ORIGINAL PAPERS

Transcultural adaptation and validation of the Celiac Dietary Adherence Test. A simple questionnaire to measure adherence to a gluten-free diet

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ABSTRACT

Background and aims: A gluten-free diet is to date the only treatment available to celiac disease sufferers. However, systematic reviews indicate that, depending on the method of evaluation used, only 42% to 91% of patients adhere to the diet strictly. Transculturally adapted tools that evaluate adherence beyond simple self-informed questions or invasive analyses are, therefore, of importance. The aim is to obtain a Spanish transcultural adaption and validation of Leffler's Celiac Dietary Adherence Test.

Methods: A two-stage observational transversal study: translation and back translation by four qualified translators followed by a validation stage in which the questionnaire was administered to 306 celiac disease patients aged between 12 and 72 years and resident in Aragon. Factorial structure, criteria validity and internal consistency were evaluated.

Results: The Spanish version maintained the 7 items in a 3-factor structure. Feasibility was very high in all the questions answered and the floor and ceiling effects were very low (4.3% and 1%, respectively). The Spearman correlation with the selfefficacy and life quality scales and the self-informed question were statistically significant (p < 0.01). According to the questionnaire criteria, adherence was 72.3%.

Conclusion: The Spanish version of the Celiac Dietary Adherence Test shows appropriate psychometric properties and is, therefore, suitable for studying adherence to a gluten-free diet in clinical and research environments.

Key words: Celiac disease. Gluten-free diet. Validation. Questionnaire. CDAT.

INTRODUCTION

Celiac disease is a chronic, immune illness consisting of permanent intolerance to gluten, which is present in cereals like wheat, barley, rye (1) and, very probably, in certain types of oats (2), causing inflammation and injury to the small intestine. A thorough study undertaken by Fasano in the United States reports a prevalence of 1:133

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in low risk groups and 1:22 in high risk groups (3), while a prevalence of 1% is the widely accepted figure in the western world (4). In Spain, Cilleruelo et al. (5) place it at 1:220, Riestra et al. (6) at 1:389, Castaño et al. (7) at 1:118, García-Novo et al. (8) at 1:370 and, more recently, Mariné et al. (9) at 1:204.

The disease is considered to be systemic and, if untreated, can give rise to a whole range of gastrointestinal and nutritional problems: osteoporosis, infertility, or some types of lymphoma (10). The only known treatment to date is a strict life-long gluten-free diet.

In a systematic review, Hall et al. (11) estimate that adherence to the diet is only between 42% and 91% among patients, depending on the definition of adherence and the type of evaluation. As for the impact of non-adherence, Leffler et al. report that 30% of cases with no improvement appear to be related to a continuous exposure to gluten in the diet (12).

Most tools used to evaluate adherence have been drawn up in languages other than Spanish. Logically, a correct transcultural adaptation allows comparisons of findings between studies (13). Although on occasions (13,14) a self-administered adaption of the questionnaire prepared by Morisky et al. (15) has been used, this team has found no validated tool to measure adherence in Spanish, and each evaluation has always been carried out using self-informed questions or serological tests.

Other more specific questionnaires include the Biagi Gluten Free Score (16), whose four items offer a score from 0 to IV in which levels 0 and I indicate a low adherence to the diet, level II shows some adherence but with important lapses, while subjects scoring III or IV follow a strict gluten-free diet, although the authors do not distinguish between these two higher levels. This scale has the advantage that it can be applied over the telephone. Another questionnaire is the TPB Questionnaire (17), with 93 items that are answered on a 7-point Likert scale. It fits

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into the Theory of Planned Behavior (18) and evaluates the strength of patients' beliefs, their evaluation of the consequences (attitude), their motivations for adhering (rules) and the power of their beliefs. While all these questionnaires which seek to evaluate adherence to a gluten-free diet are of interest, the Celiac Dietary Adherence Test (CDAT) offers the greatest possibilities for adaptation, it makes the broadest evaluation and it has begun to be used in research (17).

In 2009, Leffler developed the CDAT, a short questionnaire that provides a fast, standardized evaluation with a higher level of specificity and sensitivity than can be gleaned from an analysis of levels of tissue antitransglutaminase or self-informed questions (19).

