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

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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 enteral nutrition (EN) formula containing very high-protein- and low-carbohydrate (CHO) may facilitate blood glucose control through decreasing hyperglycemic events and reducing insulin utilization.

Objective
To investigate whether an EN formula with very high protein and low CHO content can facilitate glucose control and deliver higher protein concentrations within a hypocaloric feeding protocol.

Subjects and Methods
This was a multicenter, randomized, open-label clinical trial with parallel design.
Inclusion criteria: Mechanically ventilated, critically ill, BMI >25 and requirement for EN >5 days.
Exclusion criteria : History of surgery, trauma, Type 1 diabetes mellitus, diabetic ketoacidosis, pregnancy and need for PN.

Patients were randomized to study EN (37% protein, enzymatically hydrolyzed 100% whey protein, 29% CHO) or isonitrogenous control EN (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
  - No significant difference in protein intake between control and experimental groups (1.2 ± 0.4 and 1.1 ± 0.3g/kg ideal body weight/day respectively) (p=0.83).
  - Significant difference in total energy intake between groups: control 18.2 ± 6.0 versus experimental 12.5 ± 3.7 kcal/kg IBW/day (p<0.0001).
  - Significant difference in CHO provision between groups: control 126 ± 22 g/day versus experimental 61 ± 22 g/day (p<0.0001).
- **Primary Endpoint:**
  - No statistical difference between the mean rate of glycemic events outside the range of 6.1 - 8.3 mmol/L in the first seven days in control versus experimental groups.
- **Secondary Endpoints**:
  - Decrease in mean blood glucose in the experimental group: control 7.7 mmol/L and experimental 7 mmol/L (p=0.004)
  - Decrease in mean rate of glycemic events >8.3 mmol/L in experimental group (p=0.15)
  - Increase in normal glycemic events of 4.4-6.1 mmol/L in experimental group (p=0.0007)
  - Decrease in insulin administration by 10.9% 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 (p=0.25)

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.

Conclusion
Use of a very high protein (37%), enzymatically hydrolyzed 100% whey, low CHO (29%) 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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