Diabetes mellitus. 2014;(2):56–65

Русскоязычная версия опросника для оценки качества жизни больных с периферической полинейропатией: валидация и перспективы применения

[1]Комелягина Е.Ю., [2]Уварова О.М., [1]Анциферов М.Б.

[1]ГБУЗ «Эндокринологический диспансер Департамента здравоохранения города Москвы» (главный врач – д.м.н., профессор М.Б. Анциферов)
[2]Национальный исследовательский университет «Высшая школа экономики», Москва (ректор – Я.И. Кузьминов)

Качество жизни является многофакторным показателем субъективного восприятия пациентом различных аспектов своей жизни. Для его оценки применяются специфические и неспецифические опросники.
Цель. *Провести валидацию русскоязычной версии специфического опросника NeuroQol для оценки качества жизни больных с диабетической периферической нейропатией.*
Материалы и методы. *В исследовании принял участие 371 пациент. Всем больным проводилась оценка периферической чувствительности и магистрального кровотока. По результатам осмотра оценивалось соответствие пациента критериям включения и исключения, после чего предлагалось заполнить опросник по оценке качества жизни. Процедура валидации опросника состояла из следующих этапов: перевод, предварительное тестирование, оценка надежности, оценка валидности.*
Результаты. *По всем шкалам значения коэффициента внутреннего постоянства α Кронбаха превышали значение 0,8, что свидетельствовало о надежности опросника. Критериальная валидность определялась вычислением коэффициента корреляции Спирмена (r) между шкалами опросника и внешними параметрами. Полученные результаты продемонстрировали наличие значимой корреляции между шкалами опросника и степенью тяжести нейропатии, что соответствовало адекватной критериальной валидности NeuroQol. Психометрическая оценка опросника (конструктивная валидность) проводилась с помощью факторного анализа. Были выделены факторы, относящиеся к физической и психосоциальной составляющим качества жизни, что подтвердило валидность опросника с точки зрения его структуры.*
Заключение. *Представленные данные показали, что русскоязычная версия опросника NeuroQol является надежной и валидной. Данный опросник может использоваться для оценки качества жизни у больных с признаками диабетической периферической нейропатии, включая оценку эффективности различных методов лечения осложнения. Проведенный анализ свидетельствует о том, что более важными факторами являются не физические, а межличностные и психосоциальные составляющие. Именно на эти компоненты должны быть направлены усилия специалистов для улучшения качества жизни данной категории больных.*

Ключевые слова: *сахарный диабет; диабетическая периферическая полинейропатия; качество жизни; опросник качества жизни*

Validation and perspectives of the Russian version of the quality of life questionnaire in patients with diabetic peripheral polyneuropathy

Komelyagina E.U.[1], Uvarova O.M.[2], Antsiferov M.B.[1]
[1]Moscow State Institution of Public Health “Endocrinological Dispensary”, Moscow, Russian Federation
[2]National Research University “Higher School of Economics”, Moscow, Russian Federation

Background. *Quality of life is a multivariate indicator of patient’s perception of various aspects of his/her own life. Questionnaires (specific and non-specific) are used to assess it.*
Objective. *To validate the Russian version of the specific quality of life questionnaire “NeuroQol” in diabetic patients with peripheral polyneuropathy.*
Materials and Methods. *A total of 371 diabetic patients participated in the study. All patients were screened for the signs of peripheral neuropathy and limb ischemia. The examination results were used to evaluate the eligibility of a patient; the eligible patients were then asked to fill in the quality of life questionnaire. The validation included translation, pilot testing and assessment of reliability and validity.*
Results. *Cronbach’s alpha coefficient of internal consistency exceeded 0.8 in all scales and proved the high reliability of the questionnaire. Criterion validity was analyzed by Spearmen correlation (r) coefficient between the domains and external parameters. The results obtained revealed significant correlation between NeuroQol domains and neuropathy severity, which indicates adequate criterion validity. The psychometric assessment (construct validity) was performed using factor analysis. The physical and psychosocial factors*

DOI: 10.14341/DM2014256-65

contributing to the quality of life were identified; they confirmed the validity of the questionnaire structure.
Conclusion. *The results demonstrate that the Russian version of the NeuroQol questionnaire is valid and reliable. This questionnaire enables one to assess quality of life in patients with the signs of peripheral diabetic polyneuropathy, including evaluation of the efficiency of various treatment strategies for complications. The lack of social life and psychological conditions of patients affect their quality of life more than physical complications do. These parameters must become the focus of specialists' attention in their efforts to improve the quality of life in this category of patients.*

Keywords: *diabetes mellitus; diabetic peripheral polyneuropathy; quality of life; quality of life questionnaire*

