Forum GLUTEN-FREE
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Dr Schär Institute

Non-Coeliac Gluten Sensitivity diagnosis: it's time to be clear

In order to obtain certainty in diagnosing Non-Coeliac Gluten Sensitivity, diagnostic criteria were developed at the last international expert meeting in Salerno. They are already known as the Salerno Criteria, and were recently published in the international periodical "Nutrients".

Many people in the western world are following gluten free diets for health reasons other than a confirmed diagnosis of coeliac disease. But how many of these people are truly intolerant to gluten as compared to a self diagnosis without any clinical evidence? This question is difficult to answer because a simple and reliable test, such as a biomarker, is still not available for the diagnosis of non-coeliac gluten sensitivity (NCGS).

To clarify this situation, a group of international experts met in Salerno to draft the best criteria for diagnosing NCGS based on currently available research. This consensus was recently published in the international journal, Nutrients.

The document begins by affirming that diagnosis today is still fundamentally based on a good quality clinical history, suggesting a clear relationship between gluten consumption and the appearance of symptoms. The clinical situation is quantified by using a questionnaire where the symptoms and their severity are recorded, during the unrestricted diet and thereafter following gluten restriction. Patients who demonstrate an improvement of at least 30% of the initial symptoms are candidates for NCGS diagnosis. This in turn must be confirmed by a new double blind test of exposure to gluten (to avoid psychological interference) and placebo control (inert substances). In this respect, a patient still on the gluten-free diet will be given gluten (8 g/day) or a placebo, and the trend of symptoms will then be recorded during these phases. The NCGS diagnosis is to be considered definitively confirmed when symptoms worsen by at least 30% during re-exposure to gluten.

The dissemination of the standard Salerno criteria will favour greater uniformity of diagnosis, facilitating comprehension of a disorder that is not only very frequent but also extremely illusive as far as the pathogenic mechanisms and its natural history are concerned.

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Efficacy of a gluten-free diet in subjects with IBS-D unaware of their HLA-DQ2/8 genotype

This recent study by Professor David Sanders team in Sheffield further supports the findings of other recently published studies in this area showing that a gluten-free diet is a viable treatment option for patients with IBS-D and results in symptom improvement, irrespective of HLA DQ2/8 status.

AZIZ, A, TROTT N, BRIGGS R, ET AL

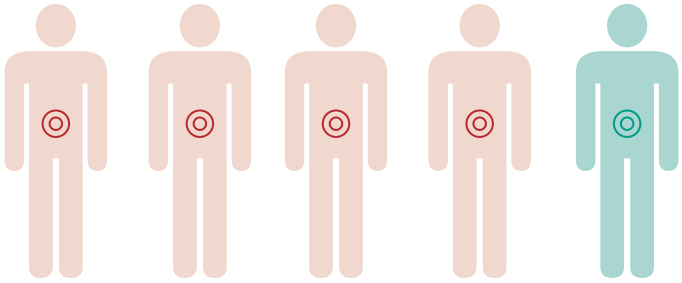
Clin Gastroenterolo Hepatol. 2016; 14(5): 696-703

