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Evaluation and Categorization of Commercially Prepared Enteral Nutrition Formulas*

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ABSTRACT

In order to investigate the types of enteral nutrition formulas currently used in hospitals and evaluate and categorize the commercially prepared enteral nutrition formulas available in the domestic market, we asked dietitians working in 6 hospitals in Seoul to complete the questionnaire and obtained compositional characteristics of 12 commercially prepared enteral nutrition formulas. The average proportion of patients receiving the commercially prepared enteral nutrition formulas (60.6%) was greater than that of patients receiving the in-hospital preparations(31.9%). In the group of patients receiving the in-hospital prepared formulas, the enteral feeding was mainly administered orally, whereas, in the group of patients receiving the commercially prepared formulas, tube feeding was the primary route of formula administration. In both groups, however, a greater proportion of patients received the formulas as total replacements of their meals and for the purpose of dietary supplementation. On the basis of major criteria for evaluation of the commercially prepared enteral nutrition formulas, the 6 products out of the 9 nutritionally complete products formulated for the purpose of dietary supplementation were grouped into the same category (standard protein, caloric density of 1kcal/ml, and tube/oral), so they were considered therapeutically comparable. However, the remaining 3 products were different in protein content(high protein) or route of administration(tube only). Of the 3 nutritionally complete products formulated specifically for the purpose of dietary therapy, 2 products were formulated for patients with renal disease, and the one product was formulated for diabetic patients. Therefore, the data in this study showed that the commercially prepared enteral nutrition formulas became an important part of the enteral nutrition for hospitalized patients in Korea, but the domestic market has not yet generated a wide variety of the formulas, not providing many choices for clinicians to manage the diets for their patients. The results of this study would be helpful for clinicians in choosing appropriate products for their patients, for manufacturers in developing new products, and for regulatory authorities to establish the regulation for the broad group of heterogeneous products that are marketed and will be developed as medical foods. In addition, the process of maintaining the categories for evaluation of the commercially prepared enteral nutrition formulas should be dynamic because new products may not reasonably fit any of the existing categories. (*Korean J Community Nutrition* 3(5) : 729~738, 1998)

KEY WORDS : medical foods · enteral nutrition formulas · clinical nutrition support.

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Introduction

The goal of clinical nutrition support in general has been described as providing calories, macronutrients, and all essential micronutrients in a form that can be utilized by the patient to restore and maintain body cell mass(Talbot 1990). Dietary departments in the hospital have provided a wide variety of diets specifically designed to provide optimal nutrition for patients with various disease states. As food technology has been remarkably advanced, however, commercially prepared enteral nutrition formulas have progressively replaced in-hospital formula preparations as indispensable therapeutic modalities in a wide variety of patients whose *ad libitium* nutrient intakes are insufficient to meet requirements, but whose gastrointestinal tracts are intact(A.S.P.E.N. Board of Directors 1987).

In the developed countries, the efficacy, ease, low risk, and low cost of commercially prepared formulas have prompted nearly all hospitals to discontinue routine in-hospital formula preparation, and have generated a rapid increase in the enteral nutrition formula market(Codex Alimentarius Commission 1996 ; Food and Drug Administration 1996). Because the number and variety of enteral nutrition formulas have increased significantly in those countries, clinicians are becoming overwhelmed by the virtual supermarket of options, and thus, often rely on the information given them by commercial representatives for help in making choices (Food and Drug Administration 1996). This may lead to the repetitive use of one or two formulas without regard to individual patient requirements, inappropriate emphasis on relatively unimportant compositional features, and employment of expensive specialized formulas when they are not indicated. Although the market of the commercially prepared enteral nutrition formulas is very small in Korea compared to the developed countries, it has been gradually increased for the past few years(Jang 1997). However, there have been no attempts to evaluate and categorize the commercially prepared enteral nutrition formulas available in the domestic market in order to help clinicians choose appropriate products for their patients.