DOI: 10.14341/DM2014256-65

Quality of Life (QOL) is an integral indicator of physical, psychological, emotional and social performance of a patient based on his/her subjective assessment [1]. It is a multivariate indicator and QOL components include psychological, social, physical and spiritual well-being. The main goal of QOL assessment is to potentially adjust its parameters in the future. Therefore, it is necessary to identify and analyse factors that significantly affect QOL. Different questionnaires are used to evaluate QOL components (except for the spiritual component, because despite its fundamental role, no methods for assessing it are available at present). Each questionnaire contains sections assessing the patient's physical state and psychosocial status. If a questionnaire assesses QOL independent of age, gender and health, it is considered to be non-specific. The most well-known non-specific questionnaires are the WHOQOL proposed by the WHO and the European EQ-5D. SF-36 and its derivatives, including the short form SF-36 and SF-12, are also non-specific. The feature that distinguishes this questionnaire from other non-specific questionnaires is the fact that it assesses QOL in relation to a patient's health without taking into account the particular nosology. However, because we analyse patients' QOL with an aim of making an attempt to improve it in the future, the data obtained by analysing non-specific questionnaires are often insufficient. Therefore, specific questionnaires are being developed and validated, with the questions taking into account the specificity of a certain disease. For example, the QVM questionnaire is used to assess QOL in patients suffering from migraine and the KDQOL-SFTM evaluates QOL in patients undergoing dialysis. There are no specific QOL questionnaires available for patients with diabetic peripheral polyneuropathy (DPN) and neuropathic diabetic foot syndrome (nDFS). In previous studies, QOL in such patients has been assessed using non-specific questionnaires, such as SF-36 and SF-12. In these studies, QOL values in patients with the painful form of DPN, non-healing ulcers and amputations were significantly worse than those in patients of comparable age and gender diagnosed with diabetes mellitus (DM) but with no complications affecting the lower extremities [2, 3]. It should be remarked that the results are easy to predict. Indeed, one can expect that patients with pain or an open wound on a foot will have a worse physical state as well as a worse psychological status than those without complications affecting their lower extremities. Therefore, the data that compares QOL values in homogeneous groups of patients are of great interest; in our case, it refers to comparing groups of patients with complications affecting the lower extremities. A number of studies have been dedicated to this topic. It has been shown that QOL values in amputees with mobile lower limbs (with prosthesis) are better than those in patients with non-healing chronic diabetic ulcers but worse than those in patients with DM who suffer no complications to their lower extremities [4, 5]. The type of amputation is also important; QOL values in patients with toe and transmetatarsal or below-the-knee amputations are better than those in patients with non-healing wounds. However, in patients with above-the-knee amputations, QOL is significantly worse than that in patients with non-healing wounds [6]. All the aforementioned results were obtained using non-specific questionnaires, which were unable to take into account specific complications or to identify the affected QOL parameters and to propose a way to adjust them. In addition, one needs to clearly assess the patient's condition depending on his physical and psychosocial status and QOL. These two are not identical. QOL does not measure the deterioration of health indicators. This indicator is evaluated by a patient himself and may be unrelated to objective heath indicators [7].

Considering the importance and social significance of DM complications such as DPN and nDFS, the NeuroQol questionnaire has been developed and validated to assess QOL values in patients with DPN. It has been shown that the NeuroQol domains are much closely related to DPN severity than the SF-12 domains; therefore, they provide a more complete picture of the relationship between DPN and QOL values [8].

The original version of NeuroQol was developed by Loreta Vileikyte, a representative of Manchester Royal Infirmary (Manchester, UK), Mark Peyrot from the Centre for Social and Community Research of Loyola College (Baltimore, MD, USA), Christhin Bundy from Manchester Royal Infirmary (Manchester, UK), Richard Rubin from John Hopkins University (Baltimore, MD, USA) and Howard Leventhal from the Rutgers University (NJ, USA). The official permission to validate the Russian version was given by its main author, L. Vileikyte

OBJECTIVE OF THE STUDY

The aim of the study was to validate the Russian version of the specific NeuroQol questionnaire to assess QOL in patients with DPN.

MATERIALS AND METHODS

The study included 371 patients who sought medical attention in branches/offices dealing with DFS in medical establishments of the Department of Health of Moscow. After detailed and careful collection of medical histories and complaints, all patients were screened for the signs of peripheral neuropathy and lower leg ischaemia.

All participants of the study volunteered to participate in the examination as a part of the study and signed informed consent forms according to GCP requirements. The protocol of the study was approved at the meeting of the local ethics committee.

Evaluation of peripheral neuropathy

The peripheral neuropathy status was established on the basis of the severity of pain and impairment of sensitivity in the lower extremities.

The Neuropathy Symptom Score (NSS) scale was used to evaluate pain severity. A single occurrence of each complaint (symptom) was given 1 point; 2 points were given if it was stronger during the night. The sum of points showed the patient's status according to the NSS scale [9].

