

Beneficial effects of oats in the gluten-free diet of adults with special reference to nutrient status, symptoms and subjective experiences

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In several studies oats have been reported to be tolerated by coeliac patients. The aim of the present study was to investigate the nutritional and symptomatic effects of including oats in the gluten-free diet, as well as the patients' subjective experiences. Twenty adult coeliac patients included large amounts of oats in their diet. Food intake, gastrointestinal symptoms, blood samples and body weight were examined and compared with examination at baseline. Diet compliance was checked monthly. The results are based on fifteen patients eating oats for 2 years plus three with only 6-months consumption. The median daily intake of oats was 93 (range 27–137) g/d, and the compliance was good. The mean intakes of Fe and dietary fibre increased ($P < 0.001$) with the oat diet, as well as the intakes of thiamin and Zn ($P < 0.02$). The bioavailability of Fe tended to decrease; this seems not to have influenced the Fe status. Temporary increased flatulence was experienced the first few weeks, as well as improved bowel function with oats in the diet. All patients who carried out the whole study period wanted to continue eating oats after the study, as they found that addition of oats in the gluten-free diet gave more variation, better taste and satiety. Oats improved the nutritional value of the gluten-free diet, had no negative effects on nutritional status and were appreciated by the subjects. Including oats can help coeliac patients following a strict gluten-free diet.

Coeliac disease: Oats: Gluten-free diet: Nutritional status: Iron bioavailability

Coeliac disease (CD), also known as gluten-sensitive enteropathy, is characterised by inflammation of the small-intestinal mucosa, caused by ingestion of wheat gluten or related proteins from barley and rye. The inflammation often leads to malabsorption of one or more nutrients. The reported prevalence of the disease varies in populations from 1:200 to 1:400 throughout Europe and North America (Parnell & Ciclitira, 1999).

For about 50 years the gluten-free (GF) diet has been the treatment of choice for CD patients. The CD patients should remove wheat, rye, barley and oats from their diet. This often means a complete change in the food habits and nutrient intake, since many foods and food-products are known to contain one or more of these cereals. Only 17–65% of CD patients adhere to a GF diet (Kluge *et al.* 1982; Kumar *et al.* 1988; Mayer *et al.* 1991; Lamontagne *et al.* 2001). Poor diet compliance or undiscovered disease is associated with complications, including increased risk of anaemia, infertility, osteoporosis and intestinal lymphoma (Mäki & Collin, 1997).

A few studies have been performed to investigate the nutritional quality of the GF diet. These studies reported that the GF diet could be deficient in fibre, vitamins and minerals, especially for women (Hakala-Lahtinen *et al.* 1981; Björkman *et al.* 1985; Grehn *et al.* 2001). In recent

years, several high-fibre GF products have been developed, based on potatoes, peas etc., being offered as specially designed for these patients. However, preliminary results from a study in Gothenburg showed that forty-seven of fifty-two subjects studied ate less fibre than recommended (S Størsrud and RA Lenner, unpublished results).

Recent studies have reported that patients with CD or dermatitis herpetiformis can tolerate moderate amounts of oats in their daily GF diet (Janatuinen *et al.* 1995, 2000, 2002; Srinivasan *et al.* 1996; Hardman *et al.* 1997; Reunala *et al.* 1998; Hoffenberg *et al.* 2000; Picarelli *et al.* 2001; Kilmartin *et al.* 2003; Størsrud *et al.* 2003). This could be advantageous, since oats are a good source of dietary fibre and of several vitamins and minerals. In addition, in the north of Europe oatmeal has been a traditional food for decades. However, there could be some negative nutritional effects related to intake of oats, caused by lower bioavailability of some minerals. This is explained by the fact that oats have a high content of phytate, which forms insoluble complexes with Fe, Zn, Mg and Ca, and also have a low phytase activity (Rossander-Hulthén, 1990).

The aim of the present study was to investigate the effects of including large amounts of oats in the GF diet regarding nutrient quality, bioavailability of Fe, nutritional

status and occurrence of gastrointestinal (GI) symptoms, as well as subjective experiences in the patients. The effects of the oat diet are compared with baseline results in the same subjects.

