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RESEARCH ARTICLE

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Psychometric properties of a questionnaire to measure adherence to treatment in patients with type 1 diabetes mellitus

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Abstract

Aim: To validate the psychometric properties of a questionnaire to measure adherence to treatment among people with type 1 diabetes mellitus and to evaluate its relationship with metabolic control.

Design: A cross-sectional study of 167 adult people with type 1 diabetes mellitus recruited from the Endocrinology Service of University Hospital Doctor Peset (Spain).

Methods: The validity of the content, construct and reliability of the instrument were evaluated and the results correlated with levels of glycosylated haemoglobin.

Results: The questionnaire was composed of 25 items and 5 dimensions, with a score of 25–150 points and an internal consistency of 0.92, according to Cronbach's coefficient α. The content of validity ratio and the construct (exploratory functional analysis, Kaiser–Meyer–Olkin index and Barlett's spherical test) were adequate. We observed a significant correlation between glycosylated haemoglobin levels and treatment adherence.

Conclusion: The questionnaire to measure adherence to treatment in type 1 diabetes mellitus is consistent, reliable and valid, showing an excellent association with degree of metabolic control.

KEYWORDS
adherence to treatment, adults, glycosylated haemoglobin, psychometric properties, type 1 diabetes mellitus

1 | INTRODUCTION

Type 1 Diabetes Mellitus (T1DM) is a chronic disease, with a worldwide prevalence ranging from 0.8 to 4.6/1,000 inhabitants (Forga, 2015). In order for therapy to have the desired benefits, the implication of the patient or, in the patient's absence, of a caregiver is vital. The objective is to achieve good individualized metabolic control, and thus avoid acute complications, prevent chronic conditions and increase patient's quality of life (Tasende et al., 2018). To maintain good glycaemic control, patients should

receive an appropriate daily dose of insulin, control their blood glucose, closely monitor their diet (including carbohydrate counting) and engage in regular physical activity (Lacomba-Trejo et al., 2018; Lohan et al., 2018).

Adequate adherence to treatment is fundamental in these patients in order to achieve the maximum possible effectiveness of the treatment (González et al., 2016). In addition, it ensures an adequate balance between the risk of serious complications and the risk associated with treatment intensification (Martyn-Nemeth et al., 2019).

The World Health Organization (WHO) defines compliance or adherence to treatment as the degree to which a patient's behaviour corresponds to medical recommendations or instructions for treatment (González & Mendoza, 2016; Salinas & Nava, 2012). Thus, measuring adherence to treatment is indispensable for detecting patients' needs and thus generating new strategies for timely and effective interventions (Achury, 2017).

It is difficult to determine an acceptable measure of adherence, as it is a multidimensional concept (Ortega Cerda et al., 2018) and can be evaluated using different methods (Pisano González & González Pisano, 2014). The most commonly used procedures to measure adherence to or compliance with treatment for T1DM are direct methods such as glycosylated haemoglobin (HbA1c) levels. However, while HbA1c is a good indicator of glycaemic control, it may not be a good indicator of behaviour; hence, a behavioural measure would complement HbA1c values. Amongst patients with elevated HbA1c values, a behavioural measure may identify ways to help patients improve their HbA1c. The most commonly used indirect methods are self-reporting, pharmacological records and structured questionnaires, the third of the three approaches being the most widely used due to their low cost, simplicity and practicality (Ho et al., 2009; Johnson et al., 2013; López Romero et al., 2016).

Currently, there are different indirect methods for measuring compliance to treatment, such as the Morisky-Green test and the Haynes–Sackett test, both of which are used to assess the degree of adherence to treatment for different chronic diseases (Rodríguez Chamorro et al., 2008; Val Jiménez et al., 1992). On the other hand, the Battle test assesses the degree of patient knowledge about different diseases (Rodríguez Chamorro et al., 2008), while the Prochaska–Diclemente test measures the degree of non-compliance with treatment with respect to the different stages of the disease (Rodríguez Chamorro et al., 2008) and the Hermes test and Herrera Carranza test are aimed at improving compliance with treatment (Jabary et al., 1999; Rodríguez Chamorro et al., 2009). In addition, the 'Brief Medication Questionnaire' (BMQ) evaluates beliefs and perceptions about the treatments of different diseases (Starsvad et al., 1999). Finally, 'The Medication Adherence Report Scale' (MARS) provides information on patient behaviour with respect to the treatment of different chronic diseases (Thompson et al., 2000).