The CDAT questionnaire comprises 7 questions, it is easy to administer and has optimal psychometric characteristics. The 7 items measure the symptomatology of celiac disease patients, their expectations of self-efficacy and their reasons for following a gluten-free diet, as well as their perceived adherence.

In its original validation, each of the 7 items showed a high correlation with the SDE (Standardized Dietitian Evaluation), a sensitivity of 73.7%, a specificity of 76.7% and the Pearson correlation was 0.823 in test-retest reliability. Internal consistency of the original scale was not calculated because of the small number of items, but in the initial scale of 85 items, before the reduction, the Cronbach α was 0.809. Its behavior in the ROC analysis in the derivation and validation groups was significantly better than that of the tissue immunoglobulin A, with areas below the curve of 0.830 and 0.652, respectively.

Hence, the aim of this research was to provide a validated Spanish version of Leffler's Celiac Dietary Adherence Test (CDAT).

METHODS

Phase 1: Translation and back translation of the questionnaire

After seeking the author's authorization for the translation of the questionnaire into Spanish, we then contacted bilingual translators. Three translators proffered translations from English into Spanish, the versions were then compared and a consensus was reached. A fourth, independent, translator was employed for the back translation and a satisfactory match was obtained.

Phase 2: Validation of the questionnaire

In order to validate the psychometric characteristics of the Spanish version, a descriptive transversal study was designed using a survey which contained a battery of questionnaires that could be answered online or on paper.

A pilot study was carried out previously on 10 celiac disease patients who responded to the CDAT questionnaire and to the other questionnaires used for the validation process, which were statistically analyzed.

Calculating the sample

The sample size for the analysis was calculated with the recommended 10-15 patients per item (20,21), so 70-105 participants were required in total.

Considering the population data, the prevalence of 1% and an infradiagnosis of 1:7 in Aragon, Spain, there are approximately 1,800 known diagnosed celiac disease cases.

Subjects were invited to participate via the main association of patients in the area, and 1,481 invitations (82.28%) were sent to associated celiac patients in Aragon of 12 years of age or more, so participants are deemed to have sufficient language competence to be able to respond to the questionnaire. The study was also publicized through the Public Health System with the aim of recruiting non associated patients. Participants, or in the case of minors their guardians, gave informed consent to participate in the research.

Participants could choose to complete the questionnaire online or with a pen and paper version and could send their answers anonymously to the association, which forwarded them to the research team. The survey was carried out between March and June 2015.

Three hundred and six (83.3% women) completed questionnaires were received from the Autonomous Community of Aragon, with respondents' ages ranging from 12 to 72 years, 89.5% of whom were associated at the time (Table I). The median of years' experience of coping with the disease was 5 (range 3-11).

Evaluation of criteria and discriminant validity

Owing to the inexistence of equivalent tests, criteria validity was analyzed using a battery of questionnaires: CeliacSE (22), GSES (23), Casellas's adaptation (13) of the CD-QOL (24) and SF12.v2 (25), and these were applied together with the translation of the CDAT made for this study in order to analyze the convergent validity in the dimen-

Table I. Sociodemographic characteristics of participants

n	306
Age	35.5 (27-46)
Sex (% females)	83.3%
Studies % (none/Primary/Secondary/ university)	2.3/10.8/29.4/57.4
Marital status % (single/married/other)	29.7/65.9/4.3
Associated illnesses % (yes)	39.2
Associated %	89.5
Adherence to GFD (% always or almost always)	94.3
Adherence to GFD (% always)	59.8
Years on GFD	5 (3-11)

GFD: Gluten-free diet.

sions found of symptomatology, self-efficacy and motivations in the gluten-free diet, and self-esteem. The discriminant validity was measured with Spearman correlations for each of these questions with each questionnaire or the dimensions therein.

Adherence to the diet

Adherence to the diet was measured through the CDAT translation with additive scores from 7 to 35, with scores below 13 indicating excellent or good compliance and scores above 17 indicating a limit or poor adherence.

