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HORIZONTAL OR VERTICAL BANDED GASTROPLASTY AFTER PRETREATMENT WITH VERY-LOW-CALORIE FORMULA DIET: A RANDOMIZED TRIAL

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Horizontal and vertical banded gastroplasty (GP) were compared as to their effectiveness and side-effects in patients pre-treated for morbid obesity with a very-low-calorie formula diet (VLCD). The pre-treatment served to select the compliant patients, to minimize the surgical hazard, and to optimize the total weight reduction.

Seventy-four consecutive patients (median age 34 years, median body weight 125.1 kg, and median overweight 93 per cent) were included according to the criteria for entry. The median weight loss on VLCD was 25.7 kg (range, 5.8–92.6 kg) and the median overweight reduction reached 46 per cent of the initial overweight (range, 9–83 per cent). Only few and mild side-effects were observed. Sixty-nine per cent of the patients fulfilled our criterion for surgery by reducing their initial overweight by at least 40 per cent. Of these, 23 and 22 patients were assigned respectively to either vertical banded or to horizontal GP. Patients and dietitians were not informed of the assignment. A significant weight loss occurred in both groups. Three months after surgery weight loss after vertical banded GP proved to be the larger ($P<0.001$). The difference became even more pronounced due to an earlier regain among patients treated with the horizontal GP. Thus, at 12 months, the net weight loss after surgery was 9.7 kg (range, −28.2–28.7 kg) in the vertical banded GP group and −1.0 kg (range, −15.0–36.5 kg) in patients treated with horizontal GP ($P<0.0005$). At this time, the total weight loss in the groups was 48.5 kg (range, 6.4–104.0 kg) and 32.6 (range, 3.7–125.1 kg) respectively ($P<0.02$), and the total reduction of overweight was greater in the group treated with vertical banded GP (80 per cent (range, 10–96) versus 56 per cent (range, 8–92), $P<0.005$). There were no deaths, and side-effects to VLCD as well as to GP were generally mild.

It is concluded that vertical banded GP is more effective than horizontal GP and that the former operation adds a significant weight loss to that obtained by VLCD. The combined treatments offer a weight reduction comparable to that observed after jejunoileal bypass. However, some regain within 1 year makes it questionable if the vertical banded GP is sufficient to prevent weight regain.

Keywords: obesity, treatment, diet, surgery, gastroplasty.

Introduction

When gastroplasty (GP) is performed in untreated morbidly obese patients important problems must be considered. Firstly, it is difficult to predict the individual weight loss[1]. This fact gives rise to problems in adjusting the treatment to the patient's need and makes it difficult to exclude patients who are not likely to obtain a satisfactory weight loss. Secondly, nutritional deficiencies are likely to

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occur if morbid obesity is to be cured by gastric surgery alone[2]. For successful weight reduction it is necessary to adhere for a very long period to a diet not only highly restricted in energy, but also take into account the limitations caused by the narrow stoma. In spite of careful instruction, it has proved impossible to make the patients comply with the necessary qualitative dietary improvements[3]. Thirdly, obesity and its associated conditions cause an increased surgical hazard[4,5].

The present study deals with a two-phase treatment designed to minimize these problems. GP was performed on the condition that a satisfactory initial weight loss had been obtained on a very-low-calorie formula diet (VLCD). The investigation focuses on the use of GP for prevention of weight regain, and compares the effectiveness of horizontal and vertical banded GP for this purpose.

Patients and methods

Of 165 patients admitted for morbid obesity between June 1981 and March 1984, all but two were consecutively evaluated according to the unrestrictive protocol criteria for entry. Seventy-one patients were excluded for the following reasons: age less than 18 or more than 54 years (22), other ongoing treatment (five), pregnancy or lactation (one), and unwillingness to co-operate or occupational or geographic factors impeding participation (43). Of the 92 patients eligible for entry, four refused the VLCD and 14 refused the surgical treatment.

After verbal and written information the remaining 74 patients (60 females and 14 males) consented to participate and were included. Their median age was 34 years (range, 19–54 years), their median body weight 125.1 kg (range, 91.4–224.0 kg), and their median overweight[6] 93 per cent (range, 61–222 per cent).