However, these questionnaires tend to be very generic, as they cover different chronic diseases. Furthermore, few studies have addressed the relationship between adherence to treatment and metabolic control in diabetes, and most of them have been conducted among children, such as 'The Diabetes Behavior Checklist', 'Adherence in Diabetes Questionnaire', 'The Diabetes Behavior Rating Scale (DBRS)', 'The Diabetes Self-Management Profile (DSMP)' and the 'DSMP-self-report questionnaire (DSMP-SR)' which are designed to evaluate adherence among children with diabetes and their caregivers (Iannotti et al., 2006; Kristensen et al., 2012; Lohan et al., 2018; Wysocki et al., 2012).

The literature shows that there are many ways to assess adherence, but not specifically in people with T1DM. Each chronic disease has different needs and therapeutic goals, and so we set out to create a questionnaire to assess adherence to treatment in people with T1DM. The main potential use of this questionnaire is that it could enable a more specific assessment of the behaviour of these patients, since adherence to treatment in itself is a behaviour.

In this context, this study had two aims: (1) to analyse the reliability and validity of the content and construct of a structured questionnaire for measuring adherence to pharmacological and non-pharmacological treatment of people with T1DM; and (2) to use the questionnaire to evaluate the degree of adherence to said treatment and correlate it with levels of HbA1c in adult people with T1DM.

2 | MATERIAL AND METHODS

2.1 | Design

A cross-sectional study was developed using a methodological approach, with the aim of creating and validating an instrument to measure adherence to treatment among people with T1DM.

2.2 | Procedure

Patients were recruited voluntarily and consecutively from the Outpatient's Department of the Endocrinology and Nutrition Service of University Hospital Doctor Peset (Valencia, Spain) according to inclusion criteria (see below), and their anonymity was respected. As an indirect method, a questionnaire (initially composed of 27 items) was designed to measure adherence to treatment and was completed (in Spanish; in other words, validated in the Spanish population) by patients in a period of approximately 15–20 min. The translation process to maintain equivalence is back-translation. The questionnaire is translated from Spanish to English, back-translated into Spanish and then the first Spanish version is compared with the Spanish back-translation. The versions were then analysed by an expert committee to identify and correct, by consensus, any discrepancies in format, wording, meaning and relevance. To assess the degree of compliance with treatment, HbA1c, as a direct method and clinical indicator, was measured in plasma by reverse-phase high-resolution liquid chromatography.

2.3 | Participants

The sample was composed of 167 adult subjects of both sexes between 18 and 69 years of age and diagnosed with T1DM at least one year prior to the study. All people with type 2 diabetes mellitus (T2DM) and adults who showed comprehension difficulties when answering the questionnaire were excluded. The study was conducted according to the guidelines laid down in the Declaration of Helsinki and was approved by the Ethics Committee of University Hospital Doctor Peset. Written informed consent was obtained from all subjects.

2.4 | Instrument development

This instrument was developed as a self-administered questionnaire to assess adherence to treatment among T1DM people. We prepared a battery of items corresponding to clinical characteristics, and the behavioural demands on people with T1DM with respect to their adherence to pharmacological and non-pharmacological treatment were also considered (American Diabetes Association, 2019). The items were constructed taking in to account insulin administration, physical activity, eating habits and stress management. Based on expert judgement, a qualitative evaluation of the items and content validation was carried out by the experts in the field, including specialists in psychology and endocrinology and nursing staff. We eventually selected 27 items, which were considered appropriate to represent the dimensions of the treatment adherence construct.

The items were evaluated with 6 types of response on the Likert scale to categorize the responses in a graded manner and subsequently organize the individuals into groups. Subjects selected the score that best represented their outlook with respect to what was being measured. The frequencies were 1 = Never, 2 = Almost never, 3 = Rarely 4 = Frequently, 5 = Almost always and 6 = Always for items 1, 2, 4, 5, 6, 8, 10–16 and 21–27. In the case of items 3, 7, 9 and 17–20, the answers were inverted: 1 = Always, 2 = Almost always, 3 = Frequently, 4 = Rarely, 5 = Almost never and 6 = Never. The total score is the sum of the items ranged from 27 to 162 points, where a higher score is associated with greater adherence to treatment. Five ranges of adherence were established to assess the degree to which patients were adhering to treatment.

