

Consensus Recommendations for Gastric Emptying Scintigraphy

A Joint Report of The Society of Nuclear Medicine and The American Neurogastroenterology and Motility Society*

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ABSTRACT

This consensus statement from members of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine recommends a standardized method for measuring gastric emptying by scintigraphy (GES). A low-fat, egg white meal with imaging at 0, 1, 2, 4 hours after meal ingestion, as described by a published multicenter protocol, provides standardized information about normal and delayed gastric emptying. Adoption of this standardized protocol will resolve the lack of uniformity of testing, add reliability and credibility to the results, and improve the clinical utility of the gastric emptying test.

INTRODUCTION

Gastric emptying scintigraphy (GES) is commonly performed to evaluate patients with symptoms that suggest an alteration of gastric emptying and/or motility (1Maurer 2006). The first use of radionuclides to measure gastric emptying was published in 1966 (2Griffith 1966). Since then, it has become the standard for the measurement of gastric motility in clinical practice because it provides a physiologic, noninvasive, quantitative measurement of solid or liquid gastric emptying (3Camilleri 1998).

While GES has been considered the standard for measuring gastric emptying, there is a lack of standardization of the test, including differences in meals used, patient positioning, frequency, and duration of imaging. There are differences in the quantitative data reported, e.g., half-time of emptying, rate of emptying (per cent per minute), or the percent retention or emptying at different time points during the study. Normal values often have not been established for some of the protocols used, and the performance characteristics of the test with the specified meal may not have been established or published.

Lack of standardization limits the clinical utility of the test, and presents problems for patients and their physicians as the latter try to interpret study results from other institutions. This often leads to repeat testing using a different protocol with which the gastroenterologist has greater familiarity and confidence. This practice presents problems for the patient as insurance companies may not reimburse a second test, or may require the patient undergo the test at a center where the protocol is suboptimal. Discrepant results between two studies can further complicate patient management.

Several professional societies (Society of Nuclear Medicine [SNM], American Gastroenterological Association [AGA], and the American Neurogastroenterology and Motility Society [ANMS]) have developed guidelines for performing GES (4Parkman 2004, 5Donohoe1999, 6Donohoe2004, 7Lin 2005). However, there has not been a consensus on a protocol that meets both the clinicians' needs and the services available at most nuclear medicine facilities. For GES to attain its full clinical potential there is a need for closer collaboration between nuclear medicine physicians and referring gastroenterologists to develop such a consensus protocol

This manuscript provides consensus guidelines from members of the ANMS and the SNM. Our goal was to propose a *single, standardized* protocol for performing GES that meets the needs of clinicians, imaging specialists, and patients.

The process leading to this joint report involved three meetings. At the first meeting (Philadelphia, April 2006), the participants focused on the needs of the patient and the referring physician, reviewed current methods considered best practice for performing GES, and addressed unresolved areas requiring further research or clarification. At the second meeting at the Society of Nuclear Medicine annual meeting (San Diego, June 2006), there were presentations and discussion of the same topics which led to the drafting of a manuscript summarizing a consensus protocol. At a third meeting at the ANMS annual meeting (Boston, September 2006), a consensus protocol was discussed and critiqued. This was followed by final discussions and revisions to this manuscript.

This manuscript represents this group's current recommendation on how to perform a solid-meal GES test for clinical practice, using readily available technology and normative data which can provide clinicians with standardized results. Throughout this process, we have recognized that the current consensus may not imply unanimity of opinion. In addition, this document does not answer all the questions raised during these discussions.

However, this manuscript addresses those aspects that the multidisciplinary group consider were in the greatest need of immediate standardization – the meal, the frequency of imaging, the duration of the test, and normative data. Technical issues concerning the acquisition and processing parameters are less controversial and do not contribute to wide variations in methodology. These have been addressed elsewhere (5Donohoe 1999, 6Donohoe 2004) and are

summarized in Appendix 1. The manuscript also identifies areas for future study, but there was overwhelming consensus on the pressing need to recommend a standardized GES test.

DISORDERS OF GASTRIC EMPTYING

Both rapid and delayed gastric emptying can cause similar symptoms. Hence, it is important to evaluate patients for both rapid and delayed gastric emptying in the same test. It is therefore appropriate to review some of the relevant clinical information on symptoms related to disorders of gastric emptying.

