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

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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 admission[1]. The NICE Sugar study illustrated more than 80% of patients in the ICU experience hyperglycemia[2]. Approximately 20-27% percent of these patients have a previous diagnosis of diabetes mellitus[2,3]. 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.

	Peptamen® Intense VHP	Replete®
Caloric Density	1.0 Kcal/mL	1.0 Kcal/mL
Protein (% energy)	92 g/L (37%)	64 g/L (25%)
Carbohydrate (% energy)	76 g/L (29%)	112 g/L (45%)
Fat (% energy)	38 g/L (34%)	34 g/L (30%)

1. Badawi et al. *Crit Care Med* 2012; 40:3180–3188 **2.** The NICE-SUGAR Study Investigators. *N Engl J Med* 2009;360:1283-97. 3. Carpenter et al. *Crit Care Med* 2015; 43:e541–e550

METHODS

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.

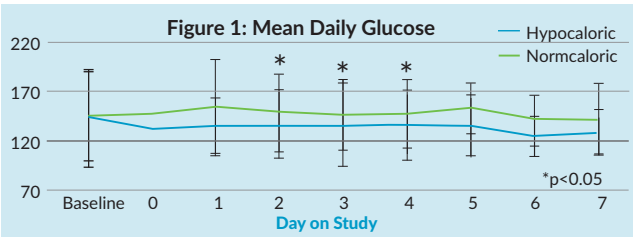
	Hypocaloric	Normocaloric
Age	60.7 ± 15.1	62.6 ± 12.1
BMI (kg/m2)	33.7 ± 4.6	32.5 ± 5.7
Female	21 (42.9%)	27 (55.1%)
APACHE II Score	25.1 ± 9.0	26.3 ± 9.2
Protein Goal (g/day)	95.2 ± 17.8	92.8 ± 18.8

PRELIMINARY RESULTS

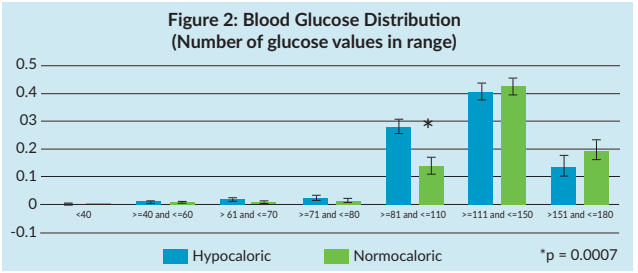
Glucose:

- 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 <81mg/dL) between groups.

PRELIMINARY RESULTS



Mean Nutritional Intake	Hypocaloric	Normocaloric
Energy (kCal/Kg IBW)	12.1 ± 4.2	16.8 ± 6.6
Protein (g/Kg IBW)	1.12 ± 0.4	1.05 ± 0.4
Carbohydrate (g/day)	59.1 ± 23.9	117.7 ± 51.4
Fat (g/day)	28.8 ± 11.7	35.7 ± 15.6



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.

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