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Original research article

Validity and reliability of the Polish version of myasthenia gravis – Quality of life questionnaire – 15 item

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ABSTRACT

Aim: The myasthenia gravis-quality of life questionnaire 15 item (MG-QOL15) is a short, and easy to use disease-specific quality of life (QOL) tool in myasthenia gravis. The aim of this study was to validate and adapt the Polish version of the MG-QOL15.

Materials and methods: The total number of 50 patients with MG were qualified for the examination. Each patient underwent neurological examination and completed the quality of life evaluation questionnaire MQ-QOL 15 after translation and back-translation. Additionally, each patient was asked to evaluate the quality of his/her life by means of questionnaire SF-36 in Polish language version.

Results: The MG-QOL15 was found to have high internal consistency, test–retest reliability, and concurrent validity.

Conclusion: The MG-QOL15 is accepted to be a valid, reliable, valuable tool for measuring disease-specific QOL in Polish patients with MG.

1. Introduction

Myasthenia gravis (MG) jest acquired autoimmune disease, the basic pathomechanism of which is based on production of auto antibodies directed against acetylocholine receptors (anti-AchR) of post-synaptic membrane of neuromuscular junction. The major symptom of MG is progressive myasthenia, for which the following are typical: symptoms of apocamnosis of extremities muscles and facial mimetic muscles, diplopia, eyelid dropping, dysphagia, dyzarthria [1,2]. Myasthenia gravis is characterized by big diversity of its course. Some patients complain about numerous clinical symptoms, which to a smaller or bigger extent make everyday functioning difficult, however, the majority of patients remain in the disease remission period due to the applied treatment. The remission condition is often not a condition without occurrence of neurological symptoms [3]. Even small MG symptoms may cause deterioration of the patients' life quality by influencing both their private and professional lives. The

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evaluation of the quality of life can be conducted using questionnaire MG-QOL 15 (MG – quality of life 15) [4]. The obtained results together with the assessment of neurological condition provide a possibility of holistic approach to a patient, and thus applying a more efficient therapy.

In our paper we want to present the obtained results of validation of the quality of life evaluation scale MG-QOL 15 of patients with myasthenia gravis, conducted on Polish population.

2. Materials and methods

2.1. Patients

The examination was conducted in Clinic of Neurology in years 2015–2016. The criteria of inclusion covered patients with diagnosed myasthenia gravis (ocular and generalized) confirmed by neurological examination and on the grounds of assessment: presence of antibodies against acetylocholine receptors, electro physiological examinations (electrostimulation and single-fibre electromyography studies), neuroimage examinations results (mediastinum MR or TK). The group was representative as regards age and gender. The specific characteristics of patients covered by the examination were presented in Table 1.

The total number of 50 patients with MG were qualified for the examination. Each patient underwent neurological examination and completed the quality of life evaluation questionnaire MQ-QOL 15 [4]. Additionally, each patient was asked to evaluate the quality of his/her life by means of questionnaire SF-36 in Polish language version [5,6]. For reliability assessment (test–retest) all the examined persons were asked to complete questionnaire MG-QOL 15 again during the follow-up visit after four weeks. The examined patients were qualified to selected groups in MGFA classification depending on the neurological evaluation of their condition [7]. The work described in this article has been carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans No. KNW/0022/KB1/68/15; uniform requirements for manuscripts submitted to biomedical journals. Each patient expressed a written consent to participation in the research.

Table 1 – Demographic and clinical characteristic of patients enrolled into the study.

Patients with myasthenia gravis (n)	50
Myasthenia character:	
Ocular (%)	48
Generalized (%)	52
Mean age (years)	60.66 ± 12.41
Average age (years)	30–81
Mean duration of disease (years)	9.48
Average of disease (years)	0.5–34
Gender:	
Female (%)	56
Male (%)	44
Mean antibodies against rec. Ach (nmol/l)	8.79
Average antibodies against rec. Ach (nmol/l)	0.1–85
Thymoma (%)	10
Residual thymus (%)	56
Tymectomia (%)	58
Electrical activity in repetitive nerve stimulation (%)	86
Treatment:	
Anticholinesterase drugs (%)	98
Steroids (%)	16
Azathioprine (%)	6
Mean doses of anticholinesterase drugs (mg per day)	197.8
Mean BMI	24.96
Average BMI	21.15–32.75
Main neurological symptoms:	
Diplopy (%)	44
Eyelids drooping (%)	72
Difficulty chewing (%)	10
Dysphagia (%)	16
Dysarthria (%)	20
Dyspnoea (%)	4
Apokamnosis symptoms of limbs and mimetics muscles (%)	40

