Developing a culturally valid and reliable quality of life questionnaire for diabetes mellitus

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إعداد استبيان موثوق وملائم ثقافياً لقياس نوعية حياة مرضى السكَّري

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الخلاصة: يتمثَّل الهدف من هذه الدراسة في تصميم استبيان ملائم ثقافياً لدراسة نوعية حياة المصابين بالسكَّري من النمطَيْن 1 و2، في جمهورية إيران الإسلامية. وقد بُنِيَتْ بنود الاستبيان الإحدى والأربعون على الجوانب الكيفيَّة وغطَّت نوعية الحياة بشكل عام وما يتعلق منها بالصحة. ومن خلال مسح وصفي قام 104 مرضى باستكمال الاستبيان؛ منهم 68 (65.4٪) من الإناث. وكان عمرهم الوسطي 50.5 سنة (الانحراف المعياري 12.8). وكان معظمهم (87٪ منهم) مرضى بالسكَّري من النمط الثاني. وكان معامل كرونباخ ألفا للاستبيان 0.98. وقد ميَّز الاستبيان بنجاح بين نوعية حياة المرضى الذين يعانون من ألم في الأطراف، أو فقدان للشهية، أو إعياء، أو إمساك، أو حكة. وأفلح الاستبيان في تحديد نوعية الحياة بشكل عام، وما يتعلق منها بالصحة بوجه خاص.

ABSTRACT The aim of this study was to design a culturally adapted questionnaire for studying quality of life (QOL) among type 1 and 2 adult diabetes patients in the Islamic Republic of Iran. The 41 items on the questionnaire were based on qualitative research and covered general and health-related QOL. In a descriptive survey, 104 patients completed the questionnaire; 68 (65.4%) were female. Mean age was 50.5 years (standard deviation 12.8). Most patients (86.5%) had type 2 diabetes. Cronbach's alpha coefficient for the questionnaire was 0.98. The questionnaire successfully distinguished the lower QOL of patients suffering from pain in the limbs, loss of appetite, fatigue, constipation and itching. The questionnaire could determine both general and health-related QOL.

Développer un questionnaire de qualité de vie pour le diabétique, culturellement valide et fiable

RÉSUMÉ Cette étude avait pour objectif la conception d'un questionnaire d'étude de la qualité de vie (QOL/QDV) chez l'adulte diabétique de type 1 et 2 adapté à la culture de la République islamique d'Iran. Les 41 items du questionnaire ont été définis sur la base d'une recherche qualitative et couvraient le spectre de la qualité de vie générale et en rapport avec la santé. Dans le cadre d'une enquête descriptive 104 patients, dont 68 femmes (65,4 %), ont rempli le questionnaire. L'âge moyen était de 50,5 ans (écart type : 12,8) et la plupart des patients (87 %) étaient porteurs d'un diabète de type 2. Pour ce questionnaire, le coefficient alpha de Cronbach a été de 0,98. Le questionnaire est en outre parvenu à parfaitement distinguer le faible niveau de qualité de vie des patients souffrant de douleurs lombaires, de perte d'appétit, de fatigue, de constipation et de prurit. Ce questionnaire devrait être à même d'évaluer la QOL/QDV générale et liée à l'état de santé.

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Introduction

Quality of life (QOL) is an important outcome in clinical trials and health care interventions [1] which is receiving increasing focus in the scientific literature, including medical sciences literature [2]. Sometimes QOL, health and satisfaction with life are used synonymously [3].

The World Health Organization (WHO) defines QOL as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad-ranging concept, affected in a complex way by the person's physical health, psychological state, personal belief and social relationships to salient features of their environment" [4]. Other experts suggest that QOL is a multidimensional, subjective and dynamic concept [5].

In medical sciences, QOL is used in 2 ways: general QOL or the general feeling of well-being [2] and health-related QOL, involving health-related problems for different diseases. A number of questionnaires are available covering both aspects [6].

Diabetes mellitus is a common and demanding health problem that has a great effect on the everyday life of patients [7]. There are several tools for the assessment of QOL in diabetes mellitus, mostly designed in North America [8]. According to the WHO definition of QOL, cultural perceptions and values play an important role in understanding the concept and the content of QOL by an individual. It is, therefore, crucial to culturally validate the existing instruments and to test their reliability or to design some specific reliable and valid instruments bearing in mind the cultural beliefs and understandings of each target group.

Taking this into consideration, it was decided to design a reliable, valid and culturally adapted questionnaire for studying QOL among adult patients with type 1 and 2 diabetes in Iran.

