Lag Phase Quantification for Solid Gastric Emptying Studies

Harvey A. Ziessman, Frank B. Atkins, Usha S. Vemulakonda, Jonathan Tall, Beth Harkness and Frederic H. Fahey
Division of Nuclear Medicine, Department of Radiology, Georgetown University Hospital, Washington, D.C.; and PET Center, Bowman Gray School of Medicine, Winston-Salem, North Carolina

This study compared the different calculation methods of the solid gastric emptying lag phase and evaluated the effect of the temporal sampling interval on the calculated value using the modified power exponential (MPE) method. **Methods:** Twenty normal control subjects and 42 patients had anterior and posterior image acquisition on a multihead gamma camera, one frame per minute × 90. ROIs were selected for the stomach, gastric antrum and small bowel. Time-activity curves (TACs) were generated for anterior, posterior and geometric mean data. The lag phase was calculated using various methods such as transition point, starting index, first appearance of bowel activity (FABA), MPE and antral peak filling time. To determine the importance of the temporal sampling rate on the calculation of the lag phase by the MPE, intervals between 1 and 20 min were analyzed. **Results:** The transition point, starting index and FABA correlated extremely high ($r = \geq 0.92$) in normal control subjects and patients. Normal lag phase values were mean 22-24 ± 10 min for transition point, starting index and FABA compared with 47 ± 18 min for the MPE method ($p < 0.0001$). The MPE correlated poorly with the other methods ($r = 0.74$). Antral peak filling time correlated poorly ($r = 0.47$) with transition point, starting index and FABA, but somewhat better with the MPE ($r = 0.70$). Comparing 15-min versus 1-min sampling intervals using the MPE, 35% of subjects had values that differed by ≥ 7.5 min and 10% had values differing by ≥ 15 min. **Conclusion:** The lag phase calculated by the MPE correlated poorly with other methods, and its accuracy was limited by the rate of the temporal sampling. The transition point, starting index and FABA all highly correlated with each other; the latter is a particularly reliable physiological indicator and is easily quantified using a small-bowel TAC.

Key Words: radionuclide gastric emptying; gastric function; lag phase; gastric physiology

J Nucl Med 1996; 37:1639–1643

The stomach is composed of two regions with physiologically distinct functions: the proximal fundus acts as a reservoir and has slow tonal contractions that result in liquid emptying, and the distal antrum, which triturates solid food into small particles (1–2 mm) that can pass through the pylorus into the duodenum (*1,2*). Radionuclide solid and liquid gastric emptying studies show this functional distinctness (*3–5*). Liquids empty monoexponentially from time zero, while solid radiolabeled meals empty in a biphasic pattern, with an initial time delay or lag phase, followed by a constant emptying rate. The lag phase represents the time from ingestion of the meal until its first arrival in the small bowel.

Although in the past, some investigators could not detect a lag phase on solid radionuclide gastric emptying studies (*6–9*), there is a general consensus that it can almost always be detected if image acquisition is frequent enough (*2,10–13*). It should not be surprising that a lag phase of 10 min duration may be missed if images are acquired every 15 min.

Some studies suggest that a delay in the lag phase may have clinical importance. It has been reported that solid gastric emptying is delayed in certain diseases due solely to a prolonged lag phase, and that some commonly used prokinetic drugs improve delayed emptying by shortening the lag phase (*10,14*).

Accurate quantification of the lag phase is mandatory when studying gastric pathophysiology or drug mechanisms. Investigators have used a variety of methods to define and calculate the length of the lag phase. Although a few have simply used visual analysis to detect the first appearance of duodenal activity (*4,13*), most have used gastric TACs and various semiquantitative indices (*5,13,14*). Others have used quantitative curve fitting techniques, e.g., a starting index (*10,15*). One such method, the modified power exponential (MPE), has been advocated and used in recent years to quantitate both a rate of emptying and the lag phase (*4,16,17*). This mathmatical model assumes that solid emptying is biphasic. It is an attractive approach since it attempts to standardize quantification of solid emptying and to improve the statistical reliability of the limited data points available in studies acquired intermittantly every 15–20 min.

Concerns, however, have been raised regarding this latter approach. For one, this model may not be appropriate since solid emptying has been reported to be linear, not exponential (*15*). There has also been controversy as to why the normal lag phase defined by the MPE is of longer duration than when reported using other methods of calculation (*18*). Finally, we were concerned that the accuracy of this technique might be affected by the temporal sampling rate.