2.2. Adaptation procedure questionnaire MG-QOL 15

Before the initiation of the validation process we obtained a permission from the author's scale to conduct translation and examinations using questionnaire. The MG-QOL 15 questionnaire was prepared in the USA by Professor Ted Burns et al. in 2008 on the grounds of myasthenia gravis (MG)-specific quality-of-life (QOL). Instrument was reduced from 60 items to 15 items while maintaining potential usefulness in the clinic and in prospective treatment trials. The quality of life evaluation form MG-QOL 15 consists of 15 questions. Each question is assigned from 0 to 4 points, the maximum number of obtainable points is 60. The particular questions constitute the evaluation of physical, emotional, social functioning as well as influence on professional and family life and pleasures. The higher the score of the examination the worse the patient perceives the quality of his/her life [4,8].

In conformity with the requirements double translation from English to Polish and again to English was made. The translation was made by two bilingual teachers (Polish and English languages) in collaboration with Polish medical doctors fluent in spoken and written English. Two independent versions of translation of the original version of MG-QOL 15 were created and on their grounds the discrepancies were corrected, with particular interest in grammatical and linguistic conditionings. Finally, a Polish language version of questionnaire MG-QOL 15 was obtained, the content of which preserved the original meaning. The next stage was to retranslate or translate again the newly obtained scale back into the original language by a translator whose native language is English but who is also fluent in Polish. The Polish version form prepared in the above manner was subjected to evaluation of linguistic correctness by having it completed by healthy Polish language speakers. The questionnaire was completed by 30 persons, who were a representative group in the aspect of gender, age and education. This procedure allowed the confirmation of proper linguistic construction necessary to understand the questions correctly.

In the next stage 50 patients again completed questionnaire MG-QOL 15 during the follow-up visit after 4 weeks from the

MG-QOL 15

Proszę wskazać w jakim stopniu każde z poniższych stwierdzeń było prawdziwe w ciągu ostatnich kilku tygodni	Wcale	Trochę	Nieco	Istotnie	Bardzo
	0	1	2	3	4
1. Jestem sfrustrowany z powodu miastenii.					
2. Mam problemy z widzeniem.					
3. Mam problemy z jedzeniem z powodu miastenii.					
4. Ograniczyłem swoją aktywność społeczną z powodu miastenii.					
5. Miastenia ogranicza moją zdolności do czerpania radości z hobby oraz innych aktywności.					
6. Mam problemy z zaspokojeniem potrzeb mojej rodziny z powodu miastenii. .					
7. W moich planach muszę uwzględniać miastenię.					
8. Miastenia miała negatywny wpływ na moje umiejętności zawodowe oraz pracę.					
9. Mam trudności w mówieniu z powodu miastenii.					
10. Mam problem z prowadzeniem samochodu z powodu miastenii.					
11. Mam obniżony nastrój z powodu miastenii.					
12. Mam problemy z chodzeniem z powodu miastenii.					
13. Mam problemy z poruszaniem się w miejscach publicznych z powodu miastenii.					
14. Czuję się przytłoczony z powodu miastenii.					
15. Mam problemy z zadbaniem o siebie (higiena i wygląd)					

Całkowita ilość punktów MG-QOL 15

Fig. 1 – MQ-QOL 15 questionnarie in the Polish language version after the translation process.

first examination. During this time no changes were introduced in the patients' therapy. The interval between the examinations was long enough to eliminate the possibility that the patients remembered the results chosen during the previous evaluation. No irregularities were found in the results obtained.

Fig. 1 presents the Polish language version of questionnaire MG-QOl 15.