Methods

After receiving approval for the research from the ethical committee of Tarbiat Modarres University, the questionnaire was constructed and validated in 3 stages.

Drawing up the questionnaire

In the first stage, the items of the questionnaire were drawn up based on a qualitative study. Two target groups were selected: patients (group A) and caregivers (group B). Group A were adults (over 18 years) who had had diabetes for ≥ 1 year. All the participants were members of the Iranian Diabetes Society, the only nongovernmental educational organization for diabetes mellitus in Tehran.

We described the study to all the people meeting the inclusion criteria (age > 18 years and at ≥ 1 year of diabetes mellitus) who were referred to the Iranian Diabetes Society during a 1-month period. We explained the research objectives in a lecture to 57 patients. After the lecture, 32 of them approached us and agreed to be interviewed (Group A). Each volunteer completed a form giving information on demographic and clinical details.

The participant selection process was specifically aimed at choosing people with a range of ages, types of diabetes, treatment modes and complications, and covering both sexes [9]. The interviews were carried out by one of the authors at the patient's house or at the premises of the Iranian Diabetes Society, whichever the patient

preferred. Patients were interviewed sequentially according to their condition. The process continued until data saturation was achieved, i.e. no new concept emerged from the data [10]. We discontinued after interviewing 15 patients (7 females and 8 males).

Thirteen patients had type 2 diabetes; 8 patients were being treated with insulin injections. The mean age of the participants in this group was 52.6 years (range 19–75 years; SD = 12.6) and the mean duration of diabetes was 10.6 years (range 1–25 years; SD = 8.7).

The health professionals who participated in this study (group B) had ≥ 5 years experience dealing with diabetes patients or those involved in research on diabetes patients. All the staff working in the Iranian Diabetes Society who met the inclusion criteria, along with a number of experts, agreed to participate. Group B comprised 11 nurses, 3 physicians, and 1 dietitian.

After obtaining written consent to be audiotape recorded, the researcher made appointments with these health professionals to conduct in-depth, face-to-face, semistructured interviews. Open questions were asked regarding patients' experiences in living with diabetes, its effects on their everyday life, their feelings about the condition, the problems that it may have caused for them and the experiences that caregivers had with patients. Again, the process was discontinued when data saturation was reached.

Common statements and concepts from both groups were recorded and the relevant/appropriate items for a questionnaire were designed based on them. For example, most patients declared that they preferred to hide their disease and this had caused them unnecessary stress. Based on this statement, an item was devised "I prefer to hide my disease" with 4 choices as possible answers never, seldom, most of the time, and always (score range 1–4). Other items such as "I think other people feel pity for me" and "I don't enjoy eating because of diabetes" were composed in the same way.

The complete questionnaire was drawn up in Farsi, and comprised 41 items. One item was specific to married patients (My wife/husband supports me) and another specific to unmarried patients (Diabetes has restricted my chance for marriage). The possible score was 40–160, higher scores indicating better QOL.

From the interviews, it was apparent that the participants considered general and health-related QOL as interrelated concepts, thus, items referring to both dimensions were included in the questionnaire. There were 13 items for assessing general QOL, involving concepts like calmness, anxiety, tension, fatigue, loneliness, spiritual beliefs and economic problems. Items assessing health-related QOL focused on the effect of diabetes on physical and psychosocial conditions. Possible scores were 13–52 for general QOL and 27–108 for health-related QOL. Higher scores indicated better QOL in both cases.

Evaluating the questionnaire

In the second stage, the basic pilot evaluation of the questionnaire was performed. The content validity of the questionnaire, the Iranian Diabetes Quality of Life (IRDQOL) questionnaire, was reviewed by 15 experts who had published ≥ 1 research papers in the QOL area. The questionnaire was then revised based on the experts' suggestions for minor changes. No item was deleted. The revised questionnaire was then sent back to the experts for approval.

The feasibility and basic reliability of the questionnaire were evaluated by conducting a pilot study. The questionnaire was filled in by 10 adult volunteers, diabetes patients

from the Iranian Diabetes Society. The pilot test was re-tested on the same sample after 2 weeks and showed a reliability correlation coefficient of ≥ 0.95.

Main survey
Data collection
In the third stage, a descriptive cross-sectional survey was conducted to assess the validity and reliability of the new instrument. All patients over 18 years old referred to the Iranian Diabetes Society during the 3 months March–May 2003 who had been treated for diabetes for ≥ 1 year and had not been hospitalized in the 2 weeks prior to the survey were asked to fill in the questionnaire. Over the 3-month period of the study, 156 patients aged over 20 years were referred to the society; 108 agreed to participate in the study and provided written consent and completed the questionnaire.