IBS-D accounts for almost one third of IBS patients and is the predominant subtype of IBS encountered in clinical practice. Research suggests that 84% of patients with IBS believe that food triggers their gastrointestinal symptoms and of these, gluten-based products are cited by approximately 1 in 4 patients as a common trigger. These observations have given rise to the clinical entity known as 'non-coeliac gluten sensitivity' (NCGS). However, NCGS remains a controversial condition due to the existence of co-existing non-gluten components (including FODMAPs) that have also been demonstrated to induce IBS symptoms. The purpose of this prospective study was to evaluate the clinical response to a gluten free diet (GFD) in a cohort of patients with IBS-D blinded to their HLA-DQ status. The long-term benefit and sustainability of a gluten free diet was also assessed. The study was conducted at the Royal Hallamshire Hospital in Sheffield between Sept 2012 and July 2015. Patients attending the gastroenterology out-patient clinic who fulfilled the Rome II criteria for IBS-D were eligible for inclusion. Coeliac disease was excluded based on negative serology and normal duodenal biopsy. Individuals with self-reported gluten sensitivity; those already on a GFD; and those with other medical conditions known to mimic IBS-D were also excluded. Seventy eight participants were selected as eligible to take part in the study, of these 48 patients agreed to enrol (24 HLA-DQ2/8+ve and 24 HLA- DQ2/8-ve). Subjects were referred to 1 of 2 senior dietitians who provided uniform information on how to undertake a GFD. Subjects were also given validated questionnaires to self-complete the day before commencing a GFD and during the GFD period, these included the IBS Symptom Severity Score (IBS-SSS), Hospital Anxiety and Depression Scale (HADS), Fatigue Impact Score (FIS), and Short-form 36 (SF-36) quality of life questionnaire. Seven subjects dropped out of the study (4 did not attend their initial dietitian appointment; 1 became pregnant; 1 started an additional diet; and 1 felt the GFD was too expensive). Those subjects remaining (21 HLA-DQ –ve; 20 HLA DQ +ve) were instructed to follow a GFD for 6 weeks, after which they returned for a follow-up appointment with the dietitians and returned their questionnaires. Dietary adherence was evaluated using a simple, validated tool. Patients were also asked if they intended to continue with a GFD for the foreseeable future. For those that answered yes, a follow-up dietitian appointment was arranged for approximately 18 months time. Importantly, both dietitians and patients were blinded to the fact that HLA-DQ2/8 status was being used as a comparative factor within the study. Following the 6-week GFD, a reduction of IBS-SSS of =50 points (indicating clinical benefit) was seen in 71% of patients, there was no difference between HLA-DQ groups.

A significant symptom reduction was seen as early as week 2 and this continued to drop between each interval at week 4 and week 6. The greatest improvements were seen in those who had the severest IBS scores at baseline. In terms of IBS subscales, a significant mean reduction in abdominal pain, pain frequency, stool dissatisfaction and life interferences was observed in both HLA-DQ subgroups, with no difference between groups. However HLA-DQ2/8-ve subjects showed a greater reduction in abdominal distension compared with HLA-DQ2/8+ve subjects (p=0.04). A significant improvement in HADS, FIS and SF-36 quality of life was also observed following a GFD, seen across both groups. However HLA-DQ2/8+ve patients experienced a significantly greater improvement in depression (p=0.02) and vitality (p=0.03) compared with the HLA-DQ2/8-ve group. At the end of the 6-week intervention, 72% of IBS-SS responders planned to continue to follow a GFD for the foreseeable future (11 HLA-DQ2/8+ve and 10 HLA-DQ2/8-ve). When these patients were contacted on average 18 months later, all were still following a GFD with a good level of adherence and reported ongoing symptom improvement without any alterations in body mass index or biochemical status (compared to baseline). The results of this study demonstrate that a dietitian-led GFD should be considered as a therapeutic option for the management of patients with IBS-D who are previously naïve to the effects of gluten. The strengths of this study lie in it's rigorously defined cohort, in which CD was excluded and patients and dietitians were blinded to the fact that HLA-DQ2/8 status was being used as a comparative factor. This study also demonstrates a real-life situation in which patients were provided with a single dietetic consultation and then left to follow the GFD themselves, rather than being provided with all meals in a heavily controlled research environment. The limitations of the study include the placebo-effect of undertaking a dietary trial, however this is unlikely to account fully for the 71% response rate observed, particularly in view of the fact that well-being was maintained at 18 months. The authors of this study speculate that the patho-physiological mechanisms resulting in symptom reduction for IBS-D patients treated with a GFD may differ according to HLA-DQ status, and this is worthy of further mechanistic exploration.

IBS

Irritable Bowel Syndrome



Effectively identifying patients with non-coeliac gluten sensitivity: results from the glutox trial

The glutox study recently published in "Nutrients" shows that in the case of every fifth IBS patient, Non-Coeliac Gluten-Sensitivity (NCGS) is the cause of the complaints. These patients experienced an improvement of their symptoms when adhering to a strictly gluten-free diet.

