NUTRITION REPORTS INTERNATIONAL

EFFECTS OF A HIGH PROTEIN SUPPLEMENT ON BODY WEIGHT AND BLOOD CONSTITUENTS OF OVERWEIGHT AND OBESE INDIVIDUALS

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ABSTRACT

Although obesity is recognized as a common problem in all affluent societies, it is excessively present in the United States. Regardless of the approach, loss of weight, while highly cosmetically and clinically desirable is not easily achieved and maintained. Drastic reduction by means of drugs, surgical procedures or highly restrictive diets frequently fail or cause serious clinical problems. In order to avoid these pitfalls and minimize participant attrition we instructed the volunteers for this study to continue with their customary daily breakfast and dinner and substitute a vitamin-mineral fortified protein supplement for lunch. The test panel included 20 females (23-59 years) with body weights 114-163+% of ideal and 9 males (24-66 years) with body weights 121-243+% of ideal. Control measurements of 21 blood constituents showed no abnormalities with exception of moderately elevated lipid constituents in 7 females and 5 males. Test periods of 1 to 24 months with the females resulted in body weight losses from 7 to 25 pounds. In the males test periods of 3 to 48 months resulted in body weight losses of 7 to 33 pounds. The differences and duration of weight losses were closely related to degree of initial overweightness and regularity of daily consumption of 8 ounces of a high protein supplement. The calcium content of the supplement (80% of USRDA) prevented bone loss frequently incurred with very low calorie high protein diets. Five of our test panel 4 females and 1 male now in their fifth year of study have sustained the weight losses of 20-33 pounds attained during the first year of the trials.

INTRODUCTION

Obesity and its clinical sequelae continue as one of the primary health problems in the U.S. In terms of actual numbers it is estimated that more than 80 million Americans are considered overweight and 40 million women are clinically obese (1,2). Statistics also show a 12 fold increase in rate among grossly obese men between 25 and 34 years of age. Recent surveys indicate that obesity, in addition to primary coronary heart disease, strokes and diabetes mellitus, may be associated with at least twenty-three other known medical conditions which collectively account for 10-15% of the annual mortality rate. The trend and magnitude of obesity increases with age in male, more so in females, and is due

primarily to food consumption in excess of regression in physical activity and reduced metabolic rate with advancing years (3). The process is slow but incidious. The yearly accretion of a single pound annually after age 25 will result in a gain of 25 pounds by age 50. The belated personal concern and realization of this weight gain problem results in frantic searches for easy ways out of the predicament. Persistent failures with the plethora of dietary schemes available to treat the disease is conspicuous by the very small degree of success. Less than 5% of those who have lost excess weight rarely maintain it for more than a year (4).

In this investigation in order to minimize participant attrition and avoidance of unphysiologic and temporary weight losses as well as untoward clinical effects of numerous "crash diets" our test panel was instructed to substitute a vitamin-mineral fortified protein supplement for their mid-day meal and continue with their usual breakfast and dinner. This dietary plan was designed to avoid disturbance of daily normal family meal customs and thereby encouraging adherence to the dietary protocol and duration of the test periods.

PROCEDURES AND METHODS

Study Panel - Prospective candidates were selected on the basis of histories of chronic overweight or obesity and prior disappointing experiences with a variety of widely advertised weight reducing schemes. The test panel included nurses, technicians, secretaries and maintenance staff personnel and housewives. Apart from their chronic weight problems all individuals in the study were in apparent good health and actively engaged in activities of daily living incident to their employment and life style. Degree of obesity was estimated from the Metropolitan Life Insurance Co. Tables of 1959 with reference to the appropriate body frames for both men and women. Individuals with body weight greater than 110%S of their "ideal" weight were included in our investigation. A recent review of the literature indicates that shortcomings of calculations based on these tables do not appear to be any greater than limitations of measurements of skin fold thickness or various biochemical modalities (5). The uniform application of this calculation proved practical and adequate for the purpose of this study:

$$\text{Initial Body Weight Status} = \frac{\text{observed weight, lbs.}}{\text{ideal weight, lbs.}} = \%S$$

$$\text{Example: Subject C.D., female} = \frac{217 \text{ lbs.}}{131 \text{ lbs.}} = 165\%S$$

