

Experiences of a gluten-free diet in patients with celiac disease: a multi-national survey

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Introduction

- Celiac disease (CeD) is a chronic, immune-mediated and systemic disorder that arises in response to dietary gluten exposure in genetically predisposed individuals.¹
 - Symptoms of CeD range from gastrointestinal effects such as diarrhea, vomiting and abdominal pain to extra-intestinal manifestations such as iron-deficiency anemia, osteoporosis and neurological symptoms.^{1,2}
- Currently, the only available management option for patients with CeD is lifelong adherence to a strict gluten-free diet (GFD).¹
 - A GFD can be difficult to maintain, and patients face many challenges in adherence, including lack of awareness from others and repeated inadvertent gluten exposure from widespread contamination of food.³⁻⁶

Aim

- To understand experiences and patient perceptions of CeD with an emphasis on a GFD.

Methods

Study design

- A multinational, cross-sectional survey investigating the impacts of CeD, including symptoms, economic burden, quality of life and GFD adherence among patients with CeD from the USA, UK, Germany and Spain, was performed in collaboration with patient advocates and clinicians.
 - Survey content was developed using insights from patient interviews and established patient-reported outcomes measures.
- This analysis focused primarily on patient experiences with a GFD.
- Celiac Dietary Adherence Test (CDAT)⁷ scores were used to assess adherence to a GFD, with an increased score reflecting worse GFD adherence.

Eligibility

- Patients with CeD from the four countries were recruited via online patient panels, partner patient advocacy organizations, social media networking and healthcare provider referrals.
- Adult patients (aged ≥ 18 years) were eligible to participate in the survey if they self-reported:
 - a CeD diagnosis confirmed with a biopsy via endoscopy, or for patients unable to undergo confirmatory biopsy, positive blood tests for serology related to CeD, and
 - adherence to a GFD for at least 6 months.
- Patients were excluded if they had a diagnosis of Crohn's disease, ulcerative colitis or microscopic colitis requiring ongoing treatment.

Statistics

- Data were analyzed using SAS v9.4 to produce descriptive summary statistics, with analysis performed by country and for all patients.

Table 1. Patient demographics and disease characteristics

Characteristic	Overall (N = 401)	USA (n = 100)	UK (n = 101)	Germany (n = 100)	Spain (n = 100)
Age, years, mean (SD)	36.3 (10.6)	37.2 (10.6)	38.1 (10.9)	38.1 (10.9)	34.4 (9.2)
Gender, n (%)					
Male	151 (37.7)	40 (40.0)	26 (25.7)	54 (54.0)	31 (31.0)
Female	249 (62.1)	60 (60.0)	74 (73.3)	46 (46.0)	69 (69.0)
Transgender male	1 (0.2)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)
Diagnosis method, n (%)					
Biopsy via endoscopy ± serology/antibody tests	313 (78.0)	80 (80.0)	81 (80.2)	79 (79.0)	73 (73.0)
Serology/antibody tests only	88 (21.9)	20 (20.0)	20 (19.8)	21 (21.0)	27 (27.0)
Diagnosis age, years, mean (SD)	26.8 (13.0)	28.6 (11.6)	26.0 (12.4)	29.9 (13.9)	22.8 (13.0)
Time from diagnosis to survey, year, mean (SD)	9.3 (10.4)	8.2 (9.2)	9.4 (11.0)	8.1 (10.2)	11.5 (10.9)
CeD severity (self-reported), n (%)					
Mild	99 (24.7)	27 (27.0)	15 (14.9)	29 (29.0)	28 (28.0)
Moderate	132 (32.9)	30 (30.0)	31 (30.7)	38 (38.0)	33 (33.0)
Severe	113 (28.2)	31 (31.0)	31 (30.7)	21 (21.0)	30 (30.0)
Very severe	57 (14.2)	12 (12.0)	24 (23.8)	12 (12.0)	9 (9.0)

CeD, celiac disease; SD, standard deviation.

Results

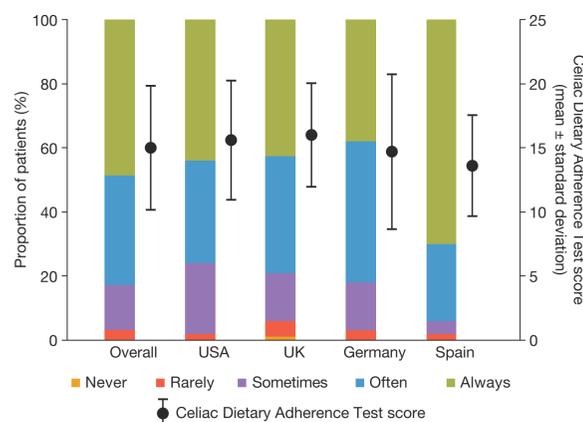
Patient demographics

- In total, 401 patients were surveyed from across the USA (n = 100), the UK (n = 101), Germany (n = 100) and Spain (n = 100).
 - Patients had an overall mean (standard deviation [SD]) age of 36.3 (10.6) years, were mostly female (62.1%) and had been diagnosed with CeD for a mean (SD) of 9.3 (10.4) years before taking the survey (Table 1).

Adherence

- The majority of patients reported 'always' or 'often' adhering to a GFD (82.8%), while less than 1% of patients reported 'never' adhering to a GFD (Figure 1).
 - Spanish patients had the highest proportion of individuals reporting 'always' or 'often' adhering to a GFD (94.0%), and the USA had the lowest proportion (76.0%).
- Among all patients rating their disease as severe, 70.0% reported 'always' adhering to a GFD, versus 32.3% of patients with mild CeD.
- Overall, the mean (SD) CDAT score was 15.0 (4.9).
 - Mean (SD) CDAT scores were generally similar over all four countries: USA: 15.6 (4.7); UK: 16.0 (4.1); Germany: 14.7 (6.1); Spain: 13.6 (4.0).
- In total, 57.1% of all patients had ingested gluten within the past month (Figure 2).

Figure 1. Self-reported patient adherence to a strict gluten-free diet



Increased Celiac Dietary Adherence Test scores reflect worse gluten-free diet adherence (scores ≥ 13 indicate inadequate gluten-free diet adherence).

Across the USA, UK, Germany and Spain, patients with celiac disease experience frequent accidental exposure to gluten

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Conclusions

- Although most patients in this study reported adhering to a gluten-free diet, many experienced difficulty in maintaining adequate adherence, with the majority experiencing frequent accidental exposure to gluten.
 - A gluten-free diet appears suboptimal as a sole method to manage celiac disease, owing to repeated inadvertent gluten exposure and a variety of common challenges to lifelong adherence.
 - These challenges remained despite the fact that patients in this survey had extensive experience of celiac disease, with an average of over 9 years since diagnosis.
- Patients who perceived their celiac disease as more severe reported higher adherence to a gluten-free diet.
- Overall, despite their best efforts to maintain a gluten-free diet, individuals across the four countries consistently experienced significant challenges in gluten avoidance and the limitations of the diet, reflecting the existence of numerous unmet needs for patients with celiac disease.

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Disclosures

David S. Sanders provided consultancy services for Takeda Pharmaceutical Company Ltd. Lisa M. Meckley and Dan A. Leffler are employees of Takeda Development Center Americas, Inc. and receive stock or stock options. Margaret Cho is a former employee of ICON plc, San Francisco, CA, USA and was employed at ICON during the conduct of this Takeda-funded research study. Sarah Clifford was an employee of ICON Clinical Research, Los Angeles, CA, USA at the time of the study and is now a Partner at Sprout Health Solutions, London, UK. She has nothing to disclose. Marilyn G. Geller is an employee of Celiac Disease Foundation, a nonprofit organization. Diandra Latibeaudiere-Gardner and Hannah B. Lewis are employees of ICON plc, which received funding from Takeda Development Center Americas, Inc. to conduct this study. Benjamin Lebwohl acts as a consultant to Takeda Pharmaceutical Company Ltd and Karyos. Heidi Urwin is an employee of Coeliac UK and has provided consultancy services (advisory board participant) for Takeda Pharmaceutical Company Ltd.

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Figure 2. Most recent patient experience of symptomatic gluten ingestion

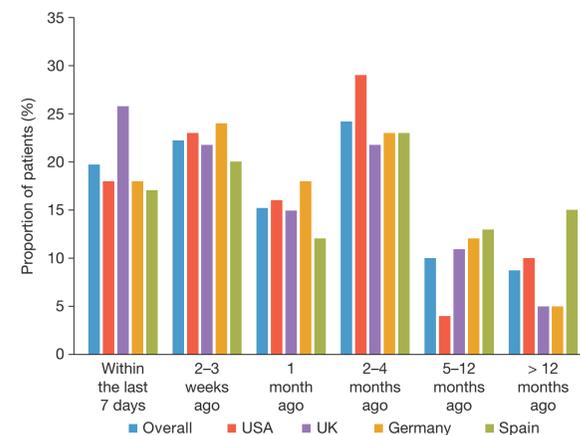
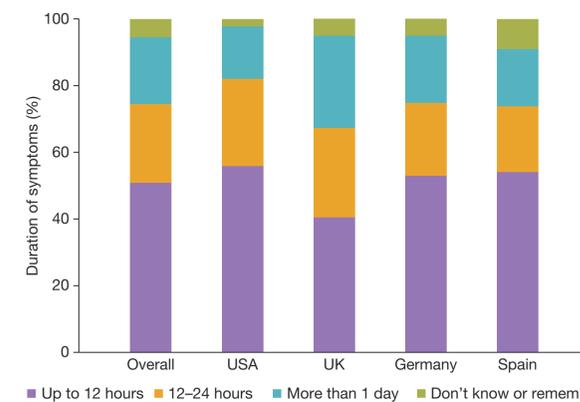


Figure 3. Duration of associated symptoms for most recent gluten exposure



- More than half of UK patients (62.4%) reported experiencing associated CeD symptoms within the past month, compared with 60.0% of German patients, 57.0% of US patients and 49.0% of Spanish patients.

