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PERFORMANCE CHARACTERISTICS OF SCINTIGRAPHIC MEASUREMENT OF GASTRIC EMPTYING OF SOLIDS IN HEALTHY PARTICIPANTS

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Abstract

Background—Gastric emptying (GE) is measured in pharmacodynamic and diagnostic studies.

Aims—To assess inter- and intra-subject coefficients of variation (COV) of scintigraphic GE measurements in healthy subjects, and associations of GE with gender and BMI.

Methods—Data from participants with scintigraphic measurements of gastric emptying of solids were analyzed. Primary endpoints were gastric emptying $T_{1/2}$ (GE $T_{1/2}$) and GE at 1, 2, 3 and 4 hours.

Results—The patient cohort consisted of 105 males and 214 females; at least 2 studies were performed in 47 subjects [16 males (M), 32 females (F)]. Inter-subject COV (COV_{inter}) for GE $T_{1/2}$ were similar in M and F: overall 24.5% (M 26.0%, F 22.5%); COV are predictably lowest for GE at 4h (COV_{inter} 9.6%). COV_{intra} for $T_{1/2}$ and GE4h were overall 23.8% and 12.6%, and were similar to COV_{inter} values. Gender (but not age or body mass index [BMI]) was significantly associated with GE T1/2 [p<0.001, F 127.6 ± 28.7 (SD) min; M 109.9 ± 28.6 min] and with GE at 1h and 2h. Repeat GE $T_{1/2}$ values in 47 participants were significantly correlated (r= 0.459, p<0.001) with median difference of −6 min (mean −1.6, range −56 to 72 min). Bland-Altman plots showed Δ GE $T_{1/2}$ similarly distributed across mean GE $T_{1/2}$ 100–155 minutes, and across studies conducted 90 to 600 days apart.

Conclusion—Inter-subject variations in scintigraphic GE results are only slightly higher than the intra-subject measurements, which are also reproducible over time in healthy volunteers. Gender, but not BMI, is significantly associated with GE results.

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DISCLOSURES

The authors have no competing interests.

AUTHORS' CONTRIBUTIONS

Michael Camilleri, M.D.: Lead investigator, PI of all projects included except for three projects; conceptualization of project; manuscript authorship

Johanna Iturrino, M.D.: Fellow co-investigator; manuscript authorship

Adil E. Bharucha, M.D.: Staff co-investigator and PI of 3 projects that are included in the analysis; manuscript authorship

Duane Burton: Lead technologist conducted all analyses of gastric emptying tests in the studies

Andrea Shin, M.D.: Verification of data and manuscript authorship

In-Du Jeong, M.D., Ph.D.: Verification of data and manuscript authorship

Alan R. Zinsmeister, Ph.D.: Conceptualization of project, statistical analysis and manuscript authorship

Keywords

reproducibility; intra-subject; inter-subject; variation

INTRODUCTION

Measurement of gastric emptying of solids is endorsed by national societies (1) for use in clinical practice to identify gastric motor function abnormalities as in gastroparesis and dumping syndrome, to investigate pathophysiological mechanisms that may be associated with patients symptoms or syndromes such as functional dyspepsia, and to evaluate the effects of treatment such as prokinetic agents in the treatment of gastroparesis or intestinal pseudo-obstruction (2) or octreotide (3) which is used in the treatment of dumping syndrome.

The most widely applied method for measuring gastric emptying involves scintigraphy. The performance characteristics of this measurement have been scarcely documented in the literature. For example, we previously reported on 37 healthy human subjects of whom approximately a half underwent repeat measurements to appraise intra-individual variation (4). Given the relatively small number of participants in the prior study and the absence of any other large study to appraise the performance characteristics of gastric emptying of solids measured by scintigraphy, the aim of this study was to assess the inter- and intra-subject variations of scintigraphic gastric emptying parameters in healthy participants, to assess whether differences in gastric emptying $T_{1/2}$ were related to the average $T_{1/2}$ measurement between 2 studies, and to ascertain if intra-subject variability was related to the time lag between studies. A second aim was to assess the associations of age, gender and body mass index (BMI) with gastric emptying of solids.

METHODS

Data Source

Data were derived in a retrospective manner from a database of previously performed gastrointestinal transit studies conducted in healthy volunteers (see Appendix for references). These volunteers included post-menopausal women and overweight and obese people without other illnesses. All the participants were evaluated by the same research team (gastroenterologist, nurses and coordinators) in a single clinical research unit, and all had clinical evaluation, including physical examination and review of the medical records, to ensure they were healthy and had no disease that could alter gastric emptying. A screening bowel symptom questionnaire using validated questions (5) was used to exclude significant gastrointestinal symptoms at the times of study.

