

## Clinical Evaluation of a Newly Developed Enteric Nutrient Given to the Neurosurgical Patients with Disturbances of Consciousness

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### Summary

An enteric nutrient 'SAN-ET-A', rich in protein and electrolytes, was given to 8 patients with disturbances of consciousness. Although the administered dosage had a calorie content so low that basal metabolism was barely maintained, the level of serum proteins increased following administration. Electrolyte imbalance was not found, and the patients did not suffer from severe renal or liver dysfunctions. No notable gastrointestinal troubles occurred except in one case. It is concluded that a low dosage of SAN-ET-A was sufficient to maintain the patients in good nutritional condition. Furthermore, it is suggested that this nutrient can be safely given for a long period.

### Introduction

A considerable number of patients admitted to neurosurgical clinics receive dietary management with tube feeding, being unable to eat or drink orally. These patients are generally placed on a low-calorie diet, by means of which basal metabolism can barely be maintained. Since most of the patients are bed-ridden, their energy requirements are essentially small and a high-calorie diet is not necessary. Furthermore, a low-calorie diet is recommended for preventing obesity, which can be one of main causes of bed sores<sup>2,4)</sup>. In contrast, even for such patients on a low-calorie diet, sufficient proteins must be given, since hypoproteinemia has adverse influence on hepatic, renal, bone marrow, and immune functions. When these functions deteriorate, patients suffer from bed sores, edema, ascites, infection, or other severe complications. Bed-ridden patients under dietary control with tube feeding, therefore, must be given a diet which is low in calorie and high in protein contents. Most enteric nutrients available as commercial products are made mainly for postoperative patients who urgently require high-calorie and protein-rich diets in order to overcome the large stress incurred in major gastrointestinal operations. High-calorie and protein-rich diets cannot be supplied simultaneously until a large amount of enteric nutrients have been given, because these nutrients are not specially prepared with a high protein content. Patients taking low dosages of these nutrients cannot receive sufficient proteins. It has been reported that some supplementary foods

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Key words: Tube feeding, Enteric nutrient, Nutrition, Disturbances of consciousness.

索引語: 経管栄養, 濃厚流動食, 栄養管理, 意識障害.

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**Table 1** The composition of SAN-ET-A

Volume	ml	100
Calory	kcal	100
proteins	g (calory %)	4.7 (18.8%)
lipids	g (calory %)	1.7 (15.3%)
(essential fatty acids	g)	(0.8)
sugars	g (calory %)	16.5 (65.9%)
ash component	g	0.7
water	g	84.4
<b>vitamines</b>		
A	IU	292
D <sub>3</sub>	IU	32.4
E	mg	2.05
B <sub>1</sub>	mg	0.10
B <sub>2</sub>	mg	0.16
B <sub>6</sub>	mg	0.26
niacin	mg	1.93
pant. acid	mg	0.86
folic acid	μg	49.0
B <sub>12</sub>	μg	1.5
C	mg	8.6
<b>minerals</b>		
Na	mg (mEq)	158 (6.9)
K	mg (mEq)	129 (3.3)
Ca	mg (mEq)	40.1 (2.0)
P	mg	63.5
Fe	mg	1.0
Mg	mg (mEq)	18.8 (1.5)
Mn	μg	6.5
Cu	μg	8.6
Zn	μg	183
Cl	mg (mEq)	160 (4.5)

osmotic pressure=430 mOsm/kg, pH=6.3

appearance: white to thin yellow

raw materials: corn dextrin, sodium casein, corn oil, vitamines, minerals

abbreviation: pant. acid; pantothenic acid

must be given for protein deficiency in such a condition<sup>1,3)</sup>.

An enteric nutrient 'SAN-ET-A' which has been purposely made to be rich in protein and electrolyte contents has recently been developed (Table 1). A dosage of this nutrient ranging from 1000 to 1400 kcal a day is said to be sufficient to nourish aged patients. It seems that SAN-ET-A is appropriate for patients who need a low-calorie and protein-rich diet. We administered this nutrient to patients who had disturbances of consciousness and were bed-ridden. The clinical evaluation of SAN-ET-A in these patients is reported in the present study.