Subjects and methods

Patients

This investigation was part of a long-term (2 years) intervention study concerning oats in the GF diet (Størsrud *et al.* 2003). Adult subjects with CD were recruited in 1996–7 from the GI clinic at Sahlgrenska University Hospital in Gothenburg, Sweden. They had to be ≥ 18 years of age and have an established diagnosis of CD, based on the presence of partial, subtotal or total villous atrophy of the duodenal mucosa before the initiation of the GF diet. Further, the participants had to have normal or almost normal duodenal villous architecture after treatment with GF diet for at least 12 months, allowing industrially purified wheat starch-based GF flours in their diet. Subjects not eating a strict GF diet or having any serious medical condition were excluded.

The Ethics Committee of the Sahlgrenska University Hospital approved the study protocol. All patients received written and oral information concerning the study before they gave their consent.

Design of the study

After a baseline examination the dietary intervention started, i.e. the inclusion of oats in the GF diet. The patients underwent examinations at fixed intervals. At baseline, and at 1.5, 6.0 and 24.0 months, dietary habits, nutritional status, body weight and height, and GI symptoms were examined. Status of intestinal mucosa by endoscopy and serological tests for antibodies to gliadin and endomysium were performed to check tolerance to oats (Størsrud *et al.* 2003). Dietary habits and GI symptoms were also investigated at 12.0 and 18.0 months. In addition, compliance to the diet and GI symptoms were checked by monthly unannounced telephone interviews throughout the study period of 2 years. At the end of the study, the subjects completed a questionnaire regarding their subjective experiences with oats in the GF diet.

Diet intervention and examination

The subjects were supposed to include 100 g rolled oats/d in their diet. This amount corresponds to three servings of hot oatmeal or ten to twelve slices of oat-enriched bread. The participants were free to choose how to include the rolled oats in their daily diet, and they were provided with recipes for GF foods including rolled oats. The oats were to replace other foods in order to maintain the same energy content as the GF diet.

Before the inclusion of oats in the diet the participants were given individual advice about their diet by a dietitian. The diet was strictly GF, allowing wheat-starch products. They received rolled oats (Kungsörnen AB, Järna, Sweden), which were free of wheat, rye and barley

as judged by ELISA technique, performed by the National Food Administration, Uppsala, Sweden. In this method, a specific monoclonal antibody to ω -gliadin detecting any prolamine contamination from wheat, rye and barley was used. Oat prolamins (avenin) are not detected by this method. The rolled oats were delivered to the participants free of charge during the study period.

The participants kept a 4 d food record at fixed intervals as previously described. For 4 d consecutively (including at least 1 d at the weekend) the patients recorded everything they ate and drank, including time of the intake and amounts of food and drink to get the meal composition. The amounts were described in household measures (decilitres, spoons, glasses etc) or in g if possible. The participants included their own recipes of GF dishes, with or without oats, and tried to describe the food as accurately as possible. Use of nutritional supplements were also recorded, but were not included in the calculations of the intake of energy and nutrients. The dietitian contacted the participants by telephone immediately afterwards if questions about the record arose.

During the 4 d food record the participants completed a questionnaire, regularly used in the clinic, concerning GI symptoms: abdominal pain and distension, flatulence, non-specified abdominal symptoms, frequency and appearance of stools. The symptoms were graded 0–3, from no symptoms to mild, moderate (bother, but do not interrupt, work) and severe symptoms (interrupt work, need to lie down). Once per month the dietitian interviewed the participants by telephone without prior notification to check feasibility of the use of oats and GI symptoms according to the questionnaire. The interviews were performed on different days to cover every day of the week. The aim was to check compliance and intake of oats and GI symptoms during the preceding 24 h period, and to encourage the participants. The subjects were also free to ask questions or give personal comments, if any.

To check the nutritional status, serum concentrations of haemoglobin, ferritin, vitamin B₁₂ (cyanocobalamin), Zn, folate, albumin and alkaline phosphatase were measured in a blood sample after an overnight fast. The analyses were performed using routine clinical laboratory methods. BMI was calculated as body weight (kg)/height (m)².

