INSTRUMENTS FOR DISEASE-SPECIFIC QUALITY-OF-LIFE MEASUREMENT IN PATIENTS WITH TYPE 2 DIABETES MELLITUS - A SYSTEMATIC REVIEW

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ABSTRACT
Diabetes mellitus is a disease which carries a considerable social impact in Bulgaria and across the world because of its high prevalence. Research literature has recently included lots of studies investigating the effects of diabetes mellitus on the quality of life of diabetic patients and also many instruments to assess these effects. Quality of life is a concept that encompasses an individual's subjective perception of physical, emotional and social well-being, including both a cognitive component (satisfaction) and an emotional component (happiness).

We review and analyse in the present article major determinants of disease-specific quality of life in patients with type 2 diabetes mellitus and the tools used for assessment.

RESULTS: Fourteen instruments for measuring quality of life in type 2 diabetes mellitus (T2DM) met our search criteria. Their contents covered different quality-of-life domains or indicators - typical diabetes symptoms, general health and quality of life, personality traits, physical functioning, mental and social well-being, treatment and quality of life. Most of the disease-specific tools had been field tested and data about their reliability and validity have been reported. Few tools had been subjected to formal assessment of their adaptability to changes.

CONCLUSIONS: Of the instruments we assessed the most promising approaches for measuring the diabetes-specific quality of life are offered by ADDQoL, DÇP and WBQ. Patients were involved in the development of these tools which have been shown by a number of studies to have good internal reliability, external and construct validity. Efforts are being continually made worldwide to develop a standard ensuring valid, reliable, easy to use tool for assessing quality of life in patients with type 2 diabetes mellitus in order to promote patients integration into society.

Key words: diabetes mellitus, quality of life, tools for disease-specific quality of life assessment in type 2 diabetes mellitus

INTRODUCTION
The world is facing an epidemic of type 2 diabetes mellitus. Some 366 million people worldwide are currently estimated to have diabetes; by 2030 this number is expected to rise to 552 million. Nearly 25% of the people over 50 years of age have impaired glucose tolerance and every year 5-8% of them develop diabetes. According to some prognoses deaths due to diabetes and its complications will double between 2005 and 2030.¹

In Bulgaria it is estimated that more than 9% of the population is affected with T2DM. And yet there is no generally available method in Bulgaria for assessing the quality of life in these patients and everyday clinical practice lacks data about the actual burden of the disease.²

Experience of leading countries in the field has shown that early diagnosis, effective prevention and treatment of diabetes mellitus and its complications, and proper patient education are essential in reducing morbidity, development and progression of complications, disability and mortality due to
diabetes and would result in improved quality of life of those patients. Meeting the psychological and social needs of patients plays an important role for the “good care” in T2DM.3-4

Quality of life (QoL) assessment is an integral component in chronic diseases management. The attention of researcher in this field is focused mainly in two directions: the one is assessment of the psychosocial functioning of patient groups and identification of specific problems and needs associated with different stages of disease. The other, which is very common, is studying quality of life in order to compare the impact of different treatment interventions on patient satisfaction.4-5

The term QoL is used in a broad context encompassing the living conditions in various countries for the purposes of social policy and presenting results from a large number of medical and psychotherapeutic practices. It is often used as a synonym of well-being, health status and satisfaction.

Quality of life as defined by WHO is “an individual’s perceptions 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”.6

Hörnquist defines quality of life as “a broad spectrum of dimensions of human experience, ranging from those associated with the necessities of life, such as food and shelter, to those associated with achieving a sense of fulfillment and personal happiness”.7

Quality of life is a concept incorporating an individual’s subjective perception of physical, emotional, and social well-being, including both a cognitive component (satisfaction) and an emotional component (happiness).8

Physical well-being generally includes the ability to function independently in activities related to the personal needs of the individual. The psychological aspects of quality of life are related to mental health, various states of stress, anxieties and enjoyment of everyday life, various positive and negative emotional states of that self assessment. The social dimensions of well-being are the most complex and difficult to measure because they involve intimate and family life activity, friendship, career, leisure, social environment and life, level of education and culture, environment and other social roles.8

Various authors provide convincing research evidence that specific quality of life self-assessment is a more powerful predictor of health care demand, morbidity and mortality than many objective measures of health. Its measurement makes it possible to evaluate scientifically the impact of quality of life on health, going far beyond the old paradigm that was limited to what can be seen under a microscope.9-11

There is a distinction between “quality of life in general” and “quality of life in diabetes mellitus”. Generic QoL tools are applicable in the general population, but are also used in specific groups and are used across different populations, conditions and diseases. Such tools can be used to compare QoL in patients with disease and healthy controls.