Additionally, a proper evaluation and categorization of commercially prepared enteral nutrition formulas need to be done in order to establish statutory definitions, regulatory standards, and compositional requirements. According to the Korean Food Code(Department of Health and Human Services 1996), these products are categorized as foods for patients, one category of special nutritional foods. However, the present statutory definition of foods for patients is not clear enough to distinguish the types of products on the basis of their uses nor identify patient populations whose nutritional support depends on them partially or entirely.

Therefore, the purpose of this study was to investigate the types of enteral nutrition formulas currently used in hospitals and evaluate and categorize the commercially prepared enteral nutrition formulas available in the market. The results of this study would be helpful for clinicians in choosing appropriate products for their patients, for manufacturers in developing new products, and for regulatory authorities to establish the regulation of the broad group of heterogeneous products that are marketed and will be developed as medical foods.

Subjects and Methods

1. Enteral nutrition formulas currently used in hospitals

In order to investigate the types of enteral nutrition formulas currently used for hospitalized patients, we asked dietitians working in 6 hospitals{Samsung Medical Center, Ewha University Medical Center (Dongdaemoon and Mog-Dong), Chungang University Medical Center(Yongsan), Yunsei University Medical Center(Yung-Dong) and Catholic University Medical Center(Yeoeuido)} in Seoul to complete the questionnaire basically designed to find which types of enteral nutrition formulas(in-hospital, commercially prepared, or combination)they were using. When the commercially prepared enteral nutrition formulas were used only as ingredients for the preparation of in-hospital formulas, they were not counted for cal-

culating the proportion of patients receiving commercially prepared formulas but counted for in-hospital preparations. When patients received the in-hospital formulas as a part of their meals as well as the commercial formulas for the purpose of supplementations to or partial replacements of some meals, they were included in the group of the combination type(in-hospital+commercial). The questions on how enteral nutrition formulas were administered(oral vs tube), how frequently they were fed(entire vs partial replacement or supplementation of patient's meals), and why they were used(dietary supplement vs diet therapy) were also included in the questionnaire. For the question on the reasons for uses of enteral nutrition formulas, patients were categorized into two groups as follows : 1) patients who have ordinary nutritional requirements but need to replace or supplement their diets with enteral nutrition formulas because of mastication or swallowing problems or insufficient consumption of ordinary diets ; and 2) patients who have physiologically distinctive nutritional requirements because of specific diseases or clinical symptoms and therefore need enteral nutrition products specifically formulated for the dietary management of the health-related conditions. The uses for the former cases were considered as the use for dietary supplement, whereas the uses for the latter cases were considered as the use for diet therapy (Food and Drug Administration 1996).

2. Compositional information on commercially prepared enteral nutrition formulas

Compositional information on the commercially prepared enteral nutrition formulas currently used in the hospitals and available in the domestic market were obtained from the labels and accompanying leaflets of the products. Total numbers of the commercially prepared enteral nutrition formulas currently available in the market and subjected for this investigation were 12 nutritionally complete formulas, 9 products manufactured by the two domestic food companies and 3 products manufactured by the foreign companies. In addition, compositions of 4 nutritionally incomplete formulas functioning as modular supplements were also investigated.

Table 1. Criteria for evaluation of enteral nutrition formulas[1)]

Categories	Parameters
Major criteria	Caloric density(kcal/ml)
	1
	1.5
	2
	Protein content(% of total kcal)
	Standard – <20
	High – ≥20
	Route of administration
	Tube/oral
	Tube only
	Cost
Minor criteria	Osmolality(mOsmol/kg water)
	Isotonic – <350
	Moderately hypertonic – 350 – 550
	Markedly hypertonic – >550
	Complexity
	Polymeric
	Oligomeric
	Fat content(% of total kcal)
	Standard – >20
	Low – 5 – 20
	Free – <5
	Fat source
	Long-chain triglycerides(LCT)
	LCT plus medium-chain triglycerides(MCT)
	Residue content
	Fiber-containing
	Low-residue
	Residue-free
	Lactose content
	Electrolyte and mineral content
	Form
	Ready to use
	Powder
	Clinical studies
Inconsequential criteria	Protein source
	Casein, lactalbumin, soy, egg albumin, beef, amino acids
	Carbohydrate source
	Corn starch, corn syrup, maltodextrin, sucrose, fructose, vegetables, glucose, oligosaccharides
	Vitamin content
	Recommended Daily Allowances(RDA) delivered in 2000kcal or less
	RDA delivered in >2000kcal