To evaluate the sensitivity of the lower extremities, a clinical neurological examination was performed, including an examination of the sensory and motor functions of the peripheral nerves. Sensory functions were evaluated using the standard approaches for evaluation of the various types of sensitivity (tactile, vibration, pain and temperature). Motor functions were evaluated on the basis of the examination of knee-jerk and Achilles reflexes.

The Semmes–Weinstein monofilament examination (weight 10 g, 5.07) was used to evaluate tactile sensitivity. The study was performed with a patient lying supine in a calm and relaxed state. A researcher touched the plantar surface of a patient's foot with the monofilament at certain points (plantar surface of the great toe and the first and fifth metatarsal heads). Tactile sensitivity was considered to be unimpaired if a patient felt 2 out of 3 touches and impaired if a patient did not feel 2 out of 3 touches [10].

Pain sensitivity was examined using a blunt needle. The study was performed on the dorslim of the great toe for both feet. Pain sensitivity was considered to be unimpaired if a patient felt pain from a stab.

Temperature sensitivity was measured using a blunt pin. The study was performed on the dorsal surface of the great toe for both feet. Temperature sensitivity was considered to be unimpaired if a patient felt a difference in temperature between the points.

Vibration sensitivity was measured by biothesiometry. The study was performed on the dorslim of the great toe for both feet and on metatarsal heads. The patient was asked to report the moment he/she started to feel the instrument vibration. Vibration sensitivity was considered to be unimpaired if a patient started to feel vibrations with the instrument set to 7–9 V.

Knee-jerk and Achilles reflexes were measured by the standard method using a reflex hammer.

Quantitative analysis of the existing disorders was performed to establish the severity of DPN using the neuropathic dysfunction score (NDS) scale developed by Young in 1986 and recommended by the Neurodiab research group of the European Association for the Study of Diabetes. To calculate the NDS, each type of sensitivity was given a certain number of points on the basis of the established disorder severity. The mean values for both feet were calculated for each type of sensitivity disorder (Table 1). NDS values between 0 and 4 points indicated a lack of disorders or an incipient character of DPN symptoms, values between 5 and 13 points corresponded to mild neuropathy and values ≥14 points corresponded to pronounced DPN [9].

A patient was classified to a group with a high risk of DFS development if he/she

- did not feel a touch of a monofilament in more than one location OR
- did not feel pain when stabbed with a blunt needle at the dorslim of the great toe OR
- did not feel vibrations during examination with a tuning fork or started to feel vibrations only with the biothesiometer set to ≥25 V [10].

Evaluation of lower limb ischaemia

Pulsation of the anterior and posterior tibial arteries measured by their palpation was used to screen for the presence of lower limb ischaemia. In some cases, the established lack or weakening of pulsation in these arteries was further confirmed independently and the ankle–brachial index (ABI = AP in the arteria popliteal / AP in the brachial artery) was calculated. The normal range of ABI values is ≥0.9 but <1.5. Lower limb ischaemia was confirmed if there was no pulsation in at least one of the tibial arteries and/or the ABI was <0.8.

The examination results were used to evaluate the eligibility of a patient; eligible patients were asked to fill in the QOL questionnaire.

Table 1

NDS [9]

Localisation	Sensitivity			Reflexes*: knee-jerk/ Achilles
	Touch	Pain	Temperature	
Right				/
Left				/
		NDS sum [(Sum of reflexes + Sum of all types of sensitivities)/2]		

Note: 0: normal sensitivity; 1: no sensitivity in toes; 2: no sensitivity up to the mid-foot; 3: no sensitivity up to the ankle; 4: no sensitivity up to the calf; 5: no sensitivity up to the knee.
*(0: normal; 1: impaired; 2: no sensitivity)

Inclusion criteria

1. Type 1 or 2 DM.
2. Age >18 years.
3. Signs of moderate or severe DPN: vibration sensitivity at >25 V and/or impairment/lack of tactile sensitivity in a 10-g monofilament test and/or an NDS of ≥10 points.
4. Ability to understand and answer the questions in the questionnaire.

Exclusion criteria

1. Lack of pulsation in at least one tibial artery.
2. ABI of <0.8.
3. Surgery to recover the blood flow within the last 6 months.
4. Amputation above the ankle joint.
5. Inability to understand and answer the questions in the questionnaire.

Patients without neuropathy were not asked to fill in the questionnaire, because the study did not validate a new instrument but an already approved one for which external specificity had been confirmed.

Questionnaire validation

The validation procedure is mandatory for new questionnaires as well as for those adapted to the language or cultural features of a certain country. In the latter case, the validation consists of the following stages: translation, pilot testing and assessment of reliability and validity.

