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The Copenhagen PRODI project: preliminary results

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Summary
A randomized clinical trial concerning treatment of moderate obesity is described. The study compares: (a) conventional 1000 kcal (4.19 MJ) diet with diethylpropion permitted: (b) isocaloric partial meal replacement with protein powder, and diethylpropion permitted; and (c) pre-meal satiation with protein powder. Preliminary results indicate equally good weight losses by the three methods

Introduction

Protein powders for the treatment of moderate obesity have become extensively used by all social classes. In this popular use a distinction can be made between two patterns: partial meal replacement and pre-meal satiation.

In the treatment of morbid obesity protein powders has proved valuable, making possible a sufficient nutrition with less than 400 kcal (1.67 MJ). However, it is unknown if use of protein powders for partial meal replacement in a 1000 kcal (4.19 MJ) diet offers any advantages over conventional calorie restriction with natural foods as to weight loss or maintenance. It is also unknown whether use of the same quantity of protein powder before meals is superior to the before mentioned regimes. Furthermore, can anorexic drugs be replaced by a satiation effect of the protein powder?

Methodology and preliminary results

In order to throw light on these questions we have set up a randomized clinical trial comparing the above mentioned two protein powder applications to our standard 1000 kcal (4.19 MJ) regime. Figure 1 illustrates schematically the regimes, and Table 1 specifies the contents as to energy distribution. Our supplementary vitamin-mineral capsule is given elsewhere[1]. Criteria for entry are listed in Table 2, and flow chart is shown in Fig. 2. At the first medical control verbal and written instructions are given.

Patients allocated to PRODI 3 are told to 'eat as little as possible of

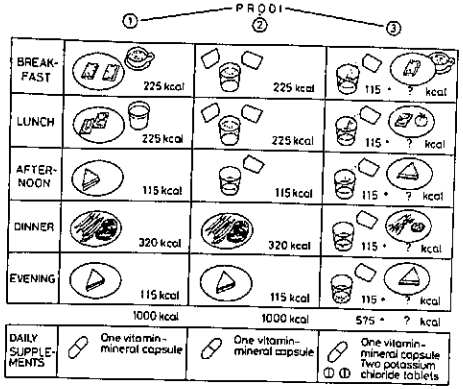

Fig. 1. Schematic representation of the regimes

Table 1. The PRODI project: daily intake. *The regimes comply with RDA's 1980[3] (calcium, phosphorus, magnesium, iron, zinc, iodine, vitamin A-D-E-C-B_1-B_2-B_6-B_{12}, biotin, niacin, and folic acid). * The regimes comply with Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) 1980[3] (sodium, potassium, chloride, copper, manganese, chromium, selenium, molybdenum, vitamin K, biotin and pantothenic acid).

	Powder (116g) mg (kcal)	Orange juice (500 ml) mg (kcal)	Other foods mg (kcal)	Total in % of RDA 1980 %
PRODI 1 (1000 kcal)				
Protein	0 (0)	0 (0)	65,000(260)	♀ 147
				♂ 120
Lipid	0 (0)	0 (0)	36,000(324)	—
CHO	0 (0)	0 (0)	104,000(416)	—
Energy, total	(0)	(0)	(1000)	—
PRODI 2 (1000 kcal)*				
Protein	53,000(212)	5,000 (20)	55,000(220)	♀ 252
				♂ 206
Lipid	4,700 (42)	2,500 (23)	18,000(162)	—
CHO	22,000 (88)	45,000(180)	13,000 (52)	—
Energy, total	(342)	(223)	(434)	—
PRODI 3 (≥575 kcal)*				
Protein	53,000(212)	5,000 (20)	?	♀ ≥ 132
				♂ ≥ 107
Lipid	4,700 (42)	2,500 (23)	?	—
CHO	22,000 (88)	45,000(180)	?	—
Energy, total	(342)	(223)		—

Table 2. The PRODI project

Criteria for entry

1. Consecutive patients
2. 20 to 59% overweight[2]
3. Age 18 to 59 years
4. No sequelae after earlier abdominal obesity surgery
5. No contraindicating disease, eg malignancy
6. No pregnancy
7. No actual treatment with certain psycopharmacological drugs
8. Absence of — or stable — diuretic treatment
9. No alcohol or drug abuse
10. Co-operability
11. Informed consent

