

# Gastroplasty Preceded by Very-low-calorie Diet— A Preliminary Report

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**ABSTRACT** Gastroplasty (GP) performed in morbidly obese patients is fraught with an unavoidable perioperative hazard, and weight loss is often unsatisfactory even on a short term. On the other hand, weight maintenance is better after GP than after diet alone. In order to increase the ultimate weight loss and reduce surgical hazards, consecutive patients of the present study receive a mandatory two-step treatment: After initial very-low-calorie formula diet (VLCD) GP is performed provided a 40% reduction of overweight has been obtained by diet. GP patients selected in this way are equally assigned to vertical banded GP or to Gomez GP. Weight control and patient education is run at group meetings.

Seventy-four patients (median weight 125.1 kg (range, 91.4–224.0 kg)) corresponding to a median overweight of 93% (range 61–222%) has started VLCD. The following data are preliminary.

Median weight loss after 8 weeks of VLCD was 17.9 kg (range, 3.6–38.4 kg). Seventy percent of the patients (95% confidence limits 55–83%) reached the limit for operation. Twenty-five patients had GP at present. Complications were rare and minor. Three months after surgery median total weight loss from VLCD plus GP was 46.0 kg (range, 26.1–64.0 kg).

## INTRODUCTION

Treatment of obesity consists of two tasks: Satisfactory weight reduction and long-term weight maintenance.

For the first purpose we and others [1,2] have described very-low-calorie formula diet (VLCD) as a safe and immediately effective non-surgical treatment. However, a proper tool for long-term weight maintenance is urgently needed. Gastroplasty (GP) might be one such tool.

The present randomised clinical trial compares the horizontal gastroplasty of Gomez with the vertical banded gastroplasty described by Mason, either of them performed after a satisfactory, large weight loss obtained through VLCD.

## PATIENTS AND METHODS

All patients admitted for morbid obesity, since June 1981 were consecutively evaluated according to the unrestrictive protocol criteria for entry listed in Table 1. Detailed verbal and written information about the project was given to all candidates. The Helsinki declaration II was observed. Seventy-four patients (60 females and 14 males) have been included. Their median age was 34 years (range, 19–54 years), their median body weight 125.1 kg (range, 91.4–224.0 kg),

Table 1 Criteria for entry

Patients consecutively admitted for obesity
Overweight $\geq$ 60%
Age 18–54 years
Absence of contraindicating disease
Absence of pregnancy and lactation
Absence of other ongoing treatment for obesity
Co-operability and practicable control

and their median overweight 93% (range, 61–222%) calculated according to a Scandinavian standard [3]. They were all screened for contraindicating diseases through clinical examination, analyses of blood and urine, ECG and liver biopsy. Treatment was started simultaneously in about 35 patients at a time.

The contents of the formula (NUPO<sup>®</sup>, Oluf Mørk Bio-Chemie, Ltd) used for VLCD are specified in Table 2. For repeated 8-week periods this formula provides the sole source of nutrition. The nutrition powder is apportioned as five daily meals, and water is added as vehicle. Between the 8-week periods with VLCD, a 2-week 900 Kcal (3.8 MJ) diet consisting of natural high-protein, low-fat and low-carbohydrate foods is prescribed. The VLCD programme is continued as long as a substantial weight loss is obtained. Anorexic agents are not allowed.

Patients are offered operation as the second step of

Table 2 Daily intake provided by NUPO® nutrition powder used for very-low-calorie diet. The powder is based on soy and milk protein

