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Health-related quality of life in diabetes mellitus and its social, demographic and clinical determinants: A nationwide cross-sectional survey

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This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. **Aims and objectives:** To investigate health-related quality of life in a representative sample of adults with diabetes mellitus in Spain, as well as its clinical and sociode-mographic determinants.

Background: Diabetes mellitus is a chronic disease causing considerable morbidity and mortality worldwide, resulting in an impaired quality of life in affected people.

Design: A nationwide cross-sectional study, based on an online survey and carried out between February–March 2016, was performed on diabetic subjects recruited through diabetic patients' organisations.

Methods: A validated Spanish-language version of the self-administered Diabetes Quality of Life questionnaire was used, with 0 being the worst and 100 the best QoL level. Determinant factors of health-related quality of life were assessed with the aid of multivariate analysis to control for confounding factors.

Results: The responses provided by 456 patients (52.4% being women) revealed an overall mean score of 66.4 ± 13.3 . *Social/vocational worries* and *diabetes-related worries* were the dimensions with the highest (74.3 \pm 20.1) and lowest (61.1 ± 20.6) scores, respectively. Younger age, female gender, having no studies and poor glycaemic control were all independent determinants for an impaired overall health-related quality of life, with most of these factors having a higher impact than the dimensions *negative impact of therapy on daily life, satisfaction with therapy* and *diabetes-related worries*. Married (or equivalent) subjects had better scores in the *diabetes-related worries* dimension. The perception of health-related quality of life progressively worsens as glycaemic control deteriorates and with an increased number of disease complications. Most of the associations did not vary significantly with the type of diabetes mellitus.

Conclusion: Overall health-related quality of life perception in the Spanish diabetic population is moderate and depends on several sociodemographic factors. Adequate glycaemic control to avoid disease complications improves perception.

Relevance to clinical practice: The results can help health professionals to develop strategies to promote diabetic patient self-care, in order to improve the metabolic control of the disease and avoid its complications, as a therapeutic goal towards an improvement in health-related quality of life perception.

KEYWORDS

diabetes mellitus, health-related quality of life, quality of life, Spain

1 | INTRODUCTION AND BACKGROUND

Diabetes mellitus (DM) has acquired a global dimension. It is estimated that 6% of the population in Western societies suffer from diabetes. There has been a rapid increase in the number of diabetic patients in recent years, to the extent that 10% of people aged over 60 years suffer from it, with an increase of 3% in the number of diabetics for each decade over the fifth decade of life. In addition, the number of diabetic people is expected to double by 2025. Anyone can be affected by diabetes, no matter what their age or location (Peyrot et al., 2013).

It is recognised that for a given prevalence of diagnosed DM in a population, there is another similar or twofold number of patients with undiagnosed diabetes (Peyrot et al., 2013). In studies carried out in recent years in Spain, the prevalence of DM in the adult population ranged between 10%–15% (Valdés, Rojo-Martínez, & Soriguer, 2007). A total of 5.3 million adults in Spain had DM in 2013, which represents 13.8% of the population (Soriguer et al., 2012), and is parallel with the forecasts of increase on a worldwide scale.

Diabetes mellitus is a chronic disease which causes considerable morbidity and mortality worldwide (Wild, Roglic, Green, Sicree, & King, 2004). As a consequence, DM requires efforts in therapeutic compliance, including dietary and other lifestyle modifications and a frequent need for insulin and other hypoglycaemic drugs (Sánchez Lora, Téllez Santana, & Gijón Trigueros, 2010). Together with an adequate glycaemic control and the prevention of chronic complications, maintaining adequate quality of life (QoL) level constitutes one of the most relevant patient-reported outcomes (PROs) in the treatment of diabetic people. PROs are increasingly important variables in evaluating the impact of chronic disease; the most commonly used being some subjective constructs based on symptoms and patient perception of health-related quality of life (HRQoL). HRQoL is a complex, multidimensional construct that is assessed with the aid of various instruments, usually in the form of questionnaires. As with other chronic conditions (Czaikowski, 1998), the interest in assessing HRQoL in DM has expanded in recent years to constitute one of the most decisive aspects of evaluating the impact of the disease, with changes in HRQoL now being considered an integral outcome of therapeutic interventions in DM, as it is for many chronic diseases (Williet, Sandborn, & Peyrin-Biroulet, 2014).

Generic instruments originally used to measure HRQoL have given way to more specific questionnaires for different chronic conditions. In the case of diabetes, several PRO measuring instruments have been developed since the late 1980s to explore HRQoL, both from a general perspective and, more recently, from a diabetes-specific perspective (El Achhab, Nejjari, Chikri, & Lyoussi, 2008).

What does this paper contribute to the wider global clinical community?

- For the first time in Spain, quality of life results for people with diabetes in the general population were shown, where previous studies have been limited to hospital environments.
- Sociodemographic aspects were major determinants of health-related quality of life (HRQOL) of the diabetic population, with type of diabetes, duration of the disease or presence of concomitant diseases having no significant impact on HRQoL perception.
- HRQoL perception improved in patients with adequate glycaemic control by adhering to therapy; besides avoiding complications from disease, metabolic control also contributed towards an increase in the overall HRQoL level in diabetes mellitus.

Evidence shows that patients with diabetes have a lower QoL than nondiabetic individuals (Thommasen, Berkowitz, Thommasen, & Michalos, 2005). Using instruments to measure HRQoL researchers are able to make comparisons between different stages in the evolution of the disease and severity of the disease and different moments in the development of patients suffering from chronic disease. Diabetes-specific HRQoL questionnaires include aspects of health that are considered to pertain to this disease and to be most important to diabetic patients, in order to show the impact of this disorder on patients' functionality and well-being. Diabetes-specific instruments have the advantage over generic ones in that they can detect small changes with clinically relevant differences, as well as provide insights into the specific mechanisms of self-care in diabetes (Bradley, 2001).