Criteria for continuation of the program after 3 months

1. Weight loss > 4 kg
2. > 10% overweight[2]

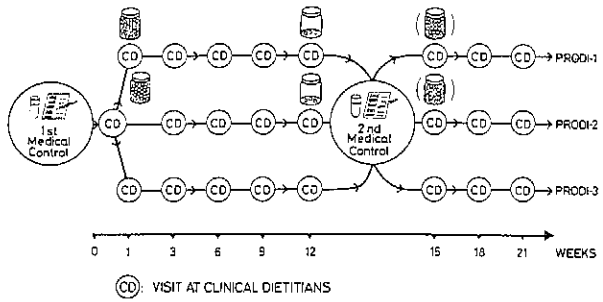

Fig. 2. PRODI flow chart

additional natural foods, if anything at all'. Anorexic drugs are excluded from PRODI 3, but 25 mg of diethylpropion is permitted maximally three times a day in PRODI 1 and 2.

Patients are not hospitalized but seen as out-patients by our clinical dieticians after 1, 3, 6, 9 and 12 weeks. At the second medical checkup the consumption of diethylpropion is quantified as a measure of hunger. If criteria for entry (numbers five to ten) are still fulfilled together with a weight loss greater than 4 kg and an actual overweight over 10 per cent[2] the program is continued in order to evaluate its long-term effect.

Our preliminary results show equally good weight losses on all three regimes (Fig. 3).

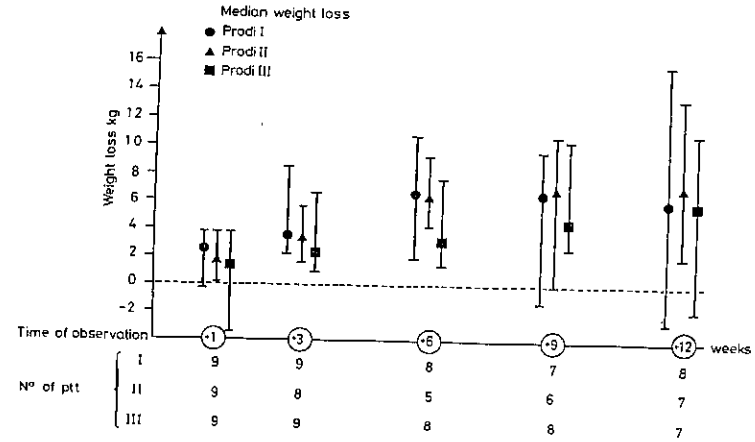

Fig. 3. PRODI preliminary results

Hopefully, the final results of the described trial will contribute to a clarification of the role of protein powders in the treatment of the moderate obesity. These new applications might also be of future value in maintaining a normalized weight obtained by more drastic regimes.

Acknowledgement – The authors are indepted to the clinical dietitians Ulla Finne and Ulla Larsen for their dedicated work. The protein powder (PRODI) and the vitamin-mineral capsule (RedavitR) were supplied by Mørk Bio-Chemie Limited, Copenhagen.

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International Journal of Obesity (1981) 5, 267-272.

Low-dose mianserin as adjuvant therapy in obese patients treated by a very-low-calorie diet

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Summary

A double blind trial examined the effects of low doses of the anti-depressant compound mianserin (10 mg nocte, Organon, Oss, Holland) on dietary compliance and weight loss in 45 obese subjects treated by a very-low-calorie diet (VLCD, 320 kcal (1.34 MJ) /day) for 16 weeks.

The total mean weight loss of the 25 patients who completed the trial was 15.5 kg ± 6.1 s.d. There was no significant difference in weight loss between the groups. More patients taking placebo (54 per cent vs 38 per cent) completed the experiment. Three patients stopped mianserin because of drowsiness, but were able to continue on the VLCD alone.

