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Validation of a New Test for Assessing the Quality of Life Perceived in Patients with Type 1 Diabetes

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Abstract

The assessment of quality of life (QoL) is an indicator of the effects of treatments. The aim of our study was to construct a new test, the DIAbetes and quality of Life (DIAL) questionnaire, to assess the QoL perceived in patients with type 1 diabetes. 298 type 1 diabetes are enrolled. DIAL total score was (median [quartiles]) 220 [114,251]; "A" score was 34 [16, 62] and mean "B" score was 63 [18, 81]. A significant correlation between test and re-test scores was observed. Results of factor analysis were compatible with a 2 factor-structure. Factor 1 accounted for 30.6% of variance and factor 2 for 7.5%. Individual items were assigned to two different subscales. DIAL showed a significant direct correlation with DQoL total scores and with Impact, Preoccupations, and Diabetes-related preoccupation subscale scores. Significant direct correlations of DIAL and its subscales were also found with SF-36 whereas an inverse correlation was observed with HbA1c and DQOL Satisfaction score. No correlation was found with BMI or age. HbA1c showed a direct correlation with DIAL 1 and total scores, as well as with DQOL satisfaction score, and inversely correlated with DQOL-Diabetes-related concern scores. Differences in either DQOL or DIAL scores between patients with and without complications were not statistically significant; DQOL, showed a significant difference between genders. DIAL has demonstrated to be more useful for the actual type 1 diabetes management and the adoption of instruments which take into account the subjective relevance of different areas, could provide a greater accuracy in measurement.

The World Health Organization defines quality of life (QoL) as "the perception that an individual has of his life, in the context of the culture in which he lives, integrating personal goals, expectations and concerns, well-being and discomfort" [1]. The purpose of treatments and care is to extend the duration of life and improve its quality. The assessment of quality of life is a fundamental indicator of the effects of treatments and organization of care. QoL is actually measurable, using questionnaires and interviews. Before being used, tools for the measurement of quality of life must be validated through the assessment of their internal and external consistency and reproducibility [2].

Instruments for the measurement of health-related quality of life can be classified in generic and disease-specific. The former has the advantage of allowing comparisons between different clinical conditions, and they are essential for the determination of quality-adjusted life years in outcome research [3]. In addition, generic measures of QoL are often more robust than disease-specific instruments. On the other hand, disease-specific tools are more sensitive to change and they can explore with greater accurateness differential effects of different therapeutic approaches [4].

In patients with diabetes, poor glycemic control, side effects of pharmacological treatment, complications of the disease, in addition to psychosocial factors, can significantly influence the course of the diabetes and cause a worsening of the patient's quality of life. Both generic and disease-specific instruments have been used for assessing QoL in people with diabetes [4,5]. Among available disease-specific questionnaires, most have been developed for type 2 diabetes [5], which is the more common form of the disease. A notable exception is the Diabetes-related Quality of Life (DQoL) questionnaire [6], which was originally developed for the Diabetes Control and Complications Trial in type 1 diabetes [7]. This test, which has been used in many studies, including some

performed in patients with type 2 diabetes, was designed in the late 1970s. At that time, the management of type 1 diabetes was very different from present, because of differences in available insulin formulations, injection/infusion devices, and instruments for glucose monitoring. Many of the questions of the DQoL are therefore obsolete. In addition, in the DQoL, as in the majority of available questionnaires, each question contributes equally to the final score; this means that the weight of each area on overall quality of life depends on the number of questions exploring that area, which was decided by the authors of the test. Since the values and expectations of clinicians and researchers who formulate a questionnaire can be quite different from those of individual patients, the test can provide a distorted picture of the actual impairment of quality of life experienced by a person with diabetes. The adoption of instruments which take into account the subjective relevance of different areas, as reported by the patient, could provide a greater accuracy in measurement [8].

Aim

The aim of our study was to construct a new test, the DIAbetes and quality of Life (DIAL) questionnaire, to assess the quality of life perceived in patients with type 1 diabetes, in line with current clinical practice, and taking into account the subjective relevance of different areas as reported by the patients.

Methods

Development of the questionnaire

The questionnaire has been developed with the contributions of several endocrinologists, psychiatrists, dietitians and nurses who were asked to list the main determinants of the general (i.e., not strictly linked with diabetes/diabetes therapy) quality of life in patients with T1DM. The same task was asked to a group of T1DM patients referring to our clinic. On the basis of the most commonly voiced factors, the authors identified 28 items. Patients involved in the development of the questionnaire were not included in the present study.

