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Techniques, Materials, Devices

Is There a Difference in Metabolic Outcome Between Different Enteral Formulas?

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ABSTRACT. *Background:* Despite appropriate enteral nutrition, many elderly patients do not reach a good metabolic outcome. Two nutrition formulas are commonly used in Israel with no evidence-based medicine to indicate preference of one over the other. *Methods:* We describe a 2-month observational study of patients fed by 1 of the 2 formulas. The first (Osmolite, Abbott Company, Abbott Park, IL) is without fiber, and the second (Easy Fiber, Easyline Company Givataim, Israel) in addition to containing fiber is also richer in protein, vitamins, and minerals. The formula was selected by the primary care physician before enrollment in the study and was not influenced by the investigators. Routine blood tests as well as body weight were monitored at the start of enteral feeding and during the 2 months following as part of the regular follow-up. *Results:* Fifty-seven patients were fed with the regular formula and 77 with the enriched one. No statistically significant differences were noted between the groups during the follow-up period, in body weight, cholesterol levels, total lymphocyte count, renal function tests, or electrolyte balance. However, in the enriched formula group there was a significant decrease in glucose ($p < .05$), and increase in albumin ($p < .05$) and hemoglobin ($p = .01$) levels. *Conclusions:* Enteral feeding with enriched formula appears to improve albumin and hemoglobin levels as well as diabetic control, thus it may be more appropriate than the nonfiber diet for use in long-term care patients. (*Journal of Parenteral and Enteral Nutrition* **31:**320–323, 2007)

Enteral nutrition is the treatment of choice for patients who cannot maintain sufficient oral intake but have a functional gastrointestinal tract. This makes it particularly common in the elderly (over 65), which comprised about 13% of the U.S. population in 2000 and is expected to reach 20% by 2030.[1] During the last decade, the number of enterally fed patients has doubled in the United States, and this trend is expected to continue in the next decade.[2,3]

Elderly patients are more vulnerable to nutrition deprivation and undernutrition, reaching 65% in long-term care homes and 58% in general hospitals,[4] increasing their morbidity and mortality.[5]

In a search of the English literature, we found few studies about the metabolic outcome of patients fed by enteral tube feeding. Metabolic outcome was defined as clinical and laboratory variables that are considered as predicting the nutrition status of the patient (eg, weight changes, improvement in blood albumin levels).

After a survey of the literature revealed a dearth of studies on the subject, we set out to observe and compare the metabolic outcome of 2 enterally applied nutrition formulas for a period of 2 months. Two nutrition formulas are used in Israel, with no evidence-based medicine to prefer one over the other.

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MATERIALS AND METHODS

One hundred seventy residents of 6 long-term care facilities in Israel who met the study entry criteria were enrolled in the study. Inclusion criteria were age over 65 years, total tube feeding (percutaneous endoscopic gastrostomy and nasogastric tubes; Table I) for the first time in their lives by 1 of the 2 nutrition formulas described below, at least 8 weeks of continuous tube feeding after enrollment, and availability of blood tests before entering the study and again 8 weeks later. The first formula, Osmolite HN from Ross

Table I
Baseline characteristics of patients in both groups (%)

	Easy Fiber	Osmolite	p Value
Number of patients	80	59	
Age (average, y)	80.8	77.9	.20
Men	19 (24)	12 (20)	.70
NG tube	68 (49)	43 (31)	.60
PEG	12 (8.6)	16 (11)	.80
Volume of formula (average)	1478 mL	1434 mL	
Weight (average, kg)	54 ± 10	59 ± 12	.02
Reason for enteral feeding			
Dysphagia	24 (30)	23 (39)	.30
Feeding difficulties	40 (50)	30 (51)	.90
Aspirations	6 (7.5)	5 (8.5)	.30
Coma	5 (6.3)	7 (12)	.40
Weight loss	9 (11)	4 (6.7)	.70
Other diagnoses			
Dementia	22 (28)	17 (29)	.90
Diabetes mellitus	18 (23)	14 (24)	.70
Sore wounds	26 (33)	13 (22)	.20

NG, nasogastric; PEG, percutaneous endoscopic gastrostomy.