Beck rating scores decreased (indicating less depression) in both groups by 50 per cent after eight weeks. With the linear self-rating scale there was no change in the placebo group but the mianserin group reported feeling less depressed ($P < 0.001$).

No significant changes were observed in ECG and routine clinical and laboratory tests. It is concluded that VLCD can be a safe and acceptable means of achieving substantial weight loss over several months. Patients do not become more depressed during treatment and there is no clinical advantage to be gained by the routine additional use of low doses of mianserin.

Introduction

The development of the very-low-calorie formula diet has provided the clinician with a highly effective tool for the treatment of obesity. Considerable experience in this department of such preparations has shown that they may be safely administered to hospital out-patients and do not significantly interfere with normal activities and employment[5, 6, 10].

In early trials, symptoms of depression appeared to develop in a number of female patients soon after embarking on the diet. Compliance soon suffered in these individuals and the resultant failure to lose weight led to a further deterioration in their mental state. Mills[9] suggested that such patients might

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The Copenhagen PLAFA project: a randomized trial of gastroplasty versus very-low-calorie diet in the treatment of severe obesity (preliminary results)

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Summary
Consecutive patients, between 18 and 54 years, suffering from morbid obesity (⩾ 60 per cent overweight) are being randomized to either gastroplasty a.m. Gomez or to a very-low-calorie diet (341 kcal, 1.43 MJ) based on a high-value protein powder with an admixture of calcium, phosphate, sodium, chloride, and magnesium. Through a supplementary daily vitamin-mineral capsule and three tablets of potassium chloride the total regime complies with the 1980 RDA. After initial hospitalization, both groups are seen as out-patients. Twenty-eight patients have so far been studied and none has dropped out. Preliminary results show a substantial weight loss without significant differences between the groups.

Introduction

A drastic reduction of energy intake is the central remedy in the treatment of morbid obesity as well as in preventing regain of an obtained weight loss. Two treatments have recently come into focus for permanent weight control. First the very-low-calorie diet (VLCD) and second, gastroplasty as the least mutilating operation among the new generation of surgical procedures. Between these two treatments there are conspicious differences: VLCD-patients have artificial food while gastroplasty patients have natural food; on the other hand, gastroplasty can be considered a more unphysiological treatment than the VLCD-regime. However, similarities are also striking: both treatments reduce calorie intake drastically, and are only limited by the minimum requirements for essential nutrients. Both treatments make heavy demands on the co-operation of the patient and on the educational efforts of the staff. Finally, none of the treatments have proved their final value as long-term results are scarce or lacking.

Methodology and preliminary results

We have initiated a prospective randomized clinical trial (named PLAFA)

comparing a VLCD-regime with gastroplasty.

Our VLCD regime is based on a protein powder made up from soy protein, lactalbumin, and casein. In order to fulfil recommendations[4] for minerals, calcium phosphate, sodium chloride, magnesium oxide, and secondary sodium phosphate have been added to the base powder. All the remaining minerals, trace elements and vitamins have been collected in one capsule. In Table 1 the composition of the 341 kcal (1.43 MJ) PLAFA regime is given. The percentage of of the 1980 recommended dietary allowances (RDAs) or — where such do not exist: the percentage of the 1980 Estimated Safe and Adequate Daily Dietary Intake (ESADDIs)[4] is noted in the right column. It is seen that RDAs or ESADDIs are complied with for all minerals, trace elements and vitamins. From Table 2 it appears that the requirements for the essential amino acids are also met.

Our criteria for entry are listed in Table 3. We have made them as liberal as possible, in contrast to most other studies of drastic obesity therapy, and the patients are admitted consecutively. Our reason is that we want our results to be applicable to the broadest possible range of obese patients. At the first consultation the patient is informed of our offers of conventional treatment and of the alternative possibilities: gastroplasty or VLCD in the PLAFA project. The principle of allocation by lot is explained. The pre-treatment medical examinations are described and the need for frequent control made clear. If the patient is interested in participating she is issued with a popular pamphlet describing both treatments. Final decision and eventual informed consent cannot be made until the next consultation. Flow-chart (Fig. 1) shows the pretherapeutic work up, including a liver biopsy. If no