Items were conceptually related to five different areas:

1. Spare time and social life: 8 items aimed at measuring the possible impact of diabetes on the main areas of personal and social functioning;

2. Work and projects: 11 items intended to measure how much diabetes interferes on the activities during the working hours and the involvement in work projects;

3. Psychological well-being: 6 items designed to evaluate the possible link between diabetes and depressive or anxiety thoughts/symptoms;

4. Physiological needs: 4 items investigating the possible interference of diabetes on eating behaviors and sleeping;

5. Couple: 2 items intended to evaluate the effect of diabetes on romantic relationships and sexual intercourses.

This choice was made in order to develop a questionnaire in a way that could be applied to wide population of T1DM patients, regardless of socio-demographic variables, educational level, occupation and duration of diabetes. The English translation (from the Italian version) of the complete text of the questionnaire, together with the scoring system, is reported in the Appendix. The translation was checked through back translation into Italian.

Each item was composed by two different questions ("A" and "B") with the answer on a 4-point Likert scale. For question "A" the patient was asked to answer how much the factor investigated by the question is relevant in his life. For question "B" the patient is asked to answer how much diabetes interferes on the same factor. The score of each item is calculated as the product of A and B. The total score of the test is the sum of the calculated scores of each item; a higher score represents a better quality of life.

The sums of the scores related to relevance ("A") and impact of diabetes ("B") for each factor were also calculated.

Patients

A consecutive series of 350 outpatients with type 1 diabetes referred to the diabetes clinics of the Careggi teaching hospital in Florence, Italy, between01/10/2015 and 01/10/2017 was enrolled in the study. Exclusion criteria were intellectual disability, not fluent Italian, or the self-report lifetime diagnosis of a severe psychiatric disorder (i.e., Psychosis or Bipolar Disorder). All patients were asked to complete the new questionnaire DIAL, SF-36 Health Survey and Diabetes Quality of Life Questionnaire (DQoL). A questionnaire was considered valid when over 85% of the items had been compiled.

Of the 350 patients invited, 52 (14.9 %) denied participation, failed to complete the questionnaires. At enrolment, all 298 were visited by an endocrinologist (L.P. and I.D.). Height and weight (for the calculation of body mass index) were measured with calibrated instruments as well as blood pressure and Hearth Rate. A blood sample was drawn for the measurement of HbA1c (measured with high performance liquid chromatography [Menarini Diagnostics, Florence, Italy]). The presence of the main diabetic complications was also assessed accordingly to national Guidelines for the management of diabetic patients. The main demographic and clinical characteristics of the 298 patients enrolled are summarized in Table 1.

Baseline characteristics	
Total Numbers (female n, %)	**298 (140;47)**
Age (years)	42.6 ± 15.0
Diabetes Duration (years)	30.3 ± 18.2
HbA1c (%)	7.6 ± 1.0
BMI (kg/m^2)	27.7 ± 7.9
PAS (mmHg)	121 ± 8
PAD (mmHg)	82 ± 7
Daily Insulin Units (UI/die)	20.8 ± 10.2
Insulin Pump (n,%)	47 (15.7)
Diabetes related complications (n;%)	
Prior cardiovascular events	0 (0)
Retinopathy	44 (14.7)
Neuropathy	26 (8.7)
Nephropathy	5 (1.6)
Diabetic Foot	3 (1.0)

Table 1: The main demographic and clinical characteristics of patients.

Validation of the questionnaire

For the test-retest reliability, 15 patients were asked to complete the questionnaire twice at a 2-week interval and it was explored by calculating Spearman's r between the scores obtained from the two administrations, both for the total score and for individual items.

Internal consistency was evaluated using Cronbach's alpha method

In order to verify concurrent and discriminant validity, as mentioned above, patients were asked to complete also the two following questionnaires:

SF-36 Health Survey: generic questionnaire for chronic conditions. The test includes 36 questions and 9 scales: physical functioning, limitations due to physical health, limitations due to emotional problems, physical pain, energy/fatigue, emotional well-being, social functioning, general health, perceived health change. For each scale the score goes from 0 to 100 [9].

DQoL - Diabetes Quality of Life Questionnaire: specific test for diabetes to assess the absolute quality of life of patients with type 1 diabetes. It includes 46 items, which investigate 4 areas: general satisfaction, global impact of the disease, concerns about social relations, concerns about diabetic disease [6].

To verify the distribution of items into subscales, factor analysis was performed, using Statistical Package for Social Sciences (SPSS) for Windows (release 20.0, IBM, 2011).