	Weight of content (mg)	Energy content (Kcal)	Total in	
			● % of RDA*	△ % of min ESADDI** ▲ % of max ESADDI**
Protein	56 400	226	♀ 128 ●	♂ 101 ●
Lipid	4 800	43		
CHO	29 700	119		
Energy (total)		388		
Calcium	800		100 ●	
Phosphorus	800		100 ●	
Potassium	2 000		107 △	
Sodium	1 500		136 △	
Chloride	2 397		141 △	
Magnesium	400		♀ 133 ●	♂ 114 ●
Iron	18		♀ 113 ●	♂ 203 ●
Zinc	15		100 ●	
Copper	3		100 ▲	
Iodine	0.15		100 ●	
Manganese	3.8		152 △	
Chromium	0.12		240 △	
Selenium	0.12		240 △	
Molybdenum	0.20		133 △	
Vitamin A	1.00		♀ 125 ●	♂ 100 ●
Vitamin D	0.01		133 ●	
Vitamin E	10		♀ 125 ●	♂ 100 ●
Vitamin K	0.14		100 ▲	
Thiamin (B <sub>1</sub> )	1.5		♀ 173 ●	♂ 127 ●
Riboflavin (B <sub>2</sub> )	1.7		♀ 175 ●	♂ 124 ●
Vitamin B <sub>6</sub>	2.2		♀ 120 ●	♂ 109 ●
Vitamin B <sub>12</sub>	0.003		100 ●	
Biotin	0.2		100 ▲	
Niacin	19		♀ 136 ●	♂ 100 ●
Vitamin C	60		308 ●	
Folic acid	0.1		100 ●	
(as monoglutamyl)				
Pantothenic acid	7		100 ▲	

\*RDA: Recommended dietary allowances [4].

\*\* ESADDI: Estimated safe and adequate daily dietary intake [4].

the programme only if a 2/5 reduction of overweight has been reached during VLCD. Patients fulfilling this criterion are equally assigned to either horizontal GP or to vertical banded GP. The assignment is not made known to patients or dietitians. This is possible because the regimen after both operations is the same. In all essentials it is as previously described [1].

Horizontal and vertical GP are performed as published elsewhere [1,5]. Weight control is run at group meetings together with a formalised patient education programme. Patients are seen weekly until three months after operation, every second week until 6th postoperative month and at least every three months thereafter.