In Spain, generic questionnaires have been used to assess HRQoL in patients with diabetes (Mata Cases, Roset Gamisans, Badia Llach, Antoñanzas Villar, & Ragel Alcázar, 2003). However, it is considered appropriate to complement these results with HRQoL assessments obtained using specific instruments (Botija Yagüe, Lizán Tudela, Gosalbes Soler, Bonet Plá, & Fornos Garrigós, 2007). Millan, Reviriego, and Del Campo (2002) validated the Spanish version of the Diabetes Quality of Life (EsDQoL)-specific questionnaire in 2002 (Reviriego,1996). However, limited research has been carried out with this instrument in Spain and has been restricted to comparing satisfaction and HRQoL of patients with type 1 DM treated with continuous

-WILEY-Clinical Nursing

4214

subcutaneous insulin infusion to those receiving multiple daily insulin injections (Pérez-García, Goñi-Iriarte, & García-Mouriz, 2015).

Several researchers have attempted to analyse what determines an impaired QoL in patients with DM, with some inconsistencies found among the several studies available. Most researchers have assessed the influence of demographic variables in determining HRQoL, without considering the potential influence of treatment adherence, comorbidities and complications of DM on QoL perceptions, especially among females, who show a higher prevalence of DM as well as an increased susceptibility to several immunemediated diseases (Chew, Mohd-Sidik, & Shariff-Ghazali, 2015; D'Souza, Venkatesaperumal, Ruppert, Karkada, & Jacob, 2016). In addition, previous assessments of HRQoL have been predominantly carried out on patients recruited in healthcare environments (Alvarado-Martel et al., 2015). While they might accurately reflect the well-being perception of the subjects they are administered on, they could not adequately reflect the overall perception of HRQoL among the general population of diabetic patients, which includes subjects with various ranges of adherence to treatment and medical followup, and varying degrees of contact with healthcare systems.

The goal of this study was to determine HRQoL levels in a representative sample of Spanish adults with DM along with its determinant factors. Specifically, we aim to (a) find out the overall QoL and underlying dimensions of Spanish adult diabetic patients; (b) identify the main sociodemographic and clinical factors related to HRQoL in diabetics; and (c) determine the influence that complications from DM and comorbid conditions have on overall HRQoL.

2 | METHODS

2.1 | Study design and study setting

A cross-sectional, descriptive, observational study was carried out between February–March 2016 on an intentionally nonprobabilistic sample of Spanish adults (aged over 18 years) with DM (irrespective of type), which intended to be representative of the national adult diabetic population.

The criteria used to define DM were that the patient had been diagnosed by a medical specialist and was affiliated with a regional association of diabetic patients that was part of the Federation of Spanish Diabetics in Spain (*FEDE*, in its Spanish abbreviation). The need to document the diagnosis and to pay association dues was considered an indication of a low risk of selection bias. All diabetic patients who correctly filled out the self-administered questionnaire forming the basis of this study were included. Subjects under 18 years of age and women being pregnant at the time of the survey were excluded from the research.

2.2 | Information sources and study variables

We designed an electronic data collection booklet that included an explanation of the aims and goals of our study and which guaranteed anonymity and confidentiality for all study subjects, along with other common ethical concerns. The booklet, together with the questionnaires in a single set, was submitted to a responsible person at every DM association in each of the 17 autonomous regions of Spain. Questionnaire sets were then forwarded to the several integrating DM associations via social media networks, where the research was advertised and members were requested to fill out the survey voluntarily.

The anonymous questionnaire sets compiled demographic information, clinical data, disease associations and complications, as well as potential determinants for HRQoL.

The main dependent variable was HRQoL level, which was assessed with the aid of a specific questionnaire, the Diabetes Quality of Life (DQoL) (Jacobson, Groot, & Samson, 1995), translated into Spanish and validated for use in this language (EsDQoL) (Robles García, Cortázar, Sánchez-Sosa, Páez Agraz, & Nicolini Sánchez, 2003). The EsDQoL consists of 46 items which patients rank on 5-point Likert scales ranging from 1-5 (1 never; 5 all the time). Four subscales measure satisfaction with therapy (15 items, range 15-75), negative treatment impact on daily life (20 items, range 20-100), social/ vocational worries (seven items, range 7-35) and diabetes-related worries (four items, range 4-20). The DQOL score is the algebraic sum of the four scores and ranges between the minimum value of 46, corresponding to the highest HRQoL level, and a maximum of 230, corresponding to the lowest HRQoL level. However, several authors recommend that this scale and its dimensions be transformed into a 0-100 scale, where 0 is the worst and 100 the best QoL score, according to widely accepted methodology based on the Medical Outcome Survey (Mateos Sánchez, 2013).

2.3 Sample size calculation

The number of patients necessary to obtain an adequate representation of the Spanish population was calculated taking into consideration the total number of people between 18–75 years of age living in Spain at January 1, 2016 (*n* = 38,978,461), a confidence level of 95% and an absolute error of 5%. As the primary dependent variable was a multiresolved questionnaire and the current prevalence of DM in Spain is unknown, we chose to use a DM prevalence of 50%, which would require a larger sample size. Thus, a minimum of 385 study subjects was needed to carry out this study with statistical adequacy. However, the research team chose to recruit the largest possible number of subjects during the study period.

2.4 Statistical analysis

Absolute frequencies were expressed with descriptive statistics, whereas relative frequencies were used for qualitative variables. Mean \pm standard deviation (*SD*) values were used for quantitative variables if they presented a normal distribution. Otherwise, median values \pm interquartile ranges were employed. For the bivariate analysis, the Student *t*-test and analysis of variance (ANOVA) were used. When the number of subjects per category was small, the Kruskal–Wallis nonparametric test was used.

Journal of Clinical Nursing-WILEY

At last, to control for any confounding bias, multivariate analyses were carried out with multiple linear regression, where the dependent variable was the score for the overall quality of life index and that of the four dimensions that comprise it. The independent variables were those selected by statistical criteria for demographic variables and by clinical criteria for clinical characteristics and disease associations and complications. The sPSS v. 20.0 software package was used for all statistical analyses.

