European Journal of General Practice

ISSN: 1381-4788 (Print) 1751-1402 (Online) Journal homepage: informahealthcare.com/journals/igen20

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To cite this article: Liina Pilv, Etienne Vermeire, Anneli Rätsep, Alain Moreau, Dragica Nikolić, Davorina Petek, Hakan Yaman, Marje Oona & Ruth Kalda (2016) Development and validation of the short version of the diabetes obstacles questionnaire (DOQ-30) in six European countries, European Journal of General Practice, 22:1, 16-22, DOI: 10.3109/13814788.2015.1093619

To link to this article: https://doi.org/10.3109/13814788.2015.1093619

EUROPEAN JOURNAL OF GENERAL PRACTICE, 2016
VOL. 22, NO. 1, 16–22
http://dx.doi.org/10.3109/13814788.2015.1093619

ORIGINAL ARTICLE

Development and validation of the short version of the diabetes obstacles questionnaire (DOQ-30) in six European countries

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KEY MESSAGE

- The DOQ-30 is a new broadly conceptualised DR-QoL instrument addressing a variety of obstacles patients might confront in everyday life.
- It is based on qualitative research in six European countries and reveals good internal reliability, and external and construct validity.

ABSTRACT

Background: Patients with type 2 diabetes reveal different obstacles in living with the disease. The EGPRN initiated a qualitative research EUROBSTACLE to create a broadly conceptualized diabetes-related quality of life (DR-QoL) instrument. It led to the development of the diabetes obstacle questionnaire (DOQ), a five-point Likert-scaled measure, consisting of 78 items in eight scales.
Objectives: To develop and validate a short, easy-to-use version of the DOQ.
Methods: A cross-sectional study with the DOQ was carried out. Participants answered the DOQ and GPs added some clinical data from their medical records. Data of 853 patients from Belgium, France, Estonia, Serbia, Slovenia, and Turkey were included in the analysis. The selection of items for the short version of the DOQ was achieved with exploratory factor analysis (EFA). Construct validity was proved with EFA and Pearson correlations between the DOQ and the new DOQ-30. Internal reliability was established with Cronbach's alpha.
Results: DOQ-30 resulted in 30 items in nine subscales. It explained 49.8% of items' variance. It shows a considerable good internal reliability and construct validity.
Conclusion: The DOQ-30 is a five-point Likert-scaled broadly conceptualized measure of DR-QoL. It addresses a variety of obstacles, such as social, psychological, cognitive and behavioural. The DOQ-30 is ready for implementation in general practice and research in Europe as a valuable instrument to assess DR-QoL.

ARTICLE HISTORY
Received 4 April 2014
Revised 28 August 2015
Accepted 2 September 2015

KEYWORDS
Clinical domain; diabetes; general practice/family medicine; general; research methodology; development of measurement instruments; operational domain; patient involvement; empowerment; self-management; easy-to-use; DR-QoL

Introduction

Diabetes is a chronic disease of high importance. In the WHO report 'global status report on non-communicable diseases 2010,' it is assessed that diabetes will become the seventh leading cause of death by 2030 (1), and diabetic patients are persistently in poor glycaemic control (2). It is known that relevant health outcomes include not only biomedical and functional dimensions of health measures but also subjective considerations such as disease self-management burden, emotional health, and social and physical functioning, the so-called diabetes-related quality of life (DR-QoL) indicators (3). Patients' self-management behaviours affect DR-QoL, for example, intensification of treatment regimen and patients' subjective cost-benefit regards can influence patients' decisions (4). Therefore, the clinical effectiveness assessments should incorporate patient-centred outcome measures.

To attempt a closer understanding of the theme from the point of view of the patient, it is of the utmost importance to research patient-directed experiences and their fears of living with diabetes (5). During the past few decades, considerable effort has been devoted to the study of patients' self-management behaviours and adherence to the treatment. In DR-QoL research, questionnaires that are in use are listed in Appendix 1 (6–25).

