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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

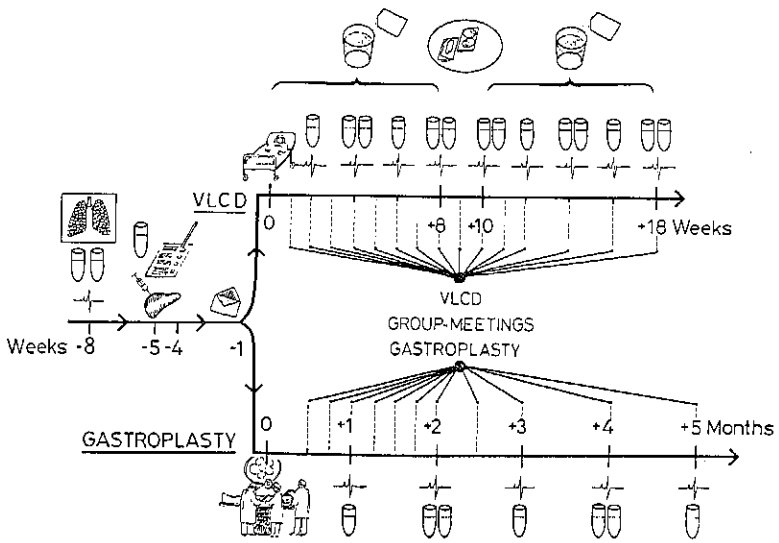

Fig. 1. Prospective randomized clinical trial (PLAFA)

Table 1. The PLAFA project: daily intake

	Powder (70 g) mg (kcal)	Orange juice (300 ml) Three KCl tablets mg (kcal)	One vitamin-mineral capsule mg	Total in % of RDA ● % of min ESADDI △ % of max ESADDI ▲ 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

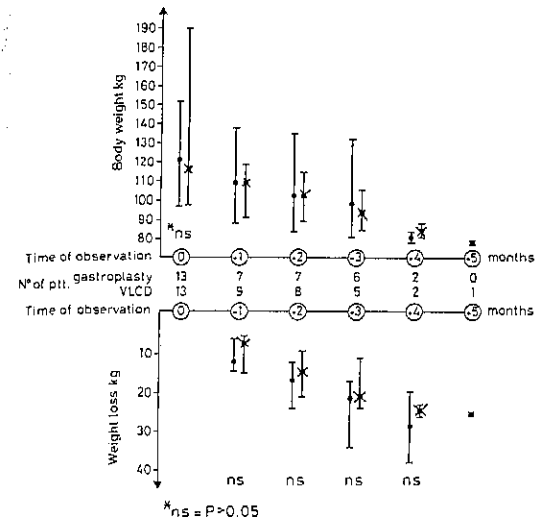

Fig. 2. PLAFA preliminary results. Median body weight and median weight loss obtained by gastroplasty (●) in 13 patients and by VLCD (x) in 13 patients

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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