2.5 | Ethical aspects

This observational study was developed based on anonymous data and was designed in accordance with the Declaration of Helsinki, as promoted by the World Medical Association (WMA). Approval by the Ethics in Research Committee at Hospital General La Mancha Centro was granted before starting the research.

3 | RESULTS

3.1 | Participants

We included a total of 456 diabetic people, who filled out the questionnaire set correctly, including 239 (52.4%) women and 217 (47.6%) men, with an average age of 40.8 ± 13.3 years (range: 18–78 years). Main demographic characteristics of the study population are summarised in Table 1. All the Spanish autonomous regions were represented, with the exception of the autonomous city of Ceuta. Distribution of subjects according to place of residence is available in Supporting Information Table S1.

3.2 | HRQoL levels in diabetic patients

The average HRQoL level in our sample, as assessed with the EsD-QoL questionnaire, was 66.4 ± 13.3 . Notably, EsDQoL scores were significantly worse for women than for men (63.9 vs. 69, respectively; p < 0.001). An impaired HRQoL in women remained significant for all the dimensions that constitute the EsDQoL score (Table 1).

Health-related quality of life levels varied significantly between the different dimensions making up the EsDQoL scale, with *social*/ *vocational worries* being the dimension that obtained the highest mean score of 74.3 \pm 20.1, meaning that this dimension had the least impact. This was followed by *negative impact of therapy on daily life*, which had an average rating of 66.2 \pm 17.6; *satisfaction with therapy*, with a score of 64.1 \pm 17.6; and lastly, *diabetes-related worries*, which had the lowest rating, namely 61.1 \pm 20.6 points, thus impacting the most on QoL perception. The distribution of each dimension is represented in Figure 1.

Bivariate analyses demonstrated statistical association between all sociodemographic factors analysed (including age, sex, occupation, education level and marital status) and one or more dimensions of HRQoL. Due to the low number of subjects in some categories of the "occupation" and "marital status" variables, they were grouped in two new dichotomous variables to be incorporated into the multivariate analysis. Additional variables "employment expectation" and "married or equivalent" grouped unemployed plus students and coupled subjects, respectively (Table 1).

With regard to clinical characteristics, our sample was composed of 366 (80.0%) patients with type 1 diabetes and 72 (15.4%) patients with type 2 diabetes, with the remaining 18 (4.6%) patients reporting a different type (comprising of those secondary to pancreatectomy, maturity onset diabetes of the young [MODY-type] or latent autoimmune diabetes in adults [LADA-type]). Mean ± SD evolution time of diabetes was 17.5 ± 11.6 years, overall. The most commonly used treatment was a multiple daily insulin injection regimen in 300 (65.8%) subjects, followed by continuous subcutaneous insulin infusion in 76 (16.7%) patients. Only 32 people (7.0%) were receiving oral antidiabetic drugs. Glycosylated haemoglobin concentration levels were below 7% in 222 (48.7%) patients, while 42 (9.2%) reported having presented at least one hypoglycaemic episode with transient loss of consciousness over the past year. As expected, bivariate analysis showed statistically significant associations between the type of diabetes and the treatment prescribed, in the sense that patients with type 1 diabetes showed worse QoL levels in the social/vocational worries dimension. An injected treatment also impacted negatively on overall HRQoL and on several specific dimensions. Both aspects, together with glycosylated haemoglobin levels, showed associations with the overall EsDQoL score and some of its dimensions. No association was found between EsDQoL scores and having suffered hypoglycaemic episodes or time of evolution of DM (Table 2).

Ninety-seven patients (21.3%) reported having suffered at least one complication of DM, the most frequent being diabetic retinopathy, which was reported by 70 (15.4%) patients. Diabetic neuropathy (mainly presented as pain in lower limbs) was reported by 28 (6.1%) patients. Only 12 patients (2.3%) reported macrovascular complications from DM.

Comorbidities of DM were reported by 109 (23.9%) respondents, the most common being hypertension, which was present in 64 patients (14%), and obesity, which was present in 54 (11.8%) patients. Complications or comorbidities were not related with the overall EsDQoL score, despite nephropathy, macrovascular diseases, neuropathy, hypertension and obesity having worse scores in the *social/vocational worries* dimension (Table 3).

3.3 | Health-related quality of life in diabetes mellitus

Multivariate analysis showed that patients' age was directly and significantly associated with HRQoL level in both the overall EsDQoL score and that of the *social/vocational worries* dimension; older patients showed better QoL scores. Patients' gender was associated with both the *negative impact of therapy on daily life* and *diabetesrelated worries* dimensions in multivariate analysis, with women exhibiting worse QoL in both cases. A statistically significant association between education level and HRQoL was also found for the **TABLE 1** Sociodemographic characteristics of the overall population who participated in this research and quality of life score according to the EsDQoL questionnaire