In addition, a blood sample was taken for assessment of HbA1$_c$ to indicate the blood glucose level over about 3 months, so it was possible to assess the relationship between glycemic control and QOL. All blood analyses were done in the Endocrinology and Metabolism Research Centre laboratory in Shariati Hospital, Tehran.

The WHO-5 questionnaire was also used on the same group of patients for the assessment of concurrent validity of our questionnaire [11]. This has been translated into a number of languages, and we used the Farsi version. It has 5 items and assesses the general psychological aspects of QOL. The possible score on this questionnaire is 0–100, higher scores indicating better QOL [11].

Patients noted the occurrence of 16 common physical signs and symptoms of diabetes (e.g. pain in the limbs, fatigue, sleep disturbance) during the week prior to the day they completed the questionnaire. Age, sex, marital status, education, dura-

tion of diabetes, type of diabetes, type of treatment and presence of other conditions were also indicated on a separate sheet. History of previous disease and reported signs and symptoms, type of diabetes and type of treatment were confirmed from the patients' medical records. Body mass index was calculated after measurement of height and weight. The total number of signs and symptoms was calculated from the patients' reports.

Data analysis
Since 4 of the questionnaires were incomplete, they were excluded from the data analysis. The answers of the other 104 respondents were analysed for this study. Descriptive statistics were used to establish frequency, range, mean and standard deviation (SD) of the demographic characteristics of the sample [12]. T-test, Pearson's correlation coefficient and non-parametric statistical methods, including the Mann–Whitney test and the Spearman correlation coefficient, were used to examine the relationship between IRDQOL scores and each variable [13]. Cronbach's alpha coefficient was calculated for IRDQOL to determine reliability and internal consistency [13].

Results

Table 1 displays demographic and clinical data of the respondents. Most (86.5%) had type 2 diabetes. Thirty-five patients were injecting insulin and 65 were taking oral pills. Mean age was 50.5 (SD 12.8) years. Mean body mass index was 26.4 (SD 4.0) kg/m². Mean duration of diabetes was 9.7 (SD 6.9) years. Mean HbA1$_c$ was 8.0 (SD 2.0).

Patients reported a mean of 4.0 (SD 3.2) signs and symptoms: 52% reported fatigue, 50% pain in the limbs and 35% sleep

Table 1 Demographic and clinical data

Characteristic	No.	%
Sex		
Male	36	34.6
Female	68	65.4
Marital status		
Married	86	82.7
Single	13	12.5
Others	5	4.8
Education		
Illiterate	10	9.7
Primary school education[a]	44	42.7
High school graduate	25	24.3
University graduate	24	23.3
Type of diabetes		
Type 1	14	13.5
Type 2	90	86.5
Type of treatment		
Oral pills	65	62.5
Insulin	35	33.7
Diet alone	4	3.8
Other conditions		
Cardiac disease	17	16.3
Hypertension	33	31.7
Severe loss of vision	9	8.7
Renal disease	6	5.8

[a]Can read and write.

disturbance. Hypertension was reported by 33 (32%) patients and 17 (16%) had cardiac disease.

The concurrent validity of IRDQOL and WHO-5 questionnaires was 0.639. Cronbach's alpha for the whole IRDQOL questionnaire was 0.98, which showed the high reliability of this scale. The exclusion of any single item did not change Cronbach's alpha more than 0.01, which showed strong internal consistency. Cronbach's alpha was 0.98 for health-related QOL questions and 0.97 for general QOL questions. These results were in agreement with the results of the pilot test retest assessment carried out prior to the main study.

Mean total IRDQOL score was 116.7 (SD 18.8), mean general QOL score was 37.01 (SD 6.4) and mean health-related QOL score was 79.7 (SD 13.8). Men had higher total and health-related QOL scores than women. Our questionnaire as well as the WHO-5 questionnaire did not show any relationship between QOL of any type and type of diabetes, treatment modality, hypertension, cardiac disease, duration of diabetes, age or $HbA1_c$ (Tables 2 and 3).

