

# Sole Source Bolus Tube Feeding Simulation Pilot Study Using Continuous Glucose Monitoring

## Study Purpose

A sole source, bolus tube feeding simulation pilot study using continuous glucose monitoring was performed comparing:

- Standard 1.2 Cal/mL formula w/ fiber
- Glucerna 1.2 Cal/mL formula w/ fiber

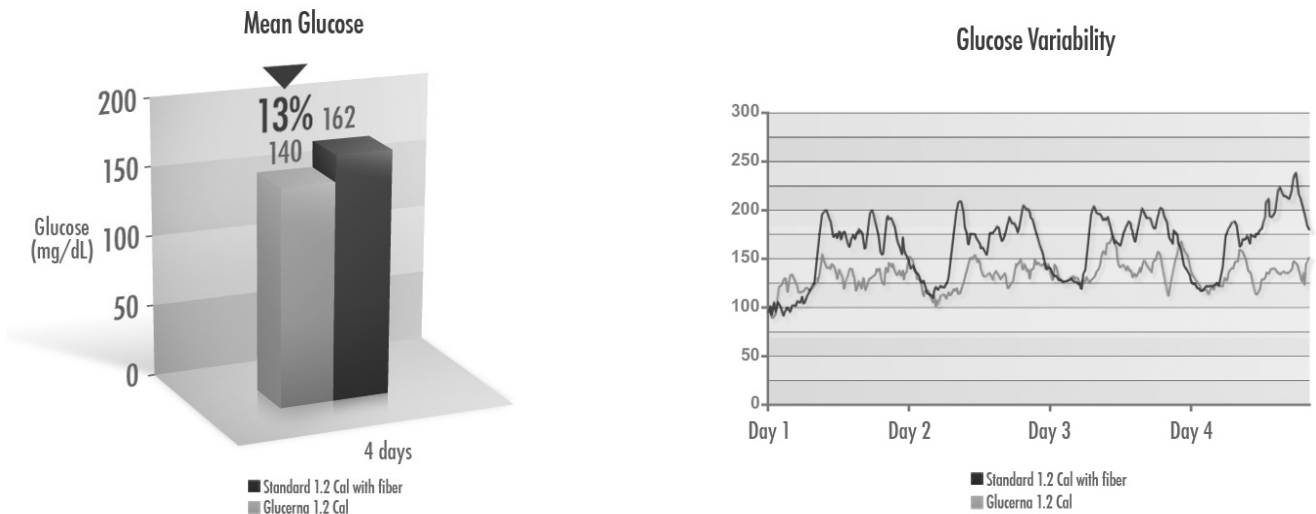
The pilot study was conducted to compare Glucerna® 1.2 Cal with a Standard 1.2 Cal/mL formula with fiber for the following: 1) mean glucose; 2) mean amplitude of glycemic excursions (MAGE). MAGE is a measure of glucose variability over time; 3) percentage of glucose readings with levels < 70, 70 to < 140, 140 to < 180, 180 to 200, and > 200 mg/dL; 4) changes in serum triglycerides; and 5) changes in urinary F<sub>2</sub>-isoprostane level to measure oxidative stress in patients with type 2 diabetes.

## Study Design

The pilot study was a randomized, prospective, double-blinded, parallel study conducted at a single site. Thirteen subjects (at least 18 years of age, male and female) were enrolled. All subjects had type 2 diabetes and were taking oral hypoglycemic agents; none were using insulin to manage blood glucose. Daily energy needs were estimated for each subject. To simulate a bolus tube feeding, each subject was instructed to orally consume either Glucerna 1.2 Cal/mL or Standard 1.2 Cal/mL formula as his or her sole source of nutrition for 4 days. Subjects were instructed to consume the same volume of study formula at each feeding, every 3 hours over a 12-h feeding cycle. Subjects avoided calorie-containing foods and beverages and vigorous exercise during the study. Subjects continued all usual medications, including oral hypoglycemic medications. Interstitial glucose was measured using continuous glucose monitoring that collected one glucose reading every 10 min. Results are presented as mean ± standard error of the mean.

## Results

Data were analyzed on 10 evaluable subjects. Caloric consumption was equivalent between the groups. The bar graphs show the mean glucose, MAGE, and percentage of glucose measurements in the specific glucose levels. The line graph shows mean glucose over the 4-d study period for both products.



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71603 MAY 2008

Glucerna products are for use under medical supervision

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Data on File. Clinical Study BK06B. Bolus Tube-Feeding Simulation Pilot Study Using Continuous Glucose Monitoring. Abbott Nutrition, Columbus, Ohio, 2008

**Mean Glucose:** Subjects consuming Glucerna 1.2 Cal/mL tended toward a lower mean glucose ( $139.7 \pm 11.0$  v.  $162.5 \pm 13.5$  mg/dL), as well as a lower mean glucose over the feeding cycle (12 h + 2 h postprandial):  $145.8 \pm 13.0$  v.  $180.7 \pm 17.3$  mg/dL (all  $p > 0.05$ ). The continuous glucose response graph demonstrates the trend that subjects consuming Glucerna 1.2 Cal/mL experienced lower glucose throughout the study compared to subjects consuming Standard 1.2 Cal/mL.

**MAGE:** Glucose variability was significantly greater in participants consuming Standard 1.2 Cal/mL ( $83.9 \pm 12.6$  mg/dL) compared with those consuming Glucerna 1.2 Cal/mL ( $45.3 \pm 5.7$  mg/dL,  $p < 0.05$ ).

Compared with Standard 1.2 Cal/mL, subjects consuming Glucerna 1.2 Cal/mL tended to spend more time in glucose levels 70 to < 140 mg/dL ( $50.0 \pm 19.5\%$  v.  $37.9 \pm 10.3\%$ ) and between 140 to < 180 mg/dL ( $41.1 \pm 16.1\%$  v.  $29.4 \pm 6.4\%$ ) and less time in hyperglycemia (180-200 mg/dL:  $7.3 \pm 5.2\%$  v.  $9.5 \pm 2.7\%$ ) and > 200 mg/dL ( $1.4 \pm 1.4\%$  v.  $23.0 \pm 11.4\%$ ) (all  $p > 0.05$ ).

**Serum Triglycerides:** Serum triglycerides tended to decrease in subjects consuming Glucerna 1.2 Cal/mL compared with Standard 1.2 Cal/mL ( $-28.3 \pm 15.3$  v.  $29.0 \pm 28.7$  mg/dL,  $p > 0.05$ ).

**Oxidative Stress:** Changes in urinary F<sub>2</sub>-isoprostane levels were greater for Glucerna 1.2 Cal/mL v. Standard 1.2 Cal/mL ( $-0.4 \pm 0.2$  v.  $-0.1 \pm 0.1$  ng/mg creatinine,  $p > 0.05$ ), which indicated an improvement in oxidative stress.

Both products were well tolerated, and no safety concerns were noted that related to either study formula.

### Conclusions

This pilot study shows that Glucerna 1.2 Cal/mL improves mean glucose levels and overall glucose stability compared with Standard 1.2 Cal/mL. Subjects consuming Glucerna 1.2 Cal/mL spent more time in target glucose ranges (70 - < 180 mg/dL) without significant hypoglycemia and less time in hyperglycemia than participants consuming Standard 1.2 Cal/mL.

This pilot is the first study to report the beneficial effects of consuming a diabetes-specific formula, like Glucerna 1.2 Cal/mL on oxidative stress, which is believed to be a key factor involved in the onset of vascular disease. In addition, this pilot study is the first to capture continuous glucose responses in a simulated bolus tube feeding regimen.