During the first examination each patient was additionally asked to complete life quality evaluation questionnaire SF-36 in Polish language version prepared by Prof. J. Tylka. It consists of eleven questions evaluating: physical functioning, role limitations due to physical health problems, bodily pain, social functioning, general mental health, role limitations due to emotional problems, vitality, general health perception. The comprehensive summary enables a complex evaluation of physical and emotional aspect of life. An additional parameter evaluated in the questionnaire is a change of health condition over a period of time. Interpreting the results: higher number of points means lower grade in life quality evaluation [5,6].

The last element on our examination was neurological assessment of patients conducted by the same examiner. A full neurological examination was conducted on the grounds of which each patient was qualified to an adequate class of Myasthenia Gravis Foundation of America clinical classification (MGFA). Class I is mild in nature, Classes II, III and IV may be further subdivided into category 'a', which primarily impacts the limbs, or 'b', which primarily affects the respiratory muscles or those of the tongue or mouth. Class V is the most severe form requiring intubation. Table 2 showed complete MGFA Clinical Classification [7].

2.3. *Statistical analysis*

For data processing elements of descriptive statistics were used, such as a geometric mean, median, standard deviation, percentage distribution, variances. The evaluation of internal coherence of test MG QOL 15 in Polish language version was conducted using Cronbach's analysis. Cronbach's alpha raw and standardized coefficients were calculated. The coherence level defined by values of standardized alpha statistics >0.80 were considered satisfying. By analyzing a potential improvement of alpha value after possible removal of successive questions the influence of particular questions on the coherence level was determined.

Evaluation of external conformity or internal conformity assessment of a tool the relation of results obtained from questionnaire MG-QOL 15 was analyzed with the results obtained from the application of a different tool for life quality assessment – questionnaire SF-36. Pearson and Spearman's correlation coefficient and statistical significance the obtained result were calculated. The reliability of the method was

Table 2 – MGFA clinical classification.

Class I	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II a	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. Predominantly affecting limb, axial muscles, or both.
Class II b	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. Predominantly affecting oropharyngeal, respiratory muscles, or both.
Class III a	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. Predominantly affecting limb, axial muscles, or both.
Class III b	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. Predominantly affecting oropharyngeal, respiratory muscles, or both.
Class IV a	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. Predominantly affecting limb, axial muscles, or both.
Class IV b	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. Predominantly affecting oropharyngeal, respiratory muscles, or both.
Class V	Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IV b.

confirmed in the test–retest reliability. Test–retest reliability was estimated from the reliability coefficient and the 95% confidence interval. Concurrent validity between scales at each visit was estimated from the Pearson and Spearman correlation coefficients. The correlations obtained in all cases were almost equal. The examination results were processed on the grounds of statistical analysis using programmes STATISTICA Data Miner 12.5 PL and EXCEL.

3. Results

The examination included the total number of 50 patients. Their average age was 60.7, of which 56% were women, and 44% men, whereas the average time of the disease was approximately 9 years. The distribution of patients according to classification MGFA was the following: 38% Class I (ocular), 20% Class II (mild, general), 14% in Class III (moderate, general), 6% Class IV (severe, general). In total 22% patients were in a state of remission after visit 1. None of the examined persons was intubated or ventilated (class V).

A total of 86% of patients were acetylcholine receptor antibody positive (AChR+) and 14% of patients were negative (AchR−). Main therapy of patients was based on anticholinesterase drugs: a total of 98% received it. 78% of patients received anticholinesterase drugs in doses below 240 mg per day and 22% of patients – equal or above 240 mg per day. Patients in a state of remission were without neurological symptoms in first visit and during gradual reduction of doses anticholinesterase drugs. All patients included into the study were presented neurological symptoms at diagnosis (retrospective analysis was prepared on the basis of medical documentation).

The average evaluation of life quality of the patients using questionnaire MG-QOL 15 was 13.38 (SD ± 11.9), with minimum obtained number of points 0 and maximum – 47. Table 3 presents percentage results received for particular questions.