The mean total IRDQOL score was 111.5 (SD 18.4) in patients suffering from limb pain while it was 121.2 (SD 18.5) in patients without pain in the limbs, i.e. significantly lower health-related QOL in the presence of this symptom ($P = 0.01$). Patients who reported fatigue had significantly lower total, health-related and general QOL scores in comparison with patients without fatigue ($P < 0.001$). Sleep disturbance had a significant relationship with lower scores for total and health-related QOL. Constipation, itching and loss of appetite also significantly affected QOL ($P < 0.05$).

Higher numbers of reported signs and symptoms were associated with lower QOL ($P < 0.001$) (Tables 2 and 3).

Discussion

Using the IRDQOL questionnaire, we did not find any relationship between glycemic control and QOL. This is in line with the study done by Trief et al. in which 3 different questionnaires were used among adult diabetes patients without finding a relationship between QOL and $HbA1_c$ [14]. There are, however, other studies that show such a relationship in children and teenagers with diabetes [15,16] and a less prominent

Table 2 Relationship between different dimensions of quality of life (QOL) and other clinical and demographic variables

Characteristic	General QOL score		Health-related QOL score		Total IRDQOL score		WHO-5 index	
	Mean (SD)	P	Mean (SD)	P	Mean (SD)	P	Mean (SD)	P
Sex								
Female	36.2 (6.5)		77.3 (13.5)		113.9 (18.3)		42.4 (24.5)	
Male	38.5 (6.0)	0.14	83.4 (13.9)	0.02	121.9 (18.8)	0.04	58.5 (28.7)	0.006
Marital status								
Single	36.5 (7.7)		77.4 (16.4)		113.8 (23.8)		48.9 (23.6)	
Married	37.4 (6.3)	0.62	80.4 (13.5)	0.55	117.8 (17.9)	0.47	48.9 (28.3)	0.87
Diabetes								
Type 1	37.0 (7.7)		77.3 (18.0)		114.4 (25.2)		56.0 (24.6)	
Type 2	37.0 (6.3)	0.73	80.0 (13.0)	0.80	117.1 (17.7)	0.62	47.0 (27.4)	0.16
Treatment								
Pills	37.4 (5.7)		80.3 (13.9)		117.8 (18.0)		47.9 (27.4)	
Insulin	36.2 (7.7)	0.58	77.5 (13.3)	0.21	113.7 (20.0)	0.30	48.8 (27.0)	0.716
Cardiac disease								
Yes	36.2 (5.4)		75.2 (17.3)		111.4 (21.4)		42.6 (26.3)	
No	37.2 (6.6)	0.42	80.5 (13.0)	0.46	117.7 (18.2)	0.21	49.3 (27.3)	0.38
Hypertension								
Yes	36.8 (6.6)		78.7 (13.7)		116.0 (18.0)		45.0 (27.1)	
No	37.1 (6.4)	0.59	80.1 (14.0)	0.86	117.3 (19.2)	0.68	49.5 (27.2)	0.30
Pain in limbs								
Yes	35.6 (6.5)		76.3 (13.9)		111.5 (18.4)		43.9 (22.9)	
No	38.5 (6.2)	0.03	82.7 (13.3)	0.04	121.2 (18.5)	0.01	52.5 (30.4)	0.15
Loss of appetite								
Yes	33.8 (8.0)		68.0 (18.8)		101.8 (25.0)		42.6 (30.7)	
No	37.6 (6.1)	0.04	81.5 (12.1)	< 0.001	119.1 (16.8)	0.02	49.1 (26.6)	0.28
Constipation								
Yes	33.1 (6.5)		73.9 (13.0)		107.8 (17.0)		36.5 (25.1)	
No	38.3 (6.0)	< 0.001	81.4 (13.8)	0.01	119.7 (18.4)	< 0.001	51.9 (26.8)	0.01
Fatigue								
Yes	34.1 (6.0)		72.8 (13.5)		107.0 (17.3)		34.2 (19.1)	
No	40.1 (5.6)	< 0.001	86.4 (10.8)	< 0.001	126.4 (15.3)	< 0.001	63.3 (26.5)	< 0.001
Itching								
Yes	33.4 (7.0)		73.4 (15.0)		106.9 (20.5)		36.0 (24.8)	
No	38.6 (5.6)	< 0.001	82.2 (12.6)	< 0.001	121.0 (16.7)	< 0.001	53.4 (26.5)	< 0.001
Sleep disturbance								
Yes	36.1 (5.8)		74.1 (13.6)		110.3 (17.7)		40.6 (26.1)	
No	37.5 (6.8)	0.2	82.4 (13.3)	< 0.001	120.0 (19.0)	0.01	52.3 (26.9)	0.03

Possible scores: total QOL 40–160; general QOL 13–52; health-related QOL 27–108; WHO-5 index 0–100. Higher score indicates better QOL.