Procedure

The first group of patients ($n = 44$) began treatment in June 1983 and the second group ($n = 30$) in June 1984. The programme was identical. Patients were not hospitalized except for the perioperative period.

First phase. The diet before surgery consisted of repeated 8-week periods with the VLCD as sole source of nutrition. Every 8 weeks the VLCD was interrupted by a 'pause diet', eaten for 2 weeks. Patients were encouraged to continue the intermittent VLCD in order to obtain the greatest possible weight loss during this phase. The diet was used as long as a substantial weight loss could be obtained. On condition that at least 40 per cent of the initial overweight had been lost on the intermittent VLCD, patients were put on the waiting list for surgery. For weight maintenance, a waiting diet consisting solely of usual food items was prescribed until surgery.

Second phase. GP was performed with a median waiting time of 10 weeks (range, 2–41 weeks). The GP diet was started 1 week after surgery, and the total hospital stay was about 12 days.

Diets

VLCD. A 388-kcal (1.6 MJ) formula satisfying current recommendations[7] regarding protein, vitamins, minerals and trace elements was delivered free of charge to the patients (NUPO, Oluf Mørk Bio-Chemie Ltd, Copenhagen). The VLCD provided five daily meals, and water was used as vehicle.

Pause diet. The formula was continued for breakfast, but the remaining four meals were composed of normal high-protein, low-fat and low-carbohydrate food items chosen from a list. The total energy allowance was 900 kcal (3.8 MJ).

Waiting diet. This diet was very similar to the pause diet, but consisted of normal food items only. Its energy content was 1000 kcal (4.2 MJ).

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Statistical calculations

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Course

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GP diet. This diet was usually started on the 7th postoperative day. During the first months it consisted simply of half portions of the waiting diet used before the operation, and thus it had an energy content of 500 kcal (2.1 MJ). Later, when a satisfactory weight loss or compliance problems called for dietary modifications, patients were instructed to gradually increase their food intake to the full level of the waiting diet without any change in the relative composition. The final level was individualized for weight maintenance. Some foods were warned against for often giving rise to impeded pouch emptying.

Common to all diets was the recommendation of 2 litres of low-energy beverages daily. During the pause diet, the waiting diet and after surgery, a supplementary multivitamin–mineral capsule (Redavit, Oluf Mørk Bio-Chemie, Ltd, Copenhagen) was delivered free of charge. Anorexic agents were not allowed.

Surgical procedures

By a block randomization, patients meeting our criteria for surgery were assigned to either horizontal GP or to vertical banded GP. The randomization code was kept from the patients and the dietitians, and the type of operation did not influence the postoperative care in any way. All operations were performed by the same surgeon (O.G.B.).

The horizontal GP was performed according to the technique described by Gomez[8], slightly modified with a reinforced staple line as previously described[9]. The vertical banded GP was performed as described by Mason[10]. The staple line was brought as close as possible to the angle of Hiss. The window edge was reinforced with interrupted silk sutures. A stoma size of 11 mm was aimed at. One patient had a cholecystectomy performed simultaneously due to gall bladder stones.

Patient education and follow-up

Information and formalized patient education was given at group meetings headed by experienced clinical dietitians. During the first week of the VLCD treatment group meetings were daily, thereafter they were held weekly. Until 3 months after surgery patients' attendance was required weekly. We reduced the requirement to one meeting per month until 1 year after surgery and thereafter gradually to two meetings per year. At the group meetings the diets were explained and details discussed. Furthermore, relevant aspects of nutrition were expounded.

Biochemical and clinical check-ups with registration of side-effects were performed every 10 weeks during the first 2 years, thereafter every 3 months. This paper deals with the results up to 1 year after surgery.

Ethics

The Helsinki Declaration II was observed. All patients consented to participate after they were informed about the randomization and all other aspects of the study plan. The protocol was approved by the local ethical committee.

