Evaluation of Low-Lactose Sustacal in the Diet of Convalescent Malnourished Infants

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SUBJECT:

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Critical Evaluation of New (or Enriched) Protein Sources (For the Prevention of Malnutrition)

ABSTRACT

Low-lactose Sustacal (Mead Johnson) was evaluated in the diets of 4 convalescent malnourished infants by comparative balance studies, and in the initial management of 5 newly admitted patients. The balance studies of 9 days on Sustacal and 9 days on a control diet based on casein suggested a slight inferiority of Sustacal in terms of nitrogen retention and weight gain, although the short time periods made the latter finding suspect. Fecal fat values were difficult to interpret because of steatorrhea in several of the patients. Increased fecal fat in the Sustacal studies, along with moderately inferior nitrogen absorption, probably accounts for the apparently inferior "biological value" and nitrogen retention. The patients managed initially with Sustacal all had uneventful courses.

MATERIALS

Sustacal (Mead Johnson) is a low-lactose food designed for use as a protein and micronutrient supplement to poor diets. Protein is supplied by sweet skim milk, casein, and soy protein isolate, carbohydrate by sucrose and corn syrup solids, and fat by partially hydrogenated soy oil. The approximate composition (W/W) is protein 5.7%, fat 2.2% and carbohydrate 13%. One hundred milliliters of the product supplies 100 calories, about 24% as protein, 55% as carbohydrate, the rest as fat. Lactose accounts for 11% of the carbohydrate. The following vitamins and minerals have been added (amount per 100 grams): vitamin A 462 mg, vitamin D 37.8 mg, vitamin E 2.73 mg, vitamin C 9.66 mg, folic acid 0.01 mg, thiamine 0.14 mg, riboflavin 0.17 mg, niacin 1.89 mg, pyridoxine 0.19 mg, cyanocobalamin 0.55 μg, biotin 28.14 μg, pantothenic acid 1.05 mg, calcium 100.8 mg, phosphorus 84 mg, iodine 13.86 μg, iron 1.68 mg, magnesium 37.8 mg, copper 0.21 mg, zinc 1.39 mg, manganese 0.29 mg. Choline has also been added. Vitamins and minerals are supplemented such that the consumption of 1200 calories per day of the product provides 100% of the recommended daily allowance of all for the average 8-10 year old child.

METHODS

Comparative studies between Sustacal and our control diet based on casein, cottonseed oil, and sucrose were done in four infants with protein (N x 6.25) providing 6.4% of calories,

as in previously reported studies (1). Cottonseed oil and sucrose were added to the Sustacal to achieve the desired protein concentration. Vitamins and minerals were supplemented as necessary.

In two infants a nine-day control period was followed by nine days on Sustacal. In two others the order was reversed. All children spent the last six days of each dietary period in the metabolic bed for collections of urine and stool. Three-day fecal fats were measured and three-day nitrogen balances were calculated. Changes in rate of weight gain and in serum albumin were monitored.

An additional five children admitted for the treatment of severe acute malnutrition (1 marasmus, 1 marasmic kwashiorkor, and 3 kwashiorkor) were managed on Sustacal as the sole source of protein for periods of 26 to 41 days. In these children, because of the high percentage of calories provided as protein by the undiluted Sustacal, when calorie intakes had to be increased above 100 Kcal per kilogram (6 gm protein per kg) this was done by adding sucrose and cottonseed oil to the product. This effectively reduced the percentage of calories provided by protein to 19% at 125 Kcal/kg and 16% at 150 Kcal/kg. In two children short periods of time were spent in the metabolic bed during the initial phase, allowing calculation of nitrogen balances at different levels of intake.

Plasma amino acids were determined in several children at various times during both the comparative and initial studies. These results will be reported separately later.

RESULTS

Table I summarizes the results of the four comparative studies. The studies were generally uneventful except for patient 424, who experienced three days of unexplained weight loss while on casein and was in negative nitrogen balance at that time. Stool fat was also increased. The reason for this was obscure as the child was clinically well. Because the results of the first three-day balance period are obviously out of line with those of the second and third periods and may have influenced subsequent nitrogen retentions, this patient's balances are presented in detail rather than averaging them. The changes in weight and serum albumin span the entire time period.