Delayed Gastric Emptying

Gastroparesis is diagnosed when symptoms such as nausea, vomiting, early satiety, postprandial fullness, abdominal discomfort and pain are associated with objective evidence of delayed gastric emptying in the absence of obstruction and typically with impairment in maintenance of normal nutrition using standard food (4Parkman 2004, 8Soykan 1998). These symptoms are also reported by some individuals with the postprandial distress subtype of functional dyspepsia (9Tack 2006). Symptoms that suggest delayed gastric emptying in patients with dyspepsia are primarily postprandial fullness, nausea and vomiting (10Stanghellini 1996, 11Sarnelli 2003). In patients with diabetes, symptoms that have been associated with delayed gastric emptying are abdominal bloating/fullness and upper abdominal pain (12Jones 2001, 13Samson 2003). Some studies, however, have shown a poor correlation between the rate of solid gastric emptying and the severity of gastric symptoms (12Jones 2001, 13Samsom 2003, 14Horowitz 1991). Furthermore, some clinical trials of drug therapy for gastroparesis show variable symptomatic benefit from pharmacologic stimulation of gastric emptying (15Snape 1982, 16Patterson 1999). In addition, some patients symptoms improve with prokinetic agents but gastric emptying remains unchanged (16Patterson 1999). Investigations are attempting to determine if factors other than a global delay in gastric emptying such as impaired fundic accommodation, antral distension, antral hypomotility, gastric dysrhythmias, visceral hypersensitivity, or psychological disturbances explain, in part, the symptoms experienced by patients with suspected gastroparesis (1Maurer 2006).

Symptoms of gastroparesis may be quantified by a validated symptom questionnaire, the Gastroparesis Cardinal Symptom Index (GCSI) (17Revicki 2003, 18Revicki 2004). The GCSI is

based on three subscales (postprandial fullness/early satiety, nausea/vomiting, and bloating) and represents a subset of the longer Patient Assessment of Upper Gastrointestinal Disorders-Symptoms (PAGI-SYM) that quantifies symptoms of gastroparesis, dyspepsia, and gastroesophageal reflux disease (19Revicki 2004).

Rapid Gastric Emptying

Rapid gastric emptying is the major factor in dumping syndrome, characteristically seen after surgery for peptic ulcer disease with and without vagotomy (20Hasler, 21Eagon). The early symptoms of “dumping” occurring in the initial hour after meal ingestion include diarrhea, abdominal discomfort, nausea, bloating, and vasomotor symptoms. Some of these symptoms may be difficult to distinguish from gastroparesis symptoms. The late dumping syndrome presents with diaphoresis, palpitations, weakness, and fainting which are secondary to reactive hypoglycemia from exaggerated insulin release.

Rapid gastric emptying of solids has been demonstrated in some patients with unexplained nausea, vomiting, bloating, and fullness (22Lin 1999). Rapid GE has recently been reported in some patients with functional dyspepsia (23Delgado 2004). Rapid gastric emptying also occurs in some diabetic patients, particularly in the early stages of Type II diabetics (24Schwartz 1996). Many of these patients have symptoms indistinguishable from those of gastroparesis. Rapid movement of food from the stomach into the small bowel with small bowel distension may explain pain and nausea, symptoms similar to those described in patients with delayed gastric emptying. Rapid emptying has been recently observed as an accompanying factor in adult patients with cyclic vomiting syndrome (25Namin 2006, 26Fajardo 2005). In one study, rapid gastric emptying was more common than delayed GE in symptomatic patients with autonomic dysfunction (27Lawal 2006).

FACTORS TO CONSIDER IN THE MEASUREMENT OF GASTRIC EMPTYING

Measurements of gastric emptying are influenced by a variety of factors which must be considered when performing GES (28Christian 1983). Factors that may influence the performance and negatively influence the clinical validity of a GES are: 1) short duration of testing; 2) extrapolated t-1/2 measurements; 3) unknown meal composition and amount

consumed; 4) medications at the time of the test; 5) poor or unknown glycemic control at the time of the test; and 6) vomiting a portion of the meal.

Patient-Related Factors to be considered for Gastric Emptying Tests

Patient-related factors that need to be considered in gastric emptying tests include medications, tobacco smoking, hyperglycemia, and gender (1Maurer 2006, 3Camilleri 1998).

Patients may be taking medications to intentionally affect gastric emptying (e.g., prokinetic agents) or medications that alter emptying as a side effect (e.g., narcotic analgesics). Depending on the reason for the test, patients may need to discontinue these medications. The period of time off medication before the test should be based on the drug half-life; for most medications, this will be 48-72 hours (3Camilleri 1998). Opiate analgesic medications and anticholinergic agents delay gastric emptying and, if not discontinued prior to the study, could result in a false diagnosis of delayed gastric emptying. Prokinetics may lead to a normal gastric emptying result in a patient with gastroparesis. Serotonin receptor (5-HT-3) antagonists, such as ondansetron, which have little effect on gastric emptying, may be given for severe symptoms of nausea and vomiting before performance of GES (29Nielson 1990).

Tobacco smoking has been shown in early studies to slow gastric emptying (30Nowak 1987, 31Miller 1989). This effect may not be related to nicotine (31Miller 1989, 32Wong 1999). Recent studies with ¹³C-octanoic breath testing, however, have shown conflicting results (33Sanaka 2005). It is recommended that patients abstain from smoking the morning of the test and throughout time gastric emptying is being imaged.