From this database, subjects participating in studies of pathophysiology or parallel-group design clinical trials were identified; only data obtained after randomization to a placebo group were included.

All participants had provided written consent in each of the previously conducted studies. The current analysis was approved by the Institutional Review Board (IRB) at Mayo Clinic, Rochester, Minnesota. Patients who had withdrawn authorization to use their records for future research purposes had their data removed from the analysis of the current study, as required by the Mayo Clinic IRB.

Gastrointestinal Transit Studies

To evaluate gastric emptying parameters, our established scintigraphic method was used (6–8). After an overnight fast, subjects ingested a ^{99m}Tc-labeled meal consisting of 2 scrambled eggs, one slice of whole wheat bread and one glass of skim milk. Using a gamma camera, abdominal images with anterior and posterior cameras of 2 minutes duration were acquired immediately following ingestion of the radiolabeled meal and at specified time points during the subsequent 4-hour period, typically every 15 minutes during the first 2 hours and every 30 minutes during the subsequent 2 hours. No participants were taking any medications (prescription or over-the-counter for the week prior to and during the testing of gastric emptying.

Data Analysis

Transit measurements—^{99m}Tc counts were quantified within a 140 keV (±20%) window. A variable region of interest program was employed to quantitate counts in the stomach.

Primary endpoint was GE $T_{1/2}$, which was measured by linear interpolation of the imaging data acquired during the 4-hour postprandial period. In addition, we quantitated GE at 1, 2, 3, and 4 hours after ingestion of the radiolabeled meal, consistent with our previous documentation that these data provide clinically relevant information (9,10) and with the subsequent studies by Tougas et al. (11) which formed the basis for the society recommendations.

Assessment of variation in gastric emptying measurements—The following principles were applied to select data for analysis:

1. Inter-subject variation was estimated by comparing the first complete set of transit parameters (GE $T_{1/2}$, GE 1h–4h) among participants.
2. Intra-subject variation was derived from the first two transit values within short (<90 days), intermediate (90–360 days), and long (>360 day) intervals.

Statistical Analysis

Endpoints of gastric emptying are expressed as mean ± SD and, where relevant, as median and 5th and 95th percentiles. Data are summarized for overall participants and by gender. Inter- and intra-subject coefficients of variation (COV) were calculated. The inter-subject COV was calculated by the SD divided by the mean and expressed as percentage. The intra-subject COV was calculated as the SD of the within subject differences divided by the overall (grand) mean of the corresponding transit measurements and expressed as a percentage. The associations of age, BMI and gender with gastric emptying measurements were assessed using an analysis of covariance model with the gastric emptying endpoints as the response variables and age, gender and BMI as predictors.

Bland-Altman plots (12) were constructed to visually assess the intra-subject variation between gastric emptying values in a subset of subjects with repeat studies. The Pearson correlation was used to assess the relationship between differences in $T_{1/2}$ measurements of gastric emptying from repeat studies and the overall mean of the two repeat studies.

RESULTS

Subject Characteristics

From the original database, 319 eligible subjects (214 female) were identified who had participated in a total of 22 studies which measured gastric emptying as part of specific research protocols (Appendix). The eligible participants' characteristics are shown in Table 1.

Intra-subject variation was estimated in 47 of the 319 participants (31 female, 16 male) in whom gastric emptying was assessed at least twice; when there were more than two studies, we selected the two that were closest in time (median 1.26 years apart, range 55days to 3.85 years).

Inter-subject Variation of Transit Parameters

Inter-subject coefficients of variation (COV) for all end points are summarized in Table 2A. Inter-subject coefficients of variation (COV) for GE $T_{1/2}$ were similar in males and females: overall 24.5% (males 26.0%, females 22.5%); COVs are predictably lowest for GE at 4 hours (COV_{inter} 9.6%).