Translation of the questionnaire

Two independent translators were employed in the first stage of translating the questionnaire from English to Russian. Discussion and reconciliation (if there were differences) of the translations resulted in the first 'forward-translated' version of the questionnaire. The forward-translated version was then translated back into English by 2 independent translators to create the 'back-translated' version. Final corrections were made by comparing the original and the back-translated version. The identified discrepancies were addressed to produce the final version, which was then used in pilot testing. Its aim was to interview a small number of patients in order to detect difficulties in understanding the questions. Twenty-seven patients took part in pilot testing; they characterised the questionnaire questions as understandable and articulated clearly and precisely. None of the patients reported any difficulty in filling the questionnaire.

Evaluation of the reliability of the questionnaire

Reliability is a measure of the questionnaire's ability to deliver consistent and precise measurements. Cronbach's alpha coefficient is calculated to study this parameter. Values of ≥0.7 are considered to be acceptable for group studies.

Evaluation of the validity of the questionnaire

Criterion validity reveals relationships between the questionnaire domains and external criteria and is calculated using the correlation coefficients between the questionnaire domains and external criteria. In our case, the external criteria included the severity of the pain syndrome, severity of the signs of sensitivity disorders and presence of non-healing wounds at the time of filling the questionnaire.

Structure validity is one of the most important indicators of questionnaire validity, because it determines the extent to which the questionnaire structure allows it to reliably measure what it is supposed to be measuring. Factor analysis is used to evaluate structure validity.

Structure of the NeuroQol questionnaire

The questionnaire consists of 28 questions classified into 6 domains. Each domain consists of 3–7 questions (Table 2).

Three domains—'pain' (burning, pins, shooting pain, etc.), 'subjective assessment of loss/reduction in sensitivity' (numbness, etc.) and 'diffuse sensory/motor symptoms' (instability when walking, weakness in hands, etc.)—assess the severity of DPN symptoms and reflect the physical state of a patient. Four domains—'limitations in daily activities' (ability to do your job, ability to do housework or to garden, etc.), 'interpersonal problems' (to what extent have your foot problems interfered in your relationships with people close to you, has your role in the family changed as a result of your foot problems, etc.) and 'emotional distress' (my foot problems have turned my life into a struggle, my self-confidence is affected because of my foot problems, etc.)—reveal the psychosocial state. The final question pertains to the overall assessment of QOL. Patients were offered 5 variants of an answer based on the Likert scale ('all the time', 'often', 'sometimes', 'rarely' or 'never'). Each answer was given 1–5 points.

RESULTS

Clinical characteristics of the group are shown in Table 3.

The study included 371 patients with DM. The median age of the patients was 60.5 ± 10.4 years, and 69% of them were women. Further, 87% had T2DM, with an average illness duration of 13.3±9.1 years and HbA_{1c} levels of 8.2%±1.3%. A total of 38% patients attended a school for patients with DM. The severity of pain symptoms (according to the NSS scale) was scored at an average of 4 points. The average level of vibration sensitivity was 35.5 ± 14.7 V (reference range: 7–10 V); the average value according to the NDS scale was 11.6 ± 5.5 points, which corresponded to moderate to severe DPN. At the time of completing the questionnaire, 44% patients had open foot ulcers; 37% had cases of neuropathic ulcers in their medical history.

At the first stage of the NeuroQol questionnaire validation, its reliability was evaluated by calculating the coefficient of internal consistency (Cronbach's alpha coefficient) for each domain. The results are summarised in Table 4.

DOI: 10.14341/DM2014256-65

Table 2

Structure of the NeuroQol questionnaire

Questionnaire domains	Number of questions	
Pain	7	Physical functions
Subjective assessment of reduced feeling	3	
Diffuse sensory/ motor symptoms	3	
Limitations in daily activities	3	Emotional functions
Interpersonal problems	4	
Emotional burden	7	
Overall assessment of QOL	1	
TOTAL	28	

Table 3

Description of the patients included in the study

Parameter	Value
Number, n	371
Male/Female, %	31/69
Age (M ± SD), years	60,5±10,4
T1DM/T2DM, %	13/87
Duration of illness (M ± SD), years	13,3±9,1
Attended a school for patients with DM, %	38
HbA_{1c} (M±SD), %	8.2± 1,3
NSS (M ± SD), points	4,1±3,0
Vibration (M ± SD), V	35,5±14,7
NDS (M ± SD), points	11,6±5,5
Ulcers (at present), %	44
Ulcers (medical history), %	37

For all domains, Cronbach's alpha coefficient exceeded 0.8, which was a good score and indicated that the questionnaire was reliable. Further redundancy analysis of the Russian version of the questionnaire using step-by-step exclusion of each component of the domain with Cronbach's alpha coefficient of ≥0.9 was not performed because of the small number of questions in these domains (3 or 4).

