Long-term effect of fibre supplement and reduced energy intake on body weight and blood lipids in overweight subjects

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Summary: A weight-reducing potential has been ascribed to high dietary fibre intake. To investigate the practical reliability of this hypothesis, fifty-three moderately overweight females (BMI>27.5 kg/m²) on reduced energy intake (1300 kcal/day) were treated for 24 weeks with a fibre supplement on a randomly, double-blind, placebo-controlled basis. The fibre was administered as an initial dose of 6 g and a maintenance dose of 4 g. Body weight and blood pressure were recorded weekly during the first 3 months and thereafter every second week. Blood samples were drawn at start and at end of the study. Initial body weights were 75.6±1.6 kg in the fibre group versus 75.5±1.6 kg in the placebo group. After treatment, mean weight loss in the fibre group was 8.0 kg versus 5.8 kg in the placebo group (p<0.05). Systolic and diastolic blood pressures were significantly reduced in both groups without differences between the groups. Serum concentrations of cholesterol, triglycerides and uric acid were significantly reduced in the group with reduced energy intake, whereas no additional effect was observed when fibre was compared with placebo. Serum concentrations of potassium and sodium did not change significantly. The results suggest that a dietary fibre supplement in combination with a hypocaloric diet is of value as an adjunct in the management of overweight.

Key words: Dietary fibre; Obesity; Weight reduction; Blood pressure

Introduction

Increased dietary fibre intake has been recommended to obtain stable energy intake and avoid metabolic disturbances such as obesity, type 2 diabetes, hyperlipidaemia and cardiovascular disease (1,2,5,7,8,10). The effect of a dietary fibre supplement to a hypocaloric diet in the treatment of overweight is still controversial (6,14). When critically reviewed, only a few controlled studies have shown a modest weight loss induced by soluble fibre supplement (11,12,13). In addition, there are numerous studies with only limited value due to lack of comparison groups, inadequate sample sizes and short duration of the observations (4).

Fibre supplement in long term studies involves problems with compliance as well as with the adherence to a low-energy diet regimen throughout the observation period. Moreover, it is unknown whether metabolic adjustments to high fibre intake may take place during long-term addition leading to a reduction in the fibre efficacy. Therefore, the aim of the present study was to investigate the effect of the fibre supplement on weight, energy intake and some anthropometric and biochemical parameters in overweight subjects in a controlled, randomised design for 24 weeks.

Material and methods

Subjects

Sixty healthy, mildly overweight females who volunteered to participate in this study were recruited by advertisement in the local newspaper. The inclusion criteria were age 18-67 year and body mass index (BMI) >27.5 kg/m². Patients with serious cardiac, renal and hepatic diseases were excluded. Patients with a history of gastrointestinal disease, type 1 diabetes, pregnancy, and patients treated with antacids, diuretics, H₂-blockers, bulk laxatives, anorectics, and oral contraceptives were also excluded.

Study design

All subjects were randomized to two groups according to BMI, the fibre group and the placebo group. Fibre tablets (Farma Food, Copenhagen, Denmark) and placebo tablets (identical in taste and appearance as fibre) were prescribed three times daily, 6 tablets to be taken 15 min before meals with 250 ml of water and 4 tablets to be taken at 3 p.m. for 8 weeks (high dosage). The dosage was then reduced to 5 tablets prescribed three times daily for the rest of the treatment period (maintenance dosage). The tablets contained a mixture of fibres from grain and citrus and consisted of...

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15% soluble fibre and 85% insoluble fibre. Patients were told to follow a 1200 kcal diet (Libra Slimming Club diet), perform their regular exercise program, and not change their smoking habits during the study. In addition to the food fibre (estimated about 15g/day), each subject consumed 6 g of fibres during a high-carbohydrate period of 8 weeks and 4 g of fibres during the maintenance dosage period, respectively. In addition, each subject received one multi-vitamin tablet daily. For vitamins and minerals, the content in this tablet was equal to 100% Recommended Daily Allowance. In order to keep the subjects motivated, they were informed in group sessions, regarding health consequences of overweight three times during the treatment period. At start, a physical examination was performed, including blood pressure measurement, height, weight and BMI (kg/m²). These procedures were repeated every week during the first 12 weeks and every fourth week during the rest of the treatment period. Duration of the study was 24 weeks with clinical visits scheduled at the same time each week. Subjects were weighed each week and side effects were recorded. Compliance with the drug treatment was checked by the returned tablets; 80% compliance was considered acceptable.

Adherence to the 1200 kcal diet was evaluated regularly during the treatment period using a standardised questionnaire. An adherence of 20% was considered acceptable.

Laboratory tests
Blood samples were drawn after an overnight fast at start and after 24 weeks. The blood samples were withdrawn into vacutainer tubes containing EDTA (1mg/ml, final concentration), and centrifuged at 1000 g for 10 min at 4°C. Hemoglobin and glucose in blood and serum concentrations of cholesterol, triglycerides, uric acid, sodium and potassium were measured using the routine methods of the Central Laboratory Department of Sentralisykehuset of Akershus, Norway.

Ethics
The study was conducted according to Helsinki declarations and with the approval of the Ethical Committee of the Health Region I in Norway. All subjects gave their informed consent.

Statistical analysis
Statistical analysis was performed in those patients who fulfilled the study according to the protocol. Differences in consecutive weight changes between the fibre and the placebo group were evaluated by using Wilcoxon rank sum test. Significance of differences between the groups was assessed by the paired Student's t-tests, defining a p-value < 0.05 as statistically significant.

Results
Of the 60 intended-to-treat patients (30 in each group) randomised to fibre and placebo treatment, 53 subjects (28/25) in the fibre group and placebo group, respectively entered the study. Seven of the subjects were not included due to sudden events between the randomisation and the start. The remaining 53 subjects completed the study according to the protocol. The treatment was well tolerated. No side effects were reported in either group.