TABLE II
Composition of the 2 study formulas

Ingredients	Easy Fiber/100 mL	Osmolite/100 mL
Calories (kcal)	110	106
Protein, g	4.4	3.7
Protein source	Sodium and calcium caseinates	Sodium and calcium caseinates, 84% Soy protein, 16%
Total carbohydrate, g	15.1	14.5
Carbohydrate source	Maltodextrin from corn, 87% Soy polysach, 13%	Hydrolyzed corn starch
Dietary fiber, g	1.4	None
Dietary fiber source	Soy fibers	None
Total fats, g	3.5	3.8
Total fats source	Canola oil, 80% MCT, 20%	High oleic staff oil, 50% Canola, 30% MCT, 20%
Vitamin K, mcg	5.4	4.3
Vitamin E, IU	3.4	2.4
Vitamin D, IU	30.3	21
Vitamin C, mg	22.6	16
Vitamin B_3 niacin, mcg	2.2	2
Vitamin B_1 thiamine, mcg	172	160
Vitamin B_2 riboflavin, mcg	194	181
Vitamin B_6 pyridoxine, mcg	227	211
Vitamin B_5 pantothenic ac., mcg	1.13	1.1
Vitamin A, IU	376	264
Vitamin B_{12} covalamin, mcg	0.71	0.64
Biotin, mcg	34	32
Choline, mg	45	32
Folic acid, mcg	45	42
Calcium, mg	90	53
Chloride, mg	72	84
Iron, mg	1.35	0.96
Iodine, mcg	11.3	8
Potassium, mg	156	101
Phosphorus, mg	75	53
Magnesium, mg	30	21
Sodium, mg	92	64
Zinc, mg	1.6	1.2
Selenium, mcg	5.4	3.8
Manganese, mg	0.37	0.26
Copper, mcg	0.15	0.11
Molybdenum, mcg	11	8
Chromium, mcg	7.5	6.4
100% DRI	1100 mL/1210 kcal	1887 mL/2000 kcal
Osmolality mosm/kg, H_2O	300	300
Water ml/L	800	841

DRI, dietary reference intakes; MCT, medium-chain triglycerides.

(Abbott Laboratories, Abbott Park, IL), is fiber free, and the second, Easy Fiber (EasyLine Company Ltd, Givataim, Israel), in addition to being enriched with fiber of soy origin, is also rich in protein, vitamins, and minerals (Table II). Osmolite meets 100% of the dietary reference intakes (DRI) for vitamins and minerals in 2000 kcal (1887 mL), and Easy Fiber, in 1210 kcal (1100 mL).

The formula was selected by the primary care physician from the line of products provided by the institute before enrollment in the study and was not influenced by the investigators. The volume, the amount of calories, and protein were calculated by the clinical dietitian of the facility according to the DRIs (28 kcal/kg for women and 27 kcal/kg for men, 0.8 g/kg of protein for both sexes).

Blood levels of glucose, urea, electrolytes, albumin, cholesterol, hemoglobin, white blood cell count (WBC), and thyroid-stimulating hormone (TSH) were measured before beginning the enteral nutrition and 8 weeks later. The patients were also weighed before and again once a month during the study. These measurements are all performed regularly on patients with new-onset enteral tube feeding in Israel as part of good medical practice. These parameters are also considered

TABLE III
Baseline laboratory tests of patients in both groups

	Easy Fiber	Osmolite	*p* Value	CI
Hemoglobin (g/dL)	11.4	11.9	.34	(0.04 to 1)
WBC (10^3/mm^3)	11.2 ± 9	8.7 ± 3	.42	(−4 to 0.1)
TLC (10^3/mm^3)	2200 ± 110	2390 ± 90	.50	(−2.3 to 4.7)
Albumin (g/dL)	3.27 ± 0.43	3.27 ± 0.43	.90	(−0.15 to 0.1)
Glucose (mg/dL)	146 ± 8	130 ± 9	.17	(−40 to 7)
Urea (mg/dL)	46 ± 24	42 ± 28	.36	(−12 to 4.6)
Creatinine (mg/dL)	0.8 ± 0.3	0.7 ± 0.25	.08	(−0.22 to 0.03)
Potassium (mmol/L)	4.4 ± 0.7	4.4 ± 0.6	.80	(−0.5 to 2)
Cholesterol (mg/dL)	166 ± 42	172 ± 41	.49	(−11% to 24%)
Triglycerides (mg/dL)	158 ± 46	147 ± 66	.78	(−36 to 27)
TSH (μ U/mL)	3.7 ± 6	2.5 ± 1.6	.20	(−0.6 to 3)

TLC, total lymphocyte count; TSH, thyroid-stimulating hormone; WBC, white blood cells.

