Original Article

Quality of Life in Patients with Celiac Disease: A Registry-Based Cross-Sectional Study in Iran

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ABSTRACT

Background: This cross-sectional study aimed to assess the impact of celiac disease (CD) on the quality of life (QoL) of individuals adhering to a gluten-free diet (GFD) in Iran.

Materials and Methods: A total of 86 adult patients with CD, following a GFD for at least 6 months, were recruited from the Golestan celiac registry. Participants completed the Celiac Disease Quality of Life (CD-QoL) questionnaire. Statistical analyses were performed using SPSS software version 16, with descriptive statistics for categorical variables, Mann-Whitney U and Fisher's exact tests for group comparisons (due to non-normal data assessed via Shapiro-Wilk test), and multivariate logistic regression to evaluate clinical factors' impact on QoL tertiles (significance at $P<0.05$).

Results: The mean age of the participants was 41.87 years, with 67.4% females. There were no significant relationships between most demographic variables (sex, age, age at diagnosis, disease duration, ethnicity, marital status) and total QoL scores or any of the four subscales (all $P>0.05$). However, individuals with non-academic education exhibited significantly higher total QoL scores compared with those with academic education ($P=0.028$). The "health concerns" subscale score was significantly lower in subjects aged 40 or younger compared with older individuals ($P=0.048$). The overall mean CD-QoL score was 58.34 ± 26.5 (range 20–100, higher scores indicate better QoL), indicating moderate impairment in QoL.

Conclusions: CD and strict adherence to a GFD can moderately impair QoL in Iranian patients, with age and educational level influencing specific subscales. These findings underscore the need for targeted support, particularly for younger patients and those with higher education, to improve dietary adherence and overall well-being in this population.

Keywords: Celiac disease, Quality of life, Gluten-free diet, Dietary adherence, Health-related quality of life, Iran, Middle Eastern population

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INTRODUCTION

Ingestion of gluten proteins found in wheat, rye, and barley can induce gluten intolerance in susceptible individuals, leading to celiac disease (CD) (1). CD is characterized by pathological features, including villous atrophy, crypt hyperplasia, and an increased number of intraepithelial lymphocytes in the small intestine. The escalating worldwide incidence of CD underscores its growing prevalence (2,3). In a systematic review and meta-analysis by Singh and colleagues, the estimated worldwide prevalence of CD ranged from 0.7% to 1.4% (2). CD management necessitates a lifelong adherence to a gluten-free diet (GFD) (4). The validation of the GFD has been established through clinical, serological, and histological means (5,6). Patients with CD must make significant changes to their dietary habits, impacting their lifestyle and quality of life (QoL) (7). The concept of QoL can be defined as an individual's subjective understanding of their status within society, taking into account prevailing cultural norms and value systems, as well as personal aspirations, anticipated outcomes, established criteria, and areas of concern (8).

Strict compliance with a GFD entails significant sacrifices and lifestyle modifications that can directly impact one's QoL (9). Recent global surveys further confirm that in low- and middle-income countries (including regions like the Middle East), limited availability, high costs, poor labeling legislation, and lack of support exacerbate these challenges, underscoring the need for context-specific research in cohorts such as Iran (10). Recent studies also highlight the mediating role of food insecurity and adherence difficulties in reducing HR-QoL in patients with CD (11). Adults with CD often face obstacles when eating out, including scrutinizing food labels, travel difficulties, and challenges during communal meals to avoid accidental gluten exposure (12, 13). Recent studies continue to report that strict GFD adherence, while essential, often leads to reduced QoL due to social isolation, higher costs, and food insecurity, particularly in non-Western contexts (11,14,15). As a result, individuals with CD are likely to reconsider their dietary habits and experience negative emotions such as anxiety, fear, and frustration, which may lead them to avoid social activities. Research into CD patients' health-related QoL has revealed slightly lower scores compared with those of healthy individuals (16).