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Introduction

Non-Coeliac Gluten Sensitivity (NCGS) is a newborn syndrome characterised by intestinal and/or extraintestinal symptoms which improve or even disappear following a gluten-free diet (GFD). Although NCGS is supposed to be a recent discovery, cases and cohorts of patients presenting with gluten-responsive clinical pictures in the absence of coeliac disease (CD) were published in the Seventies and Eighties. However, it was only in 2012 a revision of the nomenclature for gluten related disorders was proposed, to include NCGS.

The NCGS clinical picture appears extremely heterogeneous and non-specific with symptoms such as diarrhoea, constipation, bloating, nausea, epigastric pain, lack of well-being, anxiety, tiredness, fibromyalgia, chronic fatigue, foggy mind and headache.

A double-blind, placebo-controlled gluten diet is regarded as the most-effective diagnostic method.

Although NCGS does not present reliable biomarkers, a correct NCGS diagnosis is necessary to appropriately manage patients and plan for future medical, scientific and social interventions. In this scenario a double-blind placebo-controlled gluten challenge is considered the most powerful diagnostic weapon.

The aim of the glutox trial study was to investigate for NCGS subjects with different unexplained gastrointestinal symptoms through a double-blind placebo-controlled gluten challenge with cross-over.

Description of the trial

The trial was supported by the Italian Association of Gastroenterologists (Associazione Italiana Gastroenterologi ed Endoscopisti Ospedalieri – AIGO).

Fifteen gastroenterological out-patient services enrolled patients with unexplained gastrointestinal symptoms. In all the patients CD and wheat allergy were excluded.

The trial was undertaken in two consecutive phases. During phase 1 the subjects' response to the gluten free diet (GFD) was investigated; successively, during Phase 2, the patients reporting a symptomatic benefit from GFD (i.e. GFD responsive) were randomised for the double-blind gluten challenge. The stimulatory challenge consisted of consumption of gluten or placebo (depending on randomisation) for 7 days with 7 days of washout during crossover. At enrollment the clinical picture (following the Rome III criteria) and demographic parameters of the patients were recorded. Quality of life of the patients was analysed by means of the SF36 questionnaire and symptoms through 10 centimetre long visual analogue scores (VASs). Evaluated symptoms were abdominal pain, satisfaction with stool consistency, bloating, postprandial fullness, early satiety, epigastric pain and general well-being. Only patients who reported a worsening of their symptoms, i.e. VAS ≥3 cm, while taking gluten capsules compared to the placebo, were considered gluten sensitive.

Results

One hundred and forty patients (117 females, mean age 39 ± 11, BMI 22 ± 3) were enrolled. After the 21 day-long GFD, 101 subjects (88 females, mean age 39 ± 11, BMI 22 ± 4) reported a symptomatic improvement (mean VAS score 2.3 ± 1.2 vs 6.5 ± 2.2 before and after GFD respectively, p=0.001). These patients underwent the double blind, placebo-controlled, gluten challenge and 28 (all females, mean age 40 ± 12, BMI 23 ± 4) reported a severe symptomatic relapse after the blind gluten ingestion and thus they were classified as NCGS. No demographic or biochemical parameters were statistically associated with the challenge positivity. Results of the double blind challenge were not influenced by the order of the capsules (placebo or gluten). Similarly, blind gluten administration caused a deterioration of quality of life in NCGS patients. Figure 1 summarises the findings.