The questionnaire regarding subjective experiences was about positive and negative aspects of including oats in the GF diet, whether or not they the subjects would continue eating oats after the study period and in which form they preferred oats (porridge, bread, cakes, cookies, other). The questionnaire was precoded in a multiple-choice response format, with blank spaces for personal comments.

Calculations and statistical analysis

The intakes of energy and nutrients in the diet were calculated using the *Food Composition Tables – Energy and Nutrients* (Swedish National Food Administration, 1993) and the computer program MATs (Rudans Lättdata, Västerås, Sweden). Data on the nutrient content of the GF products and GF oat recipes were added to the database, as well as the participants' own recipes. Data on phytate,

tannins and haem Fe content were included in the database. The values given for the phytate intake are from analyses performed at our laboratory (Hallberg & Hulthén, 2000) by the method of Harland & Oberleas (1986). These analyses were supplemented with analysis on GF products (soft and hard breads, pasta, biscuits, muffins and flours). The bioavailability of Fe in the GF diets, before and after the inclusion of oats, was then calculated per meal, using the algorithm of Hallberg *et al.* (2000) for calculating absorption and bioavailability of dietary Fe.

The term fibre in the diet was defined as NSP, indigestible by the enzymes of the small intestine.

The results are presented as mean values and standard deviations, and medians with ranges when appropriate. Results are shown at baseline (GF diet) and at the final examination (GF diet + oats). Comparisons were made using non-parametric Wilcoxon signed rank test or paired *t* test for comparisons between means. A *P* value <0.05 was considered significant. The Bland–Altman plot was used to show the agreement between the two dietary survey methods (Bland & Altman, 1986).

Results

Subjects

Twenty adult patients, twelve women and eight men, with CD in remission were included in the study. One woman withdrew after 1 month and one man after 6 months because of abdominal symptoms (distension and flatulence). The GI symptoms in these patients did not differ from the general symptoms induced by oats ingestion in most subjects in the beginning of the study, and was probably due to the increased fibre intake (Størsrud *et al.* 2003). One woman and one man left the study after 6 months for non-medical reasons and one woman was excluded after 1 month because of lack of co-operation in the dietary survey.

Thus, a total of eighteen subjects are presented in the results, which are based on the last examination, i.e. at 2 years for fifteen subjects and at 6 months for three subjects. The mean age and body weight of the patients at baseline were 41 (SD14) (range 22–71) years and 71 (SD11) (range 53–93) kg respectively.

Diet

The median intake of oats based on the repeated 4 d food records was 93 (range 27–137) g/d. The good agreement in the individual's oat consumption over time, as measured by the two dietary survey methods (4 d food records and 24 h recalls) is shown by the correlation coefficient of 0.81 and the Bland–Altman plot in Fig. 1. As shown in Fig. 1, the mean difference between methods was near zero and all but one patient are within CI 2SD. The serological status showed that compliance to the GF diet was good (Størsrud *et al.* 2003). Antibodies to gliadin or endomysium could not be demonstrated in any of the participants, except for one person who had demonstrable anti-endomysium antibodies at 6 months. This might have been caused by accidental consumption of gluten

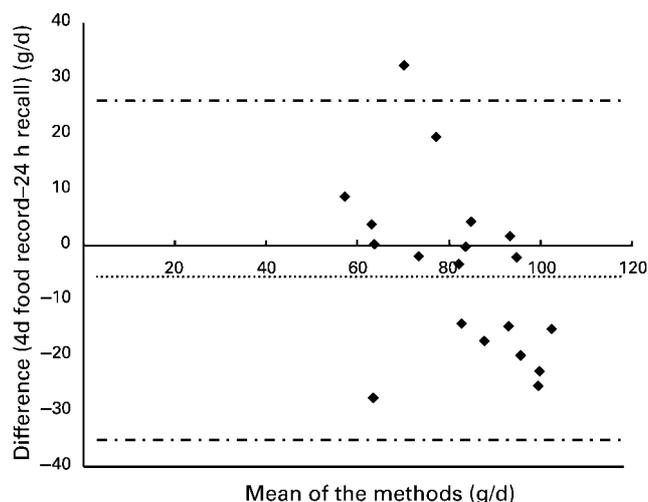


Fig. 1. Scatter diagram demonstrating the correlation between two methods of assessing mean oat intake (g oats/d; 4 d food record v. 24 h recall) in eighteen coeliac patients. For details of subjects and procedures, see p. 102. (—), Mean value; (---), mean value \pm 2SD.