Various factors influence QoL in patients with CD on GFD, including clinical presentation, age at diagnosis, sex, diagnostic delay, and educational level (17-21). Diagnostic delay is associated with reduced well-being and increased healthcare utilization (17), while older patients report more health concerns, and better adherence correlates with higher QoL scores (21). On the other hand, certain factors, like age at diagnosis and educational level, may have an indirect influence on QoL in patients with CD (20). Moreover, the improvement in QoL, anxiety, and depression following CD diagnosis suggests a direct link between diagnosis and QoL, yet it does not specify the contributing factors (19). Recent evidence reinforces that GFD adherence is associated with improved but still suboptimal QoL, with additional burdens from food insecurity, mental health issues, and lack of adequate follow-up care (21-23). Understanding these relationships is essential for providing a comprehensive view of QoL in patients with CD, incorporating both direct and indirect influences.

Despite growing recognition of CD's impact on QoL worldwide, research on strictly adherent patients in non-Western contexts like Iran remains limited. CD prevalence in Iran is approximately 1% (24), but strict GFD adherence is particularly challenging due to high wheat consumption, limited availability, and high cost of gluten-free products, cultural reliance on wheat-based foods, and socioeconomic barriers. Few studies have assessed disease-specific QoL using validated tools among adherent adults in Iran, with most focusing on questionnaire validation or general adherence rather than comprehensive QoL in registry-based cohorts.

This study addresses this gap by evaluating QoL in GFD-adherent patients from the Golestan celiac registry using the validated Persian CD-QoL questionnaire, while examining influencing factors such as sex, age at diagnosis, and disease duration.

MATERIALS AND METHODS

Study population and inclusion/exclusion criteria

In our cross-sectional study, we meticulously defined stringent inclusion criteria to ensure accurate and relevant participant selection. To capture the unique experiences of the adult population, participants had to be aged 18 years or older and sourced from the Golestan celiac disease registry database. The Golestan celiac disease registry database is a comprehensive resource aimed at collecting and documenting information on patients diagnosed with CD in the Golestan region (a regional registry with several hundred registered cases, as indicated in previous studies from the center, e.g., samples of 120–220 patients in recent reports). This database includes demographic, serological, and clinical data. The inclusion criteria encompassed individuals who met one or more of the following conditions: a serology test result indicating IgA antibodies to tissue transglutaminase (tTg-IgA) exceeding the threshold of 200 international units per milliliter (IU/mL) and/or histological findings from a small-intestinal biopsy

confirming CD. These histological findings were required to align with the established diagnostic criteria for CD, including characteristic features such as villous atrophy and an elevated intraepithelial lymphocyte count. Additionally, participants needed to have maintained adherence to a GFD for at least 6 months. In addition to the medical criteria, participants were expected to express their willingness to complete the designated CD-QoL questionnaire.

We employed a census-based sampling method, drawing our study participants from the Celiac Registry of Golestan. Initially, 150 patients within the registry met the eligibility criteria for potential inclusion in our research. Of these 150 eligible patients, 86 expressed willingness to participate and completed the QoL questionnaire, thereby meeting the inclusion criteria and becoming part of our study cohort. Participation was voluntary, which may introduce selection bias (e.g., more motivated or adherent patients may have been more likely to participate). Written informed consent was obtained from all participants.

Questionnaire

Trained researchers conducted face-to-face interviews to collect demographic data, while comorbidities were identified from medical records, including diabetes mellitus, cancers, chronic kidney disease, chronic liver disease, autoimmune disease, inflammatory disease, and psychological disorders.

The Celiac Disease Quality of Life (CD-QoL) questionnaire, specifically developed for assessing CD, consists of 20 questions divided into four clinically significant subscales: CD-related Limitations, Dysphoria, Health Concerns, and Inadequate Treatment (25). Participants were instructed to reflect on their experiences over the previous 30 days and assign a score ranging from 1 to 5 for each question. Each item was rated on a 5-point Likert scale (1 = never/not at all to 5 = all the time/a great deal), and the total scores ranged from 20 to 100, with higher scores indicating better quality of life (25, 26). The Persian translation of this questionnaire was validated by Nikniaz and colleagues. (26).