To evaluate the possible relationship between DIAL and clinical and psychometric parameters a bivariate correlation was performed using SPSS.

Results

The main demographic and clinical characteristics of the 298 patients enrolled are summarized in Table 1. The sample was predominantly composed by men (158, 53%). With respect of diabetic complications, 44 (14.8%) patients reported retinopathy, 5 (1.7%) nephropathy, 27 (9.1%) neuropathy, 3 (1%) foot ulcers and 8 (2.7%) cardiovascular complications. None of the subjects reported a lifetime diagnosis of Psychosis or Bipolar disorder. DIAL total score was (median [quartiles]) 220 [114,251]; "A" score was 34 [16, 62] and mean "B" score was 63 [18, 81]. No significant differences were found between men and women for DIAL total score and for "B", whereas "A" showed lower scores in women (34 [16, 56] vs 35 [18, 62], p<.01).

A significant correlation between test and re-test scores was observed for DIAL total score (r=.91, p<.01) and for each individual item (values of r ranged between .86 and .94). Cronbach's alpha was .90; a value of α>.80 is considered satisfactory for internal consistency.

Results of factor analysis were compatible with a 2 factor-structure, which accounted for 38.1% of total variance. Factor 1 accounted for 30.6% of variance and factor 2 for 7.5%. Individual items were assigned to two different subscales, related to factors 1 and 2, based on their factor loading after Varimax rotation (Table 2).

Scale 1 included items 9,10,11,12,13,15,18,19,20,21,22 ,23,24,25,26,27, and 28; scale 2 included items 1,2,3,4 ,5,6,7,8,16,17,18,19,20,21,24,28. Based on the content of items, the two scales therefore defined "Social and personal satisfaction [SPS]" (Scale 1) and "Work and planning [WP]" (Scale 2) (See Appendix). Correlations of DIAL scores with psychometric parameters and with the other questionnaires administered are summarized in Table 3. DIAL showed a significant direct correlation with DQoL total scores and with Impact, Preoccupations, and Diabetes-related preoccupation subscale scores. Significant direct correlations of DIAL and its subscales were also found with SF-36 AF, DF, VT, RE and SM scores, whereas an inverse correlation was observed with HbA1c and DQOL Satisfaction score.

Correlations of DIAL and DQOL scores with some demographic and clinic variables are summarized in Table 4. No correlation was found with BMI or age. HbA1c showed a direct correlation with DIAL 1 and total scores, as well

Items	"Social and personal satisfaction [SPS]" (Scale 1)	"Work and plans [WP]" (Scale 2).
1. Important decisions at work	0.119	**0.720**
2. Income and work performance	0.122	**0.573**
3.Carrier	0.200	**0.583**
4. Work satisfaction	0.188	**0.310**
5. Meals at work	0.188	**0.541**
6. Relationship at work	0.134	**0.586**
7. Colleagues' opinion	0.111	**0.478**
8. Free time	-0.25	**0.292**
9. Free-time activities Satisfaction	**0.569**	0.307
10. Loneliness	**0.838**	0.087
11. Social life	**0.715**	-0.026
12. New friends	**0.793**	0.126
13. Felling of inferiority	**0.724**	0.239
14. Couple life Satisfaction	**0.495**	0.176
15. Feeling of diversity	**0.578**	0.316
16. Long term projects	0.276	**0.740**
17. Future projects	0.289	**0.656**
18. Health Concern	**0.319**	**0.519**
19. Dependence on other people	**0.368**	**0.522**
20. Concern	**0.411**	**0.533**
21. Sadness	**0.608**	**0.383**
22. Well being	**0.419**	0.200
23. Sexual life	**0.259**	0.113
24. Travels	**0.429**	**0.443**
25. Satisfaction	**0.680**	0.206
26. Food Quality	**0.425**	0.204
27. Food Quantity	**0.451**	0.090
28.Food Pleasure	**0.311**	**0.301**

Table 2: Allocation of individual items to two different subscales, related to factors 1 and 2, based on their factor loading.