Sociodemographic variables	N = 456 n (%)	Overall EsDQoL Mean (SD)	Satisfaction with therapy Mean (SD)	Negative impact of therapy on daily life Mean (SD)	Social/vocational worries Mean (SD)	Diabetes-related worries Mean (SD)
Overall quality of life scores		66.4 ± 13.3	64.1 ± 17.6	66.2 ± 17.6	74.3 ± 20.1	61.1 ± 20.6
Age (years) Mean (SD)	40.8 (13.3)					
18–20	14 (3.1)	57.9 (13.9)	59.8 (20.7)	61.8 (12.6)	48.2 (16.0)	48.2 (25.2)
21–30	97 (21.3)	64.9 (14.0)	64.9 (16.8)	65.4 (13.3)	66.7 (20.7)	59.1 (20.9)
31–40	144 (31.6)	64.9 (13.0)	62.5 (17.5)	65.4 (13.3)	70.9 (18.2)	60.9 (19.6)
41–50	96 (21.1)	66.2 (13.6)	64.8 (17.6)	65.6 (12.5)	77.8 (20.6)	61.1 (19.5)
51–60	61 (13.4)	72.1 (11.8)	64.7 (17.7)	68.0 (12.6)	83.7 (15.3)	66.6 (22.8)
>60	44 (9.6)	66.4 (13.3)	66.1 (18.5)	70.5 (12.3)	90.1 (9.5)	68.5 (17.8)
p value**		0.001	0.620	0.084	<0.001	0.006
Sex						
Male	217 (47.6)	69.0 (12.7)	66.2 (17.1)	68.4 (12.3)	78.5 (17.5)	66.0 (19.7)
Female	239 (52.4)	63.9 (13.5)	62.2 (17.8)	64.2 (12.0)	70.5 (21.6)	57.7 (20.7)
p value*		<0.001	0.014	<0.001	<0.001	<0.001
Occupation						
Unemployed	52 (11.4)	63.5 (12.6)	62.0 (14.7)	64.8 (11.9)	65.6 (21.4)	59.0 (21.9)
Student	39 (8.6)	62.5 (14.3)	63.2 (19.9)	65.1 (12.4)	59.0 (19.5)	52.7 (21.6)
Housewife	26 (5.7)	63.9 (12.4)	59.6 (22.7)	62.6 (11.1)	82.4 (17.0)	54.3 (15.6)
Self-employed	31 (6.8)	67.8 (13.0)	64.7 (19.4)	68.0 (9.8)	75.3 (19.2)	64.3 (16.7)
Employee	223 (48.9)	65.9 (13.6)	63.6 (17.6)	70.5 (12.3)	74.2 (18.6)	62.2 (20.9)
Retired	47 (10.3)	72.5 (9.9)	67.7 (15.7)	70.9 (9.4)	89.7 (8.9)	68.8 (17.4)
Other	38 (8.3)	69.8 (14.0)	69.4 (14.1)	68.5 (13.2)	77.1 (24.0)	65.5 (21.6)
p value***		0.003	0.357	0.044	<0.001	0.002
Employment expectation						
Yes (students/unemployed)	91 (20.0)	63.1 (13.3)	62.5 (17.1)	64.9 (12.1)	62.8 (20.7)	56.3 (21.9)
No (rest of categories)	365 (80.0)	67.2 (13.2)	64.5 (17.7)	66.5 (18.9)	77.2 (18.9)	63.0 (20.1)
p value***		0.008	0.342	0.255	<0.001	0.006
Educational level						
No studies	26 (5.7)	62.1 (14.1)	58.3 (22.3)	60.9 (11.1)	79.3 (21.9)	54.4 (24.6)
Primary school	57 (12.5)	66.1 (13.1)	63.2 (17.5)	66.8 (11.7)	73.8 (22.0)	60.2 (21.7)
High school	143 (31.4)	65.7 (12.8)	63.0 (17.1)	65.5 (12.5)	74.5 (18.2)	60.8 (19.4)
University	230 (50.4)	66.4 (13.6)	65.7 (17.2)	67.1 (12.3)	73.8 (20.3)	63.6 (20.3)
p value**		0.232	0.153	0.083	0.620	0.048
Marital status						
Single	162 (35.5)	63.8 (13.8)	63.6 (17.5)	64.6 (12.8)	66.0 (21.2)	56.5 (22.3)
Married of equivalent	261 (57.2)	68.1 (13.0)	64.9 (17.5)	67.4 (12.1)	78.2 (18.4)	65.3 (18.7)
Divorced/separated	30 (6.6)	65.3 (12.3)	59.8 (18.9)	64.6 (10.8)	83.2 (12.9)	57.7 (21.6)
Widow/widower	3 (0.7)	70.1 (4.6)	60.0 (7.6)	70.9 (7.5)	94.0 (5.5)	62.5 (12.5)
p value***		0.015	0.454	0.121	<0.001	0.001
Married of equivalent						
No	195 (6.6)	64.1 (13.5)	63.0 (17.6)	64.7 (12.5)	69.1 (21.2)	56.8 (22.0)
Yes	261 (0.7)	68.1 (13.0)	65.0 (17.5)	67.4 (12.1)	78.2 (18.4)	65.3 (18.7)
p value*		0.002	0.235	0.020	<0.001	<0.001

Notes. Results are expressed in a 0–100 points scale, where 0 is the worst and 100 the best QoL score.

p values obtained through Student's t test*, analysis of variance** and Kruskal–Wallis test***.





FIGURE 1 Box plot of the global score of the EsDQoL questionnaire and its dimensions. Median and interquartile ranges are represented in the boxes, with whiskers (vertical lines) extending to a limit of 1.5 interquartile range. Results are expressed in a 0–100 points scale, where 0 is the worst and 100 the best QoL score [Colour figure can be viewed at wileyonlinelibrary.com]

satisfaction with therapy, negative impact of therapy and diabetesrelated worries dimensions, with the highest QoL perception in those patients who had a university degree. The variable "employment expectations" was significantly associated with the social/vocational worries dimension and "marital status" with the diabetes-related worries dimension. Single and equivalent status people and those waiting for a work opportunity expressed worse QoL scores (Table 4).

A statistically significant association was revealed for glycaemic control (estimated by means of glycosylated haemoglobin concentration) with the overall EsDQoL score and all its dimensions; the higher the glycosylated haemoglobin concentration, the worse the QoL score. In contrast, diabetes types, use of injected medication, severe hypoglycaemia or time of evolution of DM were not associated with HRQoL. The overall number of complications from DM was inversely associated with both the overall EsDQoL score and that of the *diabetes impact on daily life* dimension; the higher the number of complications/associated conditions, the worse the QoL perception. Conversely, the number of associated conditions (Table 4).