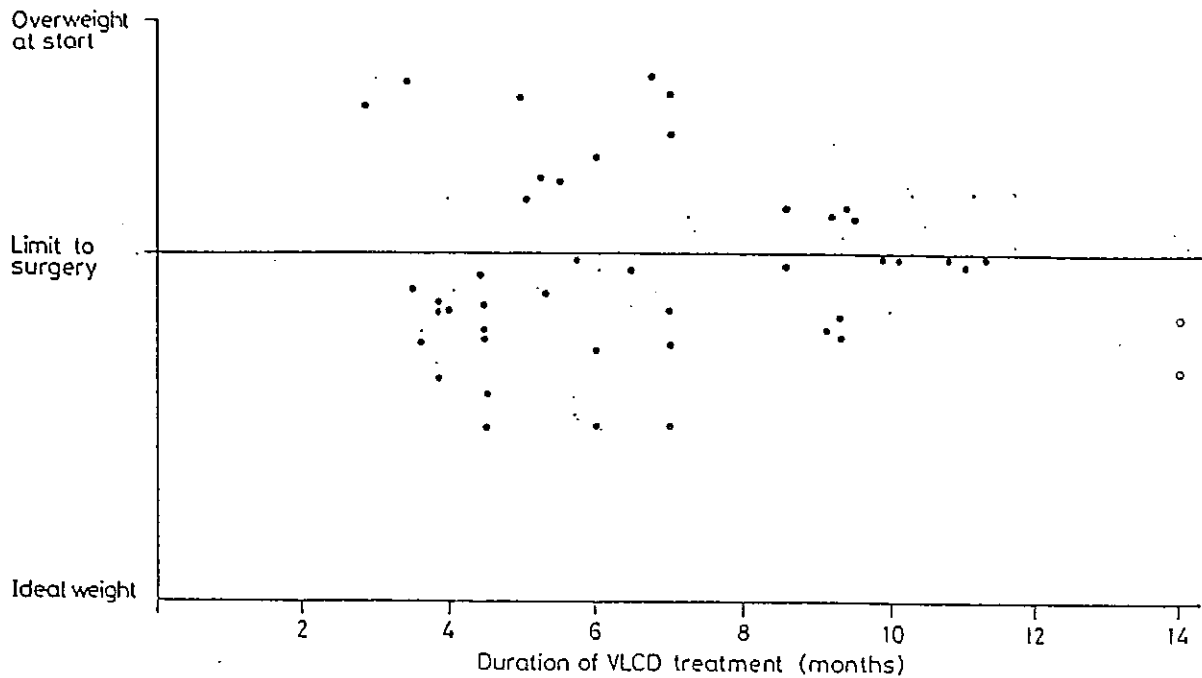


Fig. 1 Outcome of very-low-calorie formula diet in 44 patients. Time from start is indicated on the abscissa, and fraction of overweight lost is given on the ordinate. A 2/5 reduction of overweight is criterion for performing gastroplasty as the second step of the treatment. Two patients, indicated with open circles, are still attending the VLCD programme.

## RESULTS

Results are preliminary, and no comparison can yet be made between the randomised subgroups.

Median weight loss after the first eight weeks of VLCD was 17.9 kg (range, 3.6–38.4 kg,  $n = 74$ ). Final result of VLCD can at present be evaluated only for the treatment group first started (44 patients). Of these, 31 (70%, 95% confidence limits 55–83%) reached the limit for operation (Fig. 1). Two patients (5% of patients otherwise available for surgery, 95% confidence limits 1–15%) failed after successful VLCD to appear for group meetings. Until now 25 patients have had GP. Most patients have stabilised their weight 3 months after surgery. At this time median postoperative weight loss is 9.0 kg (range, 3.4–22.0 kg,  $n = 25$ ) and median total weight loss from VLCD plus GP has reached 46.0 kg (range, 26.1–64.0 kg,  $n = 25$ ). Complications to surgery are listed in Table 3. During VLCD the only observed complication was one case of gout, quickly yielding to conventional treatment.

## DISCUSSION

We have previously shown that VLCD leads to immediate weight losses not significantly different from those obtained by GP. Compared with VLCD, GP seems to possess a long-term effect on food intake, making regain

Table 3 Complications of surgery in 25 patients pre-treated with VLCD

	No.	Pct.	95% significance limits
<b>Early</b>			
Minor splenic injury (splenectomy not required)	1	4%	0–20%
Minor wound infection	2	8%	1–26%
<b>Late</b>			
Outlet obstruction	1	4%	0–20%

significantly less pronounced [1]. A comparison of therapeutic hazards is in favour of VLCD, which is safe when carried out with a nutritionally adequate formula [1,2].

Combining the good elements of both treatments has led to the present protocol, investigating a two-step regimen, in which GP is preceded by VLCD.

After GP, compliance with diet is essential for weight reduction and safety. Pretreatment with VLCD offers an opportunity to test patients' ability to comply. It should be realised that gastric obesity surgery will never succeed in patients not prepared to follow dietary advice. At the group meetings during VLCD the importance of the GP diet is explained together with its specific points.

Our experience shows that as much as 70% of the patients are able to fulfil our criterion for surgery. By addition of GP these patients obtain a total weight loss comparable with that obtained by jejunioleal bypass [6]. Through adjusting the duration of VLCD, weight loss can be individualised. This means that nearly all patients can reduce their overweight to less than 40%, which can be considered the lower limit of excess mortality from obesity [7,8].

In any kind of surgery it is an aim to eliminate risks. Obesity is a well-known surgical risk factor [9-13], the importance of which diminishes along with weight reduction. In our experience, preoperative weight reduction makes the operations much easier and safer and the postoperative management simpler. Accordingly, patient satisfaction is improved.

Although a number of arguments thus favour the use of GP as the second part of a two-step treatment, the present approach has not previously been described. Our investigation will in due time reveal weight maintenance data decisive for the choice of either horizontal or vertical banded GP after pretreatment with VLCD.

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