Correlation	**DIAL Scale 1**	**DIAL Scale 2**	**DIAL total**
DQoL satisfaction	r= 0.548 p<0.001*	r= 0.465 p<0.001*	r= 0.546 p<0.001*
DQoL impact	r= -0.402 p<0.001*	r= -0.359 p<0.001*	r=-0.404 p<0.001*
DQoL total concern	r= -0.354 p<0.001*	r= -0.350 p<0.001*	r= -0.367 p<0.001*
DQoL diabetes correlated concern	r= -0.501p<0.001*	r= -0.465 p<0.001*	r= -0.473 p<0.001*
DQoL Total	r= -0.179 p=0.001*	r= -0.173 p=0.001*	r= -0.163 p<0.002*
SF36 AF	r= -0.466 p<0.005*	r= -0.169 p<0.001*	r= -0.214 p<0.001*
SF36 DF	r= -0.217 p=0.001*	r= -0.192 p=0.001*	r=-0.220 p<0.001*
SF36 VT	r= -0.413 p<0.001*	r=-0.340 p<0.001*	r= -0.396 p<0.001*
SF36 RE	r= -0.319 p<0.001*	r= -0.269 p<0.001*	r=-0.306 p<0.001*
SF36 SM	r= -0.420 p<0.001*	r=-0.328 p<0.001*	r= -0.382 p<0.001*
SF36 SG	r= -0.500 p<0.001*	r= -0.439 p<0.001*	r= -0.491 p<0.001*
SF36 RF	r= -0.278 p<0.001*	r=-0.320 p<0.001*	r= -0.321 p<0.001*
SF36 CS	r= -0.231 p<0.001*	r= -0.158 p<0.005*	r=-0.202 p<0.001*
SF36 AS	r= -0.466 p<0.001*	r= -0.392 p<0.001*	r= -0.453 p<0.001*
* significant			

Table 3: Correlation between DIAL and psychometric parameters.

	DIAL TOT	DIAL 1	DIAL 2	DQOL TOT	DQOL SAT	DQOL IMP	DQOL TC	DQOL DCC
AGE years	r=0.076 p=0.143	r= 0.144 p=0.006*	r= 0.021 p=0.693	r=0.025 p=0.636	r= 0.029 p=0.586	r= 0.014 p=0.798	r= 0.210 p<0.005*	r= 0.076 p=0.155
DM duration years	r= -0.012 p=0.827	r= 0.021 p=0.696	r= -0.071 p=0.186	r= -0.082 p=0.129	r=- 0.029 p=0.591	r= -0.071 p =0.198	r= 0.011 p=0.847	r= 0.080 p=0.143
HbA1c mmol/mol	r= 0.013 p=0.032*	r= 0.114 p=0.031*	r= 0.098 p=0.064	r= 0.053 p=0.324	r= 0.222 p<0.001*	r= 0.086 p=0.115	r= -0.019 p=0.03*	r= -0.117 p=0.03*
* significant								

Table 4: Correlation between DIAL and demographic and clinic parameters.

	DIAL TOT		DQOL TOT	
Gender	Female 38.3 [34.5-42.1]	p=0.240	3.47 [3.42-3.51]	p= 0.045*
	Male 35.2 [31.5-38.8]		3.53 [3.48-3.57]	
Retinopathy	Yes 39.7 [32.3-47.0]	p=0.261	3.46 [3.36-3.56]	p=0.308
	No 35.6 [32.8-38.4]		3.51 [3.48-3.54]	
Nephropathy	Yes 24.4 [2.8-45.9]	p= 0.210	3.47 [3.42-3.62]	p=0.799
	No 36.6 [34-39.2]		3.50[3.47-3.53]	
Neuropathy	Yes 34.8 [26.8-42.9]	p= 0.690	3.42 [3.31-3.53]	p=0.093
	No 36.6 [33.8-39.4]		3.51[3.48-3.54]	
Diabetic foot	Yes 12.7 [3.3-22.1]	p=0.061	3.25 [2.86-3.64]	p=0.138
	No 36.7 [34.1-39.3]		3.50 [3.47-3.53]	
Cardiovascular complications	Yes 36.5 [19.6-53.4]	p=0.981	3.54 [3.27-3.81]	p=0.651
	No 36.3[33.7-39.0]		3.50 [3.47-3.53]	
Insulin pump	Yes 31.2 [26.1-36.4]	p=0.083	3.50 [3.43-3.57]	p=0.906
	No 37.6 [34.7-40.5]		3.50 [3.46-3.53]	
* significant				

Table 5: Correlation between DIAL and clinic dichotomic parameters.

as with DQOL satisfaction score, and inversely correlated with DQOL-Diabetes-related concern scores. Differences in either DQOL or DIAL scores between patients with and without complications were not statistically significant; in addition, DQOL, but not DIAL scores, showed a significant difference between genders (Table 5).