To organize individuals into groups, the following ranges of adherence were established: from 27 to 54 points (very poor adherence to treatment); from 55 to 81 points (poor adherence to treatment); from 82 to 104 points (satisfactory adherence to treatment); from 105 to 135 points (good adherence to treatment) and from 136 to 162 (very good adherence to treatment). These ranges were calculated by summing up the total response types (never, almost never, rarely, frequently, almost always and always).

In addition, ceiling and floor effects were studied for each item, considering that either of them existed when the percentage of responses grouped in the highest or lowest value of the scale was greater than or equal to 15% (Ware & Gandek, 1998).

2.5 | Data analysis

In order to determine the degree of understanding and the relationship between the items and the concept being measured, the content of the questionnaire was validated by seven experts in the field, including specialists in psychology and endocrinology and nursing staff (Carvajal et al., 2011). This type of validity is commonly known as expert judgement; evaluation is carried out in a qualitative way through of essential, acceptable but not essential and non-essential indicators (Tristán-López, 2008).

To evaluate the relevance of the items with respect to the questionnaire, and whether they sufficiently covered the dimensions related to the concept, a comprehensive assessment of the items was carried out by external experts. Based on the qualitative evaluation of the items by the experts, the content of validity ratio (CVR) formula was applied, as the only quantitative index to determine this type of validity. Calculations were made using the formula ne/*N*, where ne is the number of experts who have assessed the item as essential, and *N* is the total number of experts. The content validity index should have a value greater than the cut-off point of 0.58, which is considered acceptable according to Tristan's (2008) quantitative model.

Statistical analyses were performed using the SPSS® version 22 statistical program. Descriptive analyses of the patients' sociodemographic characteristics were carried out, and frequency statistics of clinical characteristics, adherence to treatment and HbA1c were recorded. Student *t*-tests were performed to analyse differences between men and women with regard to adherence to treatment and HbA1c. The Chi Square independence test was performed to assess differences between men and women and age groups in terms of treatment adherence and HbA1c ranges. With regard to the analysis of reliability, contingency (or internal consistency) of the questionnaire scale was assessed. Contingency describes the degree of interrelationship between the items and dimensionality (Cortina, 1993). For this purpose, Cronbach's alpha coefficient was calculated for the questionnaire items about treatment adherence (Beléndez Vázquez et al., 2007; Carvajal et al., 2011).

The validity of the construct was evaluated via a factorial analysis with the principal components method (varimax rotation) and factor extraction with the aim of distinguishing the dimensions (according to the theoretical framework) and relationships between the instrument items and calculating the measure of sample adequacy Kaiser–Meyer–Olkin (KMO) and Barlett's sphericity test (Beléndez Vázquez et al., 2007; Lacave Rodero et al., 2015).

To evaluate the degree of association between the indirect method and the direct method, we used the Chi Square independence test. The statistically significant value was estimated as $p < .05$, with a 95% confidence interval. We analysed the degree of relationship between the scales of the treatment adherence questionnaire and the different ranges of HbA1c. To this end, we established 6 ranges of HbA1c: <7% (53 mmol/mol); 7.1% (54 mmol/mol) to 7.5% (58 mmol/mol); 7.6% (60 mmol/mol) to 8% (64 mmol/mol); 8.1% (65 mmol/mol) to 8.5% (69 mmol/mol); 8.6% (70 mmol/

mol) to 9% 75 mmol/mol) and >9% (75 mmol/mol). Finally, to evaluate whether there was a correlation between the variables (HbA1c values and total score of the questionnaire), we used the Pearson correlation coefficient, estimating a significant value of $p < .05$.

3 | RESULTS

We included 167 individuals with T1DM and an average age of 41.3 ± 12.5 years, 51.5% of whom were men.

In terms of content validity and evaluation of the items by the experts, all the items were considered relevant to determine the dimensions of the construct; all were assigned a CVR value of 1, except for items 5 and 6, which obtained a CVR of 0.85. In this way, all 27 items obtained CVR values above the acceptability limit and thus can be considered relevant for determining adherence to T1DM treatment.

Internal consistency was evaluated in 153 subjects; the remaining 14 subjects were excluded, as they did not answer the questionnaire adequately. Some respondents gave two types of answers to the same item and others left some questions unanswered. Cronbach's alpha coefficient (α) was employed, with an initial result of α = .90, which increased to a final value of α = .92 when items 26 and 27 were omitted (with standardized factor loadings of less than 0.20; Table S1).

When the reliability analysis was performed once more with 25 items, a final value of α = .92 was obtained, which can be considered an excellent value (Table 1).

The total score of the questionnaire ranged from 25 to 150 points, of which five ranges of adherence were established: from 25 to 50 points (very poor adherence to treatment); from 51 to 75 points (poor adherence to treatment); from 76 to 100 points (satisfactory adherence to treatment); from 101 to 125 points (good adherence to treatment) and from 126 to 150 points (very good adherence to treatment; Table S2).

TABLE 1 Reliability of treatment adherence questionnaire items in patients with T1DM

Number		Cronbach's Alpha if item deleted
1	I take my insulin on schedule	.917
2	I administer my insulin with its corresponding adjustments according to Doctor's instructions	.915
3	For some reason I stop administering the amount of insulin indicated by the health personnel	.919
4	I follow the health personnel's instructions regarding my diet	.916
5	I avoid eating saturated fats (sausages. pastries. fried foods. precooked foods. whole milk. butter. etc.)	.921
6	I limit the consumption of flours and sugars in my diet	.918
7	For some reason I stop following the feeding recommendations of the health personnel	.916
8	I do the activity or physical exercise recommended by the health personnel	.919
9	For some reason I stop the activity or physical exercise without being indicated to do so by the health personnel	.918
10	I exercise at least 3 times a week for at least 30 min each time	.921
11	I do activities that help me manage situations of stress or tension	.921
12	When I am distressed. I do something to help me feel better	.920
13	I attend scheduled medical appointments	.918
14	I attend scheduled check-ups with the nurse	.917
15	I have my labs and other tests done when my health personnel providers tell me to do so	.919
16	I am aware of any sign or symptom that shows a worsening in my health (hypoglycaemia); for example. nervousness. anxiety. tremors. sweating. palpitations	.917
17	I need other people to remind me of the insulin guidelines	.917
18	I need other people to remind me to follow the diet ordered by the health personnel	.916
19	I need other people to remind me to do the exercise recommended by the health personnel	.917
20	If my health does not improve rapidly. I stop exercising	.920
21	I can handle stressful or tense situations	.918
22	I am able to change harmful behaviours to improve my health	.916
23	I comply with the treatment. even if it seems complicated to me	.914
24	I do what I can to get better when I am sick	.915
25	I am able to follow the recommendations given to me by the health personnel	.916
Cronbach's Alpha total		.921

The next step was to perform an exploratory factor analysis to establish how many dimensions or factors the questionnaire contained and whether or not there was a relationship between the items. The KMO sample adequacy measurement value was 0.878, and the relationship between the variables was considered reliable, with a significance level of $p < .001$, thus confirming a correlation between the variables. The exploratory factorial analysis with varimax rotation revealed 5 dimensions, with an auto-value greater than 1 and with 65.3% of total variance explained by each factor (Table 2).

Table 3 shows the matrix of main components after the rotation of each of the items. We can observe the grouping of the items in the different factors, corresponding to factor 1: insulin administration and medical visits (items 1, 2, 13, 14, 15 and item 23), factor 2: involvement in treatment (items 3, 7, 17, 18, 19 and item 20), factor 3: psychological variables (items 12, 16, 21, 22, 24 and item 25), factor 4: physical exercise (items 8, 9, 10 and item 11) and factor 5: nutritional guidelines (items 4, 5 and item 6). Regarding the 'floor effect' of the answers, item 11 of factor 4 ('physical exercise') had a minimum score of 18.2% of the cases. And with respect to the 'ceiling effect', the maximum score was reached in more than 15% of cases in 6 items of factor 1 ('insulin administration and medical visits'), 6 items of factor 2 ('involvement in treatment'), 3 items of factor 3 ('psychological variables'), 1 item of factor 4 ('physical exercise') and 1 item of factor 5 ('nutritional guidelines'). Neither of the two effects was present in 7 items.

The internal consistency of the different subscales of the questionnaire (factors) was as follows: for the subscale of insulin administration and medical visits, a value of $\alpha = .89$; for the subscale involvement in treatment, a value of $\alpha = .82$; for psychological variables, a value of $\alpha = .81$; for the subscale physical exercise, a value of $\alpha = .81$ and, finally, for nutritional guidelines, a value of $\alpha = .71$, the lowest value obtained, which was acceptable nonetheless.

After analysing the results according to sex, no statistically significant differences were found in relation to total questionnaire score ($p = .855$) or HbA1c ($p = .200$). However, significant differences were detected in the case of total score according to age, with greater adherence observed in subjects over 35 years old ($p = .004$). In contrast, no significant differences in HbA1c levels were observed in relation to age ($p = .306$).

According to the results of the questionnaire, 47.7% of patients showed good adherence to their treatment and 32.7% very good

TABLE 2 Rotated component matrix extraction method: principal component analysis of patients with T1DM

	Initial Eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	9.490	37.959	37.959	9.490	37.959	37.959	3.960	15.840	15.840
2	2.665	10.660	48.619	2.665	10.660	48.619	3.874	15.495	31.335
3	1.694	6.777	55.396	1.694	6.777	55.396	3.218	12.870	44.205
4	1.317	5.268	60.664	1.317	5.268	60.664	2.894	11.576	55.781
5	1.156	4.623	65.288	1.156	4.623	65.288	2.377	9.506	65.288
6	0.973	3.892	69.180						
7	0.928	3.713	72.893						
8	0.829	3.315	76.208						
9	0.754	3.016	79.224						
10	0.641	2.562	81.786						
11	0.530	2.122	83.908						
12	0.489	1.956	85.864						
13	0.470	1.880	87.744						
14	0.437	1.750	89.493						
15	0.388	1.551	91.044						
16	0.371	1.486	92.530						
17	0.329	1.316	93.846						
18	0.275	1.102	94.948						
19	0.269	1.075	96.023						
20	0.241	0.965	96.988						
21	0.205	0.821	97.809						
22	0.162	0.648	98.457						
23	0.149	0.597	99.053						
24	0.131	0.524	99.578						
25	0.106	0.422	100.000						

TABLE 3 Rotation method: Varimax with Kaiser normalization in patients with T1DM

	Components				
	1. Insulin administration and medical visits	2. Involvement in treatment	3. Psychological variables	4. Physical exercise	5. Nutritional guidelines
Item1	0.453	0.413	0.123	0.020	0.398
Item2	0.615	0.354	0.299	0.117	0.286
Item3	0.283	0.453	0.110	0.007	0.164
Item4	0.312	0.333	0.373	0.155	0.389
Item5	0.138	−0.028	0.091	0.041	0.853
Item6	0.033	0.148	0.240	0.162	0.809
Item7	0.140	0.455	0.338	0.200	0.433
Item8	−0.023	0.130	0.150	0.836	0.192
Item9	0.152	0.299	0.195	0.672	−0.080
Item10	0.033	0.095	0.036	0.876	0.131
Item11	0.026	−0.034	0.333	0.638	0.060
Item12	−0.020	0.005	0.647	0.312	0.143
Item13	0.879	0.180	0.111	0.097	0.037
Item14	0.886	0.225	0.115	0.075	0.019
Item15	0.847	0.133	0.100	−0.078	0.087
Item16	0.359	0.341	0.485	−0.030	0.135
Item17	0.307	0.731	0.156	0.032	0.071
Item18	0.273	0.757	0.327	−0.043	0.095
Item19	0.103	0.819	0.143	0.213	0.010
Item20	0.066	0.628	−0.077	0.364	−0.008
Item21	0.114	0.132	0.779	0.075	0.050
item22	0.204	0.157	0.688	0.237	0.189
Item23	0.479	0.427	0.436	0.204	0.309
Item24	0.325	0.412	0.538	0.194	0.243
Item25	0.397	0.363	0.451	0.144	0.261

adherence, while 16.3% showed satisfactory adherence and 3.3% showed poor adherence (Figure 1a).

Regarding the metabolic control of patients, the average HbA1c was 7.7 (61 mmol/mol) ±1.2%. Furthermore, when we analysed HbA1c values as categorical variables (Figure 1b), a total of 24.8% of subjects presented HbA1c values below 7% (53 mmol/mol), and 24.2% presented values between 7.1% (54 mmol/mol) and 7.5% (58 mmol/mol). 20.5% of our subjects obtained of HbA1c values between 7.6% (60 mmol/mol) and 8% (64 mmol/mol), and 13% between 8.1% (65 mmol/mol) and 8.5% (69 mmol/mol). As for the highest HbA1c values, 8.1% and 9.3% of subjects were in the range of 8.6% (70 mmol/ mol) to 9% (75 mmol/mol) and >9.1% (75 mmol / mol), respectively.

When we analysed the relationship between HbA1c and adherence to treatment, a statistically significant negative correlation was detected ($r = -.440$; $p < .001$; Figure 2a). Finally, when evaluating the relationship between HbA1c ranges and the degree of adherence to treatment, we observed a statistically significant association, with a value of $\chi^2 = 59.4$ and a significance level of $p < .001$ (Figure 2b).