To narrow the aspects down to the functional ones, those directly associated with disease and/or medical treatment, the term Health-Related Quality of Life was introduced.

The goals of the present study were:
- to identify the major determinants of disease-specific quality of life in patients with type 2 diabetes mellitus;
- to evaluate the measurement tools used for assessment of disease-specific quality of life in patients with type 2 diabetes mellitus;

METHODS

Systematic searches in accessible full text and bibliographic electronic databases were conducted. The objects of the analyses were the major determinants of disease-specific quality of life in patients with type 2 diabetes mellitus. The review was restricted to retrieved instruments assessed against the following predefined inclusion criteria: 1. Tools designed to assess quality of life in type 2 diabetes not requiring insulin treatment (or designed to be applied in both type 1 and 2 diabetes mellitus); 2. Tools designed for QoL assessment in adults. The following types of instruments were excluded from the review: 1. Tools designed to assess QoL in people with diabetes mellitus type 1 and/or type 2 requiring insulin treatment; 2. Tools designed for QoL assessment in children and adolescents.

The analyses of disease specific instruments meeting the criteria included: domains of quality of life, number of indicators and scales, reliability and validity and data from studies in different target groups.

RESULTS AND DISCUSSION

The concept of quality of life has been increasingly gaining popularity since 1970. The accessible electronic full text and bibliographic databases were systematically searched using as keywords
“diabetes mellitus” and “quality of life in patients with diabetes mellitus” (sources in Science Direct, Thomson Reuters Web of Knowledge) for a period of five years (2007 to March 2012). We found 22 352 articles (Thomson Reuters Web of Knowledge – 4 122), and of these 6892 were meta-analyses and reviews (Thomson Reuters Web of Knowledge – 704). The strategy of combined search using “tools for quality of life assessment in diabetes mellitus” as key words further limited the number of retrieved references down to 6029 documents, of which 1462 were meta-analyses and reviews (Thomson Reuters Web of Knowledge - 147) (Fig. 1).

A total of 14 instruments for measuring quality of life in type 2 diabetes (non-insulin dependent) met our search criteria (Table 1).

**Figure 1.** Number of retrieved results from Science Direct and Thomson Reuters Web of Knowledge using as key words “diabetes mellitus” and “quality of life in patients with diabetes mellitus” between 1970 and March 2012.

**QUALITY OF LIFE DETERMINANTS IN TYPE 2 DIABETES MELLITUS**

Quality of life is a multi-dimensional concept and health is one of its most important components along with factors such as employment, housing, education, close surroundings and environment, culture, values and spirituality. The multiaspectual character of general quality of life makes it extremely complex to measure it.

Key aspects of the quality of life concept in diabetes mellitus have been discussed by various authors.11-13

The critical analysis of various approaches for assessment of disease-specific quality of life enabled the summative and adapted presentation of the concept with regard to its applicability in the development of research methodology (Fig. 2).

**DISEASE SPECIFIC INSTRUMENTS FOR ASSESSMENT OF QUALITY OF LIFE IN TYPE 2 DIABETES MELLITUS**

All disease-specific instruments for quality of life assessment in diabetes mellitus (Diabetes Quality of Life) include different number of items across various domains, such as emotional problems, social relations, satisfaction with treatment, illness-related limitations, diet, physical functioning, etc.14-16

These measurement instruments usually take the form of short questionnaires designed to assess quality of life from the patient’s own perspective.

**THE APPRAISAL OF DIABETES SCALE (ADS)**

It includes 7 subscales (dimensions of study) for assessment of patients’ emotions and habits related to the disease. The authors suggest a useful screening instrument for assessment of adjustment to diabetes, specifically to identify those patients experiencing, or at risk for distress and those with diabetes dietary regimen adherence problems.

All items use a five-point Likert scale for the answers. The instrument has high internal reliability and has shown good to excellent validity. It is a fast tool for evaluation – it takes five minutes to complete. It has not been tested in elderly patients and in minority populations.17

**AUDIT OF DIABETES DEPENDENT QUALITY OF LIFE (AD-DQOL)**

The AD-DQOL attempts to evaluate comprehensively diabetes-specific quality of life by assessing how individuals perceive diabetes is interfering with their well being or contrarily, how diabetes may be having a positive effective in some domains.20

The instrument measures 18 domains of life and patients with type 2 diabetes mellitus were involved in its development.18-19 The items use a seven-point Likert scale for assessment of every domain and how a particular aspect of their life would be if they did not have diabetes.