1) Developed at the University of Alabama Hospitals in Birmingham, U.S.A(Heimburger & Weinsier 1985)

3. Criteria for categorization and evaluation of commercially prepared enteral nutrition formulas

The commercially prepared enteral nutrition formulas currently available in the domestic market were categorized according to the parameters in Table 1 provided by the system developed at the University of Alabama Hospitals in Birmingham, AL, U.S.A which has been used successfully as a criteria for categorization and evaluation of the enteral nutrition formulas according to therapeutic equivalence(Heimburger & Weinsier 1985). These parameters were stratified into three categories of relative importance when choosing among available formulas. The parameters which relate to major nutritional requirements or warrant consideration in every patient are defined as major. Those unrelated to nutritional requirements or necessitating consideration only in patients with specialized gastrointestinal or metabolic problems are defined as minor. Those which virtually never require a decision are termed inconsequential(Heimburger & Weinsier 1985).

Results and Discussions

1. Enteral nutrition formulas currently used in hospitals

In order to evaluate which types of enteral nutrition formulas are the most currently used in hospitals, the data are expressed as a proportion of the total number of patients receiving enteral nutrition formulas to the number of patients receiving one of the three different types of enteral nutrition formulas(in-hospital, commercial, or combination)(Table 2). On the average, the

Table 2. Types of enteral nutrition formulas currently used in hospitals (Unit : %)[1]

Hospital \ Type	In-hospital preparation	Commercial preparation	In-hospital+Commercial	Total
A	32.3	64.5	3.2	100.0
B	–	100.0	–	100.0
C	–	100.0	–	100.0
D	4.1	54.2	41.7	100.0
E	55.8	44.2	–	100.0
F	99.0	1.0	–	100.0
Average	31.9	60.6	7.5	100.0

1) Proportion of total number of patients receiving enteral nutrition formulas to the number of patients receiving each type of enteral nutrition formulas.

Table 3. Routes of administration, feeding frequency, and types of uses of enteral nutrition formulas currently used in hospital (unit : %)[1]

Hospital \ Type	In-hospital preparation						Commercial preparation							In-hospital+Commercial						
	Routes of administration		Feeding Frequency[2]		Types of uses[3]		Routes of administration		Feeding Frequency		Types of uses			Routes of administration		Feeding Frequency		Types of uses		
	Tube	Oral	Total	Partial	Diet therapy	Dietary Supplement	Tube	Oral	Total	Partial	Diet therapy	Dietary Supplement		Tube	Oral	Total	Partial	Diet therapy	Dietary Supplement	
A	100.0		100.0		40.0	60.0		100.0		100.0	33.3	66.7		100.0		100.0			100.0	
B	–	–	–	–	–	–	82.1	17.9	82.1	17.9	28.2	71.8		–	–	–	–	–	–	
C	–	–	–	–	–	–	57.1	42.9	57.1	42.9	23.8	76.2		–	–	–	–	–	–	
D	–	100.0	100.0	–	100.0	–	76.9	23.1	76.9	23.1	30.8	69.2		100.0	–	100.0	–	10.0	90.0	
E	–	100.0	–	100.0	–	100.0	97.4	2.6	100.0	–	10.5	89.5		–	–	–	–	–	–	
F	8.3	91.7	68.7	31.3	14.6	85.4	100.0	–	100.0	–	100.0	–		–	–	–	–	–	–	
Average	27.1	72.9	67.2	32.8	38.6	61.4	68.9	31.1	69.4	30.6	37.8	62.2		100.0	–	100.0	–	5.0	95.0	
Total	100.0		100.0		100.0		100.0		100.0		100.0			100.0		100.0		100.0		