TABLE IV
Changes in laboratory tests and weight after 2-month follow-up in both groups

	Easy Fiber	Osmolite	p Value*	CI
Hemoglobin (g/dL)	0.47 ± 1	0.14 ± 1.1	.002	(−0.4 to 0.9)
WBC (10^3/mm^3)	−1.6 ± 10	0.7 ± 3.7	.97	(−0.4 to 5)
TLC (10^3/mm^3)	17 ± 78	−81 ± 78	.70	(−5.3 to 0.19)
Albumin (g/dL)	0.1 ± 0.3	−0.12 ± 0.4	.002	(−0.3 to 0.09)
Glucose (mg/dL)	−35 ± 67	2.5 ± 58	.003	(13 to 61)
Urea (mg/dL)	−1.8 ± 14	−1.5 ± 27	.95	(−7 to 8)
Creatinine (mg/dL)	0.02 ± 0.36	0.01 ± 0.23	.90	(−0.1 to 1)
Potassium (mmol/L)	0.02 ± 0.8	−0.05 ± 0.6	.60	(−0.3 to 0.2)
Cholesterol (mg/dL)	1.4 ± 28	−0.22 ± 17	.80	(−13 to 9.5)
Triglycerides (mg/dL)	−7.7 ± 60	9.7 ± 71	.80	(−15 to 50)
Weight (average, kg)	0.4 ± 10	0.5 ± 10	.57	(0.1 to 1.8)

*p Value in comparison between the 2 formula groups.
CI, confidence interval; TLC, total lymphocyte count; WBC, white blood cells.

as clinical indicators of malnutrition. The data were all collected by the institutes' dietitians. The protocol of the study was approved by the local ethical committee of Kaplan-Harzfeld Medical Center.

Blood counts were measured by an automated analyzer (Technicon H*2; Technicon Instruments Corp, Terrytown, NY). Glucose, urea, electrolytes, albumin, and cholesterol were measured using a closed Hitachi system (Roche Diagnostics Systems, Basel, Switzerland) according to a guanidine hydrochloride/ferrozine reaction.

