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Celiac Disease and Gluten-Free Claims on Uncontaminated Oats

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This document was made available for comments of a scientific nature during the period of November 14, 2014 to January 27, 2015 (75 calendar days). This final version has been updated to take into consideration all relevant comments, which resulted in editing for clarity of the section on Oat sensitive individuals, which is further reflected in both the Toxicity of oats for celiac patients and the Conclusion sections.

Table of Contents

Abstract 4

Introduction 4

Safety of oats for the majority of people with CD 5

Oats sensitive individuals 7

General limitations of these studies 9

Toxicity of oats for celiac patients 9

Conclusion 10

References 11

Abstract

This manuscript provides an overview of the latest scientific data related to the safety of including uncontaminated oats in the diet of individuals with celiac disease (CD). It updates the previous Health Canada position paper (*Celiac disease and the safety of oats, HC)* which was published in 2007 and considers a number of newer studies published after the previous Health Canada position was finalised. While recognizing that a few people with CD seem to be clinically intolerant to oats, this review concludes that uncontaminated oats were safely ingested for several years by most patients with CD and that there is no conclusive evidence that the consumption of uncontaminated oats in patients with CD should be limited to a specific daily amount.

Key words: Celiac disease, oats, claims, gluten-free diet.

Introduction

People with celiac disease (CD) react adversely if they consume gluten, a protein component of certain cereal grains. The relevant gluten protein fractions for people with CD include prolamins and glutenins (*Sapone, 2012)* but the alcohol-soluble fractions (prolamins) of wheat (gliadins), rye (secalins) and barley (hordeins) are considered to be the protein constituents of most concern to celiac individuals (*Pulido, 2013*). Currently, the only treatment for CD is to continually maintain a gluten-free diet (GFD). For individuals with CD, careful review of food labels to determine if gluten-containing ingredients are present is essential to avoid acute and chronic adverse health effects. Accurate food ingredient lists, with no hidden sources of gluten, are important. The appropriate use of the term "gluten-free" on prepackaged food products helps individuals with CD to readily identify products that they can safely consume. Although a GFD brings about greater well-being in most people diagnosed with CD, maintaining such a diet is complex and requires a significant amount of effort and commitment. Moreover, the gluten free diet is often nutritionally deficient in vitamins, calcium, iron and fiber. Oats can be easily incorporated into diets and are a good source of nutrients.

The effect of a GFD with versus without oats was published in the cornerstone study of Janatuinen et al. (*New England Journal of Medicine, 1995*) where 52 adults with CD in remission and 40 adults newly diagnosed with CD were studied. Half of each group was randomised to a diet including oats (50-70g of oats per day). Those in remission were studied for 6 months and the newly diagnosed group for 12 months. There was no deterioration in the mucosal architecture in those in remission and the entire newly diagnosed group had reached resolution of symptoms and mucosal healing with exception of one patient in the control group. In a follow up of this work, 23 of the original oats-eating group and 28 patients eating a conventional GFD were re-examined at 5 years (*Janatuinen, Gut, 2002*). During the 5-year follow-up, mean intake of oats in the oats group was 34g (range 10-70) per day. In this second study, no significant differences in duodenal villous architecture, inflammatory cell infiltration or antibody titres were found between the two groups, thus providing the first evidence of safety in patients with a long-term exposure to oats.

In children, Hogberg et al. (*Gut, 2004*) randomised a group of 93 newly diagnosed children with CD to an oats (25-50g per day) and non-oats-containing GFD. No difference was seen at 12 months in either serological markers or small-bowel mucosal architecture in this double-blind multicentre study.

Despite these two studies, the inclusion of oats in the food diet of people (adults and children) with celiac disease (CD) remained controversial. In 2007, based on an extensive review of the scientific literature, Health Canada concluded that the majority of people with CD can tolerate limited amounts of oats uncontaminated with other cereal grains such as wheat, barley and rye. However, due to limited information on long-term consumption and reports that some individuals may not tolerate uncontaminated oats, Health Canada recommended that the amounts of uncontaminated oats should be limited to 20-25 g/day for children and 50-70 g/day for adults (*Celiac disease and the safety of oats, HC, 2007*).