The purpose of this study was to directly compare and evaluate various different methods for calculating the lag phase in an attempt to better understand their advantages and disadantages and hopefully to determine an optimal methodology. We also sought to investigate the effect of the temporal sampling interval on quantification of the lag phase by the MPE.

MATERIALS AND METHODS

Patients

Twenty normal volunteers and 20 patients had solid gastric emptying studies which were acquired on a triple-headed gamma camera (TRIAD, Trionix, Twinsburg, OH) for investigative purposes and were previously reported in a different study (*19*). Another 22 referral patients had studies acquired on a dual-headed camera (BIAD, Trionix).

TRIAD Normal Volunteers. The normal volunteers (9 men, 11 women) ranged in age from 18 to 42 yr (mean 28.7 ± 6.3 yr). Two of the female volunteers took birth control pills, one a bronchodilator and another nonsteroidal antiinflammatory drugs. None of the volunteers were obese, had gastrointestinal symptoms, abdominal surgeries or any known gastric or hepatobiliary disease.

Received Aug. 17, 1995; revision accepted Jan. 24, 1996.

For correspondence or reprints contact: Harvey A. Ziessman, MD, Division of Nuclear Medicine, Georgetown University Hospital, 3800 Reservoir Rd., Washington, D.C. 20007.

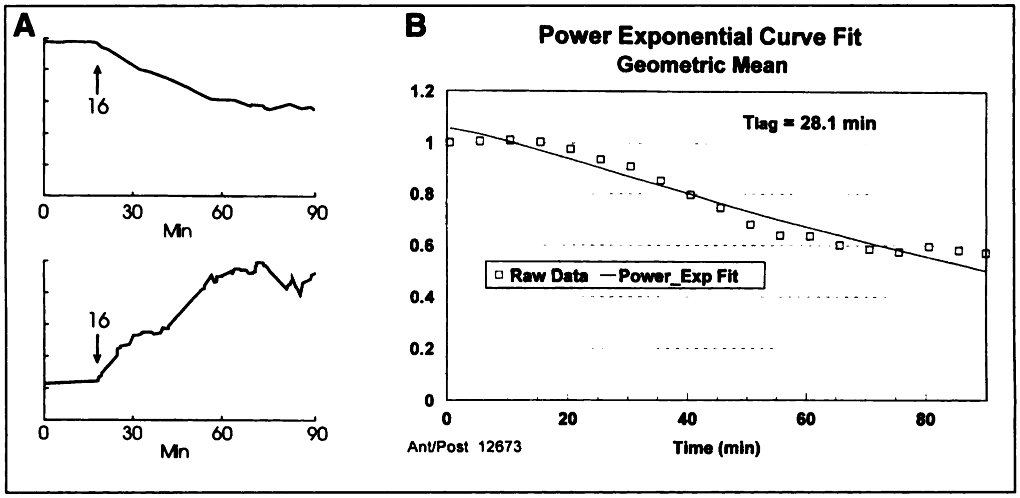

FIGURE 1. (A) Gastric TAC with clearly defined transition point and starting index at 16 min (see arrow, above). The tail of the curve flattens due to overlying small bowel activity. Small bowel TAC shows initial flat baseline activity due to scatter from the stomach, then a sharp increase in the slope at 16 min (arrow) when activity enters the small bowel (below). Note that the rate of entrance is constant until the late portion of the curve where overlap occurs. (B) MPE curve fit. The curve fit is poor, since the reverse S-curve pattern does not fit the model. The lag phase is 28.1 min, considerably longer in this same patient than when calculated by the other methods.

TRIAD Patient Group. The patients (9 men, 11 women) ranged in age from 14 to 60 yr (mean 40 ± 11.7) They were referred on a clinical basis with a variety of gastrointestinal symptoms. Only four demonstrated delayed emptying (2 s.d. from the mean or < 30% emptying at 90 min (*19*)) and three had low normal values (35,32,32%).

BIAD Patient Group. Because of the limited number of TRIAD patients with delayed emptying, an additional clinical population was investigated. Patients (7 men, 15 women) ranged in age from 18 to 81 yr (mean 40.6 ± 17.3) and had gastric emptying studies performed for various clinical indications.

Patient Preparation and Radiolabeled Meal

Patients were NPO after midnight before the study. A ^{99m}Tc-sulfur colloid labeled egg-white sandwich (3 fried egg whites, 2 pieces of toast, butter [260 calories, 40 g CHO, 5 g fat, 93 g protein]), with 200 cc water, ingested over 5–10 min. Imaging commenced immediately and all patients were imaged supine.