Discussion

The improvement of health-related quality of life is one of the main targets of the treatment of chronic disease. Measurement of this endpoint, which is mainly subjective, poses relevant methodological issues. Many validated questionnaires have been developed over the decades, both for general and disease-specific quality of life [4]. Disease-specific instruments are usually less robust and they do not allow a comparison across different conditions; on the other hand, they are usually more sensitive to change and they can be therefore precious in the comparison of treatments [5].

Many self-reported questionnaires for the measurement of disease-specific health-related quality of life in diabetes are currently in use; most of them do not discriminate between different forms of diabetes, which have a differentiated impact on quality of life. Since type 2 diabetes is much more prevalent in the population than type 1 diabetes, many questionnaires have been designed with the principal target of type 2 diabetes [5]. Conversely, the Diabetes-Related Quality of Life questionnaire (DQOL) [6], originally developed for the Diabetes Control and Complication Trial (DCCT) [7], was specifically designed for type 1 diabetes, although it has also been used in other forms of diabetes.

The evolution of therapeutic approaches over the years can substantially modify the impact of a disease on quality of life. For example, when DQOL was developed, patients with type 1 diabetes were recommended to adhere to a rigid dietary prescription, whereas today they are educated to calculate insulin doses on the basis of carbohydrate count, with no specific restriction [10]. The use of insulin pens and modern pumps, as well as novel devices for glucose monitoring, are also likely to affect the burden of diabetes management.

Most available measures of quality of life are composed of a list of questions, deemed relevant by the experts who formulated the questionnaire, which all contribute equally to the final score of the test. Conversely, clinical experience shows that symptoms of similar intensity can have a different impact on quality of life of individual patients, depending on the person's values, beliefs, needs, and expectations. Therefore, the rating of symptoms should consider not only their intensity but also their subjective relevance. In order to achieve this goal, each item of the DIAL questionnaire is composed of two questions, exploring the intensity of a symptom/limitation and the potential burden of that area, based on patients' perceptions and values.

The psychometric properties of DIAL, verified in a sample of adult outpatients with type 1 diabetes show that the test is reliable, with a satisfactory test/re-test correlation and a good internal consistency. The subscale structure, which was not defined a priori but identified through factor analysis, revealed two scales, related to Social and personal satisfaction (Scale 1) and to Work (Scale 2).

Not surprisingly, DIAL scores showed significant correlations with many scales of SF-36. This is expected, since general and disease-specific health-related quality of life are obviously correlated. The notable correlation between DIAL and DQOL, which are designed to measure the same construct, is also expected.

Duration of diabetes, degree of obesity, age, and gender did not appear to affect DIAL scores, confirming the validity of measurement of quality of life. Notably, the difference across genders observed with DQOL [7] was not detectable with DIAL, which therefore appears to be a more specific measure of diabetes-related quality of life.

The association of DIAL with HbA1c is expected: patients with impaired glucose control often show a reduced satisfaction with their management of diabetes [11].

Similarly, a higher HbA1c is associated with higher DQOL-Satisfaction scores. On the other hand, a lower level of concern with the disease, and therefore a lower score on the DQOL-DCC scale, is associated with a higher HbA1c; as a result, DQOL total score, in contrast with DIAL total score, fails to detect the impact of poor glycemic control on diabetes-related quality of life. DIAL could therefore represent a more sensitive instrument for the assessment of the effects on quality of life of clinical changes affecting glucose control.

The lack of significant differences is either DIAL or DQOL scores between patients with and without diabetic complications may seem surprising. However, the population studied showed a low prevalence of complications; for this reason, the size of the sample of complicated patients was probably insufficient to detect possible differences. In addition, the vast majority of patients classified as "complicated" were affected by initial, asymptomatic or oligosymptomatic chronic complications, which are unlikely to affect quality of life. Further studies on larger samples of patients with more severe complications are needed to verify the validity of DIAL in this specific context. One of the specific features of DIAL is that of weighing the impact of different domains on the basis of their perceived relevance, as reported by the patient. This characteristic could be useful in planning therapeutic interventions, which could be specifically addressed to areas which are considered very relevant by individual patients. The effectiveness of DIAL for tailoring educational interventions should be verified through specifically designed studies.

Conclusion

DIAL appears to be a simple and easy to fill out by patients of different age and education level. It is reliable and updated instrument for the measurement of diabetes-specific health-related quality of life in type 1 diabetes. DIAL test represents, for the first time, a good instrument to identify the "perceived" quality of life. Moreover, it is able to explore the impact of the new therapy on the quality of life in type 1 diabetes, better than the old tests. Finally, it is simple to use also by clinical.

The authors declare that they have no conflict of interest.

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