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## DIETARY FIBRE ADDED TO VERY LOW CALORIE DIET REDUCES HUNGER AND ALLEVIATES CONSTIPATION

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To examine whether supplement of dietary fibre may improve compliance to a very low calorie diet (VLCD) a nutrition powder providing 388 kcal/day (men: 466 kcal/day) was compared with a similar version containing plant fibre 30 g/day. Twenty-two obese patients entered the study. After a baseline habitual diet, they were randomized to two weeks of treatment in a single blind design to either VLCD with or without dietary fibre. Subsequently, they were crossed over for further 2 weeks of treatment. All patients completed the study. The two groups had similar weight losses (about 10 kg/4 weeks), and dietary fibre did not improve this result. During VLCD with fibre hunger ratings were significantly lower than during VLCD without fibre (fibre effect, ANOVA;  $P < 0.01$ ). Bowel movements decreased from 1.9/day on habitual diet to 0.7/day on VLCD without fibre, but increased to 1.0/day by fibre supplement (fibre effect,  $P < 0.01$ ). No effect of fibre supplementation to VLCD was found on satiety, consistency of faeces and flatulence. The supplement of dietary fibre did not influence plasma concentrations of divalent cations as calcium, iron or magnesium, nor did it add any lowering effect on plasma glucose, cholesterol or triglyceride to that of VLCD. In conclusion, the supplement of dietary fibre to VLCD may improve compliance by reducing hunger and increasing the number of bowel movements, without impairment of absorption of divalent cations.

*Keywords:* constipation, dietary fibre, divalent cations, hunger, very low calorie diet, weight loss.

### *Introduction*

Very low calorie diet (VLCD) as a nutrition powder formula diet is being widely used for the treatment of obesity, and has been documented to be effective and safe<sup>1</sup>. This regimen facilitates compliance because of its simplicity combined with a rapid weight loss which may further encourage the patient to stick to the diet. The major drawbacks are still the patients' complaints of hunger between meals, constipation and the infrequency of bowel movements.

Recently it has been shown that fibre supplementation to a conventional diet reduces hunger, increases the frequency of bowel movements and softens the consistency of the stools<sup>2</sup>. The supplementation of fibre to a formula diet designed for VLCD has not hitherto been reported.

The purpose of the present investigation was to examine if the addition of fibre to a nutrition powder improves compliance by modifying hunger, satiety, stool

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consistency and bowel movements. As fibre may impair intestinal absorption of various divalent cations and vitamins, we also monitored plasma levels of the most important metal ions together with other relevant plasma constituents.

### Methods

#### General data

Twenty-six outpatients with morbid obesity were admitted to the obesity clinic at Hvidovre Hospital between September and December 1987. Consecutive patients were included in the study if their age was between 18 and 65 years and their overweight between 20 and 100 per cent, as calculated from their ideal body weight (Metropolitan Life Insurance Co. Tables, 1983). Four patients were excluded because of abuse of alcohol or drugs, or treatment with neuroleptics known to promote obesity.

Thus 22 patients entered the study. They gave their informed consent according to the declaration of Helsinki 2. The protocol was approved by the Municipal Ethical Committee of Copenhagen

#### Design and patients

After a pre-trial baseline period of 3 days on habitual diet the patients were randomly and equally assigned by a third party to either VLCD without fibre or VLCD with fibre (see Fig. 1). The study was single-blind as the patients were informed that the trial was a comparison of two different kinds of VLCD, but no information about fibre was given. After two weeks of VLCD treatment the two groups were crossed over for further two weeks of treatment (Fig. 1). After the study the patients were treated for a further 6 months with a conventional diet of 4.2 MJ/day, combined with nutritional advice and behaviour modification.

Group 1 (VLCD minus fibre followed by VLCD plus fibre) consisted of nine women and two men aged  $31.09 \pm 9.54$  (mean  $\pm$  s.d.) with a height of  $177 \pm 7$  cm and a body weight of  $120.6 \pm 20.2$  kg, corresponding to an excess weight of  $56 \pm 18$  per cent. The patients assigned to group 2 (VLCD plus fibre followed by VLCD minus fibre) included eight women and three men aged  $37 \pm 13.27$  years (mean  $\pm$  s.d.) with a height of  $172 \pm 11$  cm and a body weight of  $114.0 \pm 22.4$  kg, and an excess weight of  $48 \pm 18$  per cent. The waist/hip ratio of group 1 was  $0.92 \pm 0.08$ , and that of group 2 was  $0.94 \pm 0.09$ <sup>3</sup>.