Hyperglycemia can delay gastric emptying. Although some data suggest that even modest degrees of hyperglycemia (≥ 144 mg/dl) retards gastric emptying (34Schvarcz 1997), it is not clear what level produces clinically significant delay in gastric emptying (35Horowitz 2002). Marked hyperglycemia with serum glucose levels ≥ 288 mg/dL significantly delays gastric emptying in diabetic patients when compared to euglycemia (36Fraser 1990). The general consensus is that blood glucose should be under reasonable control on the day of a GES to obtain a reliable measurement of gastric emptying. For diabetics, it is recommended that serum glucose be measured prior to the study, noted in the report, and if the blood glucose is greater than 275 mg/dl on the morning of the test, the glucose should be lowered with insulin to <275 mg/dl, or the study should be rescheduled for another day when the blood glucose is under better control.

Some centers administer insulin if the blood glucose level immediately before GES is >180 mg/dl and do not start the test until the glucose is less than 180 mg/dl (Horowitz personal communication).

Pre-menopausal women are reported in some studies to have slower gastric emptying than men (37Datz 1987, 38Gill 1987). A few centers use separate reference values for pre-menopausal women (10Stanghellini 1996) or limit testing to the first week of the menstrual cycle before estrogen and progesterone peak. The latter approach is suggested since separate values are not generally available for men and women. The four hour test of Tougas et al recommended in these guidelines did not show variability attributable to menstrual phase and gender (39Tougas 2001). A study of postmenopausal women administered estrogen or progesterone or combination to mimic normal hormone levels in pre-menopausal women did not demonstrate any effect of these sex hormones on gastric emptying (40Gonene 2006).

Technical Factors in Gastric Emptying Tests

There are many reasons for the current diversity of imaging and analysis of GES protocols: an individual center's meal and analysis preferences, different camera and computer systems, scheduling constraints, and processing software.

Meals currently used for measuring gastric emptying consist of a variety of foods, including chicken liver, eggs, egg whites, oatmeal, or pancakes. The content of the meal used is one of the most important variables needing standardization since gastric emptying depends on meal composition. Solids empty more slowly than liquids and digestible solids emptying more rapidly than indigestible residue (1Maurer 2006). Additionally, emptying of fats is slow compared to emptying of proteins or carbohydrates. The caloric content and volume of the test meal will also alter gastric emptying. Incomplete meal ingestion can lead to values suggesting more rapid emptying. Vomiting a portion of the ingested meal after the initial baseline image may lead to lower subsequent estimated gastric retention values, so that gastric emptying appears faster than it was.

Reported values of gastric emptying are influenced by the duration of testing and the method of analysis. Half times ($T-1/2$ values) of emptying may be potentially less accurate than percentages of retention measured at fixed time points, particularly in individuals with very prolonged emptying in which extrapolation is needed to calculate the half time if it was not

actually reached during the test. Surveys of nuclear medicine centers show wide variations in reporting rates of emptying. In a study of Canadian health care facilities, 40% of centers did not validate a normal range for their gastric emptying test meal and the range of normal values varied considerably: 20% of centers used 2 standard deviations about the mean (SD), 26% used 1 SD, 6% used 1.5 SD for normal ranges (41House 1997).

Individual preferences of both referring physicians and the imaging specialists have influenced local decisions on how to conduct GES. Currently, studies vary in length from as short as 60 minutes up to 4 hours. Studies have shown that extending measurements out to 4 hours increases the detection rate of delayed emptying (42Guo 2001, 43Ziesman 2007). As more has been learned about optimal methodology, some imaging centers have changed their protocols, but many centers have been reluctant to perform a 4 hour procedure because reimbursement is not commensurate with the time and effort needed. Reimbursement for gastric emptying scintigraphy is substantially lower than for other imaging procedures that can be done in less time on the same equipment. This economic reality however should not be an impediment to providing optimum patient care. Under current Center for Medicare and Medicaid Services (CMS) guidelines, any future increase in RVU assignment (reimbursement) will not occur until the medical community demonstrates a consensus on the requirement for more comprehensive imaging.

TOWARDS STANDARDIZATION: Validation of the proposed regimen

One multi-institutional protocol has been published which investigated a large number of normal subjects and established normal values (39Tougas 2000). One hundred and twenty-three normal subjects from 11 medical institutions in the United States, Canada, and Europe were studied in a multi-institutional and multinational study. Normal values published from other protocols were often based on smaller numbers of subjects (typically 10-35) at single institutions (44Cremonini et al). The percent gastric emptying was quantified at several time intervals after consumption of a low-fat, egg-white meal. The Tc-99m sulfur colloid radiolabeled meal consisted of the equivalent of 2 large eggs (Eggbeaters®), 2 slices bread and jam with water. Imaging was performed in the anterior and posterior projections at only four time points (0, 1, 2, and 4 hours). The geometric mean activity of decay-corrected counts (square root of the product of the anterior and posterior counts) was determined at each imaging time. Normal values were

established using the median and 95th percentile because the data were skewed, particularly at 4 hours. These authors defined the upper limits of gastric retention (95th percentile) of the 123 men and women at each of three time points: 1, 2, and 4 hours (Table 1). Delayed gastric emptying (gastric retention) was determined to be > 90% at 1 hour, >60% at 2 hours, and >10% gastric retention at 4 hours. These results currently provide the largest published data base for a standardized GES protocol (39Tougas 2000).

