

4.5 Composition of Enteral Nutrition: Fibre

January 31st, 2009

Recommendation:

There are insufficient data to support the routine use of fibre (pectin or soy polysaccharides) in enteral feeding formulas in critically ill patients.

Discussion: The committee noted the lack of a treatment effect with wide confidence intervals demonstrated by the 5 studies on soluble fibre and the one study on soy polysaccharides. Cost, feasibility and safety were not a concern.

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 (diarrhea)
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	3
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)	1
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	3
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: Do enteral feeds with fibre, compared to standard feeds result in better outcomes in the critically ill adult patient?

Summary of evidence: There were 6 level 2 studies reviewed, 5 looked at the effects of soluble fibres (Schultz 2000: pectin; Spapen 2001, Rushdi 2005 :hydrolyzed guar; Heather 1988 psyllium; Hart 1988: psyllium) and 1 study (Dobb) examined the effects of a formula containing soy polysaccharide (mainly insoluble fibre)

Mortality: Only one study reported mortality and found no difference between the groups.

Infections, LOS: There were no differences found between the groups.

Ventilator days: Not studied as an outcome

Other complications: No differences were seen in diarrhea between the groups receiving the fibre/pectin feeds (Jevity plus or Nepro + pectin) compared with placebo. Only in one study (Spapen), soluble fibre (hydrolyzed guar) was significantly associated with fewer diarrhea days ($p < 0.001$) and fewer # of patients with diarrhea (RR 0.50, CI 0.27- 0.93). Two studies did not report on the # patients with diarrhea and could not be included in the analysis. When the remaining 3 studies on soluble fibre were aggregated, there was no difference in # of patients with diarrhea between the groups (RR =0.79, 95% CI 0.43-1.45, $p = 0.4$) (see figure 1). Soy polysaccharide containing formula (Enrich) had no effect on diarrhea.

Conclusions:

- 1) No differences in diarrhea found between the groups receiving the formula containing soy polysaccharide or standard formula.
- 2) No difference in diarrhea between standard formula and formulas containing soluble fibre.

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 enteral feeds with fibre in critically ill patients

Study	Population	Methods (score)	Intervention	Mortality # (%)†		RR (CI)**	Infections # (%)‡		RR (CI)**
				Fybogel	Standard		Fybogel	Standard	
1. Hart 1988	ICU patients N = 68	C.Random: not sure ITT: yes Blinding: single (9)	Standard formula (Osmolite HN) + Fybogel vs. Standard formula (Osmolite HN) + placebo	NR	NR	NR	NR	NR	
2. Dobb 1990	ICU patients N = 91	C.Random: yes ITT: no Blinding: double (10)	Formula with soy polysaccharide (Enrich) vs Standard (Ensure)	NR	NR	NR	NR	NR	NR
3. Heather 1991	ICU CCU, general wards(ICU 41/49) Nutritionally compromised N = 49	C.Random: not sure ITT: no Blinding: no (3)	Standard formula (fibre free) + Hydrocil (psyllium) vs. Standard formula (fibre free)	NR	NR	NR	NR	NR	NR
4. Schultz 2000	Critically ill patients receiving antibiotics N = 80	C.Random: yes ITT: no Blinding: double (10)	(A) Fibre/pectin vs (B) Fibre free/pectin vs (C) Fibre/placebo (D) Fibre free/placebo	NR	NR	NR	NR	NR	NR
5. Spapen 2001	Patients with severe sepsis, septic shock, ventilated N = 35	C.Random: yes ITT: no Blinding: double (11)	Formula with soluble fibre (partially hydrolyzed guar) vs No fibre (standard)	Soluble fibre 1/13 (8)	Standard 4/12 (33)	0.23 (0.03-1.79)	Soluble fibre 13/13 (100)	Standard 12/12 (100)	NR
6. Rushdi 2005	ICU patients N = 30	C.Random: yes ITT: no Blinding: double (8)	Standard formula (Sandosource) + soluble Guar gum (Benefibre) vs. Fibre-free formula (Propeptide)	Benefibre NR	Standard NR	NR	Benefibre NR	Standard NR	NR

Table 2. Randomized studies evaluating enteral feeds with fibre in critically ill patients