The contents of the VLCD formula without fibre (NUPO, Oluf Moerk A/S) are specified elsewhere<sup>4</sup>. The fibre version contained 30 g/day plant fibre (birch) with a high cellulose (98.5 per cent) and a low pectin (< 0.02 per cent) content. It contains undetectable amounts of lignin. In an initial testing six obese patients were not able to distinguish by appearance, taste or smell between the two versions.

The nutrition powder was taken as five daily meals (men: six), with water as vehicle. The daily energy provided by the nutrition powder was 388 kcal (1.6 MJ) for women and 466 kcal (1.9 MJ) for men. The formula diet meets all international recommendations<sup>5</sup> for daily intake of protein (women 56 g, men 67 g), essential amino acids, vitamins, minerals and trace elements.

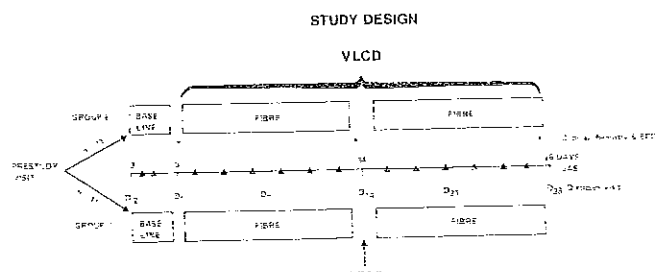


Fig. 1. Study design. The illustration shows how the patients after inclusion were maintained on habitual diet for 2 days and subsequently allocated to either VLCD plus fibre (group 2) or VLCD minus fibre (group 1) for two weeks. Hereafter they were crossed over for a further two weeks of treatment.

#### Analyses

Before treatment and after 2 weeks and 4 weeks of treatment, fasting blood samples were drawn from a cubital vein (Fig. 1). Blood haemoglobin, serum iron, calcium, phosphate, potassium, magnesium, urate, albumin, cobalamin, prothrombin, glucose, cholesterol and triglyceride were measured by routine methods. A six-lead ECG was recorded on the same occasions.

On the habitual diet and during the two VLCD periods the patients kept visual analogue scores (VAS) of satiation and hunger every second day at 3 p.m. and at 9 p.m.<sup>5</sup>, and of faecal consistency, flatulence and the number of bowel movements when the day was over.

The VAS consisted of a 100 mm scale with the two end-points representing the extremes, i.e. hunger: 'I am not hungry at all' versus 'I have never been more hungry'. The score was quantified by measurement of the length from zero to the point marked by the patient.

#### Statistics

All results are reported as mean  $\pm$  standard deviation unless otherwise indicated. The effects of VLCD and fibre were tested by a multifactor analysis of variance using Statgraphics software (Plus\*ware, STSC Inc., USA). To eliminate the effect of time and of order of treatment these variables were included as covariates. Means were evaluated with a two-sided modified *t* test<sup>6</sup>.

### Results

All 22 patients completed the study without any missed appointments or other deviations from the protocol.

The randomization resulted in slightly heavier patients in group 1 ( $120.6 \pm 20.2$  kg *v.*  $114.0 \pm 22.4$  kg). On the same energy restriction group 1 would *a priori* be expected to lose more weight. This was confirmed by the results, as the body weight in group 1 was reduced with  $7.5 \pm 1.6$  kg and  $3.6 \pm 1.5$  kg in the two periods respectively ( $P < 0.0001$ ). The corresponding weight losses in group 2 were  $6.4 \pm 1.8$  kg and  $3.3 \pm 1.1$  kg ( $P < 0.001$ ). To make the results comparable they are expressed as relative reduction in overweight in Fig. 2. As will be seen, both groups had very similar percentual reductions in overweight during the two periods. Thus fibre supplementation to the nutrition powder did not improve weight loss. The waist/hip ratio did not change in group 1 in the two periods: day 1,  $0.92 \pm 0.08$ ; day 14,  $0.92 \pm 0.08$ ; day 28,  $0.90 \pm 0.08$  (n.s.). The corresponding waist/hip ratios in group 2 were  $0.94 \pm 0.09$  to  $0.92 \pm 0.07$  and  $0.92 \pm 0.07$  (n.s.). No significant effect was observed by the fibre addition.