TRIAD. Two sets of three simultaneous projections were acquired sequentially for 30-sec frames: first, the anterior, right posterior oblique and left posterior oblique, then after the camera head rotated, the posterior, left and right anterior obliques. This sequence was repeated continuously for 90 min.

BIAD. The anterior and posterior projections were obtained simultaneously as 60-sec frames for the 90-min study.

Data Analysis

Decay-corrected data were processed on the Siemens Max-idelta (Iselin, NJ) with user-developed software. Images were reviewed in cinematic display to assist in placement of the manually drawn regions of interest (ROIs). For the data from the triple-headed camera, two ROIs were drawn, the whole stomach and small bowel; for data acquired on the dual-headed camera, a third ROI was drawn over the gastric antrum. TACs were derived for the anterior, posterior and conjugate view geometric mean derived data.

Quantification. The following lag phase determinations were determined from the anterior/posterior geometric mean gastric TAC: A transition point defined for the purpose of this study as the time where the second phase of emptying began, determined by visual inspection of the gastric TAC. A starting index was calculated by applying a linear least squares fit to the second phase of the TAC. The first and the last points were selected in the early and late portions of the linear downsloping part of the TAC. If the latter part of the curve flattened out, e.g., due to overlying bowel activity, it was omitted from the fit. The point at which the linear fit intersected 100% gastric retention was defined as the starting index. We did not quantitate the lag phase as a specific percent drop from peak counts since we have previously found that the result is very dependent on the downslope of the second phase (*19*). The small bowel TAC was used to determine the first appearance of bowel activity (FABA) by noting the time of an abrupt increase in the slope from baseline. (Figs. 1, 2).

Modified Power Exponential. A program was written in C for the computer to perform an iterative fit to a MPE function, $y(t) = 1 - (1-e^{kt})^{\beta}$, using the Levenberg-Marquardt approach similar to that reported elsewhere (*4,17*). One variation to their technique is that the y-intercept was also a parameter of the fit, and not forced through the "time-zero" data point. The lag phase was defined as the point in time in which the extrapolated exponential component from the terminal portion of the curve intersects the 100% level. A rate of emptying, k, was also determined.

Subsets of geometric mean TACs from 1 to 20-min intervals were analyzed in all three study groups to determine the importance of the temporal sampling rate on calculation of the lag phase. The antral peak filling time was determined from the peak counts of the TAC derived from a computer drawn antral ROI.

Other routine quantification performed included the percent emptying at study end, a rate of emptying determined by a linear fit (%/min) and exponential fit ($T_{1/2}$), as well as by the MPE function (k).

The results were compared and statistically analyzed to determine similarities and differences and advantages and disadvantages using these different methods for measuring the lag phase.

RESULTS

For the normal control group (n = 20), the lag phase (mean ± 1 s.d.) was determined for each method: transition point = 22.9 ± 9.9 min; starting index = 22.2 ± 10.0 min; first appearance of bowel activity (FABA) = 24.0 ± 9.0 min. There was a high correlation between these three indices (r = 0.92, 0.94, 0.96) and no statisticially significant difference between them. Men and women showed no significant difference (Student's t-test) for any of these methods.

The MPE calculation of the lag phase in the same group of normals was (mean ± s.d.) 46.7 ± 17.0 min (excluding two patients with negative values). This correlated poorly with the other three indices (transition point, starting index, FABA) (r =

TABLE 1
Lag Phase Calculations in Normal Controls

	r value (s.e.e.)		
	Starting index	First bowel appearance	Modified power exponential
Inflection point	0.96	0.94	0.76
Starting index		0.92	0.80
First bowel appearance			0.74

0.76, 0.80, 0.74) and was significantly different ($p < 0.0001$) from all of them (Table 1).

For patient data, the correlation of the MPE with the other indices was only slightly better in the TRIAD patients (18/20, excluding two with negative values) (r = 0.82, 0.82, 0.77), while the correlation between the other indices (transition point, starting index, FABA) was again considerably higher (r = 0.99, 0.98, 0.97). The MPE was a negative value in 2 normal controls and 2 patients; it was greater than twice the value of the transition point, starting index, and BA in 8 normals and 12 patients and 1.5–2.0 times greater in 6 normals and 4 patients.

In the BIAD patient group, a similar pattern was noted. The lag phase as determined by the MPE function correlated poorly with the other indices (transition point, starting index, FABA) (r = 0.64, 0.64, 0.68). The latter three indices, however, correlated (r = 0.98, 0.90, 0.92) well with each other (Table 2).