Methods - Prior to admission to the study, fasting blood samples were collected from all participants to detect any existing biochemical

parameters of ill health. The Roche Systemic Screening and Lipid Profiles employed in this investigation include measurements of 21 blood constituents (Table 1). This biochemical battery was repeated at 4 to 6 month intervals throughout the test period to ascertain safety and metabolic characteristics of the regimen. Bi-weekly body weight and dietary histories were obtained before and periodically throughout the test periods. The dietary records were analyzed for calorie, protein, carbohydrates, fat, phosphorus and calcium content from calculations of data available in USDA Report on Nutritive Value of Foods (6). However, due to the persistent and well known problems of recall, the results proved unsatisfactory as an accurate measure of actual calorie intake.

Table 1

LIST OF BIOCHEMICAL MEASUREMENTS

Test Received	Test Performed	Results	Normal Values
06/15/79	SEROLOGY A.R.T.	NON REACTIVE	
06/15/79	TOTAL PROTEIN	7.2	6.0- 8.0 GM/DL
06/15/79	ALBUMIN	3.8	3.5- 4.8 GM/DL
	GLOBULINS	3.4	2.0- 3.5
	A/G RATIO	1.11/1	1.2/1- 2.4/1
06/15/79	CALCIUM	9.0	8.5- 10.8 MG/DL
06/15/79	PHOSPHORUS	2.7	2.1- 4.6 MG/DL
06/15/79	CHOLESTEROL	185	150- 280 MG/DL
06/15/79	TRIGLYCERIDES	147	20- 170 MG/DL
06/15/79	UREA NITROGEN	14	7- 22 MG/DL
06/15/79	URIC ACID	6.6	4.0- 8.2 MG/DL
06/15/79	CREATININE	1.0	.6- 1.4 MG/DL
06/15/79	BILIRUBIN,TOTAL	.3	.1- 1.2 MG/DL
06/15/79	PHOSPHATASE,ALK.	99	30- 125 U/L
06/15/79	LACTIC DEHYDROGENASE	180	110- 225 U/L
06/15/79	SGOT-TRANSAMINASE	16	10- 30 U/L
06/15/79	GLUCOSE (SERUM)	84	65- 110 MG/DL
	CBC		
06/15/79	LEUKOCYTES	3.7 *	4.5- 10.6 THOUS/CMM
06/15/79	RBC	4.5	4.3- 6.0 MILL/CMM
06/15/79	HEMOGLOBIN	14.2	13.5- 17.6 GM/DL
06/15/79	HEMATOCRIT	44	41- 53 VOL PCT

CONTINUED ON FOLLOWING PAGE

Test Received	Test Performed	Results	Normal Values
06/15/79	MCV	96	80- 104 CU
06/15/79	MCH	30	26- 34 UUG
06/15/79	MCHC	32	31- 37 PERCENT
	CELLS DISINTEGRATED		
	LIPOPROTEIN		
06/15/79	APPEARANCE	CLEAR	
06/15/79	CHYLOMICRONS	NONE	
06/15/79	BETA	NORMAL	
06/15/79	PRE-BETA	NORMAL	
06/15/79	ALPHA	NORMAL	

The composition of the protein supplement SPP/SM which served as the mid-day meal is shown in Table 2. The protein component is derived from a soy protein isolate which thoroughly mixed with skim milk provides an ample and balanced amount of essential amino acids necessary for the biosyntheses of various body proteins. The vitamin and mineral complex was included to insure optimal nutrient balance. The estimated protein efficiency ratio (PER) of the supplement is 25 - indicative of a high qual-