### Materials and Methods

SAN-ET-A was given to 8 patients admitted to the Department of Neurosurgery, Shimane Medical University Hospital. They were all disturbed in consciousness and bed-ridden. Five pa-

Table 2 Details of the Patients

No.	Cases	Age (y.) & Sex	Diseases and Complications	Operations	Dosage (kcal)	Duration (days)	Side Effects	Nutritional Improvement	Effectiveness
1	IS	50, F	traumatic intracerebral hematoma	removal of hematoma	1200	84	mild liver dysfunction	slightly (+)	effective
2	EA	60, M	subarachnoid hemorrhage	neck clipping, decompression	600	13	(-)	slightly (+)	effective
3	YI	56, M	Arnold-Chiari malformation pneumonia	(-)	1200	56	constipation (diet, stopped)	slightly (+)	slightly effective
4	MI	63, F	subarachnoid hemorrhage	neck clipping, decompression	1200	32	diarrhea (diet, decreased)	moderately	slightly effective
5	NT	53, M	hypertensive intracerebral hematoma, hydrocephalus, pneumonia, liver cirrhosis	remova of hematoma, VP shunt	1200	17	(-)	moderately (+)	fairly effective
6	TH	85, M	subacute epidural hematoma pneumonia, renal dysfunc- tion	removal of hematoma	1200	19	(-)	stable	slightly effective
7	NH	52, F	hypertensive intracerebellar hematoma, hydrocephalus	removal of hematoma drainage, VP shunt	1200	34	diarrhea (diet, continued)	moderately (+)	effective
8	YT	53, M	acute epidural hematoma	removal of hematoma, decom- pression	1200	62	diarrhea (transient & mild)	moderately (+)	fairly effective

**Table 3** The Results of the Hematological and Serological Examinations before and after Administration of SAN-ET-A

		n=8	
		Before Administration	After Administration
TP	g/dl	6.59±0.22	6.81±0.12+
Alb	g/dl	3.48±0.16	3.55±0.18
BUN	mg/dl	13.5±1.07	15.9±2.33
Crea	mg/dl	0.69±0.04	0.75±0.06
GOT	IU	60.1±29.4	46.9±15.9
GPT	IU	76.1±48.7	43.8±13.1
ALP	KA	105.3±30.5	87.9±19.7
$\gamma$ -GTP	mU/ml	127.8±36.6	164.8±59.7
T-Bil	mg/dl	0.54±0.08	0.48±0.10
LAP	mU/ml	82±34	82±31
ChE	WU	1153±239	1155±253
LDH	WU	472±77	377±38
CPK	IU/l	64.7±19.2	35.0±16.4
TC	mg/dl	188.9±32.0	183.6±29.6
TG	mg/dl	191.5±69.0	229.7±74.6
Na	mEq/l	137.0±1.2	138.4±1.2
K	mEq/l	4.21±0.22	4.24±0.18
Cl	mEq/l	97.9±1.2	98.1±1.0
Ca	mEq/l	8.6±0.2	9.1±0.2
P	mEq/l	3.86±0.09	4.34±0.45
RBC	10 <sup>4</sup> /mm <sup>3</sup>	356.5±22.4	342.0±14.8
WBC	/mm <sup>3</sup>	96.3±7.1	79.6±12.1
Hb	g/dl	11.6±0.6	11.1±0.5
Ht	%	33.7±0.8	32.5±1.0

mean ± SE

tients were male, and 3 were female. Ages ranged from 53 to 85 years (mean age; 59). Three patients were suffering from intracerebral hemorrhage, 2 from subarachnoid hemorrhage, 2 from epidural hematoma, and one from Arnold-Chiari malformation (Table 2). In 7 patients, administration of SAN-ET-A was begun postoperatively.

SAN-ET-A was administered through a naso-epigastric tube in each patient. To one patient, who rapidly recovered from the unconscious state to take food and drinks orally, 600 kcal per day of SAN-ET-A was given. The other 7 patients were given 1,200 kcal per day. SAN-ET-A was dripped at a rate of 200 ml/h 5 cases, and at 100 ml/h in 2 cases. The dripping rate was not documented in one case. The duration of administration of SAN-ET-A ranged from 13 to 83 days (mean duration; 40 days).

