The usefulness of the original questionnaire in the evaluation of quality of life in patients with gastroesophageal reflux disease

Jacek Huk¹, Witold Wiktor¹, Tomasz Pedowski², Wioletta Masiak², Grzegorz Wallner²

Gastroenterology Department, St Hedwig Provincial Hospital in Rzeszów¹
Ordynator: dr n. med. J. Huk

2nd Department of General, Gastroenterological and Gastrointestinal Surgery, Independent Public Teaching Hospital, Medical University in Lublin²
Kierownik: prof. dr hab. G. Wallner

Gastroesophageal reflux disease (GERD) constitutes a significant health problem in societies of high socioeconomic status. The notion of quality of life is broader than the definition of health and encompasses two aspects: the subjective and objective one. The tools used for the evaluation of quality of life are questionnaires.

The aim of the study was the evaluation of the original quality of life questionnaire in patients with gastroesophageal reflux disease treated for 4 weeks with a single dose of omeprazole at 20 mg daily.

Material and methods. The original quality of life questionnaire was formulated based on the Likert method. Four time levels of complaint persistence were introduced. The patients were asked 10 questions with earlier prepared answers marked by the respondents. Each of the questions corresponded to a certain time level of complaint persistence. The data obtained from the questionnaires were subject to statistical analysis. The studies were conducted on a group of 10,623 patients. Adequate methods were used in the statistical analysis of data from obtained answers. The significance threshold for each of the studies was \( p < 0.01 \), which means that the obtained conclusions are true with the probability of at least 99%. The majority of statistical calculations were performed with the use of STATISTICA 7.0 and Excel software.

Results. Improvement of quality of life was found in all the studied aspects: physical (questions 1, 3, 4, 5, 7), functional (question 6), emotional (questions 2, 10) and social (questions 8, 9). No correlation with age or gender was found. The analysis of test correctness was conducted, revealing reliability, validity, sensitivity, appropriateness and practicality of the questionnaire.

Conclusions. 1. The original quality of life questionnaire meets the requirements for the tools evaluating quality of life in gastroesophageal reflux disease. 2. The usefulness of questionnaire was confirmed in a group of 10,623 patients with gastroesophageal reflux disease in the Polish population. 3. The questionnaire equals the international tests, while its advantages are the ease of completion and high level of perception.

Key words: gastroesophageal reflux disease, quality of life, quality of life questionnaire

In the last decade, gastroesophageal reflux disease has become a significant problem in gastroenterology, which is associated with increased incidence, impact on the reduction in the quality of life, potential complications and treatment costs (1). In societies of high socioeconomic status, daily symptoms of reflux affect approx. 7% of the population, while weekly ones – even 20% (2). In the majority of patients, complaints recur following the cure of an acute episode, which generates the need for maintenance pharmacological treatment or surgical approach (3). The deterioration of quality of life in gastroesophageal reflux disease is comparable to that in ischaemic heart disease or mild heart failure (4). Patients with
reflux disease have poorer physical and mental wellbeing than patients with diabetes, arthritis or arterial hypertension, independent of the presence or absence of esophagitis (5-8). The reflux disease affects the ability to work and its effectiveness to the comparable extent as headache or spinal pain (8).

The notion of quality of life (QL) is broader than the definition of health. Cella distinguishes two components in it (9):

1. The subjective aspect of QL – only the patient is able to assess its quality of life. Most often the evaluation is dynamic and changes with time. This is the difference between the actual level of functioning and the ideal standard. The QL assessment differs depending on the patient skill, level of adaptation to the environment and the expectations.

2. The objective aspect of QL – is multifaceted and covers such aspects as the physical, functional, emotional and social ones.
   - The physical aspect concerns the observation of the body functioning. It covers in total the disease symptoms, treatment results, general satisfaction and wellbeing as perceived by the patient.
   - The functional aspect refers to the possibility of activity adequate for individual needs, ambitions and social roles. The main point of reference is the everyday functioning.
   - The emotional aspect covers the positive and negative emotions. Feelings and impressions may be reflected in the person’s behaviour. This differentiates this aspect from the physical one in which the body dysfunctions affect the person’s behaviour.
   - The social aspect is a broad and difficult to define area of QL. It covers the perception of social support, maintenance of activity at school or work, spending of free time, as well as the person’s functioning in the family, social contacts, etc. (9).