To determine criterion validity, Spearman's rank correlation coefficient (r) was calculated between the questionnaire domains and external criteria, such as the severity of pain symptoms (NSS scale), severity of peripheral neuropathy (NDS scale) and presence of ulcers on the foot/feet at the time of filling the questionnaire. The results of the analysis are summarised in Table 5.

The results revealed a significant correlation between the questionnaire domains and neuropathy severity. The negative correlation coefficient indicated that the severity of a symptom was inversely related to the score on the scale. For example, more pronounced pain symptoms corresponded to lower values in the pain scale. It should be mentioned that no correlation was observed between neuropathy severity (NDS scale) and the pain domain in the questionnaire. It confirmed the fact that the pain symptoms were not prevalent in patients with signs of severely impaired sensitivity. Meanwhile, patients in this category more often complained of issues such as numbness in the feet. It was confirmed by the significant correlation between the NDS and the 'subjective assessment of loss or reduction of sensitivity in feet' domain in the questionnaire. Subjective assessment of the severity of pain symptoms (NSS scale) was significantly related to all physical state domains in the questionnaire and to a domain describing the emotional and psychosocial state. Similarly, impairment of sensitivity (NDS scale) was significantly associated only with a feeling of numbness (subjective assessment of loss/reduction in sensitivity) in the physical state domain of the questionnaire and with

Table 4

Cronbach's alpha coefficient for each domain of the NeuroQol questionnaire

Questionnaire domain	Number of questions	Cronbach's alpha
Pain	7	0,85
Subjective assessment of reduced feeling	3	0,81
Diffuse sensory/ motor symptoms	3	0,82
Limitations in daily activities	3	0,93
Interpersonal problems	4	0,9
Emotional burden	7	0,83

Table 5

Relationship between the questionnaire domains and neuropathy severity

NeuroQol domain	Spearman's r		
	NSS	NDS	Ulcer +
Pain	-0,590**	0,073	-0,142*
Subjective assessment of reduced feeling	-0,209**	-0,358**	-0,162**
Diffuse sensory/ motor symptoms	-0,290**	-0,121	-0,087
Limitations in daily activities	-0,055	-0,026	0,104
Interpersonal problems	-0,113	-0,247**	0,118*
Emotional burden	-0,218**	-0,181*	0,104

* p <0,05 ** p <0,01

DOI: 10.14341/DM2014256-65

Table 6.

Factorial loads on the selected factors of the questions in the questionnaire domains*

Domain factors	Physical state factors			Psychosocial factors		
	Factor 1 ('Pain')	Factor 2 ('Loss of balance')	Factor 3 ('Reduced sensitivity')	Factor 1 ('Activity and relationship')	Factor 2 ('Emotions')	Factor 3 ('Lack of self-confidence')
Lower limb burning sensation	0,779					
Tingling in feet	0,779					
Shooting pain	0,675					
Allodynia	0,641					
Strong sensation of heat or cold	0,634					
Trembling in legs	0,547					
Cramps	0,456					
Balance while walking		0,871				
Balance while standing		0,840				
Weakness in hands		0,722				
Inability to feel objects			0,882			
Inability to tell the difference between hot and cold			0,880			
Numbness			0,591			
House work				0,868		
Taking part in leisure activities				0,847		
Ability to perform paid work				0,811		
Physical dependence on family members				0,806		
Emotional dependence				0,756		
Relationships with relatives				0,755		
Role in the family				0,648		
Feeling frustrated					0,870	
Foot problems have made my life a struggle					0,764	
Difficulties					0,701	
Depression					0,612	
I feel older than I am						0,716
I am treated differently						0,702
My self-confidence is affected						0,638

*Factorial loads of <0.3 are not shown in the table.

2 domains describing the psychosocial state. The data obtained indicated that different manifestations and different severities of DPN had different impacts on the physical and psychosocial aspects of QOL. Therefore, the identified parameters demonstrated adequate criterion validity of NeuroQol.

Psychometric assessment of the questionnaire (structure validity) was performed by factor analysis using principle component analyses with varimax rotation. Factors with values of >1 were selected for factor analysis. Factor analysis was performed separately for domains describing the physical state and for those related to the psychosocial components. The selected factors explained 65% of the combined dispersion. The results are summarised in Table 6.

According to these data, the following factors related to the physical component of QOL were selected: 'pain', 'reduced sensitivity' and 'loss of balance'. Psychosocial components of QOL were represented by factors describing daily activity and interpersonal relationships ('activity and relationships'), emotional background ('emotions') and lack of self-confidence resulting from the foot complications ('lack of self-confidence').