Table 2

Soy Protein Product and Skim Milk Supplement

	Soy Protein Product SPP	Skim Milk SM	SPP/SM Supplement*
Amount oz.	1.0	8.0	8.0
Calories	110	87	197
Protein g	16	8.6	24.6
Carbohydrates g	8	12.5	20.5
Fat g	1.0	0.2	1.2
	USRDA %		
Thiamine	130	6	136
Riboflavin	120	25	145
Niacin	50	0	50
Calcium	50	30	80
Iron	70	0	70
Phosphorus	25	20	45
	Essential Amino Acids		
Methionine, mg	450	300	750
Isoleucine, mg	750	780	1530
Leucine, mg	1220	1200	2420
Phenylalanine, mg	815	588	1403
Lysine, mg	955	948	1903
Threonine, mg	580	564	1144
Tryptophan, mg	205	168	373
Valine, mg	735	840	1575
Histidine, mg	395	373	768
Protein, PER	25	25	25

*Caloric Distribution: protein, 51%; carbohydrate, 43% and fat, 6%.

ity protein source such as milk. In this connection, it should be noted, that the high calcium content of the supplement (80% of USRDA) was employed primarily to correct the estimated low daily calcium intake of our subjects - approximately 250-310 mg/day. Week long organoleptic trials with 10 prospective candidates revealed good acceptance of the supplement as a luncheon replacement and tolerance of the dietary protocol.

RESULTS

The control and test data obtained in the study of 20 females (23-59 years) and 9 males (24-66 years) are summarized in Table 3. The pre-test body weight status of the females ranged from 114-163%S and that of the males 121-243%S. Control biochemical values of fasting blood sugars, hemoglobin and serum iron fell well within the sex and age norms. The optimal level of serum cholesterol remains a muchly disputed subject, but most authorities consider the lower the level the less the risk of premature coronary heart disease (6,7). In our study the blood cholesterol content of 6 females (114-143%S) fell within the abnormal level (221-249 mg%). High cholesterol values were associated with abnormal triglyceride levels and lipoprotein type in only 2 obese subjects: TM, 144%S and

Table 3

Relationship of Initial Body Weight and Serum Lipid Levels of Overweight and Obese Females and Males to Weight Loss With a Daily Soy and Milk Protein Supplement

	No.	Subject	Age	Occupation	Body Weight		Serum Lipids			SPP/SM Supplement		
							Chol-esterol	Tri-glycerides	Lipo-protein	Test Period	Average Intake	Final Loss
			yrs.		lbs.	%S	mg%	mg%	profile	mos.	oz/day	lbs.
FEMALES	1.	BV	56	secretary	139	116	217	176	N	9	8	9
	2.	CD	23	secretary	217	165	142	58	N	7	7	20
	3.	CM	23	nurse	114	116	183	65	N	22	6	15
	4.	DR	55	lab. tech.	151	115	247*	128	N	20	8	10
	5.	DA	48	housewife	140	118	-	-	-	11	4	10
	6.	EA	62	audiologist	173	141	231	99	N	14	4	10
	7.	FM	54	nurse	159	144	213	66	N	4	7	7
	8.	GR	59	nurse	144	127	272*	96	N	13	7	15
	9.	GN	49	orthodist	187	143	250*	179*	IV*	48	7	16
	10.	GL	31	nurse	120	125	159	60	N	12	6	10
	11.	HA	42	housewife	183	144	217	73	N	5	4	10
	12.	KE	56	payroll	150	126	211	109	N	48	8	22
	13.	MJ	43	ekg tech.	174	163	209	60	N	48	8	19
	14.	OJ	47	nurse	157	132	170	117	N	2	8	10
	15.	SA	41	telephone op.	135	123	166	125	N	1	8	7
	16.	SB	53	housewife	150	133	250*	81	N	6	8	23
	17.	SP	52	nurse	140	124	245*	161	N	2	6	8
	18.	TN	59	housewife	140	114	244*	118	N	48	8	13
	19.	TM	57	nurse	159	144	234	255*	IV*	16	5	20
	20.	YV	59	nurse	172	131	243*	54	N	18	6	17
MALES	1	CP	45	maintenance	234	153	185	147	N	4	8	14
	2	DP	52	pharmacist	205	141	230	146	N	48	8	29
	3	GS	66	builder	181	125	223	191*	N	3	8	20
	4	MN	44	beautician	176	121	209	211*	IV*	7	8	7
	5	SF	30	gardener	340	243	152	124	N	4	8	33
	6	SW	50	plasterer	222	117	164	218*	IV*	14	8	22
	7	TJ	24	painter	198	122	283*	297*	II*	5	8	10
	8	TC	61	gardener	189	139	183	97	N	4	8	33
	9	WD	48	carpenter	195	147	231	204*	IV*	3	8	17

