

# Gluten-Free Diet Adherence, Symptom Burden, and Productivity Loss in Patients With Celiac Disease: An Analysis of the iCureCeliac® Patient Registry

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**Objective:** To evaluate the relationship between real-world gluten-free diet adherence, symptom burden, productivity loss, and quality of life in patients with celiac disease

## Background

- For patients with celiac disease, strict gluten-free diet adherence is the only established approach to managing the disease<sup>1</sup>
- Celiac disease is associated with substantial clinical and psychosocial burden, including persistent gastrointestinal symptoms and reduced quality of life<sup>2</sup>
- Currently there are no approved pharmacological treatments for celiac disease<sup>1</sup>

## Methods

### Study design

- This study was a retrospective analysis (January 2016–February 2024) of the iCureCeliac® Patient Registry, an international online registry of cross-sectional, self-reported insights from individuals with celiac disease
- Patients aged ≥12 years with a confirmed diagnosis (biopsy and/or serology) were included
- Gluten-free diet adherence and disease symptoms were assessed via the Celiac Dietary Adherence Test (CDAT) and the Celiac Symptom Index (CSI), respectively
  - For CDAT and CSI, higher scores indicate worse gluten-free diet adherence and disease symptom burden, respectively
- Quality of life was assessed with the Celiac Disease Quality of Life Survey (CD-QoL), with higher scores indicating poorer quality of life
- Outcomes included
  - Major symptoms in the past 4 weeks stratified by gluten-free diet adherence (CDAT score: poor [ $>16$ ]; fair [16–13]; excellent [ $\leq 12$ ])
  - Patient distribution by adherence and symptom burden (CSI score: low [ $\leq 30$ ]; moderate [31–44]; high [ $\geq 45$ ])
  - Annual work/school days missed were stratified by gluten-free diet adherence and disease symptom burden

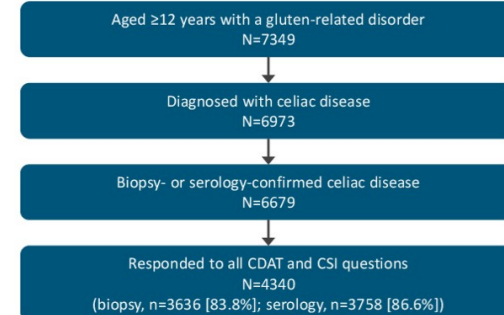
### Statistical analysis

- Key symptoms were compared between CDAT levels of poor and excellent adherence using 2-sample Z-tests and chi-squared tests
- A multiple linear regression analysis was conducted with CD-QoL scores as the dependent variable and age, gender, CDAT levels, CSI levels, and annual work/school days missed as predictors

## Demographics and Clinical Characteristics

- Overall, 4340 patients with celiac disease were included (Figure 1); mean (standard deviation [SD]) age at most recent questionnaire submission was 43.1 (15.2) years (Table 1) and 35.5 (14.3) years at first gluten-related disorder diagnosis (Table 2)

### Figure 1. Patient Disposition\*



\*For patients with multiple submission dates, the last submission date was used. CDAT, Celiac Dietary Adherence Test; CSI, Celiac Symptom Index.

- Most patients (47.7%) self-managed their celiac disease (Table 2)
- Overall, 35.9% of patients experienced diagnostic delays of ≥5 years (Figure 2); most patients (72.6%) saw 1 to 4 healthcare professionals prior to their diagnosis (Figure 3)
- Patients with low symptom burden reported better mean (SD) quality of life (50.9 [13.6]) than those with moderate (60.9 [14.0]) or high (70.4 [13.9]) symptom burden
- Patients with high symptom burden missed a mean (SD) of 30.5 (63.2) days per year

### Table 1. Patient Demographics\*

Characteristic	Total
Age at most recent questionnaire submission, mean (SD), years	43.1 (15.2)
Gender, n (%)	3726 (85.9)
Female	3726 (85.9)
Race, n (%)	3949 (95.3)
White	3949 (95.3)
Country, n (%)	3811 (88.0)
United States	3811 (88.0)
United States region, n (%)	1150 (30.3)
Midwest	1150 (30.3)
Northeast	997 (26.3)
South	828 (21.8)
West	812 (21.4)
Other	3 (0.1)

\*Proportions are based on non-missing responses (age at most recent questionnaire submission, n=4340; age group, n=4340; gender, n=4338; race, n=4144; country, n=4329; United States region, n=3790). SD, standard deviation.