Hematological and serological examinations were performed before and after the administration of SAN-ET-A. The focus of these examinations was items, such as: 1) serous proteins (total proteins; TP, and albumin; Alb), 2) renal functions (blood urea nitrogen; BUN, and creatinin; Crea), 3) liver functions (glutamic oxaloacetic transaminase; GOT, glutamic pyruvic transaminase; GPT, alkaline phosphatase; ALP,  $\gamma$ -glutamyl transpeptidase;  $\gamma$ -GTP, total bilirubin; T-Bil, leucine aminopeptidase; LAP, cholinesterase; ChE, and lactic dehydrogenase; LDH), 4) creatin phosphokinase; CPK, 5) serous lipids (total cholesterol; TC, and triglyceride; TG), 6) serous electrolytes (Na, K, Cl, Ca, and P), and 7) blood cell counts (red blood cells; RBC, white blood cells; WBC, hemoglobin; Hb, and hematocrit; Ht).

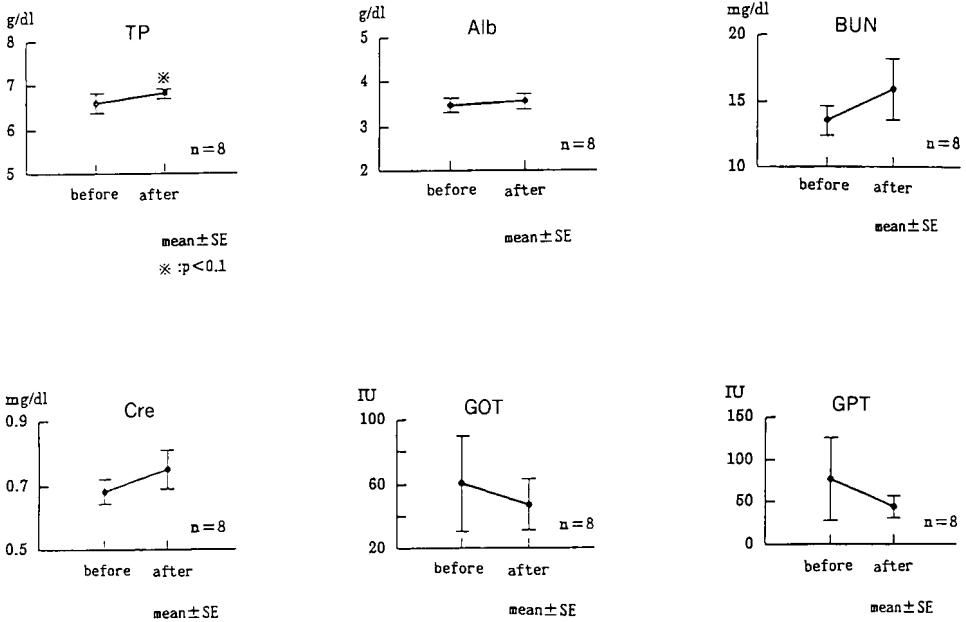


Fig. 1 The Results of the Representative Items in the Serological Examination before and after Administration of SAN-ET-A

## Results

### 1. Hematological and serological examinations

#### 1) Serous proteins (TP and Alb)

After administration of SAN-ET-A, TP increased significantly from  $6.52 \pm 0.22$  g/dl to  $6.81 \pm 0.12$  g/dl ( $p < 0.05$ ). The values of Alb also increased from  $3.48 \pm 0.16$  g/dl to  $3.55 \pm 0.18$  g/dl, but the increase was not statistically significant (Table 3, Figure 1).

#### 2) Renal functions (BUN and Crea)

After administration of SAN-ET-A, BUN increased from  $13.5 \pm 1.07$  mg/dl to  $15.9 \pm 2.33$  mg/dl. The values of Crea also increased from  $0.69 \pm 0.04$  mg/dl to  $0.75 \pm 0.06$  mg/dl. Neither of these increases were, however, statistically significant (Table 3, Figure 1).

#### 3) Liver functions (GOT, GPT, ALP, $\gamma$ -GTP, T-Bil, LAP, ChE, and LDH)

The values of GOT, GPT, ALP, and LDH decreased somewhat after administration of SAN-ET-A, and there were no notable changes in the values of  $\gamma$ -GTP, T-Bil, LAP, and ChE (Table 3, Figure 1).

#### 4) CPK

CPK decreased, but not significantly, from  $64.7 \pm 19.2$  IU/l to  $35.0 \pm 16.4$  IU/l (Table 3).

