

4.2(c) Composition of Enteral Nutrition: High Protein vs. Low Protein

January 31st, 2009

Recommendation:

There are insufficient data to make a recommendation regarding the use of high protein diets for head injured patients and other critically ill patients.

Discussion: The committee noted the lack of treatment effect with respect to both mortality and infectious complications from 1 small study in head injured patients. Given this and the concerns regarding cost, the committee decided against a recommendation. The committee agreed that given the choice of a lower protein control formula, this study should not be added to the High Fat/Low CHO section (4.2 (a)).

Values	Definition	Score: 0, 1, 2, 3
Effect size	Magnitude of the absolute risk reduction attributable to the intervention listed--a higher score indicates a larger effect size	0
Confidence interval	95% confidence interval around the point estimate of the absolute risk reduction, or the pooled estimate (if more than one trial)--a higher score indicates a smaller confidence interval	1
Validity	Refers to internal validity of the study (or studies) as measured by the presence of concealed randomization, blinded outcome adjudication, an intention to treat analysis, and an explicit definition of outcomes--a higher score indicates presence of more of these features in the trials appraised	2
Homogeneity or Reproducibility	Similar direction of findings among trials--a higher score indicates greater similarity of direction of findings among trials	1
Adequacy of control group	Extent to which the control group represented standard of care (large dissimilarities = 1, minor dissimilarities=2, usual care=3)	3
Biological plausibility	Consistent with understanding of mechanistic and previous clinical work (large inconsistencies =1, minimal inconsistencies =2, very consistent =3)	2
Generalizability	Likelihood of trial findings being replicated in other settings (low likelihood i.e. single centre =1, moderate likelihood i.e. multicentre with limited patient population or practice setting =2, high likelihood i.e. multicentre, heterogeneous patients, diverse practice settings =3.	1
Cost	Estimated cost of implementing the intervention listed--a higher score indicates a lower cost to implement the intervention in an average ICU	2
Feasible	Ease of implementing the intervention listed--a higher score indicates greater ease of implementing the intervention in an average ICU	2
Safety	Estimated probability of avoiding any significant harm that may be associated with the intervention listed--a higher score indicates a lower probability of harm	2

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Question: Compared to a lower protein enteral formula (14% calories from protein), does a higher protein enteral formula (22% calories from protein) result in better outcomes in the critically ill adult patient?

Summary of evidence: There was one level 2 study that compared the effect of a higher protein formula i.e. Traumacal to a lower protein formula i.e. Magnacal in head injured patients.

Mortality: There were no differences in mortality between the groups.

Infections: There were more bacterial infections in the group receiving the higher protein formula but this was not statistically significant (Relative Risk 1.50, 95 % confidence Intervals 0.32, 7.1)

LOS: Not reported.

Ventilator days: Not reported.

Other: Nitrogen balance was higher in the higher protein group but this was not statistically significant.

Conclusions:

- 1) A higher protein formula has no effect on mortality and infectious complications in head injured patients.

Level 1 study: if all of the following are fulfilled: concealed randomization, blinded outcome adjudication and an intention to treat analysis.

Level 2 study: If any one of the above characteristics are unfulfilled

Table 1. Randomized Studies Evaluating Higher Protein vs. Low Protein Enteral Formula in Critically ill Patients

Study	Population	Methods (score)	Intervention	Mortality # (%)		RR (CI)**	Infections # (%)		RR (CI)**
				High protein	Low protein		High protein	Low protein	
1) Clifton 1985	Head injured patients Comatose for 24 hrs N= 20	C.Random: not sure ITT: yes Blinding: no (8)	22% pro, 38 % CHO, 41 % fat, 1.5 Kcal/ml (Traumacal vs. 14 % pro, 50 % CHO, 36 % fat, 2.0 Kcal/ml (Magnacal) Isocaloric, 29 gm Nitrogen vs.17.6 gms Nitrogen	1/10 (10)	1/10 (10)	1.00 (0.07-13.9)	3/10 (30)	2/10 (20)	1.50 (0.32, 7.1)

C.Random: concealed randomization
ITT: intent to treat
NR: Not reported

± : mean ± standard deviation
** RR= relative risk, CI= Confidence intervals

TOPIC: 4.2 (a) Composition of EN: High Protein vs. Low Protein
(Reviewers: Voula Christofilos, Christine McCleary)

Article inclusion log

Criteria for study selection

Type of study: RCT or Meta-analysis
Population: critically ill, ventilated patients (no elective surgery patients)
Intervention: TPN and /or EN
Outcomes: mortality, LOS, QOL, functional recovery, complications, cost. Exclude studies with only biochemical, metabolic or nutritional outcomes.

	Author	Journal	I	E	Why Rejected
1	Clifton	J. Neurosurgery 1985	√		
2	Twyman	JPEN 1985		√	No clinical outcomes

I = included, E = excluded

References

1. Clifton GL, Robertson CS, Contant CF. Enteral hyperalimentation in head injury. *J Neurosurgery* 1985;62:186-193.
2. Twyman D, Young AB, Ott L, Norton JA, Bivins BA. High protein enteral feedings: a means of achieving positive nitrogen balance in head injured patients.. *JPEN J Parenter Enteral Nutr.* 1985 Nov-Dec;9(6):679-84.