### Acknowledgments

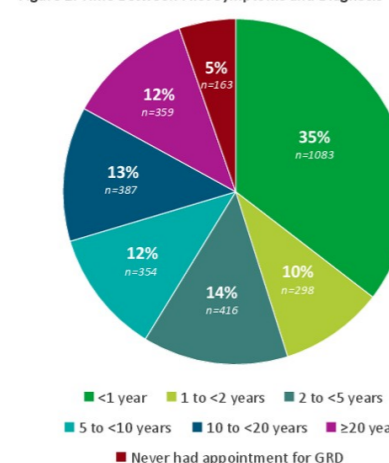
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Table 2. Clinical Characteristics\*

Characteristic	Total
Age at first GRD diagnosis, mean (SD), years	35.5 (14.3)
Age group at first GRD diagnosis, n (%)	
12–17	386 (8.9)
18–40	2445 (56.3)
41–64	1364 (31.4)
>65	145 (3.3)
Time since diagnosis, mean (SD), months	67.2 (72.9)
Managing HCP specialty, n (%)	
Self-managed	2065 (47.7)
Gastroenterologist	1693 (39.1)
Family medicine practitioner	978 (22.6)
Dietitian	190 (4.4)
Internist	162 (3.7)
Nutritionist	136 (3.1)
CD-QoL score, <sup>b</sup> mean (SD)	61.9 (15.5)
Annual work/school days missed, mean (SD), days	15.6 (45.5)

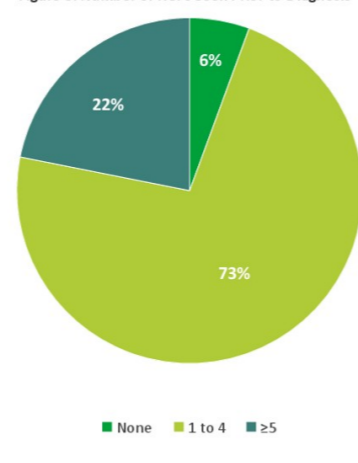
\*Proportions are based on non-missing responses (age at first diagnosis of GRD, n=4340; time since diagnosis, n=3602; managing HCP specialty, n=4338; CD-QoL score, n=3839; annual work/school days missed, n=2563). <sup>b</sup>Higher scores indicate lower quality of life. CD-QoL, Celiac Disease Quality of Life Survey; GRD, gluten-related disorder; HCP, healthcare professional; SD, standard deviation.

Figure 2. Time Between First Symptoms and Diagnosis\*



\*Proportions are based on non-missing responses (n=3060). GRD, gluten-related disorder.

Figure 3. Number of HCPs Seen Prior to Diagnosis\*

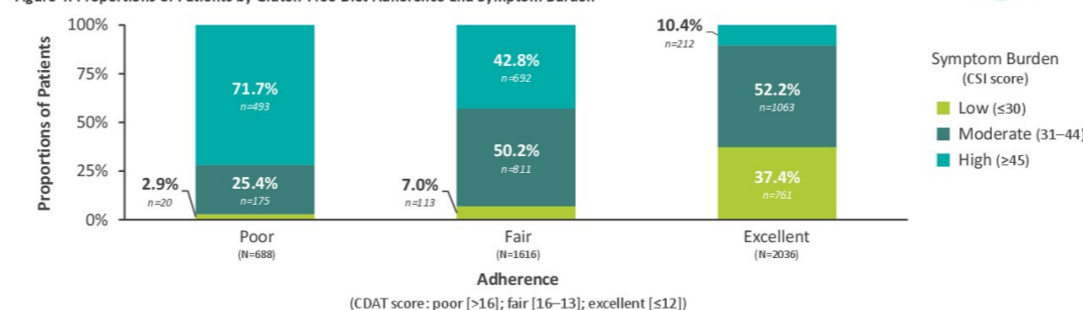


\*Proportions are based on non-missing responses (n=4312). HCP, healthcare professional.