The instrument has excellent reliability and validity and satisfactory acceptance in multi-ethnic diabetes patient groups.20

The instrument makes it possible to evaluate the relevance of every item and exclusion of items not applicable or irrelevant to the patient prior to calculating the final weighted score. The questionnaire does not take long to complete nor does it...
Table 1. Measurement tools for assessment of diabetes-specific quality of life

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Items</th>
<th>Content (domains / indicators)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The Appraisal of Diabetes Scale (ADS); Carey MP, Jorgensen RS, Weinstock RS, et al. (1991)</td>
<td>7</td>
<td>Physical functioning: uncertainty, likely to worsen, developing life goals, coping Psychological well-being: disease-related anxiety Treatment and general QoL</td>
</tr>
<tr>
<td>5 The Diabetes Quality of Life (DQOL); Jacobson AM, Barofsky I, Cleary P, et al. (1988)</td>
<td>46</td>
<td>Physical functioning Symptoms Psychological well-being Social well-being Role activities Treatment and general QoL</td>
</tr>
<tr>
<td>7 Diabetes-39 (D-39); Greg Boyer and Jo Anne L. Earp (1997)</td>
<td>39</td>
<td>Physical functioning: walking, steps, self-care Symptoms: energy, weakness, vision, sleep, complications, lose control sugar levels Global: daily activities, schedule restriction Psychological well-being: stress, depression; worries about the future/financial worries Social well-being: family/friends, sex Role activities Personal constructs: stigma Treatment and general QoL Other: perception</td>
</tr>
<tr>
<td>8 Diabetes Quality of Life Questionnaire (DQLQ); DCCT Research Group, (1988)</td>
<td>10</td>
<td>Global: diabetes/ general QoL Psychological well-being: worry Social well-being Role activities Treatment and general QoL</td>
</tr>
<tr>
<td>Instrument</td>
<td>Description</td>
<td>Domain/Aspect</td>
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<tr>
<td>9 Multidimensional Diabetes Questionnaire (MDQ); Nouwen Arie (1997)</td>
<td>Global: daily activities, limited general activity, schedule restriction Psychological well-being: worry Social well-being: travelling, family Role activities: work</td>
<td></td>
</tr>
<tr>
<td>10 Diabetes Quality of Life Clinical Trials Questionnaire, Revised version (DQLCTQ-R); Kotsanos JG, Vignati L, Huster W, Andrejasich C, et al. (1997)</td>
<td>Physical functioning: moderate/vigorous activity, walking, movement, self-care, driving car/operating machines Symptom: vitality, sleep, fatigue, physically ill, vision, nausea, pain treatment, blood sugar, polyuria, thirst, feeling hungry, tingling of the extremities Global Psychological well-being: discouraged/despair; frustrated; nervous; feel down, happy, self-respect, calm, worry Social well-being: family, friends, sex, leisure Role activities Personal constructs: stigma Treatment and general QoL Satisfaction with care: disease management Other: knowledge, attitude, perception</td>
<td></td>
</tr>
<tr>
<td>13 Problem Areas in Diabetes Scale (PAID); Polonsky WH, Anderson BJ, Lohrer PATIENT, et all (1995)</td>
<td>Physical functioning: coping Psychological well-being: emotional stress, depression, worries associated with illness and complications Treatment and general QoL</td>
<td></td>
</tr>
<tr>
<td>14 Well-Being Questionnaire (W-BQ); Bradley Clare, PhD (Nott) (1994)</td>
<td>Symptom: sleep, energy Psychological well-being: calm/nervous, discouragement, cry, distress, fear, feeling apart, well adjusted Cognitive functioning: think clearly Personal constructs: life satisfaction, life full, enjoy/happy with life</td>
<td></td>
</tr>
</tbody>
</table>
require specific instructions to administer.  

**Diabetes Care Profile (DCP)**

The instrument contains 234 items and measures the social and psychological factors related to diabetes and its treatment. The scales assess control problems, social and personal factors, positive attitude, negative attitude, self-care ability, importance of care, self-care adherence, diet adherence, medical barriers, physical activity, blood sugar monitoring, disease management, patients’ diabetes attitudes etc. Research data reveals good to excellent internal reliability and good external validity. Application of the instrument in culturally diverse populations for assessment in minority groups and elderly patients with diabetes revealed excellent reliability. A downside of the questionnaire is that it takes 30 to 40 minutes to complete.