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Supplemental data for this article can be accessed at http://dx.doi.org/10.3109/13814788.2015.1093619

ATT39, PAID, DDS, the QSD-R, DHP, ADS, and ADDQoL are focused only on some aspects such as diabetes-related distress or additionally on the activity or the eating behaviour. EDBS is a measure for elderly people. ASK-20 is not dedicated specifically to patients with diabetes, but also for other chronic diseases like asthma and congestive heart failure.

In their review articles, researchers Watkins and Connell (4) and Achhab et al. (26) were of the same opinion that DCP, DIMS, DQOL, DSQOLS, and the D-39 were broadly conceptualized diabetes-specific QoL questionnaires. They found that DQOL and DSQOLS were mainly dedicated to patients with type 1 diabetes. Patients were not involved in the derivation of items for the ADS, DCP, DIMS and D-39. Factor analysis was not used to support construct validity of the ADS, DQOL and DQLCTQ-R. Almost all instruments were developed and validated in industrialized countries (4,26). Researchers in Bulgaria assessed ADDQoL and DCP as the most promising instruments for measuring the DR-QoL (27). In research, the most often used PAID and ADDQoL are not broadly conceptualized but single-factor measures of diabetes-related distress. These are sometimes used with SF-36 (28,29) . For future research in this area, it is recommended to increase the racial, cultural and ethnic diversity of research participants, and to develop the same questionnaire for low-income countries (4,26).

In 2000, EGPRN researchers initiated the international research project EUROBSTACLE to fulfil the gap of broadly conceptualized DR-QoL instruments that take in obstacles of patients from different ethnic, cultural and healthcare systems.

The first phase, qualitative research using focus groups on 246 patients was carried out in six European countries: Croatia, Estonia, France, the Netherlands, Slovenia and the UK (30). It resulted in the creation of the diabetes obstacle questionnaire (DOQ). The DOQ is a five-point Likert-scaled instrument, consisting of 78 items grouped in eight scales. The Warwick diabetes care research user group in the UK gave feedback to the research team on the questionnaire design and content (31). In the second phase, a cross-sectional study using the DOQ was conducted in May to November 2009 on patients with type 2 diabetes (T2DM) in seven countries: Belgium, France, Estonia, Serbia, Slovenia, the UK and Turkey. The DOQ was further validated in the UK, Belgium and Estonia (31–33). The Pearson correlation coefficient was calculated between the DOQ and PAID, ADDQoL, and HbA1c in the UK and the Belgian sample to determine construct validity (31,32). A broad variety of obstacles was demonstrated by Estonian sample (33). An important disadvantage of the DOQ is that the questionnaire is rather time-consuming for patients to answer and for healthcare providers to administer. In this study, we intended to develop and validate a short, easy-to-use version of the DOQ.

Methods

Development of the dataset

The design of the cross-sectional study with the DOQ was agreed by researchers from Belgium, France, Estonia, Serbia, Slovenia and Turkey: GPs enrolled at least three consecutive outpatient diabetes patients into the study. Researchers gave a study kit comprising an information leaflet, a questionnaire, extract from their medical records with their latest clinical results, and prepaid, self-addressed envelopes to participants. The method is described elsewhere (31–33). The questionnaire was translated into native languages and back into English in all six countries. Altogether, 860 participants were enrolled in the study. Missing data analyses revealed that 441 respondents answered all items. In 66 cases, one answer was lacking and in 60 cases two answers. Seven cases with more than 25% missing data were eliminated. Consequently, the data for 853 respondents were included in statistical analyses. The number of missing values for items increased from 1.3% to 20.9%, with a mean of 4.4%.

Multiple imputations were used to handle missing data. All the results from six countries were included in the dataset to perform statistical analyses. Descriptive characteristics concerning gender, age, diabetes duration, type of diabetic treatment and complications for each included sample were computed.