The questions included in these factors (i.e. those having a large factor weight) are easy to interpret and do not contradict their underlying meaning. For example, the 'pain' factor includes only questions related to feeling pain. The 'activity and relationships' factor combines

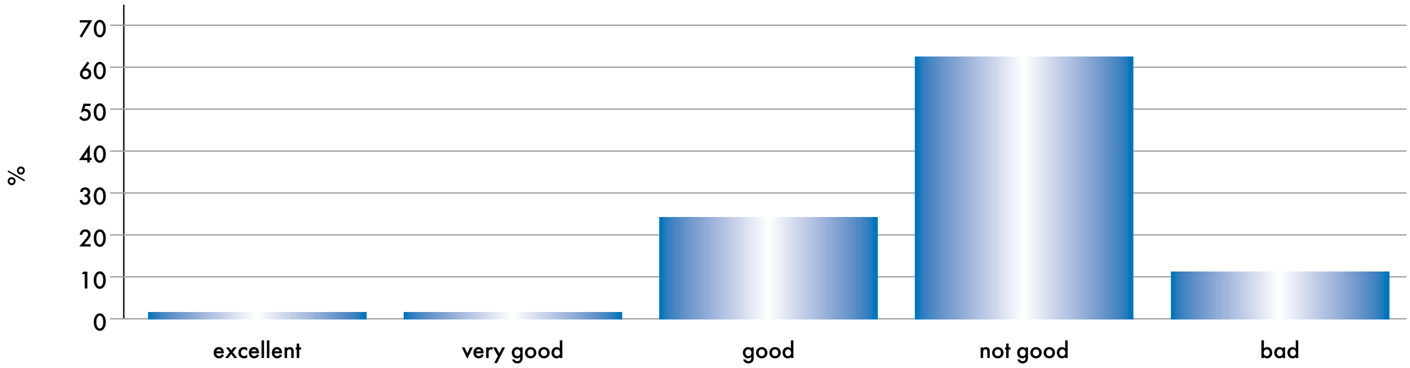

Figure 1. Overall QOL assessment values according to the NeuroQol questionnaire in patients with DPN.

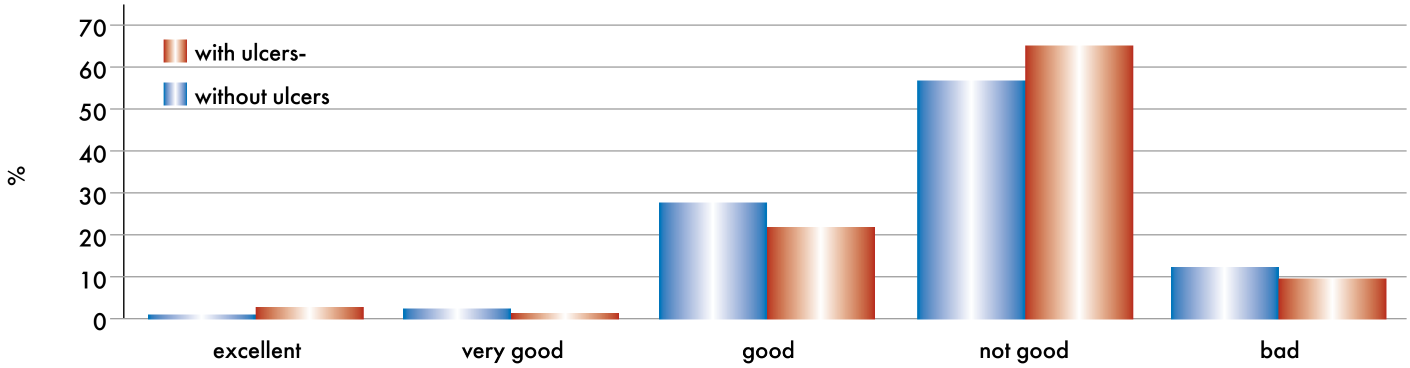

Figure 2. Overall QOL assessment values according to the NeuroQol questionnaire in patients with and without open ulcers

questions from the 'limitations in daily activity' and 'physical/emotional dependence' domains, whereas the 'emotions' and 'lack of self-confidence' factors include questions from the emotional domain in the questionnaire. All the aforementioned factors confirm the validity of the questionnaire with respect to its structure.

QOL values in patients with DPN as revealed by the specific NeuroQol questionnaire

In the overall assessment of their QOL using the scale from 1 to 5, 1.4% patients described it as 'excellent' or 'very good', 24.4% as 'good', 62% as 'not good' and 10.7% as 'bad' (Fig. 1).

In a comparative study of the overall QOL assessment at the time of filling the questionnaire, 28.7% patients with open ulcers and 21% patients without ulcers described their QOL as 'good'; 60% patients with nDFS and 67% patients without ulcers described it as 'not good' and 12.6% patients with nDFS and 9% patients without wounds described it as 'bad' (Fig. 2). The observed differences were not statistically significant.

