HYPOCALORIC HIGH-PROTEIN ENTERAL NUTRITION IMPROVES GLUCOSE MANAGEMENT IN CRITICALLY ILL PATIENTS

1Nestlé Health Science, Florham Park, NJ; 2Wake Forest University, Winston Salem, NC; 3Kingston Hospital, Kingston, Ontario, Canada; 4University of Kentucky, Lexington, KY; 5Emory University, Atlanta, GA; 6University of Chicago, Hinsdale, IL; 7Regions Hospital, St Paul, Minnesota; 8Nestec, Lausanne, Switzerland; 9Cognizant, London, United Kingdom; 10Vanderbilt University, Nashville, TN

BACKGROUND & OBJECTIVES
• Hyperglycemia in critically ill patients is associated with increased morbidity, mortality, length of hospital stay, utilization of health care resources, and cost. Approximately 46% of patients admitted to the ICU in the United States have hyperglycemia in the first 24 hours of admission1. The NICE Sugar study illustrated more than 80% of patients in the ICU experience hyperglycemia2. Approximately 20-27% percent of these patients have a previous diagnosis of diabetes mellitus3,4. Carbohydrate restriction has been utilized as a means to improve glucose control in critically ill patients. Quantity and perhaps type of protein also appears to play a role in glucose management.
• The objective of this study was to compare blood glucose control with a hypocaloric, high protein enteral tube feeding formulation versus a normocaloric, high protein formulation in overweight or obese ICU patients. We present here a preliminary analysis of the intention to treat data.

METHODS

Population:
• Prospective, randomized, open label multicenter clinical trial, mechanically ventilated critically ill, obese and overweight subjects requiring enteral nutrition
• 7 academic medical centers

Intervention:
• Random assignment:
  • Hypocaloric group, which utilized Peptamen Intense VHP, a very high protein, low carbohydrate formula
  • Normocaloric group, which utilized Replete.
• Assigned formula was delivered a target protein level of 1.5 g/kg ideal body weight.

MEASURES:
• Primary endpoint: Number of glycemic events in the first 7 ICU days >150 mg/dL or <110 mg/dL
• Serial blood glucose concentrations, markers of nutritional status and inflammation, insulin and dextrose

Statistics:
• Sample size of 100 subjects per arm calculated based on the primary endpoint
• An interim analysis was undertaken when 40 subjects completed at least five days of data collection. Preliminary data are presented here.

DEMOGRAPHICS
• Ninety eight subjects were randomized into the study at the time of interim analysis.
• 40 had at least five days of data collected.
• The remaining subjects withdrew primarily due to removal of the feeding tube.

PRELIMINARY RESULTS

Glucose:
• There was no significant difference between groups in glucose variability in the blood glucose range of 110-150 mg/dL.
• Mean glucose level was significantly lower in the hypocaloric group (128 [114, 143] vs. 140 [125, 158], p = 0.0443)
• Mean daily glucose levels were significantly lower in the hypocaloric group on days 2, 3 and 4 (p<0.05; Figure 1).
• Subjects receiving the hypocaloric formulation had significantly more blood glucose levels between 81-110 mg/dL and significantly less values <150 mg/dL (Figure 2).
• There was no significant difference in hypoglycemia (blood glucose <81 mg/dL) between groups.

PRELIMINARY RESULTS

Figure 1: Mean Daily Glucose

Figure 2: Blood Glucose Distribution (Number of glucose values in range)

Insulin:
• There was a significant decrease in the incidence of insulin administration in the hypocaloric group (delta = -12%, p = 0.044).

Adverse Events:
• There was one death in the hypocaloric group and six in the normocaloric group (p>0.11). None were product related.

CONCLUSION

These preliminary study results suggest that a hypocaloric diet with a very high protein and low carbohydrate formula can facilitate blood glucose management by decreasing episodes of hyperglycemia, decreasing insulin utilization and normalizing blood glucose levels in adult critically ill patients.

Presented at Clinical Nutrition Week, Orlando, FL. Poster prepared by Maureen Huhmann a Nestlé employee. Sponsored by Nestlé Health Science. Nestlé® is a registered trademark of Société des Produits Nestlé S.A., Vevey, Switzerland.