT data set ($r=0.863$; $p=0.003$) and the 6-hr GMBT data set ($r=0.664$; $r=0.05$). The GMBT T½ did not correlate with T½ liquids by GES using either the 4-hr GMBT data set ($r=0.085$; $p=0.83$) or the 6-hr GMBT data set ($r=0.13$; $P=0.74$). In dyspeptic patients, the GMBT also significantly correlated with the GES T½ solids by GES using the 6-hr GMBT data set ($r=0.86$; $p<0.001$) and the 4-hr GMBT data set ($r=0.86$; $P<0.001$). Combining the data from normal and dyspeptic patients, there was a significant correlation of the GMBT with GES T½ solids ($r=0.86$; $p<0.001$), regardless of whether the 4-hr or 6-hr GMBT data were used. Using the upper limit of normal (95% confidence interval), delayed gastric emptying was identified in 7 of 33 subjects by scintigraphy. The sensitivity and specificity of the GMBT for both the 4-hr and the 6-hr breath test to identify delayed gastric emptying were 86% and 94%, respectively.

In conclusion, we found a significant correlation between the GMBT, using an easily prepared muffin meal and GES of solids. We further showed a strong correlation between the half emptying times of GES with both the muffin meal and the standard egg meal used for scintigraphic gastric emptying studies suggesting that the simple muffin meal is a valid substitute for the egg meal to measure gastric emptying.

d) Pharmacological Modulation

Pharmacological modulation of gastric emptying to validate the GMBT has been performed. Two drugs with a known influence on gastrointestinal motor activity were used, erythromycin, which accelerates, and propantheline, which delays gastric emptying. Forty (40) volunteers were administered a GMBT test to determine T½ rates. Volunteers were randomly selected to receive 200 mg erythromycin intravenously or 30 mg propantheline orally, just prior to the GMBT. Erythromycin caused a significant shortening of both the gastric half-emptying time and lag phase. Propantheline, an anticholinergic drug, significantly delayed gastric half-emptying time and lag phase. These results demonstrate that the GMBT can accurately predict stimulation or delay of modulated gastric emptying by drugs. The results of pharmacological modulation of gastric emptying studies are presented below:

Effect of Erythromycin on T½ times in 20 subjects

Treatment	**T½ (mean ± SD)**	**Change from Control (mean ± SD)**
Control	**133 ± 23 minutes**	
Erythromycin	**101 ± 18[a] minutes**	**-23 ± 14%**

[a] significantly different $p<0.0001$

Effect of Propantheline on T½ times in 20 subjects

Treatment	T½ (mean ± SD)	Change from Control (mean ± SD)
Control	**155 ± 41 minutes**	
Propantheline	**191 ± 76[b] minutes**	**23 ± 31%**

[b] significantly different p=0.0072

e) Conclusions

These results show a significant correlation between the GMBT and GES for solids using an easily prepared, low-fat, standardized muffin meal. Furthermore, the GMBT is both a sensitive and specific method to detect delayed gastric emptying in dyspeptic patients. The GMBT has also demonstrated an ability to accurately predict stimulation or delay of gastric emptying modulated by drugs. The performance of this test, combined with the significantly decreased cost, decreased test and personnel time, and simpler and more efficient instrumentation requirements, make the GMBT a very attractive new methodology for assessing gastric motility disorders both in the pharmaceutical industry and ultimately in routine clinical practice.

f) References

1. Ghoos, Y. F., B. D. Maes, B. Geypens, G. Mys, M. I. Hiele, P. J. Rutgeerts and G. Vantrappen. Gastroenterology 1993; 104: 1640-1647.
2. Gonlachanvit, S., W.D. Chey, K.J. Goodman and H.P. Parkman. Dig. Dis. Sci. 2001; 46:2643-2650.
3. Bromer, M.Q., S.B. Kantor, D.A. Wagner, L.C. Knight, A.H. Mauer and H.P. Parkman. Dig. Dis. Sci. 2002; 47:1657-1663.

Patient Instructions for the Gastric Motility Breath Test

A breath test will be used to see how fast your stomach empties a solid meal   Each test will begin in the morning and last approximately 4 hours. To perform the test, you will be required to eat a low-fat muffin and drink 150 mL (5 ounces) of water. Breath samples will be collected by the study nurse or doctor twice before the meal and every 15 minutes for 4 hours after the meal.

Preparation

Before the test is performed, you must not eat anything for at least 10 hours. During this 10-hour period of not eating, you may only drink non-carbonated water, as needed.

Muffin Meal

The muffin meal contains wheat, egg, soy and milk. It is made on equipment that also makes products containing tree nuts. You should not take the test if you have allergies to these ingredients.

Testing

The test will begin in the morning, approximately 1 hour after you arrive at the clinic. After you arrive at the clinic, you must not smoke or eat anything except the muffin meal until after the 6-hour test is completed. You will drink 150 mL (5 ounces) of water with the muffin meal, and the entire muffin must be eaten in 15 minutes or less. You may not drink anything for the first 2 hours after eating the muffin meal, but may drink up to 50 mL (2 ounces) of water each hour during the final four hours of the test.