Imaging at only four time points can actually simplify scheduling and permit more efficient use of imaging equipment. This helps alleviate some of the concerns at some imaging centers that GES is too time consuming, and the efficiencies in camera use are associated with little loss of test accuracy (45Vijayankumar 2006, 46Camilleri 1991). Multiple gastric emptying tests can be performed on one camera in a single day if the starting times are staggered.

Another important factor supporting use of the Tougas' protocol is the data suggesting the superiority of a longer, 4 hour study rather than the 2 hour study (39Tougas 2000, 42Guo 2001, 43Ziessman 2007). The first reported studies promoting 4 hour imaging were from the Mayo Clinic in 1991 and 1995 (46Camilleri 1991, 47Thomforde 1995). In a study of 35 patients, the 4 hour time interval was more sensitive for detection of delayed gastric emptying than the two hour time-point. The Temple University group reported in 2001 on 127 consecutive patients referred for clinical gastric emptying studies (42Guo 2001). GES was performed with a conventional egg labeled sandwich with water. Imaging was performed at 0, 0.5, 1, 2, 3, 4 hours. The data suggested that the 3 and 4 hour imaging times detected more abnormal gastric emptying than 2 hour images, e.g., 50% of patients were abnormal at 3-4 hours versus 33% at 2 hours. Data from Johns Hopkins University has found similar results using the Tougas meal (48Goetze 2005, 42Ziessman 2007). In an investigation of 175 patients, 34 studies were abnormal at 2 hours. The 4 hour retention identified 11 additional abnormal patients who had normal emptying at two hours, a 29% increase in the number of abnormal studies.

Any GES protocol should be able to identify both rapid and slow gastric emptying. Although the symptoms of rapid emptying may be similar to those of delayed emptying (23Delgado-Aros 2004), the treatment is quite different. Use of a standardized protocol across all medical centers which includes standard time points (e.g. 0, 1, 2, and 4 hours) offers the potential of consistently defining both delayed and rapid GE. The early 1 hour time point can be used for determining rapid gastric emptying; whereas the later 2 and 4 hour time points are used

for determining delayed gastric emptying. The study of Tougas et al did not establish values for rapid emptying. Reanalysis of data from the original Tougas manuscript suggests 32% is the lower 95% confidence interval for normal emptying suggesting <30% retention at 1 hour (49Abell 2006) is indicative of rapid gastric emptying (Table 1). Other recent studies also suggest that 30% is an optimal threshold for 3 hour emptying data (43Ziessman 2007).

ITEMS FOR FURTHER INVESTIGATION

It is anticipated that GES will need to be further optimized as more studies using this protocol become available. The consensus participants therefore identified areas where more information is needed (Table 2).

Optimal Timing of Imaging

Some patients with delayed emptying at 2 hours normalize their emptying at the 4 hour time point and some individuals with normal emptying at 2 hours have delayed emptying at 4 hours (42Guo 2001, 43Zeissman). The clinical importance of delayed emptying at only certain time points is unknown. There needs to be better understanding of the use of multiple time points in combination (e.g., 2 and 4 hours). Data from Guo et al. suggest that the 3 hour time period might be as sensitive as a four hour study in detecting delayed gastric emptying (42Guo et al 1991). Although the original report for the Tougas et al data had no 3 hour measurement point, more recent studies suggest the upper limit of normal is 28% gastric retention at 3 hours after meal ingestion (50Lin 2006). A recent study using the Tougas meal have shown that the 3 hour time point is nearly comparable to the 4 hour value in detecting patients with delayed gastric emptying (50Lin 2006).

For rapid gastric emptying, currently the one hour gastric emptying value is recommended. However, the normal values were generated with a smaller subgroup of normal subjects and currently published only in abstract form for the Tougas meal (49Abell 2006). More data are needed for delineation of the cutoffs to determine rapid gastric emptying. Recent investigations also suggest that rapid emptying is detected at 15-60 minutes after meal ingestion (22Lin 1999, 23Delgado-Aros 2004). It is conceivable that earlier time points, such as a 30 minute postprandial value, may be better than one hour value for detection of rapid gastric emptying.

The time points for measuring gastric emptying may be further optimized in the future. Presently, however, there are insufficient data to recommend the 30 minute and 3 hour time points for routine use (Table 2). The current consensus recommendation is to obtain images at a minimum at 0, 1, 2, and 4 hours after meal ingestion as described originally (39Tougas 2000)

Composition of Meal

This consensus document proposes a low fat meal used as the initial screening test for gastric emptying. In some patients, a low fat, egg white meal may not prove to be an adequate functional challenge, especially for patients who report symptom exacerbations after eating lipid-rich foods (22Lin 1999). Meal composition may need to be altered depending on the patient's specific symptoms. Some European investigators have suggested adding butter (10 grams) to the low fat meal to increase the fat content. This brings the meal to a caloric content of 345 kcal with nutritional composition of 69% carbohydrate, 22% protein, 7% fat, 2% fiber. Other alternative meals may also be useful for patients with egg allergies or intolerance to eggs, and patients with gluten-sensitive enteropathy. Liquid Ensure nutrient supplement or an oatmeal meal are used by some centers. However, specific normal databases will be needed for these alternative meals before they are used clinically.

