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Original Article

Effect of unkilned and large amounts of oats on nutritional state of celiac patients in remission

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SUMMARY

Background: Moderate amounts of oats have not had any harmful effect on the nutritional state of celiac patients. Common technical processing, e.g. kilning of oats, may affect its protein structures and therefore may increase its tolerability in patients and further influence their nutritional state.

Aims: To investigate the effect of large amounts of regular kilned or unkilned oats on the nutritional status of celiac patients in remission.

Methods: The patients (13 men and 18 women) who were previously using regular kilned oats as part of a gluten free diet were randomized to consume large amounts of either kilned or unkilned oats. After 6 months the patients changed the treatment groups. The goal of the daily intake of oats was 100 g. Anthropometric measurements, food records and laboratory test were used to investigate the nutritional status.

Results: The groups did not differ from each other in nutritional status. During the oat diets, at first temporarily, the values of serum calcium, magnesium and vitamin B_{12} slightly decreased but stayed within the normal limits for the 12 months of the follow-up.

Conclusions: Unkilned or kilned oats, even in large amounts produced no harm to the nutritional status of celiac patients during over a 1-year period.
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1. Introduction

Celiac disease is a permanent state of intolerance to prolamins of wheat, rye and barley.[1] The immunological response to prolamins in gluten- sensitive people causes histological abnormalities of the small intestinal mucosa.[2,3] Treatment of celiac disease requires life-long adherence to a gluten-free diet. Histological recovery of duodenal mucosa in celiac disease after starting a gluten-free diet takes time and may be incomplete in 10% of patients even after 5 years of treatment.[4] The nutritional status of celiac patients at the time of diagnosis varies greatly as a result of the severity and duration of malabsorption associated with the disease. The improvement of nutritional status may therefore be slow after starting a gluten-free diet.[5–12] Oats in moderate amounts have not had any harmful effects on the nutrition in newly diagnosed[12,13] or celiac patients in remission.[14,15–17] There is limited knowledge about the effects of large amounts of oats[14,15] on celiac disease. In all studies the oats used have been industrially processed, e.g. kilned. Theoretically there is a possibility that kilning could change the antigenic properties of oats and be the basis of its suitability for celiac patients. Therefore, we investigated the effects of large amounts of regular kilned and unkilned oats on the nutritional state of celiac patients whose disease had been in remission for years.

2. Materials and methods

2.1. Subjects

Patients with celiac disease in remission were recruited for the study during the summer–autumn of 1998 in Kuopio University Hospital area. These patients who were previously using moderate amounts of regular kilned oats as part of their gluten-free diet were randomized either to consume large amounts of kilned (group A) or unkilned (group B) oats. After 6 months the patients changed treatment groups. The goal of the daily intake of oats was 100 g. The study consisted of 33 celiac patients in remission. One woman withdrew from the study because of abdominal symptoms. After

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6 months another female patients withdrew because of pregnancy. The final study group included 13 men and 18 women. Group A, using first kilned oats consisted of 6 men and 10 women, and group B using unkilned oats consisted of 7 men and 8 women. The mean age of the patients was 47 (range 16–64) years. The diagnosis of celiac disease had been made 8.6 (range 7–29) years earlier. The patients had followed a gluten-free diet for 8.3 (1–29) years and consumed oats for 5 (0–9) years.

The study protocol was approved by the Ethics Committee of Kuopio University Hospital. All patients received written information on the study and verbal consent was obtained before starting the trial. The patients were also informed of the possibility of withdrawing from the study at any point of time.

2.2. Diet

Initially, a nutritionist gave both verbal and written instructions about the diet. The goal of the daily intake of oats was 100 g. Half of the daily oat portion was given as oat flour and half baked in oat bread during the 12 months. The flour for the breads contained 75% oats and 25% maize flour. Other ingredients were salt, yeast and water. The oat bread contained 50% by weight of oat flour. The daily portion of 100 g of oat flour consisted of a minimum of 120 g of oat bread and 50 g of oat flour. Oat flour was used for cooking and baking according to gluten-free oat recipes. The purity of the oats was monitored during the 12 months. Samples of the flours and bread were taken randomly from each process to be tested for purity. Patients received bread and oat flour free of charge. Melia Oy, Farina Oy and Moilanen bakery (gluten-free bakery) contributed oats and oat products to the study project.