Ordered regression analysis was performed to identify predictors corresponding to certain levels of QOL. The QOL value was a dependent variable and the identified factors were independent predictors. The presence or absence of ulcers at the time of completing the questionnaire was also taken into consideration (Table 7).

No correlation was observed between QOL and the presence of an ulcer at the time of completing the questionnaire. The physical states accompanied by a loss of balance, numbness and an inability to feel objects and/or the difference between hot and cold did not affect the overall assessment of QOL by a patient. It was also not affected by a lack of confidence. Among physical factors, only pain significantly affected QOL. However, the data showed that such psychosocial factors as limitations in daily activities, interpersonal relationships and physical and emotional dependence on relatives did have a significant impact on QOL. Remarkably, as mentioned above, the assessment was not affected by either the presence or absence of open wounds.

CONCLUSIONS

The results of this study demonstrated that the Russian version of the NeuroQol questionnaire is valid and reliable. This questionnaire enables assessment of QOL in patients

Table 7

Dependence of QOL on physical and psychosocial factors.

Factor	P
'Pain'	0,049
'Reduced feeling'	0,553
'Loss of balance'	0,620
'Activity and relationships'	0,004
'Emotions'	0,000
'lack of self-confidence'	0,432

DOI: 10.14341/DM2014256-65

with signs of DPN, including evaluation of the efficacy of various treatments for illness complications. A peculiar feature of this study was the homogeneity of the studied population. All patients had signs of moderate or severe DPN. In the course of the study, it was established that the overall assessment of QOL in this somatically challenged category of patients was not affected by the presence of ulcers. The self-assessed QOL values in patients with ulcers did not differ significantly from the values reported by the patients without open foot wounds. Our analysis further confirmed the aforementioned statement that subjective assessment of QOL was not identical to measuring the physical and psychosocial status of a patient. It should also be mentioned that all patients received high quality assistance at specialised health centres in Moscow. Such assistance implied frequent monitoring of the patients' status and often resulted in positive outcomes of treatment. Therefore, patients felt well-cared for rather than abandoned, and it undoubtedly influenced their perception of their QOL. These findings were in good agreement with the publications showing that QOL values in patients undergoing specialised treatment were significantly better than those treated at regular clinics [11]. One of the indisputable advantages of NeuroQol is its ability to identify factors that significantly reduce QOL. In our study, such factors were pain symptoms and the psychosocial status of a patient. At the same time, worsening of the patient's physical state caused by a loss of balance or numbness did not affect QOL.

The data allowed evaluation of the various factors that affect QOL in patients with DM complicated by DPN and nDFS. Our data suggested that interpersonal and psychosocial factors are more important than physical factors. These factors should therefore become the focus of attention in the efforts to improve QOL in such patients.

SOURCES OF FUNDING AND DISCLOSURE INFORMATION

The research was supported by the Endocrinological Dispensary of the Moscow Department of Healthcare.

The authors did not disclose any potential or current conflict of interest related to the conduct of this research and publication of its results.

REFERENCES

1. Новик АА, Ионова ТИ. Руководство по исследованию качества жизни в медицине. 2-е издание. Под редакцией академика РАМН Ю.Л.Шевченко. Москва; 2007. [Novik AA, Ionova TI. Rukovodstvo po issledovaniyu kachestva zhizni v meditsine. Ed 2. Editors Yu.L.Shevchenko. Moscow; 2007.]
2. Vileikyte L, Rubin RR, Leventhal H. Psychological aspects of diabetic peripheral neuropathy. Diabetes Metab Res Rev 2004;20(1):13–18.
3. Galer BS, Gianas A, Jensen MP. Painful diabetic polyneuropathy: epidemiology, pain description, and quality of life. Diabetes Research and Clinical Practice 2000;47(2):123–128. DOI: http://dx.doi.org/10.1016/S0168-8227(99)00112-6
4. Carrington AL, Mawdaley SKV. The psychological assessment of diabetic people with or without foot ulcers or lower limb amputations. In: Hotta N, Greene DA, editors. Diabetic neuropathy: new concepts and insights. Oxford: Elsevier Science; 1995.
5. Carrington AL, Mawdaley SKV. Psychological status of diabetic people with or without lower limb disability. Diabetes Res Clin Pract. 1996;32(1–2):19–25. DOI: http://dx.doi.org/10.1016/0168-8227(96)01198-9
6. Eckman MH, Greenfield S. Foot infections in diabetic patients: decision and cost-effectiveness analyses. JAMA 1995;273(9):712–720. DOI: http://dx.doi.org/10.1001/jama.1995.03520330042035
7. Leventhal H, Colman S. Quality of life: a process view. Psychol Health 1997;12(6):753–767. DOI: http://dx.doi.org/10.1080/08870449708406737
8. Vileikyte L, Peyrott M. The developmeny and validation of a neuropathy- and foot ulcer-specific quality of life instrument. Diabetes Care 2003;26(9):2550–2555. DOI: http://dx.doi.org/10.2337/diacare.26.9.2549
9. Диабетическая периферическая нейропатия. Патогенез, клиника и диагностика: Методические рекомендации. М; 2000. [Diabeticheskaya perifericheskaya neyropatiya. Patogenez, klinika i diagnostika: Metodicheskie rekomendatsii. Moscow; 2000]
10. Международное соглашение по диабетической стопе. М; 1999. [Mezhdunarodnoe soglashenie po diabeticheskoy stope. Moscow; 1999.]
11. Price P. The Diabetic Foot: Quality of Life. Clinical Infectious Disease. Clinical Infectious Disease 2004;39(2):129–131.