After the multivariate analysis of variance an average VAS-score was calculated for every single patient for each of the three periods (baseline diet, VLCD minus fibre, VLCD plus fibre). The results are shown in Table 1. The effect of VLCD and fibre supplementation, respectively, are shown in the right columns. No significant difference was found between the effects in group 1 and 2 ( $P > 0.4$ ). The time course of hunger ratings are shown in Fig. 3. There was a substantial increase in hunger ratings when the patients started on VLCD (VLCD effect,  $P < 0.005$ ). This increase was reduced and became more short-lived when fibre was added to VLCD (fibre effect,  $P < 0.007$ ). Also, after cross-over of the treatments the pattern of hunger was ameliorated by fibre (Fig. 3). The average values of hunger ratings were slightly increased, from 36.5 to 44.5 per cent, when habitual diet was compared with VLCD minus fibre. This increased hunger during VLCD was improved by the addition of fibre as it decreased to 38.0 per cent. Fibre supplementation had no effect on satiety (n.s.).

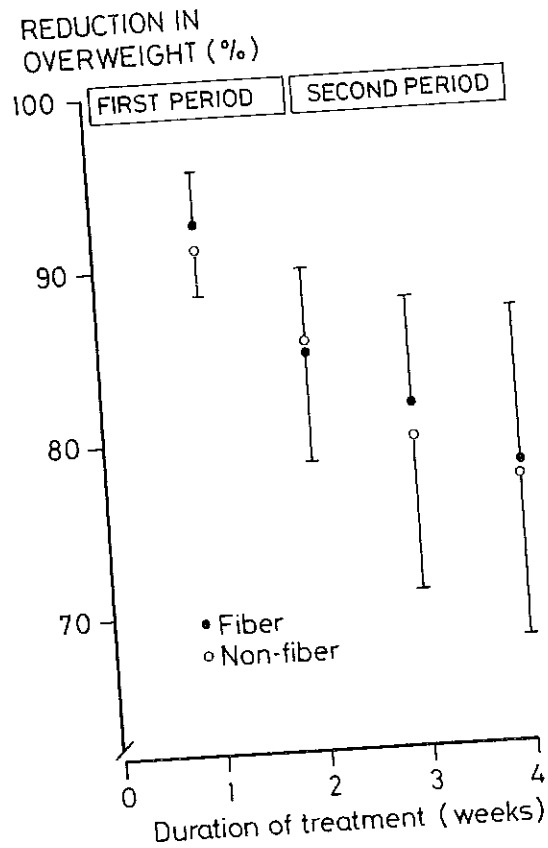


Fig. 2. Percentual reduction in overweight on VLCD with and without fibre supplementation. The initial overweight (body weight - ideal weight) is expressed as 100 per cent, and the reduced weights are calculated in per cent of the initial overweight, mean  $\pm$  s.d. No significant differences could be detected between the figures in the two groups.

Table 1. Changes in ratings of hunger, satiety, faeces consistency and flatulence, and number of bowel movements on habitual diet compared with VLCD without fibre and VLCD with fibre. Data from treatment period 1 and 2 are pooled, i.e.  $n = 22$ . Before pooling of data the effect of VLCD and fibre supplementation was tested by ANOVA.

	Habitual diet	VLCD without fibre	VLCD with fibre	VLCD effect	Fibre effect
Hunger % (VAS)	36.5	44.5	38.0	$P < 0.005$	$P < 0.01$
Satiety % (VAS)	56.7	54.4	53.4	NS	NS
Consistency of faeces % (VAS)	47.0	56.6	57.5	$P < 0.001$	NS
Bowel movements (no./day)	1.9	0.7	1.0	$P < 0.05$	$P < 0.01$
Flatulence % (VAS)	27.1	15.4	21.9	$P < 0.05$	NS

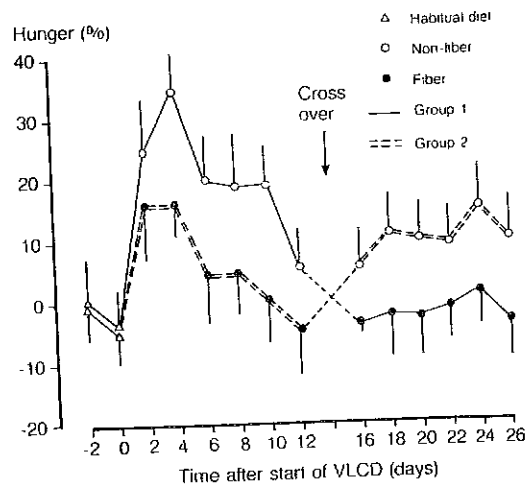


Fig. 3. Changes in hunger ratings (per cent) from habitual diet to either VLCD plus fibre or VLCD minus fibre. Values are means  $\pm$  s.e. Hunger ratings were markedly increased by VLCD ( $P < 0.005$ ), but fibre supplementation decreased the hunger ratings significantly ( $P < 0.01$ ).