Glycemic Control

More uniform management of diabetic patients undergoing GES is needed. The consensus opinion is to measure and record the blood glucose level of diabetic patients just prior to the study. The study should be performed if the patient is under reasonable glucose control, that is, fasting glucose of <275 mg/dl. There is still no consensus, however, on what should be done with insulin and oral hypoglycemic agents on the day of the study. Generally, half of the usual morning dose of insulin is given with the radiolabeled test meal. Postprandial glucose is not usually measured to determine if hyperglycemia develops postprandially during the gastric emptying test; postprandial hyperglycemia could prolong gastric emptying. Hypoglycemia may also influence gastric emptying or increase the patient's symptoms. Postprandial glucose monitoring at 2 and 4 hours may be considered in the future.

Monitoring of Symptoms

Monitoring symptoms during the gastric emptying test is currently being performed in clinical research studies (13Samsom 2003) to determine whether delay in gastric emptying correlates with symptoms. If the gastric emptying test is normal, this simultaneous recording of symptoms will inform whether the meal was an appropriate provocative test to induce the typical postprandial symptoms.

Assessment of Severity

Since there is not a close correlation between a delay in gastric emptying and symptoms, the gastric emptying test alone should probably not be used for grading the severity of the clinical disorder of gastroparesis. Grading the severity of the delay in gastric emptying has been performed in clinical research studies and might be used clinically (51Arts 2005). Grading for severity of delayed gastric emptying based on 4 hour value in groups related to the standard deviation of the normal results:

Grade 1 (mild): 11-20% retention at 4 hours

Grade 2 (moderate): 21-35% retention at 4 hours

Grade 3 (severe): 36-50% retention at 4 hours.

Grade 4 (very severe): >50% retention at 4 hours

On the other hand, a combination of the degree of gastric emptying delay and the nutritional needs or approaches necessary to support the patients' hydration and nutrition provide a better assessment of severity and facilitate the approach to management. In a recent review, mild delay was designated as 11-15%, moderate 16-35% and severe >35% retention at 4 hours (52Camilleri 2007).

Establishing normal values for the post-gastric surgery group

There is no appropriate "normal" data base to use for patients that are symptomatic after gastric surgical procedures. In postsurgical patients, the altered anatomy is likely to alter gastric emptying compared to normal subjects without gastric surgery (53Fich 1990). In general, there is delay in the emptying of solids and accelerated emptying of liquids (53Fich 1900). After Roux gastrectomy, there may be retention of solids in both gastric remnant and the Roux limb (54Miedema 1992). The normal gastric emptying of the Tougas meal in patients with different degrees of partial gastric resections (e.g., antrectomy) and different drainage procedures is not

known. This is also relevant with surgical reconstruction of the stomach, especially post-bariatric surgery of the stomach.

Assessment of proximal and distal gastric function

A unique advantage of GES is that it can characterize more completely the complex physiology of GE including proximal (fundal) and distal (antral) function. Scintigraphy permits analysis of the intragastric distribution of the test meal between the fundus and antrum. The routine GE imaging can be used to measure both regional and total GE. Visual inspection of fundal and antral gastric emptying and quantification of regional emptying with fundic and antral regions of interest can be helpful for defining abnormal physiology and explaining dyspeptic symptoms especially when global GE values are normal (55Troncon 1999, 56Gonlachanvit 2006, 57Karamanolis 2007). Studies have shown an association between symptoms of nausea, early satiety, abdominal distention and acid reflux with proximal gastric retention; whereas vomiting is associated more with delayed distal GE (56Gonlachanvit 2006). However more validation of intragastric distribution and regional emptying are necessary before this is incorporated into clinical practice.

Utility of measuring the lag time

The lag phase is the time required for commencement of gastric emptying of solid particles. It represents the time for solid food to be triturated into small particles that are then passed through the pylorus. The lag phase can be measured as the time from meal ingestion to first appearance of the radiolabeled solids in the proximal small bowel. This approach often requires frequent imaging for at least the first 60 minutes of the gastric emptying study, as the normal values have been reported to be 20 ± 10 minutes (SD) (43Ziessman 2007). It is not certain whether this physiological information is important for clinical management. Gastroparesis is often associated with a prolonged lag phase and slow post-lag emptying rate (58Camilleri 1986). However, a prolonged solid gastric emptying lag phase has been implicated in some investigations as the cause of delayed emptying in certain diseases and shortening of the lag phase by prokinetic drugs as the reason for improved emptying (59Ziessman 1992). One report has suggested the lag phase to be a sensitive indicator of the efficacy of drugs used to treat diabetic gastroparesis (60Mackie 1991). Recent reports with the Tougas meal suggest that the

length of the lag phase does not correlate with gastric emptying and does not add additional information to the percent retention at specified times (43Ziessman 2007).