*ABNORMAL VALUES

GN, 143%S (7). Of the males, subject, TJ, 122%S, was found to have abnormal cholesterol and triglyceride levels and abnormal lipoprotein profile. In subjects, MN, 121%S: SW, 137%S and WD, 147%S abnormal triglyceride levels were associated with abnormal lipoprotein profiles. Sujbect, GS, 125%S presented only the abnormal triglyceride level.

Test periods 1 to 24 months with the females resulted in body weight losses from 7 to 25 pounds. In the males test periods of 3 to 48 months resulted in body weight losses of 7 to 33 pounds. Differences in rate of weight loss appear to be closely related to degree of initial overweightness. However, regularity of daily consumption of 8 oz/day of SPP/SM supplement and duration of participation in the study were found to be very important factors in the evaluation of the weight reducing efficacy of the protocol. Typical impact of these factors on rate of weight loss in two females are illustrated in Figure 1.

The progress of nurse YV, 130%S illustrates how the weight reducing value of the supplement can be interrupted and fail by erratic adherence to the protocol. This result was found to be typical of individuals with histories of chronic obesity and numerous weight reducing trials with "fad diets." Results with nurse TM, 145%S who lost 20 pounds during the test period of 16 months in the face of supplement lapse reflects her conscious efforts to reduce her habitual food consumption. The weight loss characteristics of the 3 females and one male who with minor supplement regressions remained in the program for 4 years are collected graphically in Figures 2 and 3. The degree of weight loss is indicated by the significant differences of initial and final body weight status (%S). The sum-total of these data reflect the useful and practical weight control efficacy of the SPP/SM supplement as employed in our protocol and duration of test periods. One encouraging aspect of this project has been the willingness of some subjects to continue the SPP/SM supplement for unexpected long periods of time and to the regimen after varying periods of remission. Serial biochemical measurements of fasting blood samples during the periods of supplementation failed to show any significant changes in any of the normal or abnormal items including serum lipids listed in Table 1.

Several reports (8) on the effect of calorie restrictions to induce weight loss have shown that the concomitant fluid loss is frequently associated with increased excretion of calcium. Since the skeleton is the most likely source of calcium we decided to add serial bone density measurements to the study. The relationship of body weight loss to bone density and serum calcium changes are shown in Table 4. These data show that in no instance did body weight loss induce untoward changes in serum calcium or bone density. It is of interest to note, the normalization of serum calcium level in subject YV, F-20 from the abnormal value of 8.3 to 11.4 mg% norm within a test period of 6 months. Lastly,