Apparent nitrogen retention on Sustacal was equal to that on the casein diet only in patient 396. All other patients had significantly lower values on Sustacal, although the possibility exists that this is artifactual in the case of #424. After his first three days on negative nitrogen balance on casein there is an apparent rebound with a high retention during the next three days, falling to 28% during the last three days on casein. This is equalled during the first three-day collection (days 4-6) on Sustacal, and then a further slight fall

takes place. The mean apparent nitrogen retention for the casein periods using all three balance periods is 22%, using only the final two periods 33%. The mean for the Sustacal periods is 27%. Of some possible significance is the increase in stool wet weight during the Sustacal periods. This may represent some degree of carbohydrate malabsorption and was not seen in the other three boys.

Both #'s 392 and 430 had slightly lower retention of nitrogen while on Sustacal. The order of the diets was reversed in the two infants. Both had significantly higher fecal fat excretions while on Sustacal. By decreasing "effective" calorie intake, this could have decreased N retention.

If the nitrogen retentions on Sustacal are expressed as a percentage of those on casein, the mean value for all studies is 88.5%, if all three casein balance periods for #424 are included. If only his two final balance periods are included this value falls to 78%. A similar calculation of the mean biologic value for Sustacal expressed as a percentage of casein for all studies yields values of 97% and 85% respectively.

Despite the slight apparent inferiority of Sustacal in at least two and possibly three patients, serum albumin concentration either increased or was well maintained in all cases.

Weight gain appeared to be significantly less in patients 392 and 424 while on Sustacal. The short time periods make one hesitant to draw fast conclusions.

Fecal fats were equal on the two diets in two infants (#'s 396 and 424), were slightly elevated while on Sustacal in patient 430 and were markedly elevated on both casein, and more so, on Sustacal in patient 392. The latter patient exhibited steatorrhea in varying degrees throughout his hospital course regardless of diet and consequently these values must be interpreted with some caution.

Our experience with the use of Sustacal in the initial management of severely malnourished patients is presented in Tables II and III. As can be seen from Table II the clinical course of these patients was routine. After the initial day or two, the diet was well tolerated by all five infants. Four of the patients had edema on admission. Loss of edema and regeneration of serum albumin occurred at an acceptable rate. The seemingly long period of time to reach a calorie intake of 100 Kcal/kg in #'s 402 and 404 reflects our practice of maintaining edematous children at about 75 Kcal/kg until edema has cleared and does not represent any intolerance to the diet. The diarrhea in #402 which caused the Sustacal to be discontinued occurred when the Sustacal was changed from vanilla to chocolate but the relation to this change may have been fortuitous.

The balance data obtained during these initial periods (Table III) show good nitrogen retentions in patient 401 and a picture of constantly improving absorptions and retention

during the course of #402. The stool fats in #401 were well within the limits of normal. Initial fecal fats in #402 seemed high because of the low intake but subsequently were normal or nearly so. The meaning of these data is discussed below.

DISCUSSION

The short-term balance studies suggest a slight inferiority of Sustacal when diluted to 6.4% protein calories, relative to the control diet. Although serum albumin was well maintained in all patients, nitrogen balances are considered a more sensitive indicator for short-term studies and were inferior to casein in two and possibly three patients. The difference is not great, however, and should not be considered a major drawback of the product. Some of the result was due to inferior nitrogen absorption and some possibly to increased fecal fat. In patient 396, with the best N absorption and the lowest fecal fat, N retention and weight gain were equal on both diets.

