

Dietary Management of Blood Glucose in Medical Critically Ill Overweight and Obese Patients: An Open-Label Randomized Trial

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Objectives:

The purpose of this study was to test whether an enteral nutrition (EN) formula with very high protein and low carbohydrate (CHO) content can facilitate glucose control and deliver higher protein concentrations within a hypocaloric feeding protocol.

Background:

Stress hyperglycemia is not uncommon in critically ill patients. Exogenous insulin administration is the primary treatment for stress hyperglycemia, though often associated with side effects. Use of an EN formula containing higher protein and lower CHO may facilitate blood glucose control through decreasing hyperglycemic events and reducing insulin utilization.

Materials and Methods:

This was a multicenter, randomized, open-label clinical trial with parallel design. Patients were eligible if mechanically ventilated, critically ill, BMI >25 and requirement for EN >5 days. Exclusion criteria was history of surgery, trauma, Type 1 diabetes mellitus, diabetic ketoacidosis, pregnancy and requirement for PN.

Patients were randomized to study EN (37% protein, enzymatically hydrolyzed 100% whey protein, 29% CHO) or isonitrogenous control (25% protein, standard polymeric sodium caseinate, 45% CHO). Both diets provided 1 kcal/mL. EN was initiated within 48 hours of admission into the study. Protocol was to provide identical protein, not calories

Results:

Study participants consisted of 102 subjects with intent to treat analysis, mean age of 62 years, BMI 33 and HgbA1c 6.1. Findings were as follows:

• Nutrition Intake Days 1–5

- Protein intake was similar at 1.2 ± 0.4 and 1.1 ± 0.3 g/kg ideal body weight/day for control and experimental study EN groups respectively ($p=.83$).
- Significant difference in total energy intake between groups: control 18.2 ± 6.0 versus experimental 12.5 ± 3.7 kcal/kg IBW/day ($p<.0001$).

- Significant difference in CHO provision between groups: control 126 ± 22 g/day versus experimental 61 ± 22 g/day ($p<.0001$).

• Primary Endpoints

- No statistical difference between the mean rate of glycemic events outside the range of >110 and <150 mg/dL in the first seven days in control versus experimental groups.

• Secondary Endpoints

- Decrease in mean blood glucose in the experimental group: control 138 mg/dL and experimental 126 mg/dL ($p=.004$)
- Decrease in mean rate of glycemic events >150 mg/dL in experimental group ($p=0.15$)
- Increase in normal glycemic events of 80–110mg/dL in experimental group ($p=.0007$)
- Decrease in insulin administration in the experimental group ($p=0.048$); average daily insulin dosage in control versus experimental group was 52.9 ± 93.2 versus 43.8 ± 95.8 units/day, respectively, representing a 10.9% decrease ($p=.25$)

Discussion:

Hyperglycemia is associated with poor clinical outcomes. Problems associated with standard enteral nutrition provision has prompted exploration of alternative nutrition therapies. Changing the composition of the macronutrients in EN may lead to improvement in nitrogen retention and glucose control.

Conclusions:

Use of a very high protein, enzymatically hydrolyzed 100% whey, lower CHO EN formula was related to decreased hyperglycemic events and insulin requirements in critically ill overweight/obese patients in a medical ICU.

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