

CLINICAL TRIALS OF AN INSTANT TUBE-FEEDING FORMULA IN ENTERALLY FED PATIENTS IN HOSPITAL SETTING

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OBJECTIVES

Specific Objectives

- To assess nutritional status of patients being fed with instant tube-feeding formula
- To determine biochemical and metabolic indices in patients being fed with tube-feeding formula
- To evaluate diet tolerance to the formula
- To assess the bacteriological safety of the formula



METHODOLOGY

Subjects

- 14 adult: 11 males, 3 females
- age range: 17-71 years old
- confined at Sto. Tomas University Hospital, Clinical Division, from April 8 to June 17, 1997
- Prerequisite for inclusion criteria - Informed consent
- Inclusion Criteria
 - Patient required tube feeding with calorie density of 1 kcal/ml
 - No other dietary modification
 - Could not or would not be fed by mouth

Parameters

- ❑ Blood examination – hemoglobin, hematocrit, FBS, BUN, albumin and serum electrolytes
- ❑ Anthropometric measurements
 - Weight, skin fold thickness, mid-upper arm circumference
- ❑ Nutrient intake and % adequacy
- ❑ Microbiological examination of formula, after preparation before first feeding and before last feeding: TPC, E. coli, yeasts, molds
- ❑ Subjective Evaluation

Feeding

- ❑ Prescription
 - Day 1 – 0.5 kcal/ml, 250-300 ml x 6 feeding
 - Day 2 3– 0.75 kcal/ml, 250-300 ml x 8 feeding
 - Day 4 – 14 kcal/ml, 250-300 ml x 8 feeding
- ❑ Bolus feeding via size 16 nasogastric tube
- ❑ TER – based on Harris-Benedict equation
- ❑ Protein requirement = 1.1 g/kg
- ❑ % adequacy = $\frac{\text{Nutrient Intake}}{\text{Nutrient RDA}} \times 100$

Statistical Analyses

- Descriptive statistics
- ANOVA test

Table 1. Comparison of nutrient density of FNRI formula and commercial formula

Nutrients	FNRI Formula	Commercial Formula*
Energy, kcal	1.04	1.00
Protein, g	0.03	0.03
Carbohydrates, g	0.18	0.12
Fat, g	0.02	0.04
Ash, g	0.003	0.006
Calcium, mg	0.5	0.6
Phosphorous, mg	0.69	0.5
Iron, mg	0.02	0.01
Retinol, µg	1.4	0.005
Beta-carotene, µg	0.35	No nutrient information
Thiamine, mg	0.002	0.002
Riboflavin, mg	0.004	1.075
Niacin, mg	0.022	0.025
Vitamin C, mg	0.05	0.15
Sodium, mg	1.12	0.5
Potassium, mg	0.98	1.25
Magnesium, mg	0.18	0.2
Zinc, mg	0.0004	1.0
Manganese, mg	Tr	0.0025
Iodine, mg	ND	0.00008
Pyridoxine, mg	0.0005	0.002
Vitamin B ₁₂ , mg	0.001	0.000008
Folic Acid, mg	0.018	0.0002
Fatty Acid: Sat., g	0.003	No nutrient information
: Mono., g	0.006	No nutrient information
: Poly., g	0.013	No nutrient information
Cholesterol, mg	0.004	No nutrient information
Dietary Fiber, g	0.018	No nutrient information

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Table 2. General Profile of 14 Subjects Given Experimental Enteral-feeding Formula, STUH, 1997

Classification	Mean
Mean age (yrs)	43.0
Mean weight (kg)	48.4
Mean mid upper arm circumference (MUAC) (cm)	25.5
Mean triceps skin fold (TSF) (mm)	8.1
Mean scapula skin fold (SSF) (mm)	10.8
Body Mass Index (BMI)	18.5
(W/H ²), normal = 18.5-24.9	
Diagnosis	
Cancer (n=8)	57.1
Mandibular fracture (n=3)	21.4
Vehicular accident (n=1)	7.1
Muscular dystrophy (n=1)	7.1
Cerebral infarct (n=1)	7.1

Mean Energy Intake, Energy Prescription TER

Parameters

Volume intake	-	1614 ml
Energy intake	-	1617 kcal
Energy prescription	-	1750 kcal
% adequacy intake vs. R_x	-	92.4
Total energy requirement	-	2367 kcal
% adequacy intake vs. TER	-	64.1