Despite no differences being observed in overall or partial EsD-QoL scores according to the type of diabetes in the univariate (Table 3) and multivariate (Table 4) analyses, additional analyses were performed in the type 1 DM population which constitutes the majority of our sample (n = 366; 80%). Among them, female gender and poor glycaemic control were reconfirmed as significant determinants of a poorer quality of life overall. Glycaemic control and number of complications significantly determined the *satisfaction with therapy* dimension, while *negative impact of therapy on daily life* was only determined by female gender. Older patient age, expectations of work and better glycaemic control all determined a higher score in the *social/vocational worries* dimension. Female gender, married or

equivalent status, higher education level and improved glycaemic control determined a reduced *diabetes-related worries* score, in agreement with analysis performed on the complete series of diabetic subjects (Supporting Information Table S2).

4 DISCUSSION

The present study measured HRQoL in a substantial sample of adult patients diagnosed with DM who represented the adult Spanish diabetic population across the country. Using a specific validated instrument, both overall HRQoL level and individual dimensions constituting the EsDQoL questionnaire were scored, and their determinant factors were assessed. According to our results, HRQoL levels in the Spanish population were only moderate (average score 66.4 over 100 points as the best possible QoL level), in line with previous research carried out in our country (The DCCT Research Group 1988). However, and as a variance in relation to existing research, our study aimed not to assess HRQoL in a hospitalattended group of patients, but in those recruited from the general population, in order to achieve a more representative view of a nonselected diabetic population. A previous study carried out in a representative sample of diabetic patients recruited at multiple primary care and specialised facilities around Spain assessed HRQoL with a different questionnaire (Jódar-Gimeno et al., 2015), the results of which could not be directly compared with ours.

According to our results, the *social/vocational worries* dimension, which explores topics related to personal concerns (such as the ability to marry, have children, take out insurance or travel) and professional achievements (the ability to complete education and find and keep a job) obtained the best QoL scores in adult people with DM from Spain. In contrast, *diabetes-related worries* (which includes questions about concerns regarding the frequency of losing consciousness, changing body image, occurrence of complications because of DM or limitations in personal relationships) was the worst affected dimension in our representative sample of diabetics. It could be argued that particularities of how the economic crisis has impacted on the healthcare system in Spain in recent years and the characteristics of the Spanish national health system with universal coverage explain these particular results.

Some authors found results similar to our findings regarding sex and length of disease evolution, finding that women reported a significantly higher impact of diabetes on daily life, and also expressed more diabetes-related worries than men (Alvarado-Martel et al., 2015; Anderson, Fitzgerald, Wisdom, Davis, & Hiss, 1997; Eiser et al., 1992; Millan et al., 1996). As a result, and similar to most existing research (Chew et al., 2015; D'Souza et al., 2016), diabetic women presented a poorer HRQoL perception than men.

Age also had a significant influence on the QoL of diabetics, which was impaired in younger subjects, as previously shown in studies carried out in different countries and setting (Huang, Brown, Ewigman, Foley, & Meltzer, 2007; Jacobson, Braffett, Cleary, Gubitosi-Klug, & Larkin, 2013; Nyanzi, Wamala, & Atuhaire, 2014; Redekop et al., 2002). However, other factors which were revealed as **TABLE 2** Clinical characteristics of Spanish adult patients with diabetes mellitus and their relationship with quality of life determined with the EsDQoL questionnaire

	N = 456	Overall EsDQOL score	Satisfaction with therapy	Negative impact of therapy on daily life	Social/vocational worries	Diabetes-related worries
Clinical variables	n (%)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Type of diabetes mellitus						
Type 1	366 (80.0)	65.9 (13.5)	64.7 (17.2)	65.8 (12.4)	71.5 (20.4)	60.6 (20.8)
Type 2	72 (15.4)	69.4 (12.8)	65.3 (18.5)	68.9 (11.7)	87.1 (12.5)	66.6 (22.3)
Other types	18 (4.6)	64.3 (11.6)	57.3 (20.6)	63.8 (11.5)	81.0 (17.2)	64.2 (15.7)
p value**		0.095	0.157	0.98	<0.001	0.065
Type of treatment						
Multiple daily insulin injection (MDII)	300 (65.8)	65.6 (13.3)	63.5 (17.7)	65.7 (12.2)	73.0 (19.6)	60.8 (20.5)
Continuous sc insulin infusion (CII)	76 (16.7)	68.0 (12.6)	69.0 (14.7)	67.0 (12.3)	72.0 (21.4)	62.5 (20.5)
Oral antidiabetic drugs (OAD)	32 (7.0)	72.1 (11.8)	65.2 (16.4)	71.0 (12.1)	75.8 (21.4)	71.9 (19.4)
No insulin injectable drugs (NIID)	1 (0.2)	81.0 (NC)	83.3 (NC)	71.3 (NC)	100.0 (NC)	68.8 (NC)
MDII + CII	3 (0.7)	59.6 (9.2)	59.6 (9.2)	56.7 (5.8)	52.4 (25.8)	56.3 (27.2)
OAD + MDII	38 (8.3)	62.8 (14.9)	57.1 (21.4)	63.8 (12.7)	75.8 (21.4)	56.6 (20.6)
OAD + NIID	5 (1.1)	76.4 (9.9)	71.0 (14.4)	78.0 (8.3)	87.1 (6.5)	73.8 (18.4)
MDII + OAD + NIID	1 (0.2)	67.9 (NC)	67.9 (NC)	73.8 (NC)	75.0 (NC)	67.9 (NC)
p value***		0.019	0.043	0.028	<0.001	0.024
Injection-based treatment						
No	32 (7.0)	72.1 (11.8)	65.2 (16.4)	71.0 (12.1)	90.2 (12.0)	71.9 (19.4)
Yes	424 (93.0)	65.9 (17.7)	64.0 (17.7)	65.9 (12.2)	73.1 (20.1)	60.9 (20.5)
p value*		0.012	0.729	0.023	<0.001	0.003
Glycosylated haemoglobin concentration						
<7%	222 (48.7)	69.0 (13.0)	67.2 (17.8)	68.2 (18.3)	76.8 (18.6)	65.7 (19.7)
7%–9%	199 (43.6)	64.1 (13.3)	61.7 (17.1)	64.5 (12.4)	71.6 (21.6)	57.8 (21.5)
>9%	26 (5.7)	60.5 (12.5)	55.8 (15.2)	61.9 (12.1)	69.2 (18.9)	56.3 (15.3)
Unknown	9 (2.0)					
p value**		<0.001	<0.001	0.001	0.013	<0.001
Hypoglycaemia episode in last year						
No	414 (90.8)	66.6 (13.2)	64.2 (17.5)	66.4 (12.1)	74.6 (20.0)	62.2 (20.4)
Yes	42 (9.2)	64.4 (14.8)	63.2 (18.2)	64.4 (13.6)	71.5 (21.2)	56.7 (22.2)
p value*		0.317	0.716	0.309	0.344	0.102
Years from DM diagnosis: Mean (SD)	17.5 (11.56)					
Categorized	n (%)					
<10 years	125 (27.4)	65.1 (13.2)	62.5 (18.2)	65.3 (12.3)	72.3 (19.9)	61.8 (20.3)
10–20 years	160 (35.1)	66.9 (12.8)	65.1 (16.2)	66.9 (12.3)	74.0 (20.1)	61.2 (21.2)
20.1–30 years	115 (25.2)	65.9 (13.8)	64.0 (19.3)	65.6 (12.7)	74.1 (19.3)	59.9 (19.2)
>30 years	56 (12.3)	68.6 (14.0)	65.3 (16.6)	67.7 (12.8)	79.5 (22.2)	66.3 (22.2)
p value**		0.395	0.618	0.503	0.205	0.289