Conclusions

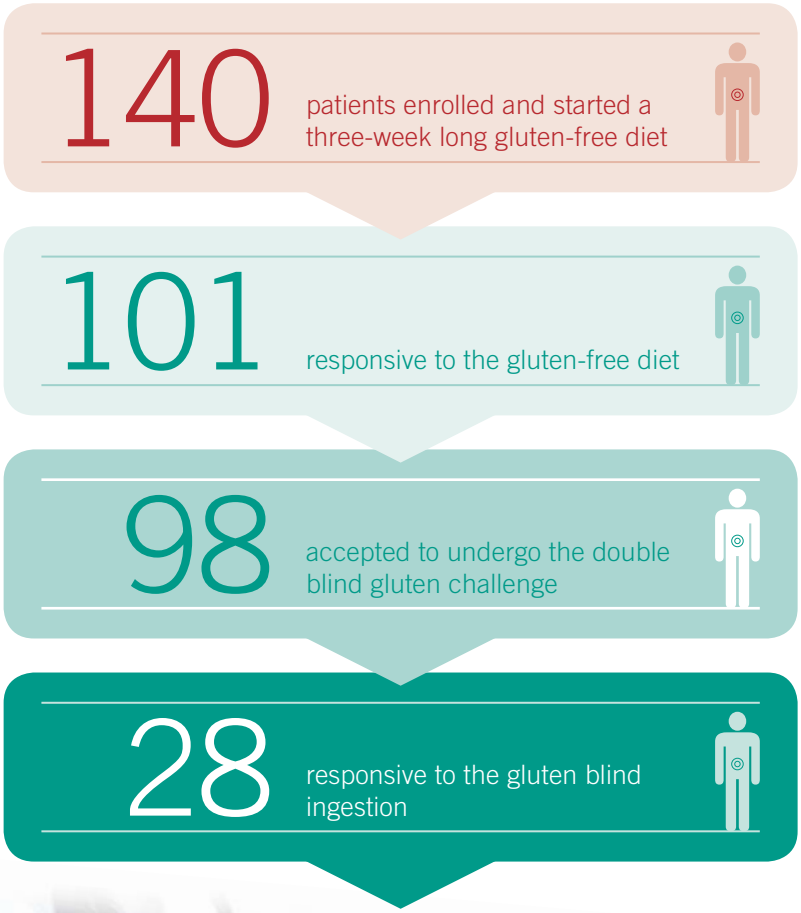
Our study confirmed the impact of gluten on human well-being and identified a group of patients with functional gastroenterological symptoms reporting a symptomatic relapse during a double-blind placebo-controlled gluten challenge. This group of patients was selected among the larger one composed of subjects responsive to GFD.

Gluten is a complex molecule that induces different human pathologies (intestinal and extra-intestinal) driven by immunomediated (autoimmune as in CD or gluten ataxia, or IgE-mediated as in allergies) and non-immunomediated mechanisms. Besides these diseases, a syndrome correlated to the ingestion of gluten without signs of immunological alterations has been recently described and named as NCGS.

Nowadays, NCGS is defined as a syndrome characterised by both intestinal and extra-intestinal symptoms that respond to GFD. Patients suspected of having NCGS should be screened for CD and WA at first to exclude the presence of any immunological alteration.

Patients suspected of NCGS should first be examined for coeliac disease and wheat allergy.

Figure 1.
Response of patients undergone to a gluten free diet and double blind gluten challenge.



However, this definition has raised some scepticism in the scientific community due to the involvement of a relevant placebo effect. Consequently, in the absence of reliable biomarkers, the introduction of a gluten challenge structured as a double-blind placebo-controlled trial with cross-over was considered important in the definition of these patients.

The Glutox trial is the first multicentre trial specifically designed to identify NCGS patients. The main strong point of our study is the strict blindness of patients and doctors, offered by the capsules, and the cross-over design, which allows a patient-by-patient assessment.

Glutox study shows: Every fifth IBS patient has NCGS.

In conclusion, our study highlighted a decrease in the level of satisfaction about overall well-being in patients with functional gastrointestinal symptoms while on a blinded gluten intake. Our protocol identified, among the group of GFD responsive patients, a smaller set of patients with NCGS and this approach can be the start for developing a diagnostic tool for NCGS.

