Anthropometric and calorimetric evidence for the protein sparing effects of a new protein supplemented low calorie preparation[1,2]

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ABSTRACT A commercial protein sparing modified fast (PSMF) preparation has been evaluated for the protein sparing effects in 15 morbidly obese patients. During a 500 kcal preparation, given during a 6-week period, mean body weight and BMI decreased significantly. Total body fat decreased from 55.8 to 41.4 kg and lean body mass and arm muscle circumference (AMC) remained unchanged. Using indirect calorimetry and under the same degree of energy expenditure, carbohydrate metabolic consumption was significantly diminished (166 to 61 g/24 hr; $p < 0.001$) but fat consumption was increased (116 to 155 g/24 hr; $p < 0.05$) while the metabolic turn-over of protein was unchanged. This new presented PSMF preparation seems to present the typical properties of a protein sparing modified fast. *Am J Clin Nutr* 1985;41: 540–544.

KEY WORDS Indirect calorimetry, obesity, lipolysis, protein sparing modified fast

Introduction

It is well known that total starvation is characterized by a strong and occasionally even dangerous negative nitrogen balance, due to high amounts of N excretion during this period (1). Also very restricted hypocaloric diets without enough protein supplements (<30 g/24 hr) show a similar negative balance over several weeks.

Considering these dangerous risks, the protein sparing modified fast (PSMF) diets have been introduced over the past few years and advocated as a safe alternative by different authors (2, 3, 4). Various "homemade" and commercial preparations are used now in several obesity centers all over the world.

Usually the protein sparing effects of this type of treatment have been documented using nitrogen balances in ambulatory (2) and metabolic ward conditions (5, 6). Using indirect calorimetry, anthropometry and nitrogen excretion studies, a balance between caloric intake and combustion can be made in order to study the real protein sparing effects. This study reports anthropometric and calorimetric evidence for this protein sparing effects of a PSMF preparation.

Patients and methods

Fifteen randomly selected morbidly obese adults (13 women and 2 men) attending the out-patient clinic, with a mean age (±SD) of 39.5 ± 9.1 years, entered a 6-week study protocol. Most of them had longstanding obesity and had already experienced different kinds of therapy. Patients receiving drugs or showing overt diabetes mellitus, hormonal disturbances or cardiac disease, were excluded from this study.

Obesity was defined as a body mass index (Wt/Ht^2) > 28, % overweight as the total/ideal body weight and AMC = MAC × π TSF (triceps skinfold mm). All patients were initially hospitalized for 1 week under metabolic ward conditions. Afterwards they were under an ambulatory control to be rehospitalized for reevaluation during

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TABLE 1
Patients data: age, body weight, BMI and overweight

	Age	Weight	BMI	% Overweight
	(y)	(kg)		
1	40	102.0	39.3	55.7
2	32	130.8	44.2	91.8
3	39	102.0	36.1	56.2
4	28	103.4	37.7	51.9
5	25	115.5	40.4	69.8
6	37	123.5	37.1	56.0
7	38	103.2	38.8	59.5
8	38	119.8	44.3	86.4
9	37	111.7	45.9	81.6
10	54	91.6	39.6	53.4
11	34	110.0	40.2	66.3
12	44	91.7	35.2	44.0
13	45	115.0	40.7	65.9
14	28	133.5	39.2	65.1
15	43	102.8	38.7	54.1

the sixth week of the protocol. **Table 1** shows all patient data of age, body weight, body mass index, and % overweight.

The diet, a new preparation (Nutroclin[R], Labaz-Sanofi, Brussels, Belgium) is a 500 kcal protein sparing modified fast with lactalbumin as the main protein source; a daily intake of 4 meals supplied in powdered sachets, consists of 54 g carbohydrates, 60 g protein, 5 g fat and all essential supplements in RDA doses. **Table 2** shows the complete composition with vitamins, minerals and trace elements.

After an overnight fast, the study group underwent an indirect calorimetry and anthropometric measurement. These measurements were performed during the initial hospitalization before the institution of the diet and during the second hospitalization at the end of the study period. Skinfold thickness was measured using the Harpenden caliper, and fat free mass and total body fat have been calculated using earlier reported formula (7, 8). LBM has been derived from the urinary creatinine excretion using the equation of Forbes and Bruining (9).