The analysis of questionnaire reliability on the grounds of statistical properties of test items and connections of particular items with the overall test result demonstrated Cronbach's raw coefficient on level 0.952 point, whereas the standard coefficient was 0.948 point. The values of Cronbach's alpha coefficient for all particular items were over 0.80 point, and a possible removal of a certain question from the questionnaire did not cause a significant change in the total analysis. The lowest coherence was observed for questions 1, 7 and 9, and the highest for questions 4, 6 and 12. Table 4

Table 3 – Percentage results received for particular questions questionnarie MG-QOL 15.

N = 50 patients	Answers (%)				
Questions	Not at all (0)	A little bit (1)	Somewhat (2)	Quite a bit (3)	Very much (4)
1. I am frustrated by my MG	36%	48%	12%	4%	0%
2. I have trouble using my eyes	26%	28%	36%	4%	6%
3. I have trouble eating because of MG	62%	18%	14%	4%	2%
4. I have limited my social activity because of my MG	46%	30%	14%	10%	0%
5. My MG limits my ability to enjoy hobbies and fun activities	32%	28%	24%	14%	2%
6. I have trouble meeting the needs of my family because of my MG	62%	20%	12%	6%	0%
7. I have to make plans around my MG	34%	32%	16%	16%	2%
8. My occupational skills and job status have been negatively affected by MG	18%	34%	18%	18%	12%
9. I have difficulty speaking due to MG	62%	22%	14%	2%	0%
10. I have trouble driving due to MG	40%	30%	12%	14%	4%
11. I am depressed about my MG	58%	26%	14%	2%	0%
12. I have trouble walking due to MG	56%	22%	10%	8%	4%
13. I have trouble getting around public places because of my MG	70%	16%	2%	8%	4%
14. I feel overwhelmed by my MG	48%	40%	10%	2%	0%
15. I have trouble performing my personal grooming needs	56%	34%	4%	6%	0%

Table 4 – Changes in the value of Cronbach alpha after the removal of the following questions of questionnarie.

N = 50 patients Questions	Cronbach's alpha evaluation
1. I am frustrated by my MG	0.887
2. I have trouble using my eyes	0.955
3. I have trouble eating because of MG	0.920
4. I have limited my social activity because of my MG	0.959
5. My MG limits my ability to enjoy hobbies and fun activities	0.917
6. I have trouble meeting the needs of my family because of my MG	0.962
7. I have to make plans around my MG	0.879
8. My occupational skills and job status have been negatively affected by MG	0.954
9. I have difficulty speaking due to MG	0.892
10. I have trouble driving due to MG	0.954
11. I am depressed about my MG	0.957
12. I have trouble walking due to MG	0.958
13. I have trouble getting around public places because of my MG	0.953
14. I feel overwhelmed by my MG	0.954
15. I have trouble performing my personal grooming needs	0.955

presents the influence of particular items of the questionnaire on general coherence level of questionnaire MG-QOL 15.

The comparison of summary results in questionnaire MG-QOL 15 showed a positive correlation with results of questionnaire SF-36 $r = 0.92$ point. It is a statistically significant result on level $p < 0.001$. Moreover, MG-QOL 15 showed a positive correlation with the evaluation of functioning in a physical aspect of scale SF-36 $r = 0.93$ point ($p < 0.001$) and a positive correlation in comparison with the mental aspect of scale SF-36 $r = 0.78$ point ($p < 0.0001$).

Additionally, the results of life quality evaluation obtained from questionnaire MG-QOL 15 were analyzed and SF-36 with current neurological condition of the examined patients summed up in classification MGFA. The obtained results demonstrated the presence of positive correlation both of form MG-QOL 15 with MGFA, where $r = 0.85$ ($p < 0.0001$) and SF-36 with MGFA respectively $r = 0.88$ ($p < 0.0001$). The above described correlations were presented in Diagrams 1–5.