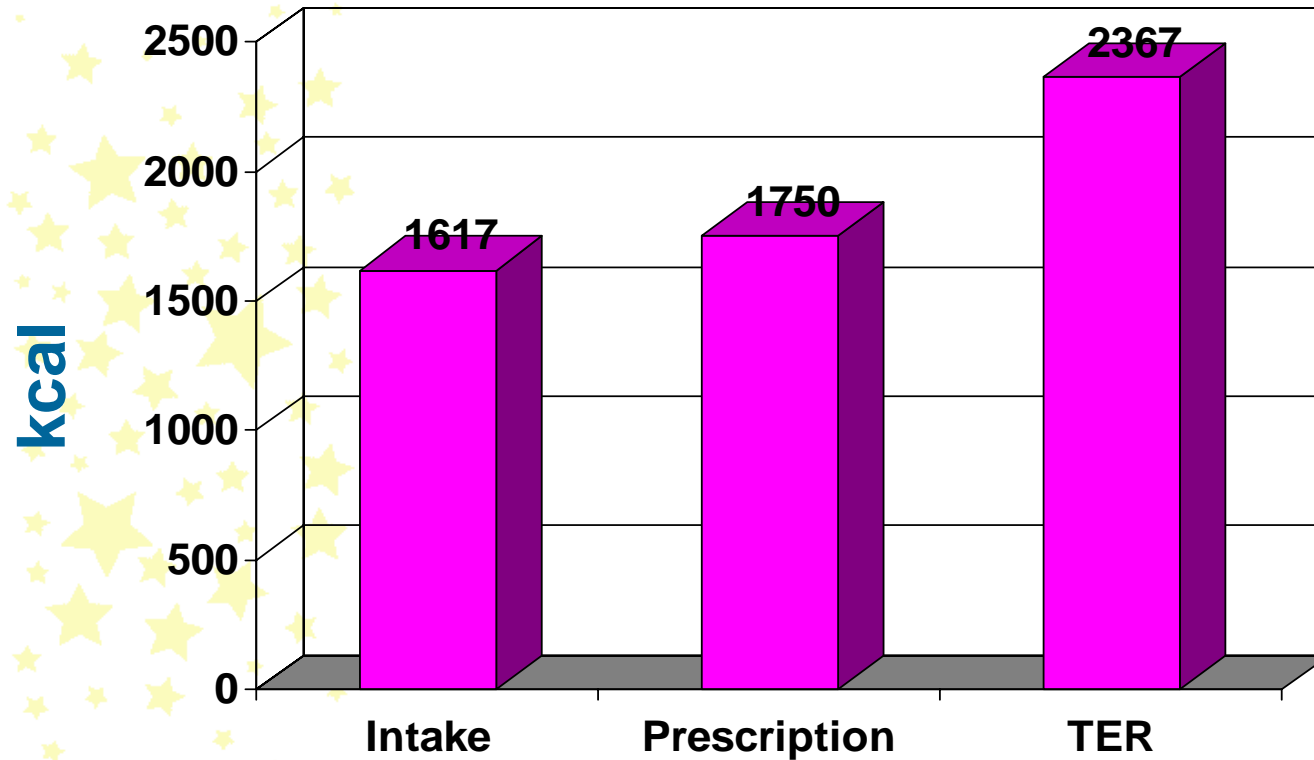


Figure 1. Comparison of Energy Intake, Prescription and Requirement

Table 3. Change in Anthropometric Measurements of 14 Subjects Given Experimental Feeding Formula

Anthropometric measurements

Change

Weight (kg)

-1.8 ns

MUAC (cm)

-1.6 ns

TSF (mm)

-0.7 ns

SSF (mm)

-0.4 ns

BMI (kg/m²)

-0.7 ns

Table 4. Mean Nutrient Intake and Percentage (%) Adequacy

Nutrient	Mean Intake	% Adequacy
Protein (gm)	50	83.9
Calcium (mg)	770	148.9
Iron (mg)	28.3	232.1
Vit. A (RE)	455	89.7
Thiamin (mg)	0.74	68.5
Riboflavin (mg)	0.08	101.2
Preformed Niacin (mg)	6.88	32.9
Ascorbic Acid (mg)	3.09	4.1

Table 5. Blood chemistry profile of 14 subjects given experimental feeding formula, STUH, 1997

Variables	Total Subjects	Phases of Feeding			
		Initial		Final	
		Mean	± S.D.	Mean	± S.D.
Hemoglobin (g/L)	14	112.2	17.80	119.9	14.90
Hematocrit (g/dL)	14	0.3	0.06	0.4	0.05
FBS (mmol/L)	14	7.9	3.70	6.6	3.09
BUN (mmol/L)	12	4.1	2.60	4.1	1.40
Albumin (g/dL)	14	3.3	0.70	4.1	0.6
Sodium (mmol/L)	14	134.3	5.20	132.1	5.30
Potassium (mmol/L)	14	3.9	0.50	4.5	0.60
Chloride (mmol/L)	14	100.0	6.28	96.4	6.70
Calcium (mmol/L)	14	1.2	0.08	1.2	0.06
Phosphorous (mmol/L)	14	0.9	0.25	1.2	0.19
Magnesium (mmol/L)	14	0.8	0.11	0.8	0.06

Table 6. Results of microbiological analysis of 13 enteral tube formula stored at room temperature

Storage Time	Total Plate Count	Coliform	Ecoli	Yeasts & Molds
1 st month of storage	3×10^4 col/g	5×10^3 col/g	1×10^3 col/g	-
2 nd month of storage	2×10^4 col/g	6×10^3 col/g	5×10^3 col/g	-
3 rd month of storage	2×10^4 col/g	2×10^3 col/g	2×10^3 col/g	-
4 th month of storage	1×10^3 col/g	2×10^3 col/g	2×10^3 col/g	2×10^3 col/g
5 th month of storage	1×10^4 col/g	12×10^3 col/g	4×10^3 col/g	-
6 th month of storage	3×10^4 col/g	5×10^3 col/g	8×10^2 col/g	-

Table 7. Percentage distribution of subjects according to overall assessment after intervention

Overall Assessment	Patient's Assessment		Physician's Assessment	
	No.	%	No.	%
Very satisfactory	1	7.1	-	-
Satisfactory	9	84.3	9	64.3
Fair	3	21.4	4	28.6
Poor	-	-	-	-
No assessment	1	7.1	1	7.1



CONCLUSION

Results of the study suggest that for a short period of time, at least, the tube-feeding formula developed by the FNRI can prevent nutritional deterioration. Despite high microbiological susceptibility of the formula, no untoward symptoms of bacterial contamination were noted. The formula was well tolerated as confirmed by the positive subjective evaluation of both patients and physicians.



RECOMMENDATIONS

- Supplementation of the formula with niacin and ascorbic acid
- Assurance of acceptable bacteriological limits of the formula must be undertaken.
- Improvement of technology to reduce viscosity.

Thankyou