The consistency of faeces changed significantly on the replacement of habitual diet with VLCD (VLCD effect,  $P < 0.001$ ). However, supplementation of fibre did not influence this change. On habitual diet the daily number of bowel movements was 1.9. This was reduced to 0.7/day on VLCD minus fibre (VLCD effect,  $P < 0.05$ ), and slightly, but significantly, improved to 1.0/day VLCD plus fibre (fibre effect,  $P < 0.01$ ).

Flatulence (also monitored by VAS-score) decreased during VLCD minus fibre from 27.1 to 18.4. Although the average value increased to 21.9 during VLCD plus fibre, the fibre effect was not significant.

The biochemical blood and plasma parameters monitored during the study are presented in Table 2. The data of the two groups of patients are presented separately. VLCD had no effect on haemoglobin, phosphate and sodium. By contrast, VLCD had an effect on the remaining variables (Table 2). Plasma iron and prothrombin transiently decreased after the first two weeks of VLCD but tended to become normal again after 4 weeks. Plasma calcium decreased only in group 2 during both periods of VLCD. Potassium decreased slightly, by 0.1–0.2 mmol/l after 2–4 weeks. Urate, albumin and cobalamin transiently increased after 2 weeks of treatment, but had returned to around baseline levels after 4 weeks. Plasma glucose was reduced by about 1 mmol/l after 2 weeks on VLCD, and increased slightly above this value after 4 weeks. Cholesterol decreased by about 1.0–1.4 mmol/l during VLCD, while triglyceride decreased by 0.4–0.6 mmol/l. No effect of fibre supplementation was detected by ANOVA. No changes occurred in ECG during weight reduction.

### Discussion

The present study confirms that VLCD is an effective treatment for obesity, as the average weight loss during a 4 week period was about 10 kg. Although fat accounts only for 75 per cent and lean body mass (LBM) for 25 per cent of total body weight loss during a nutritionally sufficient VLCD<sup>7</sup>, the reduction in LBM

Table 2. Changes in blood and plasma concentrations of various parameters from habitual diet to the two VLCD periods presented separately for both groups of obese patients. Means  $\pm$  s.e.m. ( $n = 11$ ). The effect of VLCD and fibre supplementation, respectively, was tested by ANOVA and the levels of significance are shown in the right margin. n.d. denotes not determined (laboratory error).