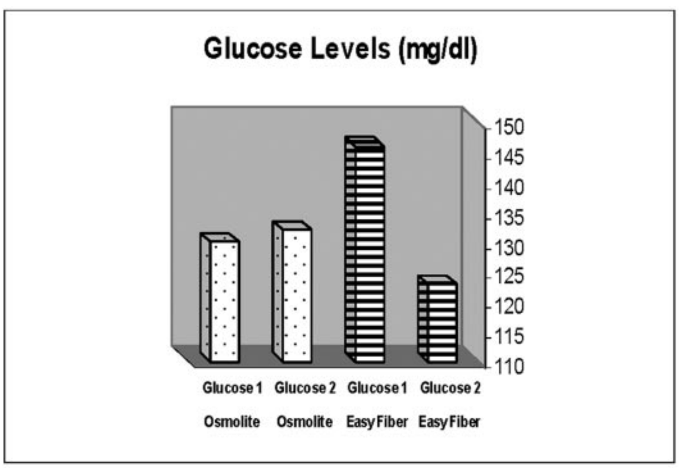
Statistical Analysis

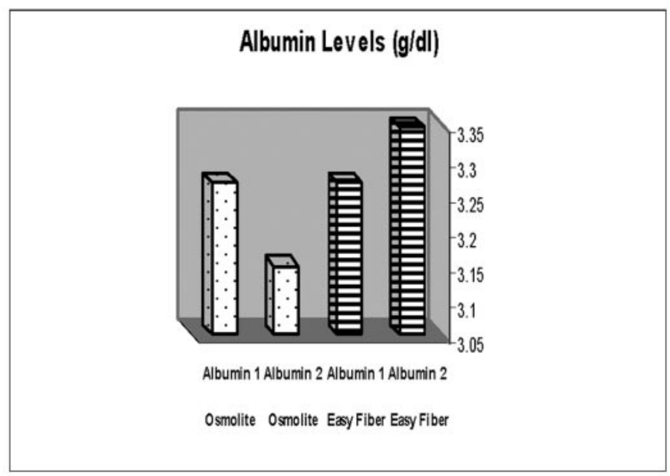
The similarity of baseline characteristics of the groups was tested using unpaired t-test or χ^2 tests. The groups were compared with respect to change over time in body weight and blood tests, using ANOVA for repeated measures. Paired t-tests were also performed on the mean of changes over the 8-week period. The statistical analyses were performed with SPSS (version 12; SPSS Inc, Chicago, IL), and significance level was set at $p > .05$.

RESULTS

Two hundred patients were suitable for the study. Sixty-one patients were withdrawn: 22 died during the study, 6 were admitted to a general hospital due to acute illness, and 33 were missing significant data.

Of the 139 patients enrolled in the study, 59 received the regular formula and 80 the enriched one. Twenty-two percent were men and 78% women, with an aver-





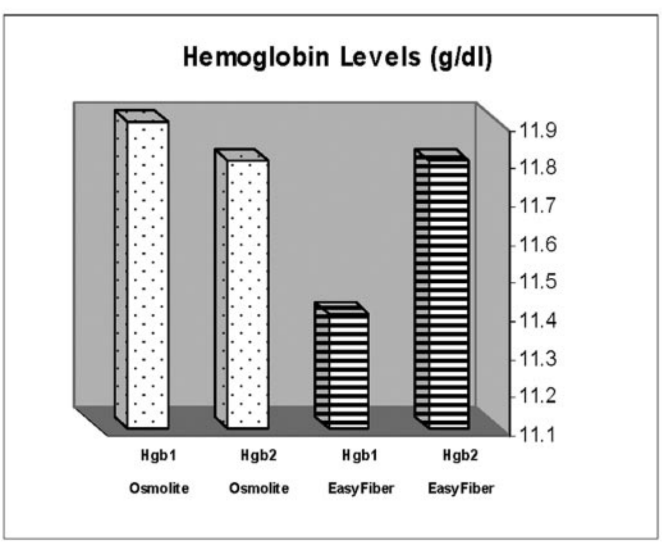


FIGURE 1. Changes in glucose, albumin, and hemoglobin levels from baseline after 2 months of feeding.

age age of 79 years. Forty-seven patients (34%) were fed enterally due to dysphagia, 70 patients (50%) because of feeding difficulty, 11 patients (8%) due to recurrent aspiration, 12 (9%) due to coma, and 13 (9%) because of weight loss. The baseline characteristics of both groups were similar (Table I), as was the baseline laboratory workup (Table III).

After 8 weeks' follow-up, there was a significant increase in hemoglobin ($p < .01$) and albumin ($p < .01$) levels in the enriched formula group (Table IV). In the regular formula, there was no statistically significant change in hemoglobin, but there was a decrease in albumin levels ($p < .05$) at the end of the 2-month follow-up. Similarly, glucose levels were significantly closer to the normal values in diabetic patients receiving the enriched formula ($p = .01$) but not in the regular one (Figure 1). No statistically significant differences were noted between the 2 groups in weight change, cholesterol levels, WBC and total lymphocyte count, renal function tests, or electrolyte balance (Table IV). Triglyceride levels showed a trend to become lower after 2-month follow-up in the enriched formula, with no statistically significant changes in the regular-formula patients.