The antral peak filling time correlated only moderately well with the MPE lag phase calculation (r = 0.70, s.e.e. = 17.7). Less than 20% of patients had values within 10%, a third within 25% of the other, and the remaining had values 50%-100% different. The antral peak filling time correlated even worse with the transition point, starting index and FABA (r = 0.46, 0.47, 0.42) (Table 2). Excluded from the analysis were one study due to patient motion, four with negative MPE values and one with a negative starting index.

The lag phase, as measured by all methods, had a poor correlation with the rate of emptying as measured by the linear or exponential fit or power exponential (k) methods ($r < 0.20$), and similar poor correlation with patient age ($r < 0.10$), or patient weight ($r < 0.15$). The lag phase measured by all methods was not significantly different in patients with slow gastric emptying as measured by the percent gastric emptying at study end (<35%) compared to those with more rapid emptying (>37%).

Effect of temporal sampling on quantification of the lag phase by the MPE: Of 51 combined normal subjects and patients [excluded were those with negative values (*6*), significant motion (*2*) and those with no emptying or other technical problems (*4*)], 18 (35%) had a time difference of ≥ 7.5 min and 5 (10%) ≥15 min in the lag time calculation when comparing the 15 min and 1 min sampling intervals. The 1 min and 5 min data were similar. The 20 min sampling data results were poorer than the 15 min data, but it was not used since the data is more limited, i.e., 20 min sampling precludes using the last 10 min of data of a 90 min study.

TABLE 2
Lag Phase Calculations in Patients

	r values (s.e.e.)			
	Starting index	First bowel appearance	Modified power exponential	Antral peak filling
Inflection point	0.98	0.90	0.64	0.46
Starting index		0.92	0.64	0.47
First bowel appearance			0.68	0.60
Modified power exponential				0.70

DISCUSSION

The length of the normal lag phase is dependent on numerous factors: meal size, food type, caloric content, particle size and methodology (*5,7–9,14,20–22*). But these factors alone do not fully explain the differences reported in the medical literature regarding its duration. For example, Christian et al. (*13*) using three methods, found the normal lag phase to be quite short (mean 8.3 min, range 4–14 min) and emphasized the importance of frequent image acquisition (30-sec frames). This was of interest since in the past (using 10–30-min acquisition intervals) they reported that a lag phase could not be detected when adequate attenuation correction was performed (*9*). Maurer et al. (*18*) criticized this study based on their investigation that found the normal lag phase to be much longer (mean 29–64 min ± 3.8 s.d.) as calculated by the MPE (images every 15 min). Although meal content was different, in our opinion, this would not fully explain the discrepant results.

Medical Literature

There are limited reported data comparing methods for calculation of the lag phase used by different investigators. In their study of normal volunteers, Christian et al. (*13*) reported that three methods (time that counts began to decrease judged by visual assessment of the gastric TAC, a 2% decrease from peak counts, and first appearance of duodenal activity) all gave similar results. Urbaine et al. (*20*) used the MPE calculation of the lag phase and reported that it highly correlated (r = 0.85) with the antral peak filling time. Only one study has directly compared these different methodologies (*23*). In that patient study, the MPE value was significantly longer and correlated poorly with the visual appearance of bowel activity or a 2% drop from peak counts (r = 0.10).

Study Data

Our study used frequent data sampling intervals (1-min frames) and compared five methods for calculating the lag phase. The results show that the lag phase, in both normals and patients, was significantly longer when calculated by the MPE as compared to other methods (transition point, starting index and FABA) ($p < 0.0001$). In contrast to the study referred to above (*20*), we found only a fair correlation between the antral peak filling time and the lag phase as determined by the MPE (r = 0.70). The antral peak filling time also correlated poorly with the transition point, starting index and FABA. Since antral activity represents an equilibrium between filling from the fundus and emptying into the duodenum, deconvolution techniques might lead to more accurate quantitation of antral kinetics and a better understanding of its significance.

Lag Phase Standard. Gastrophysiologists have described the lag phase as "the part of the solid emptying curve before the appearance of detectable amounts of radiolabel of the solid phase in the proximal small bowel" (*3,4*), therefore, it is surprising that few investigators have used the FABA to determine the lag phase on radionuclide studies (*3,13,23*). Most have focused on the gastric TAC alone. Our study is the first to quantitate the length of the lag phase using the small bowel TAC. This method is simple, reproducible and physiological. Combined use of gastric and small bowel TACs increases the certainty that the lag phase has been correctly identified (Fig. 2).