Exploratory factor analysis for the selection of items

All 78 items were inserted into exploratory factor analyses (EFA) to identify new subscales, to select the items of greater relevance, and to support construct validity for the short version of the DOQ. We used principal axis factoring (PAF) as the extraction method and Varimax with Kaiser Normalization as the rotation method. PAF is a correlation-focused approach and preferred for causal modelling (33,34). It is shown that the factor pattern obtained by Varimax gives a clearer separation of the factors (35,36). Factor loadings of >0.5 are considered good, 0.3–0.5 moderate and loadings of <0.3 are considered weak (37,38). The scree plot, eigenvalues and content analysis were examined to determine meaningful factors. Each factor represented as a new subscale. We included 4–2 items with factor loadings ≥ 0.5 into each subscale for a new short easy-to-use version of the DOQ.

Cronbach's alpha for internal reliability

Cronbach's alpha as an internal reliability index was calculated separately for all new subscales.

Pearson correlation coefficient to determine construct validity

To confirm construct validity of the new questionnaire the Pearson correlation coefficients were calculated between the scales of the DOQ and the subscales of the new shortened version of the DOQ. We summed raw scores of the scales of the DOQ and of all items loading on the subscales of the shortened DOQ. This method preserved the variation in the original data (39). Statistical analyses were conducted using the IBM SPSS Statistics Version 20 and R (version 3.1, Lavaan 0.5–17).

Results

Descriptive statistics

In the study group of 853 participants, the age of participants ranged from 27–89 years, the mean age was 64 (SD 10.5) years and the mean duration of T2DM was 7.3 (SD 6.7) years. Among the participants, 49.6% were male. The descriptive characteristics of the whole sample are presented in Table 1.

Descriptive statistics and occurrence of complication showed a considerable range between countries. The data for diabetes complications were missing in the Turkish and Belgian samples; these were marked as NR.

Exploratory factor analyses

EFA was computed on the whole set of 78 items. It resulted in item-to-factor loadings from 0.42 to 0.85 and 18 factors with an eigenvalue >1 explaining 51.5% of items' variance. A close examination of the scree plot, eigenvalues, and content analysis indicated nine meaningful subscales with four items in the first six and two in the last three—altogether 30 items. The new scale explained 49.8% of the items' variance. Compared to the 18-factor structure that explains 51.5% of items' variance, we have lost only 0.7% of items' variance by nine-factor construction. The Kaiser–Meyer–Olkin measure of sampling adequacy was 0.92, and Bartlett's test of sphericity was significant ($P<0.001$), which indicated that the nine-factor solution was appropriate. We named the short easy-to-use version of the DOQ the DOQ-30. The results are shown in Table 2 (the DOQ-30 questionnaire can be found in the Supplementary material online).

Cronbach's alpha ranged from 0.52–0.89

Cronbach's alpha was 0.52 for 'uncertainty about a consultation' containing two items drawn from different scales of the DOQ.

Pearson correlations between the DOQ and the DOQ-30

Pearson correlation between scale scores of the DOQ and the DOQ-30 showed high coefficients from 0.58–0.99. The results are shown in Table 3.

The subscale 'uncertainty about a consultation' was extracted from 'obstacles at diagnosis scale' $r=0.71$ and 'obstacles in relationships with healthcare professionals scale' $r=0.49$. The original scale 'medication obstacles scale' was cleaved into two subscales: 'medication' $r=0.58$ and 'Insulin-use' $r=0.70$. No item was presented from 'obstacles to coping with diabetes scale.' Conversely, it revealed high correlations with three new subscales: 'lifestyle changes' $r=0.58$, 'support from friends and family' $r=0.55$, and 'uncertainty about a consultation' $r=0.43$. The contents of the DOQ-30 in six countries that emerged were comparable to the original scales of the DOQ validated in the UK, Belgium, and Estonia.

Table 1. Baseline statistics of the study sample.