In order to assess the recent literature relating to CD and the safety of oats a search of scientific literature was conducted to include publications on oats and celiac disease since 2006-2007. Documents included clinical trials and recent reviews. Based on these updates, the aim of this article is to discuss the potential use of gluten-free claims on uncontaminated-oats-based products and what limitations should be placed on the introduction of oats into the diet of patients with CD.

Safety of oats for the majority of people with CD

Based on a food questionnaire, Tapsas et al. (*Nutrition Research, 2014*) included 316 children and adolescents with a biopsy-confirmed CD diagnosis (mean age 12 +/- 0.2 years) in a Swedish study to assess adverse effects of a GFD including oats. Mean time on the GFD was 6.9 years. 282 patients (90%) were consuming oats in their GFD, with 38% doing so from the first day after being diagnosed with CD. Those children were diagnosed after 2004, when the Swedish Pediatric Society recommended that oats could be included in the GFD. The other 62% were diagnosed before 2004 and changed their diets accordingly after the recommendations were launched. Most of children (82%) ate uncontaminated oats, and 45% consumed oats less than once a week. Among those who did not consume oats (11%, n=34), 13 had previously tried to eat oats, 12 had never tried, and 9 did not answer the question. Having trying oats, the reason for not continuing were that they did not like the taste (n=8), refrained because of symptoms such as abdominal pain or loose stools (n=2). No reports of major complications concerning well-being have been reported by adding oats to the GFD in this children population. However, no biopsies have been conducted in this study.

Gatti et al. (*Nutrients, 2013*) administered to 306 children (age range 4-14 years) with biopsy-confirmed celiac disease divided in 2 groups gluten uncontaminated oats products for a 6 months period of time. The addition of non-contaminated oats in one of the two groups had no impact on the clinical trend. Dyspeptic symptoms (described in other studies as related to a high amount of fiber in oats) were not recorded in the population study. The integrity of the intestinal barrier has

been evaluated by clinical symptoms (Gastrointestinal Symptoms Rate Scale - GSRS) and intestinal permeability tests (urinary lactulose/mannitol ratio) and authors concluded that the addition of non-contaminated oats in the treatment of children with CD does not cause changes in intestinal permeability and gastrointestinal symptoms. However, although not significantly different in the two groups, the number of dropouts was high (36% in group A and 28% in group B) in this study. It was also not possible to analyze the data according to the amount of ingested oats which was suggested to be up to 40g/day for older children.

In adults (106 adults including 36 with GFD-std and 70 GFD-oats, with a median duration of oat consumption of 5 years), Kaukinen et al. (*Nutrients, 2013*) concluded that daily intake and long-term consumption of oats did not result in small-bowel mucosa villous damage (assessed by small-bowel biopsies), inflammation (evaluated by IgA-class endomysium antibodies (EmA-ab) and IgA-class tissue transglutaminases antibodies (tTG-ab)) or gastrointestinal symptoms (measured by GSRS). The median intake of oats in the oats group was 20g (range 1-100) /day. Even long-term ingestion of oats had no harmful effects. However, two patients on GFD-oats and one patient on GFD-std had abnormal villous structure on biopsies.

In a Canadian prospective study, Sey et al. (*Journal of Parenteral and Enteral Nutrition, 2011*) tested the safety of uncontaminated oat products manufactured under guidelines provided by the Canadian Celiac Association. Fifteen adults with biopsy-confirmed CD of > 1 year duration challenged with 350g/week of uncontaminated oats completed the study and there were no significant changes in symptom scores, weight, hemoglobin, ferritin, and albumin during oats consumption. IgA-class tissue transglutaminases antibodies remained negative in all patients and the histology scores did not significantly change during oat challenge. Exposure duration to uncontaminated oats was 12 weeks. The only relapse occurred in a patient who became non-compliant with her gluten-free diet.