1) In each group of patients recieving different type of enteral nutrition formulas, proportion of total number of patients to the number of patients fed differently according to routes of administration, feeding frequency, or types of uses.
2) Feeding frequency was divided into the two types, and each type was defined as follows : Total, total replacement of all meals with enteral nutrition formulas ; Partial, partial replacement or supplementation of patient's meals.
3) Types of uses were divided into the two groups based on the purposes of enteral nutrition feedings as described in the Subjects and Methods.

proportion of patients receiving the commercially prepared enteral nutrition formulas(60.6%) was greater than that of patients receiving the in-hospital preparations(31.9%), and the proportion of patients receiving both types of formulas was 7.5%. However, there were large variations in the types of enteral nutrition formulas used among 6 hospitals. For example, the hospital B and C entirely used the commercially prepared formulas, whereas the hospital F used the in-hospital preparations for enteral feeding.

In each group of patients receiving the different types of enteral nutrition formulas, a proportion of the total number of patients to the number of patients fed differently according to routes of administration, feeding frequency, or types of use was also investigated, and the data are shown in Table 3. The routes of administration were divided into either tube or oral radministration, and the feeding frequency was divided into either total replacement of all meals with enteral nutrition formulas or partial replacement or supplementation of patient's meals. The purposes of enteral feeding were differentiated based on the types of use ; that is, use as dietary supplement or dietary therapy described in detail in the Subjects and Methods. The routes of administration were found to be very different among the groups of patients receiving different types of enteral nutrition formulas. In the group of patients receiving the in-hospital prepared formulas, the average proportion of patients fed by oral administration(72.9%) was greater than that of patients fed by tubes(27.1%). On the contrary, in the group of patients receiving the commercially prepared formulas, the average proportion of patients fed by tubes(68.9%) was greater than that of patients fed by oral administration (31.1%), and the patients receiving both types of formulas were fed only by tubes(100%). Unlike the routes of formula administration, the patterns of feeding frequency and types of use were similar in all groups of patients ; that is, on the average, a greater proportion of patients received enteral nutrition formulas as total replacements of their meals and for the purpose of dietary supplementation.

Because only 6 hospitals in Seoul were subjected for this investigation, it is hard to make a definite conclusion on which types of enteral nutrition formulas for what purposes are the most currently used one with what purposes. However, the data in this study clearly showed that the commercially prepared enteral nutrition formulas became an important part of the enteral nutrition for hospitalized patients in this country. In addition, there is a great potentiality for gradually replacing the in-hospital prepared formulas with the commercially prepared ones as the enteral nutrition formula market generates a variety of products, especially products specifically formulated for the dietary management of diseases, and as hospitals can make a change in the techniques for tube feeding from bolus to continuous type.

2. Categorization and evaluation of commercially prepared enteral nutrition formulas currently available in the domestic market

According to the criteria for evaluation of enteral nutrition formulas developed by the University of Alabama Hospitals in Birmingham, the parameters which relate to major nutritional requirements or warrant consideration in every patient are defined as major. Those unrelated to nutritional requirements or necessitating consideration only in patients with specialized gastrzointestinal or metabolic problems are defined as minor. Those which virtually never require a decision are termed inconsequential(Heimburger & Weinsier 1985).

The parameters for major criteria are caloric density, protein content, route of administration, and cost(Table 1). Caloric density of the formulas generally has an inverse correlation with moisture content, putting some patients at risk of volume depletion if the more dense formulas are used without additional fluid intake. This is particularly important in patients who have high endogenous renal solute loads such as high urinary urea excretion due to the rapid proteolysis during the stress state(Kagan et al 1982 ; Wilmore 1974). Protein content, expressed as percentage of total calories as protein, determines the relative amount of this major nutrient received by the patient. The formulas containing protein content no less than 20% of total calories are appropriate for patients with protein requirements increased out of proportion to calorie requirem-

ents such as those with sepsis, trauma or burns(Kagan et al. 1982 ; Wilmore 1974 ; Wolfe 1981). Route of administration, while unrelated to nutritional requirements, must be dealt with because, of the two categories tube/oral and tube only, the latter are unpalatable except to occasional patients with dysgeusia who find flavored formulas unpleasantly sweet. It is not necessary for an unflavored formula for tube only to be included in a hospital formulary when nutritionally comparable products for tube/oral are available, especially in the case of 1kcal/ml standard protein formulas.