Intra-subject Variation of Transit Parameters

COV_{intra} for $T_{1/2}$ was 23.8% and was similar to the COV_{inter} values (Table 2B). Replicate GE $T_{1/2}$ results from 47 participants (Figure 1) showed significant correlation [Pearson r=0.46; p=0.0012; the concordance correlation coefficient was also 0.46 (95%CI 0.20 – 0.65)], with a median difference of −6 minutes (mean −1.6, range −56 to 72 minutes). While the range of these differences is wide, this plot demonstrates that, based on the 5^{th} and 95^{th} %tiles of 78 and 174 minutes, respectively (Table 2A), 37/47 (79%) were within this interval on both occasions, only 7/47 subjects were delayed (>174 minutes) on one of the 2 studies, 1/47 delayed on both occasions and 2/47 had accelerated (<78 minutes) emptying on one of their studies.

A Bland-Altman plot showed the intra-subject variation for repeat measurements in relation to the average gastric emptying $T_{1/2}$ (Figure 2). The Bland-Altman plots assessing differences in replicate results showed that delta values were similarly distributed across mean GE $T_{1/2}$ values ranging between 100 and 155 minutes; fewer patients had gastric emptying outside these values, limiting this assessment. The differences in $T_{1/2}$ values over the time between studies are shown in Figure 3. Again, the differences in $T_{1/2}$ values were consistent in repeat studies conducted between 90 and 600 days. A lower variation was observed in 10 subjects with repeat studies >1000 days apart.

Effect of Age, Gender and Body Mass Index (BMI)

Table 2 shows the data broken down by gender. There was no significant effect of age or BMI (Figure 4); however, gender was significantly associated with GE $T_{1/2}$ ($p<0.0001$) and with GE at 1 hour ($p<0.0001$) and 2 hours ($p<0.0001$).

DISCUSSION

Our results show that scintigraphic assessment of gastric emptying is reproducible over the short-, intermediate-, and long-term in healthy volunteers.

Inter-subject variation was considerable (~25%) and comparable to those previously published by Cremonini et al. (4) in a smaller cohort of 37 healthy volunteers and in other studies from our laboratory (9,10). The slightly higher COV in males is probably the result of the lower mean GE $T_{1/2}$ in males. In this study, we identified that the intra-subject COV was similar (24%) to the inter-subject COV. However, the COV_{intra} was somewhat higher than the ~13% previously reported in a small sample of healthy participants studied in our laboratory (9,10). This wider COV_{intra} has important implications in the planning of therapeutic studies, since it implies that the effect size demonstrable may be similar in parallel-group design compared to crossover studies, and the former design may be preferable as it avoids potential pitfalls such as failure of participants to complete both arms of a study and the potential confounding caused by an order effect. In summary, the current data showing that the intra-subject COV was similar to the inter-subject COV argue in favor of parallel-group studies, as the number of measurements would be only modestly greater than the number in a crossover study with the potential of showing the same effect sizes. Table 3 shows an estimate of the sample sizes per treatment group that would be required to detect effect sizes ranging from 10 to 30%. In general, a clinical benefit can be anticipated with a 20–30% difference in gastric emptying $T_{1/2}$.

Over the short- and medium-term, gastric transit parameters were reproducible within subjects, and this characteristic is also critical in planning pre- and post-treatment transit measurements to study drug effects of even up to one year's duration. Beyond about three years, our limited observations on replicate studies still show stability in the measured GE $T_{1/2}$, possibly with lower variation than with shorter durations. This is important in the planning of natural history studies, although ideally this stability would be demonstrated in disease states like gastroparesis. The literature does suggest this is the case, based on a relatively small study conducted by Jones et al. who demonstrated virtually identical gastric emptying of solids during at least 12 years' follow-up in a cohort of patients with diabetic gastroparesis (13).

Given the variation observed in gastric emptying by scintigraphy, it might be considered that other methods might prove more reproducible. However, when tested head-to-head in relatively small numbers of participants, the intra- and inter-individual variations of gastric emptying by scintigraphy and by breath test were very similar (14,15). Therefore, we perceive that the variation measured reflects the intrinsic variation in the physiological process rather than a methodological artefact. Future research with repeat studies using different techniques to measure gastric emptying, such as stable isotope breath test or wireless motility capsules, is required to address this issue.

Our current study has also shown a highly significant gender association, with gastric emptying being, on average, about 15% slower in females; the reason and mechanisms explaining the slower gastric emptying of solids in females are unclear. However, there are at least three important perspectives on the effect of gender on gastric emptying in the literature. First, increased body weight is associated with faster gastric emptying of solids and liquids (16), and the female participants had lower BMI in our study. Second, administration of sex hormones to 49 postmenopausal females randomized to receive for 7 days, 400 mg per day, micronized progesterone, 0.2 mg per day estradiol, combination of the two, or placebo showed no significant effects on gastric emptying (17). The levels of estradiol and progesterone administered were selected to mimic the physiological levels of these sex hormones, and those data suggest that sex hormones alone are unlikely to explain the slower gastric emptying observed in females. Third, in the NIH gastroparesis consortium, there is a higher prevalence of females among those with idiopathic gastroparesis, though the reason is also unclear (18).