#### 5) Serous lipids (TC and TG)

The values of TC and TG, which were within normal limits in all patients, did not change significantly (Table 3).

#### 6) Serous electrolytes (Na, K, Cl, Ca, and P)

There were almost no changes in the values of Na, K, and Cl after administration of SAN-ET-

A. The values of Ca and P increased slightly, but these increases were not significant.

7) Blood cell counts (RBC, WBC, Hb, Ht)

RBC and WBC decreased, but these changes were also not statistically significant. There were almost no changes in the values of Hb and Ht after administration of SAN-ET-A.

2. Side effects

Three patients had no complications. Diarrhea occurred in 3 cases, in two of which it was transient and mild. In spite of the existence of diarrhea, administration of SAN-ET-A was possible in these 3 cases. Liver functions slightly deteriorated in one patient, but it was possible to continue to give SAN-ET-A. In one other patient, administration of this nutrient was interrupted due to abdominal distension and constipation.

3. Improvement of nutrition

The nutritional conditions became moderately improved in 4 cases, and slightly improved in 3 cases. In one case, they remained stationary.

4. Clinical evaluation

SAN-ET-A was 'fairly effective' in 2 cases, 'effective' in 3 cases, and 'slightly effective' in the other 3 cases.

## Discussion

The current trend is to nourish unconscious and bed-ridden patients with a low-calorie diet, and it is known that such patients must also receive a large volume of proteins simultaneously. A considerable number of commercial enteric nutrients are widely used not only for neurosurgical patients but also postoperatively for surgical and otosapharyngeal patients. Those products do not provide sufficient protein, although the calorie content can easily be reduced by giving a low dosage. Since hypoproteinemia can lead to several kinds of complications as described in the introduction, a low dosage of SAN-ET-A was given to patients with disturbances of consciousness in our clinic in order to provide a diet which is both low in calorie and high in proteins. As described above, SAN-ET-A is an enteric nutrient which has been developed to be high in protein and electrolyte contents.

The levels of TP and Alb, which reflect the patient's nutritional condition, increased after administration of SAN-ET-A. The increase in TP was statistically significant. The fact that bed sores did not occur in any patient may reflect a favorable level of serous proteins. No notable renal or liver dysfunctions were demonstrated in any of our patients given SAN-ET-A. These results imply that SAN-ET-A can safely be administered to unconscious and bed-ridden patients for a long period. CPK, the level of which is said to increase in patients with cerebrovascular diseases, tended to decrease. Stable levels of serous lipids, electrolytes, and blood cell counts were maintained, and it was not necessary to perform blood transfusion. In one case, the administration of SAN-ET-A had to be stopped due to abdominal distension and constipation. The other 7 patients did not have gastrointestinal troubles which necessitated a halt in SAN-ET-A administration. The nutritional condition improved in all cases except for one case which remained stable. Even the patient whose nutrient had to be discontinued exhibited improvements. Judging from these clinical outcomes, it was concluded that SAN-ET-A was effective in improving the nutritional and general condition of all 8 patients.

It is generally said that the basal metabolic rate in a patient with a prolonged disturbance of consciousness is about 1,000 kcal/day<sup>5</sup>). Our study revealed that a low dosage of SAN-ET-A, which has

a calorie content so low that basal metabolism can barely maintained, was sufficient to keep patients in good nutritional condition.

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#### 和文抄録

## 脳神経外科遷延性意識障害患者における 経管栄養食の臨床的評価

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最近, 従来のものに比べて蛋白および電解質の含量がより多い経管栄養食が開発された。8例の遷延性意識障害患者にこの経管栄養食「サンエットA」を用いたので, その臨床的評価を報告する。全ての例において基礎代謝が辛うじてまかなえる程度のカロリー量(1,200 kcal/日)しか使用しなかったにもかかわらず, 血清蛋白量は有意に上昇した。電解質異常は認められ

なかった。著明な腎機能障害や肝機能障害もみられなかった。投与を中止せざるを得ないような消化管症状を呈したのは1例のみであった。サンエットAを低いカロリーに押えて使用することは意識障害患者の栄養管理に有効であると結論された。さらに, この経管栄養食は長時間にわたって安全に使用できると考えた。