The parameters for minor criteria are osmolality, complexity, fat content, fat source, residue content, lactose content, electrolyte and mineral content, form, and clinical studies(Table 1). Osmolality does not need to be specifically considered in every patient, but it is important at times because of the possible association of diarrhea and cramping with the infusion of formulas high in osmolality(Heimburger 1982 ; Heymsfield et al. 1979). Isotonic formulas may be a more appropriate choice in patients with diarrhea during tube feeding, especially if the infusion is intrajejunal(Hunt 1959). The importance of the complexity of enteral formulas has been debated. Several studies have indicated that absorption of free amino acids is not superior to that of dipeptides and tripeptides in protein hydrolysates, although all hydrolysates are not of equal biologic value (Moog 1981 ; Silk et al. 1980 ; Young et al. 1981). Fat content is not often a major consideration in choosing among enteral formulas because the quantity of essential fatty acids required is very small and provided by all of the available nutritionally complete formulas. Fat content remains the only physiologically unique characteristic of the oligomeric formulas, since they are the only ones low in fat. Low-fat formulas are important for patients with significant malabsorption, severe exocrine pancreatic insufficiency, or hyperlipidemia whose fat intake should be restricted out of proportion to total calories(A.S.P.E.N. Board of Directors 1993). Although the differences among the various sources of long-chain fatty acids are relatively inconsequential, formulas containing medium-chain triglycerides may be desirable as an energy source for patients with malabsorption(Greenberger & Skillman 1969). Residue content is a consideration in the small group of patients in whom a larger amount of dietary bulk is desirable, such as those experiencing constipation on long-term tube feeding(A.S.P.E.N. Board of Directors 1993). Since lactose provides no advantage over other carbohydrates, lactose-containing formula is not a good choice for patients, especially those who temperarily lose lactase activity during acute illnesses(Herskovic 1969). Electrolyte and mineral content varies little among most of the commonly used formulas. Possible clinically significant exceptions include sodium content with a range of 400 to 900mg / 1000kcal and potassium content with a range of 16 to 40mEq / 1000kcal. Forms of commercially available formulas are either liquid (ready-to-use) or powder. Powdered formulas require a proper reconstitution and blending and have been found to become contaminated with bacteria during processing and administration more commonly than ready-to-use formulas(Hostetler et al 1982). Clinical studies proving efficacy of 'nutritionally complete' formulas are of minor importance since in most cases the formulas are compounded from well-known nutrient sources. Such studies, however, are vital in the evaluation of products specifically formulated for dietary therapy of diseases.

Inconsequential criteria(protein and carbohydrate source, and vitamin content) generally confer no physiological advantage although sometimes stressed as important by commercial representatives. The commonly used sources of protein and carbohydrate are comparable in virtually all feeding situations. Most nutritionally complete enteral formulas provide the adult Recommended Daily Allowance(RDA) for vitamins when 2000kcal is delivered : however, some require up to 3000kcal to reach the RDA for some vitamins, necessitating careful attention to vitamin intake if the patient is receiving a low calorie intake as enteral feeding.

The formulas differing in major criteria were not considered comparable, whereas ones differing in inconsequential criteria were grouped together. The formulas differing in minor criteria were grouped separately because the differences should be judged on an individual basis to determine their significance. Therefore, the commercially prepared enteral nutrition formu-

las currently available in the domestic market were evaluated and categorized as shown in Table 4 according to the criteria listed in Table 1. Therapeutical comparability of the formulas within the same group in terms of the type of uses, dietary supplementation or dietary therapy, was first evaluated by major criteria followed by minor criteria. Of the 9 nutritionally complete products formulated for the purpose of dietary supplementation, the 6 products were grouped into the same category with standard protein(less than 20% of total kcal) and caloric density of 1kcal/ml, and they were formulated to be administered by both tube and oral. Therefore, these 6 products can be considered comparable. The rest of the products were different from the first 6 products in route of administration and protein content ; that is, the 2 products were formulated only to be administered by tube, and one product contained high amount of protein. Although these 9 products were categorized into 3 different groups based on major criteria, they could be categorized into 7 different groups if minor criteria such as osmolality, complexity, residue content, lactose content, and fat content were considered.