Use of mathematical models for parameter estimation

Curve fitting to the data points for gastric retention over time may provide useful information on gastric emptying (61Elashoff 1983, 62Siegel 1988, 63Nusynowitz 1994, 64Camilleri 1985). The gastric emptying curve can be analyzed in several mathematical ways to determine both the emptying rate and lag phase. A curve fitting procedure such as a dual exponential equation (modified power exponential) has been used, namely:

$$y = 100[1 - (1 - e^{-kt})^b]$$

where y is the percent remaining at time t, k is an exponential emptying rate constant (fraction of amount present at time t) and b is the y intercept of the terminal exponential with slope = -k. The lag time can be then calculated as $\ln(b)/k$. Slope and lag time may be helpful to interpret borderline results. Using curve fitting techniques and a similar meal to the low fat Tougas meal, the upper limit of normal for the lag phase is approximately 45 minutes (63Nusynowitz 1994). If considering the curve fitting approach for gastric interpretation, several additional data points should be obtained such that imaging occurs at 0, 0.5, 1, 2, 3, 4 hours.

SUMMARY CONSENSUS RECOMMENDATIONS FOR A STANDARDIZED GASTRIC EMPTYING PROCEDURE

This consensus document concludes that, at the current time, the most universally acceptable meal is the low-fat, egg white meal as described by Tougas et al. Eggbeaters® or other equivalent generic commercial brands of liquid egg white are available and acceptable for use. Currently this meal and protocol has the largest normative database (39Tougas 2000). GES should be performed with imaging, at a minimum, at 0, 1, 2, and 4 hours after radiolabeled meal ingestion.

Ultimately, to have value, any standardized protocol must be followed closely. Our current consensus recommendation including the technical details on how to perform GES is presented in Appendix 1. In order to facilitate better standardization, a number of sample documents are presented. A patient information form for those undergoing the test is contained in Appendix 2 (Reference: ANMS web site: www.motilitysociety.org). A form for all patients

to complete to provide important information to assist in study interpretation is contained in Appendix 3.

This consensus statement recommends use of a single, standardized GES protocol. Adoption of this standard is important to improve how gastric emptying studies are used to direct patient care. The authors recognize that any consensus protocol has limitations. However, the one currently recommended has the largest database of normal values. Adopting this protocol will solve the problem of non-uniformity of protocols across institutions and will be a vast improvement over the diverse methods currently in use. Other questions and issues will need to be addressed in the months and years ahead before GES attains its full clinical potential (Table 2). With continued close collaboration between imaging specialists and gastroenterologists, this important physiologic test will continue to serve as a valuable tool in the diagnosis and management of gastric motility disorders.

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Table 1. Normal values for the low-fat, egg white gastric emptying scintigraphy

<u>Time point</u>	<u>Lower normal limit for gastric retention</u> A lower value suggests rapid gastric emptying	<u>Upper normal limit for gastric retention</u> A greater value suggests delayed gastric emptying
0 min		
0.5 hour	70% ^b	
1 hour	30% ^b	90% ^a
2 hour		60% ^a
3 hour		30% ^c
4 hour		10% ^a

Values are the 95th percentile confidence interval

References

a: Tougas et al (39).

b: Abell et al (49).

c: Lin et al (50).

Table 2. Issues requiring further investigation for GES

1. Interpretation of discordant results for delayed gastric emptying in the 2 and 4 hour images.
 - A. Use of multiple time points (2 and 4 hour) versus single 2 or 4 hour for delayed GE.
 - B. Clinical meaning of discordant results from 2 and 4 hour scans for normal or delayed GE
2. Optimization of the specific time points used for imaging
 - A. Use of 0.5 or 1 hour result for detection of rapid gastric emptying.
 - B. Use of 3 hour result compared to 2 and 4 hour results for detection of delayed GE.
3. Better understanding of the impact of patient-related factors that may affect gastric emptying.
 - A. Age
 - B. Gender
 - C. Menstrual cycle
 - D. Weight and BMI
4. Need for a larger database for normal values at early phases of gastric emptying:
 - A. 30 minutes after meal ingestion
 - B. 1 hour after meal ingestion
5. Evaluation of alternative meals
 - A. For patients allergic to eggs
 - B. For patients with gluten sensitive enteropathy
 - C. Use of different meals with different caloric/fat challenges.
6. Management of diabetic patients
 - A. Assessment of glucose in diabetic patients prior to the test: glucose and Hgb-A1c.
 - B. Management of hyperglycemic patients on day of test
 - C. Administration of insulin and oral hypoglycemic agents
 - D. Need for monitoring postprandial glucose
7. Need for data base of “normal” values for post-gastric surgery patients
8. Clinical value of further characterization of gastric emptying
 - A. Regional analysis of gastric emptying (separate antral and fundal measurements)
 - B. Lag phase analysis
 - C. Use of curve fitting techniques to analyze the time activity points
 - D. Dynamic antral contraction studies
 - E. Fundal accommodation studies with SPECT
9. Clinical value of liquid phase gastric emptying

Appendix 1. Consensus Method for Performing Gastric Emptying Scintigraphy

I. Patient Preparation

The referring physician should determine what medications are to be continued prior to GES. Prokinetic agents that enhance gastric emptying such as metoclopramide (Reglan), tegaserod (Zelnorm), erythromycin, domperidone (Motilium) are generally stopped at least 2 days prior to the test. Opiate analgesic medications delay gastric emptying and should also be stopped 2 days before the test. These include: Demerol, codeine, morphine, oxycontin, percodan, percocet. Anticholinergic antispasmodic agents such as Bentyl, Donnatal, Levsin, Robinul are usually stopped for 2 days prior to the test.