Experience with gluten

- When gluten-related symptoms were triggered, patients reported these occurring within 1 hour (29.4%), 1-5 hours (59.1%), 6-10 hours (4.6%) or over 10 hours (2.7%) after ingesting gluten; a small proportion of patients (4%) were unsure of the time between gluten exposure and symptom onset.
- After gluten exposure, 50.8% of all patients experienced symptoms for up to 12 hours, 23.7% for 12-24 hours and 20.2% for more than 1 day; 5.2% of patients were unsure or could not recall the duration of their symptoms (Figure 3).
- With respect to the amount of gluten ingested, patients most frequently reported that some (e.g. 'a few bites') of gluten-containing food was sufficient to trigger symptoms of CeD (33.2%).
 - This was observed in patients from the USA, Germany and Spain; in the UK, patients most commonly reported that even 'cross-contamination/cross-contact' with a small amount of gluten was enough to trigger disease symptoms.

Challenges in maintaining a gluten-free diet

- Of the most recent gluten exposure reported by patients, 83.8% of events were accidental, with a similar pattern observed across countries (Figure 4).
 - The most frequently reported reasons for accidental gluten exposure were eating at a local restaurant (40.4%), eating cross-contaminated foods (34.9%), eating on holiday/vacation (33.2%) and when visiting family or friends (32.2%).

Figure 4. Type of most recent gluten exposure and patient-reported difficulty of adhering to a gluten-free diet

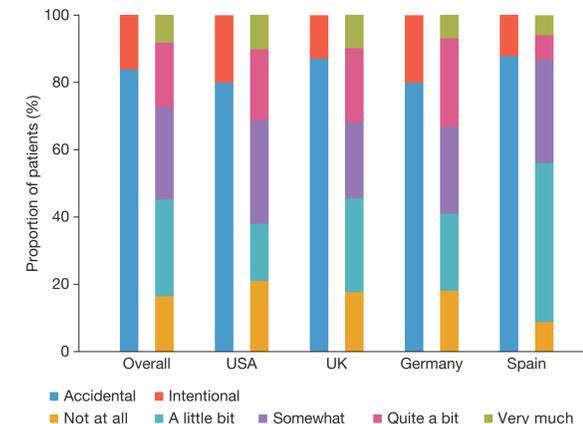
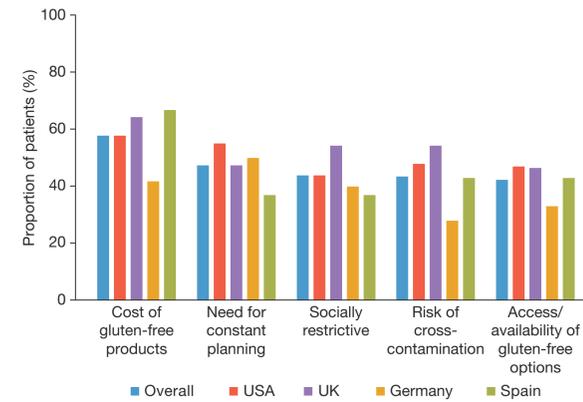


Figure 5. Most commonly reported perceived challenges in maintaining a gluten-free diet



- More than a quarter (27.2%) of patients rated the difficulty of adhering to a GFD as 'very much' or 'quite a bit', while 27.7% found it 'somewhat' difficult, 28.7% 'a little' difficult and 16.5% 'not at all' difficult (Figure 4).
- Across all four countries, the most commonly reported challenges in maintaining a GFD were the cost of gluten-free products, the need to constantly plan meals and eating arrangements ahead of time, social restrictions, the risk of gluten cross-contamination and the availability of gluten-free options (Figure 5).
 - The cost of gluten-free products was the most frequently reported challenge for patients from the USA, the UK and Spain, and the need for constant planning was the most commonly reported challenge by German patients.

Limitations

- These results may not be representative of patients outside of Europe and North America.
- Identification of CeD status was self-reported and was not verified via medical record reviews.
- Pediatric patients were not included in this study and may have different experiences with a GFD.
- Because this survey was web-based, participants may be younger and more experienced with technology than the overall adult population with CeD.
- Assessments of GFD adherence are subjective, and patients may not always be able to accurately ascertain whether they have consumed gluten.