Koskinen et al. (*Journal of Pediatric Gastroenterology and Nutrition, 2009*) studied the toxicity of oats in 23 children (median age = 13 years) with CD during a 2-year follow-up by investigating jejunal transglutaminase 2 (TG2)-targeted IgA-class autoantibody deposits. At the baseline of the study, 13 children in remission were randomized to undergo an open oats challenge and 10 children to a gluten challenge allowing the consumption of wheat, rye and barley in addition to oats. Two children experienced abdominal pain and vomiting immediately after intake of oats and were biopsied. No signs of immune activation or relapse of CD were found but these two patients might be oat intolerant. The authors concluded that consumption of oats did not induce TG2 autoantibody production at the mucosal level in children with CD.

Kemppainen et al. (*Scandinavian Journal of Gastroenterology, 2007*) attempted to demonstrate the long-term (5 years) safety of oats as part of a celiac diet. Forty-two celiac patients took part in an earlier oats intervention study for 6-12 months and 22 of these patients originally consumed oats as part of their GFD. During the 5-year follow-up, 10 patients "have felt uncertain about the safety of long-term consumption of oats" and gave up this part of the study. Finally, 12 of the 22 patients consumed oats on the 5-year period and the control group was with 20 celiac patients using a strict conventional GFD without oats. There were no differences between the duodenal

biopsies in the two groups and the long-term use of oats included in the GFD does not stimulate an immunological response locally in the mucosa of the small intestine (intra epithelial CD3, αβTCR and γδTCR T cells counts). However, some people decided to give up the study due to the subjective and non-specific complaints "uncertain feeling" or “intestinal symptoms” following consumption of oats.

Based on the same Finish cohort as the one followed by Koskinen (Koskinen et al., *Journal of Pediatric Gastroenterology and Nutrition, 2009*), Holm et al. (*Alimentary, Pharmacology and Therapeutics, 2006*) studied the long-term safety of oats in the treatment of 32 children (7-17 years) with CD in a 2-year prospective, randomized follow-up study where children with CD in remission were randomized either to oats (median daily consumption = 45g (range 13-81) /day) or gluten (oats, wheat, rye and barley) challenge. When small bowel histological relapse was verified during the gluten challenge, patients excluded wheat barley and rye from their diet but continued to consume oats for 2 years. Similarly, newly diagnosed CD children adopted an oat-containing GFD. After the 2-year trial, patients were allowed to eat oats freely in conjunction with an otherwise GFD and the clinical follow-up was extended to 7 years. Oats had no detrimental effect on intestinal histology or serology during the 2-year trial. In contrast, the gluten –challenge group relapsed after 3-12 months. After the trials 86% of the children preferred to consume oats and they all remained in remission.

For some authors oat-sensitive individuals exist but the occurrence of symptoms has not been associated with small-intestinal mucosal damage or inflammation (*Janatuinen, 2002; Peraaho, 2004*). Cooper et al. (*Clinical and Experimental Allergy, 2012*), in a review of the Literature, reaffirmed the lack of oats immunogenicity and toxicity to most coeliac patients. In another review of the Literature, Garsed and Scott (*Scandinavian Journal of Gastroenterology, 2007*) support the safe consumption of oats in the vast majority of patients with CD but "there appear to be a small subset of patients with CD who cannot tolerate oats and amongst these are individuals who appear to be oats sensitive". Some patients may react adversely to oats either because they are very sensitive to the small amount of gluten contamination of their supply of oats (< 20 ppm) or because they are oats sensitive.

Oats sensitive individuals

Several studies about oat sensitive individuals have indicated that there is a subgroup of celiac patients who experienced gastrointestinal symptoms more frequently on an oat-containing gluten-free diet than on a gluten-free diet without oats (*Holm, 2006; Hogberg, 2004; Peraaho, 2004; Lundin, 2003*). Most of these authors also report that these intestinal symptoms, including bloating and abdominal discomfort, often occur soon after starting an oat-containing diet. In most cases the symptoms disappear gradually as consumption of oats continues (*Storsrud, British Journal of Nutrition, 2003*) and this can be explained by an increased intake of fiber in oat products, and the time it takes for individuals to get used to this increase fiber intake. For Malkki et al (*Acta Alimentaria, 2004*), non-celiac individuals develop similar symptoms when they suddenly start to consume oats. However, other authors report that some oat-sensitive CD patients have oat avenin-reactive T-cells in the small intestine mucosa (*Arentz-Hansen, 2004;*

Lundin, 2003). This point seems to be confirmed recently by Sjoberg but also by Tjellstrom in 2014 and the immune status in the small intestinal mucosa is not normalized for a fraction of CD patients on a GFD containing oats.