Study	LOS days				Other				RR (CI)**
1. Hart 1988	Fybogel	Standard			Fybogel	Standard			0.94 (0.62,1.44)
	NR	NR			# Patients with diarrhea 19/35 (54)	19/33 (58)			
2. Dobb 1990	Enrich	Standard			Enrich	Standard			1.26 (0.69-2.31)
	NR	NR			Diarrhea 16/45 (36)	13/46 (28)			
3. Heather 1991	Psyllium	Standard			Psyllium	Standard			NR
	NR	NR			Stool consistency 3.29	2.24			
4. Schultz 2000	(A)	(B)	(C)	(D)	(A)	(B)	(C)	(D)	(A)+(B) vs (D)* 2.50 (0.33-18.9)
	Hospital	33.8 ± 22.1	22.4 ± 9	42.8 ± 3.3	34 ± 14.7	1/11 (9)	4/11 (36)	6/11 (55)	1/11 (9)
5. Spapen 2001	Soluble fibre	Standard			Soluble fibre	Standard			0.50 (0.27-0.93)
	ICU	19 (11-51)	17 (10-30)			# Patients with diarrhea 6/13 (46)	11/12 (92)		
6. Rushdi 2005	Benefibre	Standard			Benefibre	Standard			p <0.01
	NR	NR			# Liquid stools Day 4 1.0	2.1			
					# Liquid stools Day 1 1.0	1.2			

C. Random: Concealed randomization

† Presumed ICU mortality unless otherwise specified

‡ Refers to the # of patients with infections unless specified** RR= relative risk

ITT: Intent to treat

NR: Not reported

CI: Confidence intervals

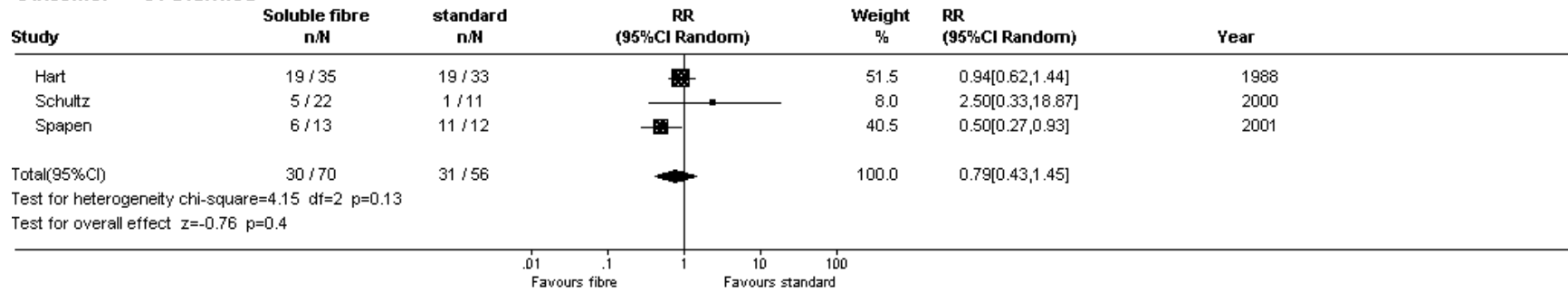
* Compared (A) + (B) to (D) for effect of pectin to placebo

*** Compared (A) + (C) to (D) for effect of fibre to placebo

Figure 1.

Comparison: 01 Soluble fibre vs. standard

Outcome: 01 Diarrhea



TOPIC: 4.5 Composition of EN: Fibre

Article inclusion log

Criteria for study selection

Type of study: RCT or Meta-analysis
Population: critically ill, ventilated patients (no elective surgery patients)
Intervention: 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	Hart	JPEN 1988	√		
2	Frankenfield	Am J Clin Nutr 1989		√	Crossover RCT
3	Dobb	Intensive Care Med 1990	√		
4	Heather	Heart and Lung 1991	√		
5	Borlase	Surgery, Gyn Obs 1992		√	Surgery pts
6	Levinson	Anaesth Intensive Care 1993		√	No clinical outcomes
7	Homann	JPEN 1994		√	Not ICU pts
8	Khalil	Singapore Med J 1998		√	Not ICU pts
9	Schultz	Am J Crit Care 2000	√		
10	Spapen	Clinical Nutrition 2001	√		
11	Rayes	Nutrition 2002		√	Surgery pts
12	Rayes	Transplantation 2002		√	Surgery pts
13	Rushdi	Clin Nutr 2004	√		
14	Homann	Clin Nutr Suppl 2004		√	Only 30% pts were ICU patients (acc to author)
15	Yang	World J Gastroenteral 2005		√	Meta-analysis, Individual studies looked at
16	Schneider	Clin Nutr 2006		√	Crossover study
17	Fussell	20 th Clinical Congress Abstracts		√	Surgery pts

I = included, E = excluded

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