before the examination. She continued eating oats and at the next measurement anti-endomysium antibodies were no longer demonstrable in this person.

The mean intakes of energy and selected nutrients are shown in Table 1. The ordinary GF diet was well balanced with a high nutrient quality compared with the Nordic Nutritional Recommendations (Nordisk Ministerråd, 1996), except for fibre.

The intake of energy and macronutrients did not change when oats were included in the diet. Comparisons are made only for nutrients substantially contributed by oats, i.e. fibre, thiamin, riboflavin, Fe and Zn, or factors affecting the bioavailability of Fe, i.e. phytate, ascorbic acid, Ca and tannins. The mean intake of Fe, dietary fibre and phytate increased ($P < 0.001$), as well as the intake of thiamin and Zn ($P < 0.02$). There was a trend towards lower fat and higher carbohydrate intake when oats were included in the GF diet. The intake of sucrose did not change.

As can be seen in Fig. 2, the intake of cereal foods increased ($P < 0.05$) when oats were included in the GF diet. There was a tendency for a reduced intake of snacks (chocolate, sweets, popcorn, peanuts etc.) and beverages (soft drinks, alcohol, coffee and tea) and only small changes in the intake of other food groups. The consumption of snacks and soft drinks during the morning decreased in the oat period. Oat biscuits and cakes with oats replaced some of the snack intake during the rest of the day.

Multiple nutritional supplementation was recorded for one person only (vitamins A, D and B₁₂, and Ca), while three others coincidentally took supplements of vitamins A, D, B₁₂ and C, and/or Fe.

Bioavailability of iron

The calculated absorption of Fe tended to decrease when oats were included in the diet. The total absorption of Fe

Table 1. Daily intake of energy and nutrients during the 2-year study period†
(Mean values and standard deviations for eighteen subjects)

	GF diet‡		GF diet + oats§		NNR
	Mean	SD	Mean	SD	
Energy					
MJ	9.5	1.8	9.4	1.6	
Energy as protein (%)	15.3	2.4	15.4	1.8	10–15
Energy as fat (%)	31.7	7.3	30.8	3.6	30
Energy as carbohydrate (%)	48.1	8.3	50.4	4.0	55–60
Energy as sucrose (%)	9.2	2.5	9.0	2.2	<10
Thiamin (mg)	1.3	0.4	1.7*	0.3	1.1/1.4
Riboflavin (mg)	1.6	0.3	1.8	0.3	1.3/1.6
Ascorbic acid (mg)	107	53	99	44	60
Calcium (mg)	1033	271	1070	252	800
Iron					
Total iron (mg)					
Women	11.1	3.7	14.3**	2.1	12–18
Men	10.8	3.1	17.1**	4.6	10
Haem iron (mg)					
Women	0.8	0.5	0.8	0.4	
Men	0.6	0.2	0.7	0.6	
Zinc (mg)	9.6	2.1	11.3*	2.1	7/9
Fibre (g)	15.1	4.9	21.8*	5.2	25–35
Phytate (mg)	123	61	351**	113	
Tannin equivalents (mg)	369	172	356	186	

GF, gluten-free; NNR, Nordic Nutritional Recommendations (1996).
 Mean values were significantly different from those of the GF diet: * $P < 0.02$, ** $P < 0.001$.
 † For details of subjects, diets and procedures, see p. 102.
 ‡ Data from the baseline examination, before including oats.
 § Data from the last examination, i.e. at 2 years for fifteen subjects and at 6 months for three subjects.
 || Female/male.

was 18.0 % for women and 17.0 % for men on the GF diet, which was reduced to 13.0 and 9.5 % respectively, when oats were included in the diet (Table 2). This can be compared to Fe absorption of about 10.0 % from the diet of the general population (Hallberg & Hulthen, 1991).