It is preferable to study menstruating females during the first 10 days of their menstrual cycle to improve the interpretation of the study and to prevent administration of radionuclide to a potentially pregnant woman.

The study should be performed in the morning after an overnight fast. If this is not possible, patients should be fasting for at least 6 hours prior to the test. The patient may take medications with some water on arising before coming for the test. Patients should refrain from smoking the morning of the test and throughout the time of imaging.

Diabetic patients should test and record their blood glucose prior to the study (fasting). Generally the fasting glucose should be < 275 mg/dl. At the time the meal is ingested, diabetic patients should self administer their insulin at a dose that is generally ½ what they normally take.

Subjects should be instructed that they will be in the imaging facility for at least 4 hours after meal ingestion and advised to bring reading material, a personal music player or other material to occupy them for the time of the study. For the time between images, the subjects can be sitting, standing, or walking but should remain in close proximity to the nuclear medicine section.

II. Meal Preparation and ingestion

The standard scintigraphic meal for gastric emptying should consist of an egg-white meal (Egg Beaters® or generic equivalent) radiolabeled with 0.5 -1 mCi ^{99m}Tc. The meal has a caloric value of 255 kcal (nutritional composition: 72% carbohydrate, 24% protein, 2% fat, and 2% fiber). An allergy to eggs is a contraindication to this meal.

Items needed for Gastric Emptying Meal

- 4 oz.(120 gm, equal to approximately two large eggs) Liquid egg white; 99% real eggs, cholesterol free, fat free, low calorie)
- 2 slices of white bread (120 kcal),
- Strawberry jam (30 g, 74 kcal)
- Water (120 ml).
- Technetium-99m sulfur colloid, 0.5 -1 mCi

The eggs can be cooked either scrambled on a hot skillet (nonstick frying pan) or microwaved in an appropriately shielded container. The eggs are served with toast, jam, and water. To prepare the meal, the liquid egg is poured into a bowl, mixed with 0.5 - 1 mCi ^{99m}Tc sulfur-colloid marker,

and cooked in a skillet (nonstick frying pan) or microwave. The egg mixture should be stirred once or twice during cooking and is cooked until it has the consistency of an omelet (3-5 min). The bread is toasted. Jelly is spread on the bread, and a sandwich is made of the jellied bread and cooked egg mixture.

The subject ingests the sandwich meal within 10 minutes. Patients may eat the egg and toast/jelly separately. For quality control, the staff technologist records how long it takes the subject to consume the meal and how much they consume. The patient should ingest the whole meal. If the patient cannot eat the entire meal, at least 50% of each component should be consumed for the test. If the patient vomits part of the meal at any time during the test, this should be indicated on the report.

III. Image Acquisition

Gamma camera images are acquired using a 140 keV ^{99}Tc photopeak with a 20% window (140 keV \pm 10%). A low energy all purpose (LEAP) collimator will maximize the count rate; a low energy high resolution collimator can also be used. Computerized digital images are required for quantification. These are acquired in a 128x128 word mode matrix.

Gamma camera images are obtained immediately after meal ingestion and at a minimum of 1, 2, and 4 hours after meal ingestion with the subject standing upright in front of a gamma camera. One minute anterior and one minute posterior timed images are acquired. These may be simultaneous if a dual-headed camera is available. If a single headed camera is used, the subject is first imaged anteriorly and then posteriorly. For patients who cannot stand or otherwise be positioned for anterior and posterior views, a single best LAO image may be substituted.

The times of the images and time to eat the meal should be recorded by the technologist to make sure imaging at specific times is adhered to.

Between imaging sessions, the subjects are permitted to sit in a designated waiting area and to walk to and from the imaging room and bathroom as desired. Strenuous activity (climbing stairs, other physician visits, or other diagnostic studies should not be scheduled concurrently.

IV. Image analysis and quantification of gastric emptying

Manual regions of interest are drawn on the anterior and posterior images for all acquisition times using an irregular ROI tool to outline the stomach. The total gastric ROI should include the fundus and antrum with particular attention to avoid any loops of small bowel in close proximity to the stomach. An exception would be if the patient has small bowel activity on the first image, then the entire field of view should be used so that time 0 includes all activity ingested.

The geometric mean of the anterior and posterior gastric counts (Ant counts X Post counts)^{1/2} for each time point is calculated and corrected for Tc99m decay (6.02 hr half life). No geometric mean attenuation correction is required for the LAO view.

The final results are expressed as percent remaining in the stomach at each time point with the total gastric counts normalized to 100% for the time $t=0$ (first image set immediately after meal ingestion).