Characteristics of subjects
At start of the study there were no significant differences between age, gender, body weight, BMI and duration of overweight subjects. * indicates significant difference from placebo. For further details, see text.

Discussion
In the present study we have studied the long-term effects of fibre supplement in mildly overweight subjects for 24 weeks. Using a treatment regimen with a combination of a hypocaloric diet, and a dietary fibre supplement in addition to regular information meetings, we succeeded in obtaining a high patient compliance and a sustained weight loss. The weight loss was more pronounced in the fibre group than in the placebo group. This agrees with other fibre studies although of short duration (1,8).

The explanation for the more rapidly achieved weight loss in the fibre group is still not clear, but may be due to the physical properties of the fibre. Fibres with differing physical characteristics can alter gastrointestinal motility and transit times in different ways. Therefore several possible modes of action have been proposed, such as lower energy intake (12), enhanced satiety (13), increased faecal energy excretion (11) or a combination of these reasons. One mechanism could be that fibre compounds bind to cholic acids and thereby reduce their absorption (9). However, this effect has been ascribed to the soluble type of fibre (14). The fibre supplement used in this study consisted mostly of insoluble fibre. However, as far as we know there are no reports comparing the weight reducing effect of the two type of fibres. Moreover, in this long term study the weight reducing effect, suggested by some studies, was not sustained, suggesting that no rebound mechanisms of actions have occurred.

Concomitant to the weight loss, reductions of serum concentrations of cholesterol and triglycerides were observed. We were, however, not able to confirm previous reports that a dietary fibre supplement can enhance a reduction of these lipids beyond that of a hypocaloric diet per se (5). When reviewing the literature, most studies report that soluble fibre improves the lipid profile in blood except for triglycerides (3,5,16), whereas in one report in hamsters insoluble fibre was linked to a reduction of the serum concentration of cholesterol (15). Therefore, the lack of reduction of serum cholesterol observed in this study is most likely ascribed to a low soluble fibre content in the supplement.

In conclusion, the present investigation shows that this dietary fibre supplement is of value as an adjunct in the management of overweight.

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**Characteristics of subjects**

At start of the study there were no significant differences between age, gender, body weight, BMI and duration of overweight (Table 1). There was a significant weight loss in the fibre group from week 4 and onwards as compared to the placebo group (p < 0.05) (Fig. 1).

The systolic and diastolic blood pressures were significantly reduced in both groups (p < 0.01) without differences between the groups (Table 2).

**Biochemical parameters**

Laboratory values before and after treatment are given in Table 3. Haemoglobin and serum uric acid decreased in both groups during treatment (p < 0.05) but no significant differences were observed between the groups (p > 0.5). Serum concentrations of cholesterol and triglycerides were significantly reduced in both groups during treatment. No additional effects in blood lipids were observed in the fibre group. Treatment did not change the serum concentrations of potassium and sodium.

**Discussion**

In the present study we have studied the long-term effect of fibre supplement in healthy overweight subjects. * indicates significant difference from value before start.

**References**


Health care expenditures in the Czech Republic (CR) totaled $4 billion in 1998 as compared to $3.1 billion in 1995 (21). If health care expenditures had only increased by the general rate of inflation, they would only have equaled $3.6 billion in 1998 (2). One reason for this increased rate of expenditures is the significant increase in the cost of medications. Medication costs in the CR in 1996 were five times higher than in 1990 (5). Health insurance companies have set financial limits and increased administrative regulations upon drug prescriptions in order to prevent further increases in medication costs. If medication costs are too high, the prescribing physician’s reimbursement is reduced. This strategy has not been entirely successful and has come at the cost of preventing patients from obtaining modern drugs that are known to cause fewer side effects.

Restrictions in the Czech Republic are designed to increase the use of older tricyclic antidepressants (TCAs) instead of selective serotonin reuptake inhibitors (SSRIs) in the treatment of major depression. The international literature suggests that use of tricyclic antidepressants does not lead to savings in direct treatment costs in major depression in comparison with the SSRIs (4,9,13,17,18,25). No prospective pharmacoeconomic study related to this issue has been performed in a former communist country. This is an interesting setting to study this issue, given the rapid transformation of the health care system in these countries.

Amitriptyline, citalopram and fluoxetine are the most frequently used antidepressants in the CR (15).

The aim of the study was to compare the costs and outcomes of using amitriptyline, citalopram and fluoxetine in the treatment of major depression. Methods: Ninety patients (69 women) with a mean age of 44.5 years (S.D. =14.3) suffering from major depression were treated with amitriptyline (N=31), citalopram (N=29) and fluoxetine (N=30). Direct medical costs and effectiveness (indicated by the number of hospitalization-free days) were assessed in a prospective, open, intent-to-treat study. Results: Neither cost nor effectiveness were significantly different among the treatment groups. Conclusion: Amitriptyline treatment is not less expensive nor more effective than citalopram or fluoxetine therapies. There is no advantage in restricting patients from treatment with SSRIs, which have fewer adverse effects and a decreased risk of a lethal overdose in comparison with tricyclic antidepressants.

This study represents a pharmacoeconomic extension of an original clinical antidepressant trial in hospitalized patients.

Material and Methods

Subjects

All patients diagnosed with depressive episodes treated with amitriptyline, citalopram or fluoxetine, who had just been discharged from the inpatient unit of the Department of Psychiatry, University Hospital in Hradec Králové from September 1st, 1994 to August 31st, 1997 were included in the study. Patients provided informed consent. Ninety patients were followed. There were more women (N=69) than men (N=21). Diagnoses according to the International Classification of Diseases-10th Version (20) were as follows: