



Skepticism Regarding Vaccine and Gluten-Free Food Safety Among Patients with Celiac Disease and Non-celiac Gluten Sensitivity

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Abstract

Background There has been a marked increase in the adoption of the gluten-free (GF) diet.

Aims To query individuals with celiac disease (CD) and non-celiac gluten sensitivity (NCGS) on their beliefs toward the health effects of gluten, and safety of vaccines and GF food products.

Methods We distributed a Web-based survey to individuals with CD and NCGS on a CD center e-mail list. We used univariate and multivariate analysis to compare responses of respondents with CD and NCGS.

Results The overall response rate was 27% (NCGS $n = 217$, CD $n = 1291$). Subjects with NCGS were more likely than those with CD to disagree with the statement that “vaccines are safe for people with celiac disease” (NCGS 41.3% vs. CD 26.4% ($p < 0.0001$), and were more likely to decline vaccination when offered (30.9 vs. 24.2%, $p = 0.007$). After adjusting for age and gender, NCGS subjects were more likely than CD subjects to avoid genetically modified (GMO) foods (aOR 2.30; 95% CI 1.71–3.10), eat only organic products (aOR 2.87; 95% CI 2.04–4.03), believe that the FDA is an unreliable source of information (aOR 1.82, 95% CI 1.26–2.64), and believe a GF diet improves energy and concentration (aOR 2.52; 95% CI 1.86–3.43).

Conclusions Subjects with NCGS were more likely than those with CD to have doubts about vaccine safety and believe in the value of non-GMO and organic foods. Our findings suggest that the lack of reliable information on gluten and its content in food and medications may reinforce beliefs that result in a detriment to public health.

Keywords Celiac disease · Non-celiac gluten sensitivity · Gluten · Vaccines

Abbreviations

CD	Celiac disease
FDA	Food and drug administration
GMO	Genetically modified food
NCGS	Non-celiac gluten sensitivity

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Introduction

Celiac disease (CD) is an autoimmune disorder triggered by gluten ingestion in genetically susceptible individuals, which impacts roughly 3 million Americans (0.7% of the US population) [1].

A large number of individuals without CD avoid gluten due to perceived adverse health effects; this condition, known as non-celiac gluten sensitivity (NCGS), is a clinical phenotype whose pathophysiology is poorly understood [2], but with an estimated national prevalence that is greater than that of celiac disease [3]. Despite this, the adoption

of a GF diet by people with NCGS is usually self-imposed [4]. Though little is known about the characteristics of non-celiac individuals on a gluten-free diet, an analysis of the National Health and Nutrition Examination Survey suggests that they have a lower body mass index and lower iron levels than the general population [5]. In addition, those with NCGS usually remain on the diet, despite the identification of other potential causes of symptoms [6]. While previous studies have examined factors associated with adherence to a gluten-free diet (GFD) and quality of life in CD and NCGS [7], none have delineated differences in beliefs and attitudes of people with CD and NCGS toward the health effects of gluten, safety of gluten-free products, and the safety of vaccines.

Diagnosis rates of CD have increased in recent decades [8, 9], and the number of people without CD, but adhering to a gluten-free diet tripled between 2009 and 2014 [3, 10]. Parallel with these increases have been a rise in interest and financial investment in gluten-free products by large food corporations, for example, General Mills' gluten-free Cheerios. However, the attitudes of individuals with CD and NCGS toward mass market gluten-free products have yet to be comprehensively studied and there is literature that doubts the safety of this food product [11]. Furthermore, concerns about the potential gluten content of oral medications may lead to skepticism regarding the safety of parenteral medications including vaccines [12]. In this study, we aimed to measure beliefs regarding the safety of these foods and medications, and to determine how demographics such as age, socioeconomic status, level of education and gender, as well as utilization of information resources affect these attitudes.

Methods

Study Population

We distributed a Web-based questionnaire to adults in a voluntary, opt-in mailing list maintained by the Celiac Disease Center at Columbia University. Non-responders received two subsequent reminder e-mails over the course of a four-week period in mid-2016. Inclusion criteria were: age ≥ 18 years, self-reported biopsy-proven CD, or self-reported NCGS with no evidence of biopsy-proven CD. Subjects that had self-reported CD without biopsy-proven diagnosis were excluded. Participants who were unsure of their diagnosis and did not report biopsy-proven CD were classified as NCGS.

Instrument

The first part of the questionnaire collected demographic information (age, gender, highest education level, employment status) and diagnosis history. Subjects were also queried on perceived safety of vaccines and gluten-free foods. We distributed the questionnaire via e-mail and used a commercially available, Web-based, survey tool (Qualtrics software). Mailing list members were sent an invitation e-mail containing an anonymous link to the survey. An explanation of the rationale of the study, noting that participation was optional and that no identifying information would be collected, was included in this invitation. Additionally, information about the study was repeated on the front page of the survey and clicking to proceed was considered to be providing informed consent to participate.

Statistical Analysis

We used Chi-square and Fisher exact tests to compare attitudes of CD versus NCGS subjects regarding vaccines, Cheerios, views on companies, views on genetically modified foods (GMOs), views on organic food, belief that gluten improves energy and concentration, belief that gluten is bad for everyone, and reliability of information provided by established organizations (FDA, professional societies, non-profit organizations, and books). We then used multivariate logistic regression, adjusting for age and gender, to assess for independent predictors of NCGS with the following survey responses: beliefs about safety of vaccines, belief about safety of gluten-free Cheerios, symptoms experienced after eating gluten, belief that gluten improves energy and concentration, presence of depression, views on GMOs, views on organic food, and reliability of information provided by the FDA. We calculated adjusted odds ratios (aORs) and 95% confidence intervals, and all reported p values are two-sided. All statistical analyses were performed using SAS version 9.4 (Cary, NC). The Institutional Review Board of Columbia University Medical Center approved this study.

Results

The questionnaire link was e-mailed to 8406 recipients; 2287 surveys were started; and 1886 were completed, for an overall response rate of 27% and completion rate of 82%. After exclusion criteria were applied, 217 subjects were classified as having NCGS and 1291 subjects were classified as having CD (total $n = 1508$). The mean age was 50.7 years, with the largest group (41.5%) falling into the 40–59 age range. The group was predominantly female, (83.3%), geographically clustered in the Northeastern United States (68.4%), held a

Table 1 Demographics of non-celiac gluten sensitivity versus celiac disease groups

Clinical characteristics	Overall (<i>n</i> = 1508)	Non-celiac gluten sensitivity (<i>n</i> = 217)	Celiac disease (<i>n</i> = 1291)	<i>p</i> value
Age (in years)				
Mean age (± SD)	50.7 (± 15.8)	50.6 (± 13.8)	50.72 (± 16.1)	.94
18–39	406 (26.9)	49 (22.6)	357 (27.7)	.01
40–59	625 (41.5)	110 (50.7)	515 (39.9)	
≥ 60	477 (31.6)	58 (26.7)	419 (32.5)	
Gender				
Males	248 (16.5)	28 (12.9)	220 (17.0)	.26
Females	1256 (83.3)	189 (87.1)	1067 (82.7)	
Other	4 (0.3)	0	4 (0.3)	
Region				
Midwest	109 (7.2)	16 (7.4)	93 (7.2)	.76
Northeast	1032 (68.4)	142 (65.4)	890 (68.9)	
South	221 (14.7)	34 (15.7)	187 (14.5)	
West	98 (6.5)	16 (7.4)	82 (6.4)	
Other	48 (3.2)	9 (4.2)	39 (3.0)	
Highest education level				
No college degree	250 (16.6)	16 (7.4)	234 (18.1)	< .0001
College degree or more	1258 (83.4)	201 (92.6)	1057 (81.9)	
Ethnicity/race				
Non-hispanic white	1407 (93.3)	195 (89.9)	1212 (93.9)	.03
Other	101 (6.7)	22 (10.1)	79 (6.1)	

college degree or more (83.4%), self-identified as non-Hispanic white (93.3%), and were currently employed (63.5%).

When comparing respondents with NCGS to those with CD (Table 1), ages of the groups were similar (NCGS 50.6 years; CD 50.7 years, $p = 0.94$), as was gender distribution (NCGS 87.1% female; CD 82.7% female; $p = 0.26$) and geographic predominance in the Northeast (NCGS 65.4%; CD 68.9%, $p = 0.76$). Education level varied among the groups, with 92.6% of the NCGS group holding a college degree or more, versus only 81.9% of the CD group, $p < 0.0001$ and in ethnic background (89.9% of the NCGS group identified as non-Hispanic white versus 93.9% of the CD group, $p = 0.03$).

When asked if they read or had been told that vaccines may contain gluten, 12.4% of respondents responded affirmatively (Table 2). When presented with the statement “vaccines are safe for people with celiac disease,” 41.4% of the NCGS group disagreed versus 26.4% of the CD group ($p < 0.0001$). Additionally, more subjects in this NCGS group were offered, but declined influenza vaccination (NCGS 30.9%; CD 24.2%, $p = 0.007$). Among subjects who had tried gluten-free Cheerios, a majority of those with NCGS (52.8%) reported an adverse reaction, compared to a minority of those with CD (36.8%, $p = 0.003$). Significantly more subjects in the NCGS group reported that they avoid

GMOs (NCGS 47.0% vs. CD 27.8%, $p < 0.0001$), attempt to only eat organic foods (NCGS 28.6 vs. CD: 12.2%, $p < 0.0001$), believe a GF diet improves energy and concentration (NCGS 40.3% vs. CD 20.7%, $p < .0001$), and believe that gluten is bad for everyone (NCGS 31.3% vs. CD 16.3%, $p < 0.0001$).

When queried regarding their trust in resources for reliable information (Table 3), participants with NCGS were more likely to rate the Food and Drug Administration (FDA) as not reliable (NCGS 27.4% vs. CD 17.2%, $p = 0.0012$). No significant differences between the two groups were seen regarding trust in university researchers, professional societies, CD organizations, or bestselling books about gluten. Likewise, there were no differences between the CD and NCGS groups regarding their impressions of reliable information sources; both groups ranked CD centers (NCGS 41.3% vs. CD 42.4%, $p = 0.13$) and online resources (NCGS 31.9% vs. CD 34.0%, $p = 0.13$) as the two most reliable sources.

On multivariate analysis, after adjusting for age and gender, we found that those with NCGS were more likely than patients with CD to believe that a GF diet improves energy and concentration aOR 2.52; 95% CI 1.86–3.43), avoid GMO foods (aOR 2.30; 95% CI 1.71–3.10), eat only organic products (aOR 2.87; 95% CI 2.04–4.03), and believe that the FDA is an unreliable source of information (aOR 1.82, 95% CI 1.26–2.64). Participants with NCGS

Table 2 Attitudes toward vaccines, gluten-free food, and views of diet and health

Questions:	Overall (<i>n</i> = 1508)	Gluten sensitivity (<i>n</i> = 217)	Celiac disease (<i>n</i> = 1291)	<i>p</i> value
Vaccines				
Are vaccines safe for people with celiac disease? (<i>n</i> = 1444)				
Yes	1032 (71.5)	119 (58.6)	913 (73.6)	< .0001
No	412 (28.5)	84 (41.4)	328 (26.4)	
Have you ever read or been told that vaccines may contain gluten? (<i>n</i> = 1505)				
Yes	187 (12.4)	34 (15.7)	153 (11.9)	.11
No	1318 (87.6)	182 (84.3)	1136 (88.1)	
Do you believe that some vaccines contain gluten? (<i>n</i> = 187)				
Yes	80 (42.8)	16 (47.1)	64 (41.8)	.50
No	11 (5.9)	3 (8.8)	8 (5.2)	
Not sure	96 (51.3)	15 (44.1)	81 (52.9)	
Did you receive the flu vaccine? (<i>n</i> = 1508)				
Yes	971 (64.4)	116 (53.5)	855 (66.2)	.007
I was offered, but declined	379 (25.1)	67 (30.9)	312 (24.2)	
I was not offered	158 (10.5)	34 (15.7)	124 (9.6)	
Cheerios				
Did you experience any adverse symptoms after eating GF Cheerios? (<i>n</i> = 828)				
Yes/Maybe	389 (38.5)	47 (52.8)	272 (36.8)	.003
No	509 (61.5)	42 (47.2)	467 (63.2)	
Apart from the recalled boxes, do you believe GF Cheerios are unsafe for people with celiac disease? (<i>n</i> = 952)				
Yes	309 (32.5)	28 (32.6)	281 (32.5)	.12
Maybe	272 (28.6)	32 (37.2)	240 (27.7)	
No	371 (39.0)	26 (30.2)	345 (39.8)	
Views on companies				
Small companies' gluten-free products are safer than large companies' gluten-free products (<i>n</i> = 1501)				
Yes/neutral	1217 (81.1)	180 (83.7)	1037 (80.6)	.29
No	284 (18.9)	35 (16.3)	249 (19.4)	
Is it a good idea for large companies to invest in making GF food? (<i>n</i> = 1502)				
Yes/neutral	1471 (97.9)	210 (96.8)	1261 (98.1)	.20
No	31 (2.1)	7 (3.2)	24 (1.9)	
Views on GMO (genetically modified) foods: (<i>n</i> = 1500)				
I do not purchase these products	459 (30.6)	102 (47.0)	357 (27.8)	< .0001
I do purchase these products	1041 (69.4)	115 (53.0)	926 (72.2)	
Views on organic foods: (<i>n</i> = 1500)				
I do not try to only eat organic products	1281 (85.4)	155 (71.4)	1126 (87.8)	< .0001
I try to only eat organic products	219 (14.6)	62 (28.6)	157 (12.2)	
Gluten-free diet improves energy and concentration (<i>n</i> = 1498)				
Yes	352 (23.5)	87 (40.3)	265 (20.7)	< .0001
No	1146 (76.5)	129 (59.7)	1017 (79.3)	
Is gluten bad for everyone? (<i>n</i> = 1503)				
Yes	277 (18.4)	68 (31.3)	209 (16.3)	< .0001
No/neutral	1226 (81.6)	149 (68.7)	1077 (83.8)	