Adherence was also measured through the self-informed question "Do you feel that you are correctly following a gluten-free diet?". The response options were never, hardly ever, sometimes, almost always and always, with "always" corresponding to strict adherence.

Life quality

Overall life quality was measured using the SF-12 v2 questionnaire and the Spanish version of the specific celiac disease questionnaire CD-QOL. The SF-12 questionnaire is a shortened version of the SF-36, which also incorporates a physical component (PCS) and a mental one (MCS) for quality of life. The CD-QOL comprises 20 questions that rate the state of health on a scale from 0 (worst) to 100 (best) and includes four dimensions (dysphoria, limitations, health problems and inappropriate treatment).

Self-efficacy

General self-efficacy was measured using the GSES scale while specific self-efficacy for adherence was measured with the CeliacSE questionnaire. The originally German GSES scale has been translated into 32 languages and has been widely used in a variety of environments. It comprises 10 items that are measured on a 4-point Likert scale ranging from "not at all true" to "exactly true", and uses additive total scores. The CeliacSE scale developed in the framework of this research comprises 20 questions and is divided into 5 areas (shopping, eating out, eating at home with others, travel and work/school). It uses an 11-point scale in which participants score their confidence to carry out a certain behavior in coping with their gluten-free diet. Scores are again additive.

Demographic variables relating to age, sex, marital status, work situation, level of education, membership of a patients association, associated illnesses and prescribed gluten-free diet and the reasons for this were incorporated to describe the sample and find the relevant differences between groups.

Internal validation was evaluated via a feasibility study including ceiling and floor effects and calculation of Cronbach's alpha. The factorial structure was analyzed by studying the main components and varimax rotation with Kaiser normalization. No study has been made to date on stability and resistance to change.

Statistical analysis

The normal distribution fit was studied using the Kolmogorov-Smirnov test. As this was negative, the percentiles 25-75

and non-parametric tests like the Spearman coefficient and the Mann-Whitney U test were used to describe the median and the analysis of differences between samples. The level of significance was p < 0.05. A factorial analysis was made using main components analysis and varimax with Kaiser normalization.

Data were treated with the SPSS program version 21 and a level of statistical significance of 0.05 was used for all the analyses. The project was approved by the Aragon Clinical Research Ethics Committee.

RESULTS

Stage 1: Translation of the questionnaire into Spanish

After translation and back translation the final questionnaire was as appears in table II, and the original 1-5 scores proposed by the author were maintained. A comprehensibility trial was made with 10 diagnosed and treated patients with no new modifications being incorporated into the questionnaire.

Stage 2: Validation of the questionnaire

According to the CDAT and the criteria established by Leffler, 72.3% of the sample showed an excellent or good adherence to the gluten-free diet and 2.7% a moderate or bad adherence (*versus* 94.3% who declared in the self-informed question that they always or almost always complied and 59.8% who stated they always complied).

On analyzing the relevance of a factorial analysis we found a KMO of 0.648 and a significant Bartlett sphericity test, with p < 0.01.

The factorial structure shows three factors that account for 65.05% of the variance (Table III). The first factor, symptomatology, grouped questions 1 and 2; the second one, motivation and self-efficacy, questions 3, 4, 6 and 7, and the third one, question 5, mood.

The feasibility study shows that 100% of the interviewees answered all the questions. Floor effect was 4.4% and ceiling effect was 1%. An analysis of the internal consistency of each factor to the adaptation returned a moderate Cronbach alpha coefficient of 0.642 and 0.601. The third factor implied only one question.

As regards concurrent validity, the lack of equivalent tests led us to study the correlations of the questions with other questionnaires or dimensions included in them. This returned significant Spearman correlations: p < 0.01 for question 1 with the MCS factor of the SF12 (0.488), and with "health problems" of the CD-QOL (0.384). The second question showed significant correlations with the PCS component of the SF-12 (-0.334) and with the same dimension of the CD-QOL (-0.200). Question 3 showed significant Spearman correlations with the CeliacSE (-0.412) and with "limitations" of the CD-QOL (-0.301).