V. Reporting

The percent remaining in the stomach at each time point is reported. The report should contain the normal values at the key time points: 1 hour (37-90%), 2 hr (30-60%) and 4 hrs (0-10%). A graph of the values plotted as a function of time may also be included in the report as a visual summary of the study results.

The report should mention the fasting blood glucose if the patient is diabetic. The report should mention medications that the patient was taking within the last 24 hours of the test that may affect gastric emptying.

The report should document the amount of the meal ingested, the total time taken to ingest the meal, and if any vomiting of the meal occurred postprandially.

The report should also describe any other unusual findings which are observed in the images such as: abnormal esophageal retention of the meal, hiatal hernia, fundal wrap, lack of fundic accommodation, evidence for retained old food particles.

Appendix 2. Sample Patient Instruction Sheet for Gastric Emptying Scintigraphy

Your doctor has ordered a test that will permit evaluation of how food moves through your stomach. These studies will be performed in the Nuclear Medicine Department.

Preparation for the Gastric Emptying Test:

- You should not eat any food after midnight the night before the test. If you smoke, do not smoke beginning on the morning of your test and throughout the time you are having the pictures of gastric emptying recorded. You may smoke after you are instructed that the test is completed.
- Some medications are generally stopped for this test. This should be discussed with your doctor or health care provider. Drugs that affect gastric emptying such as Reglan (metoclopramide), Zelnorm (tegaserod), erythromycin, Motilium (domperidone) and antispasmodics such as Bentyl, Donnatal, Levsin, Robinul are usually stopped for three days prior to this test. Do not take any laxatives on the day before or any time during your study.
- Unless otherwise directed by your doctor, the following pain medications should not be taken for two days prior to your test: Pain medications such as Demerol, codeine, morphine, oxycontin, percodan, percocet. Sedatives or tranquilizers, such as Valium, Librax, Ativan or Thorazine.
- Unless otherwise directed by your physician, you may continue your normal medications that could be taken with a small amount of water or juice up to two hours prior to your study. You should not drink coffee or tea.
- If you have diabetes, skipping breakfast may affect your need for diabetic medication. If you are a diabetic and on insulin, we request that you bring your regular morning dose of insulin with you. You can take this with the meal that will be given to you. We may reduce your insulin dose to adjust for the small size of the breakfast. Often half of your insulin is taken with the test meal. If you take oral hypoglycemic medications, generally these are taken with the meal in Nuclear Medicine. If there are any questions concerning your dose of insulin this should be discussed with your physician, radiologist, or the Nuclear Medicine physician performing the test.
- If you have diabetes, we also ask you to bring your glucose monitoring equipment to the test. We will ask you to check your glucose before the test and possibly during or after the test.
- Women, please note: This test should not be performed if you are pregnant. Inform your physician or nurse if you are pregnant or think you may be pregnant. You will be asked if there is the possibility of pregnancy. Often the test is best scheduled for females during the first ten days after the menstrual cycle.

Description of the Gastric Emptying Test:

- For this test, you will be asked to eat a meal that consists of liquid egg meal (equivalent to 2 whole eggs) on toast together with water. The meal has been labeled with an isotope that will permit pictures to be taken as the meal passes through the stomach and the GI tract.
- Pictures of short duration are acquired with you standing in front of the nuclear medicine gamma camera. Between the images you will be permitted to walk about and continue normal activities. It is suggested that you bring some reading material and/or a "Walkman" or "iPod" if you have personal music preferences. These studies try to simulate normal daily activities. The nuclear medicine rooms may be cooler than the rest of the hospital, and you may want to bring a sweater with you.
- The gastric emptying test generally takes four hours once it is started.

Appendix 3. Sample Nuclear Medicine Information Sheet for Patients Undergoing Gastric Emptying Scintigraphy to Fill Out

Your name:

Today's Date:

Your doctor:

Your age:

Your weight:

Your height:

1. What is your **main symptom** for undergoing the gastric emptying test today?

(Please circle the best answer or write in):

Heartburn Chest pain Nausea Vomiting
 Abdominal pain/Bloating/Distension Constipation Diarrhea
 Other symptom: _____

2. Do you have **diabetes**? **No** **Yes**

If yes, How long have you had diabetes? _____ years

What medications do you take: insulin pills

Did you measure your glucose this morning before the test? **No** **Yes**

If yes, what was the value?: _____

3. Do you take any **pain medications**? These include Percocet, Percodan, Demerol, Tylox, Tylenol #3, Oxycodone, Duragesic (Fentanyl) patch, Methadone, and others. **No** **Yes**

If yes, Which one(s):

How often do you take this:

When did you last take this type of medicine?

4. Do you take any **medications to speed up your GI tract** - stomach or colon? These include medications such as Reglan, Zelnorm, Domperidone, and Erythromycin. **No** **Yes**

If yes, Which one(s):

When did you last take this type of medicine?

5. List any other medications you currently take:

6. Have you had surgery on your GI tract – the esophagus, stomach, or colon? **No** **Yes**

If yes, please describe