Notes. NC: Not calculated.

Results are expressed in a 0-100 points scale, where 0 is the worst and 100 the best QoL score.

p value obtained through Student's t test*, analysis of variance** and Kruskal–Wallis test***.

significant determinants for HRQoL by regression models in our sample of diabetics did behave differently than in previous studies, including education, duration of disease, glycaemic control, disease complications or comorbid conditions. In fact, our research identified the presence of complications from DM as a significant independent factor conditioning the overall HRQoL score in patients of both sexes. This is in line with other articles reporting that patients with diabetes and a history of coronary artery disease, stroke/transitory ischaemic attack, peripheral artery disease, heart failure and peripheral neuropathy had lower levels of QoL (Wasem et al., 2013). Also **TABLE 3** Relationship between complications of diabetes mellitus or associated conditions and health-related quality of life determined by the Spanish version of the DQoL questionnaire

			Satisfaction	Negative impact of	Social/vocational	Diabetes-related
Complications from diabetes	N = 456	Overall EsDQoL	with therapy	therapy on daily life	worries	worries
mellitus and comorbid diseases	n (%)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Retinopathy						
No	386 (74.6)	66.8 (13.2)	64.7 (17.5)	66.6 (12.2)	74.8 (19.6)	62.3 (20.1)
Yes	70 (15.4)	63.7 (13.9)	61.0 (17.6)	64.2 (12.5)	71.5 (22.8)	58.0 (23.1)
p value*		0.069	0.097	0.135	0.208	0.111
Nephropathy						
No	442 (97.0)	66.3 (13.4)	64.0 (17.7)	66.3 (12.3)	73.9 (20.2)	61.5 (20.8)
Yes	14 (3.0)	68.7 (11.1)	65.0 (15.1)	64.6 (11.3)	86.2 (16.0)	65.2 (13.6)
p value*		0.505	0.530	0.608	0.024	0.516
Neuropathy						
No	428 (93.9)	66.6 (13.3)	64.5 (17.2)	66.6 (12.1)	73.9 (20.3)	61.9 (20.8)
Yes	28 (6.1)	62.5 (13.8)	58.1 (22.0)	60.3 (13.2)	81.1 (16.5)	57.6 (17.9)
p value*		0.103	0.061	0.008	0.034	0.282
Macrovascular complications						
No	444 (97.4)	66.4 (13.4)	64.2 (17.5)	66.3 (12.3)	74.1 (20.3)	61.6 (20.5)
Yes	12 (2.6)	65.1 (13.2)	60.4 (19.2)	62.4 (10.9)	83.6 (12.2)	63.5 (23.4)
p value*		0.735	0.461	0.275	0.022	0.748
Number of complications						
None	359 (78.7)	67.0 (13.1)	65.0 (17.2)	67.0 (12.0)	74.1 (19.9)	62.5 (20.0)
One	76 (16.7)	63.7 (14.5)	61.5 (18.9)	63.0 (13.6)	73.6 (21.4)	57.7 (24.0)
Тwo	15 (3.3)	64.2 (12.8)	58.8 (17.8)	64.8 (10.2)	76.9 (21.3)	60.0 (17.0)
Three	6 (1.3)	65.9 (11.1)	63.9 (20.4)	60.0 (10.7)	88.1 (12.1)	64.6 (14.1)
p value**		0.286	0.190	0.068	0.263	0.497
Hypertension						
No	392 (86.0)	66.4 (13.4)	64.7 (17.5)	66.3 (12.3)	73.2 (20.2)	61.6 (20.6)
Yes	64 (14.0)	66.0 (13.1)	61.0 (17.5)	65.6 (12.0)	80.9 (18.6)	62.0 (20.6)
p value*		0.795	0.076	0.678	0.005	0.880
Dyslipaemia						
No	442 (96.9)	66.4 (13.3)	64.1 (17.6)	66.3 (12.2)	74.2 (20.3)	61.6 (20.6)
Si	14 (3.1)	65.7 (13.7)	64.2 (16.9)	63.0 (14.4)	78.6 (16.2)	62.5 (21.4)
p value*		0.854	0.991	0.326	0.423	0.876
Obstructive sleep apnoea syndrom	ne					
No	447 (98.0)	66.4 (13.2)	64.2 (17.6)	66.2 (12.3)	74.3 (20.0)	61.7 (20.4)
Yes	9 (2.0)	64.7 (17.0)	61.7 (19.5)	65.4 (13.1)	73.4 (24.9)	56.9 (28.7)
p value*		0.701	0.673	0.844	0.892	0.489
Obesity						
No	402 (88.2)	66.4 (13.2)	64.4 (17.0)	66.1 (12.2)	73.6 (20.6)	62.2 (20.7)
Yes	54 (11.8)	66.3 (14.4)	61.7 (21.8)	66.9 (13.2)	79.5 (16.0)	57.3 (19.3)
n value*	(,	0.970	0.384	0.654	0.017	0.098
Number of comorbid conditions						
None	347 (76.1)	66.5 (13.3)	65.1 (16.8)	66.3 (12.2)	72.6 (20.7)	62.0 (20.8)
One	83 (18.2)	66.1 (12.6)	60.5 (19.7)	66.5 (12.1)	80.1 (16.2)	61.3 (18.3)
Two	20 (4.4)	63.2 (15.7)	59.1 (19.4)	62.4 (15.0)	78.2 (22.0)	56.9 (25.1)
Three	6 (1.3)	71.4 (11.8)	70.8 (15.0)	70.6 (8.7)	89.0 (16.7)	60.4 (22.9)
p value**	/	0.671	0.128	0.572	0.015	0.778