Of the 3 nutritionally complete products formulated specifically for the purpose of diet therapy, 2 products were formulated specifically for patients with renal diseases and characterized by their compositional properties such as high caloric density(2kcal/ml) and the osmolality of markedely hypertonic, and the one product was formulated specifically for diabetic patients and characterized by high protein content.

The 4 nutritionally incomplete formulas currently used in hospitals were characterized by the components they intended to supplement. The supplementing components of these formulas were carbohydrate, lipid, protein, and fiber, respectively(Table 4).

More detailed compositional properties of the 12 nutritionally complete enteral formulas are shown in Table 5. Most of the products were liquid form(ready-to-use), and only two products were powder form requiring a proper reconstitution before use. The protein sources of the formulas were casein, casein salt(sodium caseinate or sodium-calsium caseinate), casein hydrolysate, soy protein isolate, or free amino acids. Fat sources were soy oil, corn oil, or sunflower oil, and some products contained medium-chain triglycerides. Carbohydrate sources were dextrin, fructose, and sucrose. Sodium and potassium content varied little among the formulas and were ranged within 480–920mg/1000 kcal for sodium and 14–38mEq/1000kcal for potassium.

The results of the categorization in this study showed that the domestic market of enteral nutrition formulas has not yet generated a wide variety of the products, not providing many choices for clinicians to manage the diets for their patients, especially patients with

Table 4. Categorization of commercially prepared enteral nutrition formulas in therapeutically comparable groups

Parameters	Products
Nutritionally complete formulas for dietary supplementation	
Standard protein, 1kcal/ml, tube/oral	
Polymeric, lactose-free	
Isotonic	Greenbia health, isocal, Nutritional Care 300
Isotonic, fiber-containing	Nutritional Care Fiber
Moderately hypertonic	Ensure
Polymeric, lactose-containing	
Moderately hypertonic	Nutritional Care
Standard protein, 1kcal/ml, tube only	
Polymeric, lactose-free	
Isotonic	Greenbia TF
Oligomeric, lactose-free	
Moderately hypertonic, fat-free	Energen
High protein, 1kcal/ml, tube/oral	
Polymeric, lactose-free	
Moderately hypertonic	Greenbia
Nutritionally complete, specialized formulas for dietary therapy	
Standard protein, 1kcal/ml, tube/oral	
Polymeric, lactose-free, Markedely hypertonic	Greenbia RD, Greenbia RD Plus
High protein, 2kcal/ml, tube/oral	
Polymeric, lactose-free, Isotonic, fiber-containing	Greenbia DM
Nutritionally incomplete formulas (modular types)	
Carbohydrate	Calorie-S
Lipid	MCT Oil
Protein	Maxipro
Fiber	Psylliumdex