Table II. Spanish version of the CDAT

Ítem	1	2	3	4	5
1. ¿Te has encontrado con poca energía en las últimas cuatro semanas?	En ningún momento	En pocos momentos	En algunos momentos	En muchos momentos	En todo momento
2. ¿Has tenido dolores de cabeza en las últimas cuatro semanas?	En ningún momento	En pocos momentos	En algunos momentos	En muchos momentos	En todo momento
3. Soy capaz de seguir la dieta sin gluten cuando como fuera de casa	Totalmente de acuerdo	Parcialmente de acuerdo	Término medio	Parcialmente en desacuerdo	Totalmente en desacuerdo
 Antes de hacer algo, valoro cuidadosamente las consecuencias 	Totalmente de acuerdo	Parcialmente de acuerdo	Término medio	Parcialmente en desacuerdo	Totalmente en desacuerdo
5. No me considero un fracaso	Totalmente de acuerdo	Parcialmente de acuerdo	Término medio	Parcialmente en desacuerdo	Totalmente en desacuerdo
6. ¿Qué importancia tiene para tu salud la ingesta accidental de gluten?	Muy importante	Importante	Término medio/No estoy seguro	Poco importante	Nada importante
7. En las últimas cuatro semanas, ¿cuántas veces has comido a propósito alimentos que contenían gluten?	0 (nunca)	1-2	3-5	6-10	> 10

Table III. Rotated components matrix

	Component		
	1	2	3
1. ¿Te has encontrado con poca energía en las últimas cuatro semanas?	0.016	0.806	0.176
2. ¿Has tenido dolores de cabeza en las últimas cuatro semanas?	0.002	0.870	-0.023
3. Soy capaz de seguir la dieta sin gluten cuando como fuera de casa	0.622	-0.006	0.415
4. Antes de hacer algo, valoro cuidadosamente las consecuencias	0.680	0.062	0.221
5. No me considero un fracaso	0.211	0.119	0.781
6. ¿Qué importancia tiene para tu salud la ingesta accidental de gluten?	0.710	-0.113	-0.451
7. En las últimas cuatro semanas, ¿cuántas veces has comido a propósito alimentos que contenían gluten?	0.795	0.032	0.133

Method of extraction: Analysis of main components. Rotation method: Varimax with Kaiser normalization.

Question 4 correlated significantly with specific self-efficacy (-0.223), measured on the CeliacSE. Question 5 showed significant correlations with the GSES (-0.359), with "dysphoria" on the CD-QOL (-0.328) and with specific self-efficacy on the CeliacSE (-0.253). Questions 6 and 7 presented significant correlations with the CeliacSE scale of specific self-efficacy, with -0.169 and -0.225, respectively.

With the high adherence group, the self-informed question returned a significant Spearman coefficient of -0.359. The Mann Whitney U test showed significant differences in the CDAT between those who, according to the self-informed question, always follow the diet and other groups with lower adherence (p < 0.01). There were also significant differences in CD-QOL in the groups of high and low adherence in the CDAT (p < 0.01).

Discriminant validity showed that questions 1 and 2 did not present significant correlations with general self-efficacy (GSES). Question 3 showed no correlations with general quality of life or with general self-efficacy. Question 4 presented no significant correlations with general quality of life or with general self-efficacy, or with "limitations" and "health problems" of the CD-QOL. Question 6 showed no significant correlations with general quality of life or with general self-efficacy. Question 7 showed no significant correlations with general quality of life, with general or specific self-efficacy or with "limitations" or "inappropriate treatment" of the CD-QOL.

DISCUSSION

Psychosocial factors in adherence to a gluten-free diet have not been sufficiently studied and we therefore have few tools for any valid or reliable evaluation. Very few tools have been translated into Spanish and none for measuring adherence to a gluten-free diet. The Spanish version