Statistical calculations

The relative reduction of overweight was calculated as the difference between initial and actual overweight divided by the initial overweight. The two-tailed Mann–Whitney rank-sum test was used for significance testing of unpaired data. Two-way analysis of variance was performed with Friedman's test. Thereafter, when testing single data pairs, Pratt's test[11] (two-tailed) was performed. The χ^2 test was used for testing prevalences of side-effects for significant group differences. *P*-values less than 0.05 were considered significant.

Results

Course

The median duration of the intermittent VLCD was 26 weeks (range, 5–84 weeks). Fifty-one patients (69 per cent, 95 per cent confidence limits 57–79 per cent) fulfilled our criterion for surgery by reducing their overweight by at least 40 per cent. The median duration of the intermittent VLCD in these patients was also 26

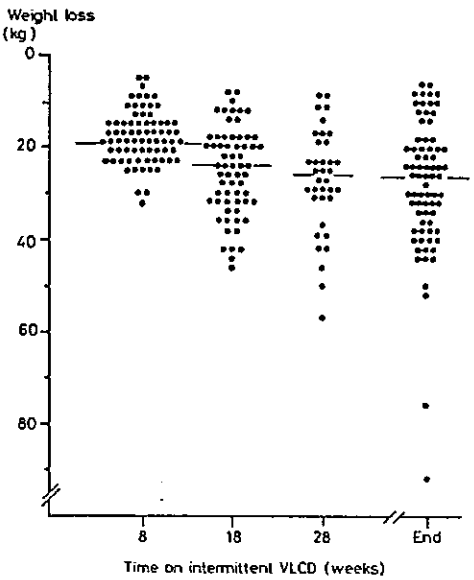

Fig. 1. *Weight loss obtained in 74 morbidly obese patients treated with intermittent VLCD for 5 to 84 weeks.*

Table 1. *Effect of intermittent VLCD on body weight and overweight in mobidly obese subjects.* The Table gives medians with ranges added.

	No. of patients	*Body weight* (kg)	*Over-weight* (%)	*Weight loss* (kg)	*Relative reduction of overweight* (%)
At start	74	125.0 91.4–224.0	93 61–222	—	—
+8 weeks	73	105.6 77.5–194.0	65 36–178	18.1 5.5–32.9	30 10–53
+18 weeks	63	99.7 72.3–187.5	55 23–155	24.7 8.3–46.2	43 13–71
+28 weeks	36	98.6 77.7–185.0	56 25–140	25.9 8.0–57.0	40 15–72
At end of VLCD	74	96.8 68.0–180.0	49 19–122	25.7 5.8–92.6	46 9–83

weeks (range, 13–84 weeks). Of the 51 patients who were successful with the VLCD, five refused operation and one was unable to keep her excess weight under the limit for operation. Of the remaining 45 patients, 23 were assigned to vertical banded GP and 22 to horizontal GP.

VLCD

Weight loss during the intermittent VLCD is shown in Fig. 1 and Table 1. For all 74 patients, the median weight loss obtained was 25.7 kg (range, 5.8–92.6 kg) and the median overweight reduction reached 46 per cent of the initial overweight (range, 9–83 per cent). All but six patients stopped the VLCD programme within 40 weeks (Fig. 2).

Side-effects during the VLCD programme are listed in Table 2.

Table 2. *Side-effects to the intermittent*

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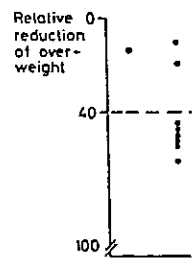

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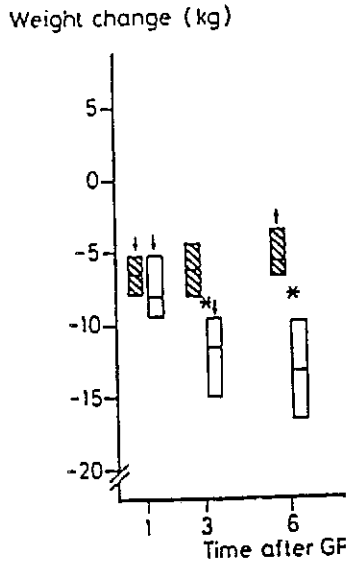

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Weight loss (kg)	*Relative reduction of overweight* (%)
—	—
18.1	30
5.5–32.9	10–53
24.7	43
8.3–46.2	13–71
25.9	40
8.0–57.0	15–72
25.7	46
5.8–92.6	9–83

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Table 2.