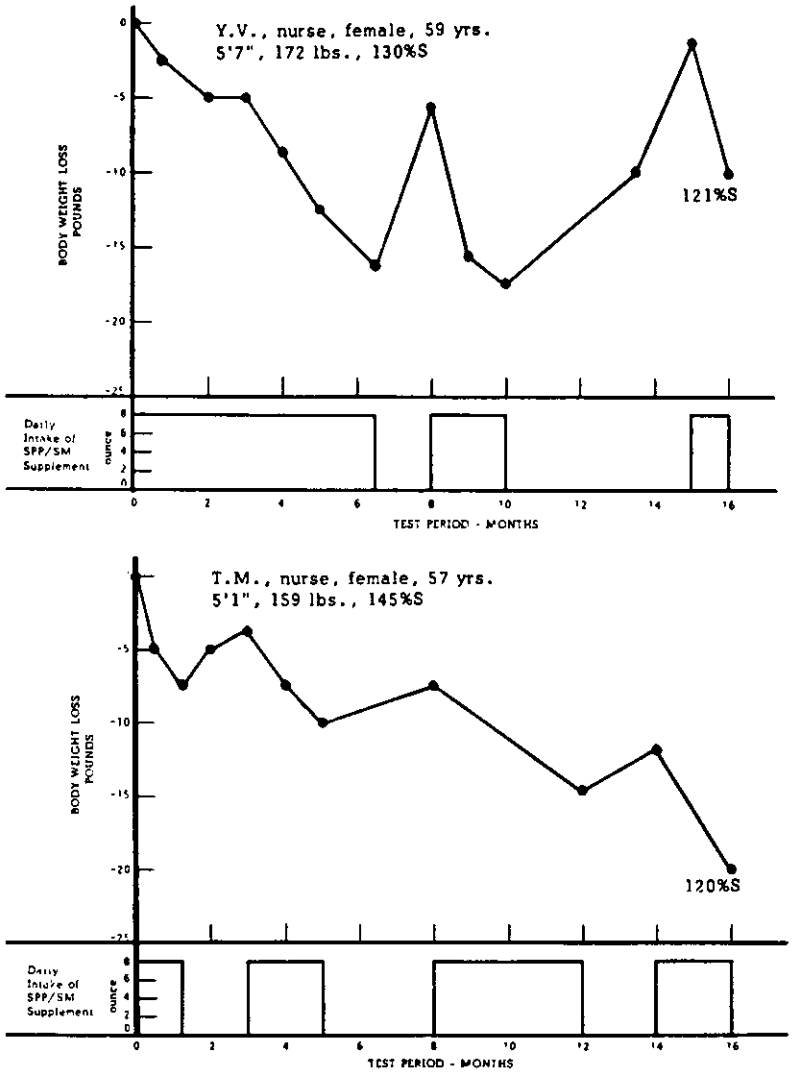

Figure 1. Relation of irregularity of intake of SPP/SM supplement to body weight loss.

attention is called to the improvements in bone density achieved in 10 of the 12 women during test periods of 4 to 24 months with the SPP/SM supplement which provided 80% of the USRDA of calcium. These results are in good accord with the counter-osteoporotic effects of daily supple-