Some of the weight changes, although occurring over short time periods, are difficult to explain. The excessive fat loss in patient 392 while in Sustacal would account for a daily calorie loss of about 10.2 Kcal/kg in excess of the losses while on casein. Assuming the cost of weight gain to be about 6 Kcal per gram (2), this might account for 1.5 to 2 gm/kg/day of the difference noted between the two diets. It is not sufficient to explain the complete difference. It is possible that at very high fat concentrations our fecal fat method underestimates the amount present. The difference noted in

#424 is also unexplained, especially when one considers the fact that the casein period includes a six-day period with a net weight change of zero. The nitrogen retentions, stool fats, and changes in serum proteins give no satisfactory clue as to why this occurred, nor does a review of the child's clinical state during the study period. The increased wet weight of the stool may have been a factor.

In the single child not manifesting steatorrhea, #396, the stool fats on both diets were similar and normal. It is difficult to draw conclusions from the other stool fats. Steatorrhea is well documented in malnourished children, especially early on in their recuperation (3), and this is frequently a problem in balance studies done in this type of patient. Our experience has been that these children may have highly variable fat excretions during this time, making definite conclusions difficult.

The initial studies were quite uneventful. It is not surprising that these patients, predominantly kwashiorkors and marasmic kwashiorkors, did well on the undiluted product. Providing 24% of calories is probably unnecessary, however, and it is doubtful that this offers significant advantage even in these protein depleted children over a diet of 10-12% protein calories. Time for disappearance of edema and rate of regeneration of serum albumin were not different. The balance studies done in these children, having been done at such a high protein intake, are subject to a high degree of error. They are

interesting in that they document the changes in both nitrogen and fat absorption during early recuperation but they do not shed a great deal of light on the product itself.

The impression of the product that one gains from these studies is that although slightly inferior to the control diet in terms of nitrogen retention at critical levels of protein intake, it is in general nutritionally of good quality. As mentioned above, the protein concentration is excessive in the undiluted form even for protein depleted children. As a supplement to most children's diets, which are generally more than adequate in protein, especially in the income group which is likely to be able to purchase the product, the same criticism is probably valid. Its greatest potential is as the main source of protein and micronutrients in an otherwise poor diet. If it is to be used therapeutically, serious consideration must be given to the possibility of replacing the hydrogenated soy oil, poorly absorbed by the malnourished, with soy oil or another highly unsaturated vegetable oil.

REFERENCES

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Table I

Comparative Studies - Sustacal

Pt. No.	Protein			Nitrogen Balances					Stool			Δ Body Wt	Serum Alb. g/100 ml	
					mg/day		% of Intake		Wt.	Fat				
	Source	% Kcal	Days	On Days	Int.	Ret.	Abs.	Ret.	g/day	g/d	% Int	g/kg/d	Δ	Final
392[a]	C	6.4	9	4- 9	2784	1079	86	39	84	13.4	22.5	5.2	-0.09	4.74
	S	6.4	12	4-12	2790	740	80	27	95	24.6	40.0	0.9	-0.02	4.72
396[b]	S	6.4	9	4- 9	2251	861	85	38	36	2.0	4.1	3.0	+0.05	3.89
	C	6.4	9	4- 9	2323	902	89	39	55	2.6	5.3	2.8	-0.10	3.79
424[c]	C	6.4	12	4- 6	2480	-9	86	--*	37	12.6	24.8	5.15[e]	+0.41	4.21[e]
				7- 9	2480	934	88	38	42	7.7	15.2			
				10-12	2480	682	85	28	90	8.4	16.5			
	S	6.4	9	4- 6	2403	698	78	29	168	10.7	21.1	2.32	+0.02	4.23
				7- 9	2403	572	77	24	111	9.5	18.7			
430[d]	S	6.4	9	4- 9	2053	561	75	27	51	9.3	21.4	6.4	+0.39	3.96
	C	6.4	9	4- 9	2120	839	83	40	61	6.9	16.0	7.1	+0.01	3.77

a CA = 15.6 HT = 71.4 (9.25) WT = 9160 (9.25) Sl. URI with Sust - T to 39^4 x 1 d in last Sust. period. Study Begun D-73.

b CA = 17.3 HT = 72.0 (9.75) WT = 8300 (7.3) Uneventful. Just recov. from diarrhea. 1st try with Sust. aborted D-108.

c CA = 14.8 HT = 66.0 (6.0) WT = 5950 (3.4) *Unexplained wt loss these 3 days. Clinically well. [e] value for all 12 days.

d CA = 8.1 HT = 59.7 (2.8) WT = 5020 (1.7) Uneventful study.