4 | DISCUSSION

This study highlights the need to incorporate into clinical practice a new, indirect and specific method to evaluate the degree of adherence to treatment among people with T1DM. In this context, insulin administration, nutritional aspects, physical exercise and stress or other psychological factors are variables that can have an impact on non-compliance with treatment due to the behavioural demands made on patients and the complexity that this requires.

Our questionnaire was designed according to standard quality criteria, and rendered good statistical results. To assess the questionnaire's reliability, we analysed the degree of relationship between items within the same scale and verified the common concept among said items (adherence to treatment). A good statistical value was observed according to Cronbach's alpha coefficient, which suggested a very high correlation (Carvajal et al., 2011).

Regarding the validity of the instrument, the KMO index and Barlett's sphericity test rendered a value of 0.87 and demonstrated statistical association between the variables. A variance of 65.8% was explained with a 5-dimensional factor structure. Therefore,

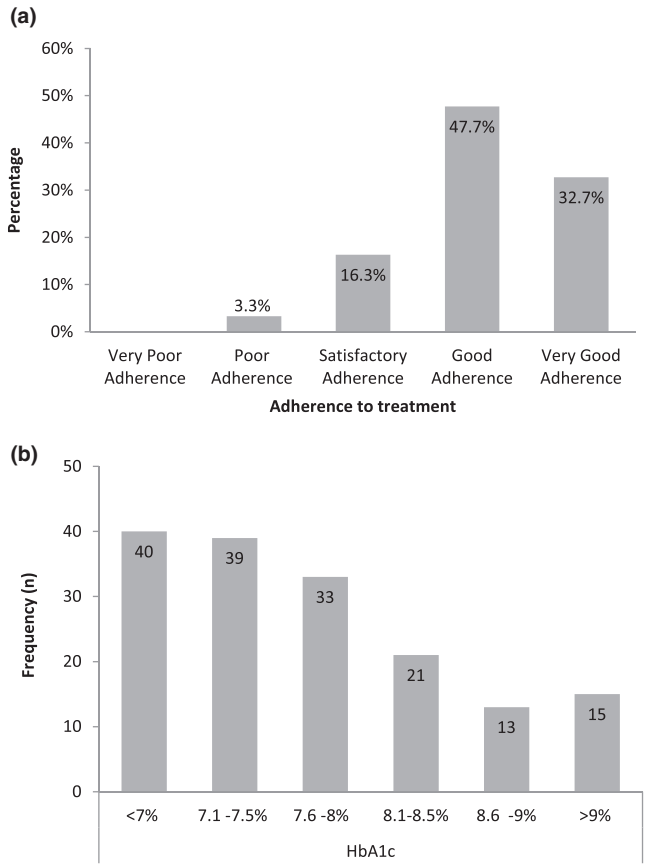

FIGURE 1 (a) Degree of adherence to treatment in people with T1DM. (b) Metabolic control of people with T1DM according to HbA1c levels

we could assume that the items were related to the construct that we were measuring with the questionnaire (González et al., 2016; Pisano González & González Pisano, 2014).

Currently, we do not have access to specific and validated questionnaires that evaluate adherence to treatment of T1DM. Most of the questionnaires available at present are limited to quantifying pharmacological aspects (Rodríguez Chamorro et al., 2008) and qualifying patients as adherent or non-adherent via already existing direct methods (such as HbA1c), without taking into account other influential variables at a given time (Ho et al., 2009; López Romero et al., 2016).

To a lesser extent, there are validated questionnaires for use with Spanish-speaking populations, such as 'The Self-Care Inventory' (SCI-R), which was designed to evaluate the degree of adherence to self-care in T1DM and T2DM (Jansá et al., 2013). It was adapted from the self-care inventory (SCI) developed for children and adolescents and updated for use in adults with T1DM and T2DM (Weinger et al., 2005). The approach to therapeutic objectives and recommendations with respect to self-care cannot be indicated to the same extent for T1DM and T2DM, since they are two different entities (American Diabetes Association, 2019). Therefore, these questionnaires do not evaluate, from a psychometric perspective, adherence to treatment of T1DM exclusively.

Adherence to treatment varies according to the class of drugs and behavioural demands on the patient, so there should be careful consideration of these differences in order to contribute to improved outcomes (McGovern et al., 2018).