Sjoberg et al. (*Clinical and Translational Gastroenterology, 2014*) studied 28 children with newly diagnosed, symptomatic CD who were randomized into a double-blind study comparing treatment with a GFD with uncontaminated oats (n=15; age: 5.8+/-4.7 years) and a standard GFD without oats (n=13; 4.2+/-3.5 years; p>0.05). The median intake of oats in the GFD-oats group was 20g (range 3-43) per day. Intestinal biopsies were collected from each child within 4 weeks before the study diet was introduced and after > 11 months on a GFD with and without oats (range: [11.3-14.9]; mean=13.3 +/-0.8 months in the GFD-oats group and 13.1 +/- 1 month in the GFD-std group; p>0.05). There was no significant difference in anti-gliadin, IgA-class endomysium antibodies and IgA-class tissue transglutaminases antibodies titers and intestinal histology score (Marsh score) between the 2 study groups before and after the GFD intervention. However, in this study, expression levels of mRNAs for 22 different immune effector molecules and tight junction proteins were also assessed as indicators of the immune status in the mucosa of the patients after intervention. It was found that the normalization of genetic markers of regulators of inflammation in some pediatric patients with CD maybe significantly reduced in the GFD-oats group compared to the GFD-std group (1/15 in GFD-oats group vs 6/13 in the GFD-std group). For the authors, these results suggested altered functions of the epithelium in the small intestine mucosa and support the notion that a fraction of CD patients tolerate oats poorly. These observations could be in line with high intraepithelial lymphocytosis counts observed in patients who had been exposed on a long-term to uncontaminated oats. However, the clinical significance of this finding is unclear as this was not associated with small intestinal injury as evident by normal mucosa (same patients in Hogberg et al. Gut, 2004). Furthermore, the methodology used to evaluate purity of oats was not as rigorous as the currently available ELISA methods (R5 ELISA) testing.

As a part of the study published by Hogberg et al. in 2004 (see above), in 2014 Tjellstrom et al. (*Alimentary Pharmacology and Therapeutics, 2014*) analysed faecal short chain fatty acid (SCFA) concentration as a marker of gut microflora metabolism. Based on a daily oats intake of 25-50g, 34 children from GFD-oats group and 37 children from the GFD-std group were included in this study. Each child was studied over a period of 1 year and delivered at least one fecal sample at 0, 3, 6, and/or 12 months. In the GFD-std group, the total SCFA concentration was high at 0 and 6 months, but significantly lower after 12 months on GFD. In contrast, the total SCFA remained at a high level throughout the year on a diet in the GFD-oats group. However, the SCFA fermentation index (ref value <0.05), which mirrors intestinal inflammation, was high in both groups after 1-year GFD. The same authors reported that a GFD-std of more than one-year duration is needed to fully normalize faecal SCFA fermentation in children with CD (*Tjellstrom et al., 2013*). Another limitation was the fact that all children in the study groups did not deliver faecal samples. In addition, some of the delivered samples were too small to permit analysis. The authors concluded that the addition of oats to the GFD was accepted and tolerated by the majority of children studied as indicated by normalisation of the small bowel mucosal architecture and decreasing celiac serology markers after 1-year treatment with GFD-

oats. However, some celiac children receiving oats may suffer chronic gut mucosal inflammation that presents a potential risk for future complications.