Although the MPE method is advocated as a way to standardize measurement of the two phases of solid emptying and to

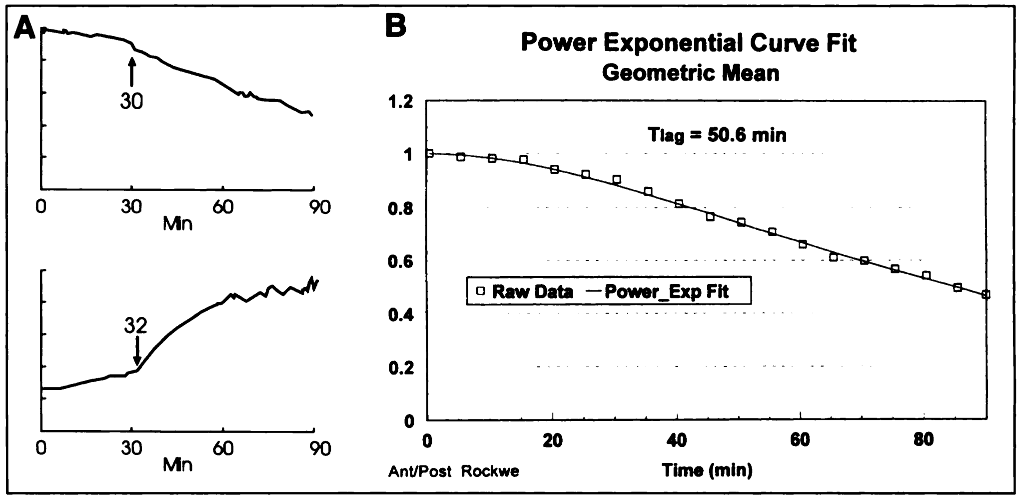

FIGURE 2. (A) Gastric TAC shows a first phase that is slightly down sloping, then a fairly distinct transition point at 30 min (arrow), followed by a relatively linear constant emptying rate (above). Small bowel TAC shows sharp break in curve at 32 min (arrow) closely correlating with the gastric TAC (below). (B) The MPE curve fit determined the lag phase to be considerably longer (50.6 min).

overcome statistical limitations of infrequent data sampling (*17*), it lacks validation. No physiological correlate has been demonstrated. Our study finds that the MPE calculation of the lag phase is measuring something other than the beginning of solid food entry into the duodenum. What it is measuring is uncertain. Since large particles require more time for trituration than small ones, one might speculate that the MPE represents the lag phase of the largest particles or perhaps some average lag value. We feel it is incumbant upon those who use the MPE to define its physiological correlate. Otherwise the number has no meaning.

On the other hand, we have shown that the starting index and transition point both measure the beginning of solid emptying into the duodenum. The small bowel TAC curve confirms this and demonstrates that once this process begins, it progresses at a constant rate (Figs. 1, 2).

MPE Limitations

Our study shows that the value of the lag phase as determined by the MPE is very dependent on the frequency of data acquisition. Using data sampled every 15 min versus every minute, over 35% of our subjects had a lag phase value that differed by ≥ 7.5 min and 10% by ≥ 15 min. Since the MPE has commonly been used with data acquired every 10–15 min or longer, this raises serious questions regarding the accuracy and even the conclusions of some past investigations using this technique. We have also observed that factors other than the temporal sampling rate affect the accuracy of the MPE. The MPE can only deal with TACs that fit the expected model, e.g., curves that are reverse S-shaped due to plateauing of the tail of the TAC, as seen when small bowel activity overlaps the stomach ROI, are hard to fit by this method (Fig. 1). TACs with downsloping of the first phase often result in a negative value.

Clinical Importance

Some studies suggest that the length of the lag phase has clinical importance. Not surprisingly, no solid lag phase can be demonstrated after surgical antrectomy and pyloroplasty (*24*). Although patients with diabetic gastroenteropathy and morbid obesity have been reported to have delayed emptying due solely to prolongation of the lag phase (*10,25*), others have also found a delayed rate of emptying (*26,27*). These discrepant findings may be due to different acquisition parameters, e.g., the temporal sampling rate, whether attenuation correction was performed, and/or different methods of quantification. Reports sugggest that metoclopramide and domperidone improve delayed gastric emptying by shortening the lag phase (*10,28*). Another study found that erythromycin abolished solid/liquid emptying discrimination, one assumes by eliminating the lag phase, although this was not calculated (*29*). More and better data is needed, since few investigators have studied both the lag phase and the rate of emptying using frequent image acquisition.

