

Continuous Tube Feeding Pilot Study Using Continuous Glucose Monitoring

Study Purpose

A pilot study was conducted in tube fed patients with type 2 diabetes and residing in long-term care facilities using continuous glucose monitoring to compare the extended glucose responses of

- Standard 1.2 Cal formula
- Glucerna 1.2 Cal formula

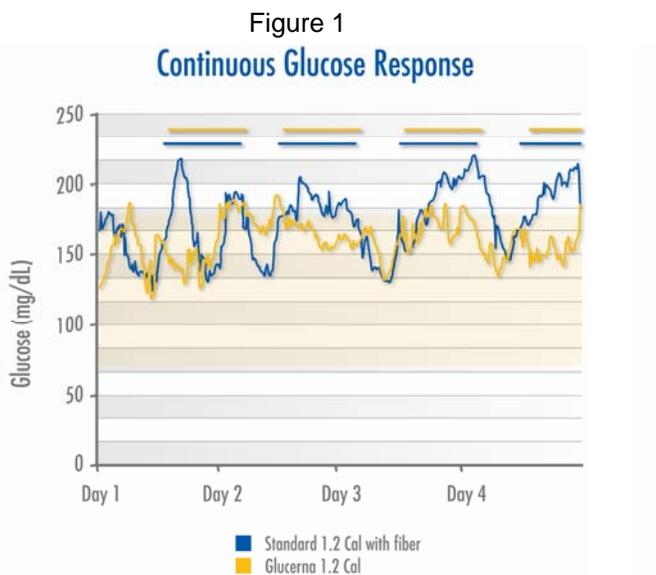
The study was conducted to compare Glucerna 1.2 Cal with a Standard 1.2 Cal/mL formula for the following measures: 1) glucose variability, assessed as the Mean Amplitude of Glycemic Excursions (MAGE), a measure of glucose variability over time; 2) mean glucose; 3) the distribution of glucose values; and 4) changes in insulin administration.

Study Design

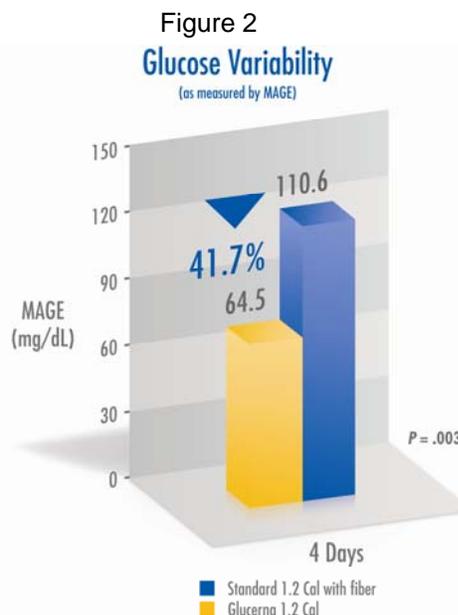
The study was a non-randomized, unblinded study conducted at three long-term care facilities. Twelve subjects (male and female) with type 2 diabetes receiving insulin were enrolled. All subjects were fed the Standard 1.2 Cal formula in the first phase using a 16-hour daily feeding schedule for 4 days. Subjects were then fed Glucerna 1.2 Cal in the second phase utilizing the same 16-hour feeding schedule for 4 days. A run-in period preceded each phase to allow subjects to acclimate to the formulas and feeding schedule. All medications were continued. Interstitial glucose was measured in each phase using continuous glucose monitoring, with one glucose measurement recorded every 10 minutes. Blood glucose levels were managed daily using bedside blood glucose monitoring and insulin was administered according to each facility's standard of practice. Results are presented as mean \pm standard error of the mean.

Results

Data were analyzed on nine subjects. Caloric consumption was equivalent between the 2 phases. The continuous glucose response graph (Figure 1) shows the average glucose over the study period for each formula. The graph also demonstrates the lower glycemic variability throughout the study while subjects were fed Glucerna 1.2 Cal compared with Standard 1.2 Cal.



Horizontal lines above line graphs represent continuous feeding



Glucose Variability: Figure 2 shows the glycemic variability (as calculated by MAGE). MAGE was significantly lower when subjects were fed Glucerna 1.2 Cal, compared with Standard 1.2 Cal overall (64.5 ± 6.8 v. 110.6 ± 15.3 mg/dL, $p = 0.003$) and for the feeding cycle (67.9 ± 11.7 v. 105.0 ± 13.2 , $p = 0.007$).

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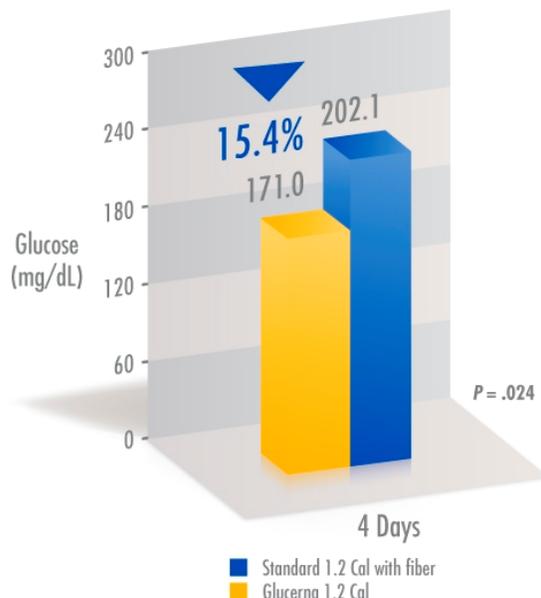
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Glucerna products are for use under medical supervision.