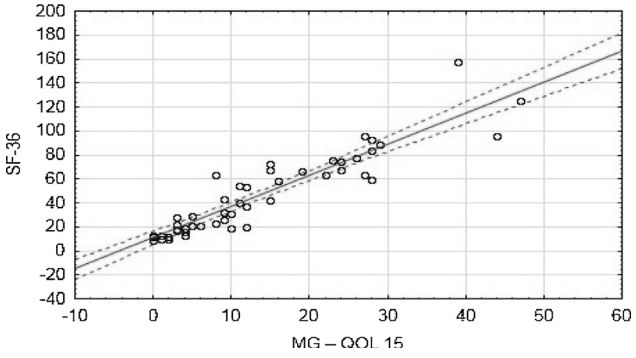


Diagram 1 – Correlation diagram questionnarie MG-QOL 15 with questionnarie SF-36.

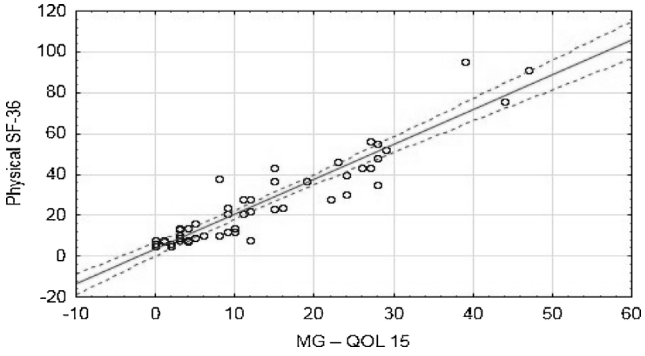


Diagram 2 – Correlation diagram questionnarie MG-QOL 15 with physical quality of life SF-36.

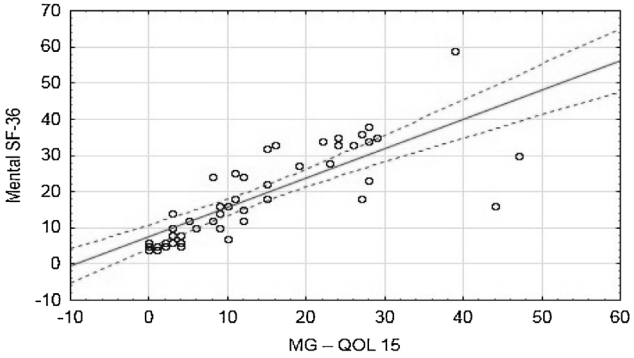


Diagram 3 – Correlation diagram questionnarie MG-QOL 15 with mental quality of life SF-36.

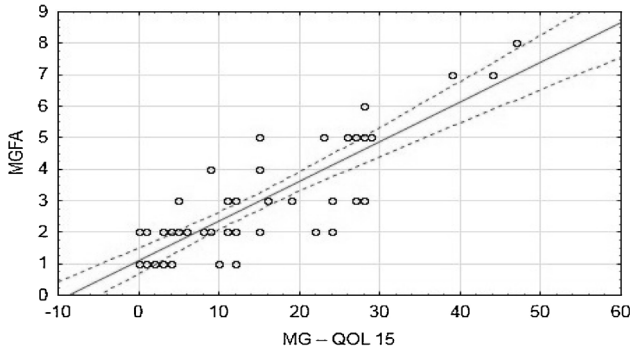


Diagram 4 – Correlation diagram questionnarie MG-QOL 15 with neurological scale MGFA.

The sensitivity and specificity of MG-QOL15 were assessed depending on various threshold values. For the needs of this research the so-called ''golden standard'' was considered the assessment of clinical condition of patients using classification MGFA. It was determined that patients qualified to group MGFA 0 – MGFA 2b in neurological assessment do not have symptoms or have poorly intensified symptoms – mild course of the disease. The patients qualified to class MGFA 3a – MGFA 5 are people with bigger or much bigger intensification of symptoms – severe course of disease. With reference to results of the quality of life assessment, the patients qualified to the first group under MGFA classification showed high evaluation

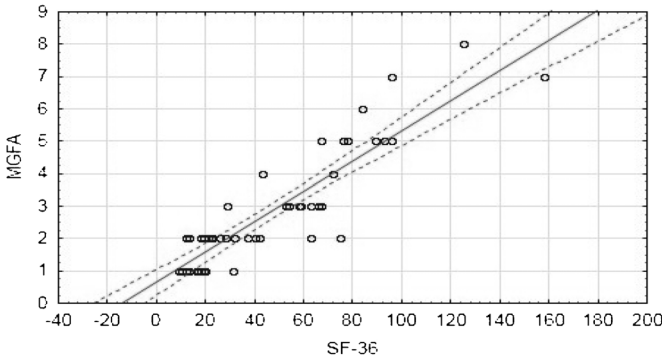
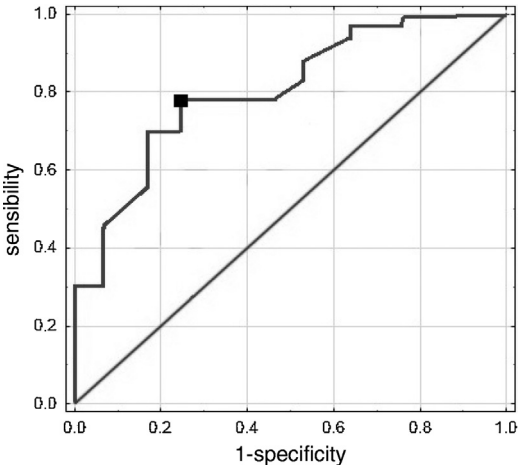


Diagram 5 – Correlation diagram questionnarie SF-36 with neurological scale MGF.

of their lives quality whereas the patients in the second group – low evaluation of their lives quality. We analyzed in details the results of MQ QOL 15 assessment conducted among patients with regards to MGFA classification. The cut-off point, determined in our validation examination MG QOL 15, equalling 15 points, in examination of Polish population of patients allowed for adequate classification of 89% of examined people – 94% persons assessing their lives quality as high and 84% persons with law assessment of their quality of lives. The result equalling 12 points allowed for classification in conformity with the specific scheme the total number of 81% patients, of which 99% persons with high assessment of quality of life and only 67% with low. The result which equals 18 points involves a slight increase of the scale sensitivity to 98% and decrease of specificity to 78% (total number of 87% adequate classifications). The analysis of ROC curve confirmed very good differentiating properties of MG QOL 15 (field under the curve equals 0.84; $p < 0.001$). Graph 6 shows ROC curve for MG QOL 15.

The test-rest method conducted on the grounds of analysis of the obtained results in an interval up to 4 weeks demonstrated high reliability of measurement in the aspect of stability of result in time, rtt = 0.89, $p < 0.001$. The highest ICC values were discovered for questions 2, 4 and 6 and questions 10–14, whereas the lowest ICC value was observed for questions 7 and 9.



Graph 6 – Receiver operating characteristic (ROC) curve of MG-QOL 15. Cut point = 15.00.

4. Discussion

On the grounds of obtained results it may be stated that questionnaire MG-QOL 15 is a reliable tool for assessment of the quality of life of patients with myasthenia gravis in Polish population. The patients considered it clear and useful in overall assessment of their health condition. The high reliability of the questionnaire is proved by satisfactory values of Cronbach's alpha coefficients (above 0.80 point) comparable to the English version of the questionnaire. The value of individual, both raw and standarized Cronbach's alpha coefficients do not suggest a necessity to remove any question. In addition, and important element is the fact that the values of raw and standarized Cronbach's alpha coefficients are very similar.

The test–retest assessment confirmed the questionnaire's reliability, no statistically significant differences were found for measurements conducted twice in a certain time interval. Despite the above we did not manage to discover the reason of low ICC values on two items. The specific course of the disease, in which the patients may feel greater tiredness as the day passes by, in combination with infection, stress or physical effort may affect the quality of life assessment. Thus, the continuous feeling of fatigue has influence on the questionnaire results and their repetitiveness may be disturbed despite preserving the neurological examination and treatment continuity. The existence of such dependencies suggests completion of the questionnaire at the same time of the day and in uniform time intervals taking into consideration factors affecting the course of the disease.