For the indirect calorimetry, using the Ergo-Oxy screen system (Jaeger Medizin, Wurzburg, Germany), the patients were instructed to breath over a 20 min period, after adaption during 15 min to obtain a steady state. Because of the occurrence of hyperventilation during the test in some patients, only 8 results definitely could be analyzed for consumption calculations in a paired way. Twenty-four-hour urine collections for estimation of daily nitrogen and creatinine excretion were performed in metabolic ward conditions; nitrogen measurements have been determined by the Kjeldahl method (10). Thyroid binding globulin was measured using a commercial RIA-kit (RIA-gnost TBG, Behring AG).

Calculations of substrate oxidation rates used the Lusk (11) equations:

$$\dot{P} = 6.25\ N \qquad \text{(a)}$$

$$VO_2 = 0.829\ \dot{C} + 2.019\ \dot{L} + 0.967\ \dot{P} \qquad \text{(b)}$$

$$VCO_2 = 0.829\ \dot{C} + 1.427\ \dot{L} + 0.775\ \dot{P} \qquad \text{(c)}$$

TABLE 2
Complete composition (daily content of 4 sachets) of the 500 kcal containing Nutroclin® preparation

		Trace-Elements	
Protein	60 g		
Carbohydrate	54 g	Iron	18 mg
Lipids	5 g	Zinc	15 mg
		Copper	2 mg
Minerals		Fluorine	1 mg
		Molybdènum	0.2 mg
Potassium	2 g	Iodine	0.15 mg
Sodium	1.014 g	Chromium ($CrCL_3 \cdot 6H_2O$)	0.06 mg
Calcium	0.98 g	Selenium	0.05 mg
Phosphorus	1 g	Vanadium	0.045 mg
Magnésium	0.5 g	Cobalt	0.02 mg
		Vitamins	
		A	3450 UI
		α-tocophérol	0.66 mg
		B1	0.92 mg
		B2	1.1 mg
		B6	1.15 mg
		B12	5 μg
		Niacin	19 mg
		Biotin	0.25 mg
		Folic acid	0.42 mg
		Pantothénic acid	9.2 mg
		C	70 mg

TABLE 3
Significant ($p < 0.001$) decrease of weight and calculated fat parameters before and after treatment (mean ± SD)

	Weight	BMI	% Overweight	Fat wt
	(kg)			*(kg)*
baseline	110.4 ± 12.7	39.8 ± 3.0	63.8 ± 13.6	55.8 ± 9.8
at 6 wk	96.0 ± 11.7	34.6 ± 3.2	42.6 ± 13.7	41.1 ± 8.7
	p < 0.001	p < 0.001	p < 0.001	p < 0.001

This set of equations can readily be solved for the individual oxidation rates (mg/min) of carbohydrate ($\dot{C}$), lipids ($\dot{L}$) and protein ($\dot{P}$) using nitrogen excretion rate (mg/min) and VO_2 and VCO_2 (L/min).

Statistical evaluations have been performed by the paired *t* test, in which each patient served as its own control.

This study was performed under the conditions of the Helsinki convention; all patients gave their informed consent.

Results

After a 6-week treatment period a highly significant ($p < 0.001$) decrease could be observed for body weight, body mass index, percentage overweight and fat weight (**Table 3**) whereas lean body mass and arm muscle circumference remained unchanged (**Table 4**).

Twenty-four hour urinary nitrogen excretion remained relatively stable varying from 12.1 g before treatment to 9.8 g at the end of the study. The amount of mg Nitrogen/mg of creatinine didn't change much either, decreasing from 8.84 to 8.17 mg.

No specific changes in labile proteins could be observed during the study period: TBG values (21.6 ± 8.6 to 22.1 ± 4.7 μg/ml) and serum albumin concentration (3.72 ± 0.29 to 3.6 ± 0.4 g/dl) remained unchanged. The respiratory quotient, decreased from 0.81 to 0.75 ($p < 0.001$) and the respiratory quotient for the non-protein substrates decreased from 0.82 to 0.75 ($p < 0.001$).

Twenty-four-hour urinary creatinine excretion (estimated as the mean of 2 consecutive days) decreased non-significantly from 1312 ± 77 to 1237 ± 93 mg/24 hr. This decrease of 75 mg/24 hr is equivalent to a decrease of 2.1 kg of LBM from 45.5 ± 8.3 to 43.4 ± 8.5 kg.

The relative amount of energy derived from carbohydrates, lipids and protein, and its change during the therapy is presented in **Table 5**. Under the same degree of energy expenditure, carbohydrate metabolic consumption was significantly diminished (166 to 61 g/24 hr) but fat consumption was increased (116 to 156 g/24 hr) while the protein combustion remained unchanged. Percent changes in nutrient combustion revealed a decrease of carbohydrate consumption from 34 to 13% and a significant increase of fat combustion to 72% of total kcal consumption.