**Diabetes Health Profile (DHP-18)**

The instrument was originally designed to identify psychosocial dysfunction among type 1 diabetes patients in an ambulatory care setting. DHP-18 has been adapted for use with patients with type 2 diabetes mellitus. The instrument content is limited and does not cover important aspects of social support, concern about future complications or satisfaction with treatment. There is evidence of its satisfactory internal reliability and validity and measurement equivalence across language groups. No research is reported in minority groups and elderly patients.

**The Diabetes Quality of Life Measure (DQOL)**

The DQOL was originally developed for use in control of clinical trials in patients with Type 1 diabetes (a version with 10 additional items is available for adolescents). Various aspects in four major dimensions are measured using a five-point Likert scale. Many of the items refer to “health related quality of life” in general and are not diabetes-specific. Some researchers express doubts about the scale’s sensitivity and its validity in measuring QoL in type 2 diabetes mellitus.

**Diabetes Impact Measurement Scales (DIMs)**

The questionnaire was developed to measure changes in health status in clinical trials of patients with type 1 and type 2 diabetes mellitus. It was designed for adults but could also be used in children and adolescents by excluding some of the questions. There is evidence of good internal reliability of all five subscales, but validity is low. There is no assessment of the instrument in elderly patients and minority groups in particular. The questionnaire takes about 15-20 minutes to complete.

**Diabetes - 39 Questionnaire (D-39)**

It was developed to evaluate the quality of life in both types of diabetes. The instrument comprises measures of various domains using seven-point

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**Figure 2. Quality of life determinants in patients with type 2 diabetes mellitus.**
visual analogue scales. Patients with diabetes were involved in the development of the tool. There is good evidence of instrument’s reliability, internal external construct validity. The analogue scales for marking the answers may be considered a limitation of this evaluative tool.29

When assessed in comparison significant correlations were established between D-39 and health survey (SF-36) scores in three comparable scales.30 The instrument has been assessed and approved in elderly patients and minority groups.

**Diabetes Quality of Life Questionnaire (DQLQ)**
It is one of the most widely recognised instruments for diabetes specific quality of life.12 It evaluates every dimension from three perspective: impact generated by diabetes, patient satisfaction and worry about anticipated effects of diabetes. The questionnaire is easy to self-administer and complete by the respondents (adults and adolescents). The patients use five-point Likert scales to answer all items.31

**Multidimensional Diabetes Questionnaire (MDQ)**
Measures quality of life in both types of diabetes providing assessment of cognitive and social factors related to diabetes.32

**Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ)**
It is composed of 142 items including demographic questions comprising 34 general and diabetes-specific domains of quality of life. It is used in both types of diabetes mellitus. The domains were initially developed from patient focus groups discussions and previously published questionnaires SF-20 and SF-36, and DQOL. The reliability and validity of the instrument was assessed in four countries and has shown good results.33-34

Internal reliability, as measured by Cronbach’s alpha, ranged from 0.81 to 0.90 for four major domains. The revised version (DQLCTQ-R) contains 57 questions and eight generic and disease-specific dimensions: physical function, energy/fatigue, health distress, general health, mental health, treatment satisfaction, treatment flexibility, and frequency of symptoms. The subscales included in the questionnaire were selected among domains which showed the greatest reliability and validity (and did not duplicate others). The revised version can be completed very quickly (in about 10 minutes).35-36

**Diabetes-Related Knowledge and Quality of Life Questionnaire**
It evaluates effectiveness of programs for diabetes education aiming to enhance knowledge, self-management of disease and distress. In the domain of social function leisure activity is studied. The questionnaire has been revised several times and the last version evaluates psycho-social dimensions of QoL.37 Reliability and validity have not been assessed in comparison with other questionnaires or clinical and socio-demographic variables.38

**The Questionnaire on Stress in Patients with Diabetes, Revised Version (QSD-R)**
It comprises items describing generally stressful situations for people with diabetes type 1 and type 2.12 Studies have established good reliability and validity as well as significant correlation of every scale with glycemic control (in the expected direction). It has not been tested in minority population groups.40-41

**Problem Areas in Diabetes Scale (PAID-1)**
It is a scale including descriptions of general problem situations for people with type 1 and 2 diabetes. It measures disease-specific fear varying form anger (“feeling angry when thinking about living with diabetes”) and interaction-related stress (“feeling that your friends and family are not supportive of diabetes management efforts”) to frustration caused by the diet regimen (“not having clear and concrete goals for diabetic care”).16 Patients use a six-point Likert scale to mark the degree to which every issue is currently a problem to them from 1 (“not a problem”) to 6 (“a serious problem”). The internal reliability is high (Cronbach’s alpha = 0.90, R = 0.83). Besides the established validity intervention assessment studies provide evidence that the instrument is easily adapted in different conditions. It was used for assessment in minority groups and in elderly people.41-42

