

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

June 28th, 2005

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, +, ++, +++ |
|---------------------|---|----------------------|
| 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 | similar direction of findings among trials--a higher score indicates greater similarity of direction of findings among trials | 1+ |
| Safe | 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+ |
| Feasible | ease of implementing the intervention listed--a higher score indicates greater ease of implementing the intervention in an average ICU | 2+ |
| Cost | estimated cost of implementing the intervention listed--a higher score indicates a lower cost to implement the intervention in an average ICU | 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 | |
| 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
NA: not available

± : 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

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| 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. |

| ID # | Author | Journal | I | E | why rejected |
|------|---------|----------------------|---|---|--------------|
| 1. | Clifton | J. Neurosurgery 1985 | √ | | |
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I = included, E = excluded

References

1. Clifton GL, Robertson CS, Contant CF. Enteral hyperalimentation in head injury. Journal of Neurosurgery 62:186-193 1985