TABLE 4
Calculated fat free body mass and arm muscle circumference (AMC) before and after treatment (mean ± SD)

	Fat free mass	AMC
	(kg)	*(cm)*
baseline	54.6 ± 10.3	23.8 ± 2.8
at 6 wk	54.6 ± 8.9	24.0 ± 2.4
	NS	NS

TABLE 5
Individual oxidation rates (g/24 hr and percent change) derived from three major nutrients, measured by Ergo-Oxyscreen, before (baseline) and at the end (6 wk) of the treatment period

	Baseline	At 6 wk	
	g/24 hr		
CHO	166	61	p < 0.001
lipids	116	156	p < 0.05
protein	71	63	NS
	% metabolic rate		
CHO	34	13	p < 0.001
lipids	51	72	p < 0.001
protein	15	15	NS

Patient compliance, evaluated by estimation of the daily urinary ketone bodies measurement and by 24 hr urinary sodium excretion (<15 mmol/24 hr under Nutroclin[R]), revealed an almost perfect compliance throughout the study.

Discussion

Since complete starvation became unpopular for most physicians because of the occurrence of different clinical and biochemical abnormalities, safer conventional and protein sparing diets have been developed for effective weight reduction of massive obesity (2, 6).

PSMF have been introduced mainly to achieve nitrogen balance during extremely restricted caloric intake (2, 12) by adding protein supplements to this diet. Starting with 40–60 g protein/day, Blackburn et al (13) even suggested a 100 g protein fraction. The supplemented protein however has to be of a high biological value which is a suggested approach to prevent cases of ventricular arrhythmia (14, 15) and sudden death. Instead of natural protein enriched food, we used in this study a commercial formula preparation under metabolic ward conditions to keep the daily amount of protein intake constant over the study period.

Anthropometric evaluation revealed a decrease of body weight and body mass index with a simultaneous decrease of skinfold thickness and total body fat. Measurements of arm muscle circumference and calculation of lean body mass confirmed a decrease in fat tissue with preservation of muscle protein. Indirect calorimetry measures total oxygen consumption and CO_2 production (16). Knowing the oxygen consumed during oxidation of each nutrient and the CO_2 produced, the metabolic turnover of the three major nutrients can be calculated (10). Indirect calorimetry has recently been proved to remain valid in the presence of lipogenesis and lipolysis (17).

Our results clearly demonstrate under the same degree of energy expenditure (±2000 kcal/24 hr), an absolute increase of fat consumption and a decrease of carbohydrate consumption, while the protein turnover remains constant. **Table 6** shows the difference (g/24 hr) between intake versus consumption during treatment.

TABLE 6
Comparison of daily intake (g/24 hr) of carbohydrates, lipids and protein (Nutroclin® content) with daily combustion (g/24 hr), derived from calorimetric measurement

	Nutroclin intake	Calorimetry consumption
CHO	54	61
LIP	5	156
PROT	60	63

When we compare intake and consumption of the three nutrients, a balance can be obtained for our specific treatment showing a ±150 g lipolysis/24 hr. Although the estimates of 24-hr substrate oxidation rates are extrapolated from only a 20 minute period of observation, the 150 g lipolysis/24 hr is in accordance with similar results already shown by Apfelbaum (4) using conventional methods.

No fecal or integumental N loss has been measured; since no patients developed diarrhea and all noted a reduced stool quantity and frequency, we estimated the fecal N loss at 0.5 g/day, as also reported by Brown et al (18). Estimating the integumental N loss at 0.5 g (19), max 10% of the daily weight loss will be lean body mass. Using the Forbes and Bruining equation (9), LBM decreased (NS) from 45.5 to 43.4 kg, which is less than the suggested 10%.

Because of this small LBM loss, the optimal protein fraction should eventually be increased by 10% or more as suggested by some authors (3).

As far as we know, this study is unique in employing indirect calorimetry to estimate substrate utilization during a typical, CHO-containing protein supplemented fast. Demonstrating the protein saving patterns both by anthropometry and by calorimetry, this study confirms the initial goal of this type of treatment, consistent with those reported by others (2, 12). Regarding the final goal of every safe treatment of morbid obesity, estimation of non-protein energy expenditure from indirect calorimetry methods offers a good solution to demonstrate protein sparing effects of PSMF preparations.

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