	Country						
	Estonia	France	Serbia	Slovenia	Turkey	Belgium	Total
Age, mean (SD)	66.7 (9.8)	65.0 (9.5)	64.2 (10.3)	63.0 (10.1)	59.3 (11.3)	65.6 (10.4)	64.1 (10.5)
T2DM duration, mean (SD)	8.6 (5.0)	10.2 (8.1)	11.0 (7.3)	9.7 (6.6)	3.7 (3.0)	1.6 (1.3)	7.3 (6.7)
Gender male, *n* (%)	61 (44.5)	105 (58.3)	50 (45.0)	74 (57.4)	57 (41.0)	76 (48.4)	423 (49.6)
Tablets treatment, *n* (%)	124 (90.5)	162 (89.5)	94 (84.7)	90 (75.6)	130 (93.5)	137 (87.8)	737 (87.4)
Insulin treatment, *n* (%)	38 (29.0)	45 (24.9)	43 (38.7)	28 (23.5)	24 (17.3)	47 (30.3)	225 (26.9)
Microvasc. comp., *n* (%)	39 (28.3)	41 (22.5)	34 (47.9)	29 (22.5)	NR	NR	143 (27.5)
Macrovasc. comp., *n* (%)	22 (15.9)	14 (7.7)	21 (29.6)	23 (17.8)	NR	NR	80 (15.4)
Diabetic foot, *n* (%)	20 (14.5)	3 (1.6)	9 (12.7)	6 (4.7)	NR	NR	38 (7.3)
Nephropathy, *n* (%)	30 (21.7)	23 (12.6)	12 (16.9)	11 (8.5)	NR	NR	76 (14.6)
Neuropathy, *n* (%)	38 (27.5)	22 (12.1)	48 (67.6)	13 (10.1)	NR	NR	121 (23.3)
Total, *n* (%)	137 (100.0)	180 (100.0)	111 (100.0)	129 (100.0)	139 (100.0)	157 (100.0)	853 (100.0)

NR, not reported.

Table 2. Factor structure in EFA of DOQ-30 of the dataset of six European countries; Cronbach's alpha of the subscales.

Subscales	Factor loadings
Relationships with medical professionals $\alpha = 0.87$	
I am not assisted in setting realistic targets for changing my lifestyle	0.720
I have not been told what to expect from my treatment	0.720
The good and bad aspects of each choice have not been discussed with me	0.713
Treatment alternatives are not explained to me	0.711
Support from friends and family $\alpha = 0.82$	
I feel I get little support from my family	0.679
I feel I get little support from my friends	0.627
I feel very alone with my diabetes	0.514
I would manage my diabetes much better if I had encouragement socially	0.484
Knowledge of the disease $\alpha = 0.82$	
I do not know as much as I need to know about the consequences of having diabetes	0.705
I do not know enough about the treatment for diabetes	0.655
I do not know as much as I need to know to manage my diabetes	0.630
I have difficulty understanding the information from literature	0.597
Lifestyle changes $\alpha = 0.75$	
My diabetes has placed a strain on my personal relationships	0.601
Changes in my diet have put a strain on my family	0.581
I feel resentful that I am obliged to change my eating habits	0.589
My diabetic diet spoils my social life	0.582
Exercising $\alpha = 0.84$	
I have not found an exercise I enjoy	0.755
I lack the motivation to exercise	0.714
I am unable to fit exercise into my lifestyle	0.637
I am unable to afford the cost of exercising on a regular basis	0.526
Self-monitoring $\alpha = 0.81$	
Self-monitoring makes me feel frustrated	0.733
I find it too uncomfortable to self-monitor	0.613
I find it especially hard to test when I am busy	0.562
Self-monitoring makes me fearful of a high reading	0.510
Uncertainty about a consultation $\alpha = 0.52$	
The way that I was told that I had diabetes made feel afraid	0.582
I feel a sense of helpless when consulting with nurses	0.507
Medication $\alpha = 0.89$	
I do not feel I am being prescribed a medication dose that is right for me	0.818
I do not feel I am being prescribed medication that is right for me	0.778
Insulin-use $\alpha = 0.78$	
Using insulin makes life too complicated	0.673
Using insulin means my diabetes is getting worse	0.729

Discussion

Main findings

At the beginning of this millennium, there were several DR-QoL measures available that did not meet requirements of a broadly conceptualized easy-to-use DR-QoL instrument. In 2000, the EGPN initiated the project EUROBSTACLE for the development of a DR-QoL instrument meeting these demands. Patients from countries with different ethnic, cultural and healthcare systems had to be involved in the development of the tool. The goal succeeded in the creation of the DOQ-30.