Table 5. Composition of nutritionally complete enteral formulas

Type of use	Products	Form[1]	Caloric density (kcal/ml)	Osmolality (mOsmol/kg water)	Package unit	Composition/package unit									Na (mg/1000kcal)	K (mEq/1000kcal)
						Protein			Fat			Carbohydrate				
						g	% of total kcal	Sources[2]	g	% of total kcal	Sources[3]	g	% of total kcal	Sources[4]		
Dietary supplementation	Greenbia	Liquid	1.0	465	200ml	12.5	25	SC, SPI	4.4	20	SO	27.5	55	DEX, FRU	920	22
	Greenbia TF	Liquid	1.0	300	200ml	7.5	15	SC, SPI	4.4	20	SO, MCT	32.5	65	DEX, FRU	514	14
	Greenbia Health	Liquid	1.0	340	200ml	7.5	15	SC, SPI	6.7	30	SO, MCT	27.5	55	DEX, SUC	635	23
	Nutritional Care	Liquid	1.0	353	250ml	9.4	16	SC, SPI	6.9	29	CO	37.5	55	DEX	628	28
	Nutritional Care 300	Liquid	1.0	300	250ml	10.1	15	SC, CH	7.1	25	CO, MCT	37.5	60	DEX	836	37
	Nutritional Care Fiber	Liquid	1.0	300	250ml	7.0	15	SC, CH	6.0	25	CO, MCT	30.0	60	DEX	480	23
	Ensure	Liquid	1.0	470	250ml	8.8	14	SCC, SPI	8.8	31.5	CO	34.3	54.5	DEX, SUC	800	38
	Isocal	Powder	1.0	300	85g	13.0	13	CAS, SPI	16.8	37	CO, MCT	50.8	50	DEX	500	22
	Energen	Powder	1.0	760	80g	14.1	17.6	AA	0.5	0.6	SO	63.5	79.4	DEX	867	19
Ditary therapy	Greenbia DM	Liquid	1.0	310	200ml	10.0	20	SC, SPI	4.4	20	SUO	30.0	60	DEX, FRU	685	16
	Greenbia RD	Liquid	2.0	890	200ml	6.0	6	SC	13.3	30	SUO, MCT	64.0	64	DEX, SUC	800	21
	Greenbia RD Plus	Liquid	2.0	950	200ml	12.0	12	SC	13.3	30	SUO, MCT	58.0	58	DEX, SUC	800	21

1) Liquid form is ready-to-use, whereas powder form needs a proper reconstitution before use.
2) Abbreviations for protein sources are as follows : SC, sodium caseinate ; SPI, soy protein isolate ; CH, casein hydrolysate ; SCC, sodium-calcium caseinate ; CAS, casein ; AA, amino acids.
3) Abbreviations for fat sources are as follows : SO, soy oil ; MCT, medium-chain triglycerides ; CO, corn oil ; SUO, sunflower oil.
4) Abbreviations for carbohydrate sources are as follows : DEX, dextrin ; FRU, fructose ; SUC, sucrose

specific diseases or clinical symptoms which alter nutrient requirements significantly. Therefore, a wide variety of new enteral nutrition formulas need to be developed and readily available for dietary management of hospitalized patients with various physiological conditions. In addition, the process of maintaining the categories for evaluation of the enteral nutrition formulas should be dynamic, since new products sometimes may not reasonably fit any of the existing categories.

Summary and Conclusion

The purpose of this study was to investigate the types of enteral nutrition formulas currently used in hospitals and evaluate and categorize the commercially prepared enteral nutrition formulas available in the domestic market. The results of this study are summarized as follows ; 1) The average proportion of patients receiving the commercially prepared enteral nutrition formulas was greater than that of patients receiving the in-hospital preparations ; 2) In the group of patients receiving the in-hospital prepared formulas, the average proportion of patients fed by oral administration was greater than that of patients fed by tubes, whereas, in the group of patients receiving the commercially prepared formulas, the average proportion of patients fed by tubes was greater than that of patients fed by oral administration ; 3) On the average, a greater proportion of patients received enteral nutrition formulas as total replacements of their meals and for the purpose of dietary supplementation ; 4) On the basis of major criteria for evaluation of commercially prepared enteral nutrition formulas, the 6 products out of the 9 nutritionally complete products for the purpose of dietary supplementation were grouped into the same category, and thus considered therapeutically comparable, but the remaining 3 products were different in protein content or route of administration ; 5) Of the 3 nutritionally complete products formulated specifically for the purpose of dietary therapy, 2 products were formulated for patients with renal disease, and the one product was formulated for diabetic patients. Therefore, the data in this study showed that the commercially prepared enteral nutrition formulas became an important part of the enteral nutrition for hospitalized patients in this country, but the domestic market has not yet generated a wide variety of the formulas, thereby not providing many choices for clinicians to manage the diets for their patients.

The results of this study would be helpful for clinicians in choosing appropriate products for their patients, for manufacturers in developing new products, and for regulatory authorities to establish the regulation for the broad group of heterogeneous products that are marketed and will be developed as medical foods. In addition, the process of maintaining the categories for evaluation of the commercially prepared enteral nutrition formulas should be dynamic because new products may not reasonably fit any of the existing categories.

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