On the other hand, there were no statistically significant effects of age (in the range 18 to 65 years) or BMI. The lack of association with BMI contrasts with the previously demonstrated associations of BMI with other motor functions such as accelerated colonic transit (19) and volume of nutrient drink intake to achieve maximum satiation (20). Our findings of a lack of association of gastric emptying with body mass are consistent with many prior studies in the literature, summarized elsewhere (21). We had also previously investigated gastric fasting and postprandial accommodation volumes in non-bulimic, asymptomatic obese subjects and observed no differences compared to normal BMI participants (22).

This study has a number of strengths, including the large sample size with the inclusion of >300 healthy volunteers. Participation in more than one study was not specifically planned through any targeted recruitment, and we believe that this cohort of 47 people self selected in a random fashion. While it is conceivable that their prior positive experience with the studies and familiarity with the research may constitute a form of bias, there were no characteristics (e.g. demographics) of this group that suggested they were different from the larger group who participated in a single study. Other potential weaknesses to consider include the retrospective manner in which data were obtained, the absence of patients with established gastric motor disorders, and the absence of patients with significantly increased BMI, as the 95^{th} %ile of the entire cohort was $37.4kg/m^2$. In addition, the observations on variation in a single center, which has standardized the procedures and has extensive experience, might be optimistic, and variation might be even greater when scintigraphic gastric emptying is used in a multicenter study.

In summary, although there is an inherent inter-individual variation of gastric emptying, these effects likely reflect true day-to-day variation in gastric function, rather than variations with the measurement technique. The degree of reproducibility allows for planning of studies to compare gastric emptying between disease groups and to demonstrate the effects of medication, thus, further validating the use of scintigraphy for assessing gastric emptying in clinical or research settings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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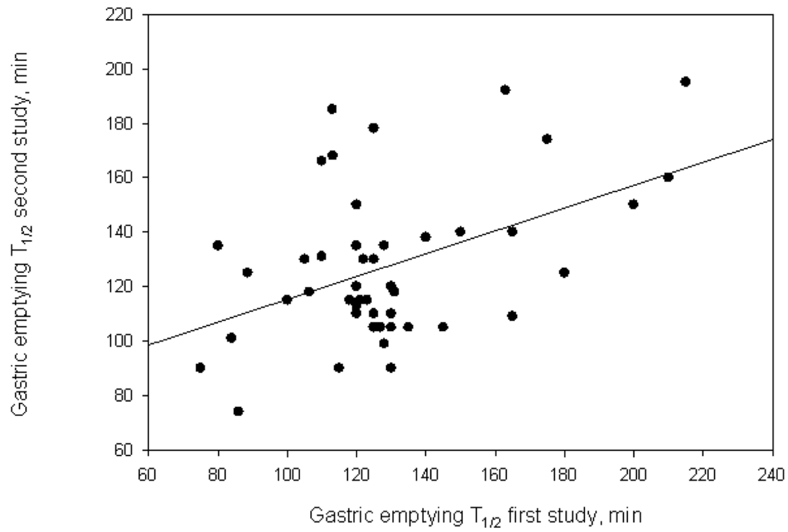

Figure 1.

Pearson correlation between first and second measurements of gastric emptying $T_{1/2}$.