The tools created with the aim of a most objective assessment of quality of life of patients are questionnaires. They should have 5 principal characteristics (10):

1. Reliability – obtaining the same results in the course of the study.
2. Validity – ability to measure phenomena occurring in the aspects (domains) of interest.
3. Sensitivity – ability to detect changes occurring in a given patient.
4. Appropriate – adjustment to a given complaint.
5. Practicality – ease of use.

It seems obvious that there is no ideal study tool covering all the aspects. Today, there are three types of questionnaires available (10, 11):

1. General questionnaires.
2. Questionnaires evaluating the intensification of disease symptoms.
3. Questionnaires specific for the disease.

None of the above-listed methods meets all the criteria which encompass: high sensitivity in GERD, detection of classical and extraesophageal symptoms in GERD, proven psychometric properties, patient’s self-evaluation and possibility of repeated use, use of graphical signs comprehensible for the patient, as well as economics and universality of the test (12).

The aim of the study was the evaluation of the original questionnaire as a quality of life study tool in patients with gastroesophageal reflux disease. The execution of this task was made possible owing to the collaboration with ZENTIVA PL Sp. z o.o. under the clinical follow up, entitled “Quality of life evaluation in patients with gastroesophageal reflux disease treated with a once-daily 20 mg dose of omeprazole during 4 weeks (ENJOY 12/HE/2005)". The usefulness and safety of use of proton pump inhibitors in the treatment of reflux disease is well documented (1, 13-16). Of significance is also the importance of the so-called omeprazole test in the diagnostics of reflux disease (17-21). In view of the above, the authors made a choice of non-invasive method of treatment of reflux disease with the aim of improving the patient quality of life.

MATERIAL AND METHODS

For the purposes of the study, a questionnaire was formulated based on the Likert method and modelled on Quality of Life in Reflux and Dyspepsia (QOLRAD) – I. Wiklund 1997) (11). When creating the questionnaire, particular emphasis was placed on the comprehensibility and ease of use by the patient. One of the priorities was deemed to be the evaluation of the trust for the diagnosis posed by the physician and the chosen therapeutic
method. Four time levels of complaint persistence were introduced, and assigned corresponding point scores:

“all the time” – 3 points
“often” – 2 points
“sporadically” – 1 point
“never” – 0 points

The questionnaire was preceded by information for the patient on what should be understood as heartburn and acid reflux. The patients were asked 10 questions with prepared answers to be marked by the respondents. Each of the answers took into account a given time level of complaint persistence. The questionnaire included the following questions:

1. How often within the last week have you experienced poor general wellbeing due to heartburn or acid reflux?
2. How often within the last week have you experienced fear for your own health due to heartburn or acid reflux?
3. How often within the last week have you experienced difficulties with falling asleep at night due to heartburn or acid reflux?
4. How often within the last week have you experienced fatigue or exhaustion due to heartburn or acid reflux?
5. How often within the last week have you experienced the need for quantitative reduction of food consumption due to intensified heartburn or acid reflux?
6. How often within the last week have you experienced the need for limiting the professional or household activities due to heartburn or acid reflux?
7. How often within the last week have you experienced the need for avoiding coffee, alcohol or ill-tolerated food due to intensified heartburn or acid reflux?
8. How often within the last week have you experienced the need for limiting the social contacts due to heartburn or acid reflux?
9. How often within the last week have you experienced deterioration of relations with household members due to heartburn or acid reflux?
10. How often within the last week have you experienced fear associated with potential bad diagnosis posed by a physician concerning the cause of heartburn or acid reflux?