**Well-Being Questionnaire (WBQ-18)**
It allows quality of life assessment in four domains: somatic symptoms, physical functioning related to diabetes, concerns and emotional functioning (discomfort), mental health and relations, role functioning, involvement in social networks. Reliability and validity have been tested and assessed in both types of diabetes. Internal consistency was very good for the four subscales and excellent for the final score. External validity assessed in comparison with final DQOL score and other psychometric measures was good. The limitations of the instrument are associated with absence of data about research in elderly patients and minority groups.43
The reviewed methods for quality of life assessment most often involve direct questionnaire studies, direct observations, interviews (face to face and telephone) using self-assessment instruments.

The questionnaires measuring diabetes-specific quality of life assess general quality as well as disease-related problems or symptoms. They are considered more sensitive than the “generic” ones in covering the various complications of the illness.44

CONCLUSIONS
On the basis of appraisal of the content, the number of indicators and evidence of reliability and validity in different target groups of the considered instruments we can conclude that the tools AD-DQoL, DCP and WBQ offer the most promising approaches to measuring disease-specific quality of life in type 2 diabetes mellitus. The development and assessment of the instruments involved patients with diabetes mellitus and there is sufficient data on their internal reliability and construct validity (internal and external).

Generic QoL questionnaires are used extensively in clinical practice but it is considered more accurate to determine self-reported quality of life in patients with diabetes mellitus using disease-specific instruments.

The choice of instrument is dependent on the type of research to be conducted, the practice setting conditions, the time for completion as well as considerations about self-administration (when possible or desired).

There is no “gold standard” for the assessment of specific health needs of people with diabetes mellitus. Regardless of the numerous generic and specific instruments used in these patients for quality of life assessment as part of their treatment plan and monitoring in various countries, there is no universal consensus about the contents of the questionnaires. This necessitates the development of a valid, reliable and easy to apply in everyday practice instrument for assessment of disease-specific quality of life in patients with type 2 diabetes mellitus (non-insulin dependent).

REFERENCES
ИНСТРУМЕНТЫ ДЛЯ ОЦЕНКИ СПЕЦИФИЧЕСКОГО КАЧЕСТВА ЖИЗНИ ПАЦИЕНТОВ, БОЛЬНЫХ САХАРНЫМ ДИАБЕТОМ ТИПА 2

Б. Левтерова, Д. Димитров, Г. Левтеров, Е. Драгова

РЕЗЮМЕ

В Болгарии, а также и во всем мире, сахарный диабет представляет социально значимое заболевание из-за своего широкого распространения. В научной литературе в последнее время имеются данные о множестве исследований эффектов сахарного диабета на качество жизни пациентов, а также и данные о наличии множества инструментов, предназначенных для оценки качества жизни. Качество жизни это понятие, включающее восприятие индивидом относительно физического, психологического и социального благополучия, включая когнитивный компонент (удовлетворение) и эмоциональный компонент (счастье). В работе делается обзорное исследование; делается идентификация и анализ основных детерминантов специфического качества жизни пациентов со сахарным диабетом типа 2 и анализ используемых инструментов для оценки.

РЕЗУЛЬТАТЫ: На критерии авторов отвечают 14 инструментов для оценки качества жизни пациентов со сахарным диабетом типа 2. Содержание инструментов охватывает различные области качества жизни или наличие различных показателей (симптомы, характерные для сахарного диабета, общее здоровье и качество жизни, личностные характеристики, физическое функционирование, психическое и социальное благополучие, лечение и качество жизни). Большинство специфических инструментов апробированы. Опубликованы данные об их надежности и валидности. Только небольшое количество инструментов подвергнуто официальной оценке относительно адаптации к изменениям.

ВЫВОДЫ: ADDQoL, DCP и WBQ предлагают весьма обещающие подходы для измерения специфического для диабета качества жизни. При создании этих инструментов участвовали пациенты. Проведенные исследования показали хорошие доказательства внутренней надежности, внешней и внутренней конструктивной валидности.

ЗАКЛЮЧЕНИЕ: В мировом масштабе продолжают усилия разработать стандарт, обеспечивающий валидный, достоверный, нетрудный при употреблении инструментарий для оценки качества жизни пациентов со сахарным диабетом типа 2, который обеспечил бы легкую интеграцию этих пациентов.