Table 2. *Side-effects to the intermittent VLCD.*

Dizziness	2 (3%)
Ortostatic hypotension	1 (1%)
Fatigue	1 (1%)
Transient loss of hair	6 (8%)
Gout	1 (1%)
Manifestation of Gilbert's disease	1 (1%)
Ructus	1 (1%)
Obstipation	2 (3%)
Dyspepsia during pause diet	2 (3%)

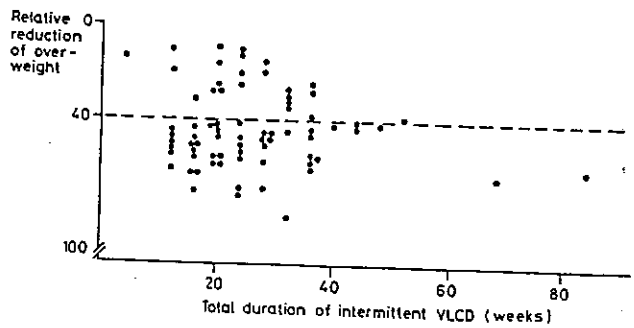

Fig. 2. *Final relative reduction of overweight obtained with intermittent VLCD only in 74 morbidly obese subjects.* Of these, 51 patients (69 per cent) reached at least a 40 per cent reduction of their overweight and thus qualified for surgery. Eleven patients lost ≥60 per cent of their overweight by the intermittent VLCD.

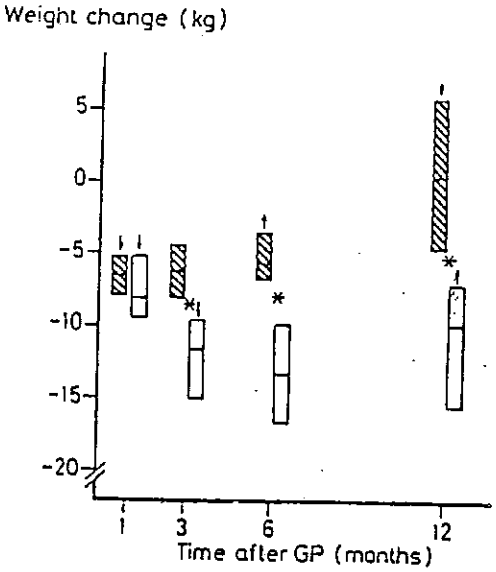

Fig. 3. *Postoperative weight loss in patients assigned to horizontal GP (hatched bars) or to vertical banded GP (open bars).* The bars indicate the 50 per cent central observations. In the bars the median is represented by a horizontal line. Significant differences between groups (all having a P value less than 0.001) are indicated with an asterisk. Within the groups, significant ($P<0.05$) changes of weight between two consecutive observation times are indicated with arrows.

GP trial

Pre-operatively, the patient group assigned to horizontal GP did not differ ($P>0.5$) from that assigned to vertical banded GP. The median pre-operative weight loss was 30.3 kg (range, 10.3–88.6) and 34.0 kg (range, 17.4–75.3), respectively, the median actual body weight was 90.6 kg (range, 65.0–135.4) and 90.1 kg (range, 73.4–125.7), respectively, and the actual overweight was 41 per cent (range, 16–94) and 46 per cent (range, 17–73), respectively.

A significant weight loss occurred after both operations (Fig. 3). However, after 3 months, weight loss became significantly ($P<0.001$) greater in patients treated with vertical banded GP. Moreover, a significant weight regain was observed as early as 6 months after horizontal GP. Thus, at 12 months, the median weight loss following surgery was −1.0 kg (range, −15.0–36.5) in this group ($n = 20$) compared to 9.7 kg (range, −28.2–28.7) in the patients ($n = 21$) treated with vertical banded GP ($P<0.001$). However, at this time a significant regain had also occurred among the patients operated with vertical banded GP (Fig. 3).