## Many patients with celiac disease reported high symptom burden and substantial productivity loss, despite adherence to a gluten-free diet

- Overall, 52.2% and 10.4% of patients with excellent adherence reported moderate to high symptom burden, respectively (Figure 4)
- Of 688 patients with poor adherence, 25.4% and 71.7% reported moderate to high symptom burden, respectively
  - A subgroup analysis by age (adolescents and adults) showed consistent results with the total population (see Supplemental Figure 1)

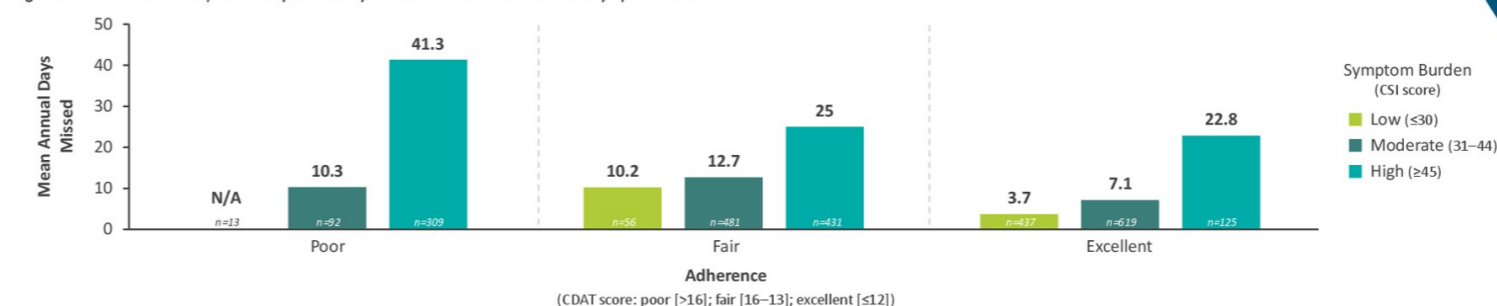
Figure 4. Proportions of Patients by Gluten-Free Diet Adherence and Symptom Burden\*



CDAT, Celiac Dietary Adherence Test; CSI, Celiac Symptom Index.

- Patients with high symptom burden and excellent adherence reported a mean (SD) of 22.8 (44.0) work/school days missed per year (Figure 5)
- Those with both high symptom burden and poor adherence missed a mean (SD) of 41.3 (80.7) work/school days per year

Figure 5. Mean Annual Work/School Days Missed by Gluten-Free Diet Adherence and Symptom Burden<sup>a,b</sup>



<sup>a</sup>A total of 2563 patients completed this question. <sup>b</sup>Wilcoxon test was used to test the differences in annual work/school days missed, with poor gluten-free diet adherence as the reference group. Mean annual work/school days missed were numerically lower for those with excellent gluten-free diet adherence vs those with poor gluten-free diet adherence,  $P=0.0626$ . CDAT, Celiac Dietary Adherence Test; CSI, Celiac Symptom Index; N/A, not available.