The percentage of T1DM people with very good and good adherence to treatment according to the ranges and results of the questionnaire accounted for 80.4% of the sample. These figures are higher than those obtained nationally in people with T1DM, when less than 30% achieved optimal glycaemic control (Sastre et al., 2012). To achieve good glycaemic control, guidelines for treatment with insulin must be accompanied by self-adjustment of insulin via carbohydrate consumption, capillary glycaemia levels and regular physical activity (Jansá & Vidal, 2009; Sastre et al., 2012).

Half the patients in our study displayed acceptable HbA1c values (<7.5%), and only a small part of the sample showed levels above 8.6%. Interestingly, 4 patients with very good adherence rendered HbA1c values >8.6%. It is possible that the perception that these patients have of their adherence to treatment creates a discrepancy. The association between glycaemic control and adherence to treatment is imperfect, and while HbA1c is a good indicator of glycaemic control, it may not be a good indicator of behaviour. This is an important issue for future research. We frequently observe studies in which HbA1c averages differ from those recommended by scientific societies (López Romero et al., 2016; Sastre et al., 2012), thus resulting in a difference between said recommendations and clinical data obtained in the T1DM population (Sastre et al., 2012). Therefore, adapting and improving the guidelines and individualized objectives of patients is a fundamental aim if an optimum glycaemic control is to be achieved (Seabury et al., 2014). In this context, we consider it essential to combine both methods (direct and indirect) to obtain a more real and adjusted measure of patients' adherence to their therapeutic regime (Pagès-Puigdemont & Valverde-Merino, 2018). Our aim with this study was to identify the degree of patient self-control and management of their disease in order to comprehend and intervene in this complex and multidimensional aspect.

We believe it is important to identify non-compliant patients and to avoid assuming a direct relationship between poor control and poor adherence to treatment. The variables and/or patterns that influence adherence to treatment need to be identified in order to modify undesirable behaviour and improve glycaemic control. That is, among patients with elevated HbA1c values, a behavioural measure could be effective in identifying ways to help these patients improve HbA1c assessment. This would increase the effectiveness of therapeutic interventions and reduce the occurrence of comorbidities and complications associated with this disease, both acute and chronic (Oliveira & Trujillo, 2017; Orozco-Beltrán et al., 2016; Sastre et al., 2012).

Nevertheless, the statistical relationship between HbA1c levels and the degree of adherence to treatment revealed by our questionnaire reveals an association between these two variables, as a reduction in HbA1c values correlated with higher adherence scores.