Quality of life was defined based on the total point score derived from the answers to the posed questions. Four values of quality of life were established:

very good – range: 0-7 points
moderate – range: 8-15 points
poor – range: 16-23 points
very poor – range: 24-30 points

At the first visit, the patients were asked to complete the quality of life questionnaire concerning 7 days preceding the doctor’s appointment. At the second visit, after 4 weeks of treatment with a single morning dose of omeprazole at 20 mg, the patients completed the quality of life questionnaire again.

The data obtained from completed quality of life questionnaires were subject to statistical analysis. The preliminary study was a pilot one conducted on three groups of patients of approx. 100 individuals each. Questionnaires that were completed incorrectly or illegibly were not included in the statistical analysis.

The quality of life questionnaires were completed by the patient independently, without any suggestions from the attending physician. Each patient answered 10 questions by marking one answer only in each question.

The study was conducted on the entire territory of Poland with the participation of 400 primary healthcare physicians. The patient recruitment was based on voluntary participation in the project.

The diagnosis of gastroesophageal reflux disease was posed based on physical examination and patient history towards typical factors such as heartburn or gastric content reflux, as per the Montreal Consensus (2, 3, 4, 21). There were also collected the data concerning the frequency of epigastric pain, bad taste in the mouth, nausea, vomiting and other more rarely described symptoms. In cases of atypical complaints or alarming symptoms, the patients were referred for upper gastrointestinal tract endoscopy and additional examinations. It was accepted that for the diagnosis of reflux disease, the presence of heartburn for at least 3 months with the minimum frequency of two mild episodes a week (complaint not to be ignored but not preventing the performance of everyday activities) was necessary (2, 3).

The study enrolled patients with diagnosed gastroesophageal reflux disease based in the history and physical examination performed by the physician participating in the follow up, in whom treatment with a single morning dose of omeprazole at 20 mg daily was recommended. At the same time, treatment with a
preparation from the class of H2 receptor antagonist was discontinued, if used previously.

The inclusion of a patient into the follow up did not influence in any way the subsequent diagnostics or treatment.

The quality of life forms completed in the course of programme implementation did not constitute the only element of patient diagnostics. Quality of life evaluation was treated as a supplementation of physical examination and history.

The study was of purely observational and non-interventional nature. The information collected during the follow up did not include personal data, which precluded subsequent identification of the patient.

Participation in the observation programme did not release the physician from the obligations set out in the relevant legal acts concerning the management of the patient, including the monitoring of adverse effects.

The study enrolled all the patients reporting to the physician participating in the programme, meeting the following criteria:
- consent to the participation in the programme
- diagnosed or suspected gastroesophageal reflux disease
- non-sing of drugs from the class of proton pump inhibitor (PPI) within the last four weeks prior to the completion of the first form.

Patients treated with drugs from the PPI class within 4 weeks prior to the initial visit were disqualified from the study. Due to the treatment applied during the follow-up period, patients below the age of 18, pregnant women and breastfeeding women were excluded from the study. All patients with other contraindications against the use of any other drugs employed during the follow-up period were also excluded.

The studies were conducted on a group of 10,623 patients. In the statistical analysis of data from the obtained answers, the following methods were used: non-parametric tests for two dependent data sets, statistical measures, statistical tests for measuring whether the differences between the mean values may be considered statistically significant, methods for testing the correlation (or its lack) between the qualitative values, analyses of normal distribution, analyses of distribution identity, rank analyses of value dependence. The significance threshold for each study was $p < 0.01$, which means that all the obtained conclusions are true with the probability of at least 99%. The majority of statistical calculations were performed with the use of Statistica 7.0 and Excel software (22-26).

RESULTS

By examining patients within the period of four weeks, it was found that the quality of life perceived by them improved significantly. Each patient could receive from 0 to 30 points in each study. While when dividing the respondents according to their status into four categories (quality of life: very poor, poor, moderate, very good), in the first study there were predominating patients with poor (48.5%) and moderate (31%) quality of life, followed by those with very poor quality of life (14%), after a 1-month treatment with omeprazole this indicator assumed for the majority of patients the following values: very good (66.9%) and moderate (28.4%). Moreover, there were only 4% of individuals with poor quality of life after the treatment, and very poor less than one percent (0.7%). The above change is presented in fig. 1.