Standardization

Although the radionuclide study has become the standard for measurement of solid and liquid emptying, it is far from a standardized test. Methodology varies between laboratories, making comparison of reported results difficult. Reasons for this are partly historical, since, until recently, only single-headed gamma cameras were available in most nuclear medicine labs. This resulted in compromises on acquisition parameters. For example, to obtain conjugate view data for attenuation correction, imaging was often performed sequentially rather than simultaneously and intermittantly (every 10–15 min) rather than continuously. Frequent image acquisition is mandatory to derive accurate quantitative data, particularly for the lag phase (*22,26*). Creative methods have been proposed and used to compensate for attenuation and at the same time achieve rapid temporal sampling with a single-headed camera (*21,30,31*). Some are complicated and have not found general acceptance; others are clinically useful, but suboptimal for quantitative research compared to the geometric mean method. For example, the LAO method is simple and has proven to be clinically useful for attenuation compensation (*31–33*), however, the geometric mean method is still necessary for accurate quantitative research. Because of current widespread availability of dual-headed cameras, we believe there is no legitimate reason not to perform quantitative gastric emptying research studies by acquiring simultaneous anterior and posterior views, geometric mean attenuation correction and frequent image acquisition.

CONCLUSION

The lag phase calculated by the MPE correlates poorly with other commonly used methods and its accuracy is severely limited by the rate of temporal sampling. In addition, its physiological correlate is unknown. On the other hand, the transition point, starting index and FABA all highly correlate with each other. Since the FABA is a physiological indicator for the beginning of gastric emptying into the small bowel, we recommend that small bowel TACs be routinely used for calculation of the lag phase.

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Gastric Emptying in Early Noninsulin-Dependent Diabetes Mellitus

K.L. Jones, M. Horowitz, B.I. Carney, J.M. Wishart, S. Guha and L. Green

Departments of Medicine and Endocrinology and the Diabetes Centre, Royal Adelaide Hospital, Adelaide, South Australia

The aims of this study were to determine in early noninsulin-dependent diabetes mellitus (NIDDM): (a) the prevalence of disordered gastric emptying of glucose; (b) the relationship between the blood glucose response to an oral glucose load and gastric emptying; and (c) the relationship between appetite and gastric emptying. **Methods:** Sixteen patients (ages 39–79 yr) with recently diagnosed NIDDM consumed 350 ml water containing 75 g glucose and ^{99m}Tc-sulfur colloid while sitting in front of a gamma camera. Blood glucose concentrations were monitored immediately before and after the drink. Hunger and fullness were evaluated using visual analog scales. The results were compared to those obtained in 13 normal subjects of similar age and body mass index. All patients and control subjects were white and non-Hispanic. **Results:** Gastric emptying was slightly slower in the NIDDM patients when compared to the control subjects (retention at 180 min 15.9 ± 2.3% versus 3.8 ± 1.0%, $p < 0.001$), but there was no significant difference in the 50% emptying time between the two groups. In the NIDDM patients, there was an inverse relationship between the magnitude of the increase in the blood glucose concentration and gastric emptying, e.g., between the area under the curve for blood glucose from 0–60 min and the intragastric retention of the drink at 60 min ($r = -0.60$, $p < 0.05$). In the NIDDM patients, fullness was greater ($p < 0.005$) both before and after the drink, and the score for hunger at 30 min was inversely related to the rate of gastric emptying ($r = -0.52$, $p < 0.05$). **Conclusion:** In patients with early NIDDM, gastric emptying of 75 g glucose is similar to that of normal subjects and is a significant determinant of the glycemic response.

Key Words: gastric emptying; appetite; glycemic control; autonomic neuropathy

J Nucl Med 1996; 37:1643–1648

Disordered gastric motility is a frequent complication of diabetes mellitus (*1*). Cross-sectional studies of patients with long-standing (>~3-yr duration) diabetes mellitus indicate that gastric emptying of solid or nutrient liquid meals is delayed in about 50% of cases and that the prevalence of delayed emptying in insulin-dependent (IDDM) (*2–5*) and noninsulin-dependent

Received Oct. 2, 1995; revision accepted Jan. 28, 1996.

For correspondence contact: Professor M. Horowitz, Department of Medicine, Royal Adelaide Hospital, North Terrace, Adelaide, South Australia, Australia 5000.