INFORMATION ABOUT THE AUTHORS

Elena Y. Komelyagina	MD, PhD, Head of the Diabetic Foot Department at the Moscow State Institution of Public Health “Endocrinological Dispensary”, Moscow, Russian Federation **E-mail: elenakomel@gmail.com**
Mikhail B. Antisferov	MD, PhD, Professor, Head of the Moscow State Institution of Public Health “Endocrinological Dispensary”, Moscow, Russian Federation
Olga M. Uvarova	Senior lecturer of the Business Intelligence Department of the Business Informatics Faculty at the National Research University ‘Higher School of Economics’; leading expert at the Institute of Companies and Market Analysis at the National Research University ‘Higher School of Economics’, Moscow, Russian Federation

DOI: 10.14341/DM2014256-65

Diabetes mellitus. 2014;(2):56–65

Русскоязычная версия опросника NeuroQoL

Ф.И.О.____ Дата рождения _____________

Сахарный диабет типа 1/типа 2 с _____г.

Язвенный дефект был/нет

Язвенный дефект есть/нет

Как часто Вас беспокоили нижеследующие жалобы в течение последних 4 недель?	Все время	Часто	Иногда	Редко	Никогда
Жжение в ногах или стопах					
Сильное чувство холода или тепла в ногах или стопах					
Покалывание в ногах или стопах					
Стреляющая или режущая боль в ногах или стопах					
Чувство дрожания (дрожи) в ногах или стопах					
Судороги					
Ощущение раздражения кожи, которое вызывает прикосновение различных предметов, таких как простыни или носки					
Онемение стоп					
Неспособность Ваших стоп ощущать разницу между горячим и холодным					
Неспособность Ваших стоп ощущать предметы					
Слабость в руках					
Проблемы с балансом и стабильностью во время ходьбы					
Проблемы с балансом и стабильностью во время стояния					
Следующие вопросы о том, как ОСЛОЖНЕНИЯ СТОП влияют на Вашу ежедневную активность, взаимодействие и чувства (ощущения)					
В течение последних 4-х недель НАСКОЛЬКО СИЛЬНО осложнения стоп влияли на	Очень сильно	Достаточно сильно	Незначительно	Чуть-чуть	Не влияют
Возможность работать?					
Возможность выполнять домашнюю работу или работу в саду/огороде?					
Возможность отдыхать (проводить досуг)?					
Насколько сильно осложнения стоп влияли на Ваши взаимоотношения с близкими людьми?					
Чувствовали ли Вы физическую зависимость, большую чем Вам хотелось бы, от близких Вам людей из-за осложнений стоп?					
Чувствовали ли Вы эмо-циональную зависимость, большую, чем Вам хотелось бы, от близких Вам людей из-за осложнений стоп?					
Изменилась ли Ваша роль в семье из-за осложнений стоп?					
Согласны ли Вы со следующим утверждением	Полностью согласен(на)	Частично согласен(на)	Не согласен (на)	Частично не согласен(на)	Полностью не согласен(на)
Меня лечат не так, как других людей, из-за осложнений стоп					
Я чувствую себя старше своих лет из-за осложнений стоп.					
Я неуверен (а) в себе из-за осложнений стоп					
Осложнений стоп превратили мою жизнь в сражение.					
Я испытываю чувство досады из-за осложнений стоп.					
Осложнения стоп вызывают массу затруднений.					
Это несправедливо, что мой диабет доставляет мне гораздо больше проблем, чем другим.					
Я боюсь потерять ногу из-за осложнений стоп					
	Очень сильно	Достаточно сильно	Незначительно	Чуть-чуть	Не снижали
В целом, я могу сказать, что проблемы со стопами снижают качество моей жизни					
	Отличное	Очень хорошее	Хорошее	Не очень хорошее	Плохое
В целом, я могу оценить качество моей жизни как					

DOI: 10.14341/DM2014256-65