Table 3 Trust in and reliability of information sources

	Overall (<i>n</i> = 1508)	Non-celiac gluten sen- sitivity (<i>n</i> = 217)	Celiac disease (<i>n</i> = 1291)	<i>p</i> value
<i>How reliable (from 1 to 10) is the information provided by the following resources?</i>				
Federal Government/FDA (<i>n</i> = 1233)				
Reliable (6–10)	1003 (81.4)	130 (72.6)	873 (82.8)	.0012
Unreliable (1–5)	230 (18.7)	49 (27.4)	181 (17.2)	
University researchers (<i>n</i> = 1213)				
Reliable (6–10)	1113 (91.8)	151 (88.3)	962 (92.3)	.08
Unreliable (1–5)	100 (8.2)	20 (11.7)	80 (7.7)	
Gastroenterology/nutrition professional societies (<i>n</i> = 1308)				
Reliable (6–10)	1159 (88.6)	159 (84.6)	1000 (89.3)	.06
Unreliable (1–5)	149 (11.4)	29 (15.4)	120 (10.7)	
Nonprofit celiac disease organizations (<i>n</i> = 1293)				
Reliable (6–10)	1184 (91.6)	172 (91.0)	1012 (91.7)	.76
Unreliable (1–5)	109 (8.4)	17 (9.0)	92 (8.3)	
The book—Wheat Belly (<i>n</i> = 509)				
Reliable (6–10)	367 (72.1)	82 (75.9)	285 (71.1)	.32
Unreliable (1–5)	142 (27.9)	26 (24.1)	116 (28.9)	
The book—grain brain (<i>n</i> = 454)				
Reliable (6–10)	337 (74.2)	74 (74.0)	263 (74.3)	.95
Unreliable (1–5)	117 (25.8)	26 (26.0)	91 (25.7)	
Most reliable information source (<i>n</i> = 1490)				
Advice from my dietician	85 (5.7)	19 (8.9)	66 (5.2)	.13
Advice from my doctor/NP/other medical professional	106 (7.1)	19 (8.9)	87 (6.8)	
Information provided by a Celiac Disease Center	629 (42.2)	88 (41.3)	541 (42.4)	
Online (blogs/Web sites)	502 (33.7)	68 (31.9)	434 (34.0)	
Print resources (books, pamphlets, handouts)	168 (11.3)	19 (8.9)	149 (11.7)	

were less likely than those with CD to believe that vaccines were safe (aOR 0.51; 95% CI 0.37–0.69), and were less likely to experience mostly diarrhea with gluten exposure (aOR 0.47; 95% CI 0.27–0.82).

Discussion

In this study, we found significant differences between the beliefs and attitudes of people with CD and those with NCGS. Subjects with NCGS were significantly more likely than those with CD to doubt vaccine safety, report an adverse reaction after eating GF Cheerios, and believe in the value of non-GMO and organic foods and that gluten is bad for everyone. To our knowledge, only one prior study directly compared the beliefs and characteristics of NCGS and CD patients [13].