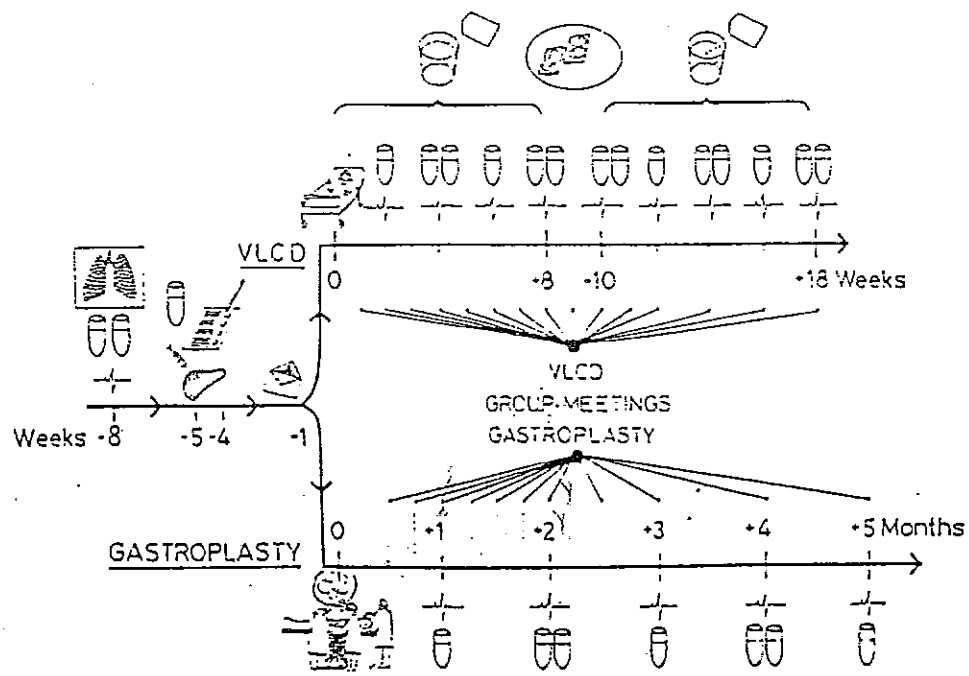

Fig. 1. Prospective randomized clinical trial (PLAFA)

Table 1. The PLAFA project: daily intake

	Powder (70 g)	Orange juice (300 ml) Three KCl tablets	One vitamin-mineral capsule	Total in % of RDA ● % of min ESADDI △ % of max ESADDI ▲
	mg (kcal)	mg (kcal)	mg	1980 %
Protein	32,000 (128)	3,000 (12)		♀ 80 ●
				♂ 63 ●
Lipid	2,800 (27)	1,500 (14)		
CHO	13,000 (52)	27,000(108)		
Energy (total)	(207)	(134)		
Calcium	800	25		103 ●
Phosphorus	800	50		106 ●
Potassium	350	2,150		133 △
Sodium	1,500	0		136 △
Chloride	1,500	1,425		172 △
Magnesium	350	25	300	♀225 ●
				♂193 ●
Iron	17	0.6	18.0	♀113 ●
				♂203 ●
Zinc			15.0	100 ●
Copper			3.0	100 ▲
Iodine			0.15	100 ●
Manganese			3.8	152 △
Chromium			0.12	240 △
Selenium			0.12	240 △
Molybdenum			0.2	133 △
Vitamin A	0		1.00	♀125 ●
				♂100 ●
Vitamin D	0	0	0.01	133 ●
Vitamin E	0		10.00	♀125 ●
				♂100 ●
Vitamin K			0.14	100 ▲
Thiamin (B_1)	0.1	0.3	1.50	♀173 ●
				♂127 ●
Riboflavin (B_2)	0.3	0.1	1.70	♀175 ●
				♂124 ●
Vitamin B_6	0.1	0.1	2.20	♀120 ●
				♂109 ●
Vitamin B_{12}		0	0.003	100 ●
Biotin			0.2	100 ▲
Niacin			19.0	♀136 ●
				♂100 ●
Vitamin C	0	125	60.0	308 ●
Folic acid (as monoglutamyl)			0.1	100 ●
Pantothenic acid			7.0	100 ▲