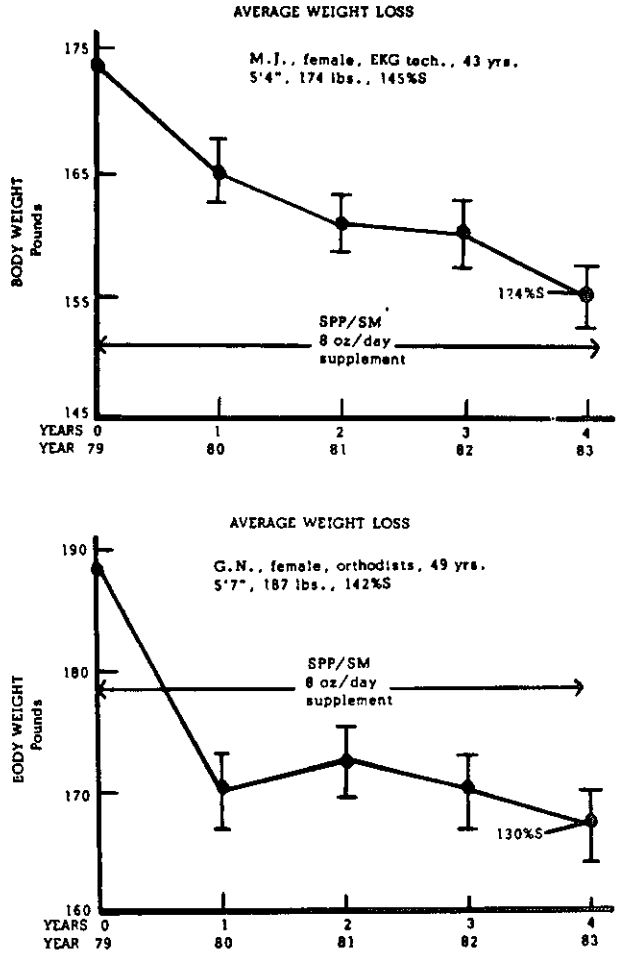

Figure 2. Variations in body weight loss with regular consumption of SPP/SM supplement.

ments of 600-850 mg of calcium on bone loss frequently found in women of 35 or more years of age which we have reported (9).

DISCUSSION

While the overweight/obesity problem is viewed as a major pressing nutritional challenge of public health concern, its precise extent remains unknown. Prevalence data vary according to the many sources of information and definition of obesity (e.g., the cut-off point between obesity,

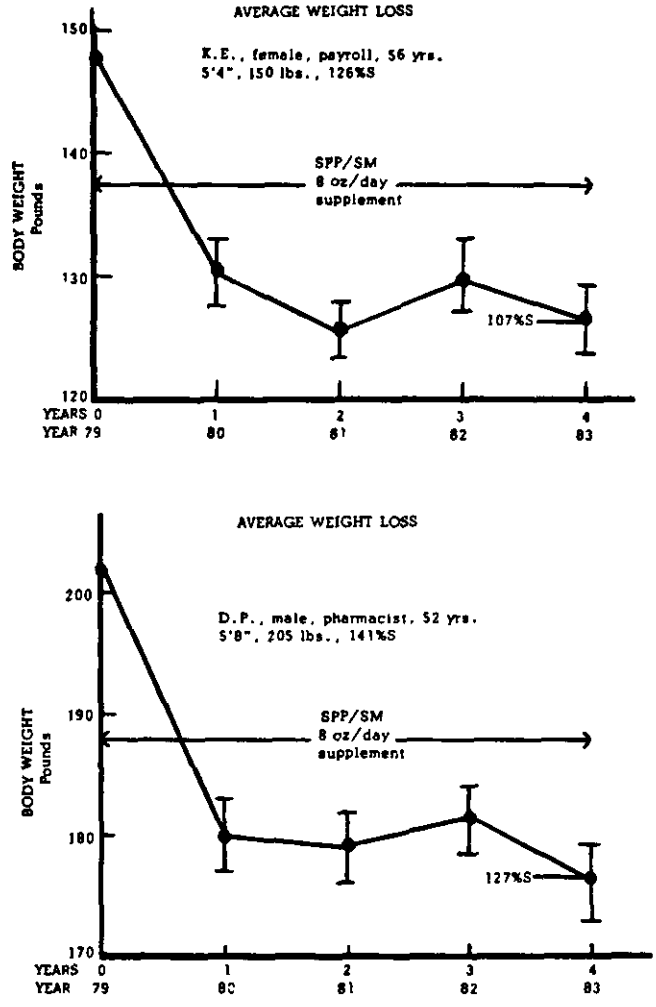

Figure 3. Consistent body weight loss with regular consumption of SPP/SM supplement.

overweight and desirable weight for height). Clinical indications that incidence of overweight/obesity is high and that untoward effects on health and longevity are impressive (10). Yet definitive data are lacking. The Framingham data show minimum mortality around average weight with increased mortality for persons weighing more or less than average. It is clear from our and many other investigations that long-term management