Group Fibre Day	1		2		ANOVA effect of VLCD		ANOVA effect of Fibre
	+	-	+	-	28	14	
Haemoglobin (mmol/l)	8.9 $\pm$ 0.9	8.8 $\pm$ 0.9	8.7 $\pm$ 0.9	8.5 $\pm$ 0.7	8.3 $\pm$ 0.5	8.5 $\pm$ 0.5	n.s.
Iron ( $\mu$ mol/l)	15 $\pm$ 7	11 $\pm$ 4	12 $\pm$ 4	15 $\pm$ 7	12 $\pm$ 4	10 $\pm$ 3	$P < 0.05$
Calcium (mmol/l)	1.25 $\pm$ 0.04	1.27 $\pm$ 0.14	1.27 $\pm$ 0.03	1.28 $\pm$ 0.03	1.25 $\pm$ 0.03	1.24 $\pm$ 0.03	$P < 0.01$
Phosphate (mol/l)	1.15 $\pm$ 0.08	1.10 $\pm$ 0.16	1.16 $\pm$ 0.15	1.09 $\pm$ 0.07	1.16 $\pm$ 0.13	1.10 $\pm$ 0.12	n.s.
Potassium (mmol/l)	4.3 $\pm$ 0.1	4.2 $\pm$ 0.3	4.1 $\pm$ 0.03	4.3 $\pm$ 0.3	4.1 $\pm$ 0.2	4.1 $\pm$ 0.3	$P < 0.01$
Sodium (mmol/l)	141 $\pm$ 2	141 $\pm$ 2	141 $\pm$ 2	141 $\pm$ 1	142 $\pm$ 1	140 $\pm$ 2	n.s.
Magnesium (mol/l)	n.d.	0.82 $\pm$ 0.03	0.83 $\pm$ 0.04	n.d.	0.80 $\pm$ 0.04	0.79 $\pm$ 0.07	n.s.
Urate (mmol/l)	0.33 $\pm$ 0.08	0.48 $\pm$ 0.16	0.35 $\pm$ 0.10	0.35 $\pm$ 0.12	0.39 $\pm$ 0.11	0.52 $\pm$ 0.13	$P < 0.01$
Albumin ( $\mu$ mol/l)	600 $\pm$ 40	634 $\pm$ 36	609 $\pm$ 30	619 $\pm$ 32	611 $\pm$ 30	636 $\pm$ 43	$P < 0.01$
Cobalamin ( $\mu$ mol/l)	266 $\pm$ 48	522 $\pm$ 189	364 $\pm$ 80	261 $\pm$ 72	385 $\pm$ 166	514 $\pm$ 187	$P < 0.001$
Prothrombin (%)	1.18 $\pm$ 0.13	0.83 $\pm$ 0.11	0.95 $\pm$ 0.18	1.14 $\pm$ 0.15	0.92 $\pm$ 0.17	0.87 $\pm$ 0.14	$P < 0.001$
Glucose (mmol/l)	5.3 $\pm$ 0.6	4.3 $\pm$ 0.7	4.5 $\pm$ 0.7	5.1 $\pm$ 0.7	4.7 $\pm$ 0.5	4.2 $\pm$ 0.5	$< 0.0001$
Cholesterol (mmol/l)	5.5 $\pm$ 1.0	4.6 $\pm$ 0.9	4.4 $\pm$ 0.7	5.5 $\pm$ 0.7	4.1 $\pm$ 0.6	4.1 $\pm$ 0.4	$P < 0.0001$
Triglyceride (mmol/l)	1.4 $\pm$ 0.6	1.0 $\pm$ 0.2	1.1 $\pm$ 0.3	1.7 $\pm$ 0.6	1.2 $\pm$ 0.3	1.1 $\pm$ 0.1	$P < 0.01$

is a normalization, as fat deposition in obesity is accompanied by an increased LBM<sup>8</sup>. The weight reduction also had a favourable effect on plasma glucose, cholesterol and triglyceride.

A very satisfactory compliance was achieved, shown by the fact that all patients adhered to the trial and lost weight. Therefore compliance could not be evaluated in terms of drop-out rate or weight gain. Regarding weight loss (and compliance) no difference could be found between the periods on the fibre and non-fibre VLCD versions. However, hunger ratings increased during the non-fibre VLCD (Fig. 3), but was reduced by fibre addition. This confirms that dietary fibre has an effect on hunger, although the mechanisms of action are not fully clarified<sup>9</sup>. Furthermore, the constipation seen during VLCD minus fibre was slightly improved by fibre supplement. This is in accordance with the generally accepted view that dietary fibre supplementation alleviates constipation<sup>10</sup>. Consequently, fibre supplementation may improve quality of life and may prove useful by enhancing diet compliance and reducing drop-out rate during a less strictly controlled weight loss programme than ours, which was organised in groups of patients with frequent control visits.

The addition of fibre to a marginally adequate diet may be deleterious, because high fibre diets containing phytate may decrease bioavailability of necessary divalent cations, although it does not seem to be of clinical importance<sup>11</sup>. Nevertheless, we decided to avoid decreased absorption of minerals and trace elements by choosing a fibre source (a non-gelling fibre) without detectable amounts of phytate and low levels of pectin. The results presented in Table 2 show the changes during VLCD in plasma parameters which previously have been described in detail<sup>12,13</sup>. However, the most important finding was that no effect of fibre supplement could be found on calcium, iron or magnesium. In contrast to fibres such as bran and to a minor degree ispagula and psyllium, fibre materials such as cellulose and pectins do not interfere with iron or zinc absorption in man<sup>14,15</sup>. In addition, water insoluble fibre, such as the one used by us, increase stool weight but have no effect on faecal bile acids or plasma cholesterol levels<sup>16</sup>. The lack of fibre effect on plasma glucose, cholesterol and triglyceride in the present study confirms this view.

In conclusion, VLCD supplement with non-gelling fibres reduces hunger and increases number of bowel movements, without causing impairment of absorption of divalent cations as calcium, magnesium or iron.

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