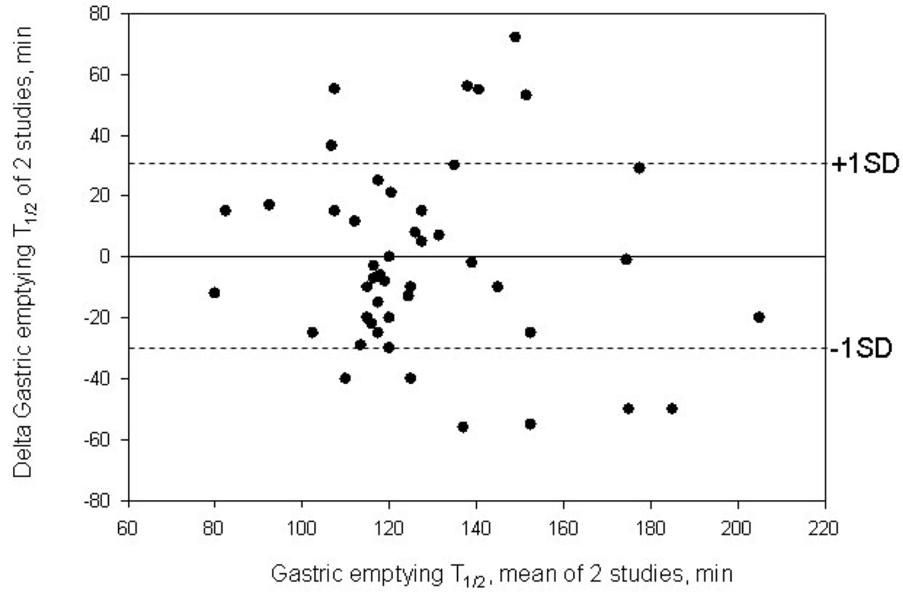

Figure 2.
Bland-Altman plots showing intra-subject variation of gastric emptying $T_{1/2}$. Plot shows 1 standard deviation as the interrupted lines. Note most data are well within 1 SD which is 30.6 min.

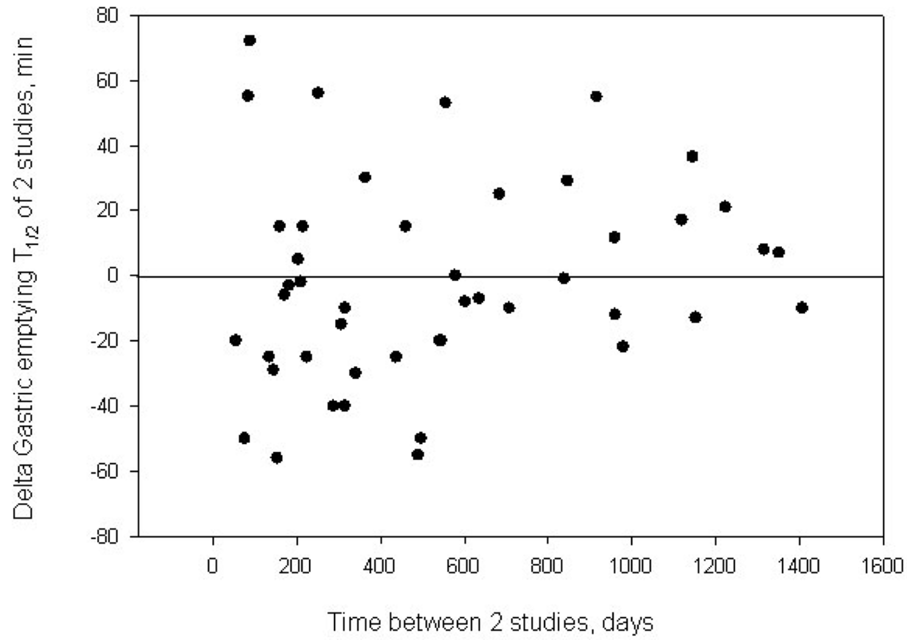

Figure 3.
Bland-Altman plots showing effect of time interval in years between consecutive measurements of gastric emptying $T_{1/2}$. There does not appear to be a difference in the variation of gastric emptying when the interval is between 90 and 500 days.

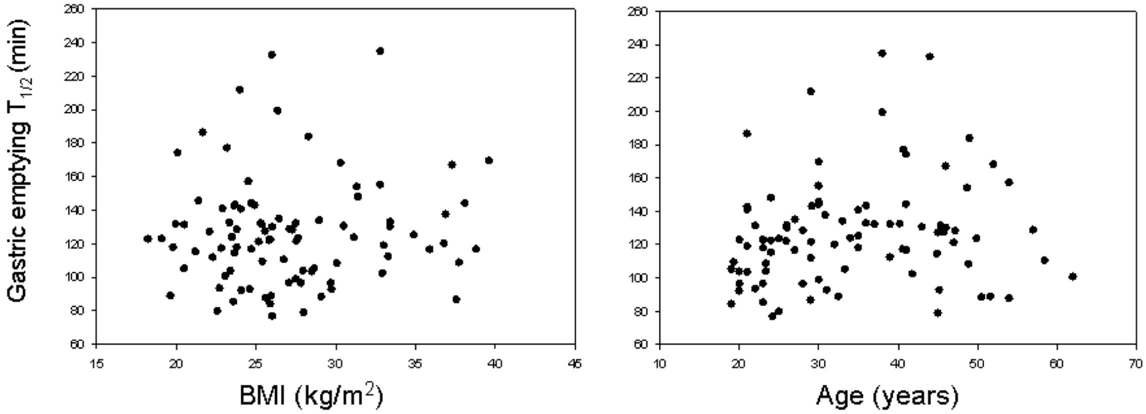

Figure 4.
Relationship of body mass index (BMI, left panel), age (right panel) and gastric emptying $T_{1/2}$. Note that no significant relationships were identified.