Table II

Initial Management - Sustacal

Pt. No.	Age Mos.	Ht-cm (H.A.-mo.)	Wt-kg (W.A.-mo.)	McLaren Score	Kcal Per kg	Kcal % Prot	No. Days	Δ Wt g/kg/d	Serum Albumin Δ	Serum Albumin Final	Edema	Other
101	20.1	74.6(12.5)	8270(8.25)	10	Lytren	--	1	- 8.5	-0.08	2.57	Yes	R Otitis &
					27	24	1	- 9.7	--	--	x 3 D.	Giardia
					58	24	2	+ 1.0	+0.16	2.73		
					75	24	7	6.0	--	--		
					90	24	10	2.9	+1.47	4.20		
					100	24	5	4.7	--	--		
102	17.3	75 (12.25)	7400(5.8)	9	Lytren	--	1	23.0	+0.17	1.81	Yes	
					14	24	2	2.0	-0.28	1.53	"	
					27	24	2	3.3	-0.05	1.48	"	
					45	24	2	- 3.6	+0.16	1.64	"	
					65	24	8	- 6.1	+1.23	2.87	"	
					90	24	12	+ 6.2	+1.19	4.06	Gone: D13	
					100	24	4	0.7	--	--		Onset Diarrhea
104	15	79 (15)	10,730(15)	8	Lytren	--	1	-26.4	--	2.31	Yes	Lowest Wt D9 =
					25	24	1	-91.0	--	--	"	Loss of 1970
					Lytren	--	1	- 6.3	--	--	"	gm
					25	24	1	-29.9	--	--	Gone: D 7	
					50	24	8	- 5.4	--	--		
					75	24	8	+ 2.7	--	--		
					100	24	11	+ 4.4	+1.26	3.57		
118	7	60.3(3.2)	4120(0.7)	1	25	24	2	0	--	3.94	No	
					50	24	1	-32.1	--	--		
					75	24	3	+ 9.4	--	--		
					100	24	8	+ 7.4	--	--		
					125	19	12	+ 2.3	--	--		
					150	16	15	+ 6.1	-0.22	3.72		
121	23	72 (9.75)	6720(4.8)	13	25	24	2	- 6.7	--	1.94	Yes	
					50	24	2	2.3	--	--	"	
					75	24	9	3.1	--	--	Gone: D11	
					100	24	8	2.7	--	--		
					125	19	16	6.1	+1.53	3.47		

Table III

Initial Studies - Sustacal: Balances

Pt. No.	Protein Source	Kcal/kg/d + % Prot.	No. of Days	Nitrogen Balances On Days	mg/day Int.	mg/day Ret.	% of Intake Abs.	% of Intake Ret.	Stool Wt. g/day	Stool Fat g/d	Stool Fat % Int.	Δ Body Wt g/kg/d	Serum Alb. g/100 ml Δ	Serum Alb. g/100 ml Fina
401	Sustacal	90-24%	10	1-3	7166	2741	--	38	--	0.7	3.9	+2.9	0.93	4.20
		100-24%	5	3-5	7963	2301	--	29	--	1.48	7.5	+4.7	-0.11	4.09
402	Sustacal	14-24%	2	1-2	972	0	40	0	370	1.5	62.1	+2.0	-0.28	1.53
		27-24%	2	1-2	1403	195	52	14	332	2.4	68.7	3.3	-0.05	1.48
		45-24%	2	1*	3242	1621	75	50	235	5.9	73.0	-3.6	--	--
		65-24%	8	7-8	4354	1573	86	36	169	1.56	14.4	-6.1	+1.23	2.87
		90-24%	12	8-9	6238	1451	88	23	63	1.14	7.3	+6.2	+1.19	4.06
		100-24%	4	3-4	7307	1925	73	26	502†	2.84	15.6	0.7	--	--

* Study stopped - Bed sore

† Δ to chocolate flavor