2.3. Follow-up investigations

Food records, symptom records, frequency questionnaire, laboratory blood tests and esophagogastroduodenoscopy with duodenal biopsies and their histopathological analyses, as well as antiendomysial antibody (EMA) assay, were used to follow the state of the patients. These analyses were used to confirm remission and to detect relapses in celiac disease. At baseline, 10 patients had partial villous atrophy and 9 had mild mucosal inflammation. Other biopsies were interpreted as normal. In the beginning of the study, all patients had normal (negative) values of EMA antibodies. There was no significant change in the histological status of the small intestinal architecture and no abnormal values of EMA occurred during the follow-up. At 12 months only 5 patients had partial villous atrophy and 4 had mild inflammation. During the 12-month follow-up no statistically significant changes were found in symptoms, as assessed by verbal rating, in the whole study group. However, there was a tendency towards increased abdominal distention (Friedman test, $p = 0.06$). The group using kilned or unkilned oats did not differ from each other regarding changes in symptoms, including abdominal pain, flatulence and diarrhea, or welfare during the first 6 months (Mann–Whitney *U*-test, $p > 0.01$). However, the groups did differ from each other in abdominal distention during the time period, as assessed with the visual scale ($p < 0.001$, Mann–Whitney *U*-test).[18]

Data on compliance with the gluten-free diet and the use of oats were obtained via questionnaire at baseline, and at 6 and 12 months. Four-day food records were kept by all subjects by using household measures at baseline, and at 1, 3, 6, 7, 9 and at 12 months. Food and nutrient intakes were calculated using the Nutrica computer program (Social Insurance Institution, Turku), which uses the Food and Nutrient Data Base of the Social Insurance Institution. The nutrient content data on the gluten-free products used were collected from the manufacturers and added into the database before calculations.

Body weight was determined with the subject standing barefoot on a digital scale (Seca 770: Dayton, Hamburg, Germany) and wearing light clothing. The height of the subjects without shoes was measured with a wall-mounted stadiometer. Body mass index (BMI) was calculated as body weight (kg)/height^2 (m). Body composition was determined by bioelectrical impedance (RJL Systems; Detroit, MI). Blood samples for laboratory tests were taken from the subjects after overnight fasting. The following analyses were made using routine clinical laboratory methods: blood hemoglobin, serum iron, serum ferritin (immunoluminometric assay), vitamin B_{12} (radioisotope dilution), calcium, magnesium, cholesterol, HDL- cholesterol, triglycerides and folic acid in erythrocytes (E-folate) (saturation analysis). Serum vitamin D metabolite was assayed as described by Parviainen et al.[19] Vitamins A and E were determined by using HPLC with ultraviolet detection by the method of De Leenheer (1979) as modified by Parviainen and Koskinen.[20]

2.4. Statistical analysis

Statistical analyses were performed using the SPSS statistical program (SPSS Inc., Chicago, IL). The results are presented as mean with SD. The linear mixed-effects model (MIXED), fitting random effect subject interaction, was used to study the consumption of oats. Differences between groups during the first 6 months were assessed with the Mann–Whitney *U*-test. Wilcoxon and Friedman tests were applied to evaluate changes during the follow-up in groups (within groups). Bonferroni correction was used in the analyses (Wilcoxon test). After the Friedman test, the distribution-free multiple comparisons based on the Friedman rank sums between the time points were used to find which time points differed significantly from each other.[21] The differences between groups in the frequency and proportion of the categorized variables as abnormal laboratory values were analyzed by chi-squared and Fisher tests.

2.5. Ethical issues

The study was approved by the Ethics Committee of Kuopio University Hospital and University of Kuopio. All subjects gave informed consent.

3. Results

The groups using either kilned or unkilned oats did not differ from each other during the follow-up in consumption of oats (MIXED, $p > 0.1$). The consumption increased during the first 6 months from 24 g to 93–96 g daily in both groups (MIXED, $p = 0.01$). During the second 6-month period the use of oats remained at the same high level (86–98 g daily) regardless of the type of oats. Mean daily intakes of nutrients in both groups were within recommended dietary allowances (minimal nutrient intake per day, Finnish recommended dietary allowances) (Kemppainen et al. unpublished results). The mean body mass index of the patients both in men and in women was 24 kg/m^2. In the general population in Finland the values were reported as 27.2 and 26.4 kg/m^2, respectively, in 2007.[22] At baseline the groups did not differ from each other in anthropometric and laboratory measurements (Tables 1 and 2), except for serum iron in men (Table 3) (Mann–Whitney *U*-test, $p = 0.004$). There also was no effect on the anthropometric measurements within or between the groups during the first 6 months, whether kilned or unkilned oats was used and the order of the diets was considered (Table 1).

Laboratory measurements are shown in Table 2. The mean value of vitamin B_{12} decreased during the first 6 months of the trial regardless of whether kilned or unkilned oats were used (Friedman

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