About 50 % of the daily quantity of oats were consumed for breakfast. Despite the increased amount of Fe in this meal, the bioavailability of Fe will be reduced, as the amount of the inhibiting factor phytate increased ($P < 0.001$) and Ca tended to increase, and the intake

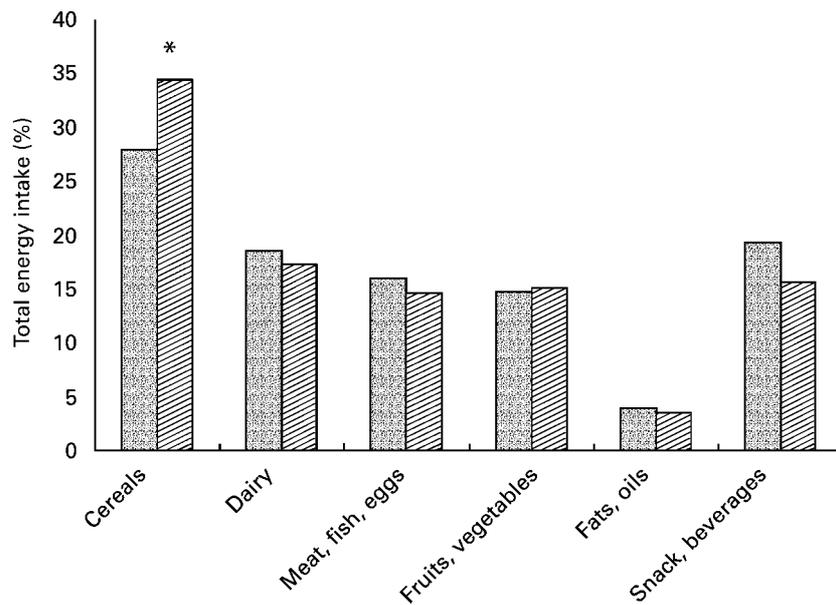


Fig. 2. Daily energy intake from different food groups (%) before and after inclusion of oats in the gluten-free diet of eighteen coeliac patients. ■, Gluten-free diet; ▨, gluten-free diet + oats. For details of subjects, diets and procedures, see p. 102. Mean value was significantly different from that of the gluten-free diet: * $P < 0.05$.

Table 2. Calculated (Hallberg & Hulthén, 2000) total absorption of iron (mg) before and during the inclusion of oats in the gluten-free diet*†

(Mean values for eighteen subjects)

	GF diet		GF diet + oats	
	Absorbed	Consumed	Absorbed	Consumed
Women	2.01	11.1	1.92	14.3
Men	1.85	10.8	1.64	17.1

GF, gluten-free.

* For details of subjects, diets and procedures, see p. 102.

† None of the changes was statistically significant.

of enhancing factors vitamin C, haem Fe, meat and fish tended to decrease (Table 3).

Nutritional status

The inclusion of oats did not change the nutritional status of the participants in any directions in the variables given in Table 4. At baseline, two of the subjects were below the reference values for haemoglobin (115 g/l, female) and serum ferritin (17 µg/l, male) respectively. After the inclusion of oats, all subjects results were within the reference values at every examinations.

Symptoms

One or several symptoms at the baseline examination were reported by 55% of the participants and two of the twenty subjects included dropped out because of abdominal symptoms. The symptoms were recorded as mild, and in a few cases as moderate. Flatulence, the most pronounced reported symptom, increased during the beginning of the study period as compared with baseline, particularly in the subjects with a low fibre intake at baseline, i.e. < 15 g/d. None of the participants complained about constipation before the study. However, personal comments during telephone interviews and questionnaires did indicate that six of eighteen patients experienced improved bowel function. There were no other changes in GI symptoms during the study period.