You must remain in a semi-reclined or seated position during the full duration of the test. If necessary, limited movement between breath collections will be allowed.

Breath samples will be collected by the study nurse or doctor two times before the meal and every 15 minutes for 4 hours after the meal. For each breath collection, you will first be asked to take a full breath (inhale) through your mouth. A straw will then be placed in your mouth, and you will be asked to breathe out (exhale) the full breath through the straw and into a tube. Just before you finish exhaling, the study nurse or doctor will remove the tube away from the bottom of the straw and then place a cap on the tube. A total of 18 breath samples will be collected during the 4-hour test.

Procedure for Conducting the GMBT

Step 1: Verify Contents Of Kit

The contents of each breath test kit should be confirmed using the checklist below:

Item	**Quantity**
Sodium 1-^{13}C-octanote (100 mg) in glass vial……	1
Test meal mix………………..................................	1
Cooking bowl ……………………………….…….	1
Spoon……….................................………………	1
Fork………................................…………………	1
Breath collection tubes……………………………	26
Straw………………………………………………	1
Gastric Motility Breath Test form……………...….	1

Step 2: Components Not Included With This Kit

- Microwave 900 watts (Adjust baking times for microwaves with different power)

Step 3: Fill out the Gastric Emptying Test Form

Fill out the top portion of the Gastric Emptying Test Form.

Step 4: Preparation of Test Meal

1. The muffin meal may be prepared within 24 hours of administration. If the muffin meal is **not** prepared within 30 minutes before giving to the patient, store the muffin meal in a refrigerator (2-8 °C). Place the mixing bowel top in place to seal muffin meal.

2. Prepare the meal with drinkable water that is not heated. The water should be kept at room temperature.

3. Pour out the sodium 1-^{13}C-octanoate powder into the graduated container.

4. Fill the ^{13}C-octanoate glass container almost to the top (3/4 full) with drinkable water. Add cap and shake for 10 seconds. If some of the water spilled (<10%) from the container, it is **not** detrimental to the test.

5. Pour the water into the graduated container.

6. Close graduated container top and shake for 30-60 seconds to dissolve the isotope in the water. If some octanoate has not dissolved after 60 seconds, add 20-30 ml drinkable water. Shake container for another 30-60 seconds until the octanoate is fully dissolved. If some of the water spilled (<10%) from the container, it is **not** detrimental to the test.

7. Fill graduated container with enough drinkable water to make a final volume of 80 ml.

8. Close graduated container and mix for a few seconds. If some of the water spilled (<10%) from the container, it is **not** detrimental to the test.

9. Open the vacuum-sealed bag and remove the top on the microwave bowl containing the dry muffin powder.

10. Add contents of graduated container to dry powder in bowl.

11. Mix ingredients thoroughly (60 seconds) with the spoon.

If the ingredients are well mixed, it should look like the picture below:

Get as much of the mix off of the spoon as possible. However, some mix still will stick to the spoon but this is fine.

12. **KEEP THE LID OFF THE BOWL WHEN COOKING**.

Microwave ingredients in bowl for 2 minutes using a 900-watt power microwave on full power. For microwaves of different power add or reduce baking time by 30 seconds. If the muffin is baked too long, it will not affect test components, but patients may find the muffin is too dry. If the muffin is baked too little, it will appear loose. Bake muffin until the consistency is firm. **It is better to overcook the muffin than undercook it because this is a test for solid phase emptying.**

13. Allow muffin to cool to room temperature before administering to the patient. Eat the muffin with a fork.

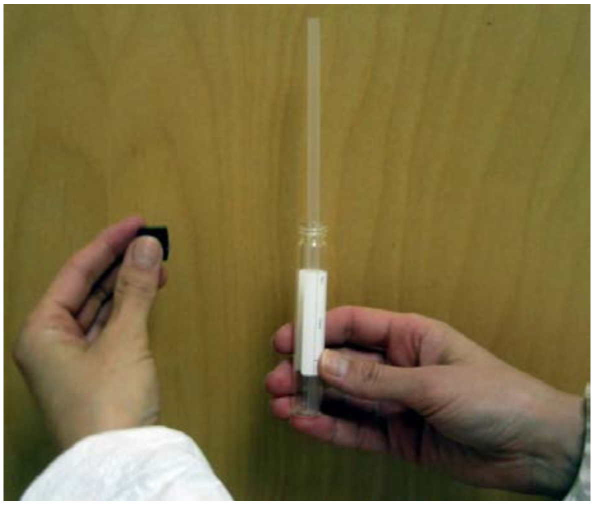
The meal is finished when the entire muffin is eaten as shown below:

Step 5: Collecting Breath Samples

The process of collecting breath samples begins **prior** to consumption of the muffin meal. During the test, patients should remain seated or reclined in a comfortable position. If movement is necessary, keep it relaxed and to a minimum. **Collect two (2) baseline breath samples as follows:**

1. Remove the cap of the Exetainer tube.

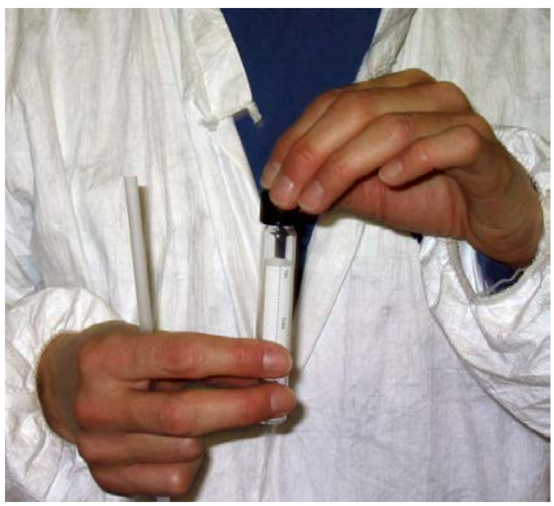
2. A straw is placed at the bottom of the Exetainer tube.



3. Place the straw in the patient's mouth with the Exetainer tube at the end of the straw. Have the patient breath normally into the straw. The patient should take a full breath from the lungs (not through the nose but out the mouth) and the entire breath exhaled into the tube via the straw.

4. Before the exhalation is complete, a research assistant withdraws the Exetainer away from the straw.

5. The blue cap is screwed on immediately so that it is "finger-tight".



The breath remains in the tube for at least 5 seconds while placing the cap on the tube. If the assistant drops the cap or delays closing the tube while collecting the breath sample, just repeat the breath collection.

6. **DO NOT OVERTIGHTEN THE EXETAINER CAP.**

7. Record the exact time of each breath collection on the Gastric Emptying Test Form.

Step 6: Administration of the Test Meal.

The breath test should be administered early in the morning. All tests should be given at approximately the same time for consistency. Prior to the testing, patients must fast for at least 10 hours. No food items may be consumed during this time. The only acceptable liquid is drinking water (non-carbonated drinking water). Record the start time of meal consumption on the Gastric Emptying Test Form. Have the patient consume the entire test meal within **10 ± 5 minutes**. **The patient must drink 150 ml of non-carbonated water with the meal**. The patient will be allowed no food or water for the first 2 hours after eating the test meal. Patients may consume 50 ml non-carbonated water per hour after 2 hours if they become thirsty during the final 4 hours of the test.

Record the test meal start time and stop time on the Gastric Emptying Test Form. Also record whether or not the patient consumed at least 90% of the test meal and, if not, the approximate amount (%) consumed. If the patient consumes < 75% of the test meal or the patient vomits within 4 hours of completing the test meal, the test should be terminated as a failed test.

Step 7: Continuation of Breath Collections after Meal

Collect breath samples after consumption of the test meal using the procedure outlined in Step 6 above. The actual time of each breath collection should be recorded on the Gastric Emptying Test Form as shown on the next page. **Record only the exact time of breath collection on the Gastric Emptying Test Form. Results are calculated based on actual time of breath collections, not theoretical times.**

Collect breath samples every 15 minutes for 6 hours. In the event of any delay in collecting a given scheduled sample, it is important to still collect that sample and all 24 samples and record all actual collection times following the administration of the meal.

Study XXXXXXXXX
Gastric Motility Breath Test Form

Study Site Number: ☐☐ Principal Investigator:___________________________

GMBT Number: ☐☐☐☐

Pt. Screening Number: ☐☐☐ Pt. Initials: ☐☐☐ Pt. Number: ☐☐☐

Date of Breath Collections: ☐☐-☐☐☐-☐☐☐☐ (ex. 12-Dec-2004)

Patient Height (cm): ☐☐☐ Patient Weight (kg): ☐☐☐.☐ (Required for Results)

Test Meal Start Time (24-hr clock): ☐☐:☐☐ Test meal stop time: ☐☐:☐☐

Was ≥ 90% of the Test Meal Consumed? ☐Yes ☐No→approximate amount consumed: ☐☐%

Tube Number	Sample Time Relative to Completion of Test Meal (min)	Actual Time Collected (24hr)	Comments
1	-10		
2	-5		
3	15		
4	30		
5	45		
6	60		
7	75		
8	90		
9	105		
10	120		
11	135		
12	150		
13	165		
14	180		
15	195		
16	210		
17	225		
18	240		

For Laboratory Use Only:

Date Received at Lab:_____________ Received by:_______________

Storage Conditions for Test Kits and Breath Samples

Shelf Life and Storage

The Gastric Motility Breath Test kit should be stored at 15º-30ºC (59º-86ºF). The contents of the kit have an expiration date listed on the kit label. Do not use beyond the expiration date stated on the label.

Specimen Storage

Store the breath test specimens at 15º-30ºC (59º-86ºF) until shipment. Send the samples to Metabolic Solutions within three (3) days after the breath samples are collected.