The Food Allergen Labeling and Consumer Protection Act became law in 2004 and went into effect in 2006. Further regulations by the FDA defining acceptable levels of gluten in GF food were enacted in 2013 [14]. This legislation now allows people with CD and NCGS to read a food label and determine if a product contains gluten [15]. Despite these developments, there remains significant uncertainty about the potential cross-contamination of gluten-free grains [12, 16] and the GF labels of items such as medications [14]. Furthermore, higher cost of gluten-free foods [17], decreased access to these products for people of lower socioeconomic status [18] (who are, in turn, less likely to be diagnosed with CD [19]), and regional variations in the prevalence of those following a gluten-free diet [20, 21] may all have contributed to our results.

Surprisingly, more than 25% of this study population with gluten-related disorders has doubts about vaccine safety despite a lack of evidence to suggest that vaccines contain

gluten [22]. The NCGS group was more skeptical than the CD group, despite having a higher average education level as a group (significantly more subjects in the NCGS group held a college degree or more). NCGS subjects were also less likely than the CD group to receive an influenza vaccine when offered by a health-care professional.

While the origin of this false belief about gluten in vaccines is unknown, this concern may have arisen out of a larger concern about the safety of medications, which have been implicated as potentially containing wheat starch or gluten as their filler [23, 24]. The connection between NCGS, a preference for organic foods, and vaccine refusal may also be explained, in part, by a trend toward general distrust of “unnatural” products or processed food. Prominent advocates of the so-called paleolithic diet have expressed a preference for organic foods as well as skepticism of vaccines and gluten-containing grains [25, 26]. In keeping with this explanation, prior studies have found that mothers who refuse vaccines are more invested in “natural” living, breastfeeding, and organic foods, and have a tendency to avoid gluten and dairy [27].

Our findings of significant concerns about vaccine safety in both groups are particularly troubling in the wider context of anti-vaccination sentiment [28]. They also replicate findings of prior studies on childhood vaccine non-compliance, which found that parents with higher-than-average education levels were more likely to request exemption from mandatory vaccination for their children [29, 30]. Misperceptions about the safety of these critical interventions may lead to outbreaks of currently controlled diseases, posing a threat to public health. This is especially important as people with CD would benefit from influenza vaccination because they have a greater risk of hospitalization due to influenza than population controls [31].

Our study has several limitations. The overall response rate was 27%, raising questions about the representativeness of our respondents and the generalizability of our results. However, the e-mail distribution list that we used includes patients as well as people interested in updates about the CD and Center activities. In addition, the nature of the population (patients already followed or involved with a major CD referral center, with a majority holding a college degree) may not be a representative sample of the typical, clinically identified CD and NCGS populations in the USA.

Although CD and NCGS are pathophysiologically distinct, studies looking at differences in belief patterns in these groups have been few. Our results suggest that patients impacted by these conditions hold dissimilar beliefs on vaccine safety, and the value of GMO and organic foods and differ in their symptomatic reactions to GF products, such as Cheerios. Interestingly, as shown in Table 2, despite a distrust of big food companies, an overwhelming majority (98%

overall, with no significant difference between the groups) believes large companies should invest in GF products. This may suggest that those with gluten-related disorders believe that their disease is important enough to warrant investment in and would benefit from less expensive GF products in the future, but are distrustful of current, early efforts by big food companies to produce safe, gluten-free products in mass quantities.

Our results suggest that patients impacted by these conditions hold dissimilar beliefs on vaccine safety, and the value of GMO and organic foods and differ in their symptomatic reactions to GF products, such as Cheerios. As such, future studies should separately consider these two populations when querying attitudes, knowledge, beliefs, and quality of life. Further pathophysiologic understanding of NCGS is needed as our finding of increased symptoms with exposure to GF Cheerios in this group may suggest that they have a sensitivity to an ingredient in the product other than gluten.

Follow-up studies should also explore the reliability of GF menu items in restaurants, safety of gluten-containing cosmetic or topical products, and if patients with CD or NCGS extend their GF diet to the rest of family members. It would be important to query participants on whether concerns about gluten content in vaccines impact the decision to vaccinate their children and whether vaccine refusal extends beyond influenza to other vaccine types.

Physicians and health-care professionals who care for these patients must understand that attitudes and beliefs vary depending on their gluten-related diagnosis. Our findings suggest that the lack of reliable information on gluten and its content in foods and medications may lead to or reinforce beliefs that result in a detriment to public health. Efforts are warranted to develop accurate and accessible information about the gluten-free status of foods and medications. Furthermore, the role of health beliefs in the pursuit of the rigorous gluten-free diet in NCGS needs to be further explored in order to optimize care for this unique patient population.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflicts of interest and nothing to declare.

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