IRDQOL = Iranian Diabetes QOL.

SD = standard deviation.

P < 0.05 indicates statistically significant relationship.

Table 3 Relationship between different dimensions of quality of life (QOL) and other clinical and demographic variables

Variable	General QOL		Health-related QOL		Total IRDQOL		WHO-5 index	
	r	P	r	P	r	P	r	P
No. of signs & symptoms	−0.517	< 0.001	−0.553	< 0.001	−0.582	< 0.001	−0.487	< 0.001
Duration of diabetes	−0.069	0.487	−0.073	0.466	−0.086	0.393	−0.094	0.357
BMI	−0.191	0.056	−0.181	0.072	−0.131	0.196	−0.203	0.046
HbA1$_c$	−0.148	0.137	−0.092	0.360	−0.114	0.255	−0.070	0.483
Age	0.003	0.973	0.057	0.570	0.049	0.696	0.037	0.713
WHO-5 index	0.627	< 0.001	0.621	< 0.001	0.672	< 0.001	1.000	–

IRDQOL = Iranian Diabetes QOL.
r = Pearson's correlation coefficient.
P < 0.05 indicates statistically significant relationship.

relationship has been demonstrated in adult patients [17].

In a study on 2048 patients over 18 years old with type 1 or type 2 diabetes, among those who had type 2 diabetes, there was a relationship between complications of diabetes and QOL but no relationship between age or duration of diabetes and QOL [18]. Our study too showed no relationship between age or duration of diabetes and any dimensions of QOL. There was, however, a relationship between some physical signs and symptoms and QOL.

In our study, 50% of patients reported pain in the limbs, mainly the feet. This is in line with the study conducted by Quattrini and Tesfaye who reported that painful lower limb symptoms occurred in 32.1% of patients with type 2 diabetes [19]. Our study showed that patients with this common physical problem had a lower QOL. The association between physical signs and symptoms and lower QOL in diabetes patients has been demonstrated in a number of studies [17,20,21]. Physical signs and symptoms can be considered indicators for construction validity in studies regarding QOL questionnaires in diabetes mellitus. Our questionnaire successfully distinguished lower QOL in patients suffering from annoying signs and symptoms such as pain in limbs, itching and sleep disturbance which showed acceptable construct validity.

Quality of life has been found to be higher in males than females [22–24]. It seems sex can be considered a predictor variable in QOL studies. This study showed significantly better health-related and total QOL in males, confirming the criterion predictive validity of the scale. In observational studies, an increasing degree of obesity has been associated with health-related QOL [18,25]. Although there was a significant inverse relationship between the WHO-5 and BMI in our study, other QOL measures did not show such a relationship.

Findings regarding the relationship between QOL and treatment regimen are ambivalent in the literature. Some studies report that patients who are treated with insulin have lower QOL [17,23]. Others, along with our own study, do not show such a relationship [18,24].

The correlation coefficient of the IRDQOL questionnaire and WHO-5 questionnaire was 0.639, which is fairly acceptable as the concurrent criterion validity. The scale might be able to predict QOL as

an important outcome in the follow-up of diabetic patients, although the predictive criterion validity of the questionnaire needs more assessment.

The scale can determine the general and health-related QOL in both type 1 and type 2 adult diabetic patients, which is an advantage of the scale.

Conclusions

Quality of life is a subjective and complicated experience which is widely used as an indicator in different clinical trials and descriptive studies. There are a number of general and health-related QOL questionnaires for diabetes mellitus. In addition to translation and validation of questionnaires in different countries, designing new questionnaires with qualitative approaches may give better understanding of cultural effects on quality of life. The questionnaire we devised has acceptable validity and reliability and has a number of advantages. The items have been derived from the people involved in the actual situation regarding living with diabetes in the cultural milieu of the Islamic Republic of Iran. It can also determine both general and health-related QOL.

The IRDQOL questionnaire successfully distinguished the lower QOL in all 3 dimensions, in patients suffering from pain in limbs, loss of appetite, fatigue, constipation and itching, the most frequent signs and symptoms, indicating acceptable construct validity of the questionnaire.

Our questionnaire might be appropriate for assessment of QOL in persons with diabetes in other countries with similar cultural backgrounds and other Islamic countries in the region. However, this would need further research; in particular, concurrent validity should be studied using other health-related QOL questionnaires for diabetes.