The development of the DOQ-30 began with the qualitative research project EUROBSTACLE on 246 patients in six European countries (30). Previously, the development of DM-QoL instrument had been based on different generic and disease-specific measures of subjective health status, followed by consultations of diabetes healthcare professionals and conversations or small, unstructured interviews with patients. For ADDQoL, there were 12 interviews (19), for D-39 an unknown number of interviews with patients (7) and for DIMS and DCP no conversations with a patient were mentioned (14,21). We did not find any qualitative research with international design in the development of a DR-QoL instrument. The EUROBSTACLE project resulted in the creation of the diabetes obstacle questionnaire (DOQ) in 78 items. We intended to create an ideal research tool of a reasonable volume by means of EFA and validate its construct with EFA and Pearson correlations between the original DOQ and the new shortened one. We formed a database for factor analysis from a cross-sectional study with the DOQ in six countries. The descriptive characteristics concerning age, gender, duration of the disease and type of treatment showed considerable differences between data of included samples (Table 1). The EFA resulted in a nine-factor structure, which explains 49.8% of the items' variance. So, the DOQ-30 in nine subscales with 30 items was created (Table 2). We decided to preserve the two-item subscale 'uncertainty with the consultation'

because of the very important theme. The subscale showed a moderate internal homogeneity with a Cronbach's alpha of 0.52. It is shown that Cronbach's alpha is influenced too much by the amount of the items included in a scale. The lower the number of items, the lower the value for Cronbach's alpha (40).

We computed Pearson correlations to ensure that by reducing the questionnaire we do not lose important information gathered in the qualitative phase of the project. It also showed very high correlation coefficients from 0.58–0.99 (Table 3). Conclusively, the results of EFA and Pearson correlation coefficients were of high construct validity.

The DOQ-30 showed comprehensive areas of barriers in everyday life with T2DM. Social aspects are studied in the scale 'relationships with medical professionals,' which primarily describes physicians' skills of communication and elucidates the concerns related to the patient, and in the scale 'support from friends and family,' which deals with loneliness and desire for support from family, friends and society. Psychological aspects are studied in the scales 'lifestyle changes,' 'exercising' and 'uncertainty about a consultation.' The scales showed how considerably resentful patients with T2DM may feel if they have to change their habits because of the disease. The scale 'knowledge of the disease' reflects cognition and understanding about the disease. The three scales 'self-monitoring,' 'medication,' and 'use of insulin' express attitudes and fears to treating process and behaviour. In comparing the DOQ-30 with other diabetes-related QoL research measures, DOQ-30 is more multidimensional and covers a comprehensive variety of barriers. Almost all diabetes questionnaires that were evaluated as broadly conceptualized exclude statements about themes, like relationships with medical personnel (DIMS, DCP, diabetes-39), physical activity (DIMS, diabetes-39), self-monitoring (DIMS), or concerns about lack of knowledge of T2DM (DIMS). However, all discussed questionnaires deal with patients' feelings and moods associated with separate aspects of psychosocial distress in diabetes. The use of DOQ-30 may help to stimulate conversation between the caregiver and patient, to explain the obstacles in adhering to their self-management, and targeted to promote patients.

Limitations

Despite the strength of its contributions, the DOQ-30 shows that some limitations have to be acknowledged.

First, the dataset contained 4.4% of missing values. We used multiple imputations to analyse incomplete data. The most optimal solution has been proposed. Second, even though the new subscales of the DOQ-30

Table 3. Pearson correlation between scale scores of the DOQ and the DOQ-30 of the dataset of six European countries. All coefficients are significant ($P < 0.001$).