DISCUSSION

There is abundant and conflicting evidence that different formula contents can influence metabolic outcome in enterally fed patients.[6–10] Patients who need enteral tube feeding are usually in advanced malnutrition, but there is a serious delay in initiation of enteral nutrition in these patients. This may be due to diagnostic delay in some patients but, more important, due to the ethical debate in the western world. The ethical debate especially concerns demented patients and involves 2 questions: whether enteral nutrition prolongs survival in demented patients or whether it adds to their quality of life. Therefore, those patients are in poor nutrition status and need an enriched formula. Improvement in nutrition support like increased protein concentration or micro- and macronutrients can positively influence the metabolic outcome, as was demonstrated in the present study. The increase in hemoglobin concentration can be explained not only by the higher concentrations of iron, vitamin B_{12}, and folic acid in the enriched formula but probably also by improvement in nutrition status of those patients.[1] The improved glucose control probably reflects the high fiber content in the enriched formula, though no previous study was performed in tube-fed patients.[11] The trend for better control of triglyceride levels probably has the same mechanism as the glucose control. Though albumin is not considered the best marker for malnutrition, the rise in its concentration is encouraging and could reflect the higher protein concentration in the enriched formula. The problem of volume overload is common in elderly patients due to multiorgan failure, especially heart and kidney failure. Osmolite meets the DRI with 1887 mL, whereas Easy Fiber meets the DRI with 1100 mL. Considering the additional water needed for rinsing the tube after each meal or medication delivered *via* the tube, the lower volume needed of daily Easy Fiber seems an advantage for the elderly.

Malnutrition is associated with severe complications such as cognitive impairment, depression and apathy, recurrent infections, anemia, pressure wounds, increased morbidity, increased hospital admission rate, prolongation of hospital stay, delay in wound healing, weight loss, recurrent fall, and fractures.[12] If improved nutrition status could have even a minor influence on those parameters, it could significantly improve quality of life and reduce costs.

CONCLUSIONS

This pilot study showed that an 8-week course of enriched enteral tube feeding can improve metabolic outcome in elderly residents and improve the control of glucose levels in diabetic patients. This could prevent complications of malnutrition and improve quality of life in those patients.

REFERENCES

1. Mitrache C, Passweg JR, Libura J, et al. Anemia: an indicator for malnutrition in the elderly. *Ann Hematol.* 2001;80:295–298.
2. Gessert CE, Mosier MC, Brown EF, Frey B. Tube feeding in nursing home residents with severe and irreversible cognitive impairment. *J Am Geriatr Soc.* 2000;48:1593–1600.
3. Grant MD, Rudberg MA, Brody JA. Gastrostomy placement and mortality among hospitalized Medicare beneficiaries. *JAMA.* 1998;279:1973–1976.
4. Stratton RJ, King CL, Stroud MA, Jackson AA, Elia M. Malnutrition universal screening tool predicts mortality and length of hospital stay in acutely ill elderly. *Br J Nutr.* 2006;95:325–330.
5. Visvanathan R. Under-nutrition in older people: a serious and growing global problem! *J Postgrad Med*. 2003;49:352–360.
6. Kaw M, Sekas G. Long-term follow-up of consequences of percutaneous endoscopic gastrostomy (PEG) tubes in nursing home patients. *Dig Dis Sci.* 1994;39:738–740.
7. Klose J, Heldwein W, Rafferzeder M, Sernetz F, Gross M, Loeschke K. Nutritional status and quality of life in patients with percutaneous endoscopic gastrostomy (PEG) in practice: prospective one-year follow-up. *Dig Dis Sci.* 2003;48:2057–2063.
8. Panos MZ, Reilly H, Moran A, et al. Percutaneous endoscopic gastrostomy in a general hospital: prospective evaluation of indications, outcome, and randomised comparison of two tube designs. *Gut.* 1994;35:1551–1566.
9. Amann W, Mischinger HJ, Berger A, et al. Percutaneous endoscopic gastrostomy. *Surg Endosc.* 1997;11:741–744.
10. Light VL, Slezak FA, Porter JA, Gerson LW, McCord G. Predictive factors for early mortality after percutaneous endoscopic gastrostomy. *Gastrointest Endosc.* 1995;42:330–335.
11. Chandalia M, Garg A, Lutjohann D, von Bergmann K, Grundy SM, Brinkley LJ. Beneficial effects of high dietary fiber intake in patients with type 2 diabetes mellitus. *N Engl J Med.* 2000;342:1392–1398.
12. Visvanathan R, Newbury JW, Chapman I. Malnutrition in older people: screening and management strategies. *Aust Fam Physician.* 2004;33:799–805.