The validity assessment of questionnaire MG-QOL 15 was confirmed by correlating the results with answers obtained in another important tool for the quality of life assessment – questionnaire SF-36. The patients who obtained more points in MG-QOL 15, i.e. their assessment of life quality was worse, also in SF-36 obtained high values. A positive correlation was observed both in mental and physical aspect. A positive correlation was confirmed with reference to neurological condition assessed on the grounds of MGFA classification. Intensification of neurological symptoms, and in particular the presence of symptoms of limbs fatigability (MGFA II b, MGFA III

b and MGFA IV b) demonstrated a significant relation with the higher number of points obtained in questionnaire MG-QOL 15.

The purpose of our research was to, first of all, adapt the scale of assessment of quality of life MG-QOL15 for patients with a certain disease, namely myasthenia gravis. We analyzed the factors which could influence the research result. Almost all patients, 98%, were undergoing therapy with anticholinesterase inhibitors, which was not modified in the last month. We did not include in the research patients classified as MGFA V class, because there was no possibility of cooperation and it would be difficult to complete the life quality assessment questionnaire. Patients with symptoms of infections had appointments for different dates of examinations. However, our assumptions did not include the influence of many factors, for example such as suffered myasthenic crisis, exacerbations of the disease requiring steroid therapy, thymectomy surgery, etc. we wanted to adjust the tool of work with patients in Polish population, and the above dependencies will be the subject of further research. The limitation is certainly the size of the examined group, nevertheless the frequency with which myasthenia gravis occurs in Polish population (10–15 persons per 100,000 population) induced us to assess the group of patients who remain under our care.

Questionnaire MG-QOL 15 is used to assess the quality of life of patients with myasthenia gravis in many countries. The validations conducted in such countries as Japan, Turkey or Iraq showed high internal reliability, repetitiveness in test–retest assessment and at the same time validity with SF-36 and the disease intensification determined by MGFA. The advantage of research on Japanese or Persian population is a bigger size group (327 and 75 persons respectively). Despite the above, our research demonstrated equally high and satisfying results of statistical analysis – internal consistency (Cronbach alpha = 0.952) and test –retest reliability (rtt = 0.89; $p < 000.1$) [9–11].

The practical application of scale MG-QOL 15 confirmed the prospective assessment of efficiency of treatment with mycophenolate mofetil conducted by Mullins et al. in patients with myasthenia gravis. The comparison showed that MG-QOL 15 demonstrates more significant results that the quality of life assessment made by questionnaire SF-36, to confirm changes in the disease course after applied treatment. The results of this research supported the application of this tool for assessment of life quality both clinically and in trials of new treatment for myasthenia gravis [12]. An application similar to the final point of assessment of efficiency of treatment of patients with myasthenia gravis after plasmapheresis treatments vs treatments with immunoglobulins was used by Barnett et al. in their research. His research also confirmed the correctness of application of scale MG-QOL 15 as a reliable tool in clinical research [13].

With reference to the discussion on reliability and relevance of questionnaire MG-QOL 15 the latest reports published in June 2016 by the author of the scale are significant. In his research, Burn et al. having analyzed over 1300 cases of patients suffering from myasthenia gravis in the aspect of life quality assessment, came to the conclusion that scale MG-QOL 15 has better clinimetric properties when applying 3 instead of 5 answers. In a new version the patients can choose from the following answers: ''not at all'', ''somewhat'' and ''very much''. MG-QOL15r is now a preferred instrument of life quality assessment for patients with myasthenia gravis. This change does not deny previously conducted research [14].

5. Summary

The evaluation of quality of life has an important role in holistic care of a patient. It provides us with information about how a patient perceives the degree of disability, difficulties in social, professional and family functioning. Moreover, it shows to what extent the patient accepts his/her health condition. MG-QOL 15 was designed and verified in order to be used in clinical and research practice in an intelligible way. We created a Polish language version of MG-QOL 15 confirming its reliability and credibility. We are aware about the limitation of our research what is the number of patients qualified for study. Further studies concerning the assessment of the quality of life among patients with myasthenia are planning. Thus, to sum up, MG-QOL 15 may be considered a suitable instrument for evaluation of physical, mental and social aspects of life of patients with myasthenia gravis.

Conflict of interest

None declared.

Acknowledgement and financial support

None declared.

Ethics

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

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