There is no clear cut-off point for the subclassification of CD-QoL scores. Following Marsilio and others (2020) (21), who used tertiles in the absence of validated cut-offs to stratify QoL levels and examine associations, scores were divided into low, medium, and high tertiles. Patients in the lowest tertile were classified as having lower QoL. This approach is exploratory and allows for relative comparisons within our sample.

Statistical analysis

Statistical analysis was performed using SPSS software version 16. Descriptive statistics were used to summarize categorical variables, presenting counts and percentages, and group comparisons were conducted using Fisher's exact test. For continuous variables, median and interquartile range were used as descriptive measures. The normality of the data was assessed using the Shapiro-Wilk test. This test is well-suited for small sample sizes, and its results guided our choice of statistical methods for analysis. Univariate analysis of continuous variables among groups was conducted using the Mann-Whitney U test. Statistical significance was determined at a P value of less than 0.05. Variables for multivariate logistic regression were selected based on clinical relevance, including those with P values < 0.05 in the univariate analysis. This analysis allows us to account for the potential confounding effects of multiple variables simultaneously, providing a more robust understanding of factors influencing QoL. As this is a cross-sectional study, the findings are associative and do not permit causal inference regarding the observed relationships.

Ethics approval and consent to participate

This study adhered to the principles of the Declaration of Helsinki. Ethical approval for the study was obtained from the Ethics Committee of Golestan University of Medical Sciences (IR.GOUMS.REC.1400.317). Informed consent was obtained from all study participants.

RESULTS:

The study included 86 patients with a definitive diagnosis of CD. The participants had a mean age of 41.87 years with a standard deviation of 12.81. Among the participants, 58 (67.4%) were women. Table 1 presents the fundamental characteristics of the population under investigation. (Table 1).

There was no significant relationship between most demographic variables, such as sex, age (categorized as 40 years or older vs. younger), age at diagnosis, duration of CD (≤5 vs. ≥6 years), ethnicity, marital status, and the total CD-QoL score or any of the four subscales (all $P>0.05$).

However, individuals with non-academic backgrounds reported significantly better overall QoL (higher total score) compared with those with academic qualifications ($P=0.028$).

The mean total CD-QoL score was 58.34 ± 26.5 (out of 100, higher scores indicate better QoL), indicating moderate impairment in QoL. Subscale means were: Limitations 57.95, Dysphoria 48.40, Health Concerns 65.17, and Inadequate Treatment 62.94.

Table 2 reveals that there were no statistically significant differences in the total QoL score and the four subscales of CD when considering sex, duration of disease, and age, except for the subscale of "health concerns." Interestingly, the score on the "health concerns" subscale was significantly lower among subjects aged 40 or younger than among older

individuals (P=0.048, Table 2).

Table 1. Basic characteristics of patients with celiac disease

Age, mean (SD); years		41.87 (12.8)
Diagnosis age, mean (SD); years		34.47 (13.6)
Duration of disease, mean (SD); years		26 (7.4)
Sex, N (%)	Male	28 (32.6)
	Female	58 (67.4)
Education level, N (%)†	Academic grade	31 (37.8)
	Non-Academic	51 (62.2)
Ethnicity†	Fars	45 (54.9)
	Others	37 (45.1)
Marriage status, N (%)	Single	23 (26.7)
	Married	63 (73.3)
Marsh classification, N (%)	Marsh I and II	14 (16.3)
	Marsh IIIa to IIIC	58 (67.4)
	Not mentioned/ no endoscopy report	14 (16.3)

† Education level and ethnicity had four missing values (valid N=82); percentages are based on valid responses.

DISCUSSION:

In this cross-sectional study, we observed a borderline QoL score among patients with CD, indicating moderate impairment in disease-specific QoL among adherent patients. The CD-QoL score varies across studies, and research on QoL in CD remains limited. As a lifelong chronic condition requiring strict, lifelong GFD adherence, CD imposes significant dietary restrictions, increased food costs, and treatment burden, negatively affecting daily functioning and QoL.