Table 4

EFFECT OF SOY AND MILK PROTEIN SUPPLEMENT ON WEIGHT LOSS AND BONE DENSITY OF OBESE FEMALES 23-62 YEARS OF AGE

Subject	Age	Test Period	Body Weight		Bone Density		Serum Calcium	
			Initial	Change	Initial	Change	Initial	Change
	yrs.	mos.	lbs.	lbs.	mils.	mils.	mg	mg
CD- F-2	23	9	217	-20	122	125	9.1	9.4
CM- F-3	23	13	114	-10	120	120	10.0	10.4
DR- F-4	55	20	151	-10	100	112	9.3	9.2
EA- F-6	62	4	173	-11	125	130	9.4	9.5
GR- F-8	59	8	144	-14	115	115	10.1	10.0
GN- F-9	49	6	187	-22	130	140	9.8	10.1
HA- F-11	42	5	183	-12	100	112	10.1	9.4
KE- F-12	56	24	150	-25	95	100	9.0	10.0
MJ- F-13	43	11	174	-12	160	160	9.6	9.2
TN- F-18	59	20	140	-15	112	115	9.3	9.3
TM- F-19	57	16	159	-20	120	130	9.5	9.3
YV- F-20	59	6	172	-17	110	115	8.3*	11.4

*ABNORMAL VALUE

of obesity necessitates basic and permanent changes in eating habits which are essential for the achievement of clinically desirable body weight.

In this connection, it is of interest to note, that a national survey (11) of food consumption practices shows that the decline in fat and carbohydrate from 1965-1977 for sex-age groups was smallest for adults 35-74 years. Despite the over-all drop in fat, intake remained well above the level recommended by the American Heart Association - 35% or less calories from fat. The largest percentage of fat came from the meat group and the milk group due to an increase in cheese consumption. Although a diverse population is represented in this survey, the results are based on recalls of the previous days food intake, they do not provide all the information we need to know about the nutritional adequacy of the American diet. Necessary additional detail can be expected when the 1977-78 data survey in which food intake data obtained for 3 days are reported.

Although obesity is generally considered to result from consumption of calories in excess of energy expenditure, there is now abundant evidence that hyperplastic obesity most likely begins at birth. A follow-up study by Eid (12) on physical growth on English children who had excessive body weight in the first six months of life showed that many fat babies may not outgrow their obesity throughout their school years. A body weight,

age and height survey in New York City by Ginsburg-Fellner and coworkers (13) revealed that significant obesity (120-160+% of ideal body weight) was present in 12.2% of 2606 nursery school boys and girls 3-6 years of age from low, middle and high income families. Knittle and associates (14) found that persistence of obesity in children and adolescents is due to rate of adipose tissue growth. Asher (15) has also reported that 44% of 269 children of 18 months to 14 years of age remained obese since infancy. In a study of 538 boys and girls from 11 to 14 years of age we found that obesity and overweightness are major untoward factors in learning progress and scholastic achievement (16).

Hyperplastic obesity is the more severe form of obesity and usually is quite refractory to treatment. The incidence of this inborn cellular error may well be the cause of the frequent failures encountered in dietary treatment of the disease. In hyperplastic obesity, regulatory mechanisms of energy balance associated with depot fat storage may be upset or the overweight child may acquire psychological attitudes about food which lead to chronic obesity in adulthood making treatment of these adults more difficult, if not, impossible. Adult onset of hypertophic obesity is primarily characterized by a more moderate increase in body fat mass than hypercellular obesity. This form of obesity is frequently associated with hypertension, decreased glucose tolerance, elevated plasma insulin and triglyceride levels. It is clear that these many forms of obesity not only confound the clinical identity of the condition but also its treatment.

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Accepted for publication: October 28, 1983.

JANUARY 1984 VOL. 29 NO. 1
ISSN 0029-6635

NUTRITION REPORTS INTERNATIONAL

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Publisher: GERON-X, INC., LOS ALTOS, CALIF.