THE GLUTOX-STUDY

The entire study "Evidence for the Presence of Non-Coeliac Gluten Sensitivity in Patients with Functional Gastrointestinal Symptoms: Results from a Multicenter Randomized Double-Blind Placebo-Controlled Gluten Challenge" is freely available at:

http://www.mdpi.com/2072-6643/8/2/84/htm

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Oats and coeliac disease

The vast majority of people with coeliac disease can include uncontaminated oats in their gluten-free diet. A small percentage of people with coeliac disease are sensitive to oats and should avoid them.

TANYA THOMAS

Freelance Dietitian

Historically it was advised that oats should be excluded from a gluten-free diet by most UK centres, however a number of studies presented from the mid-1990s onwards have indicated that uncontaminated oats are tolerated by most people with coeliac disease.[1,2] National Institute for Health and Care Excellence (NICE) guidelines advise that people with coeliac disease can choose to introduce gluten-free oats into their diet at any stage and that the decision to continue including them depends on their immunological, clinical or histological response.[3]

Gluten-free oats

Not all oats are suitable for inclusion within a gluten-free diet owing to the likelihood of contamination with gluten-containing cereals during growing or processing. The only oats suitable for inclusion within a gluten-free diet are certified (uncontaminated) 'gluten-free oats'. Labelling terms such as 'pure', 'organic' or '100% oats' do not indicate suitability for inclusion. In order to use the claim 'gluten-free', manufacturers must comply with legislation that guarantees their products (including those containing oats) contain less than 20ppm (parts per million) of gluten.[4]

Why do oats seem to be tolerated by most people with coeliac disease?

Oats contain avenin, a prolamin (storage protein) that is similar to those included under the umbrella term of 'gluten', found in wheat, rye and barley. However, most people with coeliac disease seem to be able to tolerate uncontaminated oats. This may be because there are fewer toxic epitopes in oats compared to wheat, rye and barley (although this may vary, between oat cultivars). Avenins may also be more susceptible to breakdown in the gut, rendering them less toxic.[5]

Why include oats in a gluten-free diet?

The inclusion of wholegrains (such as oats) within the diet can reduce the risk of heart disease by 15%.[6] Oats are low in fat and high in soluble fibre and have a low glycaemic index. Their inclusion within the gluten-free diet is particularly useful in people with coexistent diabetes mellitus, helping to regulate blood sugar levels and support weight management. Rich in soluble fibre, oats provide benefits to the gastrointestinal system; maintaining overall gut health, increasing stool weight and decreasing constipation.[7] Furthermore, research suggests that a gluten-free diet may be deficient in a number of nutrients including fibre and B-vitamins.[8,9] Oats may help to offset such deficiencies by providing a good source of protein, fibre, B-vitamins, magnesium, phosphate, zinc, selenium, iron.

The future for oats

Several studies have shown that oats are well tolerated by the majority of people with coeliac disease.[1,2,10] However, a small number of people with coeliac disease are sensitive to oats and their intestinal immune status fails to normalise when oats are included in the diet. In these individuals, a strong intestinal T-cell response towards oats has been observed [11], leading to the future possibility of identification of mucosal markers for oat sensitivity amongst coeliac disease.[12] It is understood that some oat strains contain more toxic prolamins than others and further research is needed to develop oat strains with a low avenin content and low immunogenicity.[13] The long term impact of eating oats in those who seemingly tolerate them also needs to be reviewed, as few studies have looked at the long-term effects of oat inclusion.

For the vast majority of people with coeliac disease oats are well tolerated and provide benefits in terms of nutrition, variety and taste. Further research is needed to examine why a small number of people with coeliac disease are unable to tolerate uncontaminated oats and what strains of oat cultivar, in what amounts are optimal for ensuring tolerance across all individuals.

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News

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We're delighted to announce the launch of the **Schär Wholesome Vitality Loaf** and **Schär Seeded Ciabatta Rolls**, now available in Tesco stores. This extension to the Schär bread range ensures patients following a gluten-free diet have a wider selection of tasty and nutritious staple products to choose from.

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To order your **free, full size sample** please call 0800 988 8470, or email professionals@drschaer.com. All Glutafin products are available to order without delivery or handling charges via our solus distributor, Alliance Healthcare.

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