Notes. Bivariate analysis. Number of complications from DM summarized any or more of retinopathies, nephropathies, macrovascular complications and neuropathies. Number of comorbid conditions included any or more of hypertension, obesity, obstructive sleep apnoea syndrome and dyslipaemia. *p*-value obtained by the Student *t* test* or Kruskal–Wallis test**.

sh version of the DQoL questionnaire) with regar	
ty of life (determined with the Spanis	
e linear regression between qualit	
Aultivariate analysis by means of multiple	phic and clinical determinants
TABLE 4	sociodemogra

	Overall EsDQoL		Satisfaction with therapy	daily life	act of therapy on	Social/vocational worrie	SS	Diabetes-related worri	SS
Variables	B Coef (95% CI)	p value	B Coef (95% CI) p v	value B Coef (95%	CI) p valu	e B Coef (95% CI)	<i>p</i> value	B Coef (95% CI)	<i>p</i> value
Female gender	-3.12 (-5.61; -0.63)	0.014	- 0.0		; -0.77) 0.009		0.241	-5.69 (9.50; -1.88)	0.004
Age	0.20 (0.05; 0.34)	0.008	0.0	359	0.086	0.46 (0.25; 0.67)	<0.001		0.228
Married or equivalent		0.142	0.5	565	0.254		0.106	5.99 (2.08; 9.90)	0.003
Primary school	7.30 (1.23; 13.38)	0.018	0.1	196 8.41 (2.73; 2	14.10) 0.004		0.278	13.12 (3.84; 22.40)	0.005
High school	5.67 (0.17; 11.17)	0.043	0.2	246 6.28 (1.13; 2	11.43) 0.01 7		0.461	12.06 (3.65; 20.48)	0.006
University degree	8.80 (3.34; 14.25)	0.002	8.06 (0.62; 15.50) 0.0	334 8.91 (3.80; 1	14.02) 0.001		0.167	16.81 (8.46; 25.15)	<0.001
Employment expectation		0.435	0.5	775	0.760	-7.93 (-12.33; -3.52)	<0.001		0.339
Type 1 diabetes		0.753	0.1	102	0.647		0.451		0.631
Diabetes type other than type 1		0.468	7.0	139	0.257		0.855		0.762
Severe hypoglycaemia		0.482	0.7	756	0.469		0.664		0.186
Time from DM diagnosis		0.785	0.5	382	0.504		0.820		0.380
Injection-based therapy		0.374	0.5	525	0.531		0.362		0.245
HbA1c 7%-9%	-4.32 (-6.8; -1.81)	0.001	-4.57 (-8.00; -1.15) 0.0	009 –3.32 (–5.67;	: -0.97) 0.006	-5.22 (-8.79; -1.64)	0.004	-6.76 (-10.6; -2.92)	0.001
HbA1c >9%	-6.99 (-12.2; -1.76)	0.009	-10.14 (-17.3; -3.0) 0.0)05 –5.15 (–10.0 ²	4; -0.25) 0.039		0.159		0.073
Number of complications ^a	-2.69 (-4.89; -0.50)	0.016	0.0	080 -3.11 (-5.16;	: -1.06) 0.003		0.332		0.121
Number of associated diseases ^b		0.827	0.5	596	0.970		0.544		0.457

glycosylated haemoglobin concentration. ^aComplications for DM included retinopathy, nephropathy and macrovascular complications. ^bAssociated diseases included hypertension, dyslipaemia, obstructive sleep apnoea syndrome and caering (no), gycosylated haemogroum concentration (</ %). For the number of complications of DM and associated continuous, the coerficient is calculated for each disease of complication. For the variable "age" and "time from DM diagnosis" values of the coefficients and their confidence intervals were determined for each complete year. Coef B: beta coefficient; 95% Cl: 95% confidence interval. HbA1c:

obesity.

paralleling previous research (Didarloo & Alizadeh, 2016), hypertension, hyperlipaemia and obesity (three frequent comorbid conditions we also assessed in our research) had a significant effect on HRQoL of Spanish diabetic patients, as stated by multivariate analyses.