Data on file. Clinical Study BK07. Continuous Tube Feeding Pilot Study Using Continuous Glucose Monitoring. Abbott Nutrition, Columbus, Ohio, December 2008

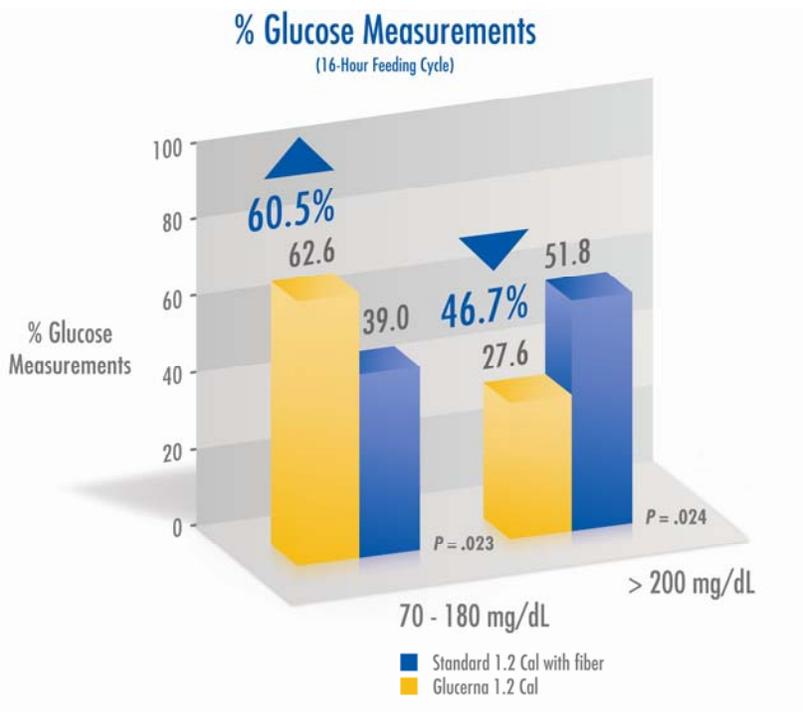
Mean Glucose: Subjects' mean glucose was significantly lower when fed Glucerna 1.2 Cal over the feeding cycle (171.0 ± 16.1 v. 202.1 ± 17.4 mg/dL, $p = 0.024$) and tended toward a lower mean glucose overall (168.0 ± 16.8 v. 186.9 ± 15.3 mg/dL, $p = 0.085$) compared with Standard 1.2 Cal.

Figure 3
Mean Glucose



Distribution of Glucose Values: During the 16-hour feeding cycle, there were 46.7% fewer hyperglycemic values (defined as glucose > 200 mg/dL) when the subjects were fed Glucerna 1.2 Cal than when fed Standard 1.2 Cal (27.6 ± 11.9 v. $51.8 \pm 11.6\%$, $p = 0.024$). In addition, there were 60.5% more glucose measures between 70-180 mg/dL during the Glucerna 1.2 Cal feeding cycle compared with Standard 1.2 Cal (62.6 ± 12.7 v. 39.0 ± 11.6 , $p = 0.023$) and no significant hypoglycemia (glucose < 70 mg/dL).

Figure 4

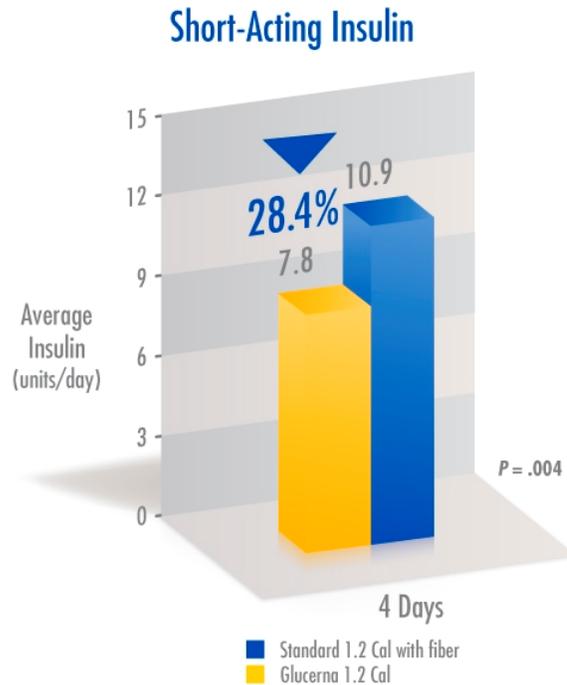


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Insulin Administration: Seven subjects received short-acting insulin either alone or in combination with intermediate- or long-acting insulin. Since the majority of subjects received short-acting insulin throughout the day, changes in the percentage of short-acting insulin were analyzed. There was a 28.4% reduction in the amount of short-acting insulin administered to subjects while they were fed Glucerna 1.2 Cal, compared to when they were fed Standard 1.2 Cal (7.8 ± 2.3 units versus 10.9 ± 3.3 units, $p = 0.004$).

Figure 5



Conclusions

This pilot study demonstrates that Glucerna 1.2 Cal improves glucose stability overall and during the feeding cycle. In addition, it shows that:

- Consuming Glucerna 1.2 Cal continuously results in a lower mean glucose compared with Standard 1.2 Cal.
- Subjects fed Glucerna 1.2 Cal had more glucose measurements between 70-180 mg/dL, experienced significantly less hyperglycemia compared with Standard 1.2 Cal, and had no significant hypoglycemia.
- Significantly less short-acting insulin was required to manage blood glucose levels with Glucerna 1.2 Cal compared with Standard 1.2 Cal.
- Both study formulas were well tolerated.

This is the third study conducted with Glucerna 1.2 Cal totaling 37 subjects. Across these three studies, the results are consistent, in that patients experience better blood glucose control compared to standard formula.

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