Acknowledgements

References

1. Fayers PM, Machin D. Quality of life: assessment, analysis, and interpretation. New York, John Wiley, 2000:27.

2. Polonsky WH. Understanding and assessing diabetes specific quality of life. Diabetes spectrum, 2000, 13(1):36–42.

3. Snoek FJ. Quality of life: a closer look at measuring patients' well-being. Diabetes spectrum, 2000, 13(1):24–9.

4. Study protocol for the World Health Organisation project to develop a Quality of Life assessment instument (WHOQOL). Quality of life research, 1993, 2(2):153–9.

5. Wood-Dauphinee S. Assessing quality of life in clinical research: from where have we come and where are we going? Journal of clinical epidemiology, 1999, 52(4):355–63.

6. Haberman MR, Bush N. Quality of life methodological and measurement issues. In: King CR, Hinds PS, eds. Quality of life from nursing and patient perspectives:

theory, research, practice, 1st ed. Toronto, Canada, Jones & Bartlett, 1998:117–39.

7. Faro B. The effect of diabetes on adolescent quality of life. Pediatric nursing, 1999, 25(3):247–54.

8. Watkins K, Connell C. Measurement of health related QOL in diabetes mellitus. Pharmacoeconomics, 2004, 22(17):1109–26.

9. Streubert HJ, Carpenter DR. Qualitative research in nursing, advancing the humanistic imperative, 2nd ed. Philadelphia, Lippincott, 1999.

10. Kendall J. Axial coding and the grounded theory controversy. Western journal of nursing research, 1999, 21(6):743–57.

11. Bech P, Gudex C, Johansen KS. The WHO (Ten) well-being index: validation in diabetes. Psychotherapy psychosomatics, 1996, 65(4):183–90.

12. Burnes N, Grove SK. The practice of nursing research: conduct, critique and utilization, 4th ed. Philadelphia, WB Saunders Co., 2001.

13. Gillis A, Jackson W. Research for nurses: methods and interpretation. Philadelphia, FA Davis, 2002:403.

14. Trief PM et al. A prospective analysis of marital relationship factors and quality of life in diabetes. Diabetes care, 2002, 25(7):1154–8.

15. Mortensen HB. Findings from the Hvidore Study Group on Childhood Diabetes: metabolic control and quality of life. Hormone research, 2002, 57(suppl. 1):117–20.

16. Varni JW et al. The PedsQL in type 1 and type 2 diabetes: reliability and validity of the Pediatric Quality of Life Inventory Generic Core Scales and type 1 Diabetes Module. Diabetes care, 2003, 26(3):631–7.

17. Testa MA, Simonson DC, Turner RR. Valuing quality of life and improvement in glycemic control in people with type 2 diabetes. Diabetes care, 1998, 21(suppl. 3):C44–52.

18. Coffey et al. Valuing health-related quality of life in diabetes. Diabetes care, 2002, 25(12):2238–43.

19. Quattrini C, Tesfaye S. Understanding the impact of painful diabetic neuropathy. Diabetes metabolic research review, 2003, 19(suppl. 1):S2–8.

20. Zetina-Lopez A et al. Impacto de los síntomas gastrointestinales sobre la calidad de vida de los pacientes diabéticos tipo 2 [Impact of gastrointestinal symptoms on health related quality of life in patients with type 2 diabetes mellitus]. Revista de investigación clínica, 2003, 55(6):594–9.

21. Brown MM et al. Quality of life associated with visual loss: a time trade-off utility analysis comparison with medical health states. Ophthalmology, 2003, 110(6):1076–81.

22. Senez B et al. Evaluation de la qualité de vie des patients diabétiques de type 2 en médecine générale [Quality of life assessment of type 2 diabetic patients in general medicine]. Presse médicale, 2004, 33(3):161–6.

23. Mata Cases M et al. Impacto de la diabetes mellitus tipo 2 en la calidad de vida de los pacientes tratados en las consultas de atención primaria en España [Effect of type 2 diabetes mellitus on the quality of life of patients treated at primary care consultations in Spain]. Aten primaria, 2003, 31(8):493–9.

24. Huang GH et al. Self-rated health among young people with type 1 diabetes in relation to risk factors in longitudinal study. American journal of epidemiology, 2004, 159(4):364–72.

25. Kaukua JK, Pekkarinen TA, Rissanen AM. Health-related quality of life in a randomised placebo-controlled trial of sibutramine in obese patients with type II diabetes. International journal of obesity, 2004, 28(4):600–5.