Besides sex and age, other conditioning sociodemographic factors such as academic level, marital status and favourable employment expectations were also revealed as significant determinants on perceived HRQoL in DM patients. While higher educational levels might provide diabetics with improved functional capacities (Awotidebe et al., 2017), its relationship with unemployment rate and HRQoL has been recently assessed in a population-based study carried out in Denmark (Nielsen, Ovesen, Mortensen, Lau, & Joensen, 2016). In this research, adults with type 1 DM experienced lower HRQoL, were more frequently unemployed and had more sick leave per year, despite being slightly better educated than the general population. As we exclusively assessed patients with DM, comparison with the general Spanish population was not possible in our research, preventing verification of whether the results of the Danish study could be extrapolated to the Spanish population. Together with sociodemographic factors, the degree of disease control (evaluated by glycosylated haemoglobin levels) and the number of complications derived from DM were the only clinical parameters that exhibited a significant influence in determining HRQoL in our series, according to multivariate analysis. In contrast, clinical aspects such as the type of diabetes, the length of evolution of the disease and the presence of hypoglycaemia were not found to be significant determinants associated with HRQoL in the diabetic population.

The emotions of patients with chronic conditions can be modulated by lifestyle interventions, in such a way that they can influence how patients perceive their HRQoL. Our study did not specifically assess the psychological characteristics (depression, anxiety and vigilant coping style) of patients in the selected sample, so we cannot rule out the potential influence of these factors on the perception of HRQoL, which is a complex intellectual construct that is determined by many more aspects than we could evaluate in this investigation. On the other hand, differences between the values and preferences that are established in different cultural environments are also possible explanations for the differences in the influence we found for several determinants of QoL, which contrasted with previous research. In particular, the type of treatment (insulin injected-based versus oral drugs) was not identified as a significant factor affecting QoL of our Spanish diabetics in multivariate analyses. In contrast, the need for insulin led to a deterioration in the QoL of type 2 diabetics in Iran (Khalili, Sabouhi, Abazari, & Aminorroaya, 2016), while the improved metabolic control of Croatian diabetics who began to use insulin meant an improvement in their QoL level (Pibernik-Okanović, Szabo, & Metelko, 1998).

In line with our results, previous research in Spain failed to demonstrate a significant influence of the type of therapy in determining differences in the overall EsDQoL score or any of its determinants when comparing a multiple daily insulin injection regimen with continuous subcutaneous insulin infusion (Pérez-García et al., 2015), at least at the maintenance treatment phase (Ruiz-de-Adana et al.,

Journal of Clinical Nursing-WILEY

2016). On the other hand, glycaemic control was shown to be a definitive determinant of HRQoL, with high glycosylated haemoglobin levels identified as an independent determinant of impaired overall EsDQoL score as well as scores of every domain in DM. We can clearly infer from these data that maintaining adequate metabolic control is essential to maintaining QoL in patients with DM; the way each patient achieves this control seems to be irrelevant.

The strength of our study comes from its ample sample size, the representative nature of the sample with regard to the diabetic population in Spain as a whole and the fact that we controlled for confounding variables by means of multivariate analysis. We also used a disease-specific instrument that had been linguistically and culturally adapted and validated for use in a Spanish context. We obtained a higher response rate from our DM patients than in some previous studies carried out in Spain (Mateos Sánchez, 2013). The lower mean age of the patients included in our research (40.8 vs. 70 years old), as well as the wide range regarding level of studies compared with the low education level of the participants in previous studies, might constitute an additional advantage of our research in terms of improved representativeness, thus overcoming problems related to filling in the questionnaire.

Our study also has several limitations due to the absence of a nonrandomised sampling protocol. The way in which we collected the data, due to the study design and the process of working through diabetic patients' organisations, hindered us from knowing the exact response rates and profiles of the patients, who may have received the questionnaire and chosen not to respond. The attitudes of patients who voluntarily responded to the questionnaire may be more favourable than those of patients who did not respond; thus, participation in this study could reflect either involvement of patients in greater control of their illness, or, on the other hand, the involvement of the most affected patients.

A lower response rate in type 2 diabetes patients (who represented only 15.4% of the whole sample), despite being the most variant of DM, undoubtedly led to under-representativeness of this part of the clinical spectrum of DM, which means that results from this research should be interpreted very cautiously when applied to these patients. This imbalance in the distribution of the sample is probably as a result of recruiting participants through patients' organisations. Most type 1 DM patients are young people more used to dealing with technology; an earlier and more severe impact of DM on their daily lives might encourage them to seek peer support. In contrast, type 2 DM usually appears with advancing age, progressively and perhaps with a latent impact compared to type 1 DM. This may explain a reduced willingness to be involved in patients' organisations. Multivariate analyses allowed controlling the effect of the type of DM as an explicative variable for HRQoL on overall results.

At last, we were not able to control the specific influence that the several conditions potentially associated with DM on HRQoL of patients (such as coeliac disease or autoimmune disorders), constituting an additional limitation of this research.

Although it could not be demonstrated, our results also suggest that HRQoL in adults with DM improves with time and adaptation WILEY-Clinical Nursing

to the disease and therapy. Better management of the disease significantly determines an improved QoL level, giving rise to the hypothesis that periodic disease monitoring would improve QoL outcomes.

To conclude, HRQoL in diabetic people is not conditioned by the type of diabetes, disease length or treatment used, but significantly depends on sociodemographic variables such as age and gender, education level and certain social circumstances such as having a partner or employment. Improving the metabolic control of the disease and avoiding complications from DM were identified as therapeutic goals towards an improvement in HRQoL perception.

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CONFLICT OF INTEREST

No potential conflict of interests relevant to this article were reported.

CONTRIBUTIONS

Study concept and design: J.R.A., A.J.L.; data acquisition and analysis: J.R.A., A.H.M.; interpretation of results: A.H.M., A.J.L., A.G.M.; drafting of the manuscript: A.J.L.; and approval of the final version of the manuscript: J.R.A., A.J.L., A.G.M, A.H.M.

GUARANTOR OF THE MANUSCRIPT

J.R.A. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the results.

PRIOR PRESENTATION

Part of this study obtained the first prize of research in nursing of the Illustrious Nursing School of Ciudad Real (Spain), Ciudad Real, April 2016.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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