Scored scales\\Scored subscales	DOQ								DOQ-30							
	78F1	78F2	78F3	78F4	78F5	78F6	78F7	78F8	30F1	30F2	30F3	30F4	30F5	30F6	30F7	30F8
DOQ																
78F1 Medication obstacles scale	0.49															
78F2 Self-Monitoring obstacles scale	0.40	0.28														
78F3 Obstacles of knowledge and beliefs scale	0.36	0.31	0.55													
78F4 Obstacles at diagnosis scale	0.47	0.34	0.58	0.53												
78F5 Obstacles in relationships with healthcare professionals scale	0.50	0.39	0.39	0.44	0.52											
78F6 Obstacles to lifestyle changes scale	0.42	0.29	0.39	0.43	0.49	0.62										
78F7 Obstacles to coping with diabetes scale	0.42	0.33	0.41	0.45	0.57	0.56	0.64									
78F8 Obstacles around advice and support scale																
DOQ-30																
30F1 Relationships with medical professionals	0.38	0.27	0.52	0.45	0.90	0.42	0.39	0.46								
30F2 Support from friends and family	0.36	0.28	0.34	0.41	0.51	0.51	0.55	0.90	0.42							
30F3 Knowledge of the disease	0.40	0.26	0.93	0.51	0.51	0.38	0.36	0.37	0.47	0.30						
30F4 Lifestyle changes	0.39	0.31	0.29	0.36	0.44	0.81	0.58	0.49	0.34	0.44	0.26					
30F5 Exercising	0.45	0.35	0.33	0.32	0.40	0.78	0.41	0.42	0.34	0.39	0.35	0.39				
30F6 Self-monitoring	0.48	0.99	0.26	0.30	0.32	0.40	0.29	0.32	0.25	0.28	0.24	0.32	0.35			
30F7 Uncertainty about a consultation	0.30	0.25	0.41	0.71	0.49	0.42	0.43	0.39	0.35	0.35	0.34	0.38	0.26	0.25		
30F8 Medication	0.58	0.17	0.31	0.31	0.36	0.22	0.29	0.26	0.29	0.20	0.29	0.20	0.17	0.14	0.24	
30F9 Insulin-use	0.70	0.35	0.22	0.14	0.24	0.32	0.25	0.25	0.19	0.23	0.25	0.23	0.34	0.35	0.15	0.15

cover those of the DOQ, we lost some information. This loss can be justified by reducing duplication of the information and creating a reasonable easy-to-use questionnaire.

As the validation of measures is an ongoing process, future studies should corroborate DOQ-30 and prove its relevance for the diabetic patient. Further research is required to evaluate responsiveness through longitudinal comparisons of instruments within clinical trials.

Conclusion

The DOQ-30 is a five-point Likert-scaled measure of DR-QoL in nine subscales and contains 30 items with good internal reliability, and external and construct validity.

The DOQ-30 addresses a variety of obstacles, which patients might confront, such as social, psychological, cognitive and behavioural. The DOQ-30 could be implemented in general practice and research in Europe as a valuable instrument to assess DR-QoL.

Acknowledgements

The authors gratefully acknowledge the patients and their GPs who agreed to participate in this study and express their gratitude to the EGPRN group. They should like to thank K. The, A. Kuusk, M.Raag, A. Rozeik and R. Salupere for their time and advice. The Turkish part of the study was supported by the Akdeniz University Project Management Unit. During the design and conduct of the study, the University of Tartu funded L. Pilv as a full-time state-funded Ph.D. student. The data referred to in the current study were gathered with the support of the Estonian Science Foundation Grant no. ETF 7596.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Appendix 1

DR-QOL RESEARCH QUESTIONNAIRES

- ATT39, measurement of emotional adjustment in diabetic patients (1986)
- D-39, diabetes-39 (1997)
- PAID, the problem areas in diabetes (1995)
- DDS, the diabetes distress scale (2005)
- QSD-R, the questionnaire on stress in patients with diabetes (1986)
- DHP-1, the diabetes health profile (2000)
- DIMS, diabetes impact measurement scales (1992)
- DQLCTQ-R, the diabetes quality of life clinical trial questionnaire (1999)
- ASK-20, questionnaire to assess barriers to medication adherence (2008)
- ADS, the appraisal of diabetes scale
- ADDQoL, the audit of diabetes-dependent QoL (1999)
- DCP, the diabetes care profile (1996)
- DQOL, the diabetes quality of life
- DSQOLS, the diabetes-specific quality of life scale
- EDBS the elderly diabetes burden scale