Table 2. The PLAFA project: daily intake of amino acids provided by 70 g protein powder (*Calculated from a body weight = 90 kg)

	mg	% of estimated daily requirement (1974)*[1]		mg	% of estimated daily requirement (1974)*[1]
Valine	1700	135	Arginine	2100	
Leucine	2900	201	Histidine	800	
Isoleucine	1600	148	Alanine	1000	
Threonine	1200	167	Serine	1500	
Lysine	2100	194	Asparagine	2800	
Methionine	600	100	Glutamine	6700	
Cystine	300		Proline	2200	
Phenylalanine	1800	208	Tryptophan	500	
Tyrosine	1200				

Table 3. The PLAFA project: criteria for entry

1. Consesecutive patients
2. ⩾ 60% overweight[2]
3. Age 18 to 54 years
4. Failure of conservative treatment
5. No sequelae after earlier abdominal obesity surgery
6. No contraindicating disease
7. No pregnancy
8. No alcohol or drug abuse
9. Co-operability
10. Informed consent

contraindicating disease is found the patient is allocated to either VLCD or gastroplasty (Gomez[2]). The two groups are supervised with the same care and within the similar organisational frame. The VLCD is started during a five day stay in hospital in order to overcome the initial difficulties. After discharge the patients are seen every second week for medical checkup, blood tests, ECG and psychological support. Furthermore, the patients are seen weekly for instruction and support at group meetings, lead by clinical dietitians. Here, patients in early stages of treatment learn from the experience of those in more advanced stages. Written instructions for the participants are given in an illustrated pamphlet. The 341 kcal PLAFA regime is carried out for eight weeks. Then follow two weeks on 900 kcal made up of high-value natural foods, except breakfast which is kept as a protein meal. From week ten the patients return to the complete PLAFA powder regime. Until now 38 patients have entered the study. Of these, three have dropped out prior to allocation because of lack of motivation, but no drop out has occurred after allocation. Twelve patients have had gastroplasty, and as many have started on VLCD.

As seen from Fig. 2 weight loss has been substantial, and so far there is no significant difference between the two groups (Mann-Whitney rank-sum test for unpaired data; P values > 0.05 are considered insignificant).

Of course, the preliminary character of the results and the shortness of the

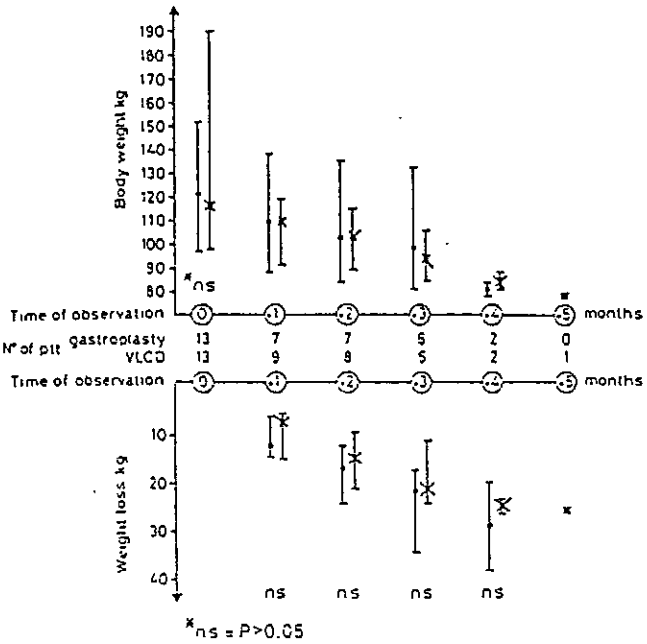

Fig. 2. PLAFA preliminary results. Median body weight and median weight loss obtained by gastroplasty (●) in 13 patients and by VLCD (x) in 13 patients

observation time must be emphasized. Between the two groups complications and inconveniences, quality of life and psychological symptoms will all be compared as well as quantitative and qualitative changes of food preferences. These data will be the subject of future reports.

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