Table 3. Intake of factors known to influence the bioavailability of iron coming from the breakfast meal before and during the inclusion of oats in the gluten-free diet†

(Mean values and standard deviations for eighteen subjects)

	GF diet		GF + oats	
	Mean	SD	Mean	SD
Energy (MJ)	2.26	0.96	2.22	0.753
Iron				
Total (mg)	2.1	1.2	4.6	1.9
Haem (mg)	0.03	0.1	0.02	0.03
Phytate (mg)	28	30	168***	47
Ascorbic acid (mg)	24	26	18	26
Meat and fish (g)	8	11	5	7
Tannin equivalents (mg)	107	86	106	89
Ca (mg)	340	120	380	108

GF, gluten-free.

Mean value was significant from that of the GF breakfast meal: *** $P < 0.001$.

† For details of subjects, diets and procedures, see p. 102.

Subjective experiences

The fifteen patients who completed the 2-year study protocol answered the questionnaire regarding subjective experiences. They all wanted to continue eating oats after the study period, as did the three individuals who dropped out or were excluded without medical reason (personal comments from these subjects during the study period).

Each of the fifteen subjects considered the inclusion of oats in the diet easy or very easy to do. The oats were used mainly as porridge (hot oatmeal), muesli, baked into bread, cakes and biscuits and occasionally in dinner-type foods (meatballs, pasta sauce). The recipes provided were appreciated and helped the subjects to include the oats in the GF diet. Thirteen of the fifteen subjects found the diet more varied and twelve experienced it as more satiating than the traditional GF diet. Ten of the fifteen subjects thought that the oats gave a very good taste to the GF diet, especially when baked into breads. Other comments were that oats in the diet were easy, cheap and also healthy.

Thirteen of the fifteen subjects answered that the only problem was the large amount of oats to be included during weekends, on vacations and when travelling abroad. Two of the participants did not find the oat diet troublesome at all.

Discussion

The inclusion of oats in the GF diet had beneficial effects in adult patients with CD in remission. Large amounts of oats were used, since the aim of the intervention study was to investigate whether or not adult CD patients tolerated (evaluated by mucosal biopsies and serological tests) large amounts oats in their daily GF diet for an extended period of time (Størsrud *et al.* 2003). The beneficial effects were most pronounced in the subjective experiences of the patients, i.e. a better taste, the satiating effect, more variability, as well as helping regulating the bowel function. These effects were independent of the amount of oats consumed.

Cereal foods contribute significant quantities of energy, protein and minerals to man's diet. Oats have unique nutritional and functional qualities (Lockhart & Hunt, 1986), a high percentage of protein of superior amino acid balance as compared with other cereals (Peterson & Brinegar, 1986), and the content of several vitamins and minerals is higher than in many gluten-containing and naturally GF cereals. An increase in the consumption of cereal foods, particularly oats, could therefore, at least theoretically, lead to an improved nutritional status.

The subjects significantly increased their intake of cereal foods, resulting in a higher mean intake of fibre, thiamin, Fe (mainly non-haem Fe) and Zn. The GF products in Sweden are usually fortified with Fe and other minerals. When exchanging some of these fortified products with the natural content of minerals in oats, the total intakes increased; however, no concomitant increase was seen in the serum levels of haemoglobin and ferritin. The bioavailability of Fe is influenced by several dietary factors, which are taken into consideration by an algorithm for predicting dietary Fe absorption (Hallberg & Hulthén, 2000). The

Table 4. BMI and nutritional status before and during the inclusion of oats in a gluten-free diet*
(Mean values and standard deviations for eighteen subjects)

	GF diet†		GF diet + oats‡		Reference values§	CV (%)
	Mean	SD	Mean	SD		
BMI (kg/m ²)	24.2	2.6	24.6	2.8	20–25	–
Haemoglobin, (g/l)						4
Women	125	8	130	7	116–149	
Men	147	9	146	9	132–166	
Serum ferritin, (µg/l)						11
Women	36	21	35	17	11–120	
Men	111	77	115	56	25–400	
Serum ALP* (µkat/l)	2.3	0.6	2.5	0.9	< 5	7
Serum albumin (g/l)	43.5	3.7	42.9	2.7	36–50	7
Serum cyanocobalamin (pmol/l)	363	166	391	239	150–700	9
Serum folate (nmol/l)	19.3	6.8	16.5	9.0	6–35	16
Blood folate (nmol/l)	307	70	287	80	200–520	

ALP, alkaline phosphatase.