Comparing the pre-operative body weight with that 12 months later, vertical banded GP had been followed by a significant ($P<0.01$) reduction, while no significant change was observed after horizontal GP.

Table 3. *Complications and side-effects after either horizontal or vertical banded GP.*

	Horizontal GP ($n = 22$)	*Vertical banded GP ($n = 23$)*	*Significance of difference*
Splenectomy required	1 (5%)	0 (0%)	n.s.
Wound infection	2 (9%)	1 (4%)	n.s.
Ventral hernia	1 (5%)	1 (4%)	n.s.
Postanaestetic jaundice	0 (0%)	1 (4%)	n.s.
Outlet obstruction	3 (14%)	0 (0%)	n.s.
Haemorrhagic gastritis	2 (9%)	0 (0%)	n.s.
Pronounced dyspepsia	2 (9%)	2 (9%)	n.s.
Occasional vomiting	4 (18%)	13 (57%)	$P<0.02$
Heartburn	2 (9%)	0 (0%)	n.s.
Obstipation	0 (0%)	1 (4%)	n.s.
Transient loss of hair	0 (0%)	1 (4%)	n.s.
Ortostatic hypotension	0 (0%)	1 (4%)	n.s.

Complications and side-effects to GP are listed in Table 3. There were no deaths (0 per cent, 95 per cent confidence limits 0–8 per cent) and few postoperative complications. Surgery was made technically easier by the pre-operative weight reduction. Side-effects were generally mild. Early outlet obstruction developed only in the horizontal GP patients (14 per cent, 95 per cent confidence limits 3–35 per cent), but this group difference was not significant. Periods of severe dyspepsia were observed in 9 per cent of both groups. Occasional vomiting was reported more frequently after vertical banded than after horizontal GP (57 per cent, 95 per cent confidence limits 34–77 per cent) compared to 18 per cent (95 per cent confidence limits 5–40 per cent; $P<0.02$).

VLCD plus GP

Twelve months after GP,
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VLCD plus GP

Twelve months after GP, the median total weight loss of the horizontal GP group had reached 32.6 kg (range, 3.7–125.1) compared to 48.5 kg (range, 6.4–104.0) in patients treated with vertical banded GP ($P<0.02$). Also the total reduction of overweight was superior in the group treated with vertical banded GP (median 56 per cent, range, 8–92) versus 80 per cent (range, 10–96), $P<0.005$).

Discussion

The pre-operative dietary treatment created a suitable basis for comparing the biological efficacy of the two different gastric procedures. The pretreatment eliminated any psychological effect of entering a treatment programme. Thus, the pretreatment reduced the considerable variability in results seen when surgery is performed at a time when expectations are sometimes too high, and energy intake is unmodified and in some cases very large. Furthermore, the patients were selected as being able to comply with a restrictive diet, and the allocation resulted in absolute comparability regarding pre-operative weight loss as well as actual body weight and overweight.

The study is the first randomized trial of the horizontal gastroplasty (GP) and the more recently introduced vertical banded GP. Our data provide convincing evidence for the higher short-term efficacy of the vertical banded GP, although there were good and bad results after either operation. Our results are in accordance with a study by Mason[9] using historical control groups. On the basis of his and other series, which however give no evidence as to the inferiority of the horizontal GP, this technique has at present been abandoned in favour of vertical banded GP.

The explanation of the different efficacy is still lacking, as is an understanding of the principles underlying the diet-supporting effect of the various GP modifications. The determinants of weight loss usually mentioned—pouch size, stoma diameter and pouch emptying rate—have all been seriously questioned[12–19]. However, ongoing studies comparing these variables in groups with different gastric operations may increase our understanding of the true determinants of weight loss.

Compared with a previous GP series performed without pre-operative weight loss[9], our patients were less affected clinically by the operation. Comparing the randomized groups of the present study, we observed a significantly higher prevalence of occasional vomiting after the vertical banded GP. However, this complaint could in no way explain the extra weight loss in this group. No other significant differences could be demonstrated.