	Quality of	f life SF 12	Quality of life CD-QOL			Self-efficacy			
Item	PCS	MCS	Limitations	Dysphoria	Health problems	Inappropriate treatment	Total	GSES	CeliacSE
1.	-0.371**	-0.488**	-0.386**	-0.355**	-0.334**	-0.228**	-0.447**	n/s	-0.174**
2.	-0.334**	-0.297**	-0.201**	-0.148*	-0.200**	-0.182**	-0.224**	n/s	n/s
3.	n/s	n/s	-0.301**	-0.292**	-0.222**	-0.155**	n/s	n/s	-0.412**
4.	n/s	n/s	n/s	-0.181**	n/s	-0.134*	n/s	n/s	-0.223**
5.	n/s	-0.300**	-0.257**	-0.328**	-0.223**	-0.194**	-0.286**	-0.359**	-0.253**

0.147*

-0.161

Table IV. Spearman correlations

n/s

n/s

n/s

n/s

7.

of Leffler's CDAT questionnaire presented here allows a quick, economic and accurate evaluation of this.

0.139*

n/s

-0 140*

To date, apart from the questionnaires, there are four ways of measuring adherence to gluten-free diets (26): a) direct questions; b) interviews with dieticians or experts; c) determining associated serology; and d) endoscopy. Logically, all these methods have their own problems of costs, sensitivity and reliability of lack of transcultural adaptation (13,27). Although endoscopy is the gold standard in celiac disease diagnosis a correct gluten-free diet is not always in line with the expected histological response (28). The criteria for determining what we consider to be a correct adherence to diet are far from enjoying any international consensus and are currently the subject of much research and controversy (29), which means that there are several perceptions of the disease and adherence to treatment, complicating thus transcultural comparisons.

The adaptation here presents good psychometric properties. Its construct validity is solid because the translation is consistent and the test maintains both the number of items and factors. It is observed that the dimensions fit well with those originally proposed by Leffer et al. (19) for symptomatology, self-efficacy and motivations, and perception of adherence to diet, although grouped as symptomatology, self-efficacy, motivation and perception of adherence and mood. The original scale formats are kept in the new version as are those of the items, so the excellent data provided by the original author can be assumed in the new version.

Although there are no similar questionnaires to study concurrent validity, this one is suitable as the questions show significant correlations with the dimensions related to general or specific self-efficacy, quality of life and "limitations", "health problems", "inappropriate treatment" and "dysphoria" on the CD-QOL. The tool suitably distinguishes other constructs with which there are no significant correlations.

The internal consistency shows excellent feasibility with all interviewees responding to all the questions and with good floor and ceiling effects below the widely accepted 15% threshold (30). The moderate levels of the Cronbach

alpha, for which we have comparable data in the original, may be due to the low total number of items, to its factorial structure or to the homogeneity of the sample, but they are sufficient for these initial stages of the research (21).

n/s

n/s

n/s

n/s

n/s

n/s

-0.169**

-0.225**

Most studies on the adherence to a gluten-free diet suffer from a lack of theoretical framework and an exact definition of what strict adherence is (11). We consider that Social Cognitive Theory (31,32) can provide this framework and that any tool for measuring adherence to a gluten-free diet should incorporate (as the CDAT does) the expectation of self-efficacy and the motivations for adherence, the associated symptomatology, knowledge of the disease, associated risk behaviors and the subjective perception of adherence. Any of these factors is insufficient in isolation but their combination affords a coherent proposal and it is this that possibly accounts for the good validity of the construct of this test.

The study has some limitations, of which the main one is that it uses self-informed data from questionnaires, with no medical data other than that declared therein, so there are no physiological correlates. These are present in the initial version of the tool developed by Leffler and make that tool solid.

There is also a clear bias towards associated patients with many years' experience of coping with the disease and good adherence to a gluten-free diet, which limits the analyses referring to the low adherence group.

It would, moreover, be useful to apply the questionnaire to other more heterogeneous samples in order to study its internal consistency in greater detail. No test-retest analysis was performed of the Spanish version nor of how change-sensitive it is; these issues should be addressed in future studies.

The tool has some important advantages, including the good properties of the original questionnaire in English, the results of this validation process and its transcultural adaptation, its easy application and the fact that there are currently few similar tools available in the world, and none in Spanish, so we can state that we have a useful tool for clinicians and researchers of celiac disease

^{**}p < 0.01; *p < 005; n/s: Not significant.

which offers an alternative to other more expensive or invasive ones.

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