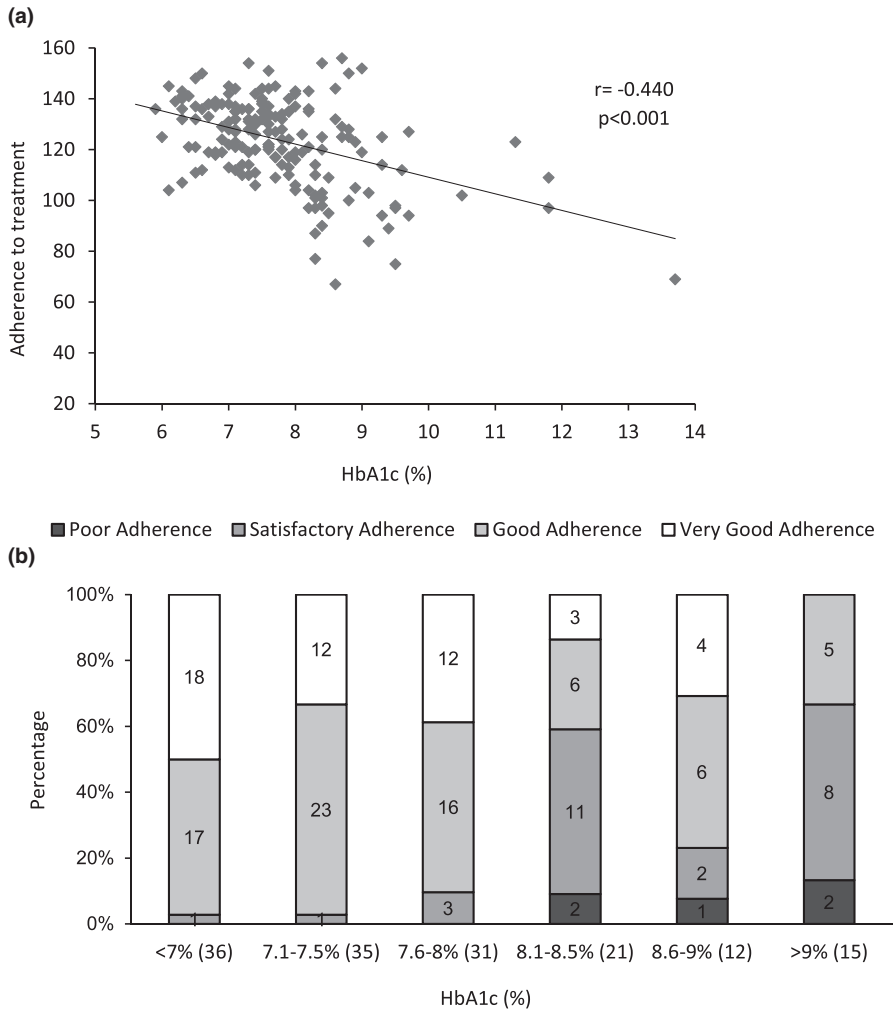

FIGURE 2 (a) Correlation between HbA1c and adherence to treatment in people with T1DM. (b) Percentage of adherence to treatment in people with T1DM according to HbA1c ranges

This study presents some limitations that need to be taken into account. First, we must bear in mind that the results obtained with an indirect method are subjective values, so it is possible to overestimate compliance and only partially identify non-compliance, since the patient responds according to his/her glycaemic control, beliefs and needs (Beléndez Vázquez et al., 2007).

A second limitation derives from the selection of patients, taking into account that they were attending scheduled endocrinology appointments, educational sessions about diabetes and/or psychological consultations. This could have resulted in bias in the completion of the questionnaire, as the subjects would have been more involved in the control of their disease from the outset.

As a final limitation, we have not performed external validity and calculated convergent validity due to the lack of specific questionnaires for assessing adherence to treatment in adult people with T1DM.

The main strength of our work is that it proves the validity of an instrument which, to our knowledge, has not yet been developed to quantify adherence to treatment in people with T1DM, at a time when there is as yet no gold standard that allows this concept to be evaluated (Gomes-Villas Boas et al., 2014; Orozco-Beltrán et al., 2016).

Our end aims are to both minimize the impact of lack of adherence to treatment and to adapt clinical strategies and interventions in order to achieve an improvement in patient quality of life and a reduction in the acute and chronic complications related to diabetes. In contrast to studies that focus exclusively on pharmacological aspects, there is a need for a comprehensive approach that takes into consideration the behaviours associated with T1DM and which addresses the need for a structured educational intervention in which the active role of patients and health professionals is essential to improve patient self-management and the effectiveness of treatment.

5 | CONCLUSION

Our results confirm the validity of our questionnaire for evaluating adherence among people with T1DM and establish a direct relationship between poor control and poor treatment adherence. It is not sufficient to detect and measure adherence by focusing only on direct clinical values; instead, it is necessary to employ both direct and indirect methods. We can conclude that our questionnaire for measuring adherence to treatment in people with T1DM is consistent, reliable and valid.

There is a clear need to incorporate specific resources into clinical practice to assess the degree of adherence to different chronic diseases, including T1DM, in order to improve clinical and sociosanitary outcomes.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

The authors' responsibilities were as follows: CG-DV, JFM-E, ES, IM-C, CM, AH-M and CB conducted the study. CG-DV, JFM-E, ES and CB provided overall supervision and the follow-up of the volunteers in the study. CG-DV, IM-C and CB performed the data analyses and collected data. CM, AH-M and IM-C assisted in the design and provided support throughout the course of the trial and analysis. CG-DV, JFM-E, ES, IM-C, CM, AH-M and CB performed statistical analyses, interpreted the data and prepared the manuscript. AH-M and CB was responsible for its final content. All authors read and approved the final version of the manuscript.

ETHICAL APPROVAL

The authors state that the procedures followed were in compliance with the regulations of the responsible Clinical Research Ethics Committee and the World Medical Association and the Declaration of Helsinki. They declare that they have complied with their site's protocols for the publication of patient data and that all patients included in the study have received sufficient information and have given their written informed consent to participate in the study. The authors have obtained the informed consent of the patients and/or subjects mentioned in the article. The author for correspondence retains that document or Right to Privacy and Informed Consent.

DATA AVAILABILITY STATEMENT

Data available on request from the authors. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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