Our data have also shown that vertical banded GP can add a significant weight loss to that obtained by VLCD. In the present protocol, however, GP was performed primarily to facilitate weight maintenance. Median weight regain 1 year after maximal VLCD-induced weight loss is about 13 kg[8]. In accordance with previous observations[9] the horizontal GP was able to prevent this regain within the first year, but the vertical banded GP succeeded in adding about 10 additional kilograms to the pre-operative weight loss. It is unknown if the higher initial efficacy of the vertical banded GP also means a better ability for long-term weight

maintenance. At present, methods for maintaining weight loss are in our opinion a crucial topic of clinical anti-obesity research. In view of the better early weight loss and acceptable side-effects, the vertical banded GP qualifies for inclusion into future clinical trials of weight maintenance procedures.

This study was not designed as a comparison of gastroplasty with or without pre-treatment. However, a range of arguments favour the pre-treatment principle in comparison with immediate gastric obesity surgery. Firstly, pre-treatment offers an opportunity to select the patients with respect to their ability to comply with a diet, which is also essential after a gastric procedure. Secondly, pre-treatment makes also possible a more liberal patient selection: many patients otherwise ineligible for surgery because of obesity complications, can be operated after a pre-operative weight loss, which reduces the surgical hazard[4]. In spite of improved surgical techniques and advanced anaesthesiological and medical support, untreated morbid obesity should still be considered an important surgical risk factor[4,5], which can probably be lowered through a pre-operative weight loss[5]. Thirdly, when performing gastric surgery without pretreatment, an acceptable weight loss requires a prolonged postoperative period with a diet, the nutritional quality of which is difficult to secure, especially in less compliant patients. When the goal is a particularly large weight loss, malnutrition is a considerable hazard[2,3]. Fourthly, the weight loss is difficult to individualize, a problem especially important for patients in need of the largest weight losses.

Finally, immediate surgery gives little opportunity to correct the patients' common belief that the surgical procedure in itself will bring about the weight loss with little need for dietary restrictions.

Thus, when operating without pre-treatment one easily ends up with quite a large fraction of patients who have been operated on with the obesity-related extra risk, but who are unwilling to diet or even cooperate in other ways; they quickly return to their habitual diet or—which may be even worse—continue without adequate supervision on a deficient diet for prolonged periods of time in order to obtain the desired weight loss.

For pre-operative weight loss, VLCD with NUPO proved highly effective. The median weight loss of the entire group was about 26 kg, somewhat more than we observed in a previous study[9] in which a less simple formula was used. In the present series, 10 patients (14 per cent, 95 per cent confidence limits 7–23 per cent) lost more than 40 kg and one patient (1 per cent, 95 per cent confidence limits 0–7 per cent) lost more than 90 kg. The median reduction of the initial overweight came close to 50 per cent. Accordingly, more than two-thirds of the patients qualified for surgery by obtaining at least a 40 per cent reduction of their initial overweight. Furthermore, even in patients treated for very long periods of time, the side effects were unimportant.

In evaluating the present report two points should be borne in mind. Firstly, the combination of VLCD and vertical banded GP offers a weight loss comparable to that obtained after jejunoileal bypass and causes much fewer complications and side-effects[20]. Secondly, the vertical banded GP is the more effective operation, but the limited observation time still leaves unanswered the question as to whether any GP can prevent a late regain of weight.

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Medical Research of Copenhag

The contents of NUPO are the
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iron 18, zinc 15, copper 3, iodin
0.20, vitamin A 1.00, vitamin D
1.7, vitamin B_6 2.2, vitamin
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Note

The contents of NUPO are the following (all given in mg): Protein 56 400, lipid 4800, carbohydrate 29 700, calcium 800, phosphorus 800, potassium 2000, sodium 1500, chloride 2397, magnesium 400, iron 18, zinc 15, copper 3, iodine 0.15, manganese 3.8, chromium 0.12, selenium 0.12, molybdenum 0.20, vitamin A 1.00, vitamin D 0.01, vitamin D 10, vitamin K 0.14, thiamin (B_1) 1.5, riboflavin (B_2) 1.7, vitamin B_6 2.2, vitamin B_{12} 0.003, biotin 0.2, niacin 19, vitamin C 60, folic acid (as monoglutamyl) 0.1, and pantothenic acid 7.

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