Table 1

Demographic Features (data show mean ± SD)

A. All participants with at least 1 measurement of gastric emptying			
	All, n=319	**Female, n=214**	**Male, n=105**
Age, y	36.2 ± 13.1	37.2 ± 12.8	34.6 ± 13.3
BMI, kg/m^2	26.9 ± 5.1	26.5 ± 5.3	27.8 ± 4.5

B. Participants with two measurements of gastric emptying						
	All, n=47		**Female, n=31**		**Male, n=16**	
	First study	**Second study**	**First study**	**Second study**	**First study**	**Second study**
Age, y	34.6 ± 11.1	36.6 ± 10.8	35.5 ± 10.6	37.7 ± 10.1	32.7 ± 12.2	34.4 ± 12.0
BMI, kg/m^2	25.4 ± 4.3	25.6 ± 4.1	24.0 ± 3.5	24.3 ± 3.0	28.1 ± 4.6	28.0 ± 4.9

Table 2

A. Values of gastric emptying at different times and inter-individual variation					
	GE $T_{1/2}$ min	GE 1h,%	GE 2h,%	GE 3h,%	GE 4h,%
All participants					
Mean ± SD	121.7 ± 29.8	18.1± 9.5	51.4 ± 15.7	78.1 ± 14.5	93.2 ± 8.9
Median (5th, 95th %ile)	120 (78.4, 174.0)	17 (4.4, 35.0)	50 (25.0, 78.5)	80 (52.0, 98.0)	96 (76.2, 100.0)
N	319	319	319	314	315
COV_{inter}, %	24.5	52.7	30..6	18.6	9.6
Females					
Mean ± SD	127.7 ± 28.7	16.5± 8.3	47.8 ± 14.3	75.3 ± 14.2	92.1 ± 9.4
Median (5th, 95th %ile)	125 (89.0, 180.0)	16 (4.3, 31.4)	47.2 (25.0, 71.0)	76 (50.0, 95.9)	94.8 (76.2, 100.0)
N	214	214	214	211	211
COV_{inter}, %	22.5	50.5	29..9	18.8	10.2
Males					
Mean ± SD	109.9 ± 28.6	21.3± 10.9	58.6 ± 15.1	83.8 ± 13.6	92.1 ± 9.4
Median (5th, 95th %ile)	105 (73.2, 165.0)	19 (4.7, 40.0)	60.0 (28.4, 82.0)	88 (55.0, 100.0)	98.3 (77.0, 100.0)
N	105	105	105	103	104
COV_{inter}, %	26.0	51.3	27..5	16.2	7.7

B. Values of gastric emptying $T_{1/2}$ on 2 repeat studies, and intra-individual variation	
All participants	
GE $T_{1/2}$ Mean ± SD	128.4 ± 25.1
Delta GE $T_{1/2}$ Mean ± SD	−1.6 ± 30.6
N	47
COV_{intra}, %	23.8
Female participants	
Mean ± SD	130.1 ± 27.2
Median (5th, 95th %ile)	−5.2 ± 38.9
N	31

B. Values of gastric emptying $T_{1/2}$ on 2 repeat studies, and intra-individual variation	
COV_{intra}, %	22.2
Male participants	
Mean ± SD	125.2 ± 20.7
Median (5^{th}, 95^{th} %ile)	5.5 ± 33.5
N	16
COV_{intra}, %	26.7

Table 3

Numbers of subjects (*based on a two-sample t-test with 80% power) needed in a two-arm study to detect various effect sizes (%) for gastric emptying $T_{1/2}$ based on mean of 122 [SD=29.8] minutes.

Effect size† (%)	Number per group* to detect listed effect size
10	84
15	36
20	21
25	13
30	9

†Effect size is the difference between groups as a percentage of the overall mean of the two groups.