General limitations of these studies

For E. Richman (*Proceedings of the Nutrition Society, 2012*), there is a lack of clear evidence and controversy about introduction of oats in the GFD. For this author, the methodology to assess potential pathology to oats is compounded by limited clinical tools of assessment. If tissue transglutaminases levels are normal, it is still possible that the small bowel villi are damaged and of course, a reduction of symptoms does not guarantee absence of small bowel atrophy.
Fric et al., in a review of the Literature (*Nutrition Reviews, 2011*) recall that the value of the clinical trials performed in adults and children may be considered limited due to (1) the small size of the cohorts, (2) the high number of withdrawals in some trials where the reason for these withdrawals was not sufficiently analyzed. (3) The 5-7 years period of oat consumption is relatively short considering the lifelong adherence to a GFD. (4) The methods of avenin isolation are often not detailed and (5) data on the characteristics of the type of oats consumed are missing. The authors concluded that a subgroup of patients with CD is intolerant to oats. The prevalence of intolerance to oats as well as the long-term risks of including oats in a GFD remain unknown.

Toxicity of oats for celiac patients

Similar to gliadins, secalins and hordeins in wheat, rye and barley respectively, prolamin fractions take the form of avenins in oats. However, oats avenin (avenae subgroup) is structurally different from the other prolamin fractions and is also present at 5-15% of total oats protein as opposed to the prolamins content of the triticae subgroup (wheat, rye, barley) which is as much as 35-50% (*Fric et al., 2011; Garsed and Scott, 2007*).
Recent research has also suggested that certain cultivars of oats could produce a different immunological response in people with CD than other cultivars. In a study published by Comino et al. (Gut, 2011) it was found that 3 groups of oat cultivars reacted differently against a specific monoclonal antibody (moAb G12 against 33-mer peptide from alpha-gliadin). One group reacted with high affinity, a group showed slight reactivity and the last group showed no detectable reactivity suggesting that the reactivity of this antibody with cereal proteins of different variety of oats was correlated to its immunotoxicity. This was confirmed by Silano et al. who found significant difference among oat cultivars in eliciting the TG2-mediated events of CD inflammation (*Eur J Nutr, 2014*). This point needs to be confirmed and data on the characteristics of cultivars of oats consumed in North America should be studied in a near future.

Conclusion

Since 2006-2007, new publications concluded that the addition of uncontaminated oats to the GFD can be accepted and tolerated by the majority of CD patients studied as indicated by normalisation of the small bowel mucosal architecture and decreasing celiac serology markers. However, a few people with CD seem to be clinically intolerant to oats.

Due to physiological mechanisms related to oat digestion and based on the results of several studies considering that medium-high amounts (40-100 g/day) of gluten-uncontaminated oats were safely ingested for several years by most patients with CD, there is no conclusive evidence that the consumption of uncontaminated oats in patients with CD should be limited to a specific daily amount. However, if most people with CD tolerate oats, there might be a few who have to avoid it in order to maintain remission or because they do not tolerate oats (oat-avenin sensitive individuals).

Among celiac patients who experienced gastrointestinal symptoms with non-contaminated oats, intestinal symptoms (dyspeptic symptoms) often occur soon after starting an oat-containing diet and can be due to an increased intake of fiber in oat products. In most cases these symptoms disappear gradually as consumption of oats continues. If symptoms do not disappear after a couple of weeks, diagnosis of oat intolerance may be discussed.

A stabilization phase should be observed before the start of a GFD which includes uncontaminated oats. Oats should only be introduced after all symptoms of CD including weight loss and growth disturbances have resolved and the individual has been on a gluten-free diet for and a minimum of 6 months. In all cases, until the prevalence of oat intolerance in CD patients is established, clinical follow-up by a physician of CD patients eating oats is recommended particularly in children. The rare individual, child or adult, who develops symptoms while consuming oats, needs to be evaluated for potential relapse of CD and for other sources of gluten contamination in their diet.

It seems also that only some uncontaminated oat cultivars trigger an immunological response in CD patients which could explain the chronic gut mucosal inflammation observed in some studies. The potential difference in immunotoxicity of these various oat cultivars may also explain the different clinical responses observed in patients suffering from CD. This point needs to be confirmed and more research is required to further clarify the role of these oats cultivars in the disease.

Long-term regular follow-up of CD patients is still recommended; those using oats may be safely followed up similarly to non-users.

This review confirms the 2007 conclusions made by Health Canada on the safety of the introduction of uncontaminated oats into the gluten free diet of individuals with celiac disease. More recent information establishes no evidence to restrict such consumption to a limited daily amount.

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