In return, low QoL could result in persisting clinical and psychological symptoms even on GFD. Conversely, adherence to GFD and QoL have direct mutual relationships (14). QoL could be measured using general tools such as the SF-36 and specific tools for each chronic disease. Most researchers use generic tools. However, studies showed that the CD-QoL survey has high internal consistency and reliability and is suggested to be used in patients with CD (22, 27). Barzegar and colleagues reported a mean CD-QoL score of 119.18 in 81 patients with CD in Iran. They concluded the excellent reliability of the Persian version of CDQ and suggested it as a good tool to assess outcomes in Iranian patients with CD (28). Nikniaz and

Table 2. CD-QoL scores stratified by duration of Celiac disease, age, and sex

	Duration, years		**P**	**Sex**		**P**	**Age, years**		**P**
	≤5	≥ 6		M	F		≤40	≥41	
CD-QoL total*	57.58	59.18	0.782	57.05	58.97	0.756	58.94	57.68	0.827
Low	20%	17.1%	0.916	25%	15.5%	0.525	17.8%	19.5%	0.867
Medium	42.2%	41.5%		35.7%	44.8%		40%	43.9%	
High	37.8%	41.5%		39.3%	39.7%		42.2%	36.6%	
Dysphoria*	48.61	48.17	0.953	49.78	47.74	0.797	47.92	48.93	0.891
Low	44.4%	36.6%	0.569	42.9%	39.7%	0.960	42.2%	39%	0.883
Medium	17.8%	26.8%		21.4%	22.4%		20%	24.4%	
High	37.8%	36.6%		35.7%	37.9%		37.8%	36.6%	
Health concern*	64.22	66.22	0.727	62.68	66.38	0.543	66	64.27	0.762
Low	15.6%	9.8%	0.718	17.9%	10.3	0.223	17.8%	7.3%	0.048
Medium	37.8%	39%		46.4%	34.5		26.7%	51.2%	
High	46.7%	51.2%		35.7%	55.2		55.6%	41.5%	
Limitations*	57.41	58.54	0.857	56.55	58.62	0.756	58.89	56.91	0.752
Low	22.2%	19.5%	0.953	25%	19%	0.524	22.2%	19.5%	0.850
Medium	37.8%	39%		42.9%	36.2%		35.6%	41.5%	
High	40%	41.5%		32.1%	44.8%		42.2%	39%	
Inadequate treatment*	59.72	66.46	0.257	59.82	64.44	0.467	63.61	62.20	0.813
Low	17.8%	9.8%	0.286	21.4%	10.3%	0.336	11.1%	17.1%	0.653
Medium	46.7%	39%		42.9%	43.1%		46.7%	39%	
High	35.6%	51.2%		35.7%	46.6%		42.2%	43.9%	

*Mean score value, CD-QoL: Celiac Disease-Quality of Life

others validated the Persian version of this questionnaire in 2021 (220 patients with CD) and suggested it as a good, reliable questionnaire for assessing QoL in Iranian patients with CD (26). Lower scores in our study (higher = better) suggest moderate impairment and highlight the potential for poor adherence if unaddressed.

Although the present study did not find any relationship between demographic and clinical variables and the total score of CD-QoL or its four sub-scales, the lack of significant associations with most demographic and clinical variables aligns with some prior studies in adherent patients, suggesting that QoL impairment in this group may be driven more by other unmeasured factors (e.g., socioeconomic barriers, access to gluten-free foods, or psychological adaptation) than by the tested characteristics. This is consistent with recent findings that QoL variability in adherent patients is more influenced by contextual and unmeasured factors than demographics (23). Previous research suggests that poor adherence to the GFD, social and economic challenges associated with lifelong adherence, comorbidities, and various intestinal and extraintestinal symptoms are linked to lower health-related quality of life (HR-QoL) (27). In a survey by Marsilio and others involving 100 individuals with CD, the mean CD-QoL total score was 80.54, indicating an overall good QoL among those adhering to the GFD (higher scores indicate better QoL) (29). However, individuals older than 35 years and those who were non-compliant with the GFD tended to experience more health concerns and exhibited symptoms of dysphoria. In comparison to Marsilio's study (21) (mean 80.54), our patients showed a lower mean score (58.34), suggesting greater impairment in disease-specific QoL. This difference may be related to cultural, socioeconomic, or access-related factors in Iran, such as limited availability and higher cost of gluten-free products.