## Celiac Disease Symptoms and Gluten-Free Diet Adherence

- Significantly lower proportions of patients with excellent adherence experienced each of the major symptoms in the past 4 weeks vs those with poor adherence (all  $P<0.0001$ ; Table 3)
- However, even among 2036 patients with excellent adherence, major symptoms were commonly reported, with the most frequent being low energy (85.7%), physical pain (80.5%), and stomach bloating (76.6%)

Table 3. Symptoms Experienced by Patients During the Past 4 Weeks by Gluten-Free Diet Adherence

Symptoms, n (%)	Poor (n=688)	Fair (n=1616)	Excellent (n=2036)	Total (N=4340)	P value*
Low energy	681 (99.0)	1582 (97.9)	1745 (85.7)	4008 (92.4)	<0.0001
Stomach bloating	637 (92.6)	1474 (91.2)	1559 (76.6)	3670 (84.6)	<0.0001
Physical pain	653 (94.9)	1496 (92.6)	1638 (80.5)	3787 (87.3)	<0.0001
Headache	649 (94.3)	1460 (90.3)	1220 (59.9)	3329 (76.7)	<0.0001
Pain/discomfort in upper abdomen/pit of stomach	633 (92.0)	1388 (85.9)	1402 (68.9)	3423 (78.9)	<0.0001
Stomach rumbling	606 (88.1)	1306 (80.8)	1327 (65.2)	3239 (74.6)	<0.0001
Diarrhea	536 (77.9)	1163 (72.0)	1214 (59.6)	2913 (67.1)	<0.0001
Hunger pains	552 (80.2)	1188 (73.5)	1169 (57.4)	2909 (67.0)	<0.0001
Nausea	525 (76.3)	1084 (67.1)	845 (41.5)	2454 (56.5)	<0.0001
Loss of appetite	498 (72.4)	1026 (63.5)	795 (39.0)	2319 (53.4)	<0.0001

\*Poor vs excellent adherence; 2-sample Z-tests and chi-squared tests were used to generate P values, with both tests producing the same results.

### Disclosures

B Lebwohl is a consultant for Dualitas Therapeutics and has served on advisory boards for Teva Pharmaceuticals. M Contente, N Magnus, and H Xie are employees of Teva Pharmaceutical Industries Ltd. M McKenna is an independent consultant. S Chatterjee and R Singh are employees of KMK Consulting, Inc., which has received payments from Teva Pharmaceuticals in relation to this study.

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## Conclusions

- Even among patients who reported being adherent to a gluten-free diet, many reported moderate to high symptom burden and substantial productivity loss
- These results suggest that gluten-free diet adherence alone may be insufficient to reduce disease burden in patients with celiac disease, underscoring the unmet need for new and effective treatments

CDAT and CSI scores were moderately correlated ( $R=0.62$ ), indicating that poorer gluten-free diet adherence was associated with greater symptom severity

## Predictors of Quality of Life

- CD-QoL scores were significantly associated with age, symptom severity, dietary adherence, and missed work/school days due to gluten-related disorder (all  $P<0.0001$ ; Table 4)

Table 4. Predictors of CD-QoL Scores

Statistics	Overall model (N=2562)		Values	
	P value	R <sup>2</sup>	Estimate	P value
Independent variables				
Age	–	–	–0.17	<0.0001
Gender	Female <sup>a</sup>		0.00	
	Male		0.67	0.4624
	Other		2.98	
CSI	Low <sup>a</sup>		0.00	
	Moderate		7.52	<0.0001
	High		13.39	
CDAT	Poor		6.12	
	Fair		4.98	<0.0001
	Excellent <sup>a</sup>		0.00	
	Annual work/school days missed		0.02	<0.0001

<sup>a</sup>Reference group. CDAT, Celiac Dietary Adherence Test; CD-QoL, Celiac Disease Quality of Life Survey; CSI, Celiac Symptom Index.

## Limitations

- This study analyzed self-reported data; missing or incomplete data may lack demographic and/or clinical detail
- Registry enrollment patterns may introduce selection bias
- Although iCureCeliac is an international registry, most participants are from the United States and are White and female, which may limit the generalizability of the results

### References

- Green PHR, et al. *J Allergy Clin Immunol*. 2015;135(5):1099-1106.
- Mogul D, et al. *Expert Rev Pharmacoecon Outcomes Res*. 2017;17(2):181-188.