* For details of subjects, diets and procedures, see p. 102.

† Results from the baseline examination, before including oats.

‡ Results from the last examination. These results do not differ statistically significant from the other examinations including oats (results not shown).

§ Sahlgrenska University Hospital, C-lab.

|| Not accredited at Sahlgrenska University Hospital, C-lab.

intake of enhancing factors (ascorbic acid, meat and fish) as well as inhibiting factors (tannins and Ca) remained unchanged when oats were included in the GF diet. These changes should therefore not influence the bioavailability of Fe in this group.

Including oats in the diet did, however, result in a high intake of phytate, almost three times the intake on the ordinary GF diets. This most probably influenced the lower bioavailability of Fe, especially for the breakfast meal. We tried to increase the absorption of Fe for breakfast by including 50 mg vitamin C in the oat-based breakfast meal. However, this had only minor positive effects and only in men, whose Fe absorption increased from 9.5 to 10.0%. This can be explained by the fact that the inhibiting factor of phytate was too strong. The relationship of increasing inhibition of non-haem Fe absorption with increasing amount of phytate has previously been shown by Hallberg *et al.* (1989). Besides, oats are considered to have low phytase activity, which is further decreased by the heat treatment of all oats, aimed to protect against fat oxidation. The negative effect on the mineral absorption of oat products would thus be greater than that of other cereals (Koiviston *et al.* 1974; Frölich *et al.* 1988).

However, it is important to note that no negative effects were seen in the haemoglobin and serum ferritin levels after the introduction of oats. The mean levels tended to be stable, and the two subjects who were below the reference values at baseline, improved during the oat period. There was no information available about on-going infections in the subjects studied, but there is no reason to think that infections have given false positive serum ferritin values.

The most important nutritional factor in the present study could be the amount of fibre, i.e. 100 g/kg rolled oats (Nordisk Ministerråd, 1986). The laxative properties of dietary fibre are established beyond dispute and contribute to a reduction in problems of constipation (Gurr & Asp, 1996).

Constipation was not reported in the GI questionnaire; however, several subjects commented on improved bowel function during the study period.

Among adverse fibre effects, increased flatulence and abdominal distension appeared initially during the study period. The flatulence decreased when the bowel adapted to the higher intake of fibre. The symptoms were most often recorded as mild, and this could reflect a normal state, even in healthy subjects (Vander *et al.* 1990). Other foods known to cause GI symptoms, for example onion, cabbage, peas and beans can also explain some of the temporary GI symptoms. However, a general recommendation would be to successively increasing the amount of oats in the diet, to avoid or reduce intestinal symptoms.

Most of the subjects answering the questionnaire regarding subjective experiences, or giving personal comments during telephone interviews, wanted to continue eating oats. The breakfast meal is often supposed to be the most troublesome when eating a GF diet. Oat porridge (hot oatmeal) has been a breakfast cereal in the Scandinavian countries for decades, and oats have further been introduced in muesli or as a tasty ingredient in bread. The breakfasts in the oat period consisted of bread and/or oat porridge or muesli, rather than mainly dairy products (e.g. yoghurt) as was seen at baseline. This change was very much appreciated by the subjects, and the consumption of snacks and soft drinks during the mornings decreased in the oat period, probably as a result of the satiating effect of oats for breakfast (subjective experiences in nine of fifteen subjects). The GF bread baked with oats and wheat-starch flour was found less crumbly, more moist and also more tasty.

Since many studies show a rather low compliance to the strict GF diet (Kluge *et al.* 1982; Kumar *et al.* 1988; Mayer *et al.* 1991), and thereby increased risk of complications, it is important to find ways to prevent this. As shown in the present study, allowing oats in the diet could increase the

nutritional value of the GF diet, as well as make the diet more pleasant for the patients and so increase compliance to the treatment.

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