Younger patients showed significantly lower scores on the "health concerns" subscale, indicating greater health worries. This may relate to life transitions (e.g., career/family start), higher health expectations, or anxiety around long-term management and comorbidities (15,21,30). While these explanations are plausible based on prior literature, they remain exploratory in our study and warrant further investigation. Targeted support and mental health resources for younger patients could help mitigate these concerns.

This study, like any research, has its limitations. While our findings provide valuable insights into the QoL of patients with CD following a GFD in Iran, it's important to acknowledge that our sample size was relatively small, and our study focused solely on a single geographic region. The modest sample size and small subgroup sizes reduced statistical power to detect differences in QoL subscales or in stratified analyses, potentially leading to under-detection of true associations. Larger studies are needed to confirm these findings. Reluctance to participate can be linked to a variety of reasons, including concerns about a lack of privacy, a lack of awareness, or a lack of feeling the need to participate. Selection bias may be present, as only 57% (86/150) of eligible registry patients participated; non-participants could differ in adherence, QoL, or other characteristics, potentially limiting generalizability. The cross-sectional design of this study precludes establishing causality; observed associations (e.g., between education level and QoL or age and health concerns) may be influenced by unmeasured confounders or reverse causation. Additionally, potential misclassification bias may arise from self-reported adherence or registry diagnostic data, although we used strict inclusion criteria (tTg-IgA >200 IU/mL and/or biopsy confirmation). These limitations may affect the generalizability of our results to broader patient populations with CD. Additionally, the cross-sectional design of the study inherently limits our ability to establish causal relationships among variables. Moreover, self-reported questionnaires are subject to recall bias, and we relied on participants' accurate recollection of their experiences over the previous 30 days. Future studies with larger and more diverse participant groups, potentially including multi-center research, could provide further insights into the complex relationship between CD, adherence to a GFD, and QoL, mitigating potential biases and increasing generalizability.

CONCLUSIONS

In this cross-sectional study, we investigated the impact of CD on the QoL of individuals adhering to a GFD. We found a moderate impairment in score among patients with CD, indicating potential challenges and concerns related to the dietary restrictions imposed by GFD. Adherence to GFD is crucial in managing CD, but it can significantly affect one's daily functioning and psychological well-being. The CD-QoL questionnaire used in this study proved to be a reliable tool for assessing the disease burden on everyday life in patients with CD. Further research is warranted to explore additional factors that may influence QoL in CD, including comorbidities, social and economic challenges, and intestinal and extraintestinal symptoms. By understanding and addressing these factors, healthcare providers can work towards improving the overall well-being and QoL of individuals living with CD.

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AUTHOR CONTRIBUTIONS

Conceptualization, S.B., M.N. and A.J.; Data curation, H.M., M.N., P.Q., H.Sh., H.N. and A.J.; Formal analysis, F.N.T.; Investigation, S.B., A.J. and M.N.; Methodology, A.J.; Supervision, S.B., and A.J; Validation, M.N. and H.M. and A.J.; Writing—original draft, M.N., A.J., P.Q., H.Sh., K.K. and H.N.; Writing—review & editing, S.B., M.N. and A.J. All authors have read and agreed to the published version of the manuscript.

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DATA AVAILABILITY STATEMENT

All data indicated and analyzed for this study are available by request to the corresponding author.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Approval from the Ethics Committee of Golestan University of Medical Sciences (IR.GOUMS.REC.1400.317) was obtained prior to conducting this study. Consent for participation was obtained from patients via an opt-out form, ensuring their voluntary involvement.

CONFLICTS OF INTEREST

The authors declare no conflict of interest related to this work.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all study participants and their legal guardians, confirming their understanding and consent to participate.

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