It was also found that in 81.7% there occurred a change towards the improvements of quality of life by at least one level, while in only 2.6% there was observed deterioration by at least one level. No marked changes were observed in the remaining patients (fig. 2).

The analysis of point differences in the quality of life enabled the obtaining of answers

![Fig. 1. Evaluation of the quality of life of patients with gastroesophageal reflux disease based on the quality of life questionnaire at the first and second visit during the ENJOY study](image-url)
concerning the size of changes (improvement) in the quality of life of patients. In questions 1 to 7 it is observable that mean changes in the quality of life occurred by at least 1 level. In questions 8 and 9 the mean changes in the quality of life occurred by 1 level. In question 10, the mean changes of fear associated with potential incorrect diagnosis improved by 1 level, yet the majority of patients did not change their mind. An average patient (randomly chosen) changed their opinion as to the general quality of life by 11 points. The improvement in quality of life was observable in all the studied aspects physical (questions 1, 3, 4, 5, 7), functional (question 6), emotional (questions 2, 10) and social (questions 8, 9). No gender or age dependence was found.

In the analysis of the test correctness, we tried to justify as proper the choice of questions in the questionnaire and show that it presented a good picture of a change in the quality of life.

The test reliability consists in the obtaining of the same results during the repeated use of the test. In the pilot study on three groups of 100 individuals each, identity of distribution and equality of means was found at the significance level of 1%. Thus, the test met the reliability requirement at the level of at least 99%. The distribution identity results are presented in tab. 1, while the assessment of means equality is presented in tab. 2.

Validity – ability to measure phenomena occurring in the aspects of interest and sensitivity – ability to detect changes, are significantly correlated (10). The test suggested by the authors measures in a precise manner the phenomena occurring in the aspects concerning the parameters of quality of life evaluation by the patients. The majority of hypotheses were proven with accuracy close to 100% (p=0). The basic statistical measures for the point difference distribution in the quality of life are presented in tab. 3.

Appropriateness of the test stems from the adjustment to the specific complaint – gastroesophageal reflux disease. Heartburn and acid reflux are the most important diagnostic criteria in gastroesophageal reflux disease and based on them the evaluation of quality of life was performed (10).

Practicality of the test stems from the high perception of respondents (98% of correctly completed questionnaires) and relatively short time needed for the completion (approx. 10 minutes). The suggested test is shorter than

<table>
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<tr>
<th>Sample</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>p</th>
<th>Equality (yes no)</th>
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<tbody>
<tr>
<td>Sums before the treatment</td>
<td>A and B</td>
<td>17,1 and 16,5</td>
<td>4,7</td>
<td>0,4&gt;0,01</td>
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<td>Sums before the treatment</td>
<td>A and C</td>
<td>17,1 and 17,3</td>
<td>5,6</td>
<td>0,78&gt;0,01</td>
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<td>Sums before the treatment</td>
<td>B and C</td>
<td>16,5 and 17,3</td>
<td>5,2</td>
<td>0,3&gt;0,01</td>
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<tr>
<td>Sums after the treatment</td>
<td>A and B</td>
<td>6,5 and 5,6</td>
<td>4,8</td>
<td>0,15&gt;0,01</td>
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<td>Sums after the treatment</td>
<td>A and C</td>
<td>6,5 and 5,9</td>
<td>4,2</td>
<td>0,39&gt;0,01</td>
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<td>Sums after the treatment</td>
<td>B and C</td>
<td>5,6 and 5,9</td>
<td>5,2</td>
<td>0,65&gt;0,01</td>
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<td>Result differences</td>
<td>A and B</td>
<td>10,7 and 10,9</td>
<td>6,2</td>
<td>0,83&gt;0,01</td>
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<td>Result differences</td>
<td>A and C</td>
<td>10,7 and 11,4</td>
<td>7,2</td>
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<td>Result differences</td>
<td>B and C</td>
<td>10,9 and 11,4</td>
<td>7</td>
<td>0,61&gt;0,01</td>
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Table 1. Results of Kruskal-Wallis test

Table 2. Dependence of means for independent values
those used to date and contains all the aspects enquired about by the other tests without the unnecessary repetition of questions. In order to check the reliability of questionnaire completion, Spearman correlation rank was used. It was tested whether large determination of answers to individual questionnaire questions is present, obtaining the results presented in tab. 4.

Both in the survey conducted before the treatment and that after the treatment, the mutual correlation of answers did not exceed 50% which means, considering that the questionnaires were completed by the same persons, that the questions were correctly selected and there are no questions describing the same aspect.

The results obtained in the study enable to state that the original quality of life questionnaire meets the requirements for the tools evaluating the quality of life in gastroesophageal reflux disease. Its usefulness was confirmed in a group of 10,623 patients from Polish population. The authors propose a broader use of the questionnaire in everyday clinical practice of physicians involved in the diagnostics and treatment of gastroesophageal reflux disease.

**DISCUSSION**

The majority of recognised quality of life questionnaires function in narrow patient groups (e.g. subject to anti-reflux surgery) or in clinical trials. The lack of Polish versions (validation) of some questionnaires and the evaluation in controlled studies does not allow the determination of the perception level of questions by the respondents.

The key premise of formulating the original quality of life questionnaire was the possibility of its use on large patient groups. Due to this, the number of questions was limited to ten and the possibility of choice to only four options. The planned time of completion according to the authors did not exceed 10 minutes.

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<th>Table 3. Basic statistical measures for the point difference distribution in the quality of life</th>
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<td>W1-W2</td>
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<th>Table 4. Correlation between the questions asked in a given study (%)</th>
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<td><strong>Before</strong></td>
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The above premises caused that all the questions of the original questionnaire related to the impact of heartburn and acid reflux on the aspects (domains) of interest of quality of life.

The physical aspect is represented by questions 1, 3, 4, 5, 7 (wellbeing, sleep disorders, fatigue, food consumption reduction, quality of consumed food lowering).

The functional aspect is represented by question 6 (professional or household work).

The emotional aspect is represented by questions 2, 10 (fear for own health, fear of incorrect diagnosis).

The social aspect is represented by questions 8, 9 (social contacts, relations with household members).

In the QOLRAD questionnaire (10) the possible answers cover 7 time periods and after the Polish validation (evaluation of usefulness in measuring the phenomena in the aspects of interest after translation into Polish), they look as follows:

- “all the time”
- “most of the time”
- “quite often”
- “sometimes”
- “rarely”
- “almost never”
- “never”

In view of the subjective evaluation by the patient of studied phenomena, in the opinion of the authors, it is more beneficial to introduce more comprehensible and less numerous options of answer. This is why in the original quality of life questionnaire there were set four possible answers corresponding to the time ranges of complaints:

- “all the time”
- “often”
- “sporadically”
- “never”

The characteristics to be met by the quality of life questionnaire: reliability, validity, sensitivity, appropriateness and practicality were proved in the quality of life study in patients treated with a single dose of omeprazole at 20 mg daily for the period of four weeks.

Reliability

In reference to the earlier presented results of analysis of questionnaire correctness it should be concluded that the test meets the reliability criterion with the probability of at least 99%, similarly to other recognised tests (10).

Validity and sensitivity

Taking into account the definition, both the characteristics are correlated and their fulfilment stems from the possibility of using statistical methods and the results of method use. The validity consists in the ability to measure the phenomena occurring in the aspects of interest. Sensitivity means the ability to detect changes occurring in a given patient. The suggested test measures in a precise manner the phenomena occurring in the parameters of quality of life evaluated by the patients. All the studies conducted by the authors with the assumed 1% error, i.e. at high level of statistical significance, provided the possibility and ability of measuring the changes in phenomena associated with the improvement of quality of life of patients after the treatment with the use of proton pump inhibitor. They also reflected the level of these changes for a given patient. The posed study hypotheses were confirmed with the accuracy close to 100% (p=0). The flow of pinions of patients using the so-called conditional distribution also showed the odds for a randomly chosen patient who after the diagnosis was classified to a given group on a change of opinion on own wellbeing. The analysis of differences enabled both the description of change size and the classification of a given patient. In addition, there existed a possibility of determining how big the change will be. This evidences that the proposed test meets in full the premises for its validity and sensitivity.

Appropriateness

The questionnaire is adjusted to the given complaint – gastroesophageal reflux disease. Heartburn and acid reflux as the most important criteria of reflux disease diagnosis are the symptoms that significantly lower the quality of life. The sequelae of the disease include reduced appetite, vitality impairment, emotional disorders, sleep disorders, impaired functioning at work an in the family (10). All these aspects are subject to assessment in the questions posed to the respondents in the original questionnaire. The individual questions are based on the as-
sumption – to what extent heartburn and acid reflux impact the individual elements of quality of life?

Practicality

The test consists of 10 questions. In each question, the options of answer choice were explained clearly and precisely. Owing to the maximal simplicity of the test, the respondent was to mark the appropriate square, and thus either the questionnaire completion or comprehension of question content did not pose any difficulties for the patient.

The test is shorter than those used internationally to date and contains aspects enquired by other tests yet without unnecessary repetition of questions (10). This may cause the fear about whether the respondents completed the form reliably, as it does not contain the so-called control questions. In respect of the earlier presented results, the authors checked the reliability with the use of Spearman rank correlation coefficient, which means that the questions were correctly selected.

The theoretical premises underlying the formulation of the original questionnaire determine its use in the study of the quality of life of patients with oesophageal symptoms of gastroesophageal reflux disease. The extraoesophageal manifestations should be evaluated based on the other disease markers, such as cough, hoarseness, improvement in spirometric parameters, etc. Then, the evaluation of the quality of life is more difficult due to the smaller number of patients or even the necessity of prolonged treatment that could potentially smooth away the disease symptoms (3, 28, 29, 30).

An interesting problem considered by the authors was question No 10 associated with the fear of incorrect diagnosis. Currently, there is promoted departure from the initial in-depth diagnostics for the benefit of diagnosis based on the clinical symptoms or diagnostic questionnaires or attempts of pharmacological treatment (1, 11, 21, 31). However, there are different approaches based on the assumption that the most optimal therapeutic option in gastroesophageal reflux disease requires precise determination of three diagnostic problems associated with GERD (32, 33):

1. documented reflux disease as the cause of subjective complaints reported by patients,
2. explanations of the cause of reflux disease in the case of a given patient,
3. identification and classification of patients for the optimal (conservative or surgical) treatment option.

The answers obtained from the respondents indicate the following:

– presence of extremely high trust in the posed diagnosis,
– small influence of this domain on the improvement of quality of life post treatment,
– generally high assessment of the healthcare service.

The level of medical knowledge in the society possibly influences the results of answers of respondents to the above question.

It should be noted that the follow up was conducted with the participation of 400 physicians from all over Poland, based on spontaneous reporting and not limited to selected patient groups. The level of questionnaire perception was high – out of 10,832 questionnaires due to incomplete data 10,623 (98%) respondents were taken into account. The time needed for questionnaire completion, as per the expectations, did not exceed 10 minutes and enabled the conduct of the assessment of quality of life during a standard doctor’s visit.

CONCLUSIONS

1. The original quality of life questionnaire meets the requirements posed for the tools evaluating the quality of life in gastroesophageal reflux disease.
2. The usefulness of the questionnaire was confirmed in a group of 10,623 patients with gastroesophageal reflux disease in the Polish population.
3. The